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S. Hrg. 116–557

COVID–19

HEARING

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

ROUNDTABLE: ARE WE PREPARED? PROTECTING THE U.S. FROM GLOBAL PANDEMICS, FEBRUARY 12, 2020

THE FEDERAL INTERAGENCY RESPONSE TO THE CORONAVIRUS AND PREPARING FOR FUTURE GLOBAL PANDEMICS, MARCH 5, 2020

REMOTE ROUNDTABLE COVID–19: HOW NEW INFORMATION SHOULD DRIVE POLICY, MAY 6, 2020

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EARLY OUTPATIENT TREATMENT: AN ESSENTIAL PART OF A COVID–19 SOLUTION, NOVEMBER 19, 2020

EARLY OUTPATIENT TREATMENT: AN ESSENTIAL PART OF A COVID–19 SOLUTION, PART II, DECEMBER 8, 2020

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ROUNDTABLE: ARE WE PREPARED? PROTECTING THE U.S. FROM GLOBAL PANDEMICS

WEDNESDAY, FEBRUARY 12, 2020

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 9:34 a.m., in room SD–G50, Dirksen Senate Office Building, Hon. Ron Johnson, Chairman of the Committee, presiding.

Present: Senators Johnson, Lankford, Scott, Hawley, Peters, Carper, Hassan, Harris, Sinema, and Rosen.

OPENING STATEMENT OF CHAIRMAN JOHNSON

Chairman JOHNSON. Good morning. I want to welcome all of our witnesses, thank you for your time and your testimony and the answers you will be providing to our questions. I want to thank everybody else for coming as well.

This obviously is an important topic. I will say up front, I am disappointed that we do not have a representative from the Department of Homeland Security (DHS) or the Department of Health and Human Services Centers for Disease Control (HHS CDC) here. I spoke with those folks. I thought I had them convinced to come, but apparently, they are doing an all-Senate briefing at 11:30. I understand the demand on their time in terms of briefing Senators, but I think it is extremely important the public understands these things as well.

I have all kinds of questions, and what I told the witnesses here is we are not going to confine your opening statements to 2 minutes or 5 minutes. I want you to provide the public information.

The main reason I called this roundtable is just to put things in perspective. The Federal Government plays a role here. We do not want the Federal Government to underreact, but we also do not want the Federal Government to overreact. I think the probability that they are going to get it just right is zero, but I think it is important that we discuss what are the considerations in the actions that we do take, what actions would be effective, what actions will largely be ineffective.

I know a number of you have already published articles, and you have had that kind of discussion. That is kind of what I want to get on the table. I want this roundtable to layout the information that the public needs to begin considering, realizing there are no

set answers yet. We just do not know all kinds of things, but there is plenty that we do know. So let us acknowledge the fact that there is a lot of unknowns in this process yet, but information in the public realm is better than not having the information out there.

I think we are seeing the difference right now between our democratic open-press system versus China where I think because of that closed system, it is probably getting closer to out of control there, where we have the real possibility by providing the public the information they need to have, providing health professionals. People are aware. They can take, hopefully, precautionary measures inside hospitals where you have severe cases. We can limit the spread of this as best as possible.

I have a prepared statement. I will just enter it into the record.[1]

Chairman JOHNSON. I will turn it over to Senator Peters.

OPENING STATEMENT OF SENATOR PETERS

Senator PETERS. Thank you, Mr. Chairman. I will be brief too.

Thank you to all of our witnesses for being here, and I will just share my disappointment as well with you, Mr. Chairman, that we do not have CDC and Homeland Security, but hopefully, we will be able to have a hearing coming up that will bring them in because I agree getting this information out in the public is really important. When folks do not know something, you can have a lot of misinformation getting around there and kind of gin up fears. We do not want to do that. We want to treat this with the seriousness that it deserves but make sure there is full transparency as to what is happening and how we are dealing with it.

I think this an important issue for us to address because this is not going to be the last time. Wherever you have a disease spreading fairly quickly—pandemics are part of human history. They have been throughout human history. They are going to continue. There are some that may argue that they become more complicated as time goes on and as we become more of an interconnected world as well. So I think we have to be thinking about this in the long term, making sure our resources are there.

I certainly was disappointed in the President's budget that shows a pretty substantial cut to programs related to pandemics at a time when we may be on the verge of a pandemic. It shows that that is shortsighted, and we have to be thinking about this from a homeland security issue as well.

We are the Homeland Security Committee. This is about protecting the homeland. I am going to be asking questions related to our capacity to produce vaccines, for example, if and when a vaccine is developed, what sort of capacity is here in the United States, and if we are relying on China to produce vaccines for us here in the United States, I suspect they will use those vaccines for their own people first before they come to the United States. That would be a very rational and reasonable expectation.

We have to make sure that we have the resources in our country to protect ourselves, not only from naturally occurring pandemics, but actually, Dr. Gerberding, we have talked about it from the

[1] The prepared statement of Senator Johnson appear in the Appendix on page 41.

weaponization as well in a different committee that I am on, Emerging Threats and Capabilities. There is also the potential for bioweapons to be used, and we need to be prepared on all fronts.

I look forward to the conversation and look forward to moving forward on this important issue.

Chairman JOHNSON. Thank you, Senator Peters.

Why do not we start with Dr. Gottlieb, and then we will kind of alternate back and forth.

TESTIMONY OF HON. SCOTT GOTTLIEB, MD, FORMER COMMISSIONER (2017–2019) OF THE FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GOTTLIEB. I do not think these are working right now, but thanks, Mr. Chairman, Mr. Ranking Member. I think they are working now. I appreciate the opportunity to be here today before you, and thank you for submitting my full statement to the record.[1]

This is a deeply concerning event, this novel coronavirus disease 2019 (COVID–19). We do not understand its true severity at this point. We do not understand the transmissibility. I think we are going to learn a lot more information in the coming weeks as we start to see outbreaks emerge in other regions of the world that are going to provide better information than we have been able to get out of China.

But the fear right now is that this could occupy that middle ground between contagion and virulence, where it is contagious enough to spread very efficiently around the world but still virulent enough to cause a lot of death and suffering when it is distributed across a very large population.

I think one of the very instructive things right now that we should keep a very close eye on is the situation in Singapore, which is growing more and more concerning by the day.

I would remind folks it is quite warm in Singapore right now, about 90 degrees at a high during the day, lows in the 70s. While we would hope that this summer would be a backstop against propagation of coronaviruses—and it typically is—it might not be in this case where you have a very novel virus that is going to transfer more easily because people do not have any cross-immunity.

Of the 50 cases that have been identified in Singapore—and they have an excellent system for doing tracking and tracing in these kinds of situations—eight are currently in the intensive care unit (ICU), and so that is at least some indication of the potential severity of this.

I want to focus my brief remarks up front today on some of the supply chain issues that this situation exposes and draw from some of the work that I did previously at the Food and Drug Administration (FDA) as well as what we seem to be learning in the setting of this current out break.

Wuhan, in particular, in the Hubei Province was a center for production of pharmaceutical ingredients but not pharmaceutical ingredients that we typically think of when we think of the active pharmaceutical ingredients (APIs) that go into manufacturing drugs and into what we call the "fill-finishing process," actually

[1] The prepared statement of Dr. Gottlieb appears in the Appendix on page 42.

taking the raw ingredient of the drug product itself and putting it in the tablet or capsule.

Typically, a lot of the APIs manufactured, some of it in China—a lot of it is manufactured in India, some of it in Europe and the United States. The fill-finishing work, actually taking that active pharmaceutical ingredient and turning it into a capsule or a tablet, that is often done in the United States or in countries like Ireland.

What goes on in China, the kind of production that they have, is actually making the starting materials for the active pharmaceutical ingredient. So the first chemicals that go into the API is oftentimes what is made in China, and in many cases, China is the sole source for that material.

A lot of the materials that were manufactured in Wuhan actually got shipped to India where the Indian generic companies did the manufacturing of the active pharmaceutical ingredient, and what we are finding now is that in many cases, China was the only supplier of these raw ingredients. So what we have identified through this episode is a critical choke point in the supply chain for pharmaceuticals and some critical pharmaceuticals, a lot of anti-infectives that are manufactured, generic anti-infectives that are manufactured in India. The starting ingredients that go into those, those intermediate products of the anti-infectives, are actually manufactured in China.

So it calls into question whether or not we have the right policies, I believe, in terms of how we look at potential disruptions in the supply chain, because our orientation historically has been focused on the finished product.

We have required manufacturers historically to report to the FDA when there are shortages or near shortages of finished product.

We have some insight into the manufacturer of API, but on the whole, we are not typically looking all the way down through the supply chain or requiring manufacturers to do that and report on what these critical choke points can be.

So it begs the question whether or not we should reconsider those policies, and it is not just in the setting of pandemics where this can become a risk. It could be political upheaval. It could be political strife. It could be situation, to your point, Mr. Chairman, where countries try to nationalize supplies, where there is a critical supply and they hold on to enough supply to satisfy their local needs in the setting of a public health crisis before they ship outside their borders.

Just in closing, some things I think we can consider going forward to try to address these kinds of contingencies and these kinds of risk to the supply chain that I believe this episode is exposing in real time, we could, first of all, work closely in the near term with manufacturers to try to get an alternative supply for these chemicals into the market.

There is idle manufacturing capacity in India. These facilities can be converted fairly quickly. The starting ingredients for pharmaceutical production does not need to be done under what we call good manufacturing practices. You do not have to apply all the stringent oversight that you would to a finished drug product be-

cause the regulation on the finished drug product is what covers the drug ingredients. So the drug ingredients do not need to meet those standards as long as the finished drug product does, and that is a long way of saying we probably could do this quickly if we wanted to convert facilities and we had a real focus on where those choke points and trying to mitigate them.

I think longer term, we should think about when we ask manufacturers to focus on shortages of final products also require them to report on the intermediate steps and intermediate ingredients that could also come into shortage that could create an adverse public health outcome.

We can require companies to identify alternative supply for some of these products. We did that after September 11, 2001 (9/11), which Dr. Gerberding probably remembers well, where we required manufacturers of critical products like insulin to identify how they would come up with alternative supply of that product should their core facility go down because of either an intentional or an unintentional act.

We could do the same thing with some of these critical facilities that supply raw ingredients for these drug products, where it is, in many cases, sole source.

We also, finally in closing, just need to focus on getting more manufacturing back into the United States, and this is where this Committee has been very helpful. When I was at the agency making investments in continuous manufacturing and other kinds of high-tech, low-labor footprints for manufacturing pharmaceutical ingredients and pharmaceutical products, that are the kinds of facilities that if you are a manufacturer, you would want to locate as close as possible to your site of sale. So a continuous manufacturing platform really lends itself to being domesticated here in the United States as opposed to doing it in another part of the world.

So these are just some ideas, some of which I worked on when I was at the agency, some of which I thought about since leaving, but I would be delighted for the opportunity to work with the Committee on these and other ideas on how we can mitigate some of the risks that have been identified in this current episode. Thanks.

Chairman JOHNSON. Thank you, Dr. Gottlieb, and I should have pointed out that you are the former Commissioner of the Food and Drug Administration.

Why do not we move next to Dr. Julie Gerberding. Dr. Gerberding was former Director of the Centers for Disease Control during the Bush Administration from 2002 to 2009. Doctor.

TESTIMONY OF JULIE L. GERBERDING, MD, FORMER DIRECTOR (2002–2009) OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GERBERDING. Thank you. It is an honor and an important opportunity to provide context and information. I really appreciate the ability to have this conversation.

I am really here wearing three hats. One is as the Chief Patient Officer at Merck. Like many multinational companies, we have lots of people working in China right now, and of course, we are concerned about our own employees. But as Dr. Gottlieb has said, we

are also worried about maintaining the supply of medicines and vaccines to the people in China who need them but also sustaining the supply chain across the board.

I am also wearing my hat as the co-chair of the Center for Strategic and International Studies (CSIS) Commission on Global Health Security, which recently published this report, which includes recommendations to Congress about what we could do to end this cycle of complacency in crisis that we continuously circulate through as these infectious diseases emerge. This is a commission that includes bipartisan members of both the House of Represenatatives and Senate. So we have a very involved Congress in this issue.

Finally, I am wearing my hat as the former CDC Director who had the privilege of serving our country during the severe acute respiratory syndrome (SARS) outbreak. I have had some firsthand experience with the first coronavirus that emerged but also lived through West Nile, monkeypox, avian influenza, and a number of other infectious disease outbreaks, and worked very hard across the entire government to try to improve our preparedness for an influenza pandemic with lots of exercises and advanced capability development. I am sober to be watching this situation unfold today, and it is a little bit of a deja vu all over again.

I thought I would just comment on kind of the big picture of how we generally approach global outbreaks like this. The first step is the detection, and in this case, I think we are fortunate that the outbreak was observed and reported and information was shared very early in the process, compared to the situation with SARS where several months went before we were aware of what was going on. So that is a positive improvement.

The second step is to contain the virus at its source, and I do not think there has been, probably in human history, a more dramatic effort to try to contain a virus than what is going on right now in China. The number of people who are on lockdown, the scope and magnitude of the population involvement in the quarantine and social distancing procedures is, in my view, completely unprecedented, and the question to us is, Will it work? Can you really keep this virus under control?

We obviously know there is spillover into several of the provinces in China and several countries around the world. We have also documented hotspots of sustained transmission. We still have a lot to learn, and certainly, the experience on the cruise ship in Japan is telling us how transmissible this can be among people who are in a confined area. So we are very concerned about the prospects for long-term containment.

If we cannot contain it, I think we need to be prepared for what are we going to do to try to slow down the spread. Slowing down spread is important because, if we have a lot of cases all at once, we simply do not have the surge capacity to manage that in our health care environment or in any of the related services that would be necessary.

Slowing down means working hard to identify the people who are infected and isolating them in a place where they cannot infect other people and having available gloves and masks and the isola-

tion materials, which is also part of this supply chain that we have some significant vulnerabilities in.

But slowing down also can involve social distancing, and by that, I mean instructing people to avoid large crowds, early school closures, so that child are not transmitting in the opportunities of person-to-person and droplet transmission that occur among young kids in school and a variety of other measures that were employed in the 1918 pandemic, for example.

These measures along are not likely to prevent community spread, but when taken as a cluster of interventions, we like to use the Swiss cheese analogy. If you hold up a piece of Swiss cheese, there are a lot of holes in it, but if you stack them on stop of one another, you can end up with a pretty effective barrier. I think that is the process of slowing down until such time as we have a vaccine or countermeasures that can be helpful in that.

I think where we are in the United States today is we are observing a clustered outbreak of a significant scale in Asia, we do not have that situation in the United States today. So we are very alert. I do not think we are alarmed at this point, but we need to be leaning in to what will the next step be if we cannot contain it. I think that is why this conversation that we are having today is so prescient because we will need congressional support and investment to make that a feasible opportunity.

So I think I will just stop there, and we can come back to some specifics about transmission, which we have provided to you in kind of this summary comparison of various viruses.

Chairman JOHNSON. Thank you, Doctor.

I think we will go next to Dr. Luciana Borio. Dr. Borio is former National Security Council Director for Medical and Biodefense Preparedness and Acting Chief Scientist for the U.S. Food and Drug Administration. Dr. Borio.

TESTIMONY OF LUCIANA BORIO, MD,[1] FORMER DIRECTOR FOR MEDICAL AND BIODEFENSE PREPAREDNESS (2017–2019) AT THE NATIONAL SECURITY COUNCIL

Dr. BORIO. Good morning, Chairman Johnson and Ranking Member Peters and Members of the Committee.

Dr. BORIO. OK. This one is working better. Thank you.

I am Dr. Borio, as you mentioned. I work for In-Q-Tel, which is a non-for-profit strategic investment firm that tailors innovative technology solutions to support the mission of the U.S. national security community, but previously, I served in U.S. Government positions and have been involved in response to many public health emergencies. So thank you for the opportunity to be here with you today.

You have heard about the numbers of the trajectory of this epidemic, but we all know that the numbers both inside and outside of China are likely much larger. There are some places where we now have significant transportation hubs to China that have not reported any cases yet, either because they do not have adequate surveillance systems or do not have access to diagnostic tests or are not looking.

[1] The prepared statement of Dr. Borio appears in the Appendix on page 48.

Even though there is a lot we do not know about this virus yet, as Drs. Gottlieb and Gerberding mentioned, the futures are very concerning for a pandemic and global spread. Even though we have seen most of this impact today in China, in Wuhan, and the citizens are suffering a tremendous amount, its impact will be felt globally.

I want to stress that even though we do not know how lethal this virus is, it is pretty clear that it is sufficiently lethal to stress severely the health care systems because of the lack of surge capacity that we have today to take care of large influx of patients with acute and serious respiratory diseases.

I would like to speak a little bit about some progress we have made since 2001 because it has been very significant progress. We are much better prepared today than we were back in 2001, and I want to acknowledge the work of Congress to help us prepare because a lot of that progress would not have been possible without the laws that were passed over the years to provide the Executive Branch with very many vital authorities to perform its duties, whether it has been establishment of the BioShield fund or the establishment of a bar that would support the private sector in technological countermeasures, Emergency Use Authorization authorities for the FDA. There are many others that proved vital for our current State of preparedness.

Over the years, it is very clear too that the Federal response enterprise that comprises many agencies, but including the CDC, the National Institute of Health (NIH), and the FDA, are stronger than ever. The coordination and communication and collaboration and resource sharing, the ability to get things done is stronger than ever.

On an optimistic note, I think it is fair to say that the science is advanced to appoint where we now can actually aim for development, evaluation, and deployment of countermeasures in time to maybe impact the course trajectory of a novel outbreak.

In the past, the efforts were designed to protect from subsequent outbreaks, but now the goal really is to impact the current one. You have heard how the NIH is moving very quickly to develop a vaccine. The CDC moved very quickly to develop diagnostic tests. So there has been progress.

Now, I would like to say that we have fallen short in some very key areas, and they cannot be overlooked going forward. One has been the lack of prioritization for diagnosis tests, and they are one of the most critical components of outbreak management and control. They are necessary for even clinical trials for vaccines. So we cannot afford to de-prioritize these vital tools for outbreak preparedness response surveillance.

As Dr. Gerberding said, the health care system is not ready for care of sick patients. So we have neglected our health care system preparedness. Much needs to be done in the public health arena, but more progress has been done at the State and local level of public health than we have achieved in the health care sector.

I love medical countermeasures. I love therapeutics and specific therapeutics, but we have to remember that they are an incremental benefit to delivery of supportive medical care. Without that

foundation, those countermeasures are not going to be useful. We need to be able to, first and foremost, take care of patients.

Last, as Dr. Gottlieb spoke about, we have not sufficiently protected our supply chain of essential medicines and medical equipment, and that needs to change going forward.

I do think that we have made some progress, but we need to brace ourselves from some difficult weeks to months to come. I believe that we are going to see a lot more cases in the United States in the near future.

I would like to acknowledge the work of the Committee to calling for the establishment of the National Biodefense Strategy in 2017 and the National Defense Authorization Act (NDAA), at your suggestion. It has been proven very important to help coordinate the Federal Government's response.

I do not want to leave this opportunity without recognizing the staff at the CDC, my former colleagues at the FDA, at DHS, at U.S. Customs and Border Protection (CBP), and other Federal agencies who I know are working around the clock to protect Americans from harm and from this epidemic.

Thank you.

Chairman JOHNSON. Thank you, Doctor.

Let us switch over to the Government Accountability Office (GAO) now. We have Nikki Clowers, who is the Managing Director for GAO's Health Care Team. Ms. Clowers.

TESTIMONY OF NIKKI CLOWERS, MANAGING DIRECTOR, HEALTH CARE TEAM, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. CLOWERS. Thank you, Chairman Johnson, Ranking Member Peters, and Members of the Committee. I thank you for having me here today to talk about GAO's infectious disease preparedness work.

Today I want to share four key lessons from our past work on outbreaks as we consider the Nation's current preparedness for and response to the 2019 coronavirus.

First, planning and coordination is critical. Although HHS is the lead Federal agency for public health and medical preparedness, multiple other Federal agencies, such as the Department of Defense (DOD) and DHS, play an important role, with State and local agencies on the front line; and of course, in today's global environment with mobile populations, coordination between countries is a must. Effective preparedness and response requires advanced planning, such as joint exercises among these entities.

Second and related to planning and coordination, entities must understand theirs and other's roles and responsibilities. Who is responsible for communicating with the public? What is the contingency plan if a key entity's ability to respond is limited? How can an entity fulfill its obligation despite these limitations? Answers to these and many other questions must be known and understood by all to ensure effective preparedness and response, and I would note that these are related to the issues that have been brought up by other witnesses about the supply chain, our reliance on drug and supplies from other countries. We have talked a lot about drugs so far, but it is also the supplies, personal protective equipment. What

happens if those are limited, and where do we get those supplies from?

Third, clear and consistent communication is essential. With the number of entities involved in preparedness and response, it is important that the government speak with one voice to avoid confusion and frustration. The lack of clear and consistent communication can also create expectation gaps, like we saw when the amount of vaccine available for the hemagglutinin one neuraminidases one (H1N1) influenza in 2009 did not meet the public's expectation.

Finally, responding to the coronavirus cannot distract us from continuing to prepare for tomorrow's threat. We need to prepare for and response to the coronavirus, but we also must continue to prepare for other public health threats, including efforts to develop needed medical countermeasures. Developing these countermeasures requires sustained attention to overcome inherent challenges, such as the high failure rate for the development of most drugs, vaccines, and diagnostic devices.

Mr. Chairman and Ranking Member, this concludes my prepared statement. I look forward to today's discussion.

Chairman JOHNSON. Thank you, Ms. Clowers.

Last but not least, we have Dr. Asha George. Dr. George is Executive Director of the Bipartisan Commission on Biodefense, formerly known as the Blue Ribbon Panel. Dr. George.

TESTIMONY OF ASHA M. GEORGE, DrPH,[1] EXECUTIVE DIRECTOR, BIPARTISAN COMMISSION ON BIODEFENSE

Dr. GEORGE. Mr. Chairman, thank you very much for the opportunity to come here today, Ranking Member Peters, and the rest of the Committee.

The Bipartisan Commission on Biodefense has appeared before this Committee before, and I think it is an important point to make because it is obvious that biodefense is a Homeland Security issue. It is not just something that is relegated to the health care and public health arenas.

As we approach this novel coronavirus virus situation now, I think I will leave the health care and medical commentary to my colleagues and just focus a little bit right now on what is happening with Homeland Security.

I think it is important to note that the Coronavirus Task Force does, in fact, have Homeland Security on it, somebody from the Department of Homeland Security, but you will note that the Homeland Security advisor is not a member of that task force.

Now, the White House can do and arrange however the White House wants to, but what that means is that that person from the Department of Homeland Security is the representative for Homeland Security interests and needs to address that at a level that would not be the same as what would happen if the Homeland Security advisor was involved.

Additionally, Homeland, as you have seen thus far, has had some important roles to play. U.S. Customs and Border Protection and the Transportation Security Administration (TSA) have been critical in working with CDC in terms of trying to screen people and

[1] The prepared statement of Dr. George appear in the Appendix on page 52.

shuttle airplanes in particular directions, but other parts of the Department have been involved as well. U.S. Citizenship and Immigration Services (USCIS), for example, has been very clear about the offices that they have in China and the need to close those down, but they understand that illness can have an impact not just there where people are trying to immigrate perhaps here to the United States, but also vice versa with people being sick there and trying to move around the world.

In addition, the U.S. Coast Guard (USCG) has issued a Maritime Safety Information Bulletin, and I think these issues or these activities on the part of the Coast Guard, CBP, U.S. Immigration and Customs Enforcement (ICE), and so forth, these are activities that are not necessarily new activities. Many of them have long, hundreds of years of responsibilities for public health that have to do with customs, that have to do with protecting our ports of entry (POE), and they are simply executing those right now, as they should.

Other parts of the Department, such as the Federal Emergency Management Agency (FEMA) and the Cybersecurity and Infrastructure Security Agency (CISA), they too have some responsibilities. I would hope that right now they are doing what Nikki suggested. They should be leaning forward right now.

We do not necessarily need to have all of the States declaring emergencies and applying for emergency assistance under the Stafford Act, but FEMA does have guidance that would enable that if that was necessary. They should be making sure everybody understands that at the State and local level, and they should be trying to figure out how that might work when HHS is already providing some assistance to begin with.

As far as infrastructure protection is concerned, we have to be worried about the worst-case scenario. It is important for Homeland to study what is happening in China, use that as a scenario for the worst-case scenario here in the United States, and then understand what impact that has on infrastructure in particular. It has got to be more than just a workforce management issue.

The Office of Infrastructure Protection has studied this and addressed it in the past with pandemic influenza, and I surely hope that they are dusting off some of those plans and thoughts and looking to apply them here again.

Other than that, I think that I would just end with a suggestion to the Committee. There are expectations in legislation that still, abound, back from the Homeland Security Act of 2002 and coming forward, in which this Committee and others directed the Department of Homeland Security to take upon themselves some responsibilities for health-related public health issues.

With the reorganization to create the Office of Countering Weapons of Mass Destruction (CWMD), there is a little confusion there now with the Chief Medical Officer and the Officer in the Management Directorate, but things like the National Biosurveillance Integration System still in the CWMD office, it is a little confusing. It is a little unclear, even within the Department, who should be doing what and how.

I believe that the Committee should take a look at that, but in particular, in the context of what is going on with novel

coronavirus, it is something that probably needs to be fixed sooner than later, especially if we are going to assume now that the Nation is going to have to deal with biological events sooner than later, something for you to think about.

Chairman JOHNSON. Thank you, Doctor.

I definitely remember the Blue Ribbon Study Panel testifying before our Committee. Actually, Senator Carper and I met with the Vice President because your number one recommendation is we need to put somebody in charge of these things. That is a prevalent problem across a host of issues and problem areas of who is going to be in charge. We have not worked that out. I think that remains, from my standpoint, a top priority.

Dr. Gerberding, I think you supplied this sheet to us. We have an acronym now. It is COVID–19.

Dr. GERBERDING. Exactly.

Chairman JOHNSON. But as I am looking at period of infectivity versus seasonal flu 1918, SARS, Middle East Respiratory Syndrome (MERS), I think what is, from my standpoint not being a doctor, most disconcerting about COVID–19 is now we are hearing it is about a 24-day contagious period, incubation period, when people are just asymptomatic. Does that tell us something about this virus?

Also, let us get it on the table. There are all kinds of news stories going about in Wuhan they had certain facilities there. Something escaped from a lab. Can you just kind of discuss what we know? If there are issues you can lay to rest, let us lay those things to rest today.

Dr. GERBERDING. Thank you.

One point I would like to make is that although this seems like it has been in the news for quite a while, these are actually early days in terms of studying the outbreak.

One of the things that disease detectives are doing right now is literally going door to door, finding a case, understanding where that person was exposed, how many people were they in contact, and what are the actual transmission frequencies. So it takes time to do that kind of shoe-leather epidemiology that has to be done.

It does not surprise me that we have some uncertainty around these numbers, and we will continue to do that. Different people are observing different populations. What we see on the cruise ship is going to be different than what we might see in a crowded hospital situation with someone who is profoundly ill and not properly isolated. So a lot of information is emerging. It makes it really hard to make predictions or to make any firm statements about what we can expect here.

But I am concerned about this virus for three reasons. First of all, we do not know if the tip of the iceberg is really the most severely ill patients who get admitted to the hospital, but that the majority of the iceberg is transmission that is going around people with mild illness or even asymptomatic illness. That is profoundly important, obviously, but at this moment in time, we do not really know what proportion of the total universe of coronavirus infection is among those most sick people. So we could be having much more transmission, but those people are not being tested.

On the other hand, this does appear to be a very virulent virus with a fatality rate that is significantly higher than what we see with seasonal influenza, as I pointed out on this chart.[1] So given that situation, I think we have to be concerned that even if most people are not very ill, there is going to be a significant impact on the overall population, and it does appear that vulnerable older people and perhaps young children are certainly not immune to this and most of the severe diseases among populations of people who have underlying disease.

Chairman JOHNSON. That is true, just seasonable flu as well. So that is on the spectrum of how virulent this really is and how deadly, correct?

Dr. GERBERDING. That is exactly right.

Chairman JOHNSON. I am reading all kinds of things. One of the reports I read was that they attempted to develop a vaccine for SARS, and they were not successful; is that true? Did we ever develop a successful vaccine for SARs?

Dr. GERBERDING. This is an important perspective for the Committee, I believe, and that is that when we have an outbreak like SARS, there is a great deal of investment in doing something quickly like developing a vaccine or a medicine.

But SARS was contained pretty quickly. 8,000 cases is a pretty small outbreak on the global scale, and the money went away. So the investment in bringing those vaccines all the way to the finish line was not made. So the work was promising but incomplete, and certainly, we do not have a SARS vaccine in the freezer today. But I think we all recognize that——

Chairman JOHNSON. Is it because we stopped working on it, or is it because there is just something inherent in that virus that makes it very difficult to produce a vaccine?

Dr. GERBERDING. I think it is because the work was not completed.

Chairman JOHNSON. OK. Good. That makes me feel better as opposed to something inherent.

Dr. Gottlieb, do you have an explanation of why these precursors are only made in China? From my standpoint, again, a former manufacturer, where there is a very labor-intensive product, I can understand that. I would not think producing precursors for drugs would be very labor-intensive as a result of a fit for a low cost-labor country like China. Why do not we maintain that here?

Dr. GOTTLIEB. A lot of the API and the chemical precursors are manufactured outside the United States because the two biggest components in terms of the cost of production are the labor inputs, No. 1, and the second biggest component is the energy inputs to producing API.

But it does beg the question with low-cost energy available in the United States. You might be better off putting one of these facilities next to a shale plant in Texas.

I think that there is an opportunity to try to re-domesticate more of this manufacturing here in the United States as the labor inputs start to diminish with different kinds of manufacturing approaches, and that is why Congress appropriated significant resources to the

[1] The chart referenced by Dr. Gerberding appears in the Appendix on page 57.

Food and Drug Administration the last couple of years to try to invest in converting more of the industry to continuous manufacturing platforms on a premise that those are high-tech, low-labor, high-energy input platforms are the kind of thing you might want to locate in downtown Boston as opposed to Mumbai, India. So, with that kind of a platform, I think we could see more manufacturing come back to the United States.

Chairman JOHNSON. As a manufacturer myself supplying to the medical field, our International Organization Standardization (ISO) certification is always what is your backup. What happens if something happens to your plant? Where can we get the supplies? It is actually quite shocking to me that we have allowed this to occur just within our manufacturing base and ISO certification, much less would a potential solution to this be with an FDA approval on a drug so that people prove that there are multiple suppliers for the precursors?

Dr. GOTTLIEB. We do that right now for certain products. So if you have a critical product where we could not sustain, from a public health standpoint, a supply disruption, the agency requires risk mitigation plans so that manufacturers have to identify what the alternative supply would be and try to maintain some supply. There are companies that literally have redundant facilities mothballed, able to be stood up to supply certain critical products. Nitric oxide gas is an example.

So you could expand those risk management plans to encompass more components of the supply chain and identification of these critical chokepoints. The manufacturers might not have full insight into it as well. They might not know that there is a sole-source supplier, but they could ferret out that information. The agency working with them can identify more of these chokepoints.

Chairman JOHNSON. I know part of the whole anti-vaccine movement, I think they had an effect in terms of how many vaccine manufacturers are in the United States, just the whole litigious society we have. Is that also a factor here, or is that not a factor?

Dr. GOTTLIEB. We made a concerted effort from a public health and national security standpoint to try to create domestic manufacturing capacity for vaccines and create some redundant capacity in the United States, including our National Strategic Chicken Stockpile for the production of influenza vaccine. So we have tried to convert more of that industry to sell base manufacturing platforms and actually invested in building up some of those platforms here in the United States, and Dr. Gerberding was instrumental in some of those efforts.

It has fallen off the radar in recent years. I think there has not been as much emphasis in trying to get those kinds of facilities into the United States.

I will just close by saying this is really critical because in the setting of a pandemic flu where a lot of these vaccines are manufactured ex-United States, the rational behavior of another country is going to be to make sure that they can supply their local population before they fulfill contracts to the United States.

Chairman JOHNSON. This ought to be a huge wake-up call for our country in terms of having those manufacturing capabilities here in America. So I hope we heed it. Senator Peters.

Senator PETERS. Thank you, Mr. Chairman.

We, the minority side, did a report on drug shortages that came out just at the end of last year, and in hospitals that we have talked to, it was interesting. One hospital, when we were talking about the report in Michigan, would say every week, they have to get together and determine which drugs will be in shortage this week that they will not be able to get in an American hospital, top-flight American hospital.

If they have those shortages and folks need the medicines, then they will go to a more expensive medicine that is not available in a low-cost generic, for example, and yet a questionable increase of clinical benefit but costs a whole lot more money. There is a significant problem, particularly with some of the drugs, as you mentioned, Dr. Gottlieb, dealing with anti-infection, things that are mass-produced and generic.

Looked at it from a supply chain, your point too, Mr. Chairman, is that what we have in this country is that we have manufacturing capability for the very high-priced drugs on patents that are obviously making a lot of money for the drug company, so that is manufactured here, but then as they go off into the generic world, then it gets really competitive. It gets more and more competitive, and then that all gets offshored. We have very low-cost drugs that do not make a whole lot of money for anybody, and those are the ones that tend to be in a shortage situation.

It is almost like a barbell. We have very high-priced drugs and we have extremely low-priced drugs and nothing in the middle, and a lot of those low-priced drugs are related to the 80 percent of the precursors that underlie so much of the necessary medicines but may not be very expensive because they are not the ones on patent right now.

So how do we deal with that? To Dr. Gottlieb, some of this deals with the government actually getting information. I think you mentioned this in your opening as to the supply of these drugs, the sources. We just do not have a good handle on that. I think there is a dearth of information that we are getting as to where these shortages could occur and where those chokepoints are. Is that accurate, and do you have some ideas on how we could fix that?

Dr. GOTTLIEB. I think that is right, Senator. I think getting better information about where some of these critical junctures are is important, but it is only going to be sufficient if we can try to couple with some incentives to get manufacturing back into these spaces and get redundant manufacturing because we are not going to be able to mandate a solution here.

The problem, I always said that there is a lot of drugs that cost too much, and I think we would agree on that. There are some drugs that cost too little, and with a lot of these sterile, parenteral, meaning injectable generic drugs—and that is really the category that goes in and out of shortages, these sterile injectable drugs.

We have driven down reimbursement to levels where they sit. The reimbursement levels sit at slightly above cost of goods. That is OK if you are developing a small molecule-pill drug, where the manufacturing complexity is relatively straightforward, but when you are dealing with a complex drug like a sterile injectable drug, where you want there to be constant investments in upgrading

manufacturing, making sure the products are subject to stringent Good Manufacturing Practices (GMP) requirements, and you are allowing a margin that is slightly above cost of goods, it is hard to get the kinds of investments in manufacturing that you need.

So what you have seen in these industries is you have seen consolidation because the reimbursement is small. So the way you make up for the margin is you produce at very big scale. So you have a handful of consolidated manufacturers that have been underinvesting in their manufacturing over time. So when something goes wrong and a facility shuts down, you can create a shortage from a single facility shutdown.

I think we need to think about how to identify these chokepoints, how to identify where things can go awry, and then thinking about how to change reimbursement schemes to drive incentives back into these markets to make it profitable to develop these drugs.

We are getting a lot of these drugs at very low prices. That is very good for consumers until there is a shortage.

Senator PETERS. Right.

It is not just the drugs. It is also medical supplies. I think, Ms. Clowers, you mentioned that as well, the broad suite of products that you need like masks and gloves that are necessary.

In fact, I understand the third largest import from China to the United States are medical supplies and drug-related issues.

Given what is happening in China, there is going to be a pretty big disruption, potentially, in that supply chain, as that is where we get most of these supplies. So we could see shortages in things like masks and gloves.

Do any of the panelists want to comment on concerns that we may have related to what is happening in China for the supply chain?

Dr. GOTTLIEB. I will just broaden that out quickly, and Dr. Gerberding could speak to this too, because we have stockpiled a lot of personal protective equipment in the Strategic Stockpile for precisely these kinds of challenges.

I think where we are likely to see some potential challenges going forward, if the supply does not get online in China, is that a lot of components of complex medical devices are also manufactured in China. So the implantable defibrillator might not be made in China, but key components are sole-sourced in China.

When you look at a lot of the manufacturers, they have anywhere from a 1- to-month inventory on hand, including the drug manufacturers. I think if this extends—we are now a month into this a little bit longer where manufacturing has been shut down. If this extends in China another month or two, I think we are going to start to see some shortages of critical components, not just the personal protective equipment, but also sophisticated electronics that go into medical devices.

Ms. CLOWERS. I was also going to mention the stockpile, and that is one of the issues where Congress can play a role was as continuing oversight in terms of the agency's management of the stockpile before outbreaks occur during the sort of normal times, if you will, in terms of are we stockpiling the right type of equipment.

I would also want to add on to the complexity job that FDA has in overseeing the manufacturing throughout the world. The inspec-

tion regime was really set up as a domestic inspection process. Over the last 20 years, as manufacturing of drugs and devices have moved offshore, it stretched their capabilities. Right now, I think it is estimated there is about 400 drug manufacturers in China. So you can see where this could have the tentacles of this type of outbreak, not only the equipment that you need to handle the current outbreak, the medicines for other types of chronic diseases or just your generic drugs that you take, what type of impacts when workers stop going to the factories to work. How will that impact the delivery of those drugs?

Dr. GERBERDING. I was just going to add that the shortage that concerns me the most is the antibiotic issue, both just in terms of supplying the drugs that we might need, but also because when people have a coronavirus infection, are in the hospital, they are very prone to develop additional drug-resistant bacterial infections on top of it. We do not have the right antibiotics to treat those infections because we have a different kind of market failure there, an inability to pay for those drugs and incentivize manufacturers to create them.

Merck is one of the few companies that has an antibiotic pipeline, and we really struggle to maintain a prudent resistance model. We have watched lots of small companies go out of business just in the last year because they cannot get the reimbursement for the innovation.

In this context, that is a really important part of the coronavirus response because often with influenza that is what people die of, the bacterial infections that complicate the underlying disease.

Senator PETERS. I appreciate that. Thank you.

I just want a quick follow-up. I am out of time, so be quick, Ms. Clowers. You mentioned the foreign inspections and the foreign manufacturing. The FDA has approximately 188 inspectors. Only 12 are dedicated to foreign inspections is my understanding, and with our dependence on drugs, that seems to be a pretty low level.

Ms. CLOWERS. I think that is in reference to the foreign cadre. There is also domestic inspectors that can play a role in the inspection process, but in general, the number of inspectors have declined. As a result, we have seen the ability of FDA to maintain a number of inspections globally decrease in recent years, and we have ongoing work looking at those issues in terms of FDA's capacity as well as the other challenges that they face conducting inspections overseas, whether it is the need of translators when they go onsite, to being able to find the firms.

We have seen instances where they go out to inspect, and they show up to a facility. The facility does not exist.

We also have situations in most foreign inspections—it is preannounced. So the firm gets about 3 months' notice or more that FDA is coming to visit, and so you can imagine what type of, maybe, cleanup goes on during those 3 months. That is different from domestic inspections where FDA could show up unannounced that day for an inspection.

Senator PETERS. Thank you. Appreciate it.

Dr. GOTTLIEB. May I comment briefly?

Chairman JOHNSON. Yes, go ahead.

Dr. GOTTLIEB. The challenge, the witness is right that a lot of foreign inspections are conducted by domestic inspectors who will rotate into foreign inspection roles or inspect foreign facilities.

It was a challenge to recruit and retain people specifically into this foreign inspection post, and so that is something that we need to address. Filling those jobs was difficult.

We are also facing a situation now where the inspectors largely have been pulled out of China, and so we need to think about from a risk management standpoint how do we now ensure the safety of American consumers from products that are coming in from China if inspectors are not on the ground.

So it might require us to rethink import sampling and rely on that more, even though it is imperfect relative to inspections, or changing the risk management plan that the agency adopts in terms of how it targets its oversight and focus more resources on products coming from China, given the fact that inspections are now being pulled out of that market.

Senator PETERS. Thank you.

Chairman JOHNSON. I think this would be a good time for me to repeat my plea to my colleagues. We ought to take the Hippocratic Oath. First, do no harm. Again, I pointed out the statistic, but as best as I can determine, out of a $3.7 trillion spend on health care, it is about $500 billion on drugs. Even at a 20 percent after-tax rate of return, which is massive, that is only $100 billion out of 3.7. So on a bipartisan basis, we beat up on the drug companies, and no doubt, there are some abuses and they need to be addressed.

Let us put it in perspective and understand the situation like this. We need pharmaceutical companies to be successful. We need to encourage manufacturing here in the United States. I mean, things like heparin are in shortage. It is ridiculous. Because we have driven any profit motivation, we have made it very risky to manufacture because the risks are high of litigation. So we need to really recognize the root cause of this.

But I will get off my soapbox and go to Senator Hassan. She can get on hers.

OPENING STATEMENT OF SENATOR HASSAN

Senator HASSAN. I am trying to think of which soapbox to get on, but thank you, Mr. Chair and ranking Member, for convening us all. Thank you to all the witnesses for sharing your expertise and your time with us today.

Dr. Gerberding, I wanted to start with a question to you and, first of all, just thank you for many years of service to our country.

Reflecting on your experience leading a number of public health agencies, I would like to hear how you think we are doing this time with respect to the coronavirus. Do you believe that the Centers for Disease Control and Prevention have sufficient staff and adequate, flexible staffing policies to manage a public health emergency of this scale or larger?

Dr. GERBERDING. Thank you for that question. I am watching from afar. I am not in the CDC Operations Center——

Senator HASSAN. Right.

Dr. GERBERDING [continuing]. I do not have insight into what is going on, on a day-to-day basis, but I have to say it makes me really proud of the CDC to see what they have been able to do so far.

I think their communication is regularized. They are getting information out. They are working very closely with the State and local health departments by building out that whole front line.

So in terms of performance in this context, I think they have a lot to be proud of.

In the broader view, I do feel like the CDC has suffered from what I refer to as the "herky-jerky funding."

Senator HASSAN. Yes.

Dr. GERBERDING. A problem occurs. A budget emerges on an emergency supplemental basis. When that emergency is gone, then that money is repurposed. That is not the way to maintain a continuous process of improvement in our overall preparedness, and it is not just about the CDC. That spills over into every State and city.

Senator HASSAN. Yes.

Dr. GERBERDING. I urge very close examination of the sustainability of the effort, moving away from reactionary funding to something that creates a more solid and allows this kind of preparedness to continuously evolve over time.

Senator HASSAN. Yes. It is a good reminder that you need to invest in the things that you hope you never need.

Dr. GERBERDING. Exactly.

Senator HASSAN. But you need to be ready for them, and that is something that I think we struggle with.

I wanted to follow up on that. As I understand it, the United States was somewhat slow to confirm potential cases of the coronavirus largely due to logistical challenges dealing with sample testing. What we were told in a couple of briefings we have had now is, specifically, the delay results from hospitals and doctors' offices having to ship—and State health departments having to ship patient samples to the CDC to be tested instead of being able to send them to local public health labs.

So now that the CDC has developed a portable diagnostic test, are there public-private partnerships that we could leverage in order to scale up the production and distribution of those tests, if necessary, so CDC can direct its focus to ongoing response efforts as the situation evolves?

Dr. Gerberding and then, Dr. Gottlieb, if you would like to follow on.

Dr. GERBERDING. So when there is a new infection of any sort, it does take a little bit of time to develop a test and perfect it, and then you have to prove its sensitivity and specificity in its actual performance before it can be released.

FDA has created provisions so that unlicensed tests can be made available to public health labs, but there are a number of quality steps that have to go on. So it does not happen as fast as I think people would have liked.

I too saw some of the reports of 36 hours to rule in or rule out infection. So it is a problem.

I think the private-public partnerships ultimately do occur.

Senator HASSAN. Yes.

Dr. GERBERDING. That is the natural history of how these tests evolve, but in the early days, I think the most important thing is to just get the reagents made and get them out to the public health lab network where people are familiar with using the Polymerase Chain Reaction (PCR) tests, et cetera, and just deal with the crisis and then move into a more stable manufacturing platform.

Senator HASSAN. OK. Dr. Gottlieb.

Dr. GOTTLIEB. So CDC made in very efficient time—and it is a real testament to the efforts of the CDC and FDA—200 test kits available to the Laboratory Response Network. Each test kit can test between 700 and 800 samples. If you assume that on a typical patient, you are going to be sending off multiple samples, you can still test for upwards of maybe 50,000 patients with the tests that have been made available.

Those are just now being put in place. There was a press release yesterday from the Public Health Department in Illinois that they just stood up that test, and so we are just beginning to get testing capacity in place.

I think two things need to happen. One, we need to broaden the criteria of who gets tested. Right now, the criteria requires that you are either a recent traveler from China or have been in touch with someone who has traveled to China or been in touch with someone who has been diagnosed with a disease. We really should be trying to test anyone who presents with an atypical severe pneumonia that tests negative for the flu, negative for the multiplex test that currently tests for different viral forms of pneumonia. We should be looking for coronavirus. We should be trying to find it in the community. That is how we are going to spot small outbreaks and prevent them from becoming larger outbreaks.

The other thing that we need to try to develop in efficient fashion is a point-in-care diagnostic, like we have for the flu, something that does not require a reference lab but can either be done in Quest Lab or some other kind of reference lab or perhaps can be done as a screening tool more at the point of care.

So you think of a company called Cefheid. It has a platform called GeneXpert that they use to test for all kinds of things, including it was, I think, adapted for Ebola as well.

One of these sort of point-of-care platforms to get these tests into the hands of physicians is to broaden screen. That is how we are going to identify an outbreak in this country quickly.

Senator HASSAN. OK. Thank you.

Dr. Gottlieb, I wanted to follow up with you too on asking you to elaborate a bit on the role that the FDA plays during a public health emergency. Can you describe the FDA's process for allowing the use of unapproved medical devices and treatments during emergencies, known as the Emergency Use Authorization (EUA), and why is it important in a public health emergency?

Dr. GOTTLIEB. I am going to ask my former FDA colleague, Dr. Borio, to comment on this as well.

Senator HASSAN. Sure.

Dr. GOTTLIEB. She headed up this program at FDA for the agency.

The agency has now issued an EUA, for the diagnostic tests. That is how they were able to get it out. So it allows the agency

to bypass some of the traditional steps that would have to be done that would extend the development timeline.

The flip side of that, though, is that at least with the diagnostics, there might have been companies capable of promulgating these tests as laboratory-developed tests inside their own reference laboratories because the technology for doing this is not that complex.

But now that the EUA has been issued, companies are unable to promulgate laboratory-developed tests. Now they affirmatively need to come into the agency to ask for permission to put those tests into the market.

Dr. BORIO. Thank you, Dr. Gottlieb.

I will say that the agency, when I was there—and my understanding, it is still the case—they are very proactive in a public health emergency with reviewing things in real time as data are received, and they are very proactive in communicating to developers what is it that is expected. It really is a very streamlined validation process because there is an urgency of getting tests out there.

It is, however, important to have a certain comfort with the validation before these tests are being used because we do not want to be in a situation like we are seeing in China, for example, where there is a little bit of a concern about whether the results are actually accurate.

So even though these tests are very routine and routinely used everywhere, they still require some training and some validation.

Last, I will just say that I cannot stress enough the importance of moving forward having a point-of-care diagnostic test. We should not be relying on a send-out test in a public health emergency. It is not the way—anything that changes the way physicians or clinicians are practicing with their patients makes the response less efficient, and the technology exists today. But these tests have had a very hard time in coming into the market because of the more systemic issues that we discussed earlier.

Senator HASSAN. All right. Thank you very much.

Thank you, Mr. Chair.

Chairman JOHNSON. So just for my colleagues here, there will be some votes being called. They are stacked. By the way, we are under discussion about sitting at our desks on these stacked votes to make it more efficient. Hopefully, we can get that accomplished.

I am going to stay here. Apparently, my vote is not going to be necessary. So I am going to keep the hearing going. All I am going to ask of my colleagues, if you are going to go and if you are going to come back, let me know, and we will try and keep it going for you. But if you are going to leave for good, let us know that as well. Senator Carper.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Thanks, Mr. Chairman.

I want to thank all of you, not just for coming here, not just for your testimony, not just for responding to us, but some of you, we know pretty well, and it is good to see you. For those who are here for their first time, welcome. Thank you for what you do with our lives, and thank you for what you do when you try to preserve a life here in this country and maybe around the world.

My colleagues heard me tell this story before, but when I was a brand-new Governor-elect, I remember meeting with a bunch of people who were giving me advice before I raised my right hand and took that oath of office. One very wise, old Methodist minister from southern Delaware once said to me these words. He said, "Tom, just remember the main thing is to keep the main thing, the main thing." I said, "Would you say that again?" He said, "The main thing is to keep the main thing, the main thing."

We are covering a lot here. We are an oversight committee. We have oversight of the whole Federal Government. There is a lot in our bailiwick, but try to help us narrow down our responsibilities here on the oversight committee, the Homeland Security Committee, what we should be focusing on as we go into this.

Nikki, would you just lead us off? Because we work a lot with GAO, as you know, and we are grateful for what your agency does.

Ms. CLOWERS. Thank you, Senator.

Senator CARPER. Just be succinct.

Ms. CLOWERS. Yes, sir.

To pick up the focus on the main thing, one of the things I would stress is that we do not lose sight of tomorrow. Responding to the coronavirus today is very important, but there is other public health threats. We cannot get in a cycle which we sometimes find ourselves in as chasing Disease X, what is going on this month, and we lose sight of the routine preparedness that needs to occur, the funding of the routine preparedness, what you would consider routine. When we lose sight of that, then we get in this sort of never-ending cycle of chasing.

Senator CARPER. OK.

Ms. CLOWERS. The other thing I would mention, as we have already discussed, is the reliance on manufacturing overseas, and so I will not go into depth on that.

The other thing I would stress is just the important role that you play as a committee in providing oversight to the agencies, both before, during, and after an outbreak. The before, making sure that they are preparing, that they have the plans in place, that they know the roles and responsibilities. After, are they conducting after-action reports? We found that often after an outbreak occurs, it does down, people want to walk away. After-action reports are not completed. If they are, they are delayed or they do not include all of the participants, and we are missing an opportunity to learn.

Then the last thing I would say is just what we have been talking about as well. There is a Federal role to play in terms of creating a market for countermeasure development. What kind of incentives can we put in place to draw manufacturers to develop needed countermeasures?

Senator CARPER. Thank you. Thanks so much.

Dr. Gerberding. Very succinct, please, the main thing.

Dr. GERBERDING. Right now in the United States, I think the main thing is to exercise how we will sustain essential services if we begin to see sustained transmission in our communities, essential services meaning health care, of course, but also all of the other Homeland Security services necessary to keep our society operational, our supply chains running, and civility among our citizens.

We have seen in previous outbreaks, for example with SARs, what happens in a community when those services are disrupted, and now is the time to exercise and make sure that we have a plan in place to do that, if this does become worse.

Senator CARPER. Thank you.

Dr. Gottlieb, good to see you. Thank you. The main thing, please, just succinctly.

Dr. GERBERDING. Modeling has shown that the time from first introduction in China, which was probably in November, to epidemic spread was about 10 weeks, if you think that cases were introduced into the United States undetected late December or early January, which is probably the case. Statistically, it is quite probable. We are going to start to see those outbreaks emerge sometime in the next 2 to 4 weeks.

I think that we should be leaning in very aggressively to try to broaden diagnostic screening right now, particularly in communities where there was a lot of immigration, where these outbreaks could emerge, to identify them early enough that they will be small enough that we can intervene to prevent more epidemic spread in this country.

Senator CARPER. Thanks so much.

Dr. Borio, same question. What is the main thing?

Dr. BORIO. I think we need to assume that we are going to see a lot more cases here, and I really worry about the health care system preparedness and ability to take care of patients, and I think we cannot afford to lose a minute in getting this health care system as ready as we can before the influx of patients arrive.

Senator CARPER. All right. Thanks. Dr. George.

Dr. GEORGE. Senator, I think that the Committee should be looking at what all of the Departments are doing right now to address coronavirus, not just for employee safety, but in terms of all of their responsibilities.

All of the Cabinet Departments and many independent agencies have responsibilities for biodefense, and those should carry forward now. We should not be waiting around. They should not be waiting around until things get much worse to lean forward, dust off their plans, and do what they need to, even if it means that they have to stand back down because things did not get as bad as they could.

Senator CARPER. OK. Thanks.

Who is the lead agency responsible for coordinating the development of a vaccine in a pandemic? I do not care who takes that one. Who is the lead agency responsible for coordinating the development of a vaccine in a pandemic? Who would like to take that? Just very briefly.

Dr. GERBERDING. NIH.

Senator CARPER. OK. That was pretty brief. Can you be more brief? [Laughter.]

What lessons did U.S. agencies and our foreign counterparts learn from formulating vaccines and treatments for SARS, for Ebola, and other global health threats?

Dr. GERBERDING. I can take the question from the perspective of Ebola because I work for the company that has the licensed Ebola

vaccine that is currently being used in the Democratic Republic of the Congo (DRC).

I think the biggest lesson overall was the incredible number of partnerships that have to emerge rapidly and effectively to bring a product rapidly through clinical testing for safety. All of the kinds of permits that have to happen to move it cross-borders, et cetera, amazing requirement for all kinds of agencies of government and civil society, and that is just getting it into the clinical development.

Once we want to get it into the country to actually use it, it brings up a whole other round, including the importance of the front-line health workers.

Senator CARPER. Last, one quick one. Can the reported 12- to month timeline for developing vaccines and treatments be shortened safely and effectively? That could be either a yes or no, and if it is a yes, then how? Just very briefly.

Dr. GOTTLIEB. You are the expert.

Dr. GERBERDING. I think the Ebola virus vaccine development proved that work that started in Canada right after the turn of the century, 13 years before Ebola emerged, really was required to get us to the point where from that point forward, we could sprint.

Now we have a new entity called the Coalition for Epidemic Preparedness (CEP) Innovation, which is a private-public partnership funded by countries, by Gates, by Wellcome, by others, civil societies, that is investing building products and vaccines through phase IIB so that they are in the freezer when one of these frightening pathogens does emerge. That will speed up our ability to act quickly.

Dr. GOTTLIEB. I will just add briefly, doing a clinical development, clinical trial in a setting of an outbreak of a deadly pathogen is exceedingly difficult, and that is something that we could be planning for right now. How are we going to construct clinical trials of products that we want to test?

They are standing up a randomized trial of an antiviral drug in China right now that was stood up very quickly. The question is, Are we going to be able to gather information from that that could inform a regulatory decision here in the United States if we ultimately want to license that product for this disease?

So thinking through how to stand up that infrastructure and get that in place in a setting of a public health crisis can greatly hasten the development timeline, and that is what we were able to do with the Ebola vaccine, where we were able to stand up a randomized trial in Western Africa to turn over the data caught on that product very quickly.

Senator CARPER. Thanks to all of you. Thank you so much.

Chairman JOHNSON. Senator Scott.

OPENING STATEMENT OF SENATOR SCOTT

Senator SCOTT. First of all, thanks to each of you for what you have done in your prior jobs and what you are doing now.

There have been reports that the coronavirus may live up to 9 days on a surface. I have the call in to the CDC to get their feedback, but do you have any views on that and whether that is possible?

Dr. GERBERDING. That is relevant in case contaminated objects prove to be a source of transmission, which would be highly unlikely and not an epidemiologic factor in most cases of respiratory virus transmission.

You have to distinguish between finding the virus, meaning maybe there is deoxyribonucleic acid (DNA) there, dead or alive, versus the virus is alive and present in sufficient quantities to be infectious. Those are two very different things. I personally am not focused on environmental contamination as a source of this. I think it is much more likely to be droplet and potentially aerosols, and that is kind of what we are seeing on the ship in the Japanese harbor.

Senator SCOTT. Anybody else? Anybody else have a different view?

Dr. GOTTLIEB. The data with coronavirus shows typically that it is probably a couple hours where you can get transmission from what we call "fomites," which is a contaminated surface, touching it and then touching your face.

There have been some studies that have looked at transfer of the virus under really ideal circumstances that are unlikely to exist in nature that shows that it could be several days.

I think for most purposes, we should assume that the virus has the capacity to live on a surface for a couple of hours. So you could get transfer from what we call a "fomite."

That is why I think one of the roots of transmission that we should be very concerned about is touching. It is not necessarily wearing face masks that is going to provide the best protection for individuals. It is going to be washing your hands and using an alcohol sanitizer appropriately.

Senator SCOTT. So we import quite a few things from China: ag products, food products, processed food, seafood, grains, even live animals. Do you think we are doing all the right things with regard to reviewing what comes in and deciding what should not be coming in until we get more information about how this coronavirus—the transmission of it?

Dr. GOTTLIEB. I think from a regulatory standpoint, Senator, that my focus would not necessarily be on the virus cross-contaminating inanimate object and coming in. So a ship package, I would have a very low level of concern around that as a route of transmission.

I think the bigger concern right now with respect to the imports coming in from China is just the lack of oversight of manufacturing. We pulled out our own inspectors from the country. You have to believe that their regulatory apparatus is stretched right now and not providing the same level of oversight, and I think it does behoove us to think of how we are going to backstop that with other kinds of approaches like greater import sampling. It is not an perfect substitute for having inspectors on the ground, but it is a substitute. We need to think about how we adapt the regulatory process and take a different risk-based approach to looking at some of these products that are still coming in that consumers here in the United States still need.

Senator SCOTT. Those inspectors, what agencies have inspectors over there?

Dr. GOTTLIEB. I know FDA does. I am sure other agencies as well have inspectors in China but not necessarily looking over FDA-regulated products.

As best I know, based on the public reporting, the U.S. FDA inspectors were recalled from the country based on the new travel guides from the State Department, and so we do not have them on the ground.

Senator SCOTT. Taiwan is not allowed, I guess, to be a member of the World Health Organization (WHO). By Communist China not allowing Taiwan to be a member, how has that impacted their ability to defend themselves against coronavirus, which they are a lot closer to it than we are?

Dr. GOTTLIEB. Taiwan has not been part of the working groups of the WHO. It has been a question for our Ambassador, Andrew Bremberg, over there, but I think it is highly unfortunate that China has continued to try to assert their political prerogatives in a setting of this crisis in terms of how they treated Taiwan.

So a lot of people have asked me why do not we receive reporting from Taiwan. It is because the Chinese are baking the Taiwanese numbers into their own estimates because they do not see it as an independent nation. So that has certainly been unfortunate. We can add to a long list of things I think the Chinese government has done here that has made our response more difficult, probably the most significant of which was not admitting that there was human-to-human transmission until January 20 on the same day that they disclosed that they had 14 health care workers that were infected.

Senator SCOTT. How comfortable are you with the numbers that are coming out of China? You read reports that they are significantly underreporting the number of cases, and there is a lot of anecdotes that the number of deaths are way, way, way higher. Do you have any feel for that?

Dr. GOTTLIEB. I will turn to Dr. Gerberding as well.

I do not trust the reporting in China, and I also believe that the China numbers reflect the most severe cases. So we are getting a skewed view of the case fatality rate and how severe this is.

I suspect that if you were able to bake in all the mild to moderate cases or asymptomatic cases, the case fatality rate would go down. It could still be quite high. I mean, even a case fatality rate of .2 or .5 could be catastrophic if this is highly contagious and spreads around the world.

But I almost believe that the issues of the reporting from China are not as relevant right now to how we perceive this epidemic and potential pandemic because we now have experience in Singapore, Japan, Hong Kong that is going to tell us a lot more about how this virus is going to spread around the world.

We now know this is epidemic in China, and whether it continues to grow or does not, that is not going to affect as much whether or not this becomes pandemic as what is happening in those other nations right now where the cases have already been exported.

I will say, though, if China does take the brakes off of some of the measures that they have taken—and they seem to be making some noises about that because they are worried about the eco-

nomic impact—that could hasten the rate at which more cases get exported out of China.

Senator SCOTT. Thank you.

Chairman JOHNSON. Senator Harris.

OPENING STATEMENT OF SENATOR HARRIS

Senator HARRIS. Thank you, Mr. Chairman.

I want to thank the panel for being here. Your experience in past public health emergencies and crises is exceptional and I think important to understanding how we should respond to the coronavirus virus.

However, the American people also, Mr. Chairman, need to hear from the officials who are currently responsible for addressing this, and we need a public hearing with current government officials as soon as possible. It is critical to my State of California.

I have spoken with some of the current officials and asked them why they are not here today, and they did not have a good response for why they are not. In fact, they went on to say, "Well, we have to take time to prepare talking points." The American people deserve them to be here this morning.

That being said, Dr. Gerberding, thank you for your service. The coronavirus outbreak demonstrates, obviously, how important it is that we respond and be prepared to respond to a public health threat. Yet just this week, President Trump released the Fiscal Year (FY) 2021 budget that cuts funding for the CDC and NIH, which you have mentioned would be the first responder or most responsible for dealing with a pandemic, and so these are obviously critical agencies that must response and need to respond to the coronavirus.

So this is one in a long line of attacks on our country's public health system that we have seen over the past 3 years from trying to repeal the Affordable Care Act (ACA), to restricting the way science can inform government decisions, to slashing our investments in global health.

So my question to you, as a former CDC Director and especially during the SARS epidemic, you must recognize, obviously, the importance of a strong public health system to guard against infectious disease threats. As Congress considers the next fiscal cycle, what public health programs would you prioritize to ensure that our country is prepared to address an outbreak, this outbreak, and any future outbreaks?

Dr. GERBERDING. Thank you for your question. It is a question that has been asked for many years, and it is frustrating to have to answer it for many years.

I will put on my hat as the chair of the Center for Strategic and International Studies commission because that is basically the question we asked as well: Where should investments be made to improve our global health security? I can share this with you. Other Members of Congress have participated in its development.

But specifically with respect to the CDC, I think the whole system of public health has been left behind as more and more of our health resources have gone into care delivery, and we have underinvested in prevention and preemptive care, including the preparedness, to mention of that.

I also think that it is a small world, and we need to have a cadre of people who are trained to be deployed to places like the DRC when there is an outbreak there so that we can lend our expertise and our competency in safe ways to be helpful at containment when the problem is somewhere else.

The third issue really relates to what Dr. Gottlieb was discussing, and that has to do with our laboratory network. Across the public health system, we depend on the Laboratory Response Network in situations like this, and they have made dramatic steps over the past 10 years or so. But there is much more to be done there, and we have to keep up with the state of the science.

I totally agree with point-of-care diagnostics for emergencies. We have a lot of work to do to really buildup the public health system, and the great thing about it, it is not just sitting there idly waiting for an outbreak. We can use it for ordinary care as well. So it has a dual purpose, and I think those are investments that make sense.

Senator HARRIS. So to your point that you have made these recommendations before, to what do you attribute the lack of progress?

Dr. GERBERDING. I think we have a general mindset that undervalues health promotion and prevention, and I include preparedness in that dimension. When something happens, as a Nation, we are very competent at making an emergency investment and stepping up in the crisis to get miraculous things accomplished, but we do not sustain it. It is complacency crisis.

Senator HARRIS. But what you are describing goes to the very core of the point of the public health model, which tells us prevention——

Dr. GERBERDING. Promotion, preparedness.

Senator HARRIS. It is the smartest and cheapest way.

Dr. GERBERDING. Absolutely.

Senator HARRIS. Then if the sniffles take on, early intervention, but if we are dealing with it in the emergency room, it is too late, and it is too expensive.

So this is not a new concept, and I am just at a loss to understand why we have not made progress, then.

Dr. GERBERDING. I would love to follow up with you in a deeper conversation than that because it is a complicated cultural issue in our country, but I think it also has to do with just generally the tendency to have wishful thinking that a bad thing is not going to happen.

Individuals do that when they smoke cigarettes or do things that they know are bad for their health, but I think as a society, we have a similar challenge.

Senator HARRIS. Can you talk with me, based on your experience and your thoughts about how we can better, what is the system in place? Because I am having a difficult time getting it, even when I have talked to current government officials, about the system for Federal funding and how it is distributed to State and local governments who in the current crisis, the coronavirus, and in past circumstances, it is not happening as it should. There seems to be a distribution of responsibility but not a distribution of resources to the State and local governments.

Dr. GERBERDING. I do not have any insight into how that is happening with the coronavirus situation. So I cannot respond in a contemporaneous way.

Generally, the funding mechanism waits for emergency supplemental to come, and then it is distributed according to population and other parameters across the public health system.

I do not think that is the optimal solution. I think we need to have these systems and the support in place.

A major vulnerability, in my opinion, it gets back to what we were discussing earlier, and that is that our health system has so little surge capacity in it. Hospitals are not going to build that without investment. We have to support hospital surge capability.

Senator HARRIS. Because in my State, for example, there are large counties like Los Angeles and smaller counties like San Benito that just simply do not have the resources that are necessary to address the issue, and they are sitting there waiting for reimbursement, with no clear indication of when they are going to get it and what will be reimbursed. Their work includes a number of things, but all of the work is being done by local officials, not Federal officials.

Dr. GERBERDING. At the end of the day, it is the front line. I am a licensed physician in your State and work at San Francisco General Hospital. So I am well aware of what you are talking about.

Senator HARRIS. Thank you for your work.

Ms. CLOWERS. Senator, may I add something about on the funding?

Senator HARRIS. Please.

Ms. CLOWERS. There are three core programs that fund State and local activities, two of which are CDC. One is Administration for Strategic Preparedness and Response (ASPR). We have looked at the funding over time. From about 2003 to 2017, each year that those programs in total, starting in 2003, awarded about $1.4 billion. It has decreased to about $1 billion now. So what we have heard from State and local officials, they really do then rely on the supplemental funding that is provided, and about that timeframe, it has been $2.9 billion for Zika, Ebola, and other types of diseases.

The concerns with the supplemental funding, while it does enable the surge capacity that is needed, often the timing is off, and so it is too late.

Senator HARRIS. Right

Ms. CLOWERS. The other mechanism that has been used is reprogramming, which we have heard the Secretary recently announce. Again, that gets the money out quick as needed, but again, what we have heard from State and local officials is that that is essentially robbing Peter to pay Paul. It takes money away from the routine preparedness, and then it delays and disrupts the preparations at that level.

Senator HARRIS. Thank you.

Thank you, Mr. Chairman.

Chairman JOHNSON. Senator Rosen.

OPENING STATEMENT OF SENATOR ROSEN

Senator ROSEN. Thank you, Mr. Chairman, and thank you for being here today for the work that you have done.

I want to agree with you and Senator Harris that we need the current administration here, not just to address today's issue on coronavirus, but our future preparedness and our readiness. It is very important.

We talk a lot about our large population centers when we have a potential pandemic like this one, but our community hospitals and clinics, just like you alluded to, they are on the front lines, particularly those in our underserved urban areas and our remote and rural areas.

Nevada, we have 300,000, about 10 percent of our population, living in frontier and remote rural areas, and so we need guidance, and we need staff that is well trained to have the right equipment ahead of time.

So for Dr. Gerberding and Dr. Borio, what Federal investments—where can we target these most effectively to ensure our local rural providers have what they need to respond, not just to a large-scale epidemic, but to mass casualty, a natural disaster? Those also have an impact on public health and the system to respond.

Dr. GERBERDING. As we said a minute ago, the front line is local. I do not think it is realistic for every health facility and every provider to be fully up to speed on every emerging infection that could occur. So we have to think about a hub-and-spoke model.

What is most important for every provider is to have the ability to be quickly updated if there is something new and emerging so that a training system is in place, the information system can quickly get information out to people, and they know what to do when the first patient appears in the emergency room with a suspicious diagnosis or something that is suspicious for an emerging infectious disease threat, and then that we have the capacity to get advice and refer or transport the person to a facility that has the more advanced infection control and care, just like we do for other complex medical problems.

But the problem is reaching the front line in a reliable and systematic way, and that requires a system of ongoing education and training that is incomplete, as you have pointed out.

I will let you talk a little bit about the medicine.

Dr. BORIO. I will just add that I agree that with the tiered approach, because that is probably most of complex medical delivery occurs, anyway, right? So not every hospital can do the most complex procedures.

But the funding has been approximately, ball park, $250 million a year, and it is being filtered through State public health systems. This funding is very necessary for planning purposes, but it is just not sufficient to really achieve preparedness. We need to find a way to go from planning to actual preparedness.

It is going to require more expectations, I think, on part of the Federal Government coupled with resources to fulfill those expectations, but we cannot stress enough how important that preparedness at the hospital level is.

Senator ROSEN. Do you think that we can potentiate using the telemedicine capabilities between our urban hospitals that are very well equipped to our rural providers that are out there? How do you think that we could best put some funding into that mecha-

nism to be sure that out in smaller communities we have some of those issues taken care of?

Dr. BORIO. It is clear that today's system does not leverage the most innovative technology that exists in the marketplace, and telemedicine is—it is hard to imagine that we are going to achieve the level of preparedness that we need to in the absence of exploring more of those technologies that include telemedicine and telehealth.

We see some progress in that regard, some increase in uptake in the medical care system, but a lot more could be done to leverage those technologies for preparedness.

Senator ROSEN. So I think that needs to be part of the funding stream perhaps as well?

Dr. BORIO. Absolutely.

Senator ROSEN. Thank you. I yield back.

Dr. GERBERDING. Could I just add one thing? Because when we are having this conversation about how do we build a cascade of preparedness, I want to go back in time to the efforts that were made when I was still at the CDC. Secretary Mike Levitt at the Department took on the issue of pandemic preparedness, heart and soul.

We went to every Cabinet Secretary in government and sat with the book about the 1918 pandemic, outlined sections of it that were relevant, and had conversations about what their Cabinet could be responsible for and contribute.

Secretary Levitt also took those of us in the Department who were involved to every State in the Nation and met with the Governor, the head of education, faith-based, you name it. The community of experts assembled in every State and then had an exercise about what they would need to do in their State, and in many States, that exercise cascaded down into cities.

So it brought attention to exactly what you are talking about. It is local, and if we do not build that preparedness into the system, we have kind of lost the game.

Senator ROSEN. We need to bring FEMA into some of these conversations too as we talk about whether it is a mass casualty, a natural disaster, a hurricane, an earthquake, something else that can happen that could leave some of our communities unprepared in the same way as for this. So maybe FEMA needs to come into this conversation training as well.

Ms. CLOWERS. Absolutely. It will require all agencies at Federal, State, and local, as well as the private sector, and that was one of the reasons why we called for a National Biodefense Strategy, which was issued in 2018, and for the first time does lay out a process for enterprise-wide strategy that looks at all the threats in an integrated way, because we cannot have the fragmentation both of understanding, trying to collect information, and integrating information, prioritizing risk. That must be done in a strategic fashion.

Senator ROSEN. Thank you.

Chairman JOHNSON. Senator Hawley.

OPENING STATEMENT OF SENATOR HAWLEY

Senator HAWLEY. Thank you, Mr. Chairman.

Thanks to all of you for being here.

I think a version of this question may have been asked, but I would like to hear the answer with my own two ears. Ms. Clowers, I will direct it to you, but anybody is welcome to answer.

When it comes to the number of cases that China is reporting, what is our assessment of the accuracy of these reports, both in terms of infections and deaths, and how do we rate these statistics in terms of trustworthiness?

Ms. CLOWERS. I would agree with the other witnesses in terms of we should look at those numbers with some questions in terms of reliability of both the number of deaths as well as the reproductive index.

Senator HAWLEY. Go ahead, Doctor.

Dr. GERBERDING. I would say one could worry about obfuscation of information, but I think more to the point, it is who is being tested. If the asymptomatic or mildly ill people are not coming forward or not being tested, then we are obviously missing the rest of the iceberg.

Dr. GOTTLIEB. Yes. I think that is a critical point that we are probably overestimating the case fatality rate right now because we are only testing more significant illness, and it is probably the case that a lot of people who have mild to moderate illness just are not even presenting to the system anymore, now that they have locked down the entire Hubei Province.

The issue right now, the questions that we need to grapple with right now are it is clear this is epidemic throughout China. Is it becoming epidemic in other parts of China? So the reporting in the other provinces is important, what is happening in Beijing.

But even more important than that, it is going to be what is happening in Singapore, Japan, Hong Kong. Why do not we have any cases in Malaysia? There has to be imported cases into Malaysia. They are just not finding them. What is happening in Western Africa? There has to be imported cases in to Africa, given all the connections. What is happening here?

There is probably spread that we are just not detecting yet, and I think that the situation in China, we are going to quickly have learned as much as we are going to learn from China, and we are going to start to focus our attention on these other regions what is becoming epidemic or at least there is sustained community transmission and where then reporting is a lot better, including Singapore, which has done exquisite reporting on their cases.

Senator HAWLEY. What do we know about the rate of reported infections in terms of the curve, the derivative curve, if you like? Is it still bending up at a pretty fast pace?

Dr. GERBERDING. Right now, a true epi-curve, exactly what you are asking for, has not really been created.

What we do see are the number of reported cases, but we do not see the curve in terms of when they started. So that is the frustration that I have. I cannot be an epidemiologist without an epidemic curve, but I think just kind of crudely looking at the numbers as they have climbed up day to day, we are still on the upslope of the curve for sure.

Senator HAWLEY. Go ahead, Dr. Borio.

Dr. BORIO. They may not have enough diagnostic test kids to test everybody who may need to be tested. So we may see a certain number reporting because that is all they could test for that day.

Dr. GOTTLIEB. Yes. The reports out of the Hubei Province a number of days ago was that they had the capacity to test 6,000 samples a day. So if you figure that there is at least a couple of samples per patient, their testing capacity was limited somewhere around 3,000, which is why we got a week worth of reporting of 3,000 new cases, probably. I think that had something to do with it.

Senator HAWLEY. Yes. Go ahead, Dr. George.

Dr. GEORGE. I would also add that we have a resource problem now too. In China and possibly elsewhere, if you have a limited number of diagnostic tests, you are not necessarily going to use those to test the people that have already passed away.

So our understanding of the entire outbreak out in China is limited by the resources that they have as well. It is not just a lack of desire on the part of the Chinese government to report.

Senator HAWLEY. Thank you. That is very helpful.

Just on the resources point and turning our focus here domestically to the United States, what measures are we taking, whether it is masks, whether it is kits, whether it is other supplies that we are going to need, if we were to see a significant uptick in cases here? What measures are we taking to make sure that we are fully and amply prepared?

Dr. GERBERDING. I think it is important to remember that we have a Strategic National Stockpile, which is an enormous reservoir of medical equipment, supplies, medicines, vaccines, et cetera, strategically situated around our country. So that is our first line of defense that would have to come into play if we were experiencing a major surge in requirements.

The stockpile is not limitless, and as we have already heard, the supply chains who are replenishing it will be very marginal at best. So I do not think it is a solution, but it will definitely help us buy some time.

Senator HAWLEY. Does anyone else have anything to add to that?

[No response.]

Can I just pursue with you, then, a worst-case scenario? Dr. George, maybe I will direct this to you in the first instance, but anybody is welcome to answer.

Based on what we are seeing in the region, in the Pacific region—Japan, South Korea, and all of East Asia—at the end of the day, what are the worst-case scenarios that we face here domestically in the Continental United States based on what we know now?

Dr. GEORGE. I think we have to look and see what is happening in these other countries and assume the same thing is going to happen here, especially when we do not understand exactly how the disease is behaving and all of its characteristics. It is something that we can do here.

I think we have to learn some lessons from some previous outbreaks as well. During H1N1, the government had assumed that pandemic influenza would start somewhere else, and in fact, there

is debate as to whether it started in the United States or in Mexico or both sort of at the same time. So we need to learn from those.

But I think it is also important for us to be looking at the new cases and the clusters that we are seeing throughout the world in places where we would not necessarily expect to see them. There is a cluster in France now, for example, and I think that should inform what we are doing here and what we are planning for.

I do not think we should be planning for the onesie-twosie cases that we have been seeing thus far in the United States. I think we have to plan for something larger.

Senator HAWLEY. When you say larger, you mean what potentially?

Dr. GEORGE. I think that we have to plan for the possibility that we have thousands of cases.

In the schools of public health, they often train us to look at the data that you have been provided, and assume that you do not have all the data. Even here in the United States, you do not have a comprehensive set of data and then multiply. So we are often taught to multiply by seven or eight times what you have been told. For every one case you see, there are seven or eight out there that you do not.

So that means, actually, we would be looking at hundreds of thousands of cases. I think that is the scale at which we should be planning.

Dr. GOTTLIEB. The strategy seems to be try the slow introduction of the virus as much as possible to push off the time at which we are going to start to see outbreaks in this country, hope that the summer provides some kind of backstop, because you typically do not see coronavirus transferring as efficiently in the summer, although that does not seem to be the case here—it is 90 degrees in Singapore right now—and hopefully buy yourself enough time to get to a vaccine or some kind of therapeutic.

So that is not an unreasonable strategy right now, given what we do not know and what we do not have, but it does behoove us to think about how are we going to try to develop a technology that could be a backstop here if this does become endemic, meaning this becomes part of the normal mix of viruses that propagate, or we start to see very large outbreaks in the United States that we do not have sufficient capacity to contain and control.

Senator HAWLEY. Last question, Mr. Chairman.

Surely, this has been asked, but again, I will ask it, just since you raised it, Dr. Gottlieb. Where are we in terms of a therapeutic or an antiviral for this strain?

Dr. GOTTLIEB. I will just comment briefly, and Dr. Gerberding has far more insight into this. There is one drug, remdesivir, that has been in the media that is manufactured by a company called Gilead that is currently in investigator-led studies in China.

There are two studies ongoing, one in mild and moderate patients, about 300 mild to moderate patients, and another study in about 450 severe patients.

If you believe that part of what is killing people with coronavirus might be an inflammatory response to the virus itself, there is a question of whether or not simply intervening at the point when someone becomes very ill to block further viral replication is going

to be beneficial at that point. It might actually do more harm by killing a lot of virus that then causes, then sort of potentiates the inflammatory response.

So there is a lot we do not know, and I do not think that we can just sort of hang our hat on the idea that we are going to have an effective antiviral here. It might be difficult.

Dr. GERBERDING. I would just add that this week, the WHO hosted a meeting of all of the parties who are involved in drugs or vaccine development for this entity and looked at what can be done to accelerate and support.

There are mechanisms to get that ball started in January, very fast in January, Coalition for Epidemic Preparedness Innovations (CEPI), which is this private-public partnership that funds early stage development work for pathogens that could cause pandemics. They funded three companies just within weeks of recognizing that this problem was emerging. So the work is getting off to a good start.

NIH is obviously priming the pump here, but the reality is it takes time. It is 2020. The work on the Ebola vaccine for the emergency response in Africa took a couple of years to really wrap up and get submitted to Federal agencies for approval, even though there is an ongoing outbreak there. We did not get our final U.S. license until December 2019.

So we have to be realistic about the timeline, even when pressured with emergency situations.

Senator HAWLEY. Thank you very much.

Thank you, Mr. Chairman.

Chairman JOHNSON. Before I turn it over to Senator Peters, I think this might be a good time to try and put these things into perspective with facts because this is what I am trying to sort out.

You started out, Dr. Gottlieb, talking about contagion versus virulence. In 2003, SARS had a little over 8,000 cases worldwide, 8 in the United States, had about a 10 percent death rate. In 2009, we had H1N1. Again, in the public perception, everybody is scared. You have SARS. You have H1N1. You had 200 million cases worldwide, 60.8 million in the United States, and a lot of people died, 150- to 500,000 people. But that is kind of true of seasonal flu as well, right? Then you had MERS in 2012, 2,500 cases worldwide, 2 in the United States, with a death rate of 34 percent. Ebola, a virus different than kind of flu.

Now you have coronavirus. It is looking to me a little bit more like H1N1, maybe more contagious, maybe not as virulent. Can you just kind of put it into—I know we do not know much about this, but where does this all fit in, in terms of seasonal flu? Was H1N1 that much different than a normal seasonal flu, just a different variety that sounded scary?

Dr. GOTTLIEB. H1N1 was a novel influenza that people did not have cross-immunity to. So it was highly contagious because of that.

I think it is hard to make an estimate on where coronavirus is going to sit in that continuum.

I think the concern that you are hearing from us and public health officials is that this could sort of occupy that sweet spot between being contagious enough that it transfer very efficiently but

still virulent enough that when distributed over a very large population, it causes a lot of death and disease.

To put it in perspective, influenza has what we call an "R-naught," meaning how many new cases are infected for every case that you have of about 1.5, I believe, 1.3, 1.5. It is 1.28.

It looks like based on the modeling that has been done, the R-naught here is going to be somewhere between 2 and 3. So this is much more infectious. The case fatality rate——

Chairman JOHNSON. That grows geometrically too, right?

Dr. GOTTLIEB. Yes.

The case fatality rate in normal influenza is .1 or less. A severe strain might be .1. Sometimes it is a little less than that.

The case fatality rate here right now, the estimates are it is about 2 percent. That is probably based on underreporting of the mild to moderate cases. So that is probably going to come down, but it might still be .2 or .5 percent. Now, that does not sound like a lot, but that is devastating. If you have something that has an R-naught of 2 to 3 and a case fatality rate of .2, that could be quite devastating.

I will say that I think we are going to know much more in the next 2 weeks as we examine what is happening in Singapore and what is happening on a very unfortunate cruise ship, because we are going to get a better estimate of how many people with disease actually progressed to severe disease.

So far in Singapore, with 50 cases identified—and I believe that they are doing a good job of identifying their cases—eight are in the ICU. That is deeply concerning to me.

Chairman JOHNSON. Talk a little bit more about Singapore. Again, you have the flu season. It gets cold. People are confined versus in the summer months. Talk a little bit about why you are simply concerned about Singapore.

Dr. GOTTLIEB. Because, first of all, it is warm right now. So you should not see efficient transfer.

Second of all, Singapore has about 3.4 million travelers from China a year. We have about 3 million. So on a statistical basis, there is no reason to believe that if Singapore got implants of this virus, we did not. You would expect them to be identified earlier in Singapore, a very dense island nation, city-State. You would expect those viruses to be identified sooner there than it would be in a big country like ours. But it does suggest, at least to me, that we probably have some community spread right now that we just have not identified yet and will identify it in time, hopefully in time to intervene to prevent further propagation and make sure that we contain the small outbreaks.

Chairman JOHNSON. One of the questions I did not get adequately answered from my standpoint when I was talking to—and by the way, in defense of the current administration, they are not ignoring us. There has been a lot of interaction. Another briefing here starts in about 5 minutes, where DHS and CDC will be there.

But in my discussions, I did not get a real clear answer. I think I finally did, but I am still—who is following up?

Let me start it this why because I might have been you, Dr. Gerberding. I think it was in your testimony. You talked about the fact that you really did not think these travel restrictions are really

going to be particularly effective. It sounds good. It seems like the responsible thing to do, but in the end—or did I read that from somebody else? Somebody in an article or in testimony really kind of toned out——

Dr. GEORGE. Senator Lieberman said it, actually, that perhaps at first, there is something to be said for travel restrictions. But beyond a certain point, especially with all the travel that has occurred, the 5 million people we believe left Wuhan before any travel restrictions were imposed, et cetera, travel restrictions are not going to remain the sole way to try and control all this.

Chairman JOHNSON. OK. So do people agree with that or disagree with that? Does somebody want to answer?

Dr. GERBERDING. If you start with the concept of containment very early on, yes, it makes sense to do everything possible to contain a new pathogen in an area.

Once you start seeing sustained community transmission elsewhere, the horse is out of the barn, and that strategy is no longer likely to have an impact.

Chairman JOHNSON. One of the questions I had is—so we have identified these—for example, we have a case in Madison. We know the flight. So I was asking, "Are we contacting everybody on that flight? Are we contacting passengers three rows to end, and who is doing that?" because I know CDC does not have the personnel. CBP does, and this is where we are talking about the whole of government. Who is going to actually follow up?

Dr. GERBERDING. So this goes back to the question earlier about the public health system. When there is a situation like that, a travel exposure, potentially, it is the local and State public health department that identify the case and begin the process of working with the airline to contact passengers. This is a routine that our Division of Quarantine at CDC does routinely coordinate, but the shoe-leather aspect of it is at the State level. That is why we need to support them.

Dr. GOTTLIEB. I would also add, Senator, our system is excellent. CDC does an excellent job of, once we identify a case, doing that track and trace and that containment in the quarantine where necessary.

I think what we should be worried about is not the cases that we know about. It is the cases we do not know about, and there are certainly cases we do not know about.

Chairman JOHNSON. Explain yourself a little bit more. That statement confused a little bit.

Dr. GOTTLIEB. We should not assume that the 13 cases that we have identified—and I think 10 of them were travel related, people who came directly from China and imported the virus into the United States—that we just managed to find all 10 people coming in from China who happen to have coronavirus, especially since we know that there is mild to moderate people or maybe even asymptomatic, but certainly people with mild to moderate disease who can transmit the disease.

We have to believe that over the course of the month or 6 weeks that this was epidemic in China, people came over from China, and we just did not identify them. Some of the modeling out of the United Kingdom (UK) suggests that we are capturing about 25 per-

cent of the cases at best. So for every case we identify, there are three or four that we did not identify. At least some of those cases probably are propagating virus at a local level, but not enough cases have accumulated yet to be identifiable.

Chairman JOHNSON. Again, I do not want to downplay this at all, but I also do not want to overhype it.

I remember when we had the Ebola outbreak, and people were projecting a million cases of Ebola. In the end, we are so fortunate. It was confined to a couple tens of thousands.

When will we know that we are out of the woods on this? Are we talking in 6 to 10 weeks, we ought to pretty well know whether we have something that is out of control?

Dr. GERBERDING. I would say yes. It is unfolding as we speak. We will be able to understand if there are more serious cases because of the numbers that Dr. Gottlieb has pointed out. As you said, the exponential spread, if we are seeing a transmission that is not detected because most cases are mild and not being tested, we will know it soon because we will begin to see more cases. They will not be directly linked to travel to China. They will be in people who were exposed to someone who has traveled to the endemic area.

Chairman JOHNSON. Seasonal flu kind of starts petering out when?

Dr. GERBERDING. It is very variable. Early spring, generally speaking. It is still actively being transmitted now. So we are not out of the woods on that one yet either.

Chairman JOHNSON. But our concern is coronavirus may not decline as other normal seasonal flus in terms of what we are looking at Singapore.

Dr. GOTTLIEB. If you look at the medical literature, you would expect the coronavirus not to transfer in the warm months, and I think people are hoping that we can prevent enough transmission that you get into the summer and that is a backstop, and then maybe we are dealing with this again in the fall. But by then, hopefully, we have a better strategy and maybe even a candidate vaccine.

But the situation in Singapore is concerning because it is warm there right now, and it seems to be transferring. We do not know the full scope of it, but they do seem to have some level of community spread right now.

Chairman JOHNSON. We have reason to believe that we should be able to develop an effective vaccine so that in a year from now, we should be protected by this?

Dr. GOTTLIEB. I will also add, it is 60 degrees in Wuhan right now.

Dr. GERBERDING. Another aspect of the seasonality is that the coronavirus—is that human beings are used to dealing with the four sort of cold-like viruses are upper-airway viruses. This is a lower airway disease, and so I do not know that I would want to predict any seasonal impact on its transmission pattern.

If you go back to 1918, we think of influenza as being a winter disease, but that was not the case with the 1918 pandemic, so lots of uncertainty, and we just need to be careful not to jump to any conclusion too early.

Chairman JOHNSON. Again, I really appreciate the time you spent answering all of our questions here. There are a lot of questions, obviously, that remain, and we will continue to press.

I will again say I am disappointed that we did not have DHS and CDC or HHS here. I am going to leave now and go to the briefing where they will be present. The public has a right to know these things. So, again, information to me is going to be helpful here.

With that, I will say that the record will remain open for 15 days until February 27th at 5 p.m. for the submission of statements and questions for the record. This roundtable is adjourned.

[Whereupon, at 11:36 a.m., the Committee was adjourned.]

APPENDIX

OPENING STATEMENT FOR CHAIRMAN RON JOHNSON
ARE WE PREPARED? PROTECTING THE U.S FROM GLOBAL PANDEMICS
WEDNESDAY, FEBRUARY 12, 2020

As prepared for delivery:

The emergence of the novel coronavirus from Wuhan, China and its arrival on our doorstep shows the threat that pandemics pose to our nation. Already, around the world, this coronavirus has infected tens of thousands of people and killed hundreds. The virus is sparking investor anxiety and straining the global supply chains we depend on. I commend the hardworking professionals at the Federal, state, and local levels that are helping to slow the spread of this virus across the U.S. But the purpose of this roundtable is to examine our response to pandemics like the coronavirus and ask what more the federal government could be doing to combat the outbreak of global infectious diseases.

The Coronavirus is not the first of its kind, and it certainly will not be the last. Our experience includes the Severe Acute Respiratory Syndrome, or SARS, in 2002; the H1N1 influenza virus, in 2009; the Middle East Respiratory Syndrome, or MERS, in 2012; and an outbreak of Ebola in 2014. In 2016, I sponsored the National Biodefense Strategy Act because it had become clear that the U.S.'s response to biological threats and diseases was disjointed. I hoped that the Federal government would develop a strategy clearly identifying "who's in charge?" of managing government-wide response efforts. We need clear roles and effective strategies in place before an outbreak hits our shores. Another piece of legislation, the 2018 National Biodefense Strategy, was a great start, but we need to focus on how it is implemented.

If we want to stop infectious diseases from becoming global problems, then we must ensure that our policies and procedures are thoughtfully developed and ready to go before the next infection crosses our borders. To achieve this goal, we must be able to answer some key questions:

First and foremost, who's in charge? We have learned that an effective response to a pandemic requires a whole-of-government approach: health officials who identify and treat the disease, homeland security officials who protect against infection, and a host of others. But our response is not effective if it is not well-managed.

Second, do we have clear strategies and plans to combat these global diseases and pandemics?

Third, what lessons have we learned from previous responses? Have we addressed and resolved those issues?

This roundtable is timely because of the recent outbreak of the Coronavirus, but these are important policy issues that will continue to be relevant. The American people need to be reassured that their government has learned the lessons of the past and is doing the best it can to protect them. I look forward to this discussion and thank our speakers for joining.



Statement by Scott Gottlieb, MD
Committee on Homeland Security and Governmental Affairs
"Are We Prepared? Protecting the U.S. from Global Pandemics."

February 12, 2020

The epidemic spread of coronavirus in China -- along with community transmission in Singapore, Hong Kong, and Japan – sharply increase the chance that we endure pandemic spread. Worse still, the novel coronavirus may become endemic. It could take a new position as a more sinister member of the seasonal pathogens that circulate each year and infect humans.

The next month is critical. We must prepare for the prospect that the virus evaded our border protections and was already introduced into the U.S. in late December or early January – when it first appears to have become epidemic in China's Hubei province. Those index cases could have seeded community spread, and eventually, outbreaks could emerge in America. We have the capacity to contain small outbreaks. But we need to be vigilant and ready.

Models suggest that from the time of first introduction of the virus into China – which we now suspect occurred sometime in November – to the time of epidemic spread in China, was about 10 weeks.[i] The experience in the U.S. is likely to be different, not least because our awareness of this risk is prompting collective action that can limit spread. But China's experience shows that if cases were imported into the U.S. in early January and remain undetected, then we could still be early in our own evolution toward broader outbreaks. Right now, we're depending largely on clinical surveillance as our primary tool for identifying potential outbreaks since we're just now deploying diagnostic tools to the Laboratory Response Network. Moreover, we still haven't broadened our screening criteria to include patients who don't have a connection to recent travel to China. This limits our ability to identify secondary spread. So, we may know we're experiencing outbreaks of this disease only when a cluster of cases of atypical pneumonia present to a hospital and trigger closer scrutiny by health officials. By that time, there could be dozens or even hundreds of cases in a local community. Controlling broader spread could become a challenge.

There are many steps we can take to address these risks, both in the setting of this current public health crisis, as well as in preparing for the next one. There will always be a next one.

Among many components of preparedness, we're dependent on the robustness of our 3,000 local health jurisdictions; the technology to rapidly deploy point of care diagnostics and develop safe and effective therapeutics and vaccines; local surveillance; federal tools to track outbreaks and contain spread; collaboration with international health partners; and sound leadership.

First and foremost, we must observe the human tragedy, and take steps to mitigate human suffering. While we don't fully understand the spread and severity of this virus, it has already caused a lot of death and suffering, and the full scope of its impact is far from finished.

Today I want to talk about another aspect of risk and response – our global supply chain for key healthcare products, and how it can become stretched in times of public health emergency.

I want to focus my observations on the vulnerability of our supply chain for drugs and medical devices. Some shortages or near shortages may be inevitable in U.S. as a result of crisis in China. Our drug and medical device supply chain is pointedly and precariously dependent on production in China for our finished goods. In many cases it isn't the finished drugs or medical devices that

are being manufactured largely or exclusively in China. Nor is it the intermediate products like the active pharmaceutical ingredients (API). It is lower margin, low technology starting materials and components that – over time – have become sole sourced in China.

Securing alternative supply in the setting of a crisis takes time. But here are steps U.S. regulators can take in the near term, working with Congress and other partners, to lessen the potential impact of supply disruptions on Americans by identifying vulnerabilities and bringing substitute supply online. There are also longer-term policy steps that we could take to reduce the vulnerabilities created by these choke points in the supply of critical public health goods.

I want to address in greater detail these issues as they relate to drugs and production in China.

About 40 percent of generic drugs sold in the U.S. have only a single manufacturer. A significant supply chain disruption could cause shortages for some of many of these products.[ii]

Last year, manufacturing of intermediate or finished goods in China, as well as pharmaceutical source material, accounted for 95 percent of U.S. imports of ibuprofen, 91 percent of U.S. imports of hydrocortisone, 70 percent of U.S. imports of acetaminophen, 40 to 45 percent of U.S. imports of penicillin, and 40 percent of U.S. imports of heparin, according to the Commerce Department. In total, 80 percent of the U.S. supply of antibiotics are made in China.[iii]

While much of the fill finishing work (the actual formulation of finished drug capsules and tablets) is done outside China (and often in India) the starting and intermediate chemicals are often sourced in China. Moreover, the U.S. generic drug industry can no longer produce certain critical medicines such as penicillin and doxycycline without these chemical components.[iv]

According to a report from the US-China Economic and Security Review Commission, China's chemical industry, which accounts for 40 percent of global chemical industry revenue, provides a large number of ingredients for drug products.[v, vi] It's these source materials --- where in many cases China is the exclusive source of the chemical ingredients used for the manufacture of a drug product -- that create choke points in the global supply chain for critical medicines.

Moreover, when it comes to starting material for the manufacture of pharmaceutical ingredients, a lot of this production is centered in China's Hubei Provence, the epicenter of coronavirus. Most drug makers have a one to three-months of inventory of drug ingredients on hand. But these supplies are already being drawn down. Among big API makers in Wuhan are Wuhan Shiji Pharmaceutical, Chemwerth, Hubei Biocause, Wuhan Calmland Pharmaceuticals.[vii]

There are steps that we can take – both in the short term as well as the long run – to expand our supply chain for making these raw and intermediate components of drug production and mitigate risks to our supply chain. In the setting of the current public health crisis related to the novel coronavirus, I want to focus my remarks today on some of these potential actions.

We're facing the potential for unprecedented supply chain disruptions. You can't easily switch component part suppliers — either starter material for the manufacture of drugs or components for device devices. You have to qualify those alternative sources, make sure they meet regulatory standards for Good Manufacturing Practices (GMPs), and meet the conditions set by those incorporating these materials into their finished goods. Even if FDA is able to offer manufacturers flexibility in making these component changes, substitutions are often complex.

Right now, we may not even be aware of the full scope of these vulnerabilities. In many cases, we don't have established systems for tracking down to the level of these components, to easily identify the choke points. This is true even when it comes to where API is sourced. We rely on our ability to track the finished products. This isn't just a coronavirus challenge. An earthquake or political unrest in a major manufacturing region could present the same problems.

How can we take steps to try and address some of these significant challenges?

First, we can work to bring on alternate supply. After Hurricane Maria devastated Puerto Rico, and took offline fully 10 percent of the manufacturing capacity for drugs intended for the U.S. market, the FDA took proactive steps to restart facilities that manufactured key products, and identify alternative suppliers for some products where significant and potentially harmful disruptions were believed to be unavoidable owing to the damage.[viii] There's idle manufacturing capacity that can be developed to address some of the immediate needs. India, for example, has about 1,500 plants that manufacture APIs and are running at 40 percent capacity.[ix]

Second, we also need a better system for identifying these supply chain choke points.

When it comes to the kinds of starting materials that may have been disrupted by the crisis in China, FDA would be dependent on manufacturers to identify these supply choke points. This is challenged by the current shortage framework. It relies on a passive reporting system from manufacturers, where we might find out too late of impending shortage. It may not work in a crisis situation like this where information and reporting are imperfect.

In the near term, FDA can issue a solicitation for such information. U.S. officials should already have some awareness of the key components that are manufactured in China, and in the Hubei Province particular. But in the longer term, we need a more systematic process for collecting this information. This is where Congress can help, by giving the FDA authority to look not only at the supply of finished products but to also identify circumstances where key components may have only a single source across an entire category of products. This may take the form of a requirement that manufacturers develop risk management plans that explicitly surface critical supply chain choke points. In turn, we could require companies to take steps to identify alternative sources in the event of a major disruption. It isn't just supply disruptions we need to be fearful of. In the setting of a public health crisis in a country that hosts the manufacture of critical components, a government may seek to withhold supply or even nationalize key facilities if the components are essential to their own relief efforts. A nation could seek to satisfy its in

country needs before they ship outside their borders. Such a circumstance arose with respect to the manufacture of flu vaccine after the H1N1 pandemic.[x]

Standing up new sources of supply is not as complex as creating new facilities for manufacturing intermediate and final drug products. That's because these starting components and ingredients fall under the GMP requirements of the finished manufacturer's supplier controls. This means that the ingredients and parts are not independently subject to GMP requirements if they're not themselves the drug product or finished device. So, this flexibility can make it easier to more quickly establish alternative manufacturing sites for the production of source material and other inputs. It doesn't require that these new facilities undergo all of the more time consuming GMP requirements as the finished drug. Only finished products need to meet these standards.

It's clear now that we are also going to have significant delays in FDA inspections of facilities in China, and maybe in other foreign locations. This could make efforts to identify new manufacturing sites more challenging if those facilities are required to be inspected by the agency. The falloff in inspectional capabilities could also create some immediate consumer risks.

There are steps we can take to offset these challenges. For example, Congress can support efforts by FDA to increase import sampling and testing of regulated goods coming from China, since the agency will be hard pressed to make up for the lost inspectional activity, even after the current crisis has subsided. This will require additional resources for FDA's inspectional program.

The FDA could also consider revising its risk-based inspection model and plan for 2020. Based on the shutdown in Chinese manufacturing and the need for alternate supplies, the agency might need to redefine the highest risk facilities and shift some of the focus of its inspection resources once facilities are brought back online. These efforts can be supported by Congress. The FDA's inspectional activities and its field force are on the front lines of the agency's historic consumer protection mission. The agency has the expertise to adapt to these challenges, but it can benefit from focused resources and authorities that support these efforts in both the near and long term.

It's not just generic drugs that could fall into shortage. Brand drugs use contract research organizations like WuXi in China for development work, and global clinical trials enroll patients China.[xi] There are 16,490 studies registered on Clinicaltrials.gov in China and 5,086 studies are currently recruiting. This is about 10 percent of all of the actively recruiting studies. The clinical trial work, as well as the work conducted by China CROs has -- in many cases -- has stopped.[xii]

As a consequence, some new drug programs could be delayed as innovators are forced to change clinical trial enrollment plans, amend protocols, or shift certain critical development activities to other CROs located in other regions. This could delay regulatory filings on new drugs.

We also must address potential device shortages. Medical devices operate under different framework than drugs. It may be harder to identify and mitigate potential shortages. We should adopt the same practices we've implemented for drugs – which requires manufactures to give

FDA early notification of potential shortage situations. More than a year ago, FDA first put forward such a proposal. That proposal was incorporated into the President's current budget.

Finally, we should also contemplate for medical devices a similar framework to the one I believe we need for drugs. It would require manufacturers to report to FDA when there is a key component that is sole sourced and where alternate supply cannot be easily obtained.

While we hope no shortages will result from the tragic epidemic, given the concentration of production work in Wuhan, the risk is real. Those risks can be reduced through careful planning.

In the long run, there are structural changes we can make to reduce these risks for when next global crisis arises. It starts with shifting our emphasis. We've been focused on the risk that finished goods can fall into shortage owing to a supply disruption. In a world where the manufacture of components and source material has become highly centralized around a small number of regions and facilities, we need to pay equal attention to identifying these other choke points and taking steps to make sure that critical production doesn't hinge on a single location.

Dr. Gottlieb is a physician and resident fellow at the American Enterprise Institute and a partner at the venture capital firm New Enterprise Associates. From 2017 to 2019 he was the Commissioner of the U.S. Food and Drug Administration, and before that served as the agency's deputy commissioner. He is a member of the board of directors of Pfizer Inc and Illumina.

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STATEMENT

OF

LUCIANA BORIO, M.D.

VICE PRESIDENT

IN-Q-TEL, INC.

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

ROUNDTABLE: ARE WE PREPARED?

PROTECTING THE U.S. FROM GLOBAL PANDEMICS

FEBRUARY 12, 2020

My Background and Career Experience

Good morning Chairman Johnson, Ranking Member Peters, and members of the Committee. I am Dr. Luciana Borio, Vice President at In-Q-Tel, the not-for-profit, strategic investor that identifies and tailors innovative technologies to support the mission of the U.S. national security community. Thank you for the opportunity to be here with you today to talk about the outbreak of COVID-19, the novel coronavirus that emerged in China at the end of 2019.

I've dedicated my career to biodefense. Shortly after completing clinical training in infectious diseases and critical care medicine at Johns Hopkins and the National Institutes of Health, right around 9/11, I joined the late D.A. Henderson at HHS to help establish what is today's Office of the Assistant Secretary of Preparedness and Response and the Biomedical Advanced Research and Development Authority (BARDA). I've served in several senior U.S. Government positions, including at the Food and Drug Administration and, most recently, at the White House National Security Council staff as Director of Medical and Biodefense Preparedness Policy. In these roles, I've been involved in the U.S. Government response to several complex public health emergencies, starting with the 2009 H1N1 influenza pandemic.

COVID-19 – The Current Situation

As of this morning – the China's National Health Commission has reported more than 42,000 confirmed cases of COVID-19 and more than 1000 deaths, exceeding the global mortality caused by the SARS outbreak in 2003. The number of cases outside of China continues to grow steadily.

The real numbers – in and outside of China - are likely much larger. Testing capacity is limited, only those with clear risk factors are being tested, and most people with mild symptoms do not seek medical care or testing.

The situation remains fluid and there is much we do not know, but a pandemic is virtually certain. Currently, the citizens of Wuhan are suffering the most, but its impact will be felt globally.

I've been asked to discuss this COVID-19 in the context of SARS, MERS, and influenza. Scientists often compare viruses in terms of their transmissibility and lethality. We are still learning about these features for this novel virus. It seems to be less lethal but more transmissible than MERS, and, perhaps, less lethal and transmissible than SARS. There is growing evidence that the COVID-19 can be transmitted before symptoms develop. Because people with no or mild symptoms go about their routine daily activities, they can serve to dramatically amplify the epidemic.

Unless the epidemic abates in the warmer months – a possibility that is less than certain – it could behave much like an influenza pandemic, spreading rapidly around the globe due to the lack of population immunity.

I want to stress that although we do not yet know how lethal this virus is, we know it is sufficiently lethal to severely strain health care systems.

Lastly, some have stated that seasonal influenza is worse because many more people die of seasonal influenza every year. Flu deserves attention, but the COVID-19 should not be construed as a lesser threat.

U.S. Epidemic Preparedness Has Improved Since 2001

We are better prepared today to combat epidemics than we were in 2001. When the SARS coronavirus emerged in 2003, few tools were in place in the United States to rapidly combat emerging infectious diseases. Much of the progress that we've made would not have been possible without the laws passed by Congress, providing the executive branch with vital authorities. These authorities established, among many others:

- The Strategic National Stockpile, a special reserve fund to incentivize companies to develop medical countermeasures for national security threats;
- BARDA to support industry partners;
- liability protection for developers of medical countermeasures in certain circumstances, thus removing a major disincentive for developers; and
- the Emergency Use Authority—or EUAs – to authorize the use of unapproved countermeasures during public health emergencies. The EUA mechanism has proven to be crucial time and time again – it provided timely access to diagnostic tests during the 2009 H1N1 influenza pandemic, the 2014 West African Ebola epidemic, the 2016 Zika epidemic in the Americas, and for this current COVID-19 epidemic.

In addition, the Federal response enterprise has learned and adapted to each crisis. The coordination that exists among Federal response agencies today is strong. And the science has advanced so much that we now aim for the development, evaluation, and deployment of medical countermeasures in time to help mitigate the impact of epidemics.

What We Must do to Achieve Adequate Resilience

Despite our collective progress, we have fallen short in 4 areas:

- We have not prioritized diagnostic tests. Diagnostic tests are one of the most critical components of outbreak management and control. Diagnostics allow us to protect the healthy and treat the sick. They allow for the efficient allocation of scarce medical resources. They enable fundamental public health measures, including biosurveillance. They are necessary for the conduct of clinical trials to evaluate vaccines and therapeutics. They are truly our first line of defense and can be readied sooner than any other countermeasure. Any vaccines and therapeutics that might be developed, will take some time, which may limit their impact on outbreak control. Whereas diagnostics are already making a difference.
- We have neglected health care system preparedness.
- We have not sufficiently protected the supply chain of essential medicines and medical equipment.
- We are not yet leveraging the latest and most innovative, flexible technologies to support even faster medical countermeasure development or the medical and public health response.

Conclusion

Although we have learned from the past and have made significant progress in combating epidemics, much work remains ahead of us and we need to brace ourselves for some difficult weeks or months to come.

Before closing, I would also like to commend this Committee on calling for the establishment of the National Biodefense Strategy in the 2017 NDAA, drawn from the recommendation of the Blue Ribbon Study Panel on Biodefense (now Bipartisan Commission on Biodefense) led by Dr. Asha George, here with us today.

Finally, I would like to recognize the staff at the Centers for Disease Control and Prevention for doing an outstanding job to delay the introduction of cases in the U.S., my former colleagues at FDA, who I know are fully dedicated to this response, and the countless civil servants at the Department of Homeland Security, Customs and Boarder Protection and other Federal agencies who are working tirelessly to protect Americans from harm.

Dr. Asha M. George

Executive Director

Bipartisan Commission on Biodefense

Written Supplemental Statement

for the

Committee on Homeland Security and Government Affairs

of the

United States Senate

Chairman Johnson, Ranking Member Peters, and other Members of the Committee, thank you for the opportunity to provide a written statement for the roundtable "Are We Prepared? Protecting the United States from Global Pandemics."

The Bipartisan Commission on Biodefense is co-chaired by former Senator Joseph Lieberman and former Governor Tom Ridge, with former Senate Majority Leader Tom Daschle, former Representative Jim Greenwood, former Homeland Security Advisor Ken Wainstein, and former Homeland Security and Counter Terrorism Advisor Lisa Monaco serving as Commissioners. The Commissioners, and I, as executive director, have addressed national and homeland security in various capacities for decades. Although we have left our previous government and military positions, we remain committed to public service and the public health, safety, and security of our Nation.

In late 2015, we issued our first report, *A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts*. As expected, we found both strengths and weaknesses, including serious gaps that four years later continue to make the Nation vulnerable. Our report contains 33 recommendations with 87 associated short-, medium-, and long-term programmatic, legislative, and policy action items, the implementation of which we believe will improve our country's ability to defend against biological threats.

We are greatly concerned about catastrophic risk to the Nation produced by biological events, including the ongoing novel coronavirus disease 2019 (COVID-19) pandemic. Some parts of the federal government have rapidly engaged in addressing the spread of COVID-19. For example, the White House decided to establish a novel coronavirus task force and put Secretary of Health and Human Services Azar in charge. More recently, and in accordance with the first recommendation from our *National Blueprint for Biodefense* to put the Vice President in charge of biodefense, President Trump put Vice President Pence in charge of the U.S. government's response to COVID-19. Interagency coordination at the federal level will be key to prevent the

disease from spreading here at home. The Vice President could start by adding the Department of Agriculture and the Department of the Interior to the novel coronavirus task force (to address the wildlife and agriculture animal reservoirs for the disease) and the Department of Veterans Affairs, which may be called upon to help distribute medical countermeasures throughout the Nation.

We also believe that the response to the spread of this coronavirus could be better. The Administration has yet to implement portions of the National Biodefense Strategy. In the Commission's *Blueprint for Biodefense,* our third recommendation called for the development and implementation of a National Biodefense Strategy. The goal of the Strategy was to unify existing presidential directives, public laws, and international treaties, partnerships, and instruments that address biodefense, as well as all of the many federal policy, strategy, and guidance documents that address bits and pieces of biodefense. Required by Congress in the National Defense Authorization Act of Fiscal Year 2017, signed into law by former President Barack Obama, and produced by the Trump Administration in September 2018, the National Biodefense Strategy should guide defense against current and future biological threats. However, we have observed and the Government Accountability Organization has noted, that implementation of the Strategy is lacking. We believe that this lack of progress negatively impacted the response to the COVID-19. The federal government would already have had a group in place – the Biodefense Steering Committee that we recommended and was established by National Security Presidential Memorandum 14 – and could have saved time when organizing the federal response to COVID-19.

At the Department of Homeland Security (DHS) specifically, U.S. Customs and Border Patrol (CBP), the Transportation Security Administration (TSA), the U.S. Coast Guard (USCG), and U.S. Citizenship and Immigration Services (USCIS) have all taken some action in response to the COVID-19 outbreak. DHS is in charge of implementing disease screening protocols at air, land, and sea ports of entry, in coordination with Centers for Disease Control and Prevention (CDC) officials.

CBP already has protocols in place to identify travelers who exhibit over symptoms of illness at U.S. ports of entry. CBP is in charge of funneling potential affected international flights bound for the United States into select airports for enhanced screening procedures, screening for potentially sick travelers, isolating and referring ill travelers to CDC Quarantine Stations, and transferring custody of animals and agricultural products that may be infected to CDC Quarantine Stations.

TSA has instructed airlines with flights into the United States from other countries to screen passengers before boarding to find out whether they have been in China recently. They are requiring check-in and gate agents or other employees to question travelers and look through recent reservations and passports for entry or exit stamps from China. Beyond this, they should be providing information about the pandemic and related guidance to the aviation industry, vetting all airline passengers coming to, departing from, or flying within, the United States, and ensuring that Transportation Security Officers and other employees are trained to deal with their contributions to this disease response.

The USCG Office of Emergency Management and Disaster Response issued Marine Safety Information Bulletin (01-20) on January 24, 2020 with coronavirus precautions, urging vessel owners, operators, and local stakeholders to report sick or deceased crew members and passengers within the last 15 days to the CDC. USCG should also be monitoring vessels known to be inbound from outbreak-affected countries and relaying this information to Captains of the Port, Districts, and CDC representatives.

USCIS temporarily closed field offices in Beijing and Guangzhou, China, rescheduling all affected appointments and sending new appointment notices to applicants. They are also allowing people here in the United States to reschedule if they are ill, with no penalty.

DHS can and should continue to play a critical role in responding to COVID-19 and future biological events, especially when it comes to communicating with state, local, tribal, territorial and private sector partners, protecting our critical infrastructure (including, but not limited to transportation systems), and understanding and managing impacts to our homeland. We cannot depend solely on the Department of Defense to come to the rescue. We should be thinking now about continuity of operations, continuity of government, and continuity of society – all DHS responsibilities.

We believe that had the Administration more highly prioritized implementing the National Biodefense Strategy, the exact roles of each federal Department and agency during COVID-19 response, would have been more clearly delineated in advance. Procedures could already have been in place to ensure swift delegation of all assignments. While we feel that DHS has a number of responsibilities in relation to COVID-19 and future pandemics and other biological threats, an incompletely implemented National Biodefense Strategy makes this difficult.

National Security Presidential Memorandum 14 put the Secretary of Health and Human Services in charge of coordinating implementation of the National Biodefense Strategy. This responsibility has in turn been delegated to the Assistant Secretary of Preparedness and Response (ASPR). While we have every confidence in the ASPR, one federal Department cannot tell other Departments, independent agencies, and independent institutions what to do and that includes providing the information needed to implement the National Biodefense Strategy. The Nation lacks strong centralized leadership of biodefense – not just COVID-19 – at the highest level of government. No single individual has been charged with the responsibility and authority to create a cohesive, effective, and efficient biodefense enterprise. At least 24 federal departments, independent agencies, and one independent institution are responsible for carrying out programs and policies for biodefense. They need to work in tandem to defend the Nation against these threats, with no confusion over goals and without duplicative expenditures the country cannot afford.

We need a leader at the White House with the policy, political, and budgetary authority sufficient to achieve what has never been achieved before in this arena. This person must set priorities, goals, objectives, and milestones for biodefense, and hold members of the Executive Branch accountable for meeting them. In our *Blueprint for Biodefense*, we recommended that the Vice President of the United States should take charge. We are grateful for this Committee's

leadership in facilitating a meeting with former Vice President Biden about this recommendation, and we applaud President Trump's decision to have Vice President Pence assume leadership of the current COVID-19 response. In implementing our recommendation in this regard, we believe that this central leadership, at the highest levels of government, will make a significant, positive difference in responding to the COVID-19 pandemic.

It is important to note that the federal government responded faster to this outbreak than some previous pandemics. We worry that the funding levels, and the accounts from which resources are being redirected, have not fully been considered. If we had a better understanding of the totality of biodefense funding across all of the federal government, an emergency supplemental request to address COVID-19 might have been more easily determined. In our *National Blueprint for Biodefense*, our fourth recommendation was to develop a biodefense budget crosscut. Congress accepted this recommendation and required that Office of Management and Budget (OMB) conduct this biodefense crosscut as part of the appropriations process for both Fiscal Year 2019 and Fiscal Year 2020, and release it along with the President's Budget Request. We understand that OMB is working on this crosscut now and hope they release it soon. It is vital to know where the federal government has already invested in biodefense and where additional investments are needed to respond to any biological threat.

The Commission also recommended in our 2018 *Budget Reform for Biodefense* report that the government fund the existing Public Health Emergency Fund at no less than $2 billion, to be replenished with regular annual appropriations. Having this funding would have helped us to respond quickly to the COVID-19 and previous outbreaks in the United States.

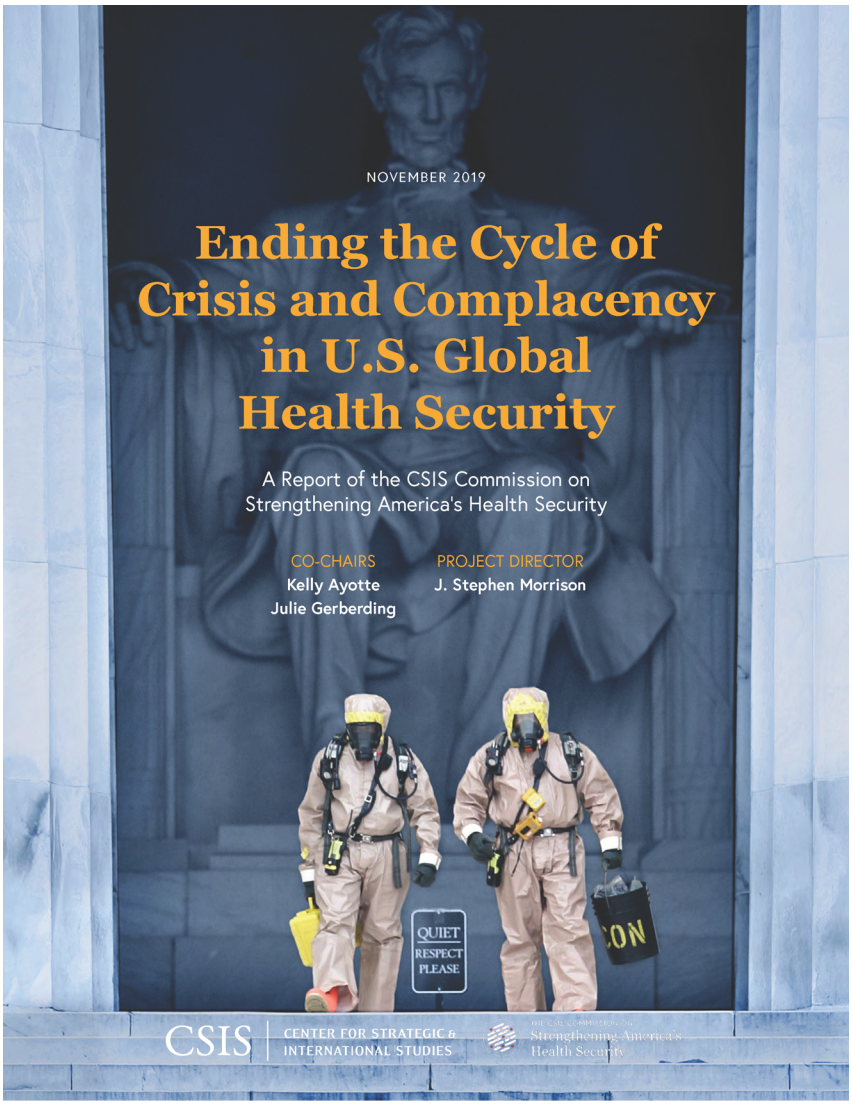
Finally, I would be remiss if I did not talk about DHS responsibilities for biodetection and integrated national biosurveillance. Having accurate and effective environmental surveillance could assist with pathogen identification and provide early warning. The federal government has spent, and continues to spend, tens of millions of dollars each year to develop, improve, and deploy biodetection technology in hopes of rapidly detecting biological attacks. Unfortunately, as this Committee is well aware, the equipment designed to detect airborne biological contaminants does not perform well and has not progressed significantly since the initial deployment of BioWatch in 2003. The federal government has also failed to efficiently and comprehensively integrate and analyze human, animal, plant, water, and soil biosurveillance data. DHS is working on a new initiative – Biodetection 21 or BD21 – to replace existing, inadequate BioWatch technology. This effort has already seen its share of problems and we have heard that the Department's only goal for the program now is to gather data. The goal for biodetection should be to detect diseases like COVID-19, as well as biological agents. Today, BioWatch and BD21 detectors can do neither.

While we are dealing with this current coronavirus outbreak now, we must look to the future. We need to plan ahead for when, not if, the next biological event occurs – and we must assume that months, not years, will be pass before we need to deal with another attack, outbreak, epidemic, or pandemic. Having centralized leadership, available emergency funding, and an accurate biodetection system are essential for ensuring that when the next biological event that occurs, we will be better prepared than we are today.

Once again, thank you for this opportunity to provide our perspective. With this testimony, I am also submitting three of the Commission's reports. We look forward to working with you to defend the Nation against biological threats.

COVID-19 2019 Novel Coronavirus: Preliminary Comparison with other Respiratory Virus Outbreaks

	Seasonal Influenza	1918 Influenza Pandemic	SARS Coronavirus	MERS Coronavirus	COVID-19
Source	"Drift" from previous human influenza strains	Zoonotic: "Shift" – strain may have derived from an avian influenza source	Zoonotic: Bats likely reservoir; palm civets in live animal markets likely proximate source	Zoonotic: Bats likely reservoir; camels likely proximate source	Zoonotic: Bats likely reservoir; proximate source not established yet but probably something in live animal markets
Dominant transmission pattern	Community (some hospital)	Community (some hospital)	Hospital "super-spreaders" (some community as well)	Hospital "super-spreaders" (limited community)	Community (households, ships) Hospital - ? "super-spreaders"
Common modes of transmission	Droplets (sneeze, cough) Fomites (contaminated objects)	Droplets Other routes possible	Droplets Aerosols during airway procedures in hospitals	Droplets Aerosols during airway procedures in hospitals	Probably Droplets Also suspect aerosols during airway procedures
Period of Infectivity (can transmit to others)	**1 day before symptoms to 5-7 days after illness begins; longer in immunosuppressed and young children**	Probably similar to seasonal influenza	Highest during second week of illness until 10 days after	Peaks with peak symptoms	**With symptoms; worry about spread when asymptomatic especially if asymptomatic infection is common**
Incubation (time from exposure to illness)	**2 days**	2 days	2-7 days; sometimes as long as 2 weeks	5 days; range 2-14 days	**? 2 days-2 weeks**
Transmissibility (R_0 = # of people a case infects-assuming no immunity and no control measures	**1.28**	1.5-2.5	3-4 at onset (biased by "super-spreaders – sick and highly infectious people)	2-5 at onset (biased by super-spreaders)	**2.2 estimated; not established yet (current range 1.5-3.5)**
Case fatality ratio (deaths/cases)	**.04%-.14% estimated for 2019-2020 season so far but too early to say**	Varied with age (estimated 50M deaths/500M infected globally	9.6% (774 deaths/(8096 cases)	34% (858 deaths/2494 cases)	**2.3% estimated; not established yet (In China, 1017 deaths/42,725 cases diagnosed by 2/11/20)**


NOVEMBER 2019
Ending the Cycle of Crisis and Complacency in U.S. Global Health Security
A Report of the CSIS Commission on Strengthening America's Health Security
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THE CSIS COMMISSION ON Strengthening America's Health Security

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About the CSIS Commission on Strengthening America's Health Security

The CSIS Commission on Strengthening America's Health Security is a two-year effort organized by the CSIS Global Health Policy Center. The Commission brings together a distinguished and diverse group of high-level opinion leaders who bridge security and health, comprising six members of Congress, past administration officials, and representatives from industry, private foundations, universities, and nongovernmental organizations. The Commission is advised by a group of preeminent subject experts. The Commission's core aim is to chart a bold vision for the future of U.S. leadership in global health security — at home and abroad.

In recent years, U.S. senior policymakers have shown greater appreciation of the growing importance of health security to U.S. national interests and of the need for a stronger, more coherent, integrated, better resourced, and more reliably sustained U.S. doctrine for global health security. There is recognition that increasing levels of global disorder and conflict across the world are resulting in destruction of public health infrastructure and capacity, reduced access to critical services for vulnerable populations, and heightened risk of sudden outbreaks. These health threats undermine the economic and political security of nations.

While formidable obstacles remain, we are convinced there is a ripeness to health security, an opportunity to press for strengthening America's policy approaches in a way that can drive forward overall U.S. global health engagement, bring about new resources, and heighten the engagement of industry and security institutions, in partnership with other partner countries, multilateral institutions, and civil organizations.

The Commission is directed by J. Stephen Morrison, CSIS senior vice president and director of the Global Health Policy Center. The Commission's Secretariat is supported by Anna Carroll and Samantha Stroman. More information on the Commission can be found on its dedicated microsite at https://healthsecurity.csis.org.

Acknowledgments

The following report is the culmination of a year and half of work by the CSIS Commission on Strengthening America's Health Security, directed by J. Stephen Morrison, CSIS senior vice president and director of the Global Health Policy Center.

CSIS staff members Anna Carroll and Samantha Stroman were indispensable to the research and writing of this report, as well as overseeing the organization and execution of the Commission's many far-flung activities. They deserve enormous praise for the high quality that has resulted from their exceptional skill and commitment.

The Commission would like to extend a special thanks to the team that laid the groundwork for and launched the Commission, including Chris Millard of the CSIS Global Health Policy Center and Rebecca Hersman, Sarah Minot, and Alice Hunt Friend of the CSIS International Security Program. The Commission would also like to thank Emily Foecke Munden for her extraordinary commitment in supporting and advancing the work of the Commission during its first year.

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DISCLAIMER

The Commissioners participated in their individual capacity, not as representatives of their respective organizations. This report represents a majority consensus; no member is expected to endorse every single point contained in the document. In becoming a signatory to the report, Commissioners affirm their broad agreement with its findings and recommendations. Language included in this report does not imply institutional endorsement by the organizations that Commissioners represent.

Letter from the Co-Chairs

Over the course of our careers, we have witnessed, often up close, a mounting number of severe health security incidents, including the 2001 anthrax attacks, SARS in 2003, and the recurrent, dangerous outbreaks of influenza and Ebola, to name but the most conspicuous. Not only did these moments demonstrate the staggering public health, economic, and political costs borne of infectious disease outbreaks and biological attacks, they have convinced us that the United States needs a far better line of defense.

Since our time serving in the U.S. government, there has been a decisive shift in U.S. policy circles—one that we each welcome and wholeheartedly embrace. Today, there is a broad consensus that health security is national security, in a world that has become more dangerous, and where the most dangerous zones are in fact where outbreaks are often arising. There is recognition that increasing levels of global disorder and conflict around the world are resulting in the destruction of public health infrastructure and capacity, reduced access to critical services for vulnerable populations, and heightened risk of sudden outbreaks. There is greater awareness of emerging and re-emerging infectious disease epidemics, the rapid spread of drug-resistant pathogens, and the risk of unregulated advances in biotechnology. A growing number of policymakers now appreciate how health security risks undermine the social, economic, and political security of nations.

Now is the time for greater U.S. leadership and action in global health security. In 2017, CSIS President and CEO John J. Hamre invited us to chair a Commission that would chart a bold vision for the future of U.S. leadership in global health security—at home and abroad. The CSIS Commission for Strengthening America's Health Security brought together a distinguished and diverse group of high-level opinion leaders who bridge security and health, comprising six members of Congress, past administration officials, and representatives from industry, private foundations, universities, and nongovernmental organizations (NGOs).

This Commission has convened experts from across sectors and disciplines to shed light on the convergence and intensification of global health security threats we face today and to inform policy options for the U.S. government to address these threats more adeptly and cost effectively. Since its public launch in April 2017, the Commission met three times, held seven public events, published 15 policy briefs and commentaries, and convened 20 working group and roundtable discussions.

To an exceptional degree, each Commissioner actively contributed substantial time and effort to these events and publications. The Commission's impressive productivity is a testament to the Commissioners' belief in the importance of global health security issues, the power of U.S. leadership, and their conviction that we must do better.

This report is the culmination of our nearly two-year effort, a genuine consensus document. The report advances a doctrine of continuous prevention, protection, and resilience in the face of a growing number and variety of health security threats—naturally occurring, accidental, and deliberate.

The report focuses on a strategic set of recommendations that are timely, impactful, and compelling and that will result in greater efficiencies in the use of scarce resources. It calls for White House leadership; adequate, sustained, and rapid financing of pandemic preparedness and response; strengthened capacities to operate in a disordered world; and heightened attention to technological challenges. We urge the Congress and the administration to take action on these critical fronts and chart a united, bipartisan path toward strengthened global health security.

Co-Chairs

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Former Senator (R-NH)



Julie Gerberding
Merck & Co, Inc



Members of the CSIS Commission on Strengthening America's Health Security

U.S. Congressman Ami Bera
(D-CA-7)



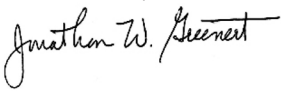
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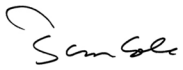
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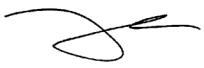
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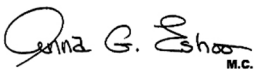
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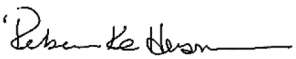
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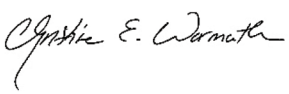
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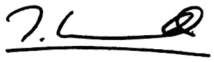
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Executive Summary

When health crises strike—measles, MERS, Zika, dengue, Ebola, pandemic flu—and the American people grow alarmed, the U.S. government springs into action.

But all too often, when the crisis fades and fear subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold.

In reality, the American people are far from safe. To the contrary, the United States remains woefully ill-prepared to respond to global health security threats. This kind of vulnerability should not be acceptable to anyone. At the extreme, it is a matter of life and death.

The CSIS Commission on Strengthening America's Health Security urges the U.S. government to replace the cycle of crisis and complacency that has long plagued health security preparedness with a doctrine of continuous prevention, protection, and resilience. Such a strategic approach can restore U.S. leadership, strengthen financing and the speed of response, foster resilient health systems abroad, enhance the U.S. government's ability to operate in disordered settings, and accelerate select technological innovations to secure the future. It will only be successful, however, if backed by sufficient political will, skilled execution, and a sustained commitment to accountability and efficiency in the use of scarce resources.

The United States faces heightened danger in an increasingly interconnected world. As the global population presses towards 9.7 billion by 2050 and expands into wild frontiers, as agriculture becomes more intensive, as cities of greater density and scale proliferate, and as the earth grows hotter, the threat of new emerging infectious diseases rises steeply.[1] Outbreaks proliferate that can spread swiftly across the globe and become pandemics, disrupting supply chains, trade, transport, and ultimately entire societies and economies.

At the same time, dangerous insecurity and conflicts are proliferating throughout the world, especially in those very places where outbreaks occur.

The business case to invest early in preparedness is crystal clear—and powerful. The United States must either pay now and gain protection and security or wait for the next epidemic and pay a much greater price in human and economic costs. The long-term costs of strategic protection and prevention programs are but a tiny fraction of the astronomic costs of episodic, often chaotic responses to sudden, emergent crises. Investing strategically now is smart and cost-effective, brings proven results, and would draw support from across the political spectrum.

The Commission urges Congress and the administration to adopt the following integrated package of critical actions:

1. Restore health security leadership at the White House National Security Council.

Health security is national security. Strong, coherent, senior-level leadership at the National Security Council (NSC) is essential to guarantee effective oversight of global health security and biodefense policy and spending, speed and rigor in decisionmaking, and reliable White House engagement and coordination when dangerous pandemics inevitably strike. Leadership on the NSC can bring about key, targeted new investments while achieving much-needed reform of fragmented programs and higher efficiencies in the use of scarce resources.

2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.

U.S. direct investments remain essential to build health system capacity. The U.S. government can best protect the American people by stopping outbreaks at their source. The Global Health Security Agenda (GHSA) has a proven track record in building health security preparedness in low- and middle-income countries through new innovative partnerships with national governments, the private sector, and civil society groups. It is common sense for the United States to continue to support that successful agenda, not disrupt it.

3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.

U.S. multilateral leadership is necessary to address the financing gap for preparedness, one of the starkest problems in health security. Congress should press for U.S. leadership to launch a challenge initiative at the World Bank that will incentivize long-term investment by fragile and conflict-affected countries in their own basic health security capacities. Such country ownership is the ultimate and only sustainable solution to the finance gap.

4. Ensure rapid access to resources for health emergencies.

Stopping a global health security crisis requires swift and early action, backed by quick-disbursing resources. Congress should increase contingency fund levels for the U.S. Centers for Disease Control and Prevention's (CDC) Infectious Diseases Rapid Response Reserve Fund and the U.S. Agency for International Development's (USAID) Emergency Reserve Fund for infectious disease outbreaks. The U.S. government should also make annual contributions to the World Health Organization (WHO) Contingency Fund for Emergencies (CFE).

5. Establish a U.S. Global Health Crises Response Corps.

Small teams of select, highly experienced U.S. civilian public health and humanitarian experts, working alongside local partners and national leaders, form the "cerebral cortex" of outbreak response. Their combined presence can be a high-impact game changer. As seen in the Democratic Republic of the Congo (DRC), when U.S. and other critically important experts are barred from outbreak zones due to insecurity, the implications are grave. The world has grown more dangerous, and the danger zones are precisely where the greatest health security risks frequently reside. Risk aversion has impeded USAID and CDC deployments into several outbreak zones besides the DRC: South Sudan, Iraq, Syria, and Nigeria. Additionally, Yemen and Afghanistan offer minimal access. Caution among policymakers has understandably increased in response to this trend, brought vividly to the fore by tragedies such as the fatal attacks upon U.S. personnel in Benghazi, Libya, in 2012. But the United States simply cannot afford to remain on the sidelines of rapidly emerging health crises. A U.S. Global Health Crises Response Corps answers today's stark new realities. It will build systematically upon—not duplicate—existing rapid response capabilities at the CDC and USAID.

6. Strengthen the delivery of critical health services in disordered settings.

The proliferation of chronic and emerging conflicts, humanitarian crises, and fragile and disordered states places an immense strain on already weak health systems, jeopardizing outbreak response. This problem has moved to center stage in U.S. global health security policy. The U.S. government should strengthen and adapt programs and capacities to deliver health services in fragile and conflicted settings that meet the special needs of acutely vulnerable populations, especially women and children. The U.S. government should prioritize the continuity of immunization systems, strengthening the protection against—and response to—gender-based violence (GBV), and strengthening the delivery of maternal and reproductive health and family planning assistance.

7. Systematically confront two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis.

There is a race underway to develop new vaccines, therapeutics, and diagnostics in light of the mounting risks of emerging infectious diseases and growing resistance. It is essential to plan strategically, with strong private-sector partners, to support targeted investments that will accelerate the development of new technologies for epidemic preparedness and response. The U.S. government should invest directly in the Coalition for Epidemic Preparedness Innovations (CEPI). There should be a heightened focus on the development of a universal flu vaccine and new antibiotics. These tools should be developed in safe and secure ways that maximize societal benefit while minimizing the potential for misuse. Across programmatic and disease areas, it should be a U.S. policy priority to adopt and integrate digital tools to improve the quality and use of data.

An unforeseen, historic communications crisis in public health is unfolding, at home and abroad. Fueled by social media, ideology, societal discontent, and the rise of online networks of anti-vaccination activists, there has been a sharp decline in popular trust in science, public health authorities, and industry. When disinformation crowds out facts, confidence can erode precipitously, and control of diseases such as measles and polio can regress. Sudden unforeseen "digital wildfires," often at moments of crisis, can derail outbreak responses. Congress should press for the U.S. government to expand its efforts to better understand this complex phenomenon, effectively communicate accurate science, restore trust and confidence, and reclaim social media as a force for good in public and global health. Knowledge and expertise outside public health will be essential in this effort: in media technology, cybersecurity, legal and regulatory regimens, communications, culture, and sociology. Innovative digital tools will lie at the center of concrete solutions.

SUMMARY OF RECOMMENDED FUNDING		
Recommendation	**Programs and Initiatives**	**Proposed Increase Over Current Level** **Figures Presented in Millions USD*[A]
1. Restore health security leadership at the White House National Security Council.	N/A	N/A
2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.	USAID	$35
	CDC	$100
3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.	Pandemic Preparedness Challenge	$30
4. Ensure rapid access to resources for health emergencies.	CDC Infectious Diseases Rapid Response Reserve Fund	$200[B]
	USAID Emergency Reserve Fund	$248
	WHO Contingency Fund for Emergencies	$25
5. Establish a U.S. Global Health Crises Response Corps.	Global Health Crises Response Corps	$50
	CDC Support to National Partners	$36
6. Strengthen the delivery of critical health services in disordered settings.	Immunizations	$6
	Women and Girls	$30
7. Systematically confront two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis.	Coalition for Epidemic Preparedness Innovations	$40
	Universal Flu Vaccine	$60
	Vaccine Confidence	$25
	Biosafety	$10
	Biosecurity	$10
TOTAL:		**$905**

A. Recommended funding amounts include both annual investments and one-time investments. For further detail, please see Appendix I: Illustrative Costing for Recommended Programs and Initiatives.
B. It is proposed that the CDC Infectious Diseases Rapid Response Reserve Fund and the USAID Emergency Reserve Fund be set and maintained at a level of $250 million each, replenished on an annual basis as warranted.

A World of Peril

We live in a world of heightened microbial danger. Infectious disease outbreaks are far more frequent, far more extreme, and impose far higher costs.[2]

An Ebola outbreak in eastern Democratic Republic of the Congo (DRC), the tenth such outbreak in the country since the virus was discovered there in 1976, has continued to simmer since August 2018 and threatens both global health and global security.[3] The international response has been gravely impeded by armed conflict and community resistance within the complex political and security context of eastern DRC. The World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern (PHEIC) on July 17, 2019, almost one year after the outbreak was announced.[A,4] As of October 2019, the outbreak has not been brought under control, and the future remains highly uncertain.

More than 3,200 cases have been confirmed, and over 2,100 people have died as of early October 2019.[5] There have been confirmed cases in Uganda and suspected cases in Tanzania.[6,7] Cases have also appeared in Goma, a populous transit hub on the Congolese border with Rwanda, the most densely populated country in Africa.[8] In this fragile context, the DRC is simultaneously experiencing concurrent outbreaks of vaccine-derived poliovirus, measles, and cholera.[9,10]

The situation in the DRC is emblematic of widening global disorder, comprised of chronic and emerging conflicts, humanitarian crises, fragile states, countries prone to repression and gross malgovernance, and stateless corners of the world. This disorder is not abating, and it has deep health security and national security implications for the United States. Increasing numbers of infectious disease outbreaks occur in these contexts, along with increasing attacks upon vital health infrastructure and increased displacement of vulnerable populations, interrupting access to critical health services. Disease and disorder fuel one another, as terrorist groups and violent extremist ideologies stoke health crises and mass migration by attacking vaccinators and other health workers from Pakistan to Syria, Yemen, Somalia, Afghanistan, and elsewhere.[11]

A. Refer to Appendix III: Glossary of Key Terms for more information on the PHEIC and other key terms and programs cited in this paper.



Health workers perform medical checkups on a new, unconfirmed Ebola patient inside a newly built Ebola treatment centre on November 7, 2018 in Bunia, Democratic Republic of the Congo.

JOHN WESSELS/AFP VIA GETTY IMAGES



"The breakdown of health and other social services in disordered settings can easily be exploited and exacerbated by terrorist groups and violent extremists. By addressing the health needs of vulnerable populations in crisis zones, we can help to strengthen community resilience, defend against terrorist exploitation, and inoculate against violent radicalization."

— Juan Zarate, CSIS and Financial Integrity Network

THE DISORDERED WORLD

The disordered world spans chronic and emerging conflicts, humanitarian crises, fragile states, places with gross malgovernance, and stateless spaces.[12] Chronic wars and unstable and fragile states have proliferated in recent years. The number of major violent conflicts has tripled since 2010, and the average duration of civil wars in progress has increased to more than 20 years.[13,14] From 2005 to 2017, the number of active crises receiving an internationally-led response almost doubled, jumping from 16 to 30.[15] This proliferation of insecurity and fragility has fueled the highest levels of displacement on record. More than 68.5 million people were forcibly displaced worldwide as of June 2018, compared to 33.9 million in 1997.

The disordered world is evolving swiftly and is generating new, destabilizing health security threats. Access to basic health services degrades significantly as security is reduced and populations are displaced. A persistent state of crisis, violence, and instability leads to the flight of indigenous health care providers and the collapse of health infrastructure. This is accelerated by the deliberate targeting of health care providers and other humanitarian actors.[16]

Current global health infrastructure is largely built on national governments and government health systems, but the disordered world is defined by the weakness or absence of effective partner governments willing or able to participate in international cooperation for health security. At the same time, the rise of populist nationalism around the world is disrupting the liberal international order and challenging traditional models of global health.

This is our new reality, and there are no quick fixes. While some actors have already begun to adapt, the challenges of the disordered world demand a more significant shift in how we operate. The recommendations proposed in this report reflect this new reality.

Today, disorder is fueling geopolitically volatile health security crises not only in the DRC but also in Syria, Yemen, Afghanistan, Pakistan, and Venezuela. The world has become more dangerous, precisely where many acute health security threats reside. This stark reality exposes several serious challenges: how are U.S. and other essential civilian public health and humanitarian experts to deploy safely into these austere environments in order to partner with local officials to detect and arrest highly dangerous outbreaks? How can the U.S. government and its partners meet the acute health and protection needs of the most vulnerable populations, in particular women and girls? And how can the U.S. government and its partners protect immunization and other critical health infrastructure prone to damage and disruption?

Seasoned U.S. civilian personnel with essential expertise from the U.S. Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (CDC) initially deployed to the most acutely affected areas of eastern DRC in August 2018, soon after the Ebola outbreak was declared. They were quickly

withdrawn after significant security incidents and have not been permitted to return since.[17] The absence of small teams of highly skilled U.S. experts from the hot zones, where they normally would join with local and international partners to provide invaluable guidance, has proven enormously costly in eastern DRC. CDC and USAID teams have experienced similar blockages to deployment on security grounds in South Sudan, Iraq, Syria, and Nigeria. Access to Yemen and Afghanistan remains starkly minimal. The CSIS Task Force on Humanitarian Access has explored the impact of intensifying blocked humanitarian access—including roadblocks or attacks on aid workers, bureaucratic constraints, and donor regulations—all of which limit the ability of humanitarian actors to reach the most vulnerable.[18]

In the coming years, the United States and its partners can expect to see repeated instances of blocked access to serious outbreaks in insecure settings. That challenge begs for a solution, namely, a dedicated commitment to prudently manage—not prohibit—such lifesaving deployments of U.S. experts.

A second peril is the threat of losing altogether an essential disease-fighting tool, antibiotics. Antimicrobial resistance (AMR) is a complex, long-range global crisis menacing the foundations on which modern medicine is built. The problem lies not just in the lack of new antibiotics; it encompasses their gross misuse in human and animal health. Drug-resistant infections now cause 700,000 deaths per year, with 230,000 of those deaths from drug-resistant tuberculosis alone.[19] Without action, annual deaths from resistant infections could rise to 10 million people per year by 2050 and cause an economic crisis similar in scale to the 2008 Great Recession.[20]

New, better vaccines and antibiotics are one essential answer to the expansion of resistance, along with strategic planning, better microbial stewardship, more careful antibiotic use, and better basic health systems. Vaccines and antibiotics have revolutionized infectious disease prevention and treatment, saved millions of lives worldwide, and advanced economic stability and growth. Yet their discovery and development increasingly occur in a deeply problematic and urgent context, characterized by market failures and uncertain economic and budgetary environments.

Advances in biotechnology may foster the development of these new vaccines and therapeutics, but they also pose an additional risk. As scientists develop and apply new biotechnologies, they may increase the transmissibility and pathogenicity of naturally occurring microbes. With these changes come greater biosafety and biosecurity concerns and the rising possibility of accidental or intentional exposure of people, animals, or the environment to dangerous, novel microbes, and even the initiation of a global pandemic.

A third swiftly evolving peril is vaccine hesitancy and the power of weaponized social media. In 2019, the WHO recognized for the first time the recent, steep decline of public trust and confidence in vaccines as among the top 10 global health challenges.[21] That striking judgment reflects a broader phenomenon: the rise of sophisticated anti-vaccine online networks and the growing mistrust of science, public health authorities, the private sector, and government, fueled by the rapid, deliberate spread of disinforma-



"The systems that have been built to combat specific diseases provide the foundation to build a strong and resilient system for health that can prevent, detect, and respond to current and new health threats. It is important that the U.S. government continue to work to manage and control endemic infectious diseases, such as tuberculosis, malaria, and HIV."

— Ambassador Mark Dybul, Georgetown University Medical Center



This picture taken on April 5, 2019 shows a nurse waiting for patients at the Rockland County Health Department in Haverstraw, Rockland County, New York. A measles outbreak there sickened scores of people and caused the county to bar unvaccinated minors in public places.

JOHANNES EISELE/AFP VIA GETTY IMAGES

tion, including conspiracy theories on social media and other digital platforms. Insular ethnic and religious communities are especially vulnerable, as are young parents.

Trust and confidence in vaccines can rapidly collapse, as has already occurred across many diverse settings, often among anxious parents who face a confusing array of information as they seek to make the best choices for their children.[22] Concurrently, vaccine advocates find themselves targeted and intimidated by the adversaries of vaccines.

Vaccine hesitancy has contributed to a regression in immunization coverage across a number of disease areas, including polio, cervical cancer, and measles. It strikes at home and abroad, in rich and poor countries alike. In 2000, measles was declared eliminated from the United States. As of August 2019, more than 1,200 cases had been identified in 30 U.S. states, the highest case count in 25 years.[23] Massive measles outbreaks are also unfolding in Ukraine, Israel, the Philippines, Madagascar, and elsewhere. Europe had nearly 83,000 cases in 2018, an astonishing number.[24] The DRC has had around 115,000 cases as of July 2019.[25]

While vaccine hesitancy is fundamentally a public health problem, the solutions and the skill sets required to understand this complex phenomenon and rebuild confidence and trust lie, in part, outside the discipline of public health: in communications and messaging; legal and regulatory measures; opinion tracking; intelligence; knowledge of local networks, trust building, and other focal areas for anthropological study; and cyber security and the understanding of social media technology.

Bad Habits, Barriers, and Vulnerabilities

Confronting twenty-first century health security threats demands a continuous, strategic response.

Yet the United States has long been mired in a cycle of crisis and complacency—resulting in ad hoc, stop-go approaches and a short-sighted dependence on emergency interim funding which inevitably sputters to its end, returning us to a state of vulnerability.

Over several successive administrations, the White House has seldom exercised sufficiently authoritative, high-level leadership, creating acute threats to U.S. national interests when dangerous outbreaks occur at home and abroad. U.S. programs on global health security are fragmented, scattered across diverse executive agencies, and not clearly prioritized. The weakness of White House leadership has left unanswered the persistent question of how to streamline programs, eliminate redundancies, and achieve higher efficiencies in the use of scarce resources.

Too often, the U.S. government has succumbed to complacency, failing to recognize the value of investing in preparedness and the huge costs of inaction, only to pay a steep price later. Having not sufficiently invested in health systems and preparedness in West Africa, the U.S. government expended nearly $2.4 billion (roughly half of the total international investment) to support the Liberian, Sierra Leonean, and Guinean efforts to arrest the 2014-2016 Ebola outbreak.[26] A recent study estimates the social and economic burden of the West Africa outbreak ultimately totaled more than $53 billion, at an average of more than $1.8 million per Ebola case.[27] Other recent outbreaks proved even more costly. The MERS outbreak in South Korea in 2015, a mere 186 cases, cost South Korea $10-13 billion—more than $50 million per case.[28]

Unforeseen biological threats can be intrinsically confusing and can require responses from multiple U.S. agencies. It is often difficult to categorize an emerging health threat definitively as a natural event, a lab accident, or a malevolent act. Outbreaks may involve pathogens the world has not seen before, emerging in unexpected places and geographies, involving heretofore unknown actors.



2003
SARS EPIDEMIC

Cost the economies of southeast Asia **between $40-45 billion.**

That is equivalent to about $5 million per case.



2014 - 2016
EBOLA OUTBREAK

Cost the global economy **over $53 billion.**

That is equivalent to more than $1.8 million per case.



2015
MERS EPIDEMIC IN SOUTH KOREA

Cost South Korea **between $10-13 billion.**

That is equivalent to more than $50 million per case.



"Today we are facing the threat of a pandemic that could kill up to 80 million people and wipe out five percent of the global economy. The Global Preparedness Monitoring Board is doing critical work in partnership with the World Health Organization and the World Bank to ensure that more countries are prepared for global health crises."

— Trevor Mundel, Bill & Melinda Gates Foundation

THE WORLD IS UNPREPARED

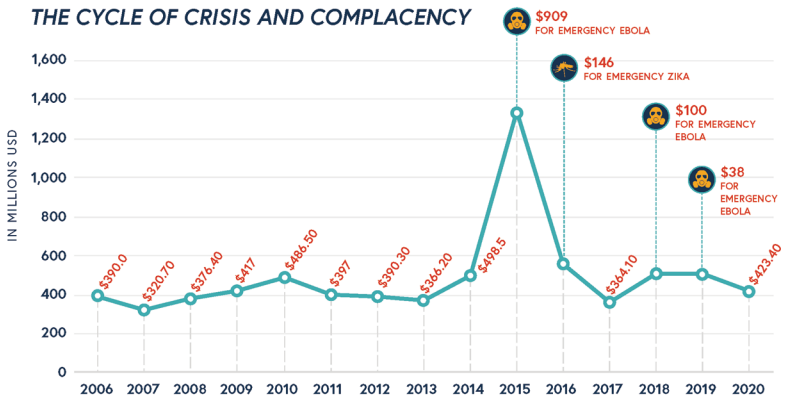
Two recent reports underscore the lack of pandemic preparedness across the globe and ponder the question of what more needs to happen now. The Global Preparedness Monitoring Board (GPMB) was co-established by the WHO and the World Bank in the aftermath of the 2014-2016 West Africa Ebola crisis. The GPMB is an independent body tasked with monitoring preparedness for global health crises.[29] It has the promise to become an authoritative, credible global oversight mechanism. In September 2019, the GPMB released its first annual report, *A World at Risk*, providing a "snapshot" of the international community's ability to prevent, detect, and respond to a global health threat.[30] The findings of the GPMB were unequivocal: the threat is growing, and the world is not prepared.

In October 2019, the Global Health Security Index reaffirmed the GPMB's findings. The Global Health Security Index is the first comprehensive assessment and benchmarking of health security and related capabilities across all 195 countries that make up the states parties to the International Health Regulations (IHR 2005).[31] The Index is unprecedented in its comprehensiveness and granularity, drawing from volumes of open-source information and the input of hundreds of scientists and public health experts. The Index proved that it is possible to design and implement a rigorous methodology to systematically measure pandemic preparedness. The Global Health Security Index candidly and soberly found that no country is fully prepared for epidemics or pandemics, concluding that collectively, international preparedness is weak. The average overall Global Health Security Index score among all 195 countries assessed was 40.2 of a possible score of 100.[32]

The GPMB report and the Global Health Security Index each appeal to heads of state and international leaders to acknowledge the enduring, stark risks posed by global health insecurity and to heighten their engagement on a sustained basis. Both reports appeal to governments, from low-income to the most advanced economies, to invest more of their own resources in preparedness.[33] The CSIS Commission on Strengthening America's Health Security applauds these efforts, which align closely with the Commission's own findings and recommendations.

Preparedness can be a tough sell. It is asking governments to invest in things that are difficult to see. The goal of preparedness is to prevent bad things from happening, which means that success is rarely flashy but more often happens quietly and out of view.

The overwhelming responsibility to lead lies with the U.S. government and its partner governments. While the private sector, foundations, and international organizations are all essential to long-term health security solutions, they cannot be relied upon to lead. In the case of the AMR crisis, for example, it is inadvisable to assume the biopharmaceutical industry will devise solutions on its own. The number of companies conducting antibiotic research and development is declining, a reflection of complex scientific, regulatory, and market challenges. The U.S. government needs to



SOURCE: Kaiser Family Foundation, "Global Health Security Funding," accessed October 2019, https://www.kff.org/interactive/budget-tracker/summary/Filter-Program-Area/Global-Health-Security/Agency/?view=range-years&startYear=2006&endYear=2020.

provide more incentives and better answers as to how to reverse this trend and preemptively tackle this health security threat.

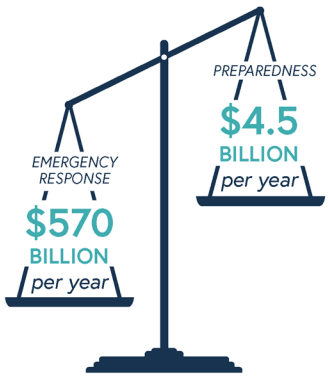
The countries that are the most vulnerable are not yet making the investments needed, even after conducting careful assessments and preparing national plans.[34] For many cash-strapped governments, budget commitments in health security compete against other worthy, politically sensitive, and very concrete priorities, including defense, education, and infrastructure. That financing gap is among the gravest challenges in health security. Chronic underinvestment has hindered genuine capacity building by low- and middle-income countries. This creates considerable innate risk of runaway outbreaks that may not be very visible at the outset but can quickly threaten U.S. national security interests as they spread. The U.S. government should develop programs which incentivize investment by the most vulnerable nations themselves.

A Moment to Change Course

Despite the barriers, new opportunities are arising.

As health security incidents occur more frequently and with higher visibility, velocity, and costs, leaders in the public, private, international, and social sectors (including philanthropies, NGOs, and academic institutions) have begun to take notice and think anew about what long-term strategy is required. Today, economists across sectors increasingly acknowledge the overwhelming business case for investment in health security. An exercise conducted in the aftermath of the 2014-2016 West Africa Ebola crisis calculated the inclusive costs of a severe influenza pandemic could be as high as $80 billion in annual economic losses and $490 billion in annual costs tied to illnesses and premature deaths, for a total of $570 billion per year.[35] In contrast, a landmark study published by the National Academies of Sciences, Engineering, and Medicine determined that the cost of investing in basic health security is a relatively modest $4.5 billion per year.[36] There is increasing understanding that the United States can afford to invest—and simply cannot afford not to invest in preventative strategies.

The cost of baseline preparedness is estimated at only about a dollar per person per year—and building and sustaining preparedness need not be an open-ended donor commitment.[37] Countries are capable of transitioning to self-reliance with the correct incentives and support. Low- and middle-income partner countries such as Vietnam, Uganda, Cameroon, Ethiopia, and Cambodia have already demonstrated their willingness to step forward, embrace independent assessments of their health security preparedness, develop national action plans, and join in capacity-building collaborations. The WHO has been central to this effort and has made significant reforms to improve its own outbreak and emergency capacity and its ability to work with key partners.



The cost of baseline preparedness is estimated at only about $1.00 per person per year.

In the United States, a stable bipartisan Congressional consensus has emerged in which health security has been



"When it comes to investing in America's global health security, an ounce of prevention is a pound of cure. Modest, sustained investment in public health preparedness each year is more effective and less expensive than paying enormous sums to respond and recover from a dangerous, major outbreak."

— Christine Wormuth, RAND Corporation



"I am proud to have forged bipartisan leadership in Congress on global health security issues. People across the country expect the federal government to be prepared to keep them safe during times of natural disasters or biological, chemical, radiological or nuclear threats to our public health and national security. Unfortunately, we remain largely reactionary in our response to pandemics and biological threats. Proactive efforts are critical to our national and health security. Bringing policymakers together to discuss these critical issues as well as the Commission's final recommendations are an essential element of advancing a coherent vision for U.S. global health security policy."

— U.S. Congresswoman Susan Brooks (R-IN-5)

largely insulated from political polarization. Though several committees and sub-committees have jurisdiction and funding authorities in this area, it has been possible to forge a unified vision of core goals and principles around pressing health security challenges.[B]

B. Refer to Appendix II: Congressional Authorities and Oversight of U.S Government Efforts to Advance Global Health Security for more information on relevant committees and subcommittees.

RECENT U.S. CONGRESSIONAL ACTION

There is strong bipartisan support in the U.S. Congress for global health security, as evidenced by the recent introduction of a number of bills in this area. Included below are highlights of recent proposed legislation related to global health security, although this is by no means an exhaustive list. The Commission is encouraged by and supportive of these efforts. They provide a foundation for sustained action by the U.S. Congress to strengthen global health security.

DEVELOPING AN INNOVATIVE STRATEGY FOR ANTIMICROBIAL RESISTANT MICROORGANISMS (DISARM) ACT OF 2019: In June 2019, Senators Johnny Isakson (R-GA) and Bob Casey (D-PA) introduced the DISARM Act.[38] This proposal seeks to strengthen the research and development pipeline for antimicrobials and would allow Medicare to reimburse qualifying hospital-administered antibiotics used to treat serious or life-threatening infections.

EBOLA ERADICATION ACT OF 2019: The Ebola Eradication Act was introduced by Senator Bob Menendez (D-NJ) in May 2019 and directs USAID to support efforts in the DRC, South Sudan, and Burundi to combat the ongoing Ebola outbreak.[39] The Senate passed the act in September 2019 (S.1340) by unanimous consent, authorizing activities to combat the Ebola outbreak in the DRC.[40] At time of writing, it awaits action in the House of Representatives.

FLU VACCINE ACT: The Flu Vaccine act was introduced by Congresswoman Rosa DeLauro (D-CT) and Senator Edward Markey (D-MA) in February 2019.[41] The Flu Vaccine Act calls for $1 billion ($200 million annually for fiscal years (FY) 2020 through 2024) to support the National Institutes of Health's (NIH) efforts to develop a universal flu vaccine.



As a leader in Congress of bipartisan efforts to strengthen international and domestic public health security preparedness and response programs, I believe Congress must maintain this momentum by continuing to address pressing health security issues, including vaccine hesitancy. Vaccinating children against deadly diseases, such as measles, is essential to U.S. health security, and I am committed to improving our efforts to reach parents with quality science and win their trust and confidence."

— U.S. Congresswoman Anna Eshoo (D-CA-18)

THE LOWER HEALTH CARE COSTS ACT OF 2019: The Lower Health Care Costs Act was introduced by Health, Education, Labor and Pensions (HELP) Committee Chairman Senator Lamar Alexander (R-TN) and Ranking Member Senator Patty Murray (D-WA) in June 2019 and reported out of the committee with broad bipartisan support in July 2019.[42] The bill includes provisions addressing vaccine hesitancy and strengthening public health data management, both of which are included in companion legislation in the House of Representatives.

PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION ACT (PAHPAI) OF 2019: In June 2019, President Trump signed PAHPAI into law.[43] PAHPAI was originally introduced in the House by Energy and Commerce Health Subcommittee Chairwoman Anna G. Eshoo (D-CA) and Congresswoman Susan Brooks (R-IN) and by Senators Richard Burr (R-NC) and Bob Casey (D-PA) in the Senate. The legislation reauthorizes and builds upon public health preparedness and response programs at the U.S. Department of Health and Human Services (HHS) and the CDC. PAHPAI authorizes $611.7 million for the Biomedical Advanced Research and Development Authority (BARDA) to implement strategic activities to address a range of public health security threats, including pandemic influenza and AMR, a $50 million increase over FY 2019 funding levels.[44] This increased investment will further support BARDA in the development of surveillance technology, diagnostics, and countermeasures for emerging and high-consequence infectious diseases with pandemic potential.

VACCINE AWARENESS CAMPAIGN TO CHAMPION IMMUNIZATION NATIONALLY AND ENHANCE SAFETY (VACCINES) ACT OF 2019: The VACCINES Act was introduced in May 2019 by Representatives Kim Schreier (D-WA), Michael Burgess (R-TX), Eliot Engel (D-NY), Brett Guthrie (R-KY), Kurt Schrader (D-OR), and Gus Bilirakis (R-FL) and Senators Gary Peters (D-MI), Pat Roberts (R-KS), and Tammy Duckworth (D-IL).[45] The VACCINES Act authorizes $6 million annually for FY 2020 through FY 2024 for the CDC to study and monitor vaccine hesitancy and conduct an expanded public awareness campaign on the importance of immunizations.

VACCINE INFORMATION AND PROMOTION (VIP) ACT OF 2019:[46] The VIP Act was introduced in June 2019 by Representatives Sheila Jackson Lee (D-TX), Eleanor Holmes Norton (D-DC), Gwen Moore (D-WI), Terri Sewell (D-AL), Ayanna Pressley (D-MA), Eddie Bernice Johnson (D-TX), Carolyn Maloney (D-NY), Donald Payne Jr. (D-NJ), and Lucy McBath (D-GA). The VIP Act authorizes $50 million annually for FY 2020 through FY 2024 for HHS to counter the rise of vaccine hesitancy through expanded vaccination education programs, public awareness, and communications campaigns.



"Health security challenges are innately complex, and require all of us working together, across agencies, jurisdictions, and even across countries, to come together and form a better line of defense. No government or private company or NGO can solve them alone. We have to come together in private-public partnerships to overcome these formidable challenges."

— Julie Gerberding, Merck & Co, Inc.

The executive branch has made considerable policy progress, as evidenced recently in the evolution of the Global Health Security Agenda (GHSA), the issuance of the updated National Biodefense Strategy in 2018—aided by the high-quality work of the Bipartisan Commission on Biodefense—and the White House Global Health Security Strategy in 2019.[47,48]

STRENGTHENING DOMESTIC PREPAREDNESS

This report highlights actions the U.S. government can take to counter health security threats around the world. Even as the Commission emphasizes the importance of stemming disease beyond U.S. borders, it also fully recognizes the vital importance of investing in domestic public health infrastructure and preparedness, which continue to lag dangerously behind what is required to protect Americans.

In this respect, the Commission complements the work of the Bipartisan Commission on Biodefense (formerly known as the Blue Ribbon Study Panel on Biodefense), which assesses and provides recommendations on strengthening the state of U.S. biodefense. It is critically important that the U.S. government invest at a higher level, on a sustained basis, in state and local public health capacity, as these officials will be on the front lines in the case of an outbreak in the United States.



"We have seen time and again that diseases do not respect national borders. We have to act simultaneously at home and abroad. At the same time that we invest in global preparedness, we must also focus on the needs within our borders: strengthening leadership, coordination, and funding to respond to public health and biological threats at home."

— Peggy Hamburg, National Academy of Medicine



"Real-time data at the fingertips of decision makers on the front lines of an epidemic speeds response efforts. The U.S. government has promoted the use of digital health tools to improve collection, analysis and use of health data, but more effort is needed by the United States and others to ensure these technologies are effectively used and safeguards for data sharing are in place prior to a crisis."

— Steve Davis, PATH

We have seen exceptional innovations emerge from the 2014-2016 Ebola crisis in West Africa, led by the private sector. An experimental Merck vaccine developed in that period underpins today's Ebola response in the DRC, where more than 230,000 persons have been immunized as of October 2019.[49] A second Ebola vaccine by Johnson & Johnson, also first developed in West Africa, is now being introduced on an experimental basis in Uganda and the DRC.[50]

More recently, randomized field trials of four experimental Ebola treatments conducted during the DRC outbreak have produced preliminary results indicating that two therapies, one developed by Ridgeback Biotherapeutics and the other by Regeneron Pharmaceuticals, can significantly increase survival if administered early.[51] Both therapies are public-private partnerships, with the National Institute of Allergy and Infectious Diseases (NIAID), BARDA, and the Department of Defense (DOD) all playing key supporting roles.[52] Together, these promising therapies have the potential to change the course of Ebola outbreaks. For the immediate crisis in the DRC, that will require overcoming chaos and violent disorder, including violent, opaque networks attacking health providers; creating a far better dialogue with mistrustful, alienated communities; and better motivating citizens to step forward early to seek treatment.

That same Ebola crisis of 2014-2016 inspired the creation of the Coalition for Epidemic Preparedness Innovations (CEPI), an alliance comprised of governments, foundations, companies, non-profits, and researchers, with a mandate to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics.[53] CEPI is off to a promising start in its first two and a half years, investing $456 million in new partnerships with the private sector, academic institutions, and other non-profit product development enterprises to develop new vaccines.[54] It is a particularly compelling innovation in health security.

DIGITAL HEALTH AND HEALTH SECURITY

Timely and accurate information to assess disease burdens, track emerging outbreaks, and support disease prevention and control measures is essential in epidemic response. Over the past decade, countries have increasingly transitioned from paper-based to digital information systems and have gained new capabilities and insights by engaging in the corresponding data. When optimized, the convergence of digital technologies and new data models with health systems, also known as "digital health," can allow countries to make more accurate and timely decisions for preventing, detecting, and responding to outbreaks.[55]

While clear successes have resulted from these initial efforts, significant challenges remain, including corruption, lack of transparency, and distrust of commercial firms.[56]

- Many health information systems are siloed and capture duplicate data, putting significant strain on

health workers who collect, manage, and use this information.

- Health information systems are not always interoperable. Their inability to reliably "talk" to one another hinders evidence-based decisionmaking.
- Many low- and middle-income countries need to boost stakeholders' capacity to design, manage, and support digital health systems, as well as effectively use data.
- Many countries lack the necessary governance structures, policies, and coherent national plans to ensure transparency and accountability, guard against corruption, and support the utilization of data to inform epidemic response decisions and actions.
- The U.S. government has not sufficiently leveraged the American technology sector's potential to advance digital health and global health security goals. Part of that process involves building trust and confidence in private-sector partners.

The United States, in collaboration with private-sector technology partners, is a global leader in creating and adopting digital health technologies for epidemic response. The U.S. government is in a strong position to leverage its resources and build on proven strategies to meet existing gaps that are prohibiting true scaling of digital technologies. Deploying these technologies and ensuring coordination with global and national partners can ensure that the necessary data and information are available in the right place, at the right time, and to the right people to speed epidemic response.

A U.S. Doctrine of Continuous Prevention, Protection, and Resilience

The seven recommendations below will enable the United States to replace the crisis-complacency cycle with a doctrine of continuous prevention, protection, and resilience—investing strategically in preparedness now so the United States can manage threats and avoid catastrophic costs later.

The doctrine aims to restore White House leadership, strengthen financing and the speed of response, build reliable partners abroad, enhance the U.S. government's ability to operate in disordered settings, and accelerate technological innovations to secure the future. It aims to strengthen accountability, prioritization, and reform of fragmented programs.

The Commission urges Congress and the administration to pursue the following integrated package of actions:

1. Restore health security leadership at the White House National Security Council.

RECOMMENDATION

The U.S. government should re-establish a directorate for global health security and biodefense on the National Security Council (NSC) staff and should name a senior-level leader in charge of coordinating U.S. efforts to anticipate, prevent, and respond to biological crises. These actions will ensure that the necessary leadership, authority, and accountability is in place to protect the United States from a deadly and costly health security emergency.

RATIONALE

Global health security and biodefense challenges pose a national security threat to the American people and require centralized leadership at the highest level of the U.S. government. While the administration has released its National Biodefense Strategy and Global Health Security Strategy and strengthened the roles of departments and agencies, top-level leadership is still needed at the White House. Global health security threats touch the equities of multiple executive agencies—including the Departments of State, Health and Human Services, Defense, and Justice, as well as the intelligence community—and require informed, coordinated attention to an array of capabilities and responses spanning medical technologies and public health interventions, intelligence gathering and preemption, and sustained high-level diplomacy to mobilize international coalitions. By definition, this zone of national security requires a strong interagency process led by the White House.

In the fall of 2016, in the aftermath of the slow, uncoordinated, and resource-intensive response to the Ebola crisis in West Africa, the White House NSC staff created the Global Health Security and Biodefense directorate. Designed to plan for and oversee rapid, efficient, government-wide responses to global health security threats, the directorate pooled NSC staff focused on domestic and international biodefense and health security issues. Led by a senior director, the directorate reported to the national security advisor and the deputy homeland security advisor, the latter of whom was designated as the lead for coordinating the U.S. response to a biological crisis. The White House also released a companion executive order in November 2016 advancing the GHSA.[57]

In the spring of 2018, the administration dissolved the NSC directorate for Global Health Security and Biodefense, and



"Health security is fundamental to U.S. national security. It is encouraging that despite a polarized U.S. Congress, this is an area where we have made meaningful progress on a bipartisan basis. We all have an interest in national security, in our health, and in making sure that we do the right thing to protect the American people."

— Kelly Ayotte, Former Senator (R-NH)

oversight of these issues was incorporated into the directorate for Weapons of Mass Destruction and Biodefense.[58] In the fall of 2018, the White House released a National Biodefense Strategy designed to strengthen the country's defenses against biological threats to health and safety.[59] President Trump also signed a National Security Presidential Memorandum on Support for National Biodefense, which reaffirmed U.S. support for the GHSA, extending through 2024, and established a Biodefense Steering Committee chaired by the secretary of Health and Human Services and responsible for the monitoring, coordination, and implementation of the strategy.[60] In May 2019, the White House released a Global Health Security Strategy, the first of its kind, which "defines the actions the Administration will take to prevent, detect, and respond to infectious disease threats, whether naturally occurring, accidental, or deliberate," and which reiterated the administration's support for the GHSA.[61]

The administration should be commended for advances in the national biodefense and global health security strategies. However, critical leadership gaps remain. It remains unclear who would be in charge at the White House in the case of a grave pandemic threat or cross-border biological crisis, whether natural, accidental, or deliberate. Over the past year, the sluggish White House response to the Ebola outbreak in the DRC is but the latest example of this problem.

And while the Biodefense Steering Committee plays an important role in implementing the National Biodefense Strategy, senior leadership in the White House is required to successfully coordinate the large number of government agencies and programs across health, security, development, and defense, as well as private-sector actors that would be involved in a response to an international public health threat. In the case of a health security emergency, White House leadership will also be critical in navigating challenging political issues like quarantines and travel bans and in communicating to and reassuring the American public. The authorities currently in place at HHS are insufficient to address these critical, complex, and often urgent interagency demands.

In addition to coordinating the interagency process, a global health security and biodefense directorate at the NSC can reform fragmented programs and ensure higher efficiencies, strengthened accountability, and better spending of scarce resources. Together with the Office of Management and Budget (OMB), it can identify, rationalize, and align funding in the U.S. president's budget across agencies.

ESTIMATED COST: N/A

2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.

RECOMMENDATION

U.S. direct investments remain essential to build health system capacity. To stop outbreaks at the source, Congress should authorize stable funding through the GHSA's 2020-2024 phase for capacity-building programs in priority countries, including the original 17 GHSA partner countries, plus other select high-risk countries, such as the DRC. Experts advise that this will involve returning the GHSA-re-



"To contain a naturally occurring outbreak, a lab accident, or a bioterrorist attack, the first response has to be the health system that identifies the pathogen, does the surveillance, finds its origin, and promotes measures to limit its damage. We must expand and sustain funding for the GHSA, the world's vehicle for building resilient public health infrastructure."

— Ambassador Jimmy Kolker, U.S. Department of Health and Human Services (former)

lated budgets of the principal executive agencies implementing the GHSA (the CDC, USAID, the U.S. Department of State, and the DOD) to FY 2015 baseline levels, with Ebola supplemental funding.

RATIONALE

The GHSA is a multi-partner initiative that facilitates burden sharing and builds local health system capacity.[62] The $1 billion in emergency supplemental funding that the U.S. government has committed to the GHSA so far (FY 2015-FY 2019) has gone a long way in helping countries to prevent or stem the spread of infectious disease outbreaks.[63] The question now is what comes next, as the emergency supplemental funding ends at the conclusion of FY 2019.

A cornerstone of the effort is the voluntary, collaborative assessment process designed to measure a country's capacity to prevent, detect, and rapidly respond to public health threats.[64] These assessments, known as Joint External Evaluations (JEEs), have been conducted in 100 countries in six regions since the GHSA was launched in 2016, and 21 additional JEEs are scheduled as of this writing.[65] Most of these assessments have been published to facilitate understanding and enable urgent gaps to be filled. The United States has been actively engaged in the JEE processes, participating in JEE missions and providing technical support to countries as they develop National Action Plans. The GHSA Private Sector Roundtable brings the private sector into this process by connecting GHSA countries with companies in the health care, finance, technology, and logistics sectors.[66]

Several U.S.-assisted GHSA countries have experienced infectious disease outbreaks in recent years, and the improved health system and preparedness capacities built with the help of U.S. agency support and other international partners have proven decisive. In October 2017, a U.S.-assisted laboratory confirmed a positive case of Marburg virus in eastern Uganda. Marburg is a lethal virus in the same family as Ebola, and this laboratory confirmation proved the first critical step in a rapid and effective Uganda-led response. The Uganda Ministry of Health deployed a rapid response team to the affected region, which was staffed in part by U.S.-supported Field Epidemiology Training Program (FETP) graduates. Ultimately, three cases were confirmed, all of



A laboratory official examines mosquito samples at the National Institute of Hygiene and Epidemiology in Hanoi in August 2018. Building health system capacity, including laboratory capacity, is critical to responding to mosquito-borne diseases and other health security challenges.

NHAC NGUYEN/AFP VIA GETTY IMAGES

which were fatal. But through effective contact tracing and community education, the Ugandan rapid response team stopped the spread of the virus.[67]

Fully funding the GHSA into the future will help the U.S. government stop outbreaks at their source—the best way to protect the American people. As the emergency supplemental funding comes to an end, there are funding gaps that should be addressed. Experts estimate that an additional $100 million per year above the enacted FY 2019 budget will be required for the CDC, and an additional $35 million per year for USAID. These investments should be understood as part of a 10-year strategy for building self-reliance among partner countries.

As part of that investment, the CDC and USAID should give serious consideration to investing $20 million per year to strengthen digital health information systems in priority countries.[68] In today's digital world, interoperable health information systems are becoming essential to facilitate evidence-based decisionmaking. That requires effective regulatory and legal oversight to ensure transparency and accountability; surveillance and laboratory systems to track emerging outbreaks and support disease control measures; digital monitoring of supply chains to ensure commodities are available when needed; and monitoring of vaccine and therapeutic delivery.

Key programs within the Departments of Defense and State should also be protected and sustained. These include the DOD Cooperative Threat Reduction (CTR) Biological Threat Reduction Program (CTR/BTRP), DOD Global Emerging Infections Surveillance and Response (GEIS) Program, and the State Biosecurity Engagement Program (State/BEP). These budgets support global health security efforts aimed at preventing deliberate and accidental outbreaks, linking law enforcement and public health officials, and detecting emerging threats as early as possible.

ESTIMATED COST:[C]
CDC: $100 million beyond FY 2019 levels (annually for 10 years).
USAID: $35 million beyond FY 2019 levels (annually for 10 years).

C. Refer to Appendix I: Illustrative Costing for Recommended Programs and Initiatives for illustrative costing of all recommendations outlined in this report.

THE DOD AND HEALTH SECURITY

The DOD contributes to overall U.S. health security through a number of programs that are aimed at countering biological threats from all sources.[69]

U.S. military medicine has a long history of landmark successes against tropical diseases affecting troops from temperate zones operating in tropical environments. Examples include the efforts against yellow fever, which were led by U.S. Army Majors Walter Reed and William Gorgas during the Spanish American War, and extensive epidemiological studies during the 1918 worldwide influenza epidemic.

Today, the DOD operates a worldwide public health, infectious disease research, and disease surveillance network to protect U.S. and allied forces against



"Historically, more military service members have died from dangerous infectious disease than from bullets. Over the last century, the U.S. military has made extensive investments to protect U.S. and allied forces from health security threats and confront and defeat these global threats. These investments remain essential to protect both the military and the general public."

— Admiral Jonathan Greenert, U.S. Navy (former)



"Global health security is national security. If we want to see truly strengthened health security, we need to better integrate the Department of Defense's unique research, mobility, and security capacities."

—General Carter Ham, U.S. Army (former)

infectious diseases and other biological hazards. These extensive programs benefit both the military and the general public.[70] A few examples include:

- The U.S. military GEIS Program, established in 1997, works closely with the DOD overseas and domestic infectious disease research laboratories, the CDC, the WHO, and others.[71]
- The Defense Threat Reduction Agency's (DTRA) Biological Threat Reduction Program (BTRP) supports international partnerships and capacity-building efforts to combat the threat of intentional, accidental, and naturally occurring biological threats.[72] BTRP works closely with regional geographic combatant commanders (GCCs) to support activities in Asia, Africa, the Middle East, and Europe. These efforts have become increasingly coordinated with activities of other programs and organizations aligning with international frameworks, such as the IHR and the GHSA
- The Military Infectious Diseases Research Program (MIDRP) manages research on naturally occurring infectious diseases, focusing on the development of vaccines and drugs, diagnostics, and vector control on illnesses most likely to impact military operations. MIDRP supports basic science, preclinical studies, and clinical trials leading to Federal Drug Administration (FDA) approval. Most of this work is carried out at DOD laboratories located in Maryland—the Walter Reed Army Institute of Research (WRAIR), the U.S. Naval Medical Research Center (NMRC), and the U.S. Army Research Institute of Infectious Diseases (USAMRIID)—as well as the overseas DOD laboratories located throughout the world.
- The DOD supports many other activities developing detection capabilities, medical countermeasures, and personal protective equipment against biological threats.
- Finally, U.S. military forces are available for disaster response anywhere in the world when necessary to augment civilian capabilities. Operation United Assistance, the DOD support for the U.S. government response to the Ebola outbreak in Liberia in 2014-2015, is the most recent and prominent example.

3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.

RECOMMENDATION

U.S. multilateral leadership is necessary to address the financing gap for preparedness, one of the starkest problems in health security. Linked to its support for the GHSA 2024 framework, in FY 2020 the U.S. government should assemble an international consortium of public and private donors to launch a five-year, $750 million Pandemic Preparedness Challenge to catalyze domestic investment in health security preparedness in the 32 fragile states eligible for financing from the World Bank's International Development Association (IDA). The United States would pledge one-fifth of the donor shares, leveraged against contributions by other donors of the remaining four-fifths.

RATIONALE

The financing gap for preparedness is one of the starkest problems in health security, especially among fragile states. The lack of preparedness in fragile and conflict-affected states—where infectious disease outbreaks are increasingly common—directly impacts and threatens



U.S. Marine Corps medics run to an American helicopter at Camp Chesty, a Marine logistics base and medical facility in central Iraq in April 2003. Strengthening and integrating the DOD's unique capabilities will be essential to a cohesive U.S. health security approach.

CHRIS HONDROS/GETTY IMAGES



"As the 2014-2016 West Africa Ebola crisis reminded us, pandemics do not respect national borders. The only long-term, sustainable solution is for governments to invest in their own preparedness. We are determined to push forward to motivate countries to address this glaring financing gap."

— U.S. Senator Todd Young (R-IN)

U.S. economic, health, and national security interests. Investments in preparedness are cost-effective and affordable, but many fragile state governments continue to underinvest at dangerously low levels. In the poorest and most fragile countries, where many needs are pressing and resources are constrained, political leaders often face difficult trade-offs between investing in longer-term preparedness versus shorter-term, more tangible efforts like building roads or schools.

However, experience suggests that with the right incentives and support, developing countries will invest their money in preparedness. In Uganda, Cameroon, Ethiopia, Vietnam, and Cambodia, for example, the governments have drawn upon their own budgetary resources and talent to bolster their preparedness, with support provided by donors under the GHSA framework. While there are several multilateral mechanisms in place to support emergency outbreak responses, much more effort is needed to partner with countries to invest in their own long-term preparedness.

Thirty-two countries eligible for IDA financing, with a total population of about 400 million people, are classi-

fied by the World Bank as fragile and conflict-affected states.[73] As of August 2019, 24 of these countries have completed JEEs of their preparedness gaps, and 15 have developed National Action Plans to address those gaps.[74] Yet most of these countries are unable to marshal sufficient domestic resources to fully fund their National Action Plans, rendering their health and preparedness systems acutely vulnerable.

To help fragile countries turn their plans into reality and build self-sustaining capacities, Congress should press the U.S. government to partner with public and private donors to launch a five-year, $750 million Pandemic Preparedness Challenge. The United Kingdom, Germany, Japan, France, Australia, Finland, Denmark, and Sweden would likely be strong partners in this effort. Saudi Arabia, the United Arab Emirates, South Korea, and others might join as well.

Administered by the World Bank, the Challenge will work in tandem with IDA financing to supplement direct investments by states themselves in capital and operational costs to strengthen preparedness. Countries whose plans and budgets are approved by the Challenge's board may be awarded up to a maximum of five years of grant funding to cover start-up and recurrent costs.

To promote self-reliance and sustainable domestic financing, the Challenge investments will be time-bound and will cover a declining share of a country's recurrent costs each year (e.g., up to 80 percent in year one and 20 percent by year five). Each Challenge country will have an exit strategy, with success measured by increases in JEE scores over the life of the investment plan. The U.S. government's share of the Challenge will be $150 million, or $30 million a year for five years, for a 1:4 leverage with other donor funding.

ESTIMATED COST:
$30 million per year for five years.



4. Ensure rapid access to resources for health emergencies.

RECOMMENDATION

To ensure that flexible funds are available early in a crisis, the USAID and CDC contingency accounts should be set and maintained at a level of $250 million each, replenished annually as needed. The United States should also pledge $25 million annually to the WHO Contingency Fund for Emergencies (CFE), using that contribution to leverage other donors to bring the CFE to its targeted $100 million level.

RATIONALE

Stopping a global health security crisis requires fast, early action. Today, demand for such action is swiftly rising as the number of major health and humanitarian crises increases, as can be seen in the DRC, Venezuela, Yemen, Afghanistan, and Syria. Expanding support for contingency funds will allow the United States to support emergency response activities by nongovernmental and international organization partners in insecure and disordered settings, where direct engagement by U.S. agencies may be more difficult or simply not feasible.



"Investing in global health security helps to ensure that the world remains a safe place and American citizens are protected from harm. To stop outbreaks at their source, we need rapid response contingency funds and we need to help other countries to invest in their own preparedness. Through the appropriations process, Congress has worked on a bipartisan basis to ensure that funding goes to countries to build and sustain health security preparedness."

— U.S. Congressman Tom Cole (R-OK-4)

In the aftermath of the slow and cumbersome response to the 2014-2016 West Africa Ebola outbreak, the U.S. government recognized the clear need for contingency funds that could be readily accessible in the case of an infectious disease emergency. A second major lesson learned from the 2014-2016 Ebola outbreak is that the CDC and USAID each play a unique and essential role in a global health security crisis, and neither is sufficient on its own. The resulting establishment of the CDC Infectious Diseases Rapid Response Reserve Fund and the USAID Emergency Reserve Fund for infectious disease outbreaks was a significant first step in addressing the gap in quick-disbursing finances.

However, independent experts have estimated that the USAID and CDC contingency accounts, at their current levels, are not sufficient to respond to the increasing number and intensity of global health crises. In FY 2019, $50 million was appropriated for the CDC contingency fund, and $2 million for the USAID contingency fund.[75,76] Experts recommend that these accounts be set and maintained at a level of $250 million each, replenished on an annual basis as warranted. It will be important to amend current policies to permit rapid disbursement of these funds during the early stages of infectious disease outbreaks.

In parallel, a U.S. annual pledge of $25 million to the WHO CFE will significantly bolster the WHO's capacity to move expeditiously in deploying staff and funding early responses to dangerous outbreaks. A contribution to the WHO CFE will allow the United States to support emergency response activities by NGOs, national governments, and international organizations in difficult-to-access settings where direct U.S. government engagement is not possible. The United States should use that contribution to leverage other donors to contribute to achieving and maintaining a $100 million CFE. No less important, the United States should prioritize expanding and ensuring sufficient financing flexibility and speed in the World Bank's emergency response facilities.

ESTIMATED COST:
CDC Infectious Diseases Rapid Response Reserve Fund: Increase to $250 million and maintain at that level.
USAID Emergency Reserve Fund: Increase to $250 million and maintain at that level.
WHO Contingency Fund for Emergencies: $25 million per year.



5. Establish a U.S. Global Health Crises Response Corps.

RECOMMENDATION

To engage and operate effectively and safely in austere, unsafe settings, the U.S. government should establish a U.S. Global Health Crises Response Corps. The Corps should be constructed on USAID and CDC existing capabilities, augmented by joint team training exercises, and provided with security, intelligence and data, and communications support. The mandate of the Corps is to respond early, with local partners, to stop outbreaks at their source and to strengthen local capacities.

RATIONALE

Small teams of select, highly experienced U.S. civilian public health and humanitarian experts, working alongside local partners and national leaders, form the "cerebral cortex" of outbreak response.



"Today the world faces a volatile convergence of instability, state weakness, and conflict. These conditions are hindering the ability of the United States to support health service delivery and outbreak response in a number of critical regions. We need to be able to deploy our best and brightest civilian experts into disordered settings where outbreaks strike."

— Rebecca Hersman, CSIS

CDC civilian experts provide on-the-ground interpretations of fast-moving, complex outbreaks and immediate advice on the precise mix of public health interventions, geographic priorities, and communications with communities and partners necessary to halt outbreaks. In addition, the CDC possesses essential expertise in epidemiology, data systems, contact tracing, and training of the local health work force.

The USAID Disaster Assistance Response Team (DART) platform, refined over the past three decades, has developed protocols and operational capacities to integrate the CDC, the Department of State, and others, as well as to interface with the U.S. military, as needed, in deploying into humanitarian emergencies.[7] USAID has essential aptitudes in large-scale logistics, contracting, and supply chain management and expertise in the critically important development sectors of water, food, and health infrastructure.

Their combined presence can be a high-impact game changer, as witnessed in the Ebola outbreaks in West Africa in 2014-2016. Inversely, when U.S. and other critically important experts are barred from outbreak zones due to insecurity, as currently seen in the DRC, disease may spread, with grave consequences.

The world has grown more perilous, and the worst danger zones are precisely where the greatest health security risks frequently reside. Yet risk aversion has impeded USAID and CDC deployments into several outbreak zones, including the DRC, South Sudan, Iraq, Syria, and Nigeria, while Yemen and Afghanistan offer only minimal access. Moreover, danger is not likely to abate in the future. If anything, it will worsen. Policymakers are understandably cautious—but failing to engage is ultimately trading one risk for another. The United States simply cannot afford to leave its key civilian capabilities on the sidelines of rapidly emerging health crises.

In combination, U.S. civilian teams from the CDC and USAID are often able to engage partner governments, civil society, and other nongovernmental providers far more authoritatively and bluntly than the WHO. Their unique impact warrants assuming higher risks than might otherwise be the case, along with making higher investments in training, support, and protection.

The Corps will be drawn from the ranks of current U.S. public health and humanitarian experts in the CDC, USAID, and the U.S. Public Health Service. The majority, it is expected, will have significant experience serving on USAID-led DART teams and as members of the CDC Global



Police officers run in Goma, DRC on December 27, 2018, during clashes with demonstrators protesting the postponement of the general elections in this area, which government officials attributed to the Ebola outbreak.

PATRICK MEINHARDT/AFP VIA GETTY IMAGES)

Rapid Response Team (Global RRT). They will receive special training and be on-call to deploy, as needed, in civilian expeditionary teams introduced for rotational assignments away from their normal duties into insecure environments. The Corps will have two tiers: Fifty highly experienced and highly trained advanced responders will be committed to deploy as teams on very short notice; and 400-500 experts will be available for deployments that can be made with careful prior planning.

The Corps will bring to the field public health expertise and operational experience in select, vitally important disciplines: incident and data management; community engagement to build trust and confidence; epidemiology; laboratory-based pathogen surveillance; and emergency humanitarian response services, including in non-health areas such as water, food relief, and shelter. The Corps should systematically invest in strengthening the capacity of local, in-country, and regional partners, including NGOs and civil society groups. Though not intended to deliver clinical health services, it can play an essential role in facilitating and expediting service delivery by local partners.

The Corps will be trained to deploy into gray zone settings prone to intermittent, localized violence that falls below the level of open armed conflict conducted by armies and irregular forces. Teams from the Corps will be equipped to deploy to two to three countries in the first one to two years. The teams will be charged with aligning their work in support of partner institutions and agencies, including the host nation, the WHO and related UN bodies, and operational NGOs.

All members of the Corps will receive training in operating as structured teams, critical languages (experts recommend French, Arabic, Portuguese, and Spanish), negotiation of local access, communications, use of local intelligence, building trust with local communities, means to minimize risks and optimize protection, and entry and extraction protocols. Training will emphasize speed and self-sufficiency in deployment, and it will be critical to ensure unencumbered access to critical supplies.

For the Corps to operate in insecure circumstances will require overt acknowledgement of the need to accept significant risks when the risks of not acting are grave. It will also require acknowledgement of the need for the Corps to receive quality, real-time, granular intelligence. To rebalance risk calculations, Congress or the administration should issue a policy statement declaring that putting U.S. civilian health response experts on the frontlines of health crises is a compelling U.S. national security interest. Follow-on steps will be needed to clarify what that means in practice in terms of revised risk calculations.

As envisioned, security will be managed on a case-by-case basis. It should be provided by the UN, host nation forces, or local police forces. The Corps will include appropriate DOD advisers, but will not call for DOD to provide security forces.

Depending on the specific situation, either the CDC or USAID should be designated as the lead agency with lead operational responsibilities, acting in close partnership with the other. The lead agency will direct a dedicated interagency process that deliberates over when to engage in public health emergencies and at what level, linked to metrics such as: severity of the outbreak; levels of insecurity and risk of escalation; health and security risks to the population and health personnel; whether there is a PHEIC declaration; and other international, regional, or national security factors. The lead agency will be charged with coordinating recruitment, training, and deployment of the Corps. It will be critically important that the relationship between the CDC and USAID be more constructive and functional. To that end, it will be important to clarify the specific roles and responsibilities of the CDC and USAID within an agreed response framework.

Ultimately, the White House will decide when and where to deploy, based on close consultation with the CDC director, the USAID administrator, the Department of State and chief of mission in the affected country, relevant Department of State security personnel, and DOD personnel, as well as through consultations with the WHO and the host government. Teams will not be deployed without host government request or consent and will deploy under the authority of the chief of mission, except under extraordinary conditions. It will be necessary to develop protocols that establish the security parameters under which the chief of mission could authorize deployment of the Corps.

ESTIMATED COST:
U.S. Global Health Crises Response Corps: $50 million per year for five years.
Strengthening the FETP, the Public Health Emergency Management (PHEM) Fellowship program, and National Public Health Institutes (NPHIs): $36 million per year for five years.



"The U.S. government has unrivaled civilian and military capabilities in detecting, preventing, and responding to global health security threats, but these capabilities don't always achieve jointness. Ensuring joint training, exercises, and deployment will only strengthen the U.S. global health security posture."

— Ambassador Karl Hofmann, Population Services International



6. Strengthen the delivery of critical health services in disordered settings.

The United States should strengthen, refocus, and adapt programs and capacities to ensure the continuity and expansion of necessary health services, including the delivery of immunizations, gender-based violence (GBV) programs, and maternal and reproductive health and family planning services in crisis settings. The health and protection needs of acutely vulnerable women and girls should be prioritized.

Immunization Programs

RECOMMENDATION

The U.S. government should lead an effort to strengthen immunization programs in disordered settings through an improved comprehensive data system to anticipate and prevent vaccine-preventable disease (VPD) outbreaks, particularly in fragile and conflicted countries; rapid response funding to likely outbreak "hotspots"; and enhanced training programs to build the capacity of community health workers operating in disordered settings to deliver immunizations.

RATIONALE

Disorder disrupts immunization programs, acutely impacting coverage and raising the risks of outbreaks. In 2017, at least 60 percent of children who were not reached with routine immunization services lived in just 10 countries, including 5 of the top 15 most fragile states in the world.[78] Twenty million people currently cannot receive vaccines due to weak primary health systems, poverty, unstable governments, and war.[79] VPD outbreaks are much deadlier in disordered settings and have a greater probability of crossing borders into more secure environments.

Global immunization partners, including U.S. agencies, have long cooperated to monitor immunization coverage, assess outbreak potential, and mobilize resources and technical assistance to deliver vaccines in disordered settings.[80] The U.S. government funds global immunization programs at the WHO and the United Nations Children's Fund (UNICEF), through the Department of State and the CDC, and at Gavi, the Vaccine Alliance, through USAID. At the January 2015 Gavi replenishment conference, the United States pledged $1 billion for the 2015 to 2018 period, and it has approved a contribution of $290 million in 2019.[81] The United States should be prepared to make a robust, multi-year commitment at the 2020 Gavi Replenishment meeting in London as well. Through USAID, the DOD, and HHS, including the CDC and the NIH, the U.S. government also supports overseas immunization programs with bilateral development and research support, technical assistance, and participation in multilateral governing structures, such as the World Health Assembly, the Gavi Board, and the GHSA.

Strengthen Data: The U.S. government should strengthen data systems to enhance national immunization registries and anticipate outbreaks. A network of data hubs integrating geospatial, demographic, political, and health information will help the global community assist fragile countries in anticipating and mobilizing to prevent potential VPD outbreaks. This network could be modeled on USAID's Famine Early Warning Systems Network (FEWS NET).[82] The CDC should share its experience establishing the Atlanta-based Global Disease Detection Operations Center, where analysts monitor global polio



An Afghan policeman (L) stands guard as a health worker administers polio drops to a child during a polio vaccination campaign on the outskirts of Jalalabad on January 26, 2016. Polio is resurging in Afghanistan and Pakistan in part due to insecurity and false rumors about the safety of the vaccine.

NOORULLAH SHIRZADA/AFP VIA GETTY IMAGES



"Our ability to operate in insecure settings is contingent on our ability to strengthen health system capacity in insecure settings. The U.S. government needs to push to expand its work with international organizations and partner governments around the world to secure global preparedness."

— Tom Frieden, Resolve to Save Lives

developments and other outbreaks.[83] The capacities of the DOD GEIS Program and overseas research laboratories, the National Geospatial Intelligence Agency, and NASA's Goddard Space Flight Center should also be harnessed to contribute to this work, much as they contribute to FEWS NET. An expert estimate of the initial pilot cost of a comprehensive data system is $4.77 million a year over five years.[84]

Emergency Funds: The United States should designate emergency immunization funds that can be quickly deployed to assist countries in delivering immunizations to predicted "hotspots" and should urge implementing and donor countries, as well as multilateral agencies, to do the same. As a Gavi donor, the United States could advocate that Gavi incorporate the flexibilities necessary to release funds quickly in response to data warning of a

possible outbreak. The U.S. government should also have contingency funds available for emergency immunization activities.

An expert estimate of the necessary cost for emergency immunization funds is $20 million a year over five years.[85] These funds could be drawn from the CDC Infectious Diseases Rapid Response Reserve Fund or the USAID Emergency Reserve Fund for infectious disease outbreaks, as needed and as appropriate. This report recommends these funds be set and maintained at a level of $250 million each, ensuring ample funding for responding to immunization emergencies as well as other infectious disease emergencies (refer to Recommendation 4 for more detail).

Training Community Workers: The United States, through USAID and the CDC, should strengthen and expand agency contributions to training programs meant to enhance the capacity of community health workers to deliver immunizations and related services in disordered settings. Flexible emergency training mechanisms are critical to provide training at the community, subnational, and national levels and enable health workers in zones identified as "at risk" to gather on-the-ground information about community immunization coverage needs and work within the local security context to deliver vaccine products quickly and safely to vulnerable communities. Ensuring that trusted community and locally based health workers, rather than outsiders, can deliver vaccines is critical. An expert estimate of the initial cost of this training program is $975,000 a year over five years.[86]

The CDC should develop and deliver context-specific, short-term training modules preparing community health workers to assess and report on local immunization coverage and needs and deliver vaccines safely within disordered settings. This training should include a focus on culturally and linguistically competent messaging and effective communication to build vaccine confidence. This training could build on the FETP and the Stop Transmission of Polio (STOP) program, which is focused on VPDs.[87] The Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET) and its parent organization, the Task Force for Global Health, link alumni of such initiatives as the CDC's FETP with their counterparts across the world.[88] The CDC could work with partners within TEPHINET and the Task Force to embed experts within country immunization programs.

The USAID-supported CORE Group Polio Project, an international network of civil society groups and local community health organizations that provides financial and technical assistance to help countries eradicate polio and address other infectious diseases, could also serve as a model in this area.[89] Some training initiatives could be integrated into existing CORE Group work.

ESTIMATED COST:
$6 million per year for five years.

Health of Women and Girls

RECOMMENDATION

The U.S. government should prioritize women's and girls' health and protection in disordered and emergency settings. Congress should authorize $30 million in flexible funding annually for five years to ensure that the extensive capacities of the U.S. government in the areas of maternal health, reproductive health, family planning, and GBV prevention and response are moved from the sidelines to the heart of crisis response.[90]

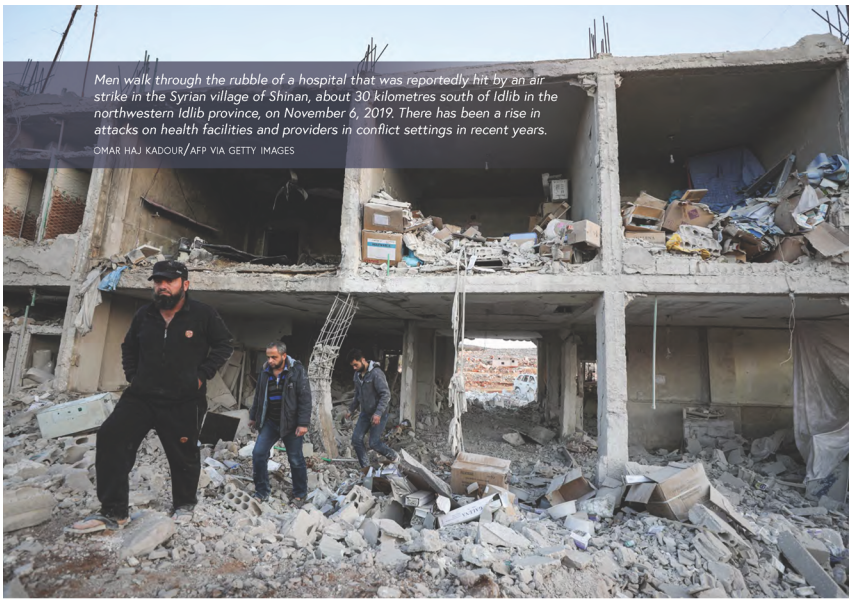
This additional flexible funding is essential to spearhead this effort and incentivize U.S. agencies and their partners to rapidly begin execution of the program. The funding is intended to attract higher-level financial commitments from existing programs at USAID and the U.S. Department of State Bureau of Population, Refugees, and Migration (PRM)—a catalytic, incremental approach that will ultimately ensure existing U.S. government resources and capacities are channeled to those disordered settings where the needs of women and girls are greatest.

The $30 million in flexible funding will be used to launch an integrated model of service delivery for women's and girls' health and safety. This model should be piloted in two to three priority emergency settings to demonstrate impact and generate data and lessons to inform future expansion and replication. This model should adapt, refocus, and integrate programs at USAID's Bureau for Global Health and Office of U.S. Foreign Disaster Assistance (OFDA), PRM, and the CDC, where appropriate.

RATIONALE

The United States has unrivaled financial and programmatic capacities in maternal health, reproductive health, family planning, and GBV prevention and response. However, the U.S. government seldom marshals these extensive capacities in emergency settings, where the needs and vulnerabilities of women and girls are most severe.

Thirty-four million women and girls of reproductive age are estimated to be in emergency situations, often explicitly targeted with sexual violence as a weapon of war.[91] Five million



Men walk through the rubble of a hospital that was reportedly hit by an air strike in the Syrian village of Shinan, about 30 kilometres south of Idlib in the northwestern Idlib province, on November 6, 2019. There has been a rise in attacks on health facilities and providers in conflict settings in recent years.

OMAR HAJ KADOUR/AFP VIA GETTY IMAGES



"One of my priorities as a Commissioner has been to make sure we don't lose sight of how health security threats impact families, especially how they impact women and children. When we plan for disaster, we need to make sure the needs of women and girls are prioritized from the start—not tacked on as an afterthought. We know, when crisis strikes, women often bear the brunt of the burden, as access to health care, including maternal care and family planning services, decreases. The U.S. government needs new capacities to deliver these critical services in the midst of disorder."

— U.S. Senator Patty Murray (D-WA)

of these women are pregnant and face additional health complications and challenges.[92] Inadequate or interrupted maternal health and family planning services contribute to maternal and neonatal mortality, unintended pregnancies, and unsafe abortions. The alarmingly high risks of GBV and severely limited access to maternal health, family planning, and reproductive health services are too often overlooked in crisis settings.

A categorical shift is required for the United States to prioritize women's and girls' health and protection in emergency settings to advance resiliency and health security. Practitioners and policymakers increasingly recognize that failing to address these gaps significantly worsens the impact and trauma of crises and significantly undermines global health security. Conversely, engaging women, girls, and communities in decisionmaking and program design can help build public trust and confidence, which is sorely lacking in many health security crises around the world.

This proposed initiative would ensure that the extensive capacities of the U.S. government in the areas of maternal health, reproductive health, family planning, and GBV prevention and response are brought to bear to ensure the health and safety of women and girls in disordered settings.

Existing U.S. Government Capacity and Gaps: The United States is the global leader in supporting humanitarian response, primarily through OFDA and PRM, which in recent years have expanded their commitment to and investments in preventing and responding to GBV, in addition to their commitment to women's health. PRM funds a range of international organizations, UN agencies, and NGOs to provide GBV prevention and response services, including through Safe from the Start, the U.S. government's flagship initiative on GBV in emergencies. OFDA leads U.S. responses to disasters overseas based on humanitarian need, focused especially on internally displaced populations, including through the deployment of DARTs. USAID's Bureau for Global Health is a global leader in supporting maternal health, reproductive health, and family planning. In April 2019, USAID announced a new $200 million five-year program called the MOMENTUM project—Moving Integrated, Quality Maternal, Newborn, and Child Health and Family Planning and Reproductive Health Services to Scale.[93]

These extensive capacities provide a strong foundation upon which to build a more robust, comprehensive, and impactful approach to women's and girls' health and safety needs in disordered and crisis settings.



Pregnant women stand in line to receive birth kits from a local NGO at a camp for Internally Displaced People (IDPs) in Kibati, north of the provincial capital city of Goma, Democratic Republic of the Congo, on November 12, 2008.

YASUYOSHI CHIBA/AFP VIA GETTY IMAGES

Secretariat: The responsibility for operationalizing this model should be shared between the USAID assistant administrator for the Bureau for Democracy, Conflict and Humanitarian Assistance (DCHA), the USAID assistant administrator for the Bureau for Global Health, and the PRM assistant secretary, in close coordination with the CDC. A working group of core subject matter experts should support the secretariat in operationalizing the model, ensuring alignment of planning and investments and promoting enhanced coordination between women's and girls' health and protection across the interagency process. The agencies should report to Congress on the impact, outcomes, and lessons learned.

Where: In its initial pilot phase, the model should be implemented in two to three crisis settings, such as the DRC, South Sudan, Syria, Venezuela, or Yemen, with the intention of generating learnings to inform potential replication in other disordered settings. To determine where the model should be operationalized, careful consideration should be given to the maternal mortality rate, the percentage of unmet need for contraception, the level of services available for adolescent girls, whether U.S. agencies or partners have access to the communities in need, and impact of the crisis on U.S. health security and foreign policy interests.

Funding and Operational Requirements: Congress should authorize quick disbursing and flexible programmatic funding through USAID—including the Bureau for Global Health and USAID missions—and PRM, in close consultation with other relevant U.S. government agencies. This funding should be used in two to three priority crisis settings to spearhead this integrated service delivery model and incentivize U.S. agencies and their partners to rapidly begin execution of the program. The additional flexible funding is just the first step. This funding will be catalytic and is intended to attract higher-level financial commitments from existing programs at USAID and PRM.

The following operational requirements should be put in place:

- Ensure that OFDA's DARTs and their implementing partners, as well as the CDC and DOD when involved, prioritize women's and girls' health and safety as part of the essential package of services offered in crisis situations.[94]
- Direct PRM to dedicate increased funding for women's and girls' health and safety in refugee and forced displacement settings and to develop criteria and accountability for its UN and NGO partners to demonstrate expertise and capacity in these areas.
- Strengthen local capacity for health care providers, community outreach workers, and NGOs to provide essential health and protection services for women and girls.
- Systematically evaluate the benefits, challenges, and costs of implementation in the first two to three cases to judge the impact of the model, improve effectiveness of integrated services and the enabling environment, and capture learnings to inform whether this model should be sustained and introduced in additional crisis settings.
- Engage diplomatically at high levels to encourage other donor countries, multilateral organizations, and UN agencies to contribute and participate in this strengthened model and to hold U.S. programs and partners accountable.

ESTIMATED COST:
$30 million per year for five years.



"The United States is the world leader in science, technology, and in global health. We need to be faster and bolder in developing new therapeutics, vaccines, and diagnostics to arrest future outbreaks. America's leadership in these areas will be essential in strengthening global health security."

— U.S. Congressman Ami Bera (D-CA-7)

7. Systematically confront two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis.

RECOMMENDATION

We are in the midst of a global technological revolution, which presents both opportunities and threats to global health security. In the face of emerging infectious disease and growing antimicrobial resistance, the United States should lead the global community in harnessing science and technology to save lives through the development of novel diagnostics and therapeutics. These efforts will require working with particularly dangerous pathogens. To prevent the accidental or intentional release of such pathogens, the United States should also make the small investments necessary to ensure that this research can be conducted safely and securely.

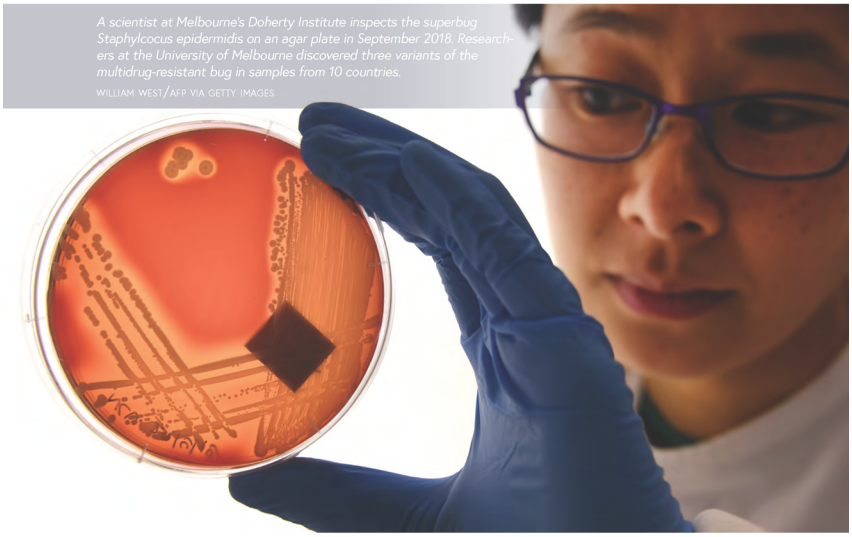
At the same time, the credibility of the scientific and medical communities is increasingly jeopardized, as misinformation and disinformation spreads rapidly across the expanding digital domain. This poses a new and urgent global health security challenge, one that the United States should lead in addressing through a concerted effort to reclaim digital and social media as a force for good.

RATIONALE

The United States is the global leader in biotechnology capacity and innovation, a result of decades of strong market conditions and public- and private-sector investment in education, research, and development. In recent months, both Congress and the administration have demonstrated their commitment to biotechnology efforts across several fields that are central to strengthening global health security. The U.S. government should build upon these recent efforts with targeted investments in the following critical areas.

Vaccines and Therapeutics

Coalition for Epidemic Preparedness Innovations (CEPI): As the infectious disease threat grows, the cost of investing in vaccine development remains prohibitively



A scientist at Melbourne's Doherty Institute inspects the superbug Staphylcocus epidermidis on an agar plate in September 2018. Researchers at the University of Melbourne discovered three variants of the multidrug-resistant bug in samples from 10 countries.

WILLIAM WEST/AFP VIA GETTY IMAGES

high. An investment in CEPI will enable the United States to further this critical preparedness mission while pooling resources and risk across multiple governmental and philanthropic partners. The U.S. government should become a CEPI coalition partner with an annual investment of $40 million. This initial investment will support CEPI's mission to accelerate the development of vaccines and platform technologies against emerging infectious diseases and ensure equitable access to these vaccines during outbreaks.

Furthermore, if the United States becomes a coalition partner, it will acquire a seat at the table early in the evolution of this promising new partnership, which will enable it to influence CEPI's decision process. A U.S. commitment to CEPI should not detract from the work of BARDA. On the contrary, in becoming a coalition partner of CEPI, the United States could better align CEPI investments with other U.S. programs and direct bilateral investments and motivate other donors, companies, and philanthropies to join the coalition.

As CEPI develops these new technologies, it will increasingly confront serious gaps in the systems and capacities needed to ensure their meaningful delivery in the case of an outbreak. Countries vulnerable to CEPI's priority diseases (e.g., MERS-CoV, Nipah virus, and Lassa virus) often lack the necessary cold chain, human resource, diagnostic, and data management capacities to effectively implement vaccination campaigns with experimental products. Creation of these capacities will likely involve partnership with Gavi, UNICEF, the WHO, product development partners, and other organizations and could have broader impacts on immunization systems beyond these priority diseases.

ESTIMATED COST
$40 million per year for five years.

Universal Flu Vaccine: Influenza is widely recognized as today's foremost health security threat. The CDC estimates that seasonal influenza has killed between 12,000 and 79,000 Americans annually since 2010, costing the United States over $10.4 billion in direct medical costs and $87 billion in total economic burden every year.[95] An influenza pandemic would be even more catastrophic. A landmark 2016 study found that a moderately severe influenza pandemic could cause as many as 700,000 deaths annually and cost as much as $570 billion globally per year.[96]

The U.S. government should increase support for the creation of a universal influenza vaccine, which would save thousands of lives every year and significantly mitigate the pandemic influenza threat. The United States is at the forefront of this scientific effort and should demonstrate leadership with investment and commitment. Experts estimate that $200 million annually over five years is necessary to reach this crucial milestone, as was proposed in the Flu Vaccine Act.[97] This constitutes an additional $60 million annually over current funding levels at the NIH. Funding for later stage universal flu vaccine research at BARDA should be maintained, as its efforts are crucial for bringing new flu products to the market. There should also be serious consideration given to expanding the CDC's complementary research on emerging and circulating influenza viruses, vaccine effectiveness, and the production of vaccine candidates for newer production platforms, as well as issues of access to this vaccine in low- and middle-income countries after it is developed.

ESTIMATED COST
$60 million over current funding levels per year for five years.

Antimicrobial Resistance: To address the growing threat of AMR, Congress should fund the implementation of the National Action Plan on Combating Antibiotic Resistant Bacteria (CARB) 2020-2025. At time of writing, the funding requirements for this effort are not publicly available. The CARB 2020-2025 plan (to be released in early 2020) is expected to provide updated data and a revised plan to enable U.S. agencies to work with partner governments and multilateral partners to stem the emergence and spread of antimicrobial resistance overseas. This includes strengthening public health interventions, including infection control and surveillance and improved antibiotic use and stewardship, as well as the development of improved vaccines and novel drugs and technologies to prevent, diagnose, and treat resistant infections.

It is critically important that U.S. agencies work with partner governments to strengthen and sustain infection control in health care facilities globally such that facilities can detect, monitor, and prevent the transmission of the most urgent antibiotic-resistant bacterial threats. In addition, by supporting countries to build surveillance systems that can collect and integrate AMR data from the medical, veterinary, agricultural, and environmental sectors, the United States can strengthen its own capacity to detect and prevent the spread of resistance. Additional technical support in this field will also enable partner governments to enact and enforce rules limiting over-the-counter availability of antibiotics and overprescribing,



"The reason why so few antibiotics are being developed is simple – the market is broken. In recent months, lawmakers on both sides of the aisle have come together to introduce important policies designed to spur the development of new antibiotics. However, to protect the American people from resistant superbugs, bold action is needed from Congress and the Administration to stimulate innovation and produce new antimicrobials that patients and society can count on."

— Jim Greenwood, Biotechnology Innovation Organization

raising standards in those countries with the least stringent standards and highest burden of drug-resistant infections.

When developing new antibiotics, the private sector remains the primary actor in bringing new drugs to market. However, the lack of a predictable, strong market for new antibiotics has caused private-sector investment to drop significantly, with the few pharmaceutical companies and biotechnology firms that remain engaged struggling to remain viable. Amid the unresolved furor over drug pricing, policymakers and the public at large may be understandably hesitant to support giving taxpayer dollars to incentivize drug companies. Nevertheless, government intervention is needed to create a robust and sustainable antimicrobial research and development ecosystem, such that companies are rewarded for the development of novel antimicrobial products and developers get a certain return.

Congress and the administration should redouble their efforts to formulate pull-incentive packages that guarantee drug developers a certain return for the development of novel antimicrobial products that address the greatest public health need. Such incentive packages are likely to win bipartisan support and should include robust stewardship and surveillance requirements, requiring developers to ensure the responsible use and accessibility of the antimicrobial product both for Americans and for patients around the globe. The DISARM Act of 2019 is a welcome step toward a sustainable marketplace that supports the antibiotic research and development pipeline while allowing health care providers to use novel antibiotics when needed.[98]

Digital Disinformation

VACCINE CONFIDENCE

The crisis in confidence in science, medicine, and vaccines is an emergent and intensifying health security threat that the United States is not yet equipped to address.

The White House should establish a new capacity under the auspices of the NSC directorate for global health security and biodefense that can lead collaboration across agencies and sectors to address this fundamentally multisectoral issue. This should include a comprehensive assessment of U.S. government capacities to monitor and counter online disinformation and misinformation around science and medicine. The focal person for this effort should engage with social media platforms and technology companies, independent media, biopharmaceutical companies, medical providers, and cybersecurity experts to inform policy formulation on this pressing issue.

The U.S. government should also establish an expanded, integrated, and sustained effort at the CDC to strengthen vaccine confidence and demand both in the United States and abroad. This should integrate all relevant capacities across the CDC and should include:

- A strategic communications initiative that is informed by behavioral psychology research to understand the determinants of local group belief systems and that provides consistent, science-based information to all audiences, both domestic and global, to



"Research and biotechnology development are critical for identifying and preparing for future infectious disease outbreaks. It is equally important that the U.S. and countries around the world bolster mechanisms to identify and reduce biological risks associated with advances in technology. Congress should allocate additional resources for biosecurity and biosafety innovation."

— Laura S. H. Holgate, Ambassador (Ret.), Nuclear Threat Initiative

counter misinformation and disinformation across multiple media platforms;

- Expanded research and survey work with global and university partners on the behavioral and social drivers of public trust and vaccine confidence and the acceptability and accessibility of services, including a U.S. Government Accountability Office (GAO) report on public attitudes toward vaccinations;
- An expanded program for the provision of technical expertise to partner governments, and U.S. states and municipalities, to generate vaccine demand;
- Expanded efforts to identify communities with low vaccination coverage and at high risk of outbreaks related to vaccine-preventable diseases, to conduct targeted and culturally and linguistically appropriate communications campaigns in those communities, and to improve vaccination rates in such communities through improved surveillance, vaccination interventions and campaigns, and research initiatives; and
- Expanded support for the Global Demand Hub, an established international platform that convenes public health officials, international organizations (including the WHO, UNICEF, and Gavi), social media firms, and civil society to research, incentivize, and coordinate vaccine demand work.

Experts estimate a minimum of $50 million in additional annual funding will be required to support this initiative over a five-year period. This increase to CDC's multi-billion-dollar annual funding for immunization could potentially be pivotal in mobilizing multiple interests behind renewing and stabilizing broad popular support for vaccines at home and abroad.[99] This proposal is broadly consistent with what is outlined in the bipartisan VACCINES Act of 2019 and the VIP Act of 2019, as well as Senate action through the Lower Health Care Costs Act of 2019.[100,101,102]

ESTIMATED COST:
$50 million per year for five years.

Biosafety and Biosecurity

Much of the funding called for in this section relates to research on especially dangerous pathogens, including pathogens with pandemic potential, and often involves the isolation, growth, and manipulation of dangerous viruses. A small fraction of the funds spent on researching dangerous pathogens should be set aside to ensure that this research is conducted safely and securely to prevent the accidental and intentional release of dangerous pathogens.

This will require investments in biosafety (to prevent the accidental exposure of people, animals, and the environment to dangerous microbes) and biosecurity (to prevent the deliberate exposure of people, animals, and the environment to dangerous microbes).[103,104]

Biosafety: Congress should allocate funding to the National Institute for Occupational Safety and Health (NIOSH) for the empirical study of safety in biological laboratories.[105] This funding will support the research needed to upgrade biosafety in the age of synthetic biology and escalating risk. Experts estimate that an initial phase of research should be funded at $10 million a year.[106]

Biosecurity: Congress should allocate funding to HHS to conduct comprehensive biosecurity oversight, in close coordination with other departments and agencies. This should include risk mitigation measures associated with life sciences dual-use research and overseeing innovations in biosecurity and microbial forensics that can reduce biological risks associated with advances in technology and better detect emerging, unusual, or engineered pathogens.

The U.S. government should expand DTRA's Biological Threat Reduction Program (BTRP) authorities to increase flexibility in detecting and countering the emergence of novel, highly communicable diseases, such as multidrug-resistant tuberculosis and artemisinin-resistant malaria.[107] The U.S. government should expand DTRA's geographic authorities to operate in all continents where health security threats exist, including South America. Furthermore, support for military overseas infectious disease research laboratories should be sustained. DOD biological research and development programs often focus on diseases not studied in other venues and result in medical countermeasures that would otherwise be delayed or not developed at all.[108]

ESTIMATED COST:
Biosafety: $10 million per year for five years.
Biosecurity: $10 million per year for five years.

Time to Act

We opened the Commission's report sounding the alarm that the U.S. government is caught in a cycle of crisis and complacency, that the American people are far from safe, and that U.S. policymakers need to think anew.

The "microbial sky" under which the United States and the rest of the world live today is increasingly crowded with health security threats, yet preparedness lags at home and abroad. At the same time, the world is increasingly disordered, and the most dangerous and inaccessible areas are also where many dangerous outbreaks arise. These realities should make anyone nervous and uncomfortable.

Over the course of deliberating on these complex challenges and the actions required to defend U.S. national interests, the Commission has settled on what we believe are cost-effective, proven, commonsense solutions that can draw support across the political divide. Now is the time for Congress and the administration to move these actions forward. It is a moment to hold ourselves and our government to greater account, to insist upon White House leadership, and to demand a higher level of rigor and discipline in the use of scarce resources. The U.S. government cannot afford waste, redundancy, or mistargeted investments.

The changes we advocate do come at a price. There is no denying that. But it is a smart investment when set against the staggering costs of inaction. We are calling for targeted investments in country partnerships, in quick response capacities, and in the U.S. government's ability to operate in insecure, disordered settings. We are calling for smart investments that will help accelerate new technologies and focus U.S. energies and the energies of others on the public health communications crisis in the age of misinformation, social media, and distrust.

The steps we have laid out are the foundation of the Commission's proposed U.S. doctrine of continuous prevention, protection, and resilience. If the U.S. government acts strategically to advance this doctrine, it can, once and for all, break the cycle of crisis and complacency and put the United States' global health security approach on a sound footing for the future.

Appendix I

Illustrative Costing for Recommended Programs and Initiatives

This appendix captures proposed, current, and historical funding levels (when available) for the recommended programs and initiatives. Figures are presented in millions USD. We have calculated the incremental difference, or additional cost beyond current funding levels, to be approximately $905 million.[D] Unless otherwise noted in the text, all recommended funding levels are annual investments over five years. It is recommended that funding levels be reassessed after five years. While the proposed funding levels represent expert estimates, additional work may be required to cost certain expanded initiatives and new program proposals.

D. The estimated incremental difference is not reflective of FY 2019 levels for new program proposals or vaccine confidence, as those numbers are unavailable.

GLOBAL HEALTH SECURITY AGENDA[1]												
Executive Agency	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	Proposed	Difference
USAID (NON-ADD)	$201	$48	$58	$55	$73	$385	$218	$73	$173	$138	$173	$35
CDC (NON-ADD)	$62	$51	$56	$54	$63	$652	$55	$58	$108	$108	$208	$100

1. Sources: Kaiser Family Foundation (KFF) analysis of appropriations bills and Congressional budget requests; Watson et al., "Federal Funding for Health Security in FY2019," Health Security 16, no. 5 (October 2018): https://doi.org/10.1089/hs.2018.0077. Sources of proposed funding levels include the Global Health Council's Global Health Security Roundtable and the Global Health Security Agenda Consortium.

PANDEMIC PREPAREDNESS CHALLENGE			
	FY19	Proposed	Difference
PANDEMIC PREPAREDNESS CHALLENGE		$30[1]	$30

1. Expert estimate of the annual investment over five years required by the United States to leverage donor funding necessary to launch a five-year, $750 million Pandemic Preparedness Challenge.

CONTINGENCY FUNDS

EXISTING FUND	FY17	FY18	FY19	PROPOSED	DIFFERENCE
CDC INFECTIOUS DISEASES RAPID RESPONSE RESERVE FUND			$50[1]	$250[2]	$200
USAID EMERGENCY RESERVE FUND	$70[3]	$35[4]	$2[5]	$250[6]	$248
WHO CONTINGENCY FUND FOR EMERGENCIES				$25[7]	$25

1. "FY2019 Operating Plan," CDC, accessed June 2019, https://www.cdc.gov/budget/documents/fy2019/fy-2019-cdc-operating-plan.pdf.

2. Expert estimate of the minimum funding levels for contingency funds at the CDC to support rapid response. Sources include the Global Health Council's Global Health Security Roundtable. These contingency fund levels are inclusive of the $20 million in contingency funds for emergency immunization activities recommended in Recommendation 6.

3. "State, Foreign Operations, and Related Programs Appropriations Bill, 2017 Omnibus Agreement Summary," U.S. Senate Committee on Appropriations, accessed June 2019, https://www.appropriations.senate.gov/imo/media/doc/FY17%20State%20Foreign%20Operations%20Conference%20Agreement%20Summary%20-%20Final.pdf.

4. "President Signs FY18 Omnibus Bill," KFF, March 22, 2018, https://www.kff.org/news-summary/congress-releases-fy18-omnibus/.

5. "FY19 Conference Agreement Released, Includes State & Foreign Operations (SFOPs) Funding," KFF, February 14, 2019, https://www.kff.org/news-summary/fy19-conference-agreement-released-includes-state-foreign-operations-sfops-funding/.

6. Expert estimate of the minimum funding levels for contingency funds at USAID to support rapid response. Sources include the Global Health Council's Global Health Security Roundtable. These contingency fund levels are inclusive of the $20 million in contingency funds for emergency immunization activities recommended in Recommendation 6.

7. Expert estimate of appropriate U.S. government contribution to the WHO CFE based on contributions of similar donor countries, including Japan ($22 million contribution in 2019), Germany ($8 million in 2019), and the United Kingdom ($5 million in 2019). See: "Contingency Fund for Emergencies (CFE) contributions and allocations," WHO, accessed June 2019, https://www.who.int/emergencies/funding/contingency-fund/allocations/en/.

GLOBAL HEALTH CRISES RESPONSE CORPS

Focus area	FY19	Proposed	Difference
GLOBAL HEALTH CRISES RESPONSE CORPS		$50[1]	$50
SUPPORT TO NATIONAL PARTNERS	$47.5	$83.5[2]	$36
PHEM (CDC)	$1.5[3]	$2.5[4]	$1
FETP (CDC)	$41[5]	$71[6]	$30
NPHI (CDC)	$5[7]	$10[8]	$5

1. Expert estimate of the cost of a pilot program is based on estimated costs of: (1) personnel; (2) training costs, including existing agency training opportunities; and (3) deployment-related costs, including first aid supplies, food and water, lodging, travel (commercial flights, not designated transport), emergency communication measures, and personal security measures. Estimate takes into account original FY 2010 non-supplemental appropriation for the U.S. Civilian Response Corps, adjusted for the size and scope of this proposed Corps.

2. Experts estimate that additional investment in these three programs will help to ensure greater national capacity in outbreak detection and management.

3. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."

4. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.

5. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."

6. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.

7. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."

8. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.

STRENGTHEN SERVICE DELIVERY IN DISORDERED SETTINGS			
Focus area	**FY19**	**Proposed**	**Difference**
IMMUNIZATIONS		$6	$6
STRENGTHEN DATA		$5[1]	$5
TRAINING COMMUNITY WORKERS		$1[2]	$1
WOMEN AND GIRLS		$30[3]	$30

1. Expert estimate of the cost of a pilot program monitoring 20 countries is based on consultation on the FEWS NET program and estimated costs for: (1) personnel; (2) database conceptualization, development, testing, and maintenance; and (3) website development, maintenance, and hosting.

2. Expert estimate of the cost of training for 150 trainees is based on estimated average cost of $6,500 per trainee for FETP-Frontline 3-month training for local public health staff.

3. Expert estimate of pilot program costs in two to three humanitarian crises, considering: (1) estimates of the number of affected women and girls in these crises from OCHA and UNHCR; (2) costs of assumed 20 percent uptake of family planning services, based on cost per couple-year of protection; (3) cost of assumed 20 percent uptake in maternal health care, based on average cost per pregnancy; (4) cost of GBV care, based on assumed 20 percent uptake; and (5) estimated cost of health care worker and community outreach worker capacity building.

CONFRONTING TECHNOLOGY CHALLENGES			
Focus area	**FY19**	**Proposed**	**Difference**
VACCINES		$290	$125
CEPI		$40[1]	$40
UNIVERSAL INFLUENZA VACCINE (NIH/NIAID)	$140[2]	$200[3]	$60
VACCINE CONFIDENCE (CDC)		$50[4]	$25
BIOSAFETY (CDC/NIOSH)		$10[5]	$10
BIOSECURITY (HHS)		$10[6]	$10

1. Expert estimate for initial annual funding level.

2. "Operating Plan for FY2019," National Institutes of Health, accessed June 2019, https://www.hhs.gov/sites/default/files/FY%202019%20NIH%20Operating%20Plan_0.pdf

3. U.S. Congress, Senate, Flu Vaccine Act, S.570, 116th Cong., 1st sess., introduced in Senate February 26, 2019, https://www.congress.gov/116/bills/s570/BILLS-116s570is.pdf.

4. Expert estimate of the additional annual funding required to expand, sustain, and integrate existing CDC programs and initiatives.

5. Expert estimate for minimum annual funding levels to support basic biosafety research. In comparison, the budgets of the Chemical Safety Board and the Nuclear Regulatory Commission each exceed $1 billion annually. For more detailed recommendations on this issue, refer to Rocco Casagrande, "Federal Funding for Biosafety Research is Critically Needed," CSIS, Commentary, August 6, 2019, https://healthsecurity.csis.org/articles/federal-funding-for-biosafety-research-is-critically-needed/.

6. Expert estimate for initial annual funding level.

Appendix II

Congressional Authorities and Oversight of U.S. Government Efforts to Advance Global Health Security

As described in White House Executive Order 13747 on "Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats" and the new Global Health Security Strategy, the U.S. government's role in global health security is a whole-of-government enterprise.[109, 110] The executive order (EO) and the strategy lay out the roles and responsibilities of the Executive Office of the President (EOP); eight Cabinet-level departments (including the Departments of State, Defense (DOD), Health and Human Services (HHS), Agriculture, Homeland Security, Treasury, Interior, and Justice); and eight sub-Cabinet agencies (including the Centers for Disease Control and Prevention (CDC), U.S. Agency for International Development (USAID), National Institutes of Health (NIH), Food and Drug Administration (FDA) and Environmental Protection Agency (EPA)). As a result, multiple Congressional authorizing and appropriations committees have jurisdiction over various aspects of this agenda, underscoring the essential interplay between international and domestic efforts to protect Americans' health and safety.

The Commission's recommendations to strengthen U.S. government support for global health security focus on a subset of departments and agencies for priority action. This list includes the Department of State, including USAID; HHS, including the CDC and the Biomedical Advanced Research and Development Authority (BARDA); the DOD, including the Defense Threat Reduction Agency (DTRA); and the Department of the Treasury. Below is a summary of the key Congressional committees with oversight of these agencies and their relevant programs. Note that most recent global health security-related authorizations have occurred via appropriations legislation, including through the five-year Ebola Emergency Supplemental spending bill which expired at the end of FY 2019.

Health and Human Services

AUTHORIZING COMMITTEES

- Senate: Health, Education, Labor and Pensions (HELP) Committee, Subcommittee on Primary Health and Retirement Security
- House: Energy and Commerce Committee, Subcommittee on Health

APPROPRIATIONS COMMITTEES

- Senate and House: Labor, Health and Human Services, Education, and Related Agencies

These committees have oversight and jurisdiction over the HHS agencies, institutes, and programs relevant for global health security, notably the activities of the CDC, FDA, NIH, and BARDA. Relevant authorizing legislation includes the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAI), which authorizes certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, including advancement of medical countermeasures. President Trump signed PAHPAI into law in June 2019.[111] The International Health Research Act of 1960 provides for international cooperation in health research, research training, and planning and authorizes the HHS secretary to enter into cooperative agreements for biomedical and health activities.

The primary relevant funding accounts or line items for global health security include: the CDC's Division of Global Health Protection (including the Global Disease Detection Program and the Field Epidemiology Training Program (FETP)), the Epidemic Intelligence Service, Emerging and Zoonotic Infectious Diseases, Public Health Preparedness and Response, Immunization and Respiratory Diseases, and the Infectious Diseases Rapid Response Reserve Fund, which was established by Congress in the FY 2019 appropriations bill; HHS's Office of Global Affairs; BARDA's emerging infectious diseases (EID) program under the Office of the Assistant Secretary for Preparedness and Response (ASPR); and NIH's Fogarty International Center.

Department of State and USAID

AUTHORIZING COMMITTEES

- Senate: Committee on Foreign Relations, Subcommittee on Africa and Global Health Policy
- House: Committee on Foreign Affairs (HFAC), Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations

APPROPRIATIONS COMMITTEES

- Senate and House: State, Foreign Operations, and Related Programs

These committees have jurisdiction over all Department of State and USAID operations and assistance programs,

including global health related programs. Relevant authorizing legislation includes the Department of State Authorities Act (last passed in 2017) and the Foreign Assistance Act of 1961. As there have not been regular authorization bills (with the exception of the PEPFAR authorization, whose extension was last authorized in 2018), most programs are authorized via appropriations. In the 116th Congress, the Global Health Security Act was introduced to codify the U.S. commitment to the Global Health Security Agenda and designate permanent leadership for coordinating the interagency response to a global health security emergency. The bill was referred to the HFAC as well as to Armed Services and the Permanent Select Committee on Intelligence.

The primary relevant accounts or line items for global health security include: the USAID Emerging Pandemic Threats Program and its PREDICT project and the Emergency Reserve Fund; the Department of State's Bureau of Oceans and International Environmental and Scientific Affairs Office of International Health and Biodefense and Bureau of International Security and Nonproliferation Biosecurity Engagement Program; and the U.S. contributions to the World Bank's International Development Association (IDA) and the World Health Organization (WHO).

Department of Defense

AUTHORIZING COMMITTEES

- Senate and House: Armed Services Committee

APPROPRIATIONS COMMITTEES

- Senate and House: Defense

These committees have oversight and jurisdiction over all DOD-supported global health security programs. The annual National Defense Authorization Act (NDAA) is the principal authorizing legislation. The primary relevant funding accounts or line items for global health security include: the Defense Threat Reduction Agency (DTRA) and its Cooperative Threat Reduction Directorate's Cooperative Biological Engagement Program (CBEP); the Armed Forces Health Surveillance Branch Global Emerging Infections Surveillance and Response Program; the Army Medical Research and Development Command's Military Infectious Diseases Research Program; the Naval Medical Research Center and Naval Research Laboratory; the Walter Reed Army Institute of Research; and the Defense Advanced Research Projects Agency (DARPA). The geographic combatant commands also engage with their international military partners on health security cooperation.

Treasury

AUTHORIZING COMMITTEES

- Senate: Committee on Banking, Housing, and Urban Affairs, Subcommittee on National Security and International Trade and Finance

- House: Committee on Financial Services, Subcommittee on National Security, International Development and Monetary Policy

APPROPRIATIONS COMMITTEES

- Senate and House: State, Foreign Operations, and Related Programs

These committees have oversight and jurisdiction over U.S. membership in, and financial support for, the World Bank's IDA and International Bank for Reconstruction and Development (IBRD) and other multilateral development banks (MDBs) and international financial institutions. Relevant recent authorization bills include the World Bank Accountability Act, introduced in the House in 2017 to authorize IDA appropriations. However, as with other Department of State and Foreign Operations-funded programs, most authorizations have occurred through the annual appropriations bills.

Appendix III

Glossary of Key Terms

ANTIMICROBIAL RESISTANCE (AMR)[112]

Many common infections are becoming resistant to the antimicrobial medicines used to treat them, resulting in longer illnesses and more deaths. Antimicrobial resistant microbes are found in people, animals, food, and the environment. They can spread between people and animals, including from food of animal origin, and from person-to-person. Poor infection control, inadequate sanitary conditions, and inappropriate food-handling encourage the spread of AMR. Misuse and overuse of antimicrobials is also accelerating AMR. Many common infections are becoming resistant to the antimicrobial medicines used to treat them, resulting in longer illnesses and more deaths, and not enough new antimicrobial drugs, especially antibiotics, are being developed to replace older and increasingly ineffective ones. AMR also increases the cost of health care, with lengthier stays in hospitals and more intensive care required. In 2016, the UN General Assembly issued a declaration calling for global action on AMR.[113]

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)[114]

BARDA was established in 2006 through the Pandemic and All-Hazards Preparedness Act (PAHPA) and reports to the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS). BARDA is responsible for the development and procurement of medical countermeasures (MCMs) to enhance the capability of the U.S. government to guard against a broad array of public health threats, including chemical, biological, nuclear, and radiological threats, as well as pandemic influenza and emerging diseases such as Ebola and Zika. BARDA supports the transition of medical countermeasures such as vaccines, therapeutics, drugs, and diagnostics from research through advanced development toward consideration for approval by the Food and Drug Administration (FDA) and inclusion into the Strategic National Stockpile.

BIOLOGICAL THREAT REDUCTION PROGRAM (BTRP)[115]

The Defense Threat Reduction Agency's (DTRA) Cooperative Threat Reduction (CTR) Directorate prevents the proliferation or use of weapons of mass destruction (WMD) by working with partner nations to secure, eliminate, detect, and interdict WMD-related systems and materials. The CTR Biological Threat Reduction Program (BTRP) addresses the biological threat aspect of this threat reduction mission. BTRP facilitates elimination, security, detection, and surveillance of especially dangerous pathogens.

COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS (CEPI)[116]

Launched at the World Economic Forum in January 2017, CEPI is a global partnership of public, private, philanthropic, and civil society organizations designed to accelerate the development of vaccines against emerging infectious diseases and to support equitable delivery of those vaccines in response to epidemics. CEPI focuses on vaccine development, licensure, and manufacturing for a target set of pathogens (currently MERS-CoV, Lassa, Nipah, Rift Valley fever, and Chikungunya) and is promoting the development of platform technologies that can be adapted to develop countermeasures to a future unknown pathogen with pandemic potential, "Disease X." As of April 2019, CEPI had secured $750 million toward its $1 billion funding target, with support from Australia, the Bill & Melinda Gates Foundation, Canada, Germany, Japan, Norway, and Wellcome Trust. The United States does not currently contribute to CEPI.

DISASTER ASSISTANCE RESPONSE TEAM (DART)[117]

The USAID Office of U.S. Foreign Disaster Assistance (OFDA) sends a DART to crisis-affected areas when required by the size and severity of a disaster. DARTs are comprised of humanitarian experts and technical advisers and are deployable within hours of an emergency. They work in cooperation with partners on the ground to assess and respond to a crisis situation. DARTs work overseas but are managed by a Response Management Team (RMT) based in Washington, D.C. RMTs work with other U.S. government agencies to plan and coordinate the response so that the DART can focus on providing support on the ground.

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY (DARPA)[118]

DARPA's mission is to make pivotal investments in breakthrough technologies for national security. DARPA's research portfolio is managed by six technical offices charged with developing breakthrough technologies. One of those offices, the Biological Technologies Office (BTO), develops capabilities that embrace the unique properties of biology—adaptation, replication, complexity—and applies those features to revolutionize how the United States

defends the homeland and prepares and protects its soldiers, sailors, airmen, and marines.[119] The BTO helps the Department of Defense (DOD) to counter novel forms of bioterrorism, deploy innovative biological countermeasures to protect U.S. forces, and accelerate warfighter readiness and overmatch to confront adversary threats.

DEFENSE THREAT REDUCTION AGENCY (DTRA)[120]

Created in 1998 by combining several DOD entities, DTRA facilitates and expedites research and development into some of the most complex, deadly, and urgent threats facing the United States and the rest of the world. DTRA's mission is to enable the U.S. government to counter the threats posed by the full spectrum of WMD, including chemical, biological, radiological, nuclear, and high-yield explosives; counter the threats posed by the growing and evolving categories of improvised threats, such as improvised explosive devices (IEDs), car bombs, and weaponized consumer drones; and ensure that the U.S. military maintains a safe, secure, effective, and credible nuclear weapons deterrent.

FIELD EPIDEMIOLOGY TRAINING PROGRAM (FETP)[121]

The U.S. Centers for Disease Control and Prevention (CDC) established the first FETP in 1980 to help epidemiologists in developing countries gain the necessary skills to collect, analyze, and interpret disease information. By training disease detectives in their own countries, the FETP helps meet the global health security goal of establishing a trained public health workforce that helps stop outbreaks at their source. There are more than 10,000 FETP graduates from 65 countries trained in disease detection and response.

GAVI, THE VACCINE ALLIANCE[122]

Created in 2000, Gavi, the Vaccine Alliance is an international public-private partnership with the mission of improving access to new and underused vaccines for children in lower-income countries. Gavi's partnership model combines the technical expertise of the development community with the business knowledge of the private sector. Gavi partners include the WHO, UNICEF, the World Bank, the Bill & Melinda Gates Foundation, civil society organizations, private-sector companies, donor and implementing country governments, and research agencies. Gavi pools demand from low-income countries and works with vaccine manufacturers to bring down prices. While donors provide long-term, predictable financing support to Gavi's efforts, all Gavi-supported countries pay a share of the vaccine cost, and that share increases as the country's income grows. Gavi's current strategy aims to reach 300 million children between 2016 and 2020, saving five to six million lives in the long term.

GLOBAL HEALTH SECURITY[123]

Global health security refers to the capacity to prepare for, detect, and respond to infectious disease threats and reduce or prevent their spread across borders. At the core of global health security are strong health systems with the resources and trained personnel needed to identify threats, respond quickly, and prevent the spread of infectious diseases. Key capacities include public health capabilities such as laboratory and digital information networks, supply chains, and frontline health workers.

GLOBAL HEALTH SECURITY AGENDA (GHSA)[124]

Launched in February 2014, the GHSA is a growing partnership comprised of more than 65 nations, international organizations, and nongovernmental stakeholders to help build countries' capacity to create a world safe and secure from infectious disease threats and elevate health security as a national and global priority. Through a set of "Action Packages," GHSA member countries collaborate toward specific objectives and targets. This international engagement includes ministries of agriculture, defense, health, development, and others, representing a whole-of-government approach. The United States has reaffirmed its commitment to the GHSA through 2024, in support of the GHSA 2024 Framework.[125] The U.S. government provides support for capacity building for 17 priority GHSA partner countries and sits on the GHSA Steering Committee.

GLOBAL HEALTH SECURITY STRATEGY (GHSS)[126]

Issued by the White House in May 2019 in response to a request from Congress in the FY 2018 omnibus appropriations bill, the GHSS outlines the U.S. government approach to strengthening global health security, including accelerating the capabilities of targeted countries to prevent, detect, and respond to infectious disease outbreaks. Together with the National Security Strategy, the National Biodefense Strategy, and the executive order on "Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats," the GHSS delineates the roles and responsibilities of executive branch agencies in protecting the United States and its partners abroad from infectious disease threats by working with other nations, international organizations, and nongovernmental stakeholders.

GRAY ZONE[127]

Recent analyses of challenges to U.S. security have identified the gray zone, a phenomenon in which actors across the globe engage in malign activities that fall somewhere in the

space between routine statecraft and open warfare. These gray zone approaches and incidents create dilemmas for the United States and its security interests but largely side-step thresholds for military escalation.

GLOBAL RAPID RESPONSE TEAM (GLOBAL RRT)[128]

The CDC Global Rapid Response Team can be deployed within the United States and overseas to respond to global public health concerns. The Global RRT is comprised of public health experts and can be deployed to provide field-based logistics, communications, management, and operations support in a public health emergency. The Global RRT can also provide long-term staffing for international emergency responses both in the field and at CDC headquarters in Atlanta, Georgia.

INTERNATIONAL DEVELOPMENT ASSOCIATION CRISIS RESPONSE WINDOW (IDA - CRW)[129]

IDA is the part of the World Bank that funds the world's poorest countries. Overseen by 173 shareholder nations, with the United States as the largest shareholder, IDA is one of the largest sources of assistance for the world's 75 poorest countries, 39 of which are in Africa, and is the single largest source of donor funds for basic social services and poverty reduction efforts in these countries.[130] IDA provides loans (called "credits") and grants to boost economic growth, reduce inequalities, and improve people's living conditions. The CRW was established in 2011 to help IDA countries access additional resources to respond to severe economic crises and major natural disasters and return to their long-term development paths. In 2015, the CRW eligibility criteria were expanded to include public health emergencies and epidemics.

INTERNATIONAL HEALTH REGULATIONS (IHR)[131]

A legally binding instrument of international law adopted by the World Health Assembly in 2005 in the wake of the SARS pandemic, the purpose of the IHR is to provide a universal framework for international public health emergency preparedness and response. The IHR aim to control the international spread of disease in ways that are commensurate with public health risks and avoid unnecessary interference with international traffic and trade. The IHR also guide the strengthening of public health surveillance and response capacities globally and require countries to report specific disease outbreaks and any event that may pose a risk to international public health. The WHO has few effective means of enforcing the IHR; however, the Joint External Evaluation (JEE) process launched in the wake of the 2014-2016 Ebola epidemic in West Africa has helped shine a light on the need for countries to strengthen their IHR compliance.

JOINT EXTERNAL EVALUATIONS (JEES)[132]

The JEEs are country-owned, voluntary, collaborative, multisectoral assessments of a country's core capacity to prevent, detect, and rapidly respond to public health risks, whether naturally occurring or due to deliberate or accidental events. The JEE process is managed by the WHO and consists of a national self-assessment and an external evaluation team with experts from all relevant sectors, such as human and animal health, food safety, agriculture, defense, and public safety. JEE results are published on the WHO website.[133] At time of writing, over 100 countries, including the United States, had completed JEEs.[134]

NATIONAL BIODEFENSE STRATEGY[135]

The National Biodefense Strategy, mandated by Congress and released on September 18, 2018, sets the course for the U.S. government to effectively counter threats from naturally occurring, accidental, and deliberate biological events. The strategy orchestrates, for the first time, a single coordinated effort across the U.S. government to assess, prevent, detect, prepare for, respond to, and recover from biological threats. The accompanying National Security Presidential Memorandum directs the secretary of Health and Human Services to serve as the federal lead in coordination and implementation of the strategy and establishes a cabinet-level Biodefense Steering Committee.

NATIONAL PUBLIC HEALTH INSTITUTES (NPHIS)[136]

NPHIs provide leadership and coordination for public health at the national level. NPHIs consolidate in-country public health functions, bringing together data and expertise while coordinating efforts across sectors. The CDC provides technical expertise in support of NPHIs' development, targeted to fit countries' public health priorities.

PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION ACT (PAHPAI)

After the September 11, 2001 attacks and the 2001 anthrax attacks, Congress mandated a dedicated effort to develop and stockpile drugs, vaccines, and diagnostics needed to protect the American people from chemical, biological, radiological, nuclear (CBRN), and pandemic threats. The first 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) created the position of the assistant secretary for Preparedness and Response (ASPR) to lead the government's response to national health emergencies.[137] The bill also created BARDA to provide industry partners with funding and technical assistance in the advanced research and development of medical countermeasures. Key federal

programs reauthorized and funded every five years through the PAHPA legislation include the BioShield Special Reserve Fund (SRF), BARDA, and the Strategic National Stockpile (SNS), which helps strengthen the pipeline and stockpile of medical countermeasures vital for national safety and defense. PAHPAI was signed into law by President Trump in June 2019 and reauthorized PAHPA.[138]

PANDEMIC EMERGENCY FINANCING FACILITY (PEF)[139]

The PEF was established by the World Bank in 2016 to be a quick-disbursing financing mechanism that provides a surge of funds to enable a rapid response to a large-scale disease outbreak. Eligible countries can receive timely, predictable, and coordinated surge financing if they are affected by an outbreak that meets the PEF's activation criteria. The PEF is the first-ever insurance mechanism for pandemic risk, offering coverage to all low-income countries eligible for IDA financing.

PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN (PHEIC)[140]

Some serious international public health crises may be designated PHEICs. A PHEIC is defined under the IHR (2005) as "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease; and (ii) to potentially require a coordinated international response."[141] The designation of a PHEIC implies that such situations are serious, unusual, or unexpected, carry implications for public health beyond the affected country's national border, and may require immediate international action. The WHO director-general makes the final determination on designating PHEICs based on technical advice from the IHR Emergency Committee.

PUBLIC HEALTH EMERGENCY MANAGEMENT (PHEM) FELLOWSHIP[142]

Established in 2013, the CDC's PHEM Fellowship program builds capacity among members of the international public health community through standardized training, mentorship, and technical assistance in public health emergency management functions and operations. The program was established in 2013 and is conducted twice a year at the CDC in Atlanta. It targets mid-career professionals who work in public health preparedness and response in countries who have signed on to the IHR.

PULL INCENTIVES[143]

Pull incentives reward the successful development of medical countermeasures by increasing or ensuring future revenue and market viability. Pull incentives can take many forms, including advanced market commitments, higher reimbursement, priority review vouchers, market exclusivity rewards, market entry rewards, patent extensions, data protection, and liability protection.

U.S. PUBLIC HEALTH SERVICE[144]

The U.S. Public Health Service is a division of HHS. Its mission is to protect, promote, and advance the health and safety of the United States. It is an elite team of over 6,500 health professionals, including physicians, dentists, nurses, therapists, pharmacists, engineers, dieticians, veterinarians, environmental health specialists, and scientists. Members of the U.S. Public Health Service serve in public health and clinical roles within the nation's federal government departments and agencies, supporting the provision of care to underserved and vulnerable populations.

VACCINE HESITANCY[145]

One of the top 10 global health threats according to the WHO, vaccine hesitancy refers to the reluctance or refusal of people to vaccinate despite availability of vaccination services. Vaccine hesitancy has been reported in more than 90 percent of countries in the world and is being fueled by a number of factors, including the spread of misinformation and disinformation about vaccine safety; complacency; inconvenience and inaccessibility; and lack of confidence. The rise of vaccine hesitancy threatens to reverse the tremendous global progress made in preventing vaccine-preventable diseases. For example, immunization for measles, a vaccine-preventable disease that was largely eliminated following widespread use of the measles-mumps-rubella (MMR) vaccine, has now decreased below the threshold set by the WHO as that required for herd immunity.

WORLD HEALTH ORGANIZATION CONTINGENCY FUND FOR EMERGENCIES (CFE)[146]

Set up as part of a series of WHO institutional reforms in the wake of the scathing criticism it received for its late response to the 2014-2016 Ebola crisis in West Africa, the CFE gives the WHO the resources to respond immediately to disease outbreaks and humanitarian crises with health consequences. The ability to respond quickly—in as little as 24 hours—before other funding is mobilized can stop a health emergency from spiraling out of control, saving lives and resources. As of March 2019, 16 countries, led by Germany, Japan, and the United Kingdom, had contributed $70 million to support the CFE.

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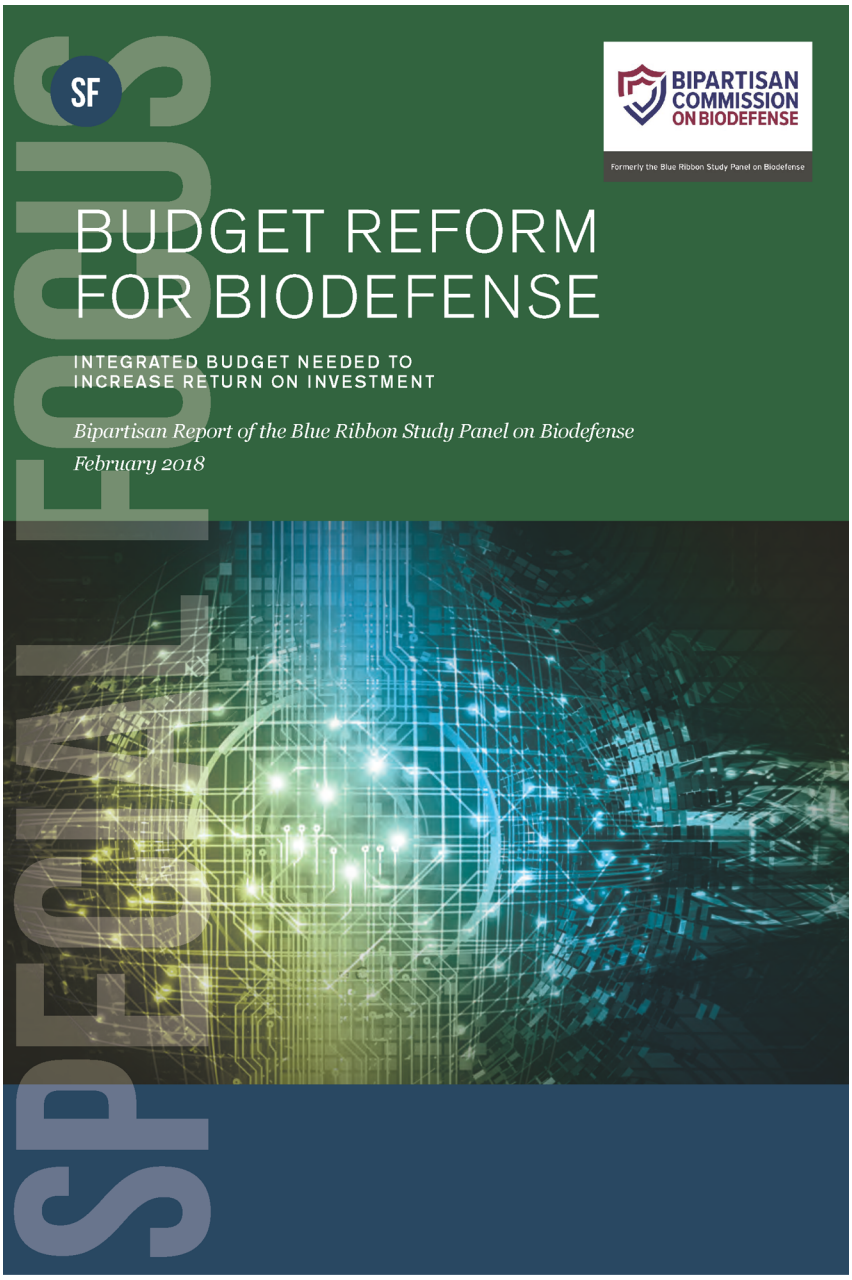
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BUDGET REFORM FOR BIODEFENSE
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Bipartisan Report of the Blue Ribbon Study Panel on Biodefense
February 2018

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February 2018



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EXECUTIVE SUMMARY

Biological threats to America and its interests overseas are increasing. Intentionally introduced, accidentally released, and naturally occurring diseases continue to pose a risk to the nation. While we have managed to contain many of these diseases and prevent major losses of life, it is only a short matter of time before a large-scale event exceeds the ability of our country and the world to prevent biological catastrophe.

Myriad federal departments and agencies are responsible for defending against these threats. Referring to their activities as a federal biodefense enterprise suggests a coordinated interagency endeavor unified in achieving common goals, but this is not the reality that exists currently. America is more vulnerable today than it should be to a biological crisis of any scale.

The ultimate success of the recently mandated National Biodefense Strategy depends on the prioritization of the activities it directs and the attachment of funding to those activities. At present, departments and agencies request funding individually, rather than collectively and for mutual benefit. They each negotiate their annual budget requests with the Office of Management and Budget (OMB), which then submits the President's Budget Request to Congress on a department and agency basis. OMB does not provide an analysis of biodefense spending across the government as part of this submission. Subsequently, multiple congressional subcommittees make funding decisions only for programs within their purview, but without considering overall biodefense spending or mission goals.

Such an integrated budget for biodefense would overcome the opaque, non-strategic spending approach characteristic of the status quo. An integrated budget (and the process needed to develop it) would facilitate coordination and reveal areas that would benefit from interagency funding initiatives and complementary investments. Performance evaluations and evidence-building metrics that accompany the budget would expose areas of effectiveness and ineffectiveness. This information would then support decision makers in making sound fiscal investments, closing capability gaps, and eliminating duplication of effort and resources – all of which would strengthen our national biodefense.

The White House should predicate its vision for long-term investment in biodefense on the National Biodefense Strategy. The Vice President of the United States should provide the leadership needed to facilitate this effort. OMB should develop an integrated biodefense request as part of the President's Budget Request that includes: (1) a biodefense budget crosscut; (2) performance outcomes for

biodefense projects, programs, and activities (PPAs); (3) an analysis of how PPAs contribute to the goals and objectives of the National Biodefense Strategy; and (4) a five-year budget plan.

Congressional leadership should convene a bicameral, bipartisan Biodefense Working Group (BWG) to determine the structures and processes for streamlined and comprehensive biodefense oversight. The BWG should make recommendations to reform congressional authorizations, budget resolutions, and appropriations with regard to all elements of the biodefense enterprise – prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation. To stay ahead of the ever-increasing biological threat, Congress should also mandate the establishment of a Future Years Biodefense Budget Program, requiring estimated expenditures and proposed appropriations for at least the current and four succeeding fiscal years.

A cohesive, integrated federal budget request for biodefense would help ensure that decision makers in the Executive and Legislative Branches comprehensively understand existing investments and priorities. Informed by the National Biodefense Strategy, Congress and the White House should take up the following recommendations to strengthen America's biodefense and use taxpayer dollars wisely.

LEADERSHIP AND DIRECTION

Development of an integrated biodefense budget begins at the White House with:

- An empowered Vice President who provides political leadership of the biodefense enterprise and helps set major budgetary priorities.
- A dedicated Deputy Assistant to the President for Biodefense within the National Security Council who supports the Vice President and provides day-to-day policy direction and coordination.
- An invested OMB Program Associate Director who provides management and budgetary guidance for biodefense.
- An allied Biodefense Coordination Council that prioritizes interagency biodefense activities and spending.

BUDGET DEVELOPMENT, EVALUATION, AND SUBMISSION

Execution of an integrated biodefense budgeting process continues with:

- Departments and agencies that base requests to OMB on mission requirements.
- OMB examiners who assess the performance and outcomes of federal projects, programs, and activities.
- OMB examiners who evaluate department and agency requests against the National Biodefense Strategy.
- A White House that submits an integrated budget request, a five-year biodefense budget plan, and a budget crosscut to Congress.

AUTHORIZATION AND APPROPRIATION

Culmination of an integrated biodefense budgeting process occurs in Congress with:

- Authorizers who use the National Biodefense Strategy as a benchmark for oversight, and require a Future Years Biodefense Budget Program plan.
- Budget Committees who consider long-term biodefense funding requirements.
- Appropriators who jointly evaluate the President's Budget Request, coordinate funding priorities across appropriations subcommittees, harmonize spending, and use multi-year funding mechanisms.
- Public-private partnerships in which all parties contribute to the development of viable incentives for research and development.
- A Public Health Emergency Fund composed of no less than $2 billion in no-year money and replenished with regular annual appropriations.
- Sustained U.S. contributions to international programs, including the Global Health Security Agenda.
- A bicameral and bipartisan Biodefense Working Group, temporarily established and empowered to make recommendations to House and Senate Leadership on the most impactful and feasible ways to achieve these goals and objectives.

BUDGETARY STATUS QUO

The process by which the government funds federal biodefense-related programs and activities precludes strategic allocation of dollars. The current system does not enable decision makers to evaluate the return on investment in existing programs, identify mission-critical gaps, or prioritize funding across requirements. The creation and sustainment of an effective national biodefense enterprise, however, depend on each of these elements. Specific weaknesses inherent in the budgetary status quo include:

- **Budgetary misalignment with the threat.** Threats should drive funding, but instead, predetermined or historic funding levels often dominate annual biodefense requests and appropriations. This results in some mission areas, like environmental biodetection, receiving millions of dollars annually even when their security value is questionable, and others, like hospital preparedness, receiving pennies per person despite gaping needs. Outdated budget development and appropriations processes disconnect funding from addressing the threat, leaving the nation vulnerable and wasting resources.
- **An opaque and uncoordinated federal interagency structure.** Strategic budgeting requires identification of all federal entities that do, should, and should not play a role in biodefense. Presently, the government distributes biodefense activities across a large number of departments and agencies (Figure 1). OMB does not provide a list of these entities, their activities, and their expenditures to Congress (or the public), which obfuscates Congress' ability to provide comprehensive oversight and make appropriations decisions in context.
- **Insufficient accounting.** The *Congressional Budget and Impoundment Control Act of 1974*, also known as the *Budget Act* (Pub. L. No. 93-344), does not require the annual President's Budget Request to be specific to any department, agency, or activity area. While OMB does submit department- and agency-level funding requests, it does not submit detailed biodefense expenditures. The Committees on Appropriations neither require nor request an accounting for overall biodefense spending.
- **Inadequate accountability.** Some programs do not sufficiently meet or reduce the biological threat while others are too expensive relative to the benefit they provide. The *Government Performance and Results*

Act (GPRA) of 1993 (Pub. L. No. 103–62, amended in 2010) provided some needed guidance for program performance, and assigned OMB responsibility for establishing crosscutting policy priorities. However, GPRA focuses on measures of performance, rather than outcomes. This does not meet the need for a biodefense system that makes the nation more secure.

- **Under-coordinated appropriations.** The subcommittee structure of the House and Senate Committees on Appropriations does not facilitate mission-oriented integration of funding. All subcommittees should share information and coordinate efforts, but they lack formal mechanisms with which to do so. The same is true for the many authorizing committees of jurisdiction responsible for informing the appropriations process.

- **Unpredictable funding.** Congress funds most discretionary programs annually, making program implementation and long-term planning subject to unpredictable funding decisions. Further, discretionary funds have been under pressure from the Budget Control Act of 2011, as amended in the *Bipartisan Budget Act of 2015* (Pub. L. No. 114-74). Volatile funding inhibits private sector capital investments in government-led efforts. Moreover, it prevents state, local, tribal, and territorial (SLTT) governments from building and sustaining needed capacities and capabilities. Reliance on continuing resolutions delays the issuance of funding to jurisdictions and interferes with planning, training, and exercising cycles.

- **Cost-prohibitive outbreak response.** The financial impact of major biological events is staggering (Figure 2). The direct and indirect economic costs of outbreaks and the response to them now regularly extend into the billions. The costs are so high (and unaccounted for in annual budgets) that supplemental requests and appropriations have become the norm to deal with them (e.g., $7.7 billion in 2009 for H1N1, $5.4 billion in 2014 for Ebola, $1.1 billion in 2016 for Zika). As these requests increasingly become the standard means for addressing public health security crises, debate over the need for funding response heightens. Delays mount and case counts rise: the *emergency* Zika supplemental took seven months to pass through Congress. Further demonstrative of the prohibitive and unsustainable nature of these costs, part of the Zika response was funded through redirection of resources from existing biodefense programs. Although a response fund is needed, more strategic and comprehensive annual budgeting that addresses pre-event requirements – like prediction research, hospital preparedness, and medical countermeasure development – would also reduce the risk and thereby mitigate some of the need for massive post-event supplemental funding.

FIGURE 1

Diffusion of biodefense activities across the federal government. The Study Panel has identified biodefense activities at the departments, independent agencies, and one independent institution listed here, and believes that there could be more with biodefense responsibilities.

DEPARTMENTS

Department of Agriculture

Department of Commerce

Department of Defense

Department of Education

Department of Energy

Department of Health and Human Services

Department of Homeland Security

Department of Housing and Urban Development

Department of Interior

Department of Justice

Department of Labor

Department of State

Department of the Treasury

Department of Transportation

Department of Veterans Affairs

INDEPENDENT AGENCIES

Central Intelligence Agency

Environmental Protection Agency

General Services Administration

National Aeronautics and Space Administration

National Nuclear Security Administration

National Science Foundation

Office of the Director of National Intelligence

United States Postal Service

INDEPENDENT INSTITUTION

Smithsonian Institution

OPPORTUNITIES FOR BUDGET REFORM

To improve extant budget processes, the Panel issued the following recommendation in its 2015 report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*:

> **Recommendation 4: Unify biodefense budgeting.** Congress should mandate the development of an integrated budget that allows Congress and the Administration to understand how the government funds the entire biodefense enterprise.

a. **Develop and execute a mandatory annual biodefense call for data.** The President and congressional appropriators should require the Director of OMB to conduct this data call, coordinated by the Vice President. Each department and agency should catalogue all of their biodefense programs and indicate which support specific biodefense requirements in the National Biodefense Strategy and which do not. The submissions should include historical annual expenditures for each program and predicted future needs.

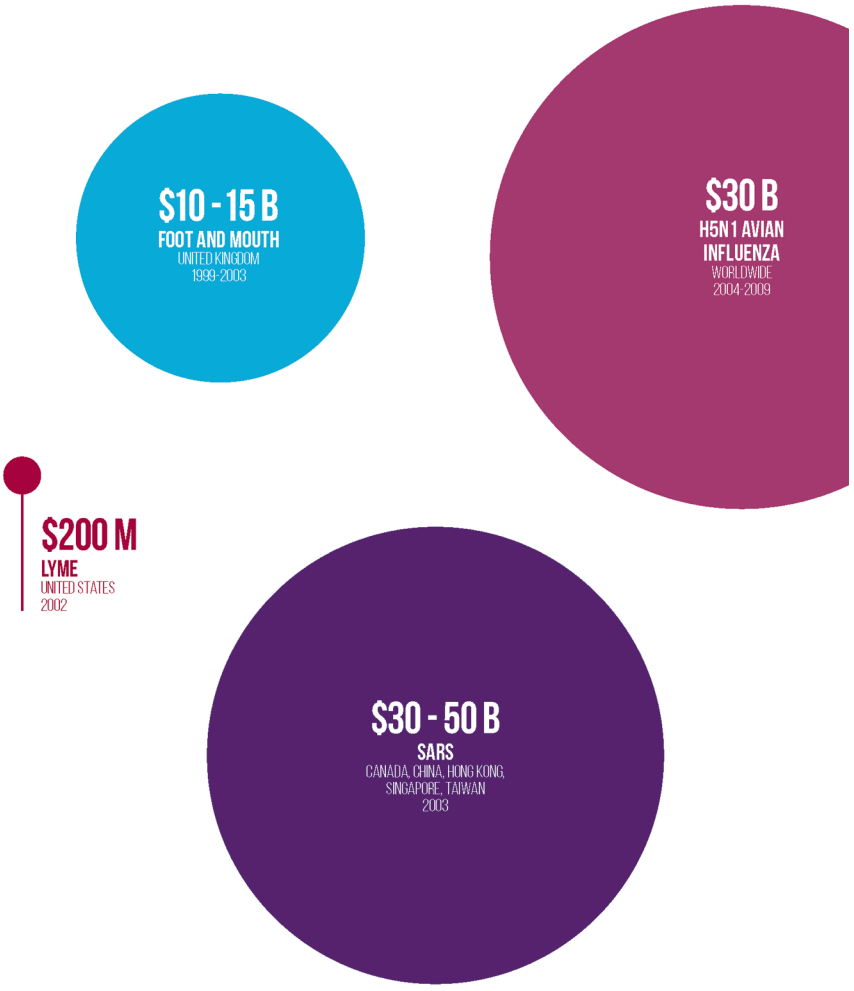
b. **Conduct a crosscutting biodefense budget analysis.** Using the information collected in the data call, the Vice President and the Director of OMB should identify gaps and overlaps in and among federal programs. OMB should use this analysis to inform the budgetary guidance it sends to departments and agencies for the coming fiscal year.

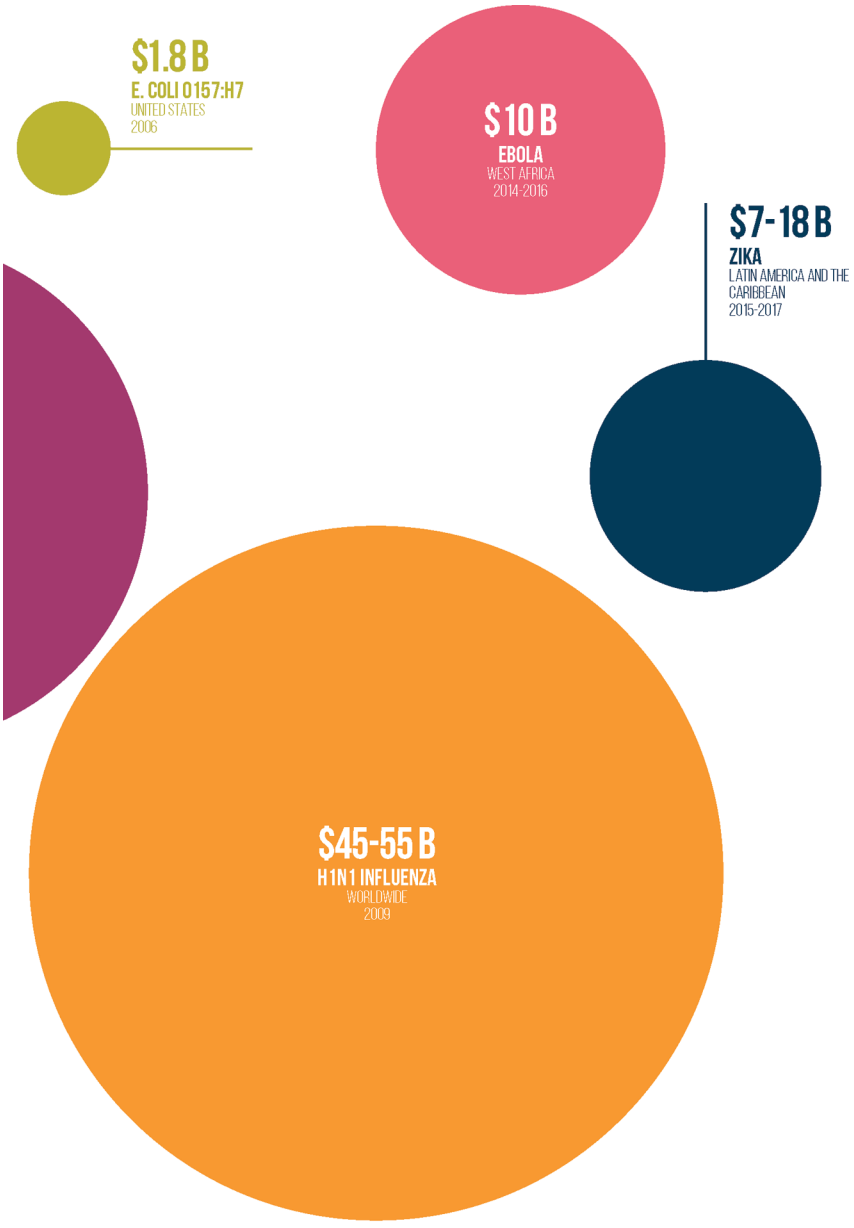
c. **Align budget items to the National Biodefense Strategy of the United States of America.** The Director of OMB should require that all annual budget request submissions pertaining to biodefense adhere to the guidance from OMB, based on the National Biodefense Strategy and the budget crosscut.

d. **Provide predictable and multi-year funding for all biodefense programs.** The President should request funding for all biodefense activities in the annual budget request, including multi-year requests for those programs that the Vice President and Director of OMB determine would benefit from such forward funding. Additionally, departments and agencies should provide multi-year grants, contracts, and/or cooperative agreements wherever possible.

FIGURE 2

Estimated economic impact of selected infectious disease outbreaks. Infectious disease outbreaks are placing an increasingly high economic burden on local, national, and global economies. The displayed costs show a sampling of direct and indirect economic impacts of selected human, livestock, and zoonotic outbreaks. Information is based upon BioEra, World Bank, and United Nations Development Programme data. Data gaps and the use of varying methodologies limit full accounting and figures are not drawn perfectly to scale. Refer to EcoHealth Alliance and World Bank for data and more information on the economic impact of emerging infectious diseases.




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E. COLI O157:H7
UNITED STATES
2006
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WEST AFRICA
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$7-18 B
ZIKA
LATIN AMERICA AND THE CARIBBEAN
2015-2017
$45-55 B
H1N1 INFLUENZA
WORLDWIDE
2009

The passage of the *National Defense Authorization Act of 2017* (Pub. L. No. 114-328) means that – for the first time – the federal development of a comprehensive national strategy for biodefense is law. As the drafting process necessitates consideration of the entire spectrum of biodefense activity occurring across the federal government, implementation will also require consideration of budgets to pay for it. The completed National Biodefense Strategy will thus provide a strong platform from which planners and decision-makers can ensure coordination and funding of efforts to meet the biological threat.

Policymakers, therefore, have an opportunity to transform the status quo. A series of changes to structure and process as outlined herein could greatly improve national security and the way taxpayer dollars are spent.

EXECUTIVE BRANCH

White House Leadership. The Panel previously recommended that the Vice President should provide the political leadership of the biodefense enterprise. This leadership should include oversight of the biodefense budget. For day-to-day policy development and coordination, the President should designate a Deputy Assistant to the President for Biodefense in the National Security Council to support the Vice President in this endeavor. The OMB Director should also empower a Program Associate Director (PAD) to manage the entire biodefense portfolio. The Deputy Assistant, with the input of the designated PAD and the newly established Biodefense Coordination Council at the White House, should provide biodefense budget recommendations to the Vice President.

Precedent: The DCI and the DNI

Prior to the intelligence reforms instituted after September 11, 2001, the Director for Central Intelligence (DCI) was responsible for gathering and submitting the budgets of all intelligence agencies at once. While the DCI could not influence agency budget submissions, the DCI could express to the President and Congress concerns regarding budget gaps and redundancies. Today, the Director of National Intelligence (DNI) is in charge of the National Intelligence Program budget and works with the Under Secretary of Defense for Intelligence to develop the Military Intelligence Program budget. Both budgets are fully visible to and influenced by the DNI.

Biodefense Coordination Council. The Panel previously recommended that the White House establish and manage a Biodefense Coordination Council. Through this Council, the Vice President should prioritize interagency activities, ensure department and agency accountability, and provide policy and budgetary

recommendations for biodefense. The Vice President should populate the Council with Deputy Secretaries from all departments and agencies with biodefense responsibilities, as well as non-federal stakeholders. The Biodefense Coordination Council should maintain communication with all other White House Councils to coordinate and exchange information.

Department and Agency Budget Requests. Deliberations of the White House officials and the Biodefense Coordination Council described above should inform the annual funding guidance provided by OMB to the departments and agencies. This guidance should stress the importance of both agency-level and broader mission requirements as drivers of funding requests to OMB. Departments and agencies should provide evidence of program effectiveness in meeting these requirements in their annual requests, as evaluation of PPA effectiveness depends on the availability and use of strong metrics. The Administration should categorize biodefense as a Cross-Agency Priority (CAP) Goal in accordance with the *GPRA Modernization Act of 2010* (Pub. L. No. 111-352), and develop such metrics in keeping with the Implementation Plan for the National Biodefense Strategy. The Deputy Director for Management at OMB, through the Performance and Personnel Management Directorate and in conjunction with the biodefense PAD, should work with the White House on the creation and implementation of performance targets for the biodefense CAP Goal. Agencies should base their budget requests to OMB on performance and outcome measures that exceed GPRA requirements. Doing so would provide legitimate support for continued investment in useful activities and allow decision-makers to consider options for activities in greater need. For major projects, the White House and Congress should require departments and agencies to develop business plans that emphasize interagency coordination and public-private partnerships.

OMB Analysis and Evaluation. The Study Panel previously recommended undertaking an analysis to delineate capability gaps based on the National Biodefense Strategy, and then mapping those gaps to resource needs. As part of this process, OMB should annually issue a mandatory biodefense call for data, using a clear definition for biodefense (in accordance with the National Biodefense Strategy) to help departments and agencies determine what constitutes biodefense activities and programs. OMB should use these data to conduct a crosscutting budget analysis. With congressional fiscal support, OMB should develop and implement a web-based portal to facilitate this information collection. This portal should capture spending and activity data in a structured and relational manner to enable evidence-based policymaking. For instance, data should be coded to reflect not only fiscal expenditures, but also the means by which resources (e.g., personnel) are invested to achieve biodefense mission requirements. OMB should leverage authorities already provided by the *Digital Accountability and Transparency*

Act of 2014 (Pub. L. No. 113-101), which requires rigorous public disclosure of expenditures. Submissions from departments and agencies based on strong performance and outcome measures would help OMB evaluate requests in the context of all biodefense programs and activities across the federal government. The Office of Science and Technology Policy (OSTP) should play an integral role in the evaluation of biodefense research and development requests.

OMB Submission to Congress. Using the data, information, and analysis provided through the above process, OMB should provide an integrated biodefense budget request to Congress. This submission should be a holistic presentation of all department and agency requests across the federal government, ensuring that the overall request aligns with the National Biodefense Strategy and aids congressional appropriations and related authorization decisions. The following should comprise the request: (1) the biodefense budget crosscut conducted per the data call described above; (2) the performance outcomes for biodefense PPAs; (3) an explanation for how PPAs contribute to the goals and objectives of the National Biodefense Strategy; and (4) a five-year Future Years Biodefense Budget Program plan.

Precedent: National Arctic Research Budget

The *Arctic Research and Policy Act of 1984* (Pub. L. No. 98-373) established the U.S. Arctic Research Commission, primarily charged to develop a comprehensive national Arctic research policy. A key element of the law directed OMB to consider all federal agency requests related to Arctic research as one integrated request. The law required the establishment of an interagency committee that would provide the coordination, data, and assistance to prepare an integrated, multiagency budget request for Arctic research. The law also required OMB to review the request for its adherence to a five-year plan for Arctic research (required by the same Act), and directed OSTP to review all budget requests related to the Arctic.

OMB should display the information in various ways, such as by National Biodefense Strategy goals and objectives, and by functional area (e.g., biodetection and biosurveillance, medical countermeasures, preparedness). OMB should develop the request by planning for sustained and, where appropriate, increased funding to prevent erosion of capability and capacity in core programs (those OMB deems effective, long-term, and thus subject to inflation). This request would incentivize private sector participation and planning. OMB should include a Future Years Biodefense Budget Program plan in the annual budget submission. Similar to the Department of Defense (DOD) Future Years Budget Program (10 U.S. Code § 221), this plan should summarize all biodefense programs and resources, and address at least five years – the current fiscal year for which funds are being

requested, and the following four fiscal years. This display of and plan for predicted expenditures would force advanced and strategic planning, encourage private sector participation, and enable Congress to consider at least five years of cost data during the appropriations process.

FIGURE 3

Process for Developing the Biodefense Budget



LEGISLATIVE BRANCH

Congress retains tremendous power to ensure the adequacy of the federal biodefense enterprise in general, and to mandate an integrated approach to budgeting and appropriations. As the Executive Branch improves its process through development of a National Biodefense Strategy and an integrated budget aligned to that Strategy, Congress has a parallel opportunity to refine its own processes with respect to authorization and appropriations.

At present, numerous committees and subcommittees in both the House and the Senate share authorizing responsibility for biodefense. This largely reflects the Executive Branch's own structure. It also mirrors shared congressional homeland security jurisdiction, which increases the difficulty of advancing homeland security legislation. Committees undertake oversight along jurisdictional lines ascribed to them through House and Senate rules, but only a few spend substantial time focusing on biodefense as a comprehensive topic. This selective oversight reflects insufficient congressional engagement to address many of the most significant biodefense challenges America faces, except when a crisis occurs and reaction becomes imperative. Conversely, fragmented jurisdiction has resulted at times in excessive interest, leading to unnecessary disputes over real and perceived legislative purview. No incentive or structures currently exist to encourage further coordination and cooperation amongst these disparate jurisdictions.

Similarly, the subcommittee structure of the House and Senate Committees on Appropriations does not facilitate mission-oriented integration of funding. All subcommittees need to share information and coordinate efforts, but lack formal mechanisms with which to do so.

Congressional Biodefense Working Group. Early in 2018, House and Senate leadership should jointly establish a temporary, bicameral, bipartisan Biodefense Working Group (BWG), appointing representatives from all committees of jurisdiction. The primary task of the BWG would be to determine what structures and processes would enable streamlined and comprehensive biodefense oversight. Because biodefense requires broad governmental activity, the health consequences of biological events alone should not drive working group membership or chairs. Rather, Leadership should appoint committee chairs, ranking members, and other members from committees with responsibility for prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation of biological threats to sit on the BWG. Leadership must also allocate resources and staff sufficient to support the group.

The BWG should issue a series of recommendations to House and Senate leadership no later than the end of the 115th Congress. They should implement them at the start of the 116th Congress. These recommendations should address:

Authorization reform. The National Biodefense Strategy and its implementation plan will be the first comprehensive tool provided to Congress to enable oversight of the entire enterprise. The BWG should assess whether the current designation of responsibilities across authorizing committees adequately covers all elements of biodefense described by the Strategy. It should evaluate how Congress can best provide legislative guidance regarding elements of the Strategy, not on an ad hoc basis, but in a coordinated fashion. A Biodefense Authorization Act could be a powerful tool for regular congressional focus and input on the issue. The working group should determine the role and process to create such an Act, and the frequency of reauthorization. Authorization of specific spending levels in this bill would establish authorizers' priorities for appropriations. The bill should reflect the input of all authorizing committees of jurisdiction, but particular committees should spearhead its development. The BWG should identify which existing committee or committees in the House and Senate could best serve as that focal point or whether leadership should appoint a special committee.

Budget reform. The House and Senate Committees on the Budget produce annual budget resolutions in their respective chambers. Each Committee's budget resolution should include a figure for overall biodefense spending. The Committees should utilize the annual integrated biodefense budget submission from OMB in their decision-making. The BWG should propose how the Committees on the Budget should use the National Biodefense Strategy, Biodefense Authorization Act, and other means to inform the annual budget resolutions better. The group should consider the advantages of multi-year funding for certain types of programs when developing its recommendations.

Appropriations reform. The BWG should determine how the Appropriations Committees could best evaluate an integrated biodefense budget request. Twelve subcommittees comprise the Appropriations Committee in each chamber and work annually to develop twelve appropriations bills. Upon submission of the integrated biodefense budget request to Congress each fiscal year, these subcommittees should work together to identify areas of programmatic overlap and gaps in their respective jurisdictions. The subcommittees should coordinate with each other to appropriate funds in accordance with the biodefense budget request, the National Biodefense

Strategy, and levels authorized in statute by the Biodefense Authorization Act or elsewhere. The appropriations committees should work closely with their corresponding authorizers to ensure unity in biodefense appropriations and policy. They should also require a strong evidence base for continued support of PPAs, consistent with the recent congressional focus on evidence-based outcomes, as recommended in September 2017 by the bipartisan Commission on Evidence-Based Policymaking.

Integrated Budget Request. Congress recently eliminated a long-standing requirement for OMB to issue an annual homeland security budget crosscut (previously, 31 U.S.C. § 1105 (a)(35) 1974), which included information relevant to biodefense. This provision should be reinstated and adjusted to require more detail and analysis than had become the norm for the crosscut in recent years. Congress should consider requiring the development of an integrated biodefense budget submission that includes a thorough crosscut and analysis via further amendment to this statute, if OMB chooses not provide such a submission voluntarily.

Future Years Biodefense Budget Program. Congress should amend 31 U.S.C. § 1105 (a)(35) 1974 to establish a Future Years Biodefense Budget Program, requiring the Director of OMB to submit to Congress a yearly Future Years Biodefense Budget Program plan with the President's Budget Request. The plan should include the estimated expenditures and proposed appropriations for at least the current and four succeeding fiscal years. The amendment should require the Director of OMB to ensure that expenditure estimates and proposed appropriations for any fiscal year are consistent with the total estimated expenditures and appropriations deemed necessary to support the biodefense PPAs of all departments and agencies.

ESSENTIAL FINANCIAL TOOLS

Multi-year Funding. The yearly nature of budgetary and appropriations processes makes long-term planning and stability for critical security programs difficult, if not impossible. Congress requires recipients to use, obligate, or relinquish most funding by the end of the fiscal year. However, Congress can explicitly make funds available for use in more than one year. Generally, Congress authorizes such multi-year funding because some programs will take years to execute fully, and they, therefore, require funding over an extended period. OMB and Congress should commit to providing multi-year, long-term funding for certain biodefense programs and grants.

One type of multi-year funding is the advance appropriation, in which funding becomes available after the year in which an appropriations act passed. This prevents programmatic gaps that can occur due to annual appropriations variability, and demonstrates longer-term commitment to certain activities beyond a yearlong funding cycle. For MCM development and other costly long-term research, it is imperative that Congress commits resources to federal and private sector efforts. Such an approach is not without precedence in biodefense. A ten-year advance appropriation for Project BioShield (FY 2004-2013) became law because Congress justified it and the Vice President supported it. This type of guarantee provides strong incentives for research and development programs that might otherwise be abandoned.

Precedent: Project BioShield Advance Appropriation

In 2004, Congress passed the *Project BioShield Act* (Pub. L. No. 108-276). This law created a 10-year Special Reserve Fund of $5.6 billion to be available from FY2004-FY2013 for the procurement of MCM. This advance appropriation helped generate a market for much-needed countermeasures that the private sector would otherwise have had no incentive to develop. The market stability it created helped enable the successful addition of 14 MCM products to the Strategic National Stockpile.

At a minimum, Congress should reinstate the advance appropriation for the BioShield Special Reserve Fund (SRF). The BWG should also evaluate other areas that would benefit from multi-year funding, including grants that strengthen public health security. Congress should rightly retain budgeting flexibility and caps on advance appropriations in order to ensure the integrity of allocations. However, Congress should also commit to long-term funding for select elements of biodefense, similar to its commitment to national defense.

Private Sector Incentives. While relatively expensive, MCM development, capabilities, infrastructure, and assets have far-reaching impact, enabling a range of core capacities including deterrence, preparedness, and response. Attention to MCM development has waned, however, and investments are orders of magnitude below what they should be for a comparable threat. With no guarantee of predictable and sustained public sector support, profit, or patients for clinical trials, companies find it difficult to justify investments in MCM development, straining the public-private partnerships required to execute this mission. The Strategic National Stockpile may be in much better shape than it was a decade ago, but its sustainability is in doubt and gaps continue to persist.

Congress and the Administration must renew their commitment to a BioShield SRF advance appropriation. They also need to create additional incentives to encourage private sector investment that complements government commitments, and

to ensure investment in MCM that the SRF does not cover (e.g., for emerging infectious diseases, influenza). The public and private sectors should cooperatively discuss, develop, and implement a set of incentives that may include traditional authorities (e.g., other transactional authority) and creative financing methods (e.g., securitization of an MCM asset portfolio). The Department of Health and Human Services Assistant Secretary for Preparedness and Response and the DOD Deputy Assistant Secretary of Defense for Chemical and Biological Defense should lead this initiative, which should involve substantive partnerships with the Department of the Treasury, White House Council of Economic Advisors, and National Economic Council. The government must ensure that the return on investment by both performers and investors is commensurate with the risk they assume and the high value of the goods and services they provide to our national security.

BIOLOGICAL DISASTER RESPONSE FUNDING

Domestic Public Health Emergency Funding. The Disaster Response Fund (DRF) for natural disasters, the Public Health Emergency Fund (PHEF) for widespread human health emergencies, and the Commodity Credit Corporation (CCC) for agricultural emergencies are some of the institutionalized means by which the federal government funds response to different events. Among these, only the PHEF does not receive an annual appropriation or reimbursement. In 1983, Congress appropriated $30 million for the fund, an amount insufficient to address a public health catastrophe. Congress has not explicitly appropriated any money for the PHEF since 1993. Today, only about $57,000 remains. Recent history reveals that adequate response to public health emergencies requires resources that are far more substantial. In 2014, in response to the Ebola outbreak, Congress appropriated $5.4 billion in emergency funding. When the Zika virus emerged in 2016, the Obama Administration requested almost $1.9 billion to address the threat and Congress ultimately appropriated $1.1 billion.

The nation requires a rapid response fund triggered not only by a declared public health emergency, but also, at times, in advance of any such declaration to preempt a major problem. Congressional proposals to seed such a fund have ranged from $300 million to $5 billion. Viewed in the context of historical supplemental funding levels described above and taking these proposals into consideration, $2 billion is a reasonable level of baseline funding for now. This level can be revisited if strategic annual biodefense investments ultimately mitigate response costs. The Administration and Congress, therefore, should: (1) infuse no less than $2 billion into the PHEF; (2) commit to regular annual appropriations utilizing a consistent methodology and no-year funding for the PHEF, similar to provisions for the DRF

and CCC; (3) provide guidance on triggers for use, which may or may not include declaration of a public health emergency; and (4) update criteria for what events the PHEF will cover. Congress and the Administration should consider the input of SLTT end-users in developing these triggers and criteria.

Global Response Funding. Preventing the spread of disease at its source is less expensive than paying for post-outbreak domestic and international response. Congress and the Administration should commit to playing a long-term role in global health security by sustaining U.S. budget commitments for federal implementing agencies like the Department of State, DOD, U.S. Agency for International Development, and Centers for Disease Control and Prevention. They must also support international institutions such as the World Health Organization (WHO) and World Bank, as well as novel public-private partnerships like the Coalition for Epidemic Preparedness Innovations. At a minimum, as the initial U.S. financial commitment to the Global Health Security Agenda reaches its five-year endpoint, the Administration and Congress should recommit to funding and supporting the American contribution to this program. Prevention forestalls outbreaks, but when prevention is not possible, global response efforts are critical. The United States should assume a leadership role in transforming the existing WHO-centric response model into a distributed response framework predicated on global public-private partnerships.

Mitigating Risk. Beyond MCM lie additional opportunities for public-private partnerships that will increase mission effectiveness while sharing costs. Leveraging private sector models for risk management, such as catastrophe models used by the insurance industry that allow insurers and reinsurers, financial institutions, corporations, and the government to evaluate and manage catastrophic risk, could elevate the government's risk tolerance. The federal government should also encourage other countries, global companies, and international organizations to invest in biodefense by offering to partner with them through multilateral agreements, cooperative agreements, and other such mechanisms.

CONCLUSIONS

The Executive Branch and Congress do not comprehensively assess how the government currently spends its biodefense dollars. This lack of clarity prevents departments and agencies from identifying gaps and setting long-term strategy. A comprehensive and systematic analysis of redundancies and gaps across the biodefense enterprise is a critical step toward assigning responsibilities, resources, and metrics to meet those needs.

It will take time to produce an integrated biodefense budget. The White House should first establish the recommended leadership and coordination structure, while Congress establishes the BWG. These elements will enable all other activities, including:

- Federal department and agency requests for funding in keeping with their biodefense responsibilities;
- OMB evaluation of biodefense spending across the government; and
- Congressional authorization and appropriations in accordance with overall spending and mission targets.

The entire process would mature in about three years, but could begin demonstrating value much earlier. The National Biodefense Strategy should provide a foundation for all efforts to implement biodefense policy and law, and help to increase coordination and oversight. The Biodefense Authorization Act would support execution of the Strategy.

Biological events occur too frequently to allow inefficient funding mechanisms and ineffective programmatic efforts to risk lives and our national security. As disease outbreaks, other emergencies, and disasters continue to affect public health security, the nation must take a more business-like approach to biodefense budgeting. Executing the recommendations herein will ensure that the biodefense enterprise uses taxpayer dollars wisely to defend the nation against biological threats.

ACRONYMS

BWG ..... Biodefense Working Group
CAP ..... Cross-Agency Priority
CCC ..... Commodity Credit Corporation
DCI ..... Director for Central Intelligence
DNI ..... Director of National Intelligence
DOD ..... U.S. Department of Defense
DRF ..... Disaster Response Fund
GPRA ..... Government Performance and Results Act
MCM ..... medical countermeasure(s)
OMB ..... Office of Management and Budget
OSTP ..... Office of Science and Technology Policy
PAD ..... Program Associate Director
PHEF ..... Public Health Emergency Fund
PPAs ..... Projects, Programs, and Activities
SLTT ..... State, Local, Tribal, and Territorial
SRF ..... Special Reserve Fund
WHO ..... World Health Organization


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Formerly the Blue Ribbon Study Panel on Biodefense

HOLDING THE LINE ON BIODEFENSE

STATE, LOCAL, TRIBAL, AND TERRITORIAL REINFORCEMENTS NEEDED

BIPARTISAN REPORT OF THE
BLUE RIBBON STUDY PANEL ON BIODEFENSE

October 2018



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October 2018



BLUE RIBBON STUDY PANEL ON BIODEFENSE

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EXECUTIVE SUMMARY

The US Census Bureau counts a staggering 89,004 local governments in the United States. Among them are 3,031 counties, 19,522 municipalities and 16,364 townships.[1] There are 573 tribes,[2] 14 territories, and thousands of other special districts across America–each with a responsibility to serve the people who call those places home. Sometimes that service is in response to an emergency.

Our hometown heroes – emergency medical services, police, firefighters, doctors, nurses, pharmacists, lab technicians, public health professionals – are on the front lines keeping us safe. Maybe it's from a flash flood from a stalled rainstorm. Perhaps it's from a derailed train carrying hazardous liquids. These types of incidents can be handled with resources provided by local and state governments, but when events are severe - widespread in scope and damage – they may require intervention by our federal government. Whether it's a terrorist attack (e.g., September 11, 2001) or a natural disaster (e.g., Hurricane Katrina), the nation will quickly step up and respond, offering additional support and funding.

Unfortunately, there is grave concern that a large-scale biological event will prove to be the exception to this rule. Devastation could be vast and swift, and local resources would be very quickly depleted. The thousands of state, local, tribal, and territorial (SLTT) governments that are the backbone of our nation will have to fend for themselves for far too long until federal assets arrive, and Congress can provide emergency supplemental funding to support response and recovery.

In October 2015, the Blue Ribbon Study Panel on Biodefense issued its first report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*. The majority of the report's recommendations focused on our national government, touching only briefly on SLTT needs. The Panel promised to return to them later and revisited these issues during a special focus meeting on the campus of the University of Miami in January 2018. The Panel explored needed SLTT emergency medical services, hospital, pharmacy, laboratory, and public health department capabilities and capacities necessary to respond to large-scale biological events.

The Panel found that basic biological preparedness, response, and recovery infrastructure varies widely throughout the United States, placing the entire

nation at risk. If one community, for example, does not have access to a laboratory in their state that can quickly identify a biological threat, then they are immediately vulnerable and so are those who live in bordering states. It reminds us that states, localities, tribes, and territories play a huge role in national security. We would like to see state governors, territorial governors and administrators, tribal leaders, mayors, borough council presidents, and township supervisors make biodefense a greater priority before biological attacks, accidents, outbreaks, epidemics, and pandemics place the lives of their constituents at risk.

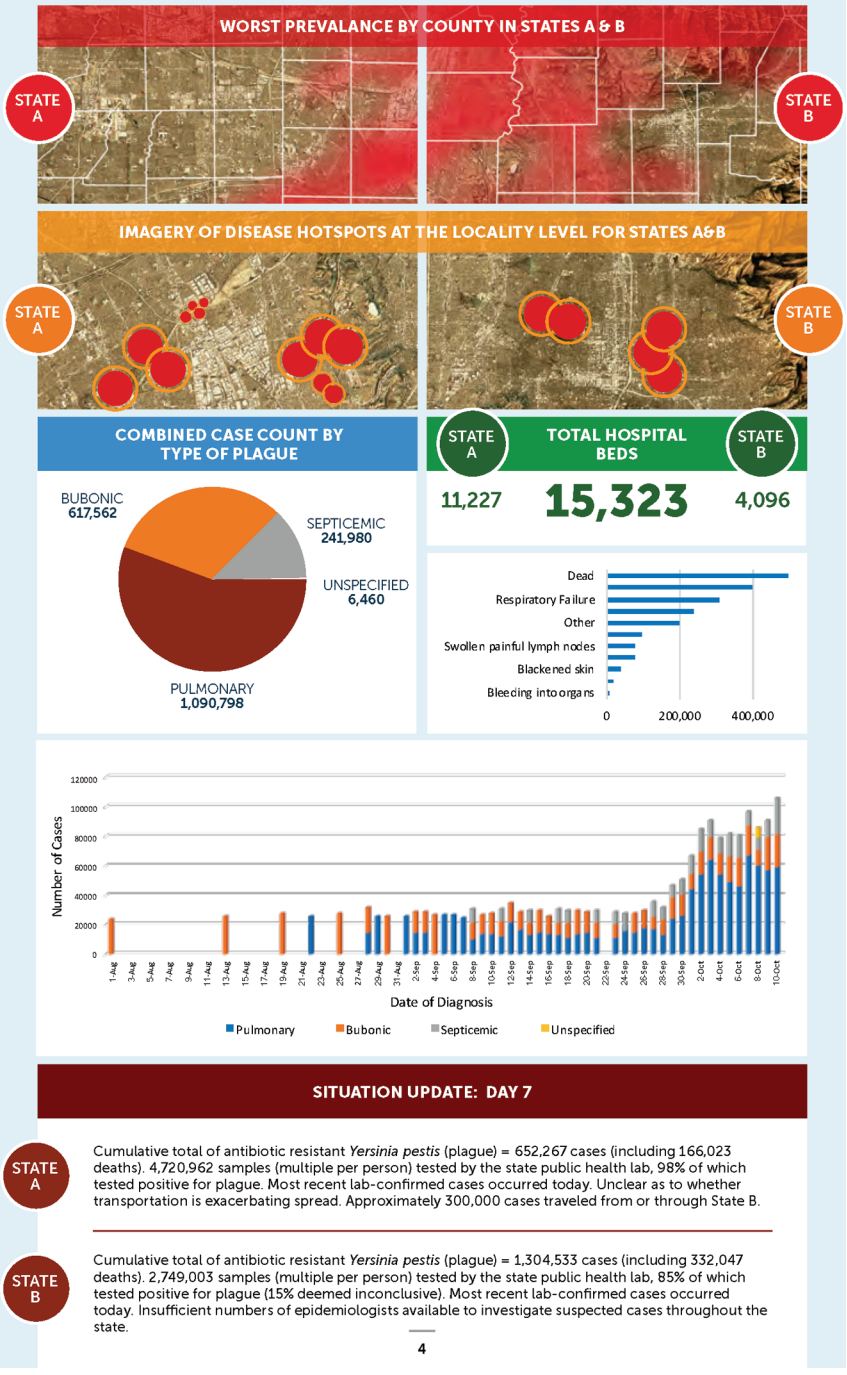
In the pages that follow, the Panel recommends key steps that will increase the capability of SLTT to share with the federal government the burden of preparedness for, response to, and recovery from large-scale biological events. These eight recommendations are:

- Unify and establish a new National Emergency Medical Services system, including the creation of a National Emergency Medical Services Agency at the Department of Health and Human Services.
- Improve distribution of the Strategic National Stockpile and other stores of pharmaceuticals, equipment, and essential medical supplies, with enhanced training and assured access to pharmacy readiness data.
- Layer health care delivery across the nation and plan for when hospitals and other facilities are overwhelmed and overrun.
- Authorize all laboratory response networks to test for biological agents.
- Allow federally recognized tribes to enter into their own Public Health Emergency Preparedness cooperative agreements with the Centers for Disease Control and Prevention.
- Strengthen biosurveillance in, and eliminate burdensome transportation requirements for, the territories.
- Allocate response funding before biological crises occur with a credible Public Health Emergency Fund and sufficient assistance under the Stafford Act.
- Address public expectations by making biodefense a priority for all elected leaders throughout the nation.

HYPOTHETICAL SCENARIO FOR MULTIPLE UNEXPLAINED OUTBREAKS OF PLAGUE

Plague has broken out in two states and the initial response is slow. The public health departments in both states are on their own until the case counts make it obvious that what these states are experiencing is not normal. It does not take long until the governors are involved. They want to know what is going on and they are looking for answers quickly, but information is only trickling in from hospitals and local government health departments. Eventually, the federal government offers some preliminary support, but only after they make two frightening discoveries: the disease has been genetically engineered and aerosolized, and two terrorist groups are claiming that they have successfully attacked the United States with plague. Outbreaks are expected to continue for months. A hypothetical governors' dashboard, along with a reporter's notes, follow.

HYPOTHETICAL GOVERNORS' DISEASE DASHBOARD



SITUATION UPDATE: DAY 7

STATE A

Cumulative total of antibiotic resistant *Yersinia pestis* (plague) = 652,267 cases (including 166,023 deaths). 4,720,962 samples (multiple per person) tested by the state public health lab, 98% of which tested positive for plague. Most recent lab-confirmed cases occurred today. Unclear as to whether transportation is exacerbating spread. Approximately 300,000 cases traveled from or through State B.

STATE B

Cumulative total of antibiotic resistant *Yersinia pestis* (plague) = 1,304,533 cases (including 332,047 deaths). 2,749,003 samples (multiple per person) tested by the state public health lab, 85% of which tested positive for plague (15% deemed inconclusive). Most recent lab-confirmed cases occurred today. Insufficient numbers of epidemiologists available to investigate suspected cases throughout the state.

HYPOTHETICAL REPORTER'S NOTES FROM INTERVIEWS

Governor, State A: "We continue to see hundreds of cases of antibiotic-resistant plague. I urge our citizens to seek immediate treatment at your local hospitals."

Governor, State B: "We have been stricken with plague and cannot deny the serious implications of this disease. I'm asking our citizens to shelter in place. I've called the National Guard to assist with medical treatment and maintain lawful order."

Director, Public Health Laboratory (BSL-3), State B: "We heard that the CDC is developing a new testing protocol for this strain of plague, but does it matter? At this point, we're using the tests we have for plague and determining whether these organisms are antibiotic resistant ourselves."

CEO, major hospital coalition, State A: "This disease is antibiotic resistant, and unusual, in that it appears to be highly transmissible from person-to-person. We ran out of the supplies for palliative care days ago. We have no more to provide."

Secretaries of Agriculture and Health, State B: "We keep sending requests to get the national stockpiles sent here. The feds have always promised us they could get at least part here in 48 hours, but we haven't received anything in four days."

Superintendent, State Police, State A: "We have the authority to enforce a quarantine, but the Governor hasn't ordered one. I have no problem with that. What I do have a problem with are the folks coming over the border from State B, where their Governor has told his citizens to shelter in place."

President, University of State B: "I have almost 100,000 students, faculty, and other staff here at my university. We're sheltering in place but running out of food. I won't prevent parents from coming here to get their kids. I can't take care of them."

Commanding General, State B National Guard: "I've been told to maintain order. We'll do whatever it takes to maintain that order."

President, cross-border Tribal Nation: "I'm pretty sure we're on our own. We've got our own hospital, some medical supplies, and a couple of Indian Health Service doctors. That's about it. But who knows? We may be better off than the others. We know how to get along without medicines."

Chief, Emergency Medical Services, State A: "We're sending our personnel into harm's way, to bring sick people out of their homes and to the hospitals. Every day, some of my folks get sick, too. What are the communities going to do when there aren't any more of us to help? It's not like the doctors and nurses can come out of the hospitals and bring people in."

Special Agent in Charge, FBI Field Office, State A: "All I can tell you is that two terrorist groups have claimed responsibility for these attacks and that some sort of aerosolized agent may have been used. Anything else requires clearance. We'll share information with the Governors and both fusion centers when we can."

Director, Centers for Disease Control and Prevention: "The CDC confirms that the strain of Yersinia pestis affecting State A and State B is antibiotic resistant. At this time, we are not sending contents of the Strategic National Stockpile to these states because we have received warnings about other impending attacks throughout the Nation."

President, United States of America: "Today, I declared major disasters in State A and B. I have ordered federal aid to supplement state and local response efforts in the areas affected by the plague. I expect the entire federal government to provide all of the assistance they can."

Administrator, Federal Emergency Management Agency: "We are working to determine whether we can provide assistance and are deferring to the Department of Health and Human Services to address this rapidly escalating emergency in accordance with Emergency Support Function 8. FEMA may not duplicate assistance provided or available under the authority of another federal agency or from insurance. We have to wait and see what sort of support HHS is going to provide."

Secretary of Health and Human Services: We are working to transfer funds from other accounts to help these states and save lives. Unfortunately, Congress never put enough money into the Public Health Emergency Fund. The last time I checked, there was about $30,000 in there. It might as well be zero. I can't do anything with that to help the millions in those two states."

Secretary of Agriculture: "Our National Veterinary Stockpile is far smaller than the human stockpile. We'll send what we think will help, but I have to be honest, it won't help much."

Administrator, Environmental Protection Agency: "This is a biological event. It is not the responsibility of the EPA to contain or clean this up."

Secretary of Defense: "The nation has been attacked. The Governor of State B has activated the National Guard. Most of the National Guard for State A is deployed to the Middle East. We are sending some of the Reserves to State A, but our first priority is to defend the nation against further attacks and keep our enemies from taking advantage of this situation to attack us with other weapons. We will not pull back from our current deployments throughout the world. We have to maintain national security."

Doctor, local hospital, State A: "We're doing the best we can with what we've got, but it's not enough. And we're being overrun by the worried well. The situation is impossible."

Director, Wildlife Agency, State B: "We have been working with the US Geological Survey's National Wildlife Health Center and our colleagues in State A's wildlife agency. We are trying to monitor where the rodents are, so that we can identify and control the spread of this disease. We can't afford to ignore these reservoirs. If we do, we are not going to be able to eliminate this disease."

Citizen, home-bound, State A: "Who knows? Maybe I'm safer here."

Director, Department of Health, State B: "I have more bad news. We are going to see cases for months after we get these outbreaks under control."

INTRODUCTION

Shortly after the 2001 anthrax attacks, in which five Americans were killed and 17 were sickened in what is widely considered the worst biological attack in United States (US) history, the Executive and Legislative Branches of our government made significant investments to improve America's ability to respond to bioterrorism. The government also invested in the development of SLTT response capability and capacity. Some of the newly established federal and SLTT programs were successful, but many subsequently languished as recurring budget cuts and declining awareness of the biological threat rendered them ineffective.

Eight years later, in 2009, political interest once again focused on a biological incident, only this time it was pandemic influenza. That is when H1N1 cases first appeared in Mexico and the United States, despite the prevailing assumption that an influenza pandemic would begin in Asia. The United States scrambled to manage H1N1 outbreaks. Increased congressional interest resulted in several hearings, and the US House of Representatives Committee on Homeland Security issued a report entitled, *Getting Beyond Getting Ready for Pandemic Influenza*.[3] Despite this additional attention, Congress added little to existing legislation at the time. While governors, mayors, and other locally elected officials throughout the country expressed serious concern, they concentrated most of their efforts on managing the spread of the disease and communicating to their constituents. Then-Governor of Maryland Martin O'Malley and former Representative (now Senator) Chris Van Hollen launched a summit of federal and non-federal stakeholders on the campus of the National Institutes of Health to address pandemic influenza,[4] but aside from vocally supporting the need for vastly improved national preparedness and response, they directed most of their attention to Maryland's response to the H1N1 pandemic.

Elected officials set priorities in their SLTT budgets to address hazards that occur frequently in their jurisdictions or that place their jurisdictions at risk. For some hazards (e.g., energy grid blackouts, hurricanes, tornadoes), combinations of voluntary SLTT and federally mandated programs contribute to preparedness. The infrequency of epidemics and pandemics means they rarely attract enough political attention to produce the proactive legislation

and sustained funding needed to support SLTT and national preparedness, response, and recovery. The public and its elected officials tolerate far more disease (e.g., the thousands of cases of Chikungunya still prevalent in Florida, New York, and Puerto Rico) than they should.

How we respond to biological events–especially those large in scale and impact– is now out of balance with how we prepare. Currently, SLTT entities respond immediately to these events, only to wait for federal support to follow. In January 2018 at the University of Miami, the Panel held a special focus meeting to examine the situation. Co-chaired by former Secretary of Health and Human Services Donna E. Shalala and former US Representative James C. Greenwood, this daylong meeting allowed current and former SLTT officials, academics, and private sector experts to describe the difficulties they face on the front line of biodefense. They made it clear that although the country has made progress since 2001, SLTT personnel require additional support from the federal government to ensure that the states, localities, tribes, and territories are better prepared for large-scale biological events. Based on the input received during the meeting and additional research, the Panel developed the following policy recommendations to improve preparedness, response, and recovery by SLTT emergency medical services (EMS), pharmacies, hospitals, laboratories, and public health departments. These recommendations build on those found in the Panel's 2015 report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts (Blueprint for Biodefense)* and other Panel publications.

FORTIFY EMERGENCY MEDICAL SERVICES

Local EMS, firefighters, and police will be among the first to respond to a biological event. In most cases, they will not know which disease they are dealing with. It will be too early for anything but cursory, preliminary diagnosis and identification.

During the late 1990s, some EMS and other first responders received training and participated in exercises based on several biological (and chemical) scenarios as part of the Nunn-Lugar-Domenici Domestic Preparedness Initiative.[5] However, the anthrax events of 2001 resulted in a narrow policy perspective—that the nation should prepare mostly for anthrax. This perspective was based on some false assumptions which included: (1) if we could not prepare for anthrax, we could not prepare for any other biological agent; and (2) the use of anthrax once meant that using anthrax again would be easier and more likely than an attack with any other biological agent. Subsequently, support for even anthrax preparedness declined in favor of funding all-hazards preparedness, making biological hazards just one of many threats to consider. Today, many of those previously trained under the Domestic Preparedness Initiative have retired, and current EMS and other first responders receive little or no training in how to deal with biological agents and those infected with them.

Recognizing the critical role that emergency service providers play in preparing for, responding to, and recovering from biological events, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

Recommendation 15: Provide emergency service providers with the resources they need to keep themselves and their families safe.

ACTION ITEMS

a. Provide vaccines to responders who request them.

b. Provide medkits to emergency service providers and their families.

c. Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.

In November 2016, the Obama Administration updated the National Response Framework, assigning responsibility for the management and direction of emergency medical response assets (including EMS) to the Secretary of Health and Human Services during large-scale emergencies and disasters.[6] This policy is in keeping with the other emergency medical responsibilities of the Department of Health and Human Services (HHS) during such events,

but the federal government's role in this area has largely been limited to the Federal Emergency Management Agency (FEMA) national ambulance contract, implemented by HHS to coordinate patient transportation. The Department of Transportation (DOT) has historically been the most active federal department with regard to EMS and has shared responsibility for it with the Department of Defense (DOD), DHS, HHS, and Federal Communications Commission. HHS and DOT have not yet developed coordinated plans and policies, leaving deployed EMS assets without equipment, support, and direction when they need it most–during disaster response.

EMS providers receive inadequate funding and reimbursements for the pre-hospital emergency health care that they provide. While SLTT governments, DHS, and HHS provide some operational funding through grant programs, medical reimbursements fall under the sole domain of HHS via the Centers for Medicare and Medicaid Services (CMS). CMS and commercial insurance do reimburse EMS for transportation services (i.e., when EMS transports patients to hospitals), in keeping with the transportation priority placed on EMS more than 50 years ago. Today, however, EMS professionals are also responsible for pre-hospital health care, and in some rural areas are also considered part of the public health community. Despite the dependence of patient survival and other outcomes on high-quality and immediate treatment well before entering a hospital or other health care establishment, EMS professionals receive very few additional reimbursements or payments for the health care they deliver. Reimbursement-based funding requires EMS to provide services in routine and disaster situations before reimbursement occurs and does not pay for readiness activities beforehand to do so.

To rectify this, the Panel believes it is necessary to:

Unify and establish a new National EMS System. Current demands far exceed requirements for rapid transportation and limited treatment that Congress originally envisioned for EMS more than 50 years ago. It is time to provide a federal home for EMS that is responsible for developing policy and serving as an advocate for preparedness, quality, funding, and reimbursement.

ACTION ITEMS

a. **Assess SLTT EMS capability to respond to biological terrorism and warfare.** Congress should amend the Defense Against Weapons of Mass Destruction Act of 1996 (Title XIV, Public Law 104-201) to require the Secretary of Defense, Secretary of Health and Human Services, Secretary of Homeland Security, and Secretary of Transportation to submit a report to Congress containing: (1) an assessment of the ability of SLTT EMS and the federal government to provide emergency medical services in response to domestic terrorist incidents involving biological weapons; (2) needed improvements; (3) measures to achieve such improvements (including additional resources and legislative authorities required); and (4) federal support of SLTT EMS preparedness, response, and recovery efforts.

b. **Establish a biological emergency response assistance program.** Congress should amend the Defense Against Weapons of Mass Destruction Act of 1996 (Title XIV, Public Law 104-201) to require the Secretary of Defense, Secretary of Health and Human Services, Administrator of the FEMA, and Administrator of the Environmental Protection Agency (EPA) to provide SLTT EMS and other first responders with training and expert advice regarding emergency response to the use or threatened use of biological weapons, including biological weapons of mass destruction, biological agents, and related materials. Assistance available under this program should include training in the use, operation, and maintenance of equipment for: (1) detecting biological agents; (2) monitoring the presence of such biological agents; (3) protecting emergency personnel and the public; and (4) decontamination.

c. **Review extent and quality of EMS.** Congress should direct the Secretary of Health and Human Services, in collaboration with the Secretary of Defense, Secretary

of Homeland Security, and Secretary of Transportation, to conduct a national EMS assessment, and periodic, comprehensive, and independent reviews and evaluations regarding the extent and quality of EMS provided throughout the nation. Congress should direct the Secretary of Health and Human Services to prepare and submit annually to Congress a report on EMS that includes: (1) an evaluation of the adequacy of EMS in the United States during the period covered by the report; (2) an evaluation of the extent to which such services are adequately reimbursed by CMS, other health insurance programs, and all federal EMS grant programs; (3) an evaluation of the alignment of preparedness grant funds across all grantmaking federal agencies; and (4) recommendations for legislation needed to provide adequate SLTT EMS.

d. **Inform the delivery of EMS during large-scale biological events, mass casualty events, disasters, and other national emergencies.** The Secretary of Health and Human Services, in coordination with the Secretary of Defense and Secretary of Transportation, and in consultation with the Administrator of FEMA, should provide criteria, guidance, and instructions to inform the delivery of EMS during large-scale biological events, mass casualty events, disasters, and other national emergencies, in keeping with ESF-8. The Secretary of Health and Human Services should direct the Assistant Secretary for Preparedness and Response (ASPR) to provide technical assistance, subject matter expertise, and direct program services to help SLTT EMS prepare for, respond to, and recover from disasters, large-scale biological events, mass casualty events, and other national emergencies.

e. **Expand medical necessity rules for EMS reimbursement regarding pre-hospital health care.** Congress should direct the Administrator of CMS, in collaboration with the ASPR and EMS providers, to expand medical necessity rules for EMS reimbursement, ensuring comprehensiveness

without reimbursing unnecessary ambulance trips, while also providing necessary pre-hospital health care to all patients requiring such services without prior inquiry as to the ability to pay. This may include mechanisms such as amending the Social Security Act to make EMS a provider type, as recommended previously by the National Academies of Science, Engineering and Medicine.[7]

f. **Establish a National EMS Agency.** Congress should amend the Public Health Service Act of 1944 (P.L. 78-410, 58 Stat. 682, 42 U.S.C. ch. 6A, § 201 et seq.) and the Highway Safety Act of 1966 (P.L. 89-564, 80 Stat. 731) to create a cohesive national EMS program under the purview of HHS, in coordination with DHS, DOD, and DOT, and in consultation with FEMA. Congress should direct the Secretary of Transportation to transfer EMS responsibilities of the National Highway Traffic Safety Administration Office of Emergency Medical Services to the Secretary of Health and Human Services regarding federal coordination and collaboration, federal planning, development of curricula standards and training guidelines, and the development and imposition of other EMS standards responsibilities. Congress should transfer relevant appropriations from DOT to HHS for this purpose. The Secretary of Health and Human Services should establish the National EMS Agency within the Office of the ASPR.

IMPROVE STOCKPILE DISTRIBUTION AND PHARMACY READINESS

The CDC is not responsible for distributing the contents of SNS pallets when they arrive at a locality. The CDC trains SLTT personnel (with an emphasis on the Urban Area Security Initiative jurisdictions) to execute this responsibility and establish point(s) of distribution in advance of SNS deployments. Many SLTT personnel feel that this training is inadequate and that training pallets should contain more than just contents to respond to anthrax. The CDC also reports dissatisfaction with SLTT training performance. While all levels of government recognize the need for and value of training, the program has yet to yield broadly acceptable results.

Recognizing the pressing need for life-saving medicines and medical supplies when biological events exceed SLTT resources, and the benefit of prepositioning some medical countermeasures (MCM) and other contents of the Strategic National Stockpile (SNS) in or near high-risk localities, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

Recommendation 23: Allow for forward deployment of Strategic National Stockpile assets.

ACTION ITEMS

a. Determine logistics and funding needs.

b. Implement forward deployments.

Public bystanders are often the first to respond to emergencies in their immediate vicinity. Recognizing this, the Red Cross increased its efforts to train the public in first aid, cardiopulmonary resuscitation, and automated external defibrillation. As a result, more people know how to respond in a variety of emergencies, and many workplaces and public spaces possess first aid kits and automated external defibrillators. Charlotte Douglas Airport in North Carolina also emplaced public access bleeding control kits in areas where shootings and other events could cause excessive blood loss. While helpful, previous training is not necessary to use these first aid kits, defibrillators, or bleeding control kits. Easy-to-follow directions are provided, and the public has neither stolen nor destroyed these openly available medical supplies and equipment. The public must be similarly prepared to take reasonable steps to care for themselves, their families, and their neighbors as a critical element of national preparedness for biological events.

The pharmaceutical distribution and sales systems in the United States are pervasive and familiar to the public. The public already obtains over-the-counter and prescription drugs, as well as essential medical supplies, from their local pharmacies. The government has worked with health care distributors and pharmacy chains to distribute medicines during crises. Delays occurred without formal agreements in place ahead of time, but otherwise, this public-private partnership worked well during recent emergencies.

The CDC Division of Strategic National Stockpile works with industry partners to improve SNS resiliency by monitoring commercial supply chain inventory, increasing access to personal protective equipment and MCM, and allowing for redundant distribution of MCM, information, and material. However, to ensure that the public can obtain the medicines, medical equipment, and other essential medical supplies they need (whether or not the contents of the SNS are deployed), the federal government requires data regarding pharmacy readiness, operational status, and capacities so that it can assist SLTT response to and recovery from large-scale biological events and disasters. Healthcare Ready, a private sector 501(c)(3) organization, gathers these data and helps the private sector communicate that information to the public sector (i.e., HHS, SLTT departments of health).[10] Private sector funding makes this information sharing possible. Should Healthcare Ready be unable to obtain enough private sector funding to support itself, SLTT and federal governmental entities will lose access to these data, leaving the US government without the information upon which it has come to depend during disasters.

To rectify and address these issues, the Panel believes it is necessary to:

Improve distribution of pharmaceuticals, medical equipment, and other essential medical supplies needed to treat those affected by large-scale biological events.

ACTION ITEMS

a. **Improve, expand, enhance, and sustain SLTT training to receive and distribute SNS contents.** Congress should amend the Public Health Service Act (P.L. 78-410) to require the ASPR and the CDC Division of State and Local Readiness to work with SLTT stakeholders to improve

existing SNS training offerings, taking into consideration current limited SLTT abilities to distribute SNS pallets upon receipt. In executing this directive, the ASPR and CDC should build on previous experiences working with private sector entities (e.g., pharmacy chains) to distribute pharmaceuticals for public health purposes, include this option in plans, and train accordingly. Congress should also amend the Public Health Service Act (P.L. 78-410) to direct the CDC to immediately develop and make available training pallets for some naturally occurring infectious diseases and biological agents that would require SNS contents that are different from or in addition to those deployed for anthrax.

b. **Ensure availability and access to pharmacy readiness data.** The ASPR cannot assume that Healthcare Ready will always receive enough funding from industry to gather and provide these data to HHS. A cooperative agreement recognizes that both the federal government and a non-federal organization should work together to achieve outcomes that support society. The ASPR should enter into a cooperative agreement to ensure that public (including HHS) and private sector entities know whether pharmacies are still capable of operating in areas stricken by large-scale biological events and disasters.

INCREASE HEALTH CARE SURGE CAPACITY

Many hospitals and other health care entities operate at and often beyond capacity, trying to meet the needs of the communities they serve. They do not possess the excess capacity needed to respond to large-scale biological events. In the absence of government-issued quarantine and isolation orders confining the ill and those possibly exposed to specific geographic areas, the public will flood their local hospitals. The usual actions taken when they reach capacity (e.g., temporary diversion of patients from an emergency room when it is full) will not be an option since health care deliverers in surrounding areas will also be affected.

Some health care professionals insist that regardless of scale, hospitals and other health care entities will respond to biological events by surging their regular activities the same way they already frequently do. They will seek to maintain the standard of care for every patient, until their facilities' resources disappear. Many health care and public health disaster response professionals disagree—they believe that surging regular activities will be insufficient to respond adequately to large-scale biological events and that regular surge experience will prove no match

Recognizing that hospitals and other health care entities (e.g., medical clinics, community health centers, long-term care facilities) across the nation lack adequate guidance and resources to respond to large-scale biological events, the Panel issued the following recommendations in its 2015 *Blueprint for Biodefense*:

Recommendation 18: Establish and utilize a standard process to develop and issue clinical infection control guidelines for biological events.

ACTION ITEMS

a. Standardize the development of clinical infection control guidelines before biological events occur.

b. Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.

c. Require training based on these guidelines.

Recommendation 19: Minimize redirection of Hospital Preparedness Program funds.

ACTION ITEMS

a. Cap Hospital Preparedness Program management and administration costs at three percent.

b. Assess the impact of the Hospital Preparedness Program.

for thousands of patients seeking medical treatment simultaneously, over a prolonged period. The health care and public health communities will only be able to provide what care they can to the largest number of people, not the highest quality of care to each individual in every circumstance. There is little in the law, however, that allows for altered health care delivery requirements, even in such resource-constrained circumstances.

Recommendation 20: Provide the financial incentives hospitals need to prepare for biological events.

ACTION ITEMS

a. Adopt a disaster preparedness portfolio.

b. Link Centers for Medicare and Medicaid Services incentives and reimbursement to new accreditation standards.

Recommendation 21: Establish a biodefense hospital system.

ACTION ITEMS

a. Stratify hospitals.

b. Develop accreditation standards for each stratum.

c. Associate Centers for Medicare and Medicaid Services funding.

Health care leaders also often assume that: (1) biological emergencies affecting health care entities either do not occur or occur rarely; and (2) biological events that exceed capability to deliver patient care are and will not be the norm. Unfortunately, the impact of a poor medical response to a critical incident can be enough to ruin reputations, close departments, lose funding, and shutter health care institutions.[11] Many lives need not be lost for the public to lose confidence in the ability of a hospital or other health care entity to provide health care. Administrators, chief executive officers, and board members acknowledge the negative impact on profit and attendant loss in revenue if biological emergencies occur and biological events exceed health care response capabilities. They may also recognize that biological events threaten the communities in which they operate, but they consistently underestimate the biological risk faced by their institutions.

Current federal programs and directives to fund and require preparedness for biological terrorism and other biological events that could affect national security (e.g., Hospital Preparedness Program, Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers[12]) do not provide hospitals and other health care entities with enough financial incentive to pay for and maintain unused capability. Reactionary grants, hurried transfers of funds from one program to another,

and emergency supplemental funding also demonstrate that the nation does not provide enough advance funding to help the health care community respond to disease events that exceed normal crisis thresholds.

Business priorities also place health care entities and alliances at odds with health care coalitions. With alliances, health care organizations affiliate with each other, augmenting individual member offerings and allowing members to leverage other institutional brands. On the other hand, coalitions of health care entities work together, sharing resources within the geographic bounds associated with their accreditation and addressing the needs of those they strive to serve. While coalitions take a softer view on the profit orientation of competition, they realize greater profits and sustain fewer losses during those emergencies that exceed the capacity of independent health care institutions and alliances. Unfortunately, coalitions composed of interdependent health care entities can also be difficult to manage because what affects one member of such a group affects them all. It may be that a weak link brings down the entire enterprise and that a significant stressor to the system causes the entire system to fail at once.

To rectify and address these issues, the Panel believes it is necessary to:

Establish a national stratified health care delivery system capable of surging medically to respond to large-scale biological events. Hospitals in any region in the United States must be able to surge medically to respond to and recover from large-scale biological events.

ACTION ITEMS

a. **Establish medical surge capability and capacity for large-scale biological events.** The Administrator of CMS should make planning to surge medically part of accreditation requirements for hospitals that receive CMS funding. In addition to CDC, other HHS agencies (e.g., Agency for Health Research and Quality) and offices, the Occupational Safety and Health Administration, and by extension, the Department of Labor, should issue guidelines and performance standards for medical surge.

Congress should amend the Public Health Service Act (P.L. 78-410) to allow for more flexible treatment options when biological events rapidly drain and eventually deplete available resources and require the Secretary of Health and Human Services to undertake a national assessment of infection control resources and infrastructure.

b. **Communicate the business case for a stratified biodefense health care delivery system.** The Administrator of CMS and ASPR should work together with the American Hospital Association to develop and communicate a comprehensive business case for a national stratified biodefense health care delivery system. This business case should, at a minimum, address the potential for increasing or maintaining profit margins, decreasing losses, and reducing risk to reputation when hospitals are called upon to treat patients infected with dangerous pathogens.

c. **Assess risk to reputation.** Regardless of disease type or assessment of potential exposure of patients who may be treated in the future, hospitals and other health care entities should assess risk to their reputation by: (1) learning from the negative experience of other health care entities who dealt with disease events previously; and (2) surveying the communities they serve to determine how poor management of a disease event would impact patient utilization of their facilities.

AUGMENT LABORATORY RESPONSE

Public health and public safety officials need to identify the organism they are dealing with in order to respond effectively and efficiently to a biological event. Quick and geographically close laboratory testing is critical for effective decision-making, disease management, and law enforcement. Not all laboratories, however, possess the same capabilities, biosafety, or biosecurity. As with hospitals, they lend themselves naturally to stratification and the creation of networks.

Laboratory networks exist that test for biological agents and infectious diseases that could affect national security. President William J. Clinton issued Presidential Decision Directive 39: US Policy on Counterterrorism in 1995. Four years later, the CDC worked with the Federal Bureau of Investigation (FBI) and Association of Public Health Laboratories (APHL) to establish the Laboratory Response Network for Bioterrorism (LRN) (now called the LRN for Biological Threats) in 1999, partially fulfilling the requirement for HHS to identify biological agents and provide health care, pharmaceutical, and public health support to counter biological terrorism. As the first among laboratory networks (many of which are still in nascent developmental stages twenty years later) established by federal departments and agencies, the LRN proved its mettle by testing thousands of white powder specimens during the anthrax events of 2001. It continues to test many specimens suspected of containing anthrax and other biological agents, as well as additional dangerous pathogens such as severe acute respiratory syndrome (SARS), influenza, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Ebola, and Zika. LRN

Recognizing the value of a laboratory network regarding animal and zoonotic diseases, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

Recommendation 14: Improve surveillance of, and planning for, animal and zoonotic disease outbreaks.

ACTION ITEMS

b. Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.

The Panel reiterated this recommendation in its 2017 report, *Defense of Animal Agriculture*, stating that:

Congress should continue to fund the National Animal Health Laboratory Network in [Fiscal Year] 2018 and thereafter at no less than authorized levels, leaving open the possibility that additional funds may be required to fulfill the Network's mission as the need to rapidly diagnose outbreaks grows.

laboratories use standardized protocols, providing valid and reliable results to decision makers and discoverable information for legal proceedings.

Despite the remarkable success of the LRN and its stellar partnerships with non-traditional public health agencies (e.g., law enforcement) and private institutions (e.g., clinical laboratories, universities), Congress has never authorized the LRN. This poses a problem for congressional oversight, especially since the LRN is composed of several types of laboratories (both public and private sector) that receive funding from a variety of governmental sources. Dedicated funding for the LRN is also at risk whenever Congress decreases or changes appropriations for the CDC (which provides funding to state and local health departments via the Public Health Emergency Preparedness Cooperative Agreement, and to APHL to support the operations and management of the LRN through a cooperative agreement).

In addition to the LRN, other laboratory networks have been established and are in various stages of development. These are the: DOD Laboratory Network, Environmental Response Laboratory Network (funded by EPA), Food Emergency Response Network (funded by the Department of Agriculture (USDA) and the Food and Drug Administration (FDA)), NAHLN (funded by USDA), National Plant Diagnostic Network (funded by USDA), and the Veterinary Laboratory Investigation and Response Network (funded by FDA).[13] Of these, only the NAHLN has been authorized by Congress. Each of these networks is organized differently, with varying component laboratories. All are stratified to some extent, and all but the DOD Laboratory Network claim some non-federal governmental laboratories as members. Federal departments and agencies provide varying levels of support to these networks and do not place equal priority on the development of needed laboratory capability and capacity. The resultant patchwork is weak, with insufficient congressional oversight and inadequate appropriations.

To rectify and address these issues, the Panel believes it is necessary to:

Authorize all laboratory networks that test for biological agents. Laboratory networks provide critical data in support of preparedness for, surveillance and detection of, response to, attribution of, and recovery from biological events.

ACTION ITEMS

a. **Authorize and fund the Laboratory Response Network for Biological Threats.** While the LRN is well regarded and supported, the complicated nature of its membership and dependence on CDC for funding via cooperative agreements put the Network at risk. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services to enter into cooperative agreements, contracts, grants, or other legal instruments with eligible laboratories to formalize the LRN. Congress should require those territories with public health laboratories to join the LRN. Congress should authorize and appropriate $200,000,000 annually to carry out these requirements.

b. **Authorize and fund the Environmental Response Laboratory Network, Food Emergency Response Network, National Plant Diagnostic Network, and Veterinary Laboratory Investigation and Response Network.** Congress should amend the: (1) Farm Bill (P.L. 113-79) to authorize the National Plant Diagnostic Network under the auspices of USDA; (2) Farm Bill (P.L. 113-79) and Federal Food, Drug, and Cosmetic Act (P.L. 75-717) to authorize the Food Emergency Response Network under the auspices of USDA and FDA; (3) National Environmental Policy Act (P.L. 91-190) to authorize the Environmental Response Laboratory Network under the auspices of EPA; and (4) Federal Food, Drug, and Cosmetic Act (P.L. 75-717) to authorize the Veterinary Laboratory Investigation and Response Network under the auspices of FDA. Congress should direct each of these departments and agencies to enter into cooperative agreements, contracts, grants, or other legal instruments with eligible laboratories to formalize these networks. Congress should require those territories with public health laboratories to join these networks.

c. **Establish requirements for all laboratory networks that test for biological agents.** Congress should direct the Secretary of Agriculture, Secretary of Health and Human Services, Administrator of EPA, and Commissioner of FDA, to better defend against novel, emerging, reemerging, or existing intentionally introduced, naturally occurring, and accidentally released biological threats to public health in a timely manner by establishing: (1) standards and interoperable data formats; (2) necessary capacity and capability to utilize standardized test procedures, reference materials, and equipment; (3) laboratory biosafety and biosecurity positions and requirements; (4) quality management system requirements; (5) chain-of-custody and other evidentiary requirements as established and communicated by the FBI; (6) rapid electronic reporting, exchange, and transmission of data; and (7) evaluation requirements for emergency preparedness, detection, response, attribution, and recovery. To the extent practicable and to the extent capacity and specialized expertise may be necessary, priority should be given to existing state, local, and territorial laboratory facilities that are already executing these responsibilities.

Managing Department/Agency	Laboratory Network
DOD	DOD Laboratory Network
CDC	Laboratory Response Network for Biological Threats
USDA	National Animal Health Laboratory Network
USDA	National Plant Diagnostic Network
USDA and FDA	Food Emergency Response Network
EPA	Environmental Response Laboratory Network
FDA	Veterinary Laboratory Investigation and Response Network

RECTIFY SHORTFALLS IN TRIBAL PUBLIC HEALTH EMERGENCY PREPAREDNESS

American Indian and Alaska Native (AI/AN) tribes are sovereign entities with inherent authority to govern themselves and their own governance structures. As such, the tribes are entities separate from states, localities, and territories. Furthermore, AI/AN tribes have a unique relationship with the federal government that is shaped by the federal Indian trust responsibility—which is in turn constructed by federal law, legal precedence, and treaties entered into with the tribes. The federal trust responsibility embodies the promise that the federal government made to support the prosperity and health of the tribes.

Federally recognized AI/AN tribes are not eligible to enter into their own PHEP cooperative agreements with the CDC. Instead, tribes are forced to work with state and local public health entities to receive PHEP support, sometimes as part of a pass-through arrangement. The CDC encourages, but does not require, states to work with or fund tribes within their jurisdictions as a component of their respective PHEP cooperative agreements.

The CDC Public Health Emergency Preparedness Cooperative Agreements currently makes funds available to 50 state, 4 local,[14] and 8 territorial[15]—but no tribal—public health departments to strengthen their ability to respond to a variety of threats and associated emergencies. Many heavily rely on these funds to support their public health emergency preparedness efforts. Without this funding, they would not have sufficient resources for necessary staffing, supplies, planning, training, and exercises.[16] Various Administrations and Congresses have repeatedly cut funding for the Public Health Emergency Preparedness (PHEP) program. To rectify this issue, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

Recommendation 17: Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels.

ACTION ITEMS

a. Appropriate PHEP funding to authorized levels or the President's Budget Request, whichever is higher.

With hundreds of federally-recognized tribes and tribal entities, tribal public health needs and the appropriate funding and structures to address those needs understandably vary. Current funding to the states, however, does not adequately take the emergency preparedness needs of the tribes into account. Without direct allocations from the PHEP, tribes are only able to

dialogue with states about how preparedness funds could be utilized for the benefit of the tribes. Without direct funding, tribes lack the ability to direct their own planning and determine for themselves the best approach to invest preparedness resources.

In recognition of the need for dedicated resources for AI/AN tribes, CDC recently issued separate funding opportunities to bolster tribal public health infrastructure, providing limited funding relative to the need and to no more than 25 tribes. This program focuses on building and implementing basic public health infrastructure. It does not incorporate the emergency preparedness and response capabilities required by the PHEP.

To rectify and address these issues, the Panel believes it is necessary to:

Give federally recognized American Indian and Alaska Native tribes the opportunity to enter into their own Public Health Emergency Preparedness cooperative agreements and obtain technical assistance. Congress and the Administration must make public health emergency preparedness part of the federal Indian trust responsibility to support the health of the tribes. The tribes, as sovereign entities, have the right to decide for themselves how to direct and shape public health emergency preparedness for their communities. They deserve to apply for and utilize PHEP funding directly.

ACTION ITEMS

a. **Make PHEP funding available directly to the tribes.** Congress should amend the Public Health Service Act (P.L. 78-410) to authorize and fund the CDC to make PHEP tribal cooperative agreements directly available to the 573 federally-recognized tribes,[17] establish eligibility criteria, and increase CDC PHEP program funding and operations accordingly. Not every tribe will choose to receive their funding directly from CDC, but all tribes should be afforded the opportunity to make their own determination. This approach should offer flexibility to those tribes that cannot or do not want to support their own, separate

public health emergency preparedness programs, allowing them to continue to enter into agreements with states and localities to support these activities.

b. **Proactively bolster tribal public health emergency preparedness.** The Director of CDC, in collaboration and coordination with the Director of the Indian Health Services (IHS), should provide annual guidance and technical assistance to help tribal health departments with strategic planning and emergency public health preparedness. Through its Center for State, Tribal, Local, and Territorial Support, and Office of Tribal Affairs and Strategic Alliances, the CDC should utilize permanent tribal liaisons to conduct regular outreach and education to tribal governments (including direct consultations and site visits when requested) regarding funding opportunities and use of public health preparedness funds. CDC should also place tribal liaisons in each of its other centers, to ensure that they consider tribal needs. Federal technical assistance should address tribal public health emergency preparedness and response, the conduct of exercises, and how to establish and meet preparedness and response-oriented performance goals.

c. **Strengthen tribal epidemiology.** Congress should increase appropriations to the IHS for the purpose of strengthening tribal epidemiology centers (TECs) with additional funding. The IHS should develop criteria for allocating resources to the TECs, in consultation with tribal representatives and the National Indian Health Board.

OVERCOME BARRIERS TO TERRITORIAL BIOSURVEILLANCE AND EMERGENCY RESPONSE

The federal government recognizes the value of SLTT biosurveillance efforts and has invested resources through grants and cooperative agreements to further enhance non-federal vigilance for biological threats. Unfortunately, the federal government has not always issued guidance along with this funding to ensure that those monies are effectively utilized to prepare for major public health emergencies.

Recognizing the gulf between federal biosurveillance activities and those of their SLTT counterparts, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

Recommendation 12: Empower non-federal entities to become equal biosurveillance partners.

ACTION ITEMS

a. Create an interagency biosurveillance planning committee.

Planning and training must also take into consideration the specific needs of US insular areas (i.e., US territories and the freely associated states)[18] that receive direct public health preparedness assistance from the federal government. These areas face different logistical and resource challenges than the rest of the United States. Even with the funds provided through programs like PHEP, insular areas often do not have enough public health infrastructure or plans in place to respond to biological threats on their own. The quality of biosurveillance programs varies among insular areas, and they find it difficult to produce and obtain data. Despite their locations and the ease with which to travel through them to other areas in the United States, the federal government has yet to establish the robust biosurveillance needed to ensure national security.

Territories and other insular areas continue to find it very difficult to scale up their response to large public health emergencies, partly because geographical and policy constraints prevent them from obtaining needed medical supplies. For example, in September 2017, Hurricane Maria devastated Puerto Rico, including much of its public health infrastructure. In the aftermath of the storm, long-standing federal shipping policies prevented the territory's officials from obtaining basic supplies and other essential medical resources. Section 27 of the Merchant Marine Act (P.L. 66-261), also known as the Jones Act, requires that only US vessels carry goods shipped to Alaska, Hawaii, and Puerto Rico

from any other US port. Oftentimes, the other US territories are also impacted, as their shipping routes include these two states or Puerto Rico. Though not the primary cause of the slow public health response, the Jones Act did inhibit the ability of the US mainland to send supplies to Puerto Rico in the days and weeks after Hurricane Maria made landfall.

To rectify and address these issues, the Panel believes it is necessary to:

Provide US insular areas with robust public health preparedness and response tools. The federal government must increase its engagement with the territories and freely associated states and share its expertise to assist them in fully leveraging public health resources.

ACTION ITEMS

a. **Provide enhanced planning and technical assistance.** The Director of CDC should provide insular areas with the technical assistance necessary to plan for large-scale biological events, focusing on tailored and generally applicable preparedness goals and regular exercises to test the capabilities of their public health systems. Plans should take existing resource limitations into account and maximize available assets to help the territories and freely associated states better prepare for, respond to, and recover from public health crises and large-scale biological events.

b. **Strengthen biosurveillance and data collection.** Congress should amend the Public Health Service Act (P.L. 78-410) to require the Secretary of Health and Human Services, in coordination with the Secretary of State, Secretary of Defense, and Secretary of Homeland Security, to develop and enhance the biosurveillance capabilities of each US territory and freely associated state. This includes close collaboration with the insular governments to establish permanent monitoring systems with technical and diagnostic reachback to the CDC. The Department of

State, DOD, DHS, and HHS should also develop a platform for sharing and integrating data obtained from these biosurveillance efforts.

c. **Reduce barriers to transporting resources during a public health emergency.** Congress should amend Section 27 of the Merchant Marine Act of 1920 (P.L. 66-261) to allow automatic, emergency exemptions from Jones Act shipping requirements whenever the Secretary of Health and Human Services declares a public health emergency, or when there has been a declaration made under the Stafford Act that applies to Alaska, Hawaii, or the insular area in question. Congress should also direct the Secretary of Homeland Security, acting through the Administrator of FEMA, in coordination with the Secretary of Health and Human Services, the Secretary of Defense, the Secretary of State, and other relevant federal agencies, to: (1) evaluate challenges to transporting supplies and personnel to US insular areas immediately before and during public health emergencies; (2) develop recommendations to address those challenges; and (3) produce a deployment strategy that assigns roles and responsibilities throughout the federal government. As part of this evaluation, FEMA should consult with the territories and freely associated states, US states that may be called upon to support insular emergency response, associations with territorial members or interests, and the American Red Cross.

ALLOCATE RESPONSE FUNDING BEFORE BIOLOGICAL CRISES OCCUR

Existing statutory language for the Public Health Emergency Fund (42 U.S. Code § 247d (b)) inadequately describes how the Fund can be used. On the few occasions where the account was previously funded and utilized, congressional appropriations only addressed specific threats. This leaves Congress with little information regarding how well the Fund would work as originally conceived. There is also no consensus regarding how much funding would be needed, or how use of the Fund could improve response to public health emergencies. As a result, Congress has been reluctant to provide additional appropriations for the PHEF.

Congress must examine the utility of the Fund and clearly identify triggers, eligible activities, and accountability. Currently, funds can only be dispensed when the Secretary of Health and Human Services makes a public health emergency declaration. However, funding may be needed to get ahead of biological threats before they reach the nation's borders—well before the Secretary declares a public health emergency. Congress has yet to consider additional triggers (e.g., presidential declaration) to release resources from the PHEF.

The Panel addressed domestic public health emergency funding in its 2018 report, *Budget Reform for Biodefense: Integrated Budget Needed to Increase Return on Investment*. In this report, the Panel stated that the nation requires:

A rapid response fund triggered not only by a declared public health emergency, but also, at times, in advance of any such declaration to preempt a major problem. Congressional proposals to seed such a fund have ranged from $300 million to $5 billion.

ACTION ITEMS

a. Infuse no less than $2 billion into the Public Health Emergency Fund (PHEF).
b. Commit to regular annual appropriations for the PHEF.
c. Provide guidance on triggers for PHEF.
d. Update criteria for events covered by PHEF.

Not all response activities should wait until after biological events occur. Success greatly depends upon the commitment of readily available funding before such events occur, and at levels exceeding those currently available for public health emergency preparedness, response, and recovery activities. Waiting for supplemental appropriations could leave the nation's public health

community without the emergency funding it needs to address large-scale biological events. Other emergency funding sources (e.g., the Commodity Credit Corporation, the Disaster Relief Fund) may also be applicable should a catastrophic biological event occur, keeping in mind that they are not intended to replace or augment appropriations made for other federal departments and agencies. FEMA previously considered pandemic influenza and the possibility of providing assistance to states and territories under the Stafford Act.[19] Although current FEMA policy and guidance allows for direct federal assistance to state, tribal, and territorial governments under a Stafford Act emergency declaration,[20] further clarification is needed regarding eligibility for this assistance.

To rectify and address these issues, the Panel believes it is necessary to:

Ensure consistent, adequate response funding and guidance for public health emergencies. Even with a robust, preparedness-oriented public health system in place, the need for sustained, reliable response funding to address biological threats will always exist. Dedicated funding, combined with support from existing response funds, will reduce response times and save lives during large-scale biological events.

ACTION ITEMS

a. **Reform the PHEF to ensure clarity of use, transparency, and accountability.** Congress should amend the Public Health Service Act (42 U.S. Code § 247d(b)) to clarify the structure of the PHEF and the categories of activities eligible to receive assistance. Congress should determine eligibility criteria for assistance, include robust accountability mechanisms, and consider circumstances for distribution of funding outside of public health emergency declarations made by the Secretary of Health and Human Services. Although Congress should allocate funding primarily for immediate emergency response to biological threats, Congress should also make funding available for certain other activities (e.g., time-sensitive

research, development of medical countermeasures) that could assist in responding to future outbreaks, events for which appropriations are not otherwise already available.

b. **Clarify SLTT eligibility for biological disaster assistance under the Stafford Act.** Large-scale biological events in the United States would drive the governors to declare states of emergency, request presidential emergency and disaster declarations, and apply for disaster assistance. FEMA should clarify eligibility for direct federal assistance under the Stafford Act to states, localities, tribes, and territories during declared emergencies involving pandemic influenza and other biological agents with large-scale consequences.

c. **Delineate HHS and FEMA assistance to SLTT governments for public health emergency response.** Congress should require HHS and FEMA to provide: (1) a report on the assistance they will offer states, localities, tribes, and territories;[21] (2) an action plan for future coordination; and (3) additional guidance for SLTT officials regarding federal public health emergency response assistance and coordination. In addition to the information regarding federal responsibilities found in the National Response Framework, HHS and FEMA should establish a memorandum of understanding to better define the SLTT assistance they each would provide during large-scale biological events.

ASSUME BROADER LEADERSHIP OF BIODEFENSE

The US system of federalism affords states a great deal of autonomy. The state governors, territorial governors and administrators, mayors, and other elected officials are powerful and responsible for setting goals and objectives for their own jurisdictions. They can and must set their own requirements for preparedness, response, and recovery well before biological events occur.

Political leaders will find themselves in situations where they must make tough decisions, particularly in the face of potentially catastrophic consequences. This makes the need for accurate biological risk assessments even more important. For example, poor understanding of the real risk of Ebola to New Jersey in 2014 resulted in the unnecessary quarantine of a nurse returning from Sierra Leone. New Jersey Governor Chris Christie based his decisions, at least in part, on an inaccurate assessment of biological risk.

Recognizing the need for national leadership to eliminate weaknesses at every interface during disaster response between the federal and SLTT governments, and the public and private sectors, the Panel issued the following recommendations in its 2015 *Blueprint for Biodefense*:

Recommendation 1: Institutionalize biodefense in the Office of the Vice President of the United States.

ACTION ITEMS

a. Empower the Vice President with jurisdiction and authority.

b. Empower the Vice President with budget authority.

Recommendation 2: Establish a Biodefense Coordination Council at the White House, led by the Vice President.

ACTION ITEMS

a. Require broad federal participation.

b. Invite broad non-federal stakeholder participation.

c. Structure the Council for consensus and accountability.

While often informed only by what they watch and read in works of fiction, the public expects the health care community to treat patients in all circumstances. While the public may hope for the best care in all situations, it understands the concept of doing the best job possible with limited resources. They expect more than an all-or-nothing approach to health care delivery and public health management, especially in response to and recovery from public health emergencies and disasters.

To rectify and address these issues, the Panel believes it is necessary to:

Make biodefense a priority for all elected leaders throughout the nation. Leadership of the biodefense enterprise is not only the responsibility of the Administration, but the responsibility of all elected leaders at every level of government. Each will find themselves belatedly managing biological events that occur in their jurisdictions if they do not recognize biological threats and take steps in advance to address them. They must assume that for large-scale biological events affecting huge regions of the United States, if not the entire nation, federal assets may not be readily or continuously available to send to every affected area. All SLTT leaders should make biodefense a high priority for their governance and act accordingly.

ACTION ITEMS

a. **Establish health care and public health emergency preparedness, response, and recovery expectations in the states, localities, tribes, and territories.** State, local, tribal, and territorial leaders do not have to wait for Congress or the federal government to act before establishing health care and public health expectations in their jurisdictions. As Hurricane Katrina so clearly demonstrated, repeated requests and demands of the federal government to provide assistance may not come to fruition completely or quickly. Taking this into consideration, SLTT government officials must establish their own requirements for health care entities and public health departments in their jurisdictions to prepare for large-scale biological events, and to demonstrate the capacity and capability to respond to and recover from them. To fulfill these requirements, SLTT personnel with biodefense responsibilities should obtain leadership training to ensure that they can provide the necessary guidance and structure needed to effectively guide non-federal biodefense activities.

b. **Add biological risk management to agendas.** It behooves elected officials and other politicians to add the need to manage health care and public health risks to their agendas. This is a politically critical issue, known to destroy political careers when poorly addressed. Elected officials and political appointees must take up medical surge, public health emergency and related issues, commit to drafting and passing meaningful legislation to address them, hold responsible parties accountable via strong oversight, make site visits to hospitals, and demonstrate to the public that they are aware of the biological events which may befall them. Elected officials and political appointees should include questions regarding the risk of high-impact diseases in the polls they conduct, and use this information to inform their health care and public health agendas.

c. **Address public expectations.** Politically, our elected officials must address public expectations. Ignoring the public fails to protect elected officials and political appointees when crises occur and affect public health. Informing public expectations now, with more than the entertainment industry's view of health care and public health readiness and response, is the most beneficial way to serve the public and achieve political success.

CONCLUSION

The United States is unaccustomed to responding to events that exceed resources available within the nation. With time and additional appropriations, the nation eventually responded extensively to terrorist events (e.g., September 11, 2001) and naturally occurring disasters (e.g., Hurricanes Irma and Maria). Unfortunately, the Panel expects that large-scale biological events will prove to be the exceptions. States, localities, tribes, and territories will have to fend for themselves while the federal government puts what assets it has available towards ensuring national security and societal stability.

We can describe scenarios in which fast-moving and deadly diseases spread throughout the nation and the world. We can zero-out resource availability in inventories and spreadsheets, and accurately describe the impact on patient management, waste management, disposition of the dead, public safety, and public health. Despite the predictability these afford, each level of the government has yet to develop sufficiently comprehensive plans for addressing the need to provide for public health, safety, and security during and after large-scale biological events.

Public health takes a population approach to health and health care delivery. Public health officials make decisions based on population data and statistics, and in a highly resource constrained environment, they make decisions that favor the greater good, doing the best they can for the most people. Beyond a certain point during a biological catastrophe, everything will become public health. Leaders will then have to do the best they can with the resources they have at their disposal to ensure the survival of the constituents for whom they are responsible.

We can take steps now to reduce the impact large-scale biological events will have on our states, localities, tribes, and territories. By rectifying shortfalls in EMS, improving SNS distribution and pharmacy readiness, increasing hospital surge capacity, augmenting laboratory response capacity, rectifying shortfalls in tribal emergency preparedness, overcoming barriers to territorial biosurveillance and response, delineating response funding before biological crises occur, and assuming broader leadership of biodefense, we can enable all levels of government and the private sector to defend the nation against biological threats and their potentially large-scale consequences.

APPENDIX A: ALL PANEL SLTT RECOMMENDATIONS TO-DATE

RECOMMENDATIONS TO INCREASE STATE, LOCAL, TRIBAL, AND TERRITORIAL ABILITY TO PREPARE FOR, RESPOND TO, AND RECOVER FROM LARGE-SCALE BIOLOGICAL DISASTERS

	Recommendations in the 2015 *Blueprint for Biodefense*, 2017 *Defense of Animal Agriculture*, and 2018 *Budget Reform for Biodefense*	**Additional Recommendations in the 2018 *SLTT Reinforcements Needed for Biodefense***
Fortify Emergency Medical Services	**Recommendation 15:** Provide emergency service providers with the resources they need to keep themselves and their families safe. (*2015 Blueprint for Biodefense*) a. Provide vaccines to responders who request them. b. Provide medkits to emergency service providers and their families. c. Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.	Unify and establish a new National EMS System. a. Assess SLTT EMS capability to respond to biological terrorism and warfare. b. Establish a biological emergency response assistance program. c. Review extent and quality of EMS. d. Inform the delivery of EMS during large-scale biological events, mass casualty events, disasters, and other national emergencies. e. Expand medical necessity rules for EMS reimbursement regarding pre-hospital health care. f. Establish a National EMS Agency.
Improve Stockpile Distribution and Pharmacy Readiness	**Recommendation 23:** Allow for forward deployment of Strategic National Stockpile (SNS) assets. (*2015 Blueprint for Biodefense*) a. Determine logistics and funding needs. b. Implement forward deployments.	Improve distribution of pharmaceuticals, medical equipment, and other essential medical supplies needed to treat those affected by large-scale biological events. a. Improve, expand, enhance, and sustain SLTT training to receive and distribute SNS contents. b. Ensure availability and access to pharmacy readiness data.

	Recommendations in the 2015 *Blueprint for Biodefense*, 2017 *Defense of Animal Agriculture*, and 2018 *Budget Reform for Biodefense*	**Additional Recommendations in the 2018 *SLTT Reinforcements Needed for Biodefense***
Increase Health Care Surge Capacity	**Recommendation 18:** Establish and utilize a standard process to develop and issue clinical infection control guidelines for biological events. (*2015 Blueprint for Biodefense*) a. Standardize the development of clinical infection control guidelines before biological events occur. b. Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events. c. Require training based on these guidelines. **Recommendation 19:** Minimize redirection of Hospital Preparedness Program (HPP) funds. (*2015 Blueprint for Biodefense*) a. Cap HPP management and administration costs at three percent. b. Assess the impact of the HPP. **Recommendation 20:** Provide the financial incentives hospitals need to prepare for biological events. (*2015 Blueprint for Biodefense*) a. Adopt a disaster preparedness portfolio. b. Link Centers for Medicare and Medicaid Services (CMS) incentives and reimbursement to new accreditation standards. **Recommendation 21:** Establish a biodefense hospital system. (*2015 Blueprint for Biodefense*) a. Stratify hospitals. b. Develop accreditation standards for each stratum. c. Associate CMS funding.	Establish a national stratified health care delivery system capable of surging medically to respond to large-scale biological events. a. Establish medical surge capability and capacity for large-scale biological events. b. Communicate the business-case for a stratified biodefense health care delivery system. c. Assess risk to reputation.

	Recommendations in the 2015 *Blueprint for Biodefense*, 2017 *Defense of Animal Agriculture*, and 2018 *Budget Reform for Biodefense*	Additional Recommendations in the 2018 *SLTT Reinforcements Needed for Biodefense*
Augment Laboratory Response	**Recommendation 14:** Improve surveillance of, and planning for, animal and zoonotic disease outbreaks. (*2015 Blueprint for Biodefense*) a. Fund the National Animal Health Laboratory Network (NAHLN) at a level that allows it to achieve success. Congress should continue to fund the NAHLN. (*2017 Defense of Animal Agriculture*)	Authorize all laboratory networks that test for biological agents. a. Authorize and fund the Laboratory Response Network for Biological Threats. b. Authorize and fund the Environmental Response Laboratory Network, Food Emergency Response Network, National Plant Diagnostic Network, and Veterinary Laboratory Investigation and Response Network. c. Establish requirements for all laboratory networks that test for biological agents.
Rectify Shortfalls in Tribal Public Health Emergency Preparedness	**Recommendation 17:** Fund the Public Health Emergency Preparedness (PHEP) cooperative agreement at no less than authorized levels. (*2015 Blueprint for Biodefense*) a. Appropriate PHEP funding to authorized levels or the President's Budget Request, whichever is higher.	Give federally recognized American Indian and Alaska Native tribes the opportunity to enter into their own PHEP cooperative agreements and obtain technical assistance. a. Make PHEP funding available directly to the tribes. b. Proactively bolster tribal public health emergency preparedness. c. Strengthen tribal epidemiology.
Overcome Barriers to Territorial Biosurveillance and Response	**Recommendation 12:** Empower non-federal entities to become equal biosurveillance partners. (*2015 Blueprint for Biodefense*) a. Create an interagency biosurveillance planning committee.	Provide US insular areas with robust public health preparedness and response tools. a. Provide enhanced planning and technical assistance. b. Strengthen biosurveillance and data collection. c. Reduce barriers to transporting resources during a public health emergency.

	Recommendations in the 2015 *Blueprint for Biodefense*, 2017 *Defense of Animal Agriculture*, and 2018 *Budget Reform for Biodefense*	**Additional Recommendations in the 2018 *SLTT Reinforcements Needed for Biodefense***
Allocate Response Funding Before Biological Crises Occur	Rapid response fund triggered not only by a declared public health emergency, but also, at times, in advance of any such declaration to preempt a major problem. (*2018 Budget Reform for Biodefense*) a. Infuse no less than $2 billion into the Public Health Emergency Fund (PHEF). b. Commit to regular annual appropriations utilizing a consistent methodology and no-year funding for the PHEF. c. Provide guidance on triggers for PHEF use. d. Update criteria for events covered by the PHEF.	Ensure consistent, adequate response funding and guidance for public health emergencies. a. Reform the PHEF to ensure clarity of use, transparency, and accountability. b. Clarify SLTT eligibility for biological disaster assistance under the Stafford Act. c. Delineate HHS and FEMA assistance to SLTT governments for public health emergency response.
Assume Broader Leadership of Biodefense	**Recommendation 1:** Institutionalize biodefense in the Office of the Vice President of the United States. (*2015 Blueprint for Biodefense*) a. Empower the Vice President with jurisdiction and authority. b. Empower the Vice President with budget authority. **Recommendation 2:** Establish a Biodefense Coordination Council at the White House, led by the Vice President. (*2015 Blueprint for Biodefense*) a. Require broad federal participation. b. Invite broad non-federal stakeholder participation. c. Structure the Council for consensus and accountability.	Make biodefense a priority for all elected leaders throughout the nation. a. Establish health care and public health emergency preparedness, response, and recovery expectations in the states, localities, tribes, and territories. b. Add biological risk management to agendas. c. Address public expectations.

APPENDIX B: PROPOSED GUBERNATORIAL HEARINGS

The State Governors and Territorial Governors and Administrators must ensure that their subordinate agencies and personnel meet legislative and other mandates, and do so in a coordinated fashion. These proposed hearing topics reflect major recommendations outlined in this report, and additional ideas for consideration.

Issue

EMS Requirements and Shortfalls

Summary

The origin of EMS lies with the National Highway Safety Act (P.L. 89-564) in 1966. What started as a means for providing preliminary first-aid and rapid transportation from high-speed accidents to nearby hospitals has become a major health care and public safety asset, upon which every community in the nation depends. EMS is now out of alignment with its federal sponsor, DOT, and inadequately informed by the department responsible for health care certification and guidance, HHS. Within the state or territory, which agency(s) should take responsibility for EMS? Do they need additional funding? How can local EMS benefit from lessons learned by DOD (medics and others) and vice versa–especially when DOD medics are based within the state or territory?

Issue

Distribution of the SNS and other Pharmaceuticals, Equipment, and Essential Medical Supplies

Summary

The CDC provides training to states and localities to help prepare them to be able to distribute the contents of the SNS. Some state recipients of this training do not believe this training is adequate. Within the state or territory, has the department of health received training? What do they think of it? What are their recommendations to improve it? What plans do they and local pharmacies throughout the state or territory have in place to distribute needed pharmaceuticals, medical equipment, and essential medical supplies? Does the state or territory have a way to determine pharmacy readiness during and after biological disasters?

Issue

Medical Surge and Hospital Accreditation and Reimbursement

Summary

Hospitals throughout the nation are operating at or beyond capacity every day. Additionally, every hospital in the state or territory cannot be expected to treat every patient exposed to biological agents, especially during significant, difficult to control outbreaks. How well have hospitals in the state or territory met CMS hospital accreditation requirements? Do any of these hospitals receive HPP funding? Do they think they will receive sufficient reimbursement from CMS and commercial health insurance if they had to treat thousands of patients infected during a large-scale biological event? Which hospitals made investments to increase their ability to treat novel infectious diseases (especially in response to Ebola)? How do they feel about not getting reimbursed for those investments? What plans (if any) do they have in place to deal with the worried well?

Issue

Laboratory Response

Summary

State public health laboratories are members of the LRN and other laboratory networks. How does the state public health laboratory director feel about the testing protocols put out by the CDC? What recommendations do the public health laboratories have to improve these protocols? How would they characterize the relationship they have with local FBI field offices in the state? For the territories, why are the territorial public health laboratories not part of the LRN and other networks? What plans do they have in place to send specimens to state public health laboratories that are LRN and other network members?

Issue

Territorial Roles and Requirements in Biodefense

Summary

How can the territory, associated state, or area in which the US exercises extraterritorial jurisdiction overcome weaknesses in biosurveillance and biodetection? What do they need from the federal government to increase their biodefense?

Issue

Tribal Public Health

Summary

The Bureau of Indian Affairs, Indian Health Service, and Centers for Disease Control and Prevention all have roles to play in helping to improve tribal public health, but seem to lack goals for outcome-focused assistance. Funding opportunities for tribes to improve their own public health infrastructure and programs is also lacking. What is the current state of tribal public health emergency preparedness? How can we better integrate the tribes into mutual aid agreements? How should the governors and administrators ensure that the tribes are included in PHEP cooperative agreements? What role could the Tribal Epidemiology Centers (TECs) play in tribal, state, and national biosurveillance efforts? What can the federal government do to bring other TECs up to the same level as that of the Navajo Nation?

APPENDIX C: PROPOSED CONGRESSIONAL HEARINGS

Congress must ensure that federal departments and agencies meet congressional and other mandates, and do so in a coordinated fashion. These proposed hearing topics reflect major recommendations outlined in this report, and additional ideas for consideration.

Issue

Federal Responsibility for EMS

Summary

The origin of EMS lies with the National Highway Safety Act (P.L. 89-564) in 1966. What started as a means for providing preliminary first-aid and rapid transportation from high-speed accidents to nearby hospitals has become a major health care and public safety asset, upon which every community in the nation depends. EMS is now out of alignment with its federal sponsor, DOT, and inadequately informed by the department responsible for health care certification and guidance, HHS. Should all or some responsibility for EMS shift from DOT to HHS? What funding shortfalls exist, and which department should be responsible for providing it? How can local EMS benefit from lessons learned by DOD (medics and others) and vice versa?

House Committee(s): Armed Services • Energy and Commerce • Transportation and Infrastructure

Senate Committee(s): Armed Services • Health, Education, Labor, and Pensions • Commerce, Science, and Transportation

Issue

Management of the Strategic National Stockpile

Summary

The National Pharmaceutical Stockpile (NPS) was created in 1999. The Homeland Security Act of 2002 made DHS responsible for the NPS in 2003, and the NPS was renamed the Strategic National Stockpile (SNS) that same year. HHS assumed control of the SNS after the Project BioShield Act became law in 2004. The CDC has been in charge of the SNS since then. The Trump Administration would like the HHS ASPR to take over management of the SNS. How would the HHS ASPR manage the SNS differently than the CDC? Would the ASPR need additional personnel to manage the SNS? How would ASPR management change SNS program performance and improve state and local support? How will CDC and ASPR work together?

House Committee(s): Energy and Commerce

Senate Committee(s): Armed Services • Health, Education, Labor, and Pensions

Issue

Medical Surge and Hospital Accreditation and Reimbursement

Summary

Hospitals throughout the nation are operating at or beyond capacity every day. Additionally, every hospital cannot be expected to treat every patient exposed to biological agents, especially during significant, difficult to control outbreaks. While CMS reimburses health care for disease treatment, it has issued few preparedness and response requirements to hospitals. Given the limitations of the HPP, how can CMS better incorporate emergency preparedness into its hospital accreditation requirements and health care reimbursement schema? How should the HHS ASPR and CMS Administrator work together to improve hospital preparedness?

House Committee(s): Energy and Commerce

Senate Committee(s): Health, Education, Labor, and Pensions

Issue

Diagnostics

Summary

While laboratory testing (performed by the LRN, NAHLN, and other laboratory networks) remains the gold standard for disease identification, the nation needs diagnostics as well, for use in both laboratory and patient care settings. How have CDC-produced diagnostics performed in state and local laboratory settings? What is the role of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) in addressing diagnostics and how has PHEMCE interacted with other HHS agencies to increase the number of diagnostics available to the nation? What is the state of research in this regard? What contributions can DOD and other departments make?

House Committee(s): Agriculture • Armed Services • Energy and Commerce • Homeland Security

Senate Committee(s): Agriculture • Armed Services • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs

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Issue

Territorial Roles and Requirements in Biodefense

Summary

US territories are subnational administrative divisions directly overseen by the federal government. Unlike the states and tribes, territories are not sovereign. How do biodefense requirements vary with unincorporated organized, incorporated and unincorporated unorganized, inhabited and uninhabited territories, and associated states? How can the US overcome weaknesses in biosurveillance and biodetection in the territories, associated states, and areas in which the US exercises extraterritorial jurisdiction? What role can the federal government play in biodefense in this area and on behalf of the nation as a whole?

House Committee(s): Armed Services • Energy and Commerce • Foreign Affairs • Homeland Security • Natural Resources

Senate Committee(s): Armed Services • Energy and Natural Resources • Foreign Affairs • Health, Education, Labor, and Pensions • Homeland Security

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Issue

Tribal Public Health

Summary

The Bureau of Indian Affairs, Indian Health Service, and Centers for Disease Control and Prevention all have roles to play in helping to improve tribal public health, but seem to lack goals for outcome-focused assistance. Funding opportunities for tribes to improve their own public health infrastructure and programs is also lacking. What is the current state of tribal public health emergency preparedness? How can we better integrate the tribes into mutual aid agreements? How should Congress modify the PHEP to address cross-border tribes? What role could the TECs play in tribal, state, and national biosurveillance efforts? What can the federal government do to bring other TECs up to the same level as that of the Navajo Nation?

House Committee(s): Natural Resources • Energy and Commerce

Senate Committee(s): Indian Affairs • Health, Education, Labor and Pensions

APPENDIX D: METHODOLOGY

The Blue Ribbon Study Panel on Biodefense was established in 2014 to inform US biodefense and to provide recommendations for change. The Panel is supported by a suite of ex officio members, fiscal sponsorship by Hudson Institute, and funds from foundations and industry.

RESEARCH QUESTIONS

In order to address SLTT ability to prepare for, respond to, and recover from large-scale biological events, and gaps in the related biodefense enterprise and biodefense body of knowledge, the Panel developed the following research questions:

1) Are our priorities correct?

2) Are our investments commensurate with the challenge?

3) Can we benefit from rebalancing investments or is new funding required?

4) What have we done that has brought a significant return on investment?

5) What else should we be doing that we are not?

PRELIMINARY RESEARCH

The Panel reviewed previous research efforts, scientific studies, reports by congressional and presidential commissions (including the US Commission on National Security/21st Century, Commission on Terrorist Attacks on the United States, Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, and Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism); presidential directives; statute and proposed legislation; Government Accountability Office reports; and federal strategies, plans, budgets, organizational constructs, and programs related to defense against deliberately introduced and naturally occurring biological events with catastrophic potential. This review: (1) allowed for an assessment of the comprehensiveness of efforts to address the postulated and actual SLTT preparedness, response, and recovery challenges they were intended to meet; and (2) determined how the understanding of

the threat, knowledge base, and elements of the biodefense enterprise should change in light of this assessment. This review also informed the structure and topics of the formal meeting of the Panel.

FORMAL PANEL MEETING

The Panel organized its formal meeting on this subject in accordance with national and SLTT policy. During this day-long meeting, Panel members, ex officios, and staff received: (1) information regarding current relevant national policy, legislative issues, and federal departmental and agency programmatic activities; and (2) statements from current and former federal and SLTT officials, thought leaders, and subject matter experts. Panel staff summarized major insights, areas for improvement, and recommendations articulated by meeting speakers, and conducted preliminary high-level analysis of this meeting for Panel and ex officio review.

ANALYSIS

Panel staff used qualitative methods to analyze this information. The Panel examined the oral and written statements provided by meeting speakers and mapped their findings and recommendations to the capabilities required. Panel staff further evaluated each finding and recommendation, including additional policy research and interviews with subject matter experts and former high-level officials, as well as considering the Panel's own experience. Throughout the process, the five questions defined previously provided the basis for assessment. This approach allowed the Panel, ex officios, and staff to identify organizational, legal, policy, and programmatic issues and to recommend specific solutions. Panel staff did not use statistical and other quantitative methods for this study. This study is not considered pseudo-qualitative/quasi-quantitative.

STUDY LIMITATIONS

Funding and other resource constraints prevented the Panel from performing site visits. In addition, a number of biodefense programs and policies; intelligence, raw data, and documents; appropriations and budget documents; and other sensitive pieces of information are classified or otherwise unavailable, and were not reviewed by the Panel as this was a wholly unclassified endeavor.

APPENDIX E: MEETING AGENDA AND SPEAKERS

Meeting held at the University of Miami, Coral Gables, FL

SPECIAL FOCUS MEETING: SLTT ABILITY TO RESPOND TO LARGE-SCALE BIOLOGICAL EVENTS

JANUARY 17, 2018

Opening Remarks

- Former Secretary of Health and Human Services Donna E. Shalala, Blue Ribbon Study Panel on Biodefense
- Former Representative James C. Greenwood, Blue Ribbon Study Panel on Biodefense

Political Perspective

Need to ensure that states, localities, tribes, and territories possess the resources, capabilities, and capacity to respond to large-scale biological events.

- Richard Serino, Distinguished Senior Fellow, Harvard School of Public Health; former Deputy Administrator, Federal Emergency Management Agency; former Chief, Boston Emergency Medical Services

Panel One – Community and Pre-Hospital Assets and Resources

Use of SLTT pre-hospital assets and resources, and the ability of communities to respond to large-scale biological events.

- Nicolette A. Louissaint, PhD, Executive Director, Healthcare Ready
- Jimmy Mynatt, AAE, Assistant Aviation Director, Operations, Charlotte Douglas International Airport
- James Robinson, Assistant Chief, Denver Health Paramedic Division

Panel Two – Hospital Preparedness and Response

SLTT leadership in hospital preparedness, training, and response; the recent Centers for Medicare and Medicaid Emergency Preparedness Rule; and the need for a stratified biodefense hospital system.

- David Zambrana, PhD, DNP, MBA, RN, Senior Vice President and CEO of Jackson Memorial Hospital
- David Marcozzi, MD, MHS-CL, FACEP, Associate Professor, Co-Director of the Program in Health Disparities and Population Health, University of Maryland School of Medicine; Assistant Chief Medical Officer for Acute Care, University of Maryland Medical Center
- Alexander P. Isakov, MD, MPH, Executive Director, Office of Critical Event Preparedness and Response, Emory University

Panel Three – Public Health Response and Population Management

Public health roles and responsibilities when responding to biological events affecting large groups, and how the public health community must interface with the health care delivery and public safety communities.

- Celeste Philip, MD, MPH, Surgeon General and Secretary, Florida Department of Health
- Scott J. Zimmerman, DrPH, Director, Division of Public Health, North Carolina State Laboratory of Public Health
- Tina Batra Hershey, JD, MPH, Assistant Professor, Health Policy and Management; Assistant Director for Law and Policy, Center for Public Health Practice, University of Pittsburgh Graduate School of Public Health

Lunch Keynote – Local Response, Global Perspective

Local response to a large-scale biological event placed into global context.

- Julio Frenk, MD, PhD, MPH, President, University of Miami

Panel Four – Working the Interfaces

Federal support of local response requirements and the need for federal agencies to work with SLTT officials.

- Michael Fraser, PhD, MS, Executive Director, Association of State and Territorial Health Officials
- Joseph M. Henderson, MPA, Director, Office of Safety, Security and Asset Management, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, Department of Health and Human Services; Faculty, National Preparedness Leadership Initiative, T.H. Chan School of Public Health and Kennedy School of Government, Harvard University

Closing Remarks

- Former Representative James C. Greenwood, Blue Ribbon Study Panel on Biodefense
- Former Secretary of Health and Human Services, Donna E. Shalala, Blue Ribbon Study Panel on Biodefense

ACRONYMS

AI/AN	American Indian and Alaska Native
APHL	Association of Public Health Laboratories
ASPR	Assistant Secretary for Preparedness and Response, Department of Health and Human Services
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services, Department of Health and Human Services
DHS	Department of Homeland Security
DOD	Department of Defense
DOT	Department of Transportation
EMS	emergency medical services
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
HPP	Hospital Preparedness Program, Department of Health and Human Services
IHS	Indian Health Service, Department of Health and Human Services
LRN	Laboratory Response Network for Biological Threats (previously known as the Laboratory Response Network for Bioterrorism)
MCM	medical countermeasure(s)
MERS-COV	Middle East Respiratory Syndrome Coronavirus
NAHLN	National Animal Health Laboratory Network
NPS	National Pharmaceutical Stockpile
PHEF	Public Health Emergency Fund
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP	Public Health Emergency Preparedness program (cooperative agreements)
SARS	Severe Acute Respiratory Syndrome
SLTT	state, local, tribal, and territorial
SNS	Strategic National Stockpile
TEC	Tribal Epidemiology Center
US	United States
USDA	Department of Agriculture

ENDNOTES

1. US Census Bureau. (2012). Census of Governments. Washington, DC: US Census Bureau. See: https://www.census.gov/programs-surveys/cog.html.

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8. Or the ASPR, if Congress transfers the SNS in accordance with the President's Budget Request for Fiscal Year 2019.

9. Or the ASPR, if Congress supports transfer of the SNS, in accordance with the President's Budget Request for Fiscal Year 2019.

10. For more information about Healthcare Ready, see: https://www.healthcareready.org/.

11. For instance, the brand of the Texas Health Presbyterian Hospital in Dallas is now associated with its faltering response to Ebola.

12. Centers for Medicare and Medicaid Services. (2016). Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, Final Rule (81 FR 63860). Washington, DC: Department of Health and Human Services. See: https://www.regulations.gov/document?D=CMS-2013-0269-0377.

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14. Localities receiving PHEP awards are Chicago, IL; Los Angeles County, CA; New York, NY; and Washington, DC. See: https://www.cdc.gov/phpr/readiness/phep.htm.

15. Territories and freely associated states receiving PHEP awards are American Samoa, Guam, US Virgin Islands, Norther Mariana Islands, Puerto Rico, Federated States of Micronesia, Republic of Marshall Islands, and Republic of Palau. See: https://www.cdc.gov/phpr/readiness/phep.htm.

16. PHEP funding is intended to build upon jurisdictional efforts, not replace them. Recipients must provide at least 10% in matching funds.

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20. Regardless of any FEMA recommendation, the President retains sole authority to approve requests for Stafford Act emergency declarations.

21. Prior documentation, including most recently FP-104-009-001 lists Pre-Scripted Mission Assignments that provide detailed examples of potential assistance and cost-share requirements in responding to biological events. These do not overlap with assistance that Congress has authorized HHS to provide. FEMA assistance would be limited to Direct Federal Assistance and would not reimburse SLTT costs for protective measures.


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CITATION UPDATE

Please note that due to our name change, we have updated our copyright and citation as follows:



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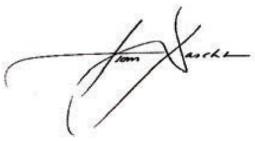
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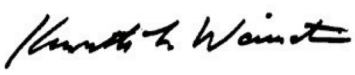
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PREFACE

October 28, 2015

To the President, Congress, and the American People:

The United States is underprepared for biological threats. Nation states and unaffiliated terrorists (via biological terrorism) and nature itself (via emerging and reemerging infectious diseases) threaten us. While biological events may be inevitable, their level of impact on our country is not.

We convened the Blue Ribbon Study Panel on Biodefense to assess how much has been done to address the biological threat and what remains undone. Despite significant progress on several fronts, the Nation is dangerously vulnerable to a biological event. The root cause of this continuing vulnerability is the lack of strong centralized leadership at the highest level of government.

Crisis after biological crisis has forced the United States to act. Naturally occurring threats such as influenza, Ebola, and Chikungunya are bypassing borders to emerge in nations oceans away, and exact a continued toll. The Islamic State of Iraq and the Levant (also known as ISIL and Da'esh) is devastating the Middle East while espousing the value of biological weapons for their ability to cause massive loss of life. The U.S. government has mishandled extremely dangerous viruses and bacteria in some of its highest level laboratories. The Nation lacks the leadership, coordination, collaboration, and innovation necessary to respond.

This Panel (through public meetings, targeted interviews, and extensive research) examined the national state of defense against biological attacks and emerging and reemerging infectious diseases, of the order that could cause catastrophic loss of life, societal disruption, and loss of confidence in our government. We scrutinized the status of prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation – the spectrum of activities deemed necessary for biodefense by both Republican and Democratic Administrations, and many experts outside of government. We identified substantial achievements, but we also found serious gaps and inadequacies that continue to leave the Nation vulnerable to threats from nature and terrorists alike.

Successive Presidents, beginning with William J. Clinton and followed by George W. Bush and Barack H. Obama, enacted policies intended to strengthen national biodefense. As a result, many federal departments and agencies took action and the majority of these programs received bipartisan congressional support. Yet fourteen years after the last report of the U.S. Commission on National Security/21st Century, eleven years after the report of the National Commission on Terrorist Attacks upon the United States, ten years after the report of the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, and seven years since the report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, the insufficiency of our myriad and fragmented biodefense activities persists because biodefense lacks focused leadership. Capable individuals oversee elements at the department and agency levels, but no steward guides them collectively.

As leaders in past Administrations and Congresses, we, the members of the Panel, had a role in our national biodefense and we share responsibility for its shortcomings. Our intent is to help remedy the correctable shortfalls by identifying specific short-, medium-, and long-term programmatic, legislative, and policy actions in this report. We urge those in leadership positions to implement our recommendations with utmost haste. Lives are in the balance.

We provided this charge to ourselves – without a commission from Congress or the President – and tried not to duplicate the work of previously mandated commissions and appointed panels. Instead, we built on and contemporized their insights, observations, and recommendations. While we originally intended to assess both biological and chemical threats, we came to believe that the more immediate concern regarding loss of life is the biological threat and that in focusing on it, there will be collateral benefits for dealing with the chemical threat as well.

Biodefense touches many aspects of society, falling within the purview of national security, homeland security, public health security, and economic security. As such, it requires an enterprise approach – eliminating stovepipes; transcending agency-centric activity; drawing upon stakeholders throughout government, academia, and the private sector; and recognizing the extraordinary breadth of the challenge – to provide flexible solutions that address the full spectrum of the threat. Most importantly, the Nation needs an overarching leader who recognizes the severity of the biological threat and possesses the authority and political will to defend against it. This top-level leader, together with leaders throughout the enterprise, must guide efforts and ensure that the combined impact of biological threats, vulnerabilities, and consequences are managed using a common biodefense strategy.

As former Secretary of the Navy Richard Danzig told us, "We don't really get to choose what we have to prepare for." We have no choice – the Nation must take action to defend against the biological threat. We have done much already, but we need the leadership only a top-level official can bring to bear to optimize the biodefense enterprise. We believe that our recommendations will make America more secure, and we will continue to monitor actions taken to improve our national biodefense posture. If you take and demand action now, you can save lives. There is no greater calling or responsibility.



Joseph I. Lieberman
CHAIR



Thomas J. Ridge
CHAIR

EXECUTIVE SUMMARY

BACKGROUND

The Blue Ribbon Study Panel on Biodefense was established in 2014 to assess gaps and provide recommendations to improve U.S. biodefense. The Panel – supported by a suite of distinguished ex officio members and staff with deep expertise in science, policy, intelligence, and defense; institutional hosting through Hudson Institute and the Inter-University Center for Terrorism Studies at Potomac Institute for Policy Studies; and funds from academia, foundations, and industry – determined where the United States is falling short of addressing biological attacks and emerging and reemerging infectious diseases.

Individuals from all levels of government, industry, academia, and advocacy provided their perspectives at a series of four day-long meetings with the Study Panel. They addressed the pillars of biodefense outlined in Homeland Security Presidential Directive (HSPD) 10:

THREAT AWARENESS
biological warfare related intelligence; assessments; anticipation of future threats

PREVENTION AND PROTECTION
proactive prevention; critical infrastructure protection

SURVEILLANCE AND DETECTION
attack warning; attribution

RESPONSE AND RECOVERY
response planning; mass casualty care; risk communication; medical countermeasure (MCM) development; decontamination

REPORT ORGANIZATION

The Nation has made some progress with biodefense and this report does not dismiss this. Rather than catalog success, however, this report delineates areas needing improvement and provides key recommendations to address them. Although challenges undoubtedly exist in all of the capability areas needed for biodefense, this report describes that subset brought to the Panel's attention as being the most problematic. It also pushes beyond the limits of HSPD-10 to urge greater inclusion of issues like animal health and global engagement as key components of the biodefense mission. This report contains proposals for an effective leadership construct and a renewed governance structure. It provides a detailed blueprint for reform with action items that are categorized by time to completion (summarized in Table 1): short-term (in one year or less); medium-term (within one to three years); and long-term (within three to five years).

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and sustained levels of financial support to state, local, territorial, and tribal health departments. The federal government must also increase support to hospitals, through tighter management of Hospital Preparedness Program funds, development of Centers for Medicare and Medicaid Services incentives, and accreditation of select hospitals as biodefense specialty centers.

Public-private partnerships are fundamental to any efforts toward development, distribution, and dispensing of MCM. We must produce a MCM response framework that is predicated on non-federal input, collaboration, and implementation, and that allows for pre-deployment of stockpiles. Finally, the federal government must lead efforts to secure vulnerable pathogen data.

THE NEED FOR LEADERSHIP TO DRIVE INNOVATION

The innovative process of scientific discovery is inherently fraught with uncertainty. Yet biodefense efforts urgently call for a much greater focus on innovation than ever before – because biological threats are imminent, biological vulnerabilities have existed for too long, and the complexity of the threat requires equally complex solutions. Biodefense also requires sustained prioritization and funding to ensure that success realized thus far is maintained, and that opportunity and innovation are pursued.

We must revolutionize the development of MCM for emerging infectious diseases, fully fund and incentivize the MCM enterprise, and remove bureaucratic hurdles to MCM innovation. We must develop a system for environmental detection that leverages the ingenuity of industry and meets the growing threat. We must overhaul the Select Agent Program to enable a secure system that simultaneously encourages participation by the scientific community. Finally, we must help lead the international community toward the establishment of a fully functional and agile global public health response apparatus.

CONCLUSIONS

We have reached a critical mass of biological crises. Myriad biological threats, vulnerabilities, and consequences have collectively and dramatically increased the risk to the Nation. They have also, we believe, garnered the attention of enough people who understand the threat is real, want to mobilize and take action, and can provide for effective national biodefense.

Leadership moves America forward. A central and authoritative leader – who, by recommendation of this report, is the Vice President – can foster substantial progress in biodefense. Once installed as this leader, the Vice President (and the interagency team of experts who will work to realize the strategic vision of the Executive and Legislative Branches) can also foster substantial progress, much of it in the near term. This is especially true for coordinating federal activities, forging intersectoral partnerships, and revolutionizing the ways in which we approach this mission space.

Dramatic improvements are within our reach if we follow a national blueprint for biodefense, establish leadership, and engage in major reform efforts that build on the good work that is already in place.

TABLE 1: RECOMMENDATIONS AND ACTION ITEMS

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
1	**Institutionalize biodefense in the Office of the Vice President of the United States.**				
	a	Empower the Vice President with jurisdiction and authority.	•		
	b	Empower the Vice President with budget authority.	•		
2	**Establish a Biodefense Coordination Council at the White House, led by the Vice President.**				
	a	Require broad federal participation.	•		
	b	Invite broad non-federal stakeholder participation.	•		
	c	Structure the Council for consensus and accountability.	•		
3	**Develop, implement, and update a comprehensive national biodefense strategy.**				
	a	Collate the whole of biodefense policy.	•		
	b	Identify requirements within all extant policies.	•		
	c	Assess spending history and value.		•	
	d	Produce the National Biodefense Strategy of the United States of America and its Implementation Plan.		•	
	e	Develop a gap analysis based on this comprehensive strategy.		•	
	f	Institute a major quadrennial biodefense review.			•
4	**Unify biodefense budgeting.**				
	a	Develop and execute a mandatory annual biodefense call for data.	•		
	b	Conduct a cross-cutting biodefense budget analysis.	•		
	c	Align budget items to the National Biodefense Strategy of the United States of America.		•	
	d	Provide predictable and multi-year funding for all biodefense programs.		•	
5	**Determine and establish a clear congressional agenda to ensure national biodefense.**				
	a	Develop joint congressional oversight agendas.	•		
6	**Improve management of the biological intelligence enterprise.**				
	a	Create a National Intelligence Manager for Biological Threats.	•		
	b	Make biological weapons programs and related activities a discrete intelligence topic.	•		
	c	Address bystanders.		•	
	d	Distribute assessments.	•		

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
7	**Integrate animal health and One Health approaches into biodefense strategies.**				
	a	Institutionalize One Health.		•	
	b	Develop a nationally notifiable animal disease system.		•	
	c	Prioritize emerging and reemerging infectious diseases.		•	
8	**Prioritize and align investments in medical countermeasures among all federal stakeholders.**				
	a	Ensure National Institutes of Health research supports civilian medical countermeasure priorities.		•	
	b	Ensure funding allocations are appropriate to meet the need.		•	
	c	Require a biodefense spend plan from the National Institute of Allergy and Infectious Diseases.	•		
9	**Better support and inform decisions based on biological attribution.**				
	a	Establish a national biological attribution decision-making apparatus.		•	
	b	Place the Federal Bureau of Investigation in charge of the National Bioforensics Analysis Center.	•		
10	**Establish a national environmental decontamination and remediation capacity.**				
	a	Include the Federal Emergency Management Agency in efforts to address remediation.	•		
	b	Assign responsibility to the Environmental Protection Agency for environmental decontamination and remediation.	•		
	c	Conduct studies of those exposed to disease-causing agents.		•	
11	**Implement an integrated national biosurveillance capability.**				
	a	Implement the National Strategy for Biosurveillance.	•		
12	**Empower non-federal entities to be equal biosurveillance partners.**				
	a	Create an interagency biosurveillance planning committee.	•		
13	**Optimize the National Biosurveillance Integration System.**				
	a	Assess the viability of the National Biosurveillance Integration System as the prime integrator of biosurveillance information.	•		
	b	Incentivize data sharing.		•	
14	**Improve surveillance of and planning for animal and zoonotic outbreaks.**				
	a	Increase opportunities for animal health data collection.		•	
	b	Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.	•		
	c	Develop guidance for the serious implications of companion animal and wildlife zoonoses.		•	

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
15	**Provide emergency service providers with the resources they need to keep themselves and their families safe.**				
	a	Provide vaccines to responders who request them.		•	
	b	Provide medkits to emergency service providers and their families.		•	
	c	Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.	•		
16	**Redouble efforts to share information with state, local, territorial, and tribal partners.**				
	a	Strengthen the Joint Counterterrorism Assessment Team.	•		
	b	Strengthen the ability of local police intelligence units to address the biological threat.	•		
	c	Enable fusion centers to address the biological threat.	•		
17	**Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels.**				
	a	Appropriate Public Health Emergency Preparedness funding to authorized levels or the President's request, whichever is higher.	•		
18	**Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.**				
	a	Standardize the development of clinical infection control guidelines before biological events occur.	•		
	b	Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.	•		
	c	Require training based on these guidelines.		•	
19	**Minimize redirection of Hospital Preparedness Program funds.**				
	a	Cap Hospital Preparedness Program management and administration costs at three percent.	•		
	b	Assess the impact of the Hospital Preparedness Program.		•	
20	**Provide the financial incentives hospitals need to prepare for biological events.**				
	a	Adopt a disaster preparedness portfolio.		•	
	b	Link Centers for Medicare and Medicaid Services incentives and reimbursement to new accreditation standards.		•	
21	**Establish a biodefense hospital system.**				
	a	Stratify hospitals.	•		
	b	Develop accreditation standards for each stratum.		•	
	c	Associate Centers for Medicare and Medicaid Services funding.		•	

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
22	**Develop and implement a Medical Countermeasure Response Framework.**				
	a	Produce a comprehensive framework to guide medical countermeasure distribution and dispensing planning.		•	
23	**Allow for forward deployment of Strategic National Stockpile assets.**				
	a	Determine logistics and funding needs.	•		
	b	Implement forward deployments.		•	
24	**Harden pathogen and advanced biotechnology information from cyber attacks.**				
	a	Develop and implement a security strategy for stored pathogen data.		•	
	b	Provide the research community with tools and incentives to secure its data.		•	
	c	Develop cyber-threat information-sharing mechanisms for the pathogen and advanced biotechnology communities.		•	
25	**Renew U.S. leadership of the Biological and Toxin Weapons Convention.**				
	a	Continue to strengthen implementation of the Biological and Toxin Weapons Convention where U.S. support is unequivocal.	•		
	b	Set U.S. goals for the Biological and Toxin Weapons Convention and determine the conditions necessary to achieve them.	•		
	c	Develop three actionable recommendations for Biological and Toxin Weapons Convention verification.		•	
	d	Establish better biological weapons sentencing guidelines in statute.		•	
26	**Implement military-civilian collaboration for biodefense.**				
	a	Conduct a review of military-civilian collaborative efforts.	•		
	b	Establish military-civilian biodefense collaboration.		•	
	c	Clarify parameters for military support to civilian authorities in response to a domestic biological attack.		•	
	d	Update and implement military biodefense doctrine.		•	
27	**Prioritize innovation over incrementalism in medical countermeasure development.**				
	a	Prioritize innovation in medical countermeasures at agencies with biodefense responsibilities.	•		
	b	Exploit existing innovation.	•		
	c	Revolutionize development of medical countermeasures for emerging infectious diseases with pandemic potential.		•	
	d	Establish an antigen bank.		•	

Recommendation			Term to Execute		
	Action Item		Short	Medium	Long
28	**Fully prioritize, fund, and incentivize the medical countermeasure enterprise.**				
	a	Fund the medical countermeasure enterprise to no less than authorized levels.	•		
	b	Re-establish multi-year biodefense funding for medical countermeasure procurement.	•		
	c	Address prioritization and funding for influenza preparedness.	•		
	d	Improve the plan for incentivizing the private sector and academia.	•		
29	**Reform Biomedical Advanced Research and Development Authority contracting.**				
	a	Return contracting authority to the Biomedical Advanced Research and Development Authority.	•		
	b	Leverage previously provided authorities.	•		
	c	Eliminate Office of Management and Budget review of BioShield procurements.	•		
30	**Incentivize development of rapid point-of-care diagnostics.**				
	a	Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases.		•	
31	**Develop a 21st Century-worthy environmental detection system.**				
	a	Fund the development of advanced environmental detection systems to replace BioWatch.	•		
	b	Replace BioWatch Generation 1 and 2 detectors.			•
32	**Review and overhaul the Select Agent Program.**				
	a	Undertake a major reassessment of the Select Agent Program.	•		
	b	Overhaul the Select Agent Program.		•	
33	**Lead the way toward establishing a functional and agile global public health response apparatus.**				
	a	Convene human and animal health leaders.	•		
	b	Establish the response apparatus.		•	

SCENARIO

The following hypothetical situation, told from the perspective of a congressional Committee Chairman, provides context for this report by portraying a biological attack sufficient to cause the catastrophic consequences with which this report is concerned. The scenario describes the different populations (human, animal) an agent could target and from which it could emerge, some of the key interagency capabilities required to address the agent and its impacts, and the consequences of failure in these capability areas.

SCENARIO

JOINT INQUIRY INTO ADMINISTRATION AND CONGRESSIONAL ACTIONS BEFORE AND AFTER THE BIOTERRORIST ATTACKS OF 2016

U.S. SENATE, SELECT COMMITTEE ON INTELLIGENCE AND U.S. HOUSE OF REPRESENTATIVES, PERMANENT SELECT COMMITTEE ON INTELLIGENCE

I call the Joint Inquiry Committee to order. Nine weeks ago, terrorists unleashed insidious biological attacks on our Nation's Capitol during our Independence Day celebrations. The infectious agent they used ultimately led to the deaths of 6,053 Americans. Many of our own colleagues and staff fell ill and died. Thousands more were killed in coordinated attacks in allied nations in the days that followed.

The attack here in Washington, D.C. used aerosol delivery devices we could see, but did not know contained dangerous organisms. We discovered later that other attacks had already begun elsewhere in the Nation, using methods we have yet to identify that spread the disease among livestock in rural communities.

Delays in recognition – because most veterinarians and physicians had never seen Nipah virus – meant animals and people were sick for more than a week before we realized what had happened. And now we are being told that the virus, which in nature does not spread easily among people, was genetically modified to increase its ability to spread from animal to animal, animal to person, and person to person.

Biological agents have now been used again to attack the United States, defying predictions and hopes that this would never happen. Obviously, those predictions were wrong.

For years, the Intelligence Community and others said that although terrorists intended to develop and use biological weapons, they lacked the leadership, organizational wherewithal, infrastructure, expertise, and social support to actually develop and deploy them.

We were also told that there are lines beyond which even terrorists would not tread.

Despite these assurances, terrorists have now used biological weapons to conduct attacks here and throughout the world. The basis of their capability has become painfully clear: they have the leadership, numbers, funding, infrastructure, and expertise to achieve large-scale goals and objectives.

Their multipronged attacks occurred within a very short timeframe – just one week.

The terrorists were successful because the government – including Congress – failed. They took advantage of our failure to achieve early environmental detection of the agent, failure to quickly recognize its occurrence in livestock, failure to rapidly diagnose the disease caused in sick patients, failure to consistently fund public health and health care preparedness, failure to establish sufficient medical countermeasure stockpiles, failure to make sure that non-traditional partners communicate. Ultimately, they took advantage of our failure to make biodefense a top national priority.

Sadly, much as the 9/11 Commission observed in its analysis of the attacks of 2001, the attacks of 2016 occurred because of another "failure of imagination."

SCENARIO

There were failures of prediction, early warning, and detection:

- The Intelligence Community failed to warn of a well-planned and direct attack on the United States and its global interests.
- HHS, USDA, and DHS failed to detect the biological agent upon release.

There were and continue to be failures to respond appropriately:

- HHS and USDA still have no way to treat exposed people or animals.
- The CDC, USDA, DHS, FBI, and DOD failed at their initial efforts at identification and attribution.
- Critical infrastructure is faltering because workers cannot or will not report to their jobs because they lack protection.
- Emergency service professionals are struggling valiantly to do their jobs, all while keeping their own families safe, in the absence of adequate protection.
- DOD must remove itself from the domestic response while it redirects resources and expertise to defend the United States against enemies seeking to take advantage of these vulnerabilities.

The Nation failed to heed the advice of the 9/11 Commission, the WMD Commission, and many other experts who warned of the dangers of biological terrorism and warfare.

We must now add the failure to appreciate the threat, generate political will, and take action in the face of looming danger.

This is only the second time in the history of Congress that two permanent committees have joined to conduct a bicameral investigation, the first being for the 9/11 investigation. We are holding this hearing today to find out exactly what happened, how this leadership failure occurred, and what needs to be done to recover from these attacks. We also intend to see what it will take to prevent additional attacks and to make sure we have done all we can to be prepared in case these efforts fall short. We will hear from three panels of witnesses:

First, from the four governors of the states and one U.S. territory where these biological attacks occurred.

Second, from the Secretary of State, the Secretary of Defense, the Attorney General, and the Director for National Intelligence, whom we call upon to explain why they missed indications of the impending use of biological weapons.

Third, from the Secretary of Agriculture, the Secretary of Health and Human Services, and the Secretary of Homeland Security, whom we ask to explain their extraordinary challenges in surveillance, detection, identification, response, and attribution.

The Chair now recognizes the Ranking Member of the Committee for an opening statement.

INTRODUCTION: THE CHALLENGE OF LEADERSHIP

The biological threat carries with it the possibility of millions of fatalities and billions of dollars in economic losses. The federal government has acknowledged the seriousness of this threat and provided billions in funding for a wide spectrum of activities across many departments and agencies to meet it. These efforts demonstrate recognition of the problem and a distributed attempt to find solutions. Still, the Nation does not afford the biological threat the same level of attention as it does other threats: There is no centralized leader for biodefense. There is no comprehensive national strategic plan for biodefense. There is no all-inclusive dedicated budget for biodefense.

Biological threats – including biological warfare, bioterrorism, and infectious disease – are not new. The United States engaged in a biological warfare program from 1943 to 1969[1] not only to develop biological weapons for offensive use, but also to develop programs and countermeasures to help defend against the use of biological weapons by the former Soviet Union and other enemies.[2] The United States eventually decided that the use of biological weapons could not achieve military aims without resulting in questionable control of both affected areas and the disease imparted by these weapons. We shifted to a defense-only program thereafter, allowing for civilian agencies to address the dangers associated with naturally occurring infectious diseases. The passage of time during which we believed that other nations had ceased their own offensive biological weapons programs led us to reduce the priority placed on addressing biological threats.

The former Soviet Union began its biological weapons program in the 1920s. While the Soviet Union signed onto the Biological and Toxin Weapons Convention (BWC) and claimed to have discontinued its biological weapons program in the 1970s, Soviet defectors and other sources relayed that the program continued into the 1990s, producing thousands of tons of weaponized biological agents and the weapons themselves, and renewing apprehension.[3] Today, Russia still has not allowed inspectors into all of its facilities capable of producing biological weapons. South Africa also built and maintained an arsenal into the 1990s with the intent of using agents like human immunodeficiency virus (HIV) and Ebola on opponents of apartheid.[4] For these and other reasons, President William J. Clinton became concerned and directed White House staff to evaluate the veracity of various biological scenarios and assess federal efforts to build defenses against intentionally introduced and naturally occurring biological events. After a flurry of briefings and the implementation of new programs to improve domestic biodefense against high-impact events such as bioterrorism and pandemic influenza, investments eventually began to wane until the anthrax attacks in 2001 again revived interest.

The biological threat has not abated. At some point, we will likely be attacked with a biological weapon, and will certainly be subjected to deadly naturally occurring infectious diseases and accidental exposures, for which our response will likely be insufficient. There are two reasons for this: 1) lack of appreciation of the extent, severity, and reality of the biological threat; and 2) lack of political will. These conditions have reinforced one another.

This chapter addresses the following:

I. The Biological Threat is Real and Growing

II. Previous Commissions Have Expressed Concern

III. The United States Lacks Centralized Biodefense Leadership

I. THE BIOLOGICAL THREAT IS REAL AND GROWING

Current and former federal officials, as well as a number of private sector experts,[5] believe that the biological threat is real and growing, and urge increased activity to defend the nation against it.[6] This biological threat is multifaceted. Unlike other threats, those that are biological in nature can be borne of malicious intent, more benign human activity, or simple chances of nature.

The Department of State (DOS) assesses that China, Iran, North Korea, Russia, and Syria continue to engage in dual-use or biological weapons-specific activities and are failing to comply with the BWC.[7] Caches of incompletely destroyed or buried biological weapons materials from old state programs[8] can now be accessed again by new state programs, and then smuggled to other regions for use in today's wars and by today's terrorists.[9] Weapons that once consumed a great deal of time and resources to make now take far less, and it is reasonable to believe that what the United States could accomplish more than 40 years ago, others can accomplish now.[10]

The resources necessary to produce biological weapons[11] are more easily obtained by states and terrorists than in years past.[12] For example, regarding ISIL, former Representative Mike Rogers believes that, "the longer they have freedom of operation in any space that contains those kinds of elements, I think that's dangerous to the United States and our European allies."[13] Additionally, terrorist organizations,[14] domestic militia groups,[15] and lone wolves[16] have expressed intent to use and shown some capacity to develop biological weapons. Advances in science have led to a convergence of biology and chemistry, and an ability (through synthetic biology) to create and combine agents. All of this has expanded the number and types of potential biological weapons[17] and made it more difficult to fully comprehend the enormity of the threat.[18]

Discerning surreptitious intent to develop biological weapons that could inflict catastrophic effects on the United States is an enormous intelligence challenge. Despite the dire consequences associated with and its own abiding concern about the biological threat, the Intelligence Community (IC) has neither been provided with nor itself dedicated sufficient resources to collect, analyze, and produce intelligence regarding the biological threat to the same extent as it has with other types of threats. The ubiquity of knowledge necessary to weaponize biological agents also prevents the IC from using more traditional nation-specific or expertise-specific approaches to intelligence collection. Additionally, the IC has not been able to invest in or hire sufficient numbers of scientists and others with needed expertise and ability to participate in biological intelligence activities. This is not to say that the IC has made no attempts at collection, analysis, and dissemination of intelligence relevant to the biological threat. However, the vast nature of the threat is out of proportion with the limited resources and emphasis dedicated to addressing it by the IC as well as those that task and request information from the IC.

Pandemic and highly pathogenic influenzas challenge the globe every year and result in the loss of thousands of human and frequently millions of animal lives, respectively.[19] Globally prevalent diseases for which countermeasures have already been developed are mutating and defeating what little we have to treat them.[20] Emerging diseases – such as Dengue fever and Chikungunya – are occurring with greater frequency, spreading throughout the United States, and lack treatments. Naturally occurring diseases can also devastate livestock, crops, and dairy or produce supplies, harming millions of people and producing a debilitating effect on the U.S. economy.

Accidents can also result in the release of harmful pathogens. Some laboratory leaders have paid insufficient attention to the details necessary to ensure laboratory biosafety and have inadvertently contributed to the biological threat. Poor biosafety resulted in the unintended release of anthrax from Russian laboratories in 1979,[21] anthrax from a U.S. military laboratory at Dugway Proving Grounds in 2015,[22] and *Burkholderia pseudomallei* from a Tulane University research center in 2014.[23] These incidents underscore how much we still have to learn about the hardiness of biological agents, the checks necessary to ensure biosafety standards are being met, and the science of how long it takes laboratories to realize that previously effective procedures no longer work.

Poor biosecurity also increases the biological threat.[24] Even our highest level government laboratories have fallen short in this regard. For example, in 2001, anthrax was illicitly removed from the U.S. Army Medical Research Institute on Infectious Disease and used in the perpetration of the anthrax attacks that year. Decades-old vials of smallpox virus were found in a U.S. Food and Drug Administration (FDA) freezer on the campus of the National Institutes of Health (NIH) in Bethesda, Maryland in 2014, even though previous searches had been conducted in order to fulfill the requirement that all remaining U.S. stocks be consolidated at the Centers for Disease Control and Prevention (CDC).[25] Major mishaps at the CDC that same year resulted in investigations, inspections, congressional hearings, and closure of certain laboratories that tested for suspected bioterrorist agents.[26] Exacerbating the problem was that these breaches of biosecurity resulted in the temporary (yet extended) restriction of laboratory activities and closure of laboratories that perform critical testing and research necessary to meet and reduce the biological threat – leaving the Nation with diminished capability to secure itself.

II. PREVIOUS COMMISSIONS HAVE EXPRESSED CONCERN

Some leaders in the political community have indeed appreciated the large and multifaceted nature of the biological threat, including the members of earlier commissions. Each referenced the biological threat, took this threat seriously, noted the potential for significant impact, and called for action. The U.S. Commission on National Security/21st Century (Hart-Rudman, 1999, 2000, and 2001) recognized the potential for epidemics to become pandemics and the dual-use nature of scientific discoveries.[27] The Commission on Terrorist Attacks on the United States (9/11 Commission, 2004) echoed Hart-Rudman and posited that more than two dozen terrorist groups were pursuing biological materials but that high-level government leaders were expressing varying levels of concern regarding this threat.[28] The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction (WMD) (Robb-Silberman, 2005) joined the Hart-Rudman and 9/11 Commissions in their concern and described in excruciating detail the failings and weaknesses of the IC regarding the biological threat.[29] Finally, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (Graham-Talent, WMD Commission, 2008) reaffirmed the findings of these previous commissions and determined that the priority placed on addressing the biological threat was too low to ensure national security.[30] Despite the observations made by these commissioners over more than 20 years, and despite action and progress in some areas, no one has yet taken the lead to address this threat in a strategic and coordinated fashion.

III. THE UNITED STATES LACKS CENTRALIZED BIODEFENSE LEADERSHIP

The centralization of leadership at the highest levels of government is the norm only for those issues deemed to require such centralization. These are typically matters fundamental to the well-being of the Nation (e.g., national security, homeland security, economic security). Occasionally, a subset of these rises to the fore: counterterrorism, influenza pandemic preparedness, an acute economic crisis. In these cases, an official is often placed in charge, sometimes permanently, but often only temporarily.

The United States has utilized a number of options for centralizing leadership around issues of national importance. These include: 1) placing a federal department or agency official in charge; 2) assigning responsibility to White House staff; 3) naming a czar; or 4) placing an elected official in charge. The last three Presidential Administrations have taken one or more of these approaches to address biodefense, with varying levels of success, and with only partial centralization. What each approach lacked was a figure whose job it was to ensure that all of the federal government was strategically working toward the common goal of comprehensive biodefense.

PLACING A FEDERAL DEPARTMENT OR AGENCY OFFICIAL IN CHARGE

The dissolution of the United States' offensive biological weapons program in 1969 forced a change in the offensive/defensive leadership paradigm for biological threats. Dropping the offensive program, assuming a defensive-only posture, and increasing commitments from other nations that they were not developing or using biological weapons meant that the Department of Defense (DOD) would no longer take a primary leadership role in biodefense.

The Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) – departments with the responsibility for addressing the impact of biological threats to humans, animals, and plants – did not take up the mantle of leadership or were not successful when they tried. For example, HHS was unable to effectively lead other members of the Executive Branch to produce a national strategy for pandemic influenza. This requirement was initially assigned to the Department of Health, Education and Welfare by President James E. Carter in 1977 and carried over when the new HHS was created in 1980. It was subsequently removed from HHS by President George W. Bush and finally fulfilled by the White House when it produced the National Strategy for Pandemic Influenza in 2005 and the Implementation Plan for this Strategy in 2006.

In accordance with the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006 (P.L. 109-417), Congress mandated that the HHS Assistant Secretary for Preparedness and Response (ASPR) be responsible for interagency coordination of preparedness for and response to biological events. Congress also intended for the ASPR to be a (and some would argue *the*) leader of national biodefense efforts, although the statute is limited to preparedness and response elements of biodefense. The ASPR played a role in managing some aspects of the recent Ebola crisis (e.g., overseeing the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) MCM efforts, administering Ebola supplemental funding for hospital preparedness). However, President Barack H. Obama did not place the ASPR in charge of overall Ebola response coordination, having chosen instead to name a coordinator independent of the departments and agencies. Even if the ASPR had coordinated this and other biological crises in their entirety, in reality there is no mandate for the ASPR

to lead all interagency activities across the entire biodefense enterprise. Further, it is unclear how leadership and coordination on the part of the ASPR would fit within the requirements of the National Response Framework, especially since mention of the ASPR was removed from the Framework when it was last updated.

There are also presidential and congressional mandates and intent for the Secretary of Homeland Security to lead and coordinate interagency activities in support of homeland security – addressing biological and chemical attacks, accidents, or events affecting the homeland. In 2009, then-Secretary of Homeland Security Janet Napolitano took charge of the interagency response to the H1N1 influenza pandemic, prior to the confirmation of Secretary of Health and Human Services Kathleen Sebelius. The Department of Homeland Security (DHS) followed some of its plans for leadership and coordination, but set aside others even within the Department (e.g., making last minute changes to previously established and exercised plans, identified leaders, and responsibilities that had originally been assigned to the U.S. Coast Guard). When DHS experienced limited success in leading and coordinating interagency efforts during the H1N1 pandemic, the White House took over.

ASSIGNING RESPONSIBILITY TO A MEMBER OF THE WHITE HOUSE STAFF

Since the establishment of the National Security Council (NSC) staff, typically, at least one staff member has addressed some aspect of biodefense. Some of the appointments have been strategic and forward-looking; others have been reactive to events. The first person to formally address biodefense policy at the White House was an assistant surgeon general from the U.S. Public Health Service, detailed to the NSC by Secretary of Health and Human Services Donna Shalala in 1998. This dedicated biodefense policy position was eliminated following the 2000 election. In the months following the attacks on September 11, 2001 and the anthrax attacks shortly thereafter, a variety of White House staff and detailees were assigned to work on anthrax specifically and biodefense more generally. In 2002, Assistant to the President Tom Ridge created a biodefense directorate in the newly formed Homeland Security Council (HSC) and staffed it with a Special Assistant to the President and three additional full-time professionals. This office remained in place within the HSC through the end of the Bush Administration. Following the 2008 election, President Obama merged the HSC staff with the NSC staff and eliminated this biodefense office. Instead, he distributed various biosecurity functions throughout the NSC, including the WMD Terrorism and Threat Reduction, Development and Democracy, and Resilience Directorates. (President Obama did appoint a WMD Coordinator, discussed below, but this position was not focused on biodefense). When Ebola emerged in the United States in 2014, the President appointed a dedicated Ebola czar to coordinate the U.S. government's response from the White House.

Opinions vary regarding the effectiveness of the present NSC organizational construct to address biodefense. Some argue that its efforts are fractionated, while others contend that the wider variety of staff involved allows for broader involvement of multiple policy offices across the spectrum of biodefense activities. While it is possible for other White House councils and offices to address biodefense,[31] they generally only do so when a specific biodefense issue affects a prominent ongoing responsibility (such as when the White House National Economic Council assessed the impact of a foot-and-mouth disease outbreak on the U.S. economy). Regardless of specific title or location in the chain of command, the imprimatur of the President can help overcome the challenges faced by multiple federal departments and agencies that must act and work together to achieve biodefense aims.

This was one of the reasons that Congress – through the Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53, herein referred to as the 9/11 Act) – created the Office of the U.S. Coordinator for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. The 9/11 Act specifies that this Office house a Coordinator and Deputy Coordinator, appointed by the President and responsible for serving as the principal advisors to the President on all matters relating to WMD proliferation and terrorism. The 9/11 Act goes on to make this Coordinator (often referred to as the WMD Coordinator) responsible for developing a comprehensive national strategy and individual policies to combat WMD proliferation and terrorism, incorporating (among other things): measurable targets and milestones with which to hold agencies accountable; identification of gaps, duplications, and inefficiencies in existing programs and initiatives; plans to strengthen and expand the scope of existing programs and initiatives; new and innovative programs to address emerging challenges and threats; coordination among the various federal agencies involved in addressing this threat; and plans to strengthen U.S. commitment to international non-proliferation efforts.

President George W. Bush did not implement this recommendation. President Obama named Dr. Gary Samore as the WMD Coordinator in 2009, without submitting him for the Senate confirmation called for in statute. His focus was far more on nuclear threats than biological. Upon Dr. Samore's departure, Dr. Elizabeth Sherwood Randall took on these and additional responsibilities as the Coordinator on Defense Policy, Countering Weapons of Mass Destruction and Arms Control in 2013 (also without being Senate confirmed) but left that position a year later when she became the Deputy Secretary of Energy. The position of the WMD Coordinator is not currently filled. The difficulty of subjecting White House staff to congressional mandate is that it is up to the President to decide how best to manage his or her staff, not Congress. A mandated position also may not fit logically within organizational constructs that change as Administrations and their priorities change. Congress implicitly seems to respect this Presidential authority and has not forced the issue of ensuring that any President fill this position.

NAMING A CZAR

Certain topics achieve distinction as having national impact, but require more subject matter expertise and focused effort than departments and agencies in the Executive Branch can afford to dedicate. The term czar is occasionally and informally used to identify the individual the President has appointed to address such an issue if it is high priority and of great interest. Czars are political appointees that may or may not be confirmed by the Senate, with positions that may or may not carry over from one Administration to another. While czars often enjoy a higher profile than other members of the White House staff, those that do not hold institutionalized or authorized positions often lack sufficient authority or power to enact necessary change because they oversee only one particular part of policy. A number of czars have addressed various biological threats, including avian influenza, Ebola, and terrorism.[32]

PLACING AN ELECTED OFFICIAL IN CHARGE

Little has been done to establish a strong, well-funded, centralized authority overseeing national efforts in biodefense. This lack of high level and centralized leadership prevents critical problems from receiving proper focus and attention within the Executive Branch. It also weakens those efforts that exist among the agencies that strive to work in the absence of such leadership. While it is the nature of democracies to be reactive, reactionary policies and programs do not serve the Nation's best interest when it comes to the biological threat. Time and again, the United States has been forced to respond to intentional, naturally occurring, and accidental biological events,

with real human, animal, environmental, and financial costs. These complex interagency responses can either be reactive, or they can be planned, funded, and exercised ahead of time under the guidance of a centralized leader.

The President should retain flexibility to address biodefense at the White House in whatever way he or she chooses. However, such flexibility should not continue to result in the absence of a concentrated and continuous effort across Administrations. Further, if the White House takes charge or is expected to take charge of every significant biological event, then this responsibility should be institutionalized.

This responsibility can be institutionalized in a number of offices in the White House, including that of the Vice President. The Vice President has a direct line to the President and, when imbued with authority as the President's proxy, can act on his or her behalf. There is precedent for Vice Presidents assuming responsibility for various initiatives. For example, President Clinton appointed Vice President Albert A. Gore to lead the National Performance Review[33] in 1993 and made the Vice President responsible for translating the recommendations of the Review into improved government performance and results. The Vice President's leadership was critical to producing a bill that was sent to Congress to address these requirements. While Congress did not pass that bill, it did produce and pass the Government Performance and Results Act (GPRA), which addressed many of the Review's recommendations. Vice President Gore retained responsibility for seeing that the Act was implemented and personally held the Executive Branch accountable in this regard.

The primary goal of centralization is to place the coordination and oversight responsibility in a location that will have sufficient authority regardless of personalities or party in power, and in a position with the ability to make executive decisions. The Vice President possesses these attributes.

Recommendation 1

Institutionalize biodefense in the Office of the Vice President of the United States. Institutionalizing this responsibility in the Office of the Vice President will ensure that biodefense will be addressed by every Administration, at the highest levels, and with adequate access to the President.

ACTION ITEMS:

a. **Empower the Vice President with jurisdiction and authority.** The President should place the Vice President in charge of national biodefense. The Vice President should take necessary action to ensure adequate biodefense for the United States, address relevant international issues and requirements, and coordinate the U.S. biodefense enterprise. The President should also provide the Vice President with jurisdiction within, and authority to coordinate among, the various relevant councils in the White House.

b. **Empower the Vice President with budget authority.** The President must give the Vice President authority to review and advise on all agency biodefense budgets to achieve national security goals for biodefense at any point during the budget development and submission process. This authority should extend to directing the budget submissions of departments and agencies, in collaboration with the Director of the Office of Management and Budget (OMB).

The Nation has not come to fully appreciate the severity of the biological threat and our leaders have not demonstrated the political will to fully address it. We must address these shortcomings by prioritizing the following areas: 1) coordination and accountability among federal departments and agencies; 2) collaboration between federal and non-federal stakeholders; and 3) innovation that addresses both lingering and novel problems. The chapters that follow explore each of these in turn.

CHAPTER 1: THE NEED FOR LEADERSHIP IN ACHIEVING COORDINATION

Biodefense necessitates complex and sophisticated multi-disciplinary efforts, successful navigation of which requires coordination among government, academia, and industry. Centralized effective leadership is necessary to align these efforts. Because such leadership is lacking, federal biodefense activities are insufficiently coordinated. Authority and responsibilities are dispersed among many cabinet agencies, without the benefit of a single leader to provide directives and receive reports. Thus, while outcomes of individual department and agency efforts may or not be successful, no one is held fully accountable for the necessary outcomes of a mission-oriented and integrated biodefense enterprise.

This problem is further complicated by the lack of a comprehensive biodefense strategy. A decade of profusion of policy directives indicates well-intentioned efforts to facilitate progress, yet the staggering number has resulted in a fragmented enterprise made less stable as Administrations pass from one to the next and priorities change. Additionally, a unified approach to budgeting is a vital part of any strategic interagency effort, and this is lacking as well. This undoubtedly means that spending is redundant in some areas and deficient in others.

The lack of coordination manifests in a variety of areas of critical importance to biodefense: the gathering and dissemination of intelligence; consideration of animal health and one health approaches as central tenets of health security; prioritization of emerging threats; and investment in areas including MCM, bioterror attribution, and decontamination and remediation.

Congressional oversight and legislation are critical for ensuring that the biodefense enterprise works. Congressional efforts have been hampered, however, by the lack of a comprehensive and cohesive biodefense strategic plan from the Executive Branch, as well as extensive cross-committee jurisdiction that often dilutes congressional focus.

This chapter addresses coordination and accountability in the following areas:

I. The Imperative for Cogent Governance
II. Improving Intelligence Community Efforts
III. Recognizing and Institutionalizing the One Health Concept
IV. Coordinating Medical Countermeasure Efforts
V. Establishing an Attribution Apparatus
VI. Taking Charge of Decontamination and Remediation

I. THE IMPERATIVE FOR COGENT GOVERNANCE

NEED FOR A COORDINATING BODY AT THE WHITE HOUSE

To address cross-sectoral issues, organizations often form coalitions. Agencies within the federal government sometimes create coalitions of their own volition. However, competing priorities and demands more often dominate their day-to-day activities and drive them to operate independently. The White House has also established coalitions to achieve certain aims, but

these efforts to obtain consensus have at times resulted in diluted strategies and plans that all stakeholders can agree on but which do little to move the needle.[34]

As many as a dozen departments and agencies participate in biodefense,[35] a mission space with governmental and nongovernmental members and activities authorized, ordered, and guided by various statutes, presidential directives, and other policy documents. Some of these departments and agencies show substantial initiative and execute on big or important ideas in biodefense; others work in a supportive capacity; still others engage temporarily, sporadically, or with limited enthusiasm. More than fifty political appointees[36] have been given some part of the biodefense mission, but largely act independently. Because of the scope of this scheme, these appointees often have little awareness of similar or potentially synergistic activities throughout the federal government, creating an inefficient and costly system that may not meet overarching mission objectives. A much more coordinated approach is called for that leverages the resources of the Nation that exist beyond those of the federal government.

Recommendation 2

Establish a Biodefense Coordination Council at the White House, led by the Vice President. A coalition approach is needed to create cohesion among departments, agencies, states, localities, territories, tribes, and industry. Such an approach can help smooth the competing priorities and demands that drive organizations to operate independently.

ACTION ITEMS:

a. **Require broad federal participation.** The Vice President should direct all departments and agencies that address biodefense (in keeping with the National Biodefense Strategy of the United States of America per Recommendation 3) to hold a seat on the Biodefense Coordination Council. The designees should be at the Deputy Secretary level.

b. **Invite broad non-federal stakeholder participation.** In addition to the primary designees, the Vice President should include a state governor, a mayor, a territorial governor/administrator, a tribal leader, and private sector leaders representing critical infrastructure sectors that are vital to the success and continuity of biodefense.[37]

c. **Structure the Council for consensus and accountability.** The Vice President should lead the primary designees and the members as a coalition that will prioritize needed activities, designate responsibilities, and ensure accountability. Each federal department and agency with a seat on the Council should be charged, through the National Biodefense Strategy, with deliverables that the Council will develop and periodically evaluate.

A SINGLE, COMPREHENSIVE, AND HARMONIZED STRATEGY IS NEEDED

The sheer number of federal documents that address biodefense indicates significant interest in the subject and intent to deal with it through statute and executive direction (Table 2). In addition to or as a result of the documents listed in Table 2, the Executive Branch has promulgated numerous other policy and planning documents, which only add to the spectrum of requirements.

These include the National Strategy for Pandemic Influenza (2005) and its associated Implementation Plan (2006); the updated National Response Framework (2008), its Biological Incident Annex, and other associated annexes;[38] the 2014 PHEMCE Strategy and Implementation Plan (2014); and the National Strategy for Countering Biological Threats (2009). Together, these provide a foundation for federal biodefense activities. But the large number of documents reflects a system that has become too fragmented to be enforced and implemented in a coherent, prioritized, and unitary fashion. Biodefense for the 21st Century (HSPD-10) was the most comprehensive strategic biodefense document at the time it was drafted. Defense of United States Agriculture and Food (HSPD-9), however, was issued independently and the two directives are distinct. HSPD-10 is now more than a decade old and numerous other related policy directives have been issued and important programs begun since then. The National Strategy for Countering Biological Threats, which by title sounds like a comprehensive document, is actually more focused on supporting a subset of mission areas outlined in HSPD-10, largely with respect to international efforts.

Operating in the absence of a comprehensive biodefense strategy has made the need for comprehensive biodefense planning clear. Many additional planning documents often only address isolated elements of biodefense (e.g., post-exposure prophylaxis for certain bioterrorist agents) or individual diseases (e.g., pandemic influenza) and are not always incorporated into broader plans. Additionally, many of the plans developed over the past decade used models of naturally-occurring infectious diseases rather than weaponized pathogens.[39] DHS, DOD, HHS, and USDA made assumptions about the time and resources needed to treat severely ill persons and animals exposed to biological agents, but have not reexamined these suppositions in light of recently declassified information from the U.S. biological weapons program.

The lack of a comprehensive, cohesive, and regularly updated strategy has resulted in disorganization and confusion, particularly as Administrations change and the institutional knowledge associated with them is lost. Biodefense planning has become driven by agencies with requirements that may or may not meaningfully contribute to national biodefense. A single, comprehensive, and harmonized strategy to pull these myriad documents together is lacking.

TABLE 2: EXAMPLES OF BIODEFENSE DIRECTIVES, PUBLIC LAWS, AND TREATIES[40]

PRESIDENTIAL DIRECTIVES

- National Security Decision Memorandum (NSDM) 35 (1969)
- NSDM- 44 (1970)
- Homeland Security Presidential Directive (HSPD) 4, the National Strategy to Combat Weapons of Mass Destruction (2002)
- HSPD-7, Critical Infrastructure Identification, Prioritization, and Protection (2003)
- HSPD-8, National Preparedness (2011)
- HSPD-9, Defense of United States Agriculture and Food (2004)
- HSPD-10, Biodefense for the 21st Century (2004)
- HSPD-18, Medical Countermeasures Against Weapons of Mass Destruction (2007)
- HSPD-21, Public Health and Medical Preparedness (2007)
- Presidential Policy Directive 2, National Strategy for Countering Biological Threats (2009)

PUBLIC LAWS

- The Biological Weapons Anti-terrorism Act of 1989 (P.L. 101-298)
- The Chemical and Biological Weapons Control and Warfare Elimination Act of 1991 (P.L. 102-182)
- The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (P.L. 107-56)
- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188)
- The Homeland Security Act of 2002 (P.L. 107-296)
- The Project BioShield Act of 2004 (P.L. 108-276)
- The Pandemic and All-Hazards Preparedness Act of 2006 (P.L. 109-417)
- Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53)
- The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5)
- A multitude of appropriations laws that contain additional requirements

INTERNATIONAL TREATIES, PARTNERSHIPS, AND INSTRUMENTS

- Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1974)
- The Australia Group (1985)
- United Nations Security Council Resolution 1540 (2004)
- International Health Regulations (2005)
- Global Health Security Agenda (2014)

Recommendation 3

Develop, implement, and update a comprehensive national biodefense strategy. The Vice President should direct the development of the National Biodefense Strategy of the United States of America. This strategy should be comprehensive and harmonized, and should define all Executive Branch organizational structures and requirements, modernization and realignment plans, and resource requirements necessary for implementation.

ACTION ITEMS:

a. **Collate the whole of biodefense policy.** The NSC should collate all extant biodefense policies, laws, and treaties that promulgate defense responsibilities against intentionally introduced, accidentally introduced, and naturally occurring biological threats.

b. **Identify requirements within all extant policies**. Based on the body of policy documents identified in action item 3a, the NSC and other relevant offices in the White House should catalogue responsibilities and delineated requirements in all biodefense-related laws, directives, and other policy documents. Other relevant White House offices and councils beyond the NSC should further examine requirements in keeping with their areas of expertise and responsibility.[41]

c. **Assess spending history and value.** The Director of OMB should identify how much funding has been budgeted and appropriated for each requirement identified in action item 3b. OMB should audit performance and determine if requirements are still appropriate, and if not, provide options for refining, moving, or eliminating them.

d. **Produce the National Biodefense Strategy of the United States of America and its Implementation Plan**. The Vice President (using the information collected from action items 3a, 3b, and 3c) should develop a comprehensive national biodefense strategy and implementation plan. Departments and agencies must be held accountable for the elements of the plan for which they have been made responsible. A progress report should be provided to Congress annually.

e. **Develop a gap analysis based on this comprehensive strategy**. Congress should direct the Government Accountability Office (GAO) to analyze gaps in resources mapped against the requirements of the National Biodefense Strategy and estimate resource requirements for small-, medium-, and large-scale events.

f. **Institute a major quadrennial biodefense review**. At the direction of Congress and under the management of the Vice President, the NSC should conduct a major quadrennial biodefense review of all relevant departments and agencies, with a report and updated National Biodefense Strategy submitted on behalf of the Executive Branch to Congress by the Vice President.

UNIFYING THE BIODEFENSE BUDGET

Nearly $80 billion was spent on biodefense from FY2001 through FY2014.[42] The majority of this was put toward multi-hazard programs and about 10 percent toward biodefense-only initiatives. Allocations for individual programs or mission spaces have risen and declined depending on the circumstances of the day, but in general, about $6 billion is annually spent on biodefense and related hazards. It is difficult to determine the adequacy of this funding level in the absence of an interagency biodefense strategy and a unified biodefense budget.

Awareness on the part of OMB of budgetary requirements and expenditures does not empower any part of the Executive Branch to control, coordinate, or prioritize biodefense activities. There is no unified concept or determination of what is meant by biodefense, leading OMB, House and Senate Committees on Appropriations, and private sector organizations to calculate differing budgetary totals. While some aspects of organizational budgets and appropriations bills are classified and many biodefense activities overlap with non-security public health efforts, these are not reasons to give up on determining how much is and should be spent on each element of biodefense. A unified approach to budgeting would enhance congressional oversight and allow the White House to better determine whether ongoing programs are aligned with the President's priorities. Additionally, many biodefense activities would greatly benefit from multiyear funding. The biodefense enterprise is no different from the national defense enterprise, which receives multiyear funding for a variety of its programs.

Recommendation 4

Unify biodefense budgeting. Congress should mandate the development of a unified budget that allows Congress and the Administration to understand how the entire biodefense enterprise is funded.

ACTION ITEMS:

a. **Develop and execute a mandatory annual biodefense call for data.** The President and congressional appropriators should require the Director of OMB to conduct this data call, coordinated by the Vice President. Each department and agency should catalogue all of their biodefense programs and indicate which support specific biodefense requirements in the National Biodefense Strategy and which do not. The submissions should include historical annual expenditures for each program and predicted future needs.

b. **Conduct a cross-cutting biodefense budget analysis.**[43] Using the information collected in the data call, the Vice President and the Director of OMB should identify gaps and overlaps in and among federal programs. This analysis should be used to inform OMB budgetary guidance sent to departments and agencies for the coming fiscal year.

c. **Align budget items to the National Biodefense Strategy of the United States of America.** The Director of OMB should require that all annual budget request submissions pertaining to biodefense adhere to the guidance from OMB, based on the National Biodefense Strategy and the budget cross-cut.

d. **Provide predictable and multi-year funding for all biodefense programs.** The President should request funding for all biodefense activities in the annual budget request, including multi-year requests for those programs that the Vice President and Director of OMB determine would benefit from such forward funding. Additionally, departments and agencies should provide multi-year grants, contracts, and/or cooperative agreements wherever possible.

MORE COMPREHENSIVE OVERSIGHT IS NEEDED

Congressional oversight, appropriations, authorizations, and investigations of Executive Branch activities are essential. The 9/11 Commission and the WMD Commission recommended that Congress reform its dysfunctional homeland security oversight system. To this day, that oversight remains fragmented across at least 108 committees and subcommittees that claim some authority through Senate and House rules for homeland security oversight.[44] In biodefense, about two-dozen committees have authority for oversight, with one to two subcommittees per committee maintaining specific purview. Actual oversight, however, seems to occur among only a handful of interested committees. While this can prevent oversight discordance, it also means that some important activities escape congressional oversight altogether.

Frequently, the topics that the more active committees assess (e.g., threat awareness, biosurveillance and detection, MCM) comprise only a small subset of the broad range of issues that require substantial oversight. With some notable exceptions, most of the oversight (particularly through hearings) that occurs is in reaction to an event. Proactive oversight agendas are limited. The most common topics are frequently conducted as post hoc reviews of major missteps of federal program execution or how the government is managing current outbreaks. Many of the issues that deserve more congressional oversight are discussed in this report, and include IC activities to address the biological threat, adequacy of funding, animal disease surveillance (particularly zoonotic diseases), challenges in biological attribution, and military/civilian collaboration in biological research and development (R&D). Congress must exercise its authority on these issues more proactively, comprehensively, and in a coordinated manner.

Lacking an end-to-end strategy for biodefense, however, Congress must guess how responsibilities and requirements should fit together. This makes effective oversight much more difficult. Further, the extensive cross-committee jurisdiction described can dilute Congressional focus. The problem is less that there are too many committees exercising oversight jurisdiction, and more that they need to exercise that jurisdiction more frequently. Congress needs to lean forward, determine in which areas it has neglected oversight, develop a dedicated oversight agenda, and exercise it to ensure the entire biodefense mission space is addressed. (See Appendix A for suggested topics for the congressional oversight agenda.) Finally, Members of Congress are often insufficiently briefed on the threat, and as a result, may not deal with it urgently. This must change.

Recommendation 5

Determine and establish a clear congressional agenda to ensure national biodefense. Congress must ensure that the Nation is protected by an efficient, effective biodefense enterprise through augmented and coordinated congressional oversight.

ACTION ITEM:

a. **Develop joint congressional oversight agendas.** At the start of each congressional session, Senate and House leadership should direct each committee with biodefense jurisdiction, in accordance with House and Senate rules, to convene for an in-depth classified biological threat briefing. Leadership should ensure that all identified committees include pressing biodefense topics in their oversight agendas. These agendas should include joint committee and joint chamber hearings and other oversight activities.

II. IMPROVING INTELLIGENCE COMMUNITY EFFORTS

The IC is addressing the biological threat, but overall, the Community is unable to adequately collect and analyze intelligence due to insufficient resource allocation. The priority level placed on addressing the threat is not high enough to warrant the reallocation of resources (including human) necessary for increased collection, analysis, and distribution. This means that the Director of National Intelligence (DNI) is unable to dedicate sufficient human and other resources, enable IC agencies to establish or maintain relationships necessary for collection, or develop new strategies to gather information. The efforts the IC has been able to execute thus far are not well coordinated, with various agencies addressing different aspects of the threat. Additionally, the IC has taken some information that bystanders (those who are near to malevolent actors but are not directly involved in their actions) may possess into consideration, but has not been able to institute a full-scale program dedicated to this collection. For these reasons, the IC has not produced the sort of comprehensive analysis of the biological threat that it has for other threats.

Recommendation 6

Improve management of the biological intelligence enterprise. The DNI should address the biological threat in the same way that other issues have been handled that cut across multiple intelligence agencies.

ACTION ITEMS:

a. **Create a National Intelligence Manager for Biological Threats.** The DNI should create a National Intelligence Manager (NIM) for Biological Threats and ensure that this NIM interacts appropriately with other NIMs who address some aspect of the biological threat. The DNI should make this new NIM the executive agent for distributing certain funds for biological intelligence activities, transferring responsibility from the Central Intelligence Agency.

b. **Make biological weapons programs and related activities a discrete intelligence topic.** The DNI should ensure that the IC assigns priorities to countries and non-state actors as they relate to biological weapons programs and activities. The IC should broaden focus to address classes of biological agents, as opposed to individual diseases. The IC should also collaborate with the private sector when conducting this analysis and ensure that scientific and other expertise resident within the Community is sufficient to develop biological threat futures.

c. **Address bystanders.** The DNI should ensure that the IC develops intelligence collection strategies that address bystanders, who may be able to provide useful information.

d. **Distribute assessments.** The DNI should ensure that the IC dedicates sufficient intelligence and scientific resources to collection and analysis to produce and distribute comprehensive biological threat assessments to all members of the biodefense enterprise.

III. RECOGNIZING AND INSTITUTIONALIZING THE ONE HEALTH CONCEPT

Among the bioterror threats for which DHS has issued a Material Threat Determination (MTD), all, except for smallpox, are zoonotic, meaning that they reach human beings through animals. The same holds true with the threat of emerging infectious disease.[45] Sixty percent of infections due to emerging infectious diseases are leaping into the human population via animals (with 72 percent of these coming from wildlife) and at an accelerating rate.[46]

HSPD-10 requires disease surveillance of and detection in both human and animal populations. Divisions between human and animal health are artificial, since most pathogens of concern often affect both. Viewing them as parts of a whole is what defines a One Health approach to healthy populations. Together, human, animal, and environmental health comprise a dynamic and interconnected system that requires leadership and a strategic and coordinated approach to pull together traditionally fragmented divisions of expertise, responsibility, and authority while working effectively at the human-animal interface.[47]

Efforts to achieve human health must be grounded in an ecological understanding of the entire health picture. While there has been some good work toward this end – for example, the development of a Rift Valley Fever vaccine for ruminants that in turn helps prevent transmission to humans – conversations about the protection of human health by controlling or avoiding emerging infectious diseases in an animal host are in general extremely limited. This is likely due to the

distributed nature of health-related responsibilities across the federal government, with a given department or agency typically supporting either human health or animal health, but not both (and with wildlife authorities rarely included at all). This is also due to the lack of leadership vision to recognize the interconnectedness of health across species.

Inadequate attention and funding is even more severe in the animal and environmental health sectors than in public health. It is hard to believe that the United States lacks a nationally reportable list of animal diseases in domestic and wild animals comparable to that for humans. The USDA does require the reporting of foreign animal diseases (e.g., foot-and-mouth disease), and the United States participates in reporting of animal diseases to the World Organization for Animal Health (OIE). Yet reporting for domestic animal diseases is not required. Such a system would allow much greater information availability and coordination of effort across the government and with non-government stakeholders. In 2014, the USDA published a concept paper on what such a reporting system would look like.[48] It is time to move from concept to implementation. Reporting of animal diseases would allow for quicker response, reduced impacts on animal and human health, and better informed priorities regarding livestock infectious diseases.

A One Health approach can also inform priorities for human infectious diseases. When it became clear in 2014 that no countermeasures for Ebola were ready for the largest Ebola outbreak the world had ever seen, many policy conversations that followed were about priorities. We must have a means of determining what to fund with finite resources. The threats and risks among agents of both bioterror and emerging infectious diseases are equally serious. MTDs have been very important for the prioritization of activities around biodefense, yet there is no analogous prioritization system for emerging diseases.

The only way to direct multi-agency resources to where they are most needed, and to prevent the now-common approach of governing reactively through emergency supplemental funding, is to approach emerging infectious disease threats more strategically. Creating an emerging infectious disease priority list meaningful enough for utility across biodefense efforts and flexible enough to meet unexpected threats and the emergence of new diseases will not be easy. An inflexible list could allow unexpected and novel pathogens to blindside biodefense efforts. Different agents have drastically diverse effects on human health, human psychology, animal health, the environment, and the economy. Therefore, different stakeholders will place varying values on each pathogen.[49]

When developed correctly with built-in flexibility, however, an emerging infectious disease priority list could help drive an organized and strategic approach to biodefense. Information of the kind that programs like the U.S. Agency for International Development's EPT PREDICT program afford is critical to the integrity of any such listing. A careful, thoughtful, adaptable, and transparent approach to developing the prioritization methodology is also important, as is a methodically developed and highly deliberate effort to consider the public health, economic, and security implications of a spectrum of pathogens and pathogen groups.

Recommendation 7

Integrate animal health and One Health approaches into biodefense strategies. Effective solutions for defense against emerging infectious disease and bioterror threats lie at the interface of human, animal, and environmental health.

ACTION ITEMS:

a. **Institutionalize One Health.** The White House should lead all relevant agencies to a new level of understanding, planning, and operating with respect to biodefense that includes an animal health and, more broadly, a One Health mindset. The Vice President should direct the NSC to review all strategic biodefense documents to ensure that animal health and environmental health agencies are identified and assigned responsibility, and that their activities are fully aligned and coordinated with other biodefense activities and are current with respect to new science and evidence.

b. **Develop a nationally notifiable animal disease system.** The Administrator of the USDA Animal and Plant Health Inspection Service (APHIS), working with the Director of the Department of the Interior (DOI) U.S. Fish and Wildlife Service and other partners as appropriate, should develop a nationally notifiable animal disease list and implement a reporting system for states, localities, territories, tribes, and other owners of disease information. USDA should afford DHS, HHS, and other agencies engaged in biodefense access to the data in this system.

c. **Prioritize emerging and reemerging infectious diseases.** The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture and Secretary of Defense, should prioritize emerging infectious disease threats. They should consider using a multi-criteria decision analysis tool and transparent methodology to develop these determinations. They should address pathogens and pathogen families with the potential to cause a catastrophic public health emergency sufficient to affect national security, including agents known to infect wildlife and domestic animals. The list should drive funding in surveillance, response planning, MCM development, and any activities revealed as gaps per action item 3e.

IV. COORDINATING MEDICAL COUNTERMEASURE EFFORTS

NIH is a basic research institution, created more than a century ago to organize the medical research efforts of the federal government.[50] The culture of basic research at NIH is distinct from the applied research culture of the Biomedical Advanced Research and Development Authority (BARDA). This poses a challenge to interagency coordination, but one that is surmountable.

Per HSPD-10 and the Project BioShield Act of 2004 (P.L. 108-276), NIH must work with DHS, DOD, and other agencies to shape and execute an aggressive MCM research program. The establishment of the PHEMCE, an interagency coordinating body, has enabled better coordination along these lines, but it is still not optimal, particularly in terms of aligning NIH and

BARDA. The lack of coordination and focus speaks to the critical need to fashion a national strategy that establishes national funding priorities, not institutional ones. NIH's National Institute of Allergy and Infectious Diseases (NIAID) conducts research that is exceptionally important to defense against biological terrorism and emerging infectious diseases. All NIAID biodefense research, however, must be conducted with a transparent and strategic connection to end-user requirements.

Federally-funded scientific investigators are more likely to engage in early stage research, rather than to use the more private sector approach of focusing on specific product goals and end-user needs. This is one reason that Ebola MCM were not available when they were needed. In order to construct and implement an overarching vision, the PAHPA required a PHEMCE strategy and implementation plan, as well as a coordinated five-year budget plan that would update Congress and stakeholders on the entire MCM enterprise. This includes: basic research at NIH; advanced R&D at BARDA; approval, clearance, licensure, and authorized use of products; and procurement, stockpiling, maintenance and replenishment in the Strategic National Stockpile (SNS) at CDC. The 2014 PHEMCE report and multiyear budget described roles for each department and agency and how they would meet PHEMCE's overarching goal to supply civilian MCM. Congress must conduct the detailed oversight that is necessary to ensure that these goals are being met.

NIH receives more than a billion dollars for biodefense annually ($1.7 billion enacted in FY 2014 for the PHEMCE portfolio), primarily administered by NIAID for early stage R&D. Of the $1.7 billion at NIAID, only 15 percent ($257 million) is spent on agents determined to be material threats. Further, only $415 million is provided to BARDA annually for advanced development of biodefense MCM candidates.[51] It is unclear why advanced development – the far more costly stage of MCM development – is funded at a fraction of the amount of early R&D. The biopharmaceutical industry invests more than half of its budget in advanced development, while at DOD the number is only about 30 percent, and at HHS, only 10 percent.[52] Investment strategies must match product development goals. The PHEMCE has worked to address this by submitting a multiyear budget to Congress, in which NIAID spending was included. The level of detail, however, offers limited insight into NIAID's specific spending priorities for the numerous MCM candidates in its portfolio.

Recommendation 8

Prioritize and align investments in medical countermeasures among all federal stakeholders. The success of the MCM enterprise will be predicated on a highly coordinated approach among the PHEMCE partners to prioritize and budget for the right countermeasures.

ACTION ITEMS:

a. **Ensure National Institutes of Health research supports civilian medical countermeasure priorities.** The Vice President should ensure that PHEMCE priorities, as well as those agents that have been determined to be material threats, guide NIH biodefense research investments and ensure delivery of MCM candidates that address PHEMCE MCM priorities.

b. **Ensure funding allocations are appropriate to meet the need.** The Vice President should assess whether the level of funding allocated for biological agents that have received an MTD, and the proportion of funding allocated for early R&D of MCM candidates versus advanced R&D, is appropriate for maximizing opportunity to achieve overall success. The unified budget per Recommendation 4 provides a mechanism to achieve this harmonization. If the funding level for BARDA needs to be increased, that must be requested.

c. **Require a biodefense spend plan from the National Institute of Allergy and Infectious Diseases.** Pursuant to action items 8a and 8b, and concurrent with the President's annual budget request, the Director of NIAID should annually submit a plan to Congress that describes in detail the goals for NIAID MCM research investments, including transition to advanced research, development, and procurement planning at BARDA. The Director of NIAID should base this plan on the development of MCM candidates targeted against agents that have received an MTD, as well as to priorities identified on the emerging infectious disease list developed per action item 7c. The Director of NIAID should include ways to strengthen the bridge between NIAID and BARDA so that products can more easily transition from early stage development to advanced R&D.

V. ESTABLISHING AN ATTRIBUTION APPARATUS

The ability to attribute crimes to their perpetrators is a necessary component of effective prosecution. Attribution is a challenge in any context, and becomes increasingly difficult with the involvement of numerous investigators and when unusual or novel weapons are used to execute crimes. This is the case with biocrimes, biological terrorism, and biological warfare. When biological agents are used for attacks, not only must crimes be attributed to particular perpetrators, but the pathogens and their sources must also be correctly identified. The United States has yet to fully establish this capability due to the inherent challenges associated with microbial forensic techniques and related analysis.

The law enforcement and public health communities have clear responsibilities for the investigations that fall under their respective domains. The intelligence, defense, and scientific communities also have important roles to play. Some excellent work, largely initiated by the Federal Bureau of Investigation (FBI), has established cross-pollination among these communities. Yet the work is complicated. Representatives from these groups must align and support one another's investigations. This must occur despite differences in information sharing norms and requirements among these communities, and there being no single community that is in charge of the others for the purposes of attribution. Compounding

this challenge is the occasional addition of other communities (e.g., agriculture, commerce, homeland security, wildlife) as well as classification issues that result in some duplication of effort and parallel activities. The need for close coordination and collaboration is clear, but arrangements among all of these communities have yet to be formalized. Further, each of the principal agencies in these communities lacks the resources, processes, and infrastructure necessary to establish a system that meets the variety of tactical, operational, and strategic needs for attribution.

There is also no formal decision-making apparatus in place to assist leaders in addressing biological crimes and other events. The informal system lacks standards for and burdens of proof; requirements for source information; and standards for acceptable evidence, information, and intelligence. Response exercises rarely take attribution into consideration.

The National Bioforensics Analysis Center (NBFAC), part of the DHS National Biodefense Analysis and Countermeasures Center, conducts technical analyses in support of federal law enforcement investigations and attempts to coordinate multi-agency biological forensic efforts. The NBFAC has not become the resource for biological forensics the Nation needs. The DHS Science and Technology (S&T) Directorate (which administers the NBFAC) has struggled to coordinate with and serve other agencies, because it is not an operational organization and because its scientific goals sometimes run at cross-purposes to those of the operational communities it could serve. As a result, agencies sometimes decline to work with or utilize NBFAC. The FBI is by far the primary user of the NBFAC, and the facility should have been under the purview of the FBI from its inception.

Recommendation 9

Better support and inform decisions based on biological attribution. The United States has yet to fully establish biological attribution capability due to the inherent challenges associated with microbial forensic techniques and related analysis. There is no formal apparatus that uses attribution information to inform decisions.

ACTION ITEMS:

a. **Establish a national biological attribution decision-making apparatus.** The Vice President should direct the Secretary of State, Secretary of Defense, Secretary of Homeland Security, the Attorney General, and the DNI to establish and formalize this apparatus. They should inform this apparatus with: 1) standards/burdens of proof in the U.S. criminal justice system; 2) evidence, information, and intelligence regarding the source; 3) accuracy, reliability, timeliness, credibility and defensibility of that evidence, information, and intelligence; and 4) national security considerations. This apparatus should be exercised to inform decisions and to ensure that these decisions are defensible.

b. **Place the Federal Bureau of Investigation in charge of the National Bioforensics Analysis Center.** The FBI is the primary customer of NBFAC and has the needed credibility and influence to allow NBFAC to fulfill its role in biological forensics and attribution. Congress should amend The Act to Enact Title 5 of the U.S. Code, "Government Organization and Employees," and make the FBI responsible for the NBFAC, its administration, and its activities, including interagency support and coordination. Congress should reallocate appropriations accordingly. Congress should also increase its oversight over NBFAC activities.

VI. TAKING CHARGE OF DECONTAMINATION AND REMEDIATION

NEED FOR ADDITIONAL RESEARCH

Environmental remediation is the application of countermeasures to eliminate an agent from a geographically defined area. Additional research is needed to develop standards and protocols for the elimination or reduction of new infections caused by pathogens hiding in a particular environment. Natural environments are not pristine and often contain microbes at low levels tolerated by humans. Returning an environment to its baseline level after an event cannot be accomplished without first having measured the baselines, and this has not been systematically attempted. Further, while the Environmental Protection Agency (EPA) has issued some remediation guidance,[53] it seems no agency is statutorily responsible for deciding when an affected area has been sufficiently decontaminated, remediated, and cleared for re-occupancy.

Decontamination is also an issue in need of substantial additional effort. The Executive Branch is aware of this and a number of departments and agencies coordinate with each other and collaborate with the Office of Science and Technology Policy (OSTP) to study environmental decontamination and remediation.[54] For example, a number of government agencies have collaborated to study remediation needs according to certain scenarios. Unfortunately, the results of these studies are of limited utility because many of these scenarios were extremely specific and cannot necessarily be applied to the wide variety of potential biological agents that could be used in an attack. Additionally, OSTP has since determined that research using disease- and scenario-specific approaches to determining remediation requirements is extremely costly.

The DHS S&T Directorate and Office of Health Affairs (OHA) partner with OSTP to conduct studies to determine post-biological event environmental decontamination and remediation requirements. Yet environmental remediation is an element of recovery, an aspect of emergency management addressed by the Federal Emergency Management Agency (FEMA). Further, the release of biological agents may also create an emergency in a locality that may qualify for FEMA grants and other assistance. For these reasons, FEMA should also be at the table for these OSTP conversations and studies.

DOD and EPA conduct research in this area, with more limited efforts undertaken by other agencies (e.g., DHS, HHS, USDA). Both civilian and military programs are challenged by insufficient funds, increasing resistance of microbes to materials and treatments that would be used to decontaminate and remediate the environment after the release of biological agents, the

large number of organisms that could be used in biological weapons, and the potential for those weapons to end up in a variety of environmental contexts, from air to water to soil.

NEED TO MANDATE RESPONSIBILITY FOR ENVIRONMENTAL DECONTAMINATION AND REMEDIATION

The EPA often inspects areas for accidental releases of biological agents and requests have been made of the Agency to conduct environmental decontamination and remediation following biological releases. The collection of environmental specimens to inform these activities can be difficult, however, when the EPA works with others (who may not be sufficiently trained) to collect environmental samples in support of these activities.[55] The EPA also uses a lengthy process to determine whether it should take responsibility for remediating an environment that has been contaminated with biological agents. This is because the EPA's history of holding companies responsible for having released contaminants into the environment (e.g., Superfund activities) does not align well with biological releases. The EPA may decide it should not remediate an area itself, instead providing options for decontamination and remediation that can be executed by others, including non-federal governmental agencies, academia, and industry. However, areas remain contaminated and unsafe during the time it takes to make a decision.

Recalling that the EPA initially balked at taking responsibility for remediating the congressional offices that were affected by the anthrax events of 2001, it is still unclear exactly who should be held responsible for environmental remediation when biological agents have been released accidentally or intentionally. Cost is a significant factor (e.g., estimates for the remediation of the Brentwood postal facility were as high as $130 million more than ten years ago[56]). There is no funding held in reserve for bioremediation by the EPA or any other agency. Some agency must be made responsible for biological environmental remediation and for coordinating similar and contributing efforts by other federal agencies. HSPD-10 states that the EPA coordinates with other departments and agencies in developing standards, protocols, capabilities, strategies, guidelines, and plans – but it does not make the EPA responsible for conducting biological remediation or decontamination, or for coordinating efforts with other agencies to do so.

NEED FOR COORDINATED EFFORTS TO MONITOR HEALTH AND THE ENVIRONMENT AFTER EXPOSURE

Long-term monitoring is needed to ensure that pathogen contamination is reduced or eliminated, and that those affected (i.e., humans, animals, plants) are not re-exposed, do not suffer initially unnoticed reactions to the pathogens, and have not become pathogen reservoirs. Long-term monitoring of health has been undertaken for those exposed to a variety of contaminants during 9/11 response and recovery operations. However, the opportunity to participate in similar studies was not offered to those potentially exposed to anthrax on Capitol Hill in 2001. If there were any low-level immunological responses to the use of this biological agent, they were likely missed because no one was looking for them.

Some monitoring is undertaken after confirmed or suspected exposure, but not necessarily as a matter of policy or urgency. DOD monitors some military personnel exposed to a variety of contaminants. Other agencies (e.g., DOI, HHS, USDA) also monitor personnel exposed to pathogens in the course of their work, but only when the need seems dire. We are wasting the opportunity to ensure human and animal health and a clean environment, and to gather data on how biological agents impact health and the environment. Exposed individuals deserve better than to discover that they have been infected, or that countermeasures are not working, only after they have become obviously ill.

Recommendation 10

Establish a national environmental decontamination and remediation capacity. The Nation must be able to decontaminate and remediate affected environments in a coordinated, predictable fashion. This national capacity must be sufficient to address accidents, bioterror threats, and emerging infectious diseases.

ACTION ITEMS:

a. **Include the Federal Emergency Management Agency in efforts to address remediation.** The Vice President should ensure that FEMA is included in interagency efforts led by OSTP and other federal efforts to study and determine policy regarding remediation after biological attacks.

b. **Assign responsibility to the Environmental Protection Agency for environmental decontamination and remediation.** Congress should amend the National Environmental Policy Act of 1969[57] to place the Administrator of the EPA in charge of environmental decontamination and remediation after accidental releases and biological attacks. The EPA should assume operational responsibility and coordinate with other agencies, non-federal governments, academia, and private sector organizations for environmental decontamination and remediation after accidental releases and biological attacks.

c. **Conduct studies of those exposed to disease-causing agents.** The Vice President and Congress should require the Secretaries of DOD, DOI, HHS, USDA, and the Department of Veterans Affairs (VA) to monitor those that come under their purview when they have or could have been exposed during or as a result of accidental releases, natural occurrences, and biological attacks. The Vice President and Congress should require the Secretary of Health and Human Services to conduct cross-sectional studies of those exposed to anthrax on Capitol Hill and elsewhere during the events of 2001.

CHAPTER 2: THE NEED FOR LEADERSHIP IN ELEVATING COLLABORATION

Recognizing that complex policy problems cannot be addressed by a single agency, the GPRA Modernization Act of 2010 (P.L. 111-352) required all federal agencies to collaborate on everything from information sharing to operations.[58] Applied to biodefense, the paradigm described must move beyond federal agencies and out to other levels of government and nongovernmental stakeholders.

While some activities are inherently federal, many of the most complex policy problems require input from and actions by these non-federal stakeholders to achieve success. Biodefense is an excellent example of such a complex policy problem. State, local, territorial, and tribal governments and nongovernmental partners carry out many critical biodefense activities from preparedness to recovery, but are often not consulted during policy development.

The federal government must also drastically increase the support provided to jurisdictions to allow them to build and sustain their biodefense capabilities. The rapid and accurate identification of pathogens moving through humans, animals, or the environment is a foundational capability, yet significant advances in biosurveillance and detection remain elusive because of technological barriers and bureaucratic challenges to effective collaboration and cooperation. The emergency services sector has been calling for increased support for some time, especially in terms of protective measures and access to threat information. Dwindling federal financial support has left hospitals and local health departments unable to fully prepare to serve their communities. Local communities are struggling to assure their populations that they can deliver the contents of the SNS quickly in a public health emergency. Finally, private and academic laboratories and other stakeholders struggle to prevent cybersecurity breaches to databases containing sensitive pathogen information.

Collaboration among industry, academia, and local health authorities – and a leader, such as the Vice President, who is willing to promote and hold federal agencies accountable for this collaboration – are needed to overcome these challenges.

This chapter addresses collaboration in the following areas:

I. Achieving an Integrated Biosurveillance and Biodetection Capability
II. Supporting Emergency Preparedness
III. Creating Incentives for Hospital Preparedness
IV. Advancing Planning for Medical Countermeasure Distribution and Dispensing
V. Dealing with Cyber Threats to Pathogen Security
VI. Reengaging with the Biological and Toxin Weapons Convention
VII. Moving Beyond Defense Support to Civil Authorities

I. ACHIEVING AN INTEGRATED BIOSURVEILLANCE AND BIODETECTION CAPABILITY

Surveillance and detection are the means by which we achieve the earliest possible situational awareness for biological events that affect people, animals, the food supply, and the environment. They are fundamental capabilities that enable us to prevent or mitigate the consequences of these events. They also enable protection of national and local critical infrastructure, and support response and recovery operations.

Optimal surveillance and detection require a nationwide array of sensors and detectors at many levels, interconnected and working in parallel. This system must be expansive and address many aspects of disease spread, including human health (e.g., clinical, diagnostic), animal health (e.g., livestock, wildlife, companion), and sociocultural events (e.g., mass gatherings, burials). Surveillance and detection systems need to work quickly, indicating the presence of an agent in hours, not days or weeks. Such a capability can usefully inform rapid response operations, saving lives and other resources. Along with this capability, methods for information sharing between surveillance and biodefense partners are also needed. Many stakeholders could benefit from improved communication and real-time awareness.

HSPD-10 described ongoing federal efforts in 2004 to develop "an integrated and comprehensive attack warning system to rapidly recognize and characterize the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment." At the time this system was proposed, it was bold, far-reaching, and necessary. Attempts thus far to accomplish it have been timid, narrow, and unsuccessful. As of 2015, the United States still lacks a nationwide, population-based disease surveillance system for human health. This is unacceptable.

The White House has failed to prioritize integrated biosurveillance and Congress has failed to mandate interagency participation, causing this insufficiency. As a result, an implementation plan to establish this capability has not yet been issued. Although the National Strategy for Biosurveillance was issued in 2012, it was very high level and lacked an accompanying implementation plan. The White House has drafted the plan, but as of publication of this report, has not yet released it. Without such a plan, interagency coordination and stakeholder involvement are far from optimal. The delay is likely due to the extreme interagency and stakeholder difficulties with information sharing, and insufficient leadership to make solving those difficulties a priority.[59]

Recommendation 11

Implement an integrated national biosurveillance capability. The White House must finalize and release the implementation plan for the National Strategy for Biosurveillance.

ACTION ITEM:

a. **Implement the National Strategy for Biosurveillance.** Under the direction of the Vice President, NSC staff should finalize and release the implementation plan for this strategy. The plan must describe roles and responsibilities for specific departments and agencies, and provide metrics and goals for the individuals responsible. The plan must identify information required by decision makers (federal, state, local, territorial, tribal, private sector) to manage a biological event; these requirements should then be used to determine needed data sources, technology, and operational processes to achieve situational awareness and response capabilities. The plan should encourage and incentivize private sector input.

The current U.S. system consists of myriad surveillance and detection systems, operated by numerous agencies at many levels of government and within the private sector, with some working better than others and many not communicating with one another. Lower-level reporting into government systems – the key to early disease identification – is often delayed or provides too little data to provide real-time warning. Additionally, existing systems do not necessarily support existing response concepts of operations. For instance, the current system of syndromic surveillance – that which depends upon open source information, voluntary reporting of protected data, and astute clinical identification – lags behind the precise and timely communication of information needed to adequately support rapid response.

Recommendation 12

Empower non-federal entities to become equal biosurveillance partners. A timely response to a biological event cannot occur without increased collaboration among federal, state, local, territorial, and tribal jurisdictions, as well as non-governmental stakeholders.

ACTION ITEM:

a. **Create an interagency biosurveillance planning committee.** The Secretary of Homeland Security should make this committee the nexus for active collaboration with non-federal government and non-governmental partners. This group will clarify and coordinate the response and recovery goals, objectives, and activities of federal, state, local, territorial, and tribal agencies and non-governmental partners following the determination that a biological event has occurred.

By statute, DHS is charged with "integrating and analyzing data relating to human health, animal, plant, food, and environmental monitoring systems."[60] The National Biosurveillance Integration System (NBIS) was envisioned to fulfill this charge and to provide early warning. Despite the best of intentions, DHS has been unable to meet this mandate, in large part because other federal agencies were not required in the statute to share data or information with DHS. For example, NBIS does not have real-time access to CDC syndromic data, USDA food animal epidemiologic data, or VA hospital data. Laboratory data are only incorporated insofar as information is reported by state, local, territorial, and tribal departments of health into other systems that feed NBIS. Plenty of data are available, but agencies have little impetus for voluntarily sharing it, and no leader is forcing the issue. DHS continues to pursue access to this information, but is years behind where Congress and the Administration expected the system to be.

The lack of required interagency sharing of surveillance data means that NBIS can only function properly if the White House forces it to work. Without a strong and enforced executive order requiring agencies to cooperate on biosurveillance and detection, share data, and staff such a venture comprehensively, NBIS will continue to fail to fulfill its mandate.

Sensitive and specific biosurveillance can be attained only through a distributed network of activities. Medical records, clinical laboratory data, food recall data, human and animal pharmaceutical consumption, food and animal health surveillance, and water and air quality monitoring are examples of existing troves of data that could be shared with NBIS with the necessary leadership, correct approach, and comprehensive agreements. In return, the data owners could receive aggregated NBIS data, analyses, or other incentives.

A process must be put in place to provide for such mutually beneficial data sharing. Ownership is a barrier to interagency and private-to-public data sharing, but this challenge is not insurmountable. The collection and sharing of data in support of data owners' daily business processes – access to analytics, awareness of big-picture trends – could provide incentives to data owners to participate. Pilot programs have successfully shared surveillance and detection data within a limited number of states. The trusted third party model may also be successful for information sharing. Under this model, an independent third party builds trust, and coordinates data sharing and administration of a cloud-based temporary data storage system designed to feed into a national biological common operating picture. No government ownership or long-term data storage on government servers occurs in this model, which should help satisfy many of the concerns of data owners.

Recommendation 13

Optimize the National Biosurveillance Integration System. NBIS must be optimized to meet its potential as both an early warning and a situational awareness system capable of working across the interagency.

ACTION ITEMS:

a. **Assess the viability of the National Biosurveillance Integration System as the prime integrator of biosurveillance information.** As directed by the Vice President, the NSC should immediately examine NBIS to determine whether expenditures have yielded sufficient amounts of useful information to decision makers beyond DHS. A serious effort at planning and prioritization on the part of the White House is the only means to achieve success in this complicated interagency endeavor. If it cannot be achieved, the current effort should be discontinued.

b. **Incentivize data sharing.** The NSC should convene data owners and other stakeholders to evaluate incentive options and determine which are most viable for data and information sharing. These incentives should then be built into NBIS, or a different construct as determined by the NSC and Congress.

Animal health surveillance should not be segregated from the model of comprehensive biosurveillance described. What if, instead of simply identifying the location of an insidious zoonotic outbreak, one could identify its reservoir, the place in the animal world where it is hiding?

Livestock health surveillance is currently performed for the benefit of agriculture and food animal production. These data are typically unavailable on a regular basis to federal agencies with surveillance responsibilities outside of the USDA. Likewise, systematic collection of companion animal health data that would help detect any significant changes in the prevalence of zoonotic illness relevant to human health is almost entirely lacking. Enormous volumes of data exist, such as through franchised veterinary hospital systems with electronic medical records, and veterinary diagnostic laboratories, but these are untapped resources. Similarly, surveillance data of wildlife infectious diseases are collected disparately among federal agencies, non-federal governmental agencies, universities, and nongovernmental organizations. Their programs are not currently designed to provide comprehensive biosurveillance, nor to generate readily available information for other federal agencies with surveillance responsibilities.

The National Animal Health Laboratory Network (NAHLN), an effort to detect biological threats to the Nation's food animals, is necessary for effective biosurveillance. The NAHLN is a public-private cooperative effort between the USDA, the American Association of Veterinary Laboratory Diagnosticians, and publicly funded state veterinary diagnostic laboratories. The collective and integrated work of its members allows for improved detection of emerging and zoonotic diseases, which helps protect animal health, public health, and the food supply. The veterinary diagnostic labs that are members are quite literally on the front lines of disease detection. Established in 2002, the NAHLN is funded through a combination of grants, fee-for-testing services, and administrative support from USDA. It has struggled to maintain even $10 million worth of annual funding, its appropriations cut over the years to pay for other programs. As a result, the laboratories are unable to meet the threat and have at times eliminated positions and testing capacity for foreign animal diseases. Ten million dollars is a very small price to pay to protect one of America's major industries and portals for disease emergence. After the NAHLN struggled for years to obtain sufficient funding, in 2014 Congress authorized a specific funding line at $15 million per year.[61] NAHLN must be funded to this authorized level in order to meet the need.

Finally, although the establishment of policies to guide the emergency management of companion animals was strongly pursued following Hurricanes Katrina and Rita, there is little evidence of infectious disease management guidance and planning for animals following the Ebola crisis. The cost of quarantine and care for a single dog in Texas suspected of Ebola exposure was nearly $27,000.[62] No formal, federal collaborative efforts are in place to develop plans or guidance that meaningfully and comprehensively incorporate policies, procedural recommendations, and requirements for dealing with a zoonotic infection that may be borne by dogs, cats, other companion animal species, or wildlife.

Recommendation 14

Improve surveillance of and planning for animal and zoonotic outbreaks. Government agencies must prioritize the collection of animal pathogen data, and support new means of integrating it into analysis of human data. Agencies must also plan for major impacts of companion animal and wildlife zoonoses.

ACTION ITEMS:

a. **Increase opportunities for animal health data collection.** Congress should fund and facilitate enhanced opportunities for data collection at the livestock and wildlife levels via DHS, DOI, and USDA. The Secretary of Homeland Security, via NBIS, should further DHS collaborations with federal, state, local, territorial, tribal, and private sector entities that collect animal health data. Establishing partnerships with these stakeholders for data and information sharing will require incentives.

b. **Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.** The Administration should request and Congress should fund the NAHLN at its authorized levels.

c. **Develop guidance for the serious implications of companion animal and wildlife zoonoses.** The Director of the CDC and the Administrators of FEMA and APHIS, in collaboration with non-federal stakeholders, should develop guidance for states, localities, territories, and tribes to handle companion animal infections in the event of a major zoonotic disease outbreak. States, localities, territories, and tribes can then base their own planning requirements on this guidance. Congress should amend the Robert T. Stafford Disaster Relief and Emergency Assistance Act[63] to require the Administrator of FEMA to ensure that state, local, territorial, and tribal emergency preparedness and response plans address the handling of zoonoses of companion animals and wildlife.

II. SUPPORTING EMERGENCY PREPAREDNESS

The Emergency Services Sector is a critical infrastructure sector that is the Nation's first line of defense for preventing, preparing for, responding to, and recovering from incidents of many kinds, including biological threats. This sector consists of law enforcement, fire and emergency

services, emergency management, emergency medical services, and public works. It is the sector responsible for the protection of the 15 other critical infrastructure sectors as defined by DHS.[64] While not included in the DHS definition, public health responders also provide critical emergency services following a biological threat. All of these responders are ready at any time to deal with an extraordinary number of potential incidents. While DHS, HHS, and other agencies have done good work to equip and train responders to address biological threats, gaps remain.

MEDICAL COUNTERMEASURES AND OTHER PROTECTIVE MEASURES FOR FIRST RESPONDERS NEEDED

Emergency services providers are subject to a disproportionate threat because they work in the midst of disasters.[65] Research demonstrates that communities will be at a disadvantage during a biological crisis if essential response personnel feel that they or their families are insufficiently protected.[66] For example, only 20 percent of paramedics in one survey said they would remain on duty without a vaccine and protective gear – a number that rose to 91 percent if these protections were provided.[67]

Any material threat to homeland security is a threat not just to the general population, but also to the responders who will serve them.[68] After an MTD was issued for anthrax, and because a vaccine was available in surplus, discussions began about whether this vaccine should be offered to first responders. Short-dated, surplus anthrax vaccine doses owned by the federal government expire by the hundreds of thousands each month and are discarded. A voluntary vaccination program for anthrax or other threats for which vaccines are available could boost preparedness and has had significant bipartisan support in Congress.[69] DHS has been formulating a pilot program to provide anthrax vaccine to emergency services providers for more than half a decade. In 2015, due to bureaucratic delays and inability to establish the needed occupational health system to administer such a program, there is still no program that provides this minimal protection to the protectors.

In addition to vaccines, the government could make available other MCM to emergency services providers. The CDC conducted a pilot in St. Louis, Missouri in 2005 to pre-position antibiotic kits (known as medkits) in the homes of emergency service providers. The goal was to provide protection for these responders and their families in the event of an emergency. The pilot was considered a success and demonstrated that these professionals could manage the kits without misusing them. Similar pilots with the U.S. Postal Service (USPS) proved the same. To date, these initiatives have not been implemented as programs, in part because some public health officials remain concerned about misuse. Although an FDA Emergency Use Authorization (EUA) or other means of temporarily eliminating regulatory hurdles would be required for medkits, the pilots demonstrate this can be done.

Non-pharmaceutical interventions are just as important. Recommendations regarding the type and use of personal protective equipment (PPE) to protect against biological events are available, and range from gloves and masks to military-grade protective over-garments. Most responders only possess the PPE necessary to operate within current community environments and only after decades of experiences with HIV and influenza. Specific standards or guidelines for PPE are still needed, and their development will require special attention to unique requirements of the various emergency services subsectors.[70]

Recommendation 15

Provide emergency service providers with the resources they need to keep themselves and their families safe. This will fulfill the Nation's commitment to these professionals while also helping to ensure their participation in the event of a biological emergency.

ACTION ITEMS:

a. **Provide vaccines to responders who request them.** The Secretary of Homeland Security must ensure that the DHS pilot program to provide emergency service providers with anthrax vaccines is implemented. The Secretary should make doing so an immediate priority. If successful, the Secretary should formalize the program and extend it to meet other threats.

b. **Provide medkits to emergency service providers and their families.** The Director of the CDC, the Commissioner of the FDA, and the ASPR should finalize plans for prepositioning medkits with emergency service providers and their families, and request annual funding to implement the program.

c. **Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.** The Secretary of Health and Human Services should commission the Institute of Medicine (IOM) to examine current PPE research and requirements in light of potential biological threats. The IOM should conduct this assessment in conjunction with the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration (OSHA), and representatives from all of the major emergency service associations.

THREAT INFORMATION INSUFFICIENTLY SHARED WITH EMERGENCY SERVICES

Emergency service providers might be able to better target their efforts to address biological threats and protect themselves if they had more information regarding the threat, relevant vulnerabilities, and potential consequences.[71] Yet much of the available information about current and potential biological threats is often classified. Recognizing this, the IC has attempted to declassify at least some of this information and provide it to non-federal governmental entities. For example, state, local, territorial, and tribal first responders and public safety professionals, as well as federal intelligence analysts from the National Counterterrorism Center, DHS, and FBI, are members of the Joint Counterterrorism Assessment Team (JCAT, resident in the Office of the DNI). The team strives to jointly research, produce, and disseminate counterterrorism intelligence to non-federal governmental entities.[72] Still, the federal government has found it difficult to overcome institutional prohibitions against sharing information with non-federal personnel. As a result, these programs do not function as originally intended.

Partly to solve this problem, some local police entities have developed their own intelligence function, allowing them to develop intelligence and distribute information to others within their locality. While police departments continue to develop and implement their own intelligence programs in various areas, these programs are far from ubiquitous and only address the biological threat in small part.

Recommendation 16

Redouble efforts to share information with state, local, territorial, and tribal partners. Emergency service providers are valid customers of threat-related information. The IC must recognize this, work to eliminate barriers, and share more information with the emergency services sector about the biological threat.

ACTION ITEMS:

a. **Strengthen the Joint Counterterrorism Assessment Team.** The DNI should improve upon the partnerships (with first responders and other non-federal personnel) that are critical to the effective performance of the DNI-hosted JCAT. The DNI should solicit their feedback on how JCAT can function in a way that allows these stakeholders to participate more fully and provides more value to them. The DNI should use this feedback to improve the program.

b. **Strengthen the ability of local police intelligence units to address the biological threat.** The Attorney General and the DNI should share analytic methods relevant to these units to assist in the development of more robust and effective biological threat analysis.

c. **Enable fusion centers to address the biological threat.** The Administrator of FEMA and the DHS Under Secretary for Intelligence and Analysis should provide technical assistance to fusion centers to enable them to obtain needed biological information and intelligence from all relevant federal, non-federal governmental, and private sector partners.

EMERGENCY PREPAREDNESS SUPPORT FOR LOCAL HEALTH DEPARTMENTS CANNOT BE ALLOWED TO WANE

Infectious diseases impact national security and easily cross borders. Federal support for state, local, territorial, and tribal public health emergency preparedness is, therefore, a reasonable use of taxpayer dollars. The CDC's Public Health and Emergency Preparedness (PHEP) cooperative agreements are the primary avenue by which federal funding reaches state, local, territorial, and tribal health departments to support public health emergency preparedness. More than $10 billion has reached 62 PHEP jurisdictions since the program began in 2002.[73]

PHEP funds support activities such as the purchase of electronic disease surveillance systems, establishment of local emergency operations centers, expansion of laboratory infrastructure, hiring of epidemiologists and laboratorians, and training of employees in emergency response protocols. Although the biothreat has grown since 2002, the funding to address the potential impact of that threat through PHEP activity has declined relentlessly since its initiation (due to both decreased Presidential budget requests and reduced congressional appropriations). Since a high of $940 million in FY 2002, the last appropriation (FY 2015) was $661 million. The FY2016 request would further reduce that amount to $643.6 million.

Administrations have touted the success of the program while simultaneously scaling back their budget requests. Some federal grant programs have been grounded in the notion that the grants may be used to establish capabilities, at which point grantees can transition the funding responsibility for maintaining those capabilities to themselves. This is not a reasonable

concept for public health emergency preparedness. State, local, territorial, and tribal health budgets have been decimated since the financial crisis of 2008. Withholding dedicated emergency preparedness funds may preserve federal bottom lines, but it further diminishes national preparedness.

Recommendation 17

Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels. Congress and the Administration must recognize that gains in public health preparedness locally benefit all jurisdictions nationally. They must also recognize that states, localities, territories, and tribes do not have the financial capacity to maintain past gains achieved by PHEP through their own budgets.

ACTION ITEM:

a. **Appropriate Public Health Emergency Preparedness funding to authorized levels or the President's request, whichever is higher.** Congress authorized $641.9 million per year from FY2013-2017.[74] Congress demonstrated a willingness to fund more than this in FY2015, and should at a minimum meet the President's request for FY2016. More importantly, the Administration and Congress should reverse the downward slide of funding for this program that is vital to supporting the activities of public health departments that benefit not only their own population centers but those of the entire country.

III. CREATING INCENTIVES FOR HOSPITAL PREPAREDNESS

Hospitals have received varying levels of support to prepare for biological events, especially bioterrorism and pandemic influenza. Prior to the establishment of the HHS Hospital Preparedness Program (HPP) in 2002, hospitals undertook preparedness activities,[75] but without dedicated federal funding. Since its inception, the HPP has been a small component of overall spending on hospital preparedness. While the HPP expanded in 2012 to include all healthcare facilities, funding was reduced to $250 million from an original appropriation of $645 million in 2003. OSHA has issued guidance for decades, and the Joint Commission (previously the Joint Commission on Accreditation of Healthcare Organizations), Det Norske Veritas, Health Facilities Accreditation Program, and Center for Improvement in Healthcare Quality – all healthcare accrediting agencies – have introduced preparedness criteria into their accreditation requirements. Additionally, hospitals have attempted to address preparedness for bioterrorism and other infectious disease events as part of their overall disaster preparedness.[76] Certain requirements associated with highly infectious diseases and low frequency biological events fit well within hospital disaster preparedness frameworks designed to address earthquakes, hurricanes, and other disasters, but other requirements do not.

HOSPITAL INFECTION CONTROL CHALLENGED BY EBOLA

During the Ebola outbreak of 2014, it became clear that hospital preparedness varied widely. A few hospitals were well prepared to serve as treatment centers for infected patients, but the vast majority of others were completely unprepared and struggled to catch up. Historically, OSHA has developed and issued PPE guidelines to hospitals, but in a sudden turn, the CDC did so regarding Ebola and without working with or adequately consulting OSHA. As a result, the guidelines initially issued by CDC were insufficient to meet the needs of hospitals. Flawed guidelines released by the CDC to hospitals (which addressed issues not under CDC purview, such as PPE and hospital operations), inadequate coordination between CDC and OSHA regarding federal messaging and waste management, poor training regarding the implementation of the requirements described in those guidelines, and insufficient attention paid to some potentially useful hospital disaster plans exacerbated already insufficient levels of preparedness. The prior operating assumption – that all healthcare facilities should prepare to manage patients instead of proposing a system for identification and transfer to special treatment locations – led to overwhelming resource and training requirements during the Ebola crisis. Although many hospitals became far more proficient and capable of handling Ebola patients, the passage of time since the last Ebola case and the lack of additional patients coming to the United States make it unlikely that the same level of serious infectious disease-specific proficiency will be maintained.

Recommendation 18

Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events. The time to change the way in which federal agencies issue guidelines is not in the middle of a crisis. Both the CDC and OSHA have relevant contributions to make and must work together and with private sector experts to develop and issue hospital guidelines now, in advance of the next outbreak.

ACTION ITEMS:

a. **Standardize the development of clinical infection control guidelines before biological events occur.** Congress should direct the Secretary of Health and Human Services and the Secretary of Labor to implement a process (involving experts throughout the federal government and the private sector) to develop clinical guidelines for treatment, infection control, use of PPE, waste management, and other activities needed in the hospital setting. The Secretary of Health and Human Services and the Secretary of Labor should direct the CDC and OSHA, respectively, to identify specific steps within this process and make the description of that process readily and publicly available in advance of a biological event.

b. **Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.** During events occurring in the United States, the Vice President should direct the Secretary of Health and Human Services and the Secretary of Labor to convene a standing group of experts (including those from outside of the federal government) that reviews feedback from federal, state, local, territorial, tribal, and private health care facilities, and meets at least weekly to evaluate, update, and reissue clinical guidance.

c. **Require training based on these guidelines.** The Secretary of Health and Human Service and the Secretary of Labor should regularly provide training for end users in the implementation of the guidelines.

OPTIMIZING HOSPITAL PREPAREDNESS FUNDING

Federal funding for hospital preparedness[77] represents approximately 1/100th of one percent of the Nation's total healthcare spending.[78] This relatively small amount of money, coupled with the need to coordinate across health care systems and communities, drove the development of hospital coalitions. Still, hospital coalitions have been unable to make up for insufficient funding.

In response to the Ebola events, HHS provided grants through HPP designed to help hospitals become more proficient in addressing Ebola.[79] The funding represents less than 12 cents per American over five years. As important as Ebola-related hospital preparedness funding has been, disease-specific funding is the most inefficient, costly manner in which to fund preparedness for biological events. Politically, reacting in this manner is an understandable result of needing to take some action. Practically, this reaction is unsustainable and it is unclear how much of a contribution disease-specific hospital preparedness grants will make to overall hospital preparedness.

The HPP has experienced progressively reduced funding, with the exception of the recent limited increases associated with Ebola. Further reducing the amount of HPP funding available, the ASPR routinely keeps back 7-10 percent of the grant funds for administrative expenses, despite its receiving dedicated appropriations to fund its own operations.[80] No more than three percent of funds should go toward management and administration. The HPP has never received the full support it needs from Congress or presidential administrations since its inception. In order to determine how much HPP funding is necessary to ensure hospitals are prepared for biological and other events, a thorough evaluation of the costs, successes, and failures of the HPP is called for.

Recommendation 19

Minimize redirection of Hospital Preparedness Program funds. The vast majority of the funding appropriated to HPP must reach grant recipients. HPP managers must base the application of these funds on a thorough review of successes and challenges within the program to date.

ACTION ITEMS:

a. **Cap Hospital Preparedness Program management and administration costs at three percent.** Congress should amend the Public Health Service Act to require that no less than 97 percent of appropriated HPP funds go directly to HPP grantees.[81]

b. **Assess the impact of the Hospital Preparedness Program.** Congress should task the GAO to evaluate the impact of HPP grants on hospital preparedness. This evaluation should address, at a minimum: 1) the extent to which the goals of the HPP are being met; 2) how HPP funds should be allocated (e.g., based on risk); and 3) whether funding for the HPP is sufficient.[82] The ASPR and Congress should then use the results of the evaluation to determine reforms and funding needed to optimize the program.

FUNDING ASSOCIATED WITH ACCREDITATION

Hospitals also qualify for funding via the Centers for Medicare and Medicaid Services (CMS) at HHS by fulfilling accreditation requirements for various specialties. Accreditation is a critical node in this complicated system that attempts to link performance to payment. However, preparedness for bioterrorism and other deadly infectious disease events has not been incorporated into either hospital accreditation or funding requirements arising out of CMS.[83]

Healthcare accrediting agencies are aware of the need for preparedness and have issued planning guidelines to address it. Joint Commission leadership has testified before Congress and others on the need to prepare for bioterrorism and other exigent circumstances. However, these deeming entities have not issued standards specific to bioterrorism preparedness or preparedness for highly infectious diseases. Instead, for example, the Joint Commission includes such biological events as one among many hazards included in the term all-hazards and requires an all-hazards emergency management plan, hazard vulnerability self-assessments, familiarity with the Incident Command System, and exercising of plans. During Joint Commission visits, assessors evaluate the plan and how well trained staff are for all hazards. The goal of this approach is to develop and maintain a strong foundation upon which all hazards – including bioterrorism and highly infectious disease events – can be managed well.[84] Opportunities exist as part of health delivery reform to improve hospital preparedness for disasters and biological threats, including through the application of the ASPR National Healthcare Preparedness Guidelines.[85] If biothreat preparedness were also made an accreditation requirement, the potential for increased CMS funding – far greater than that available via the HPP – should provide a strong financial incentive for hospitals to prepare for biological events.

Recommendation 20

Provide the financial incentives hospitals need to prepare for biological events. Preparedness must be included within the health delivery reform efforts of CMS and private sector payers. Bioterrorism and highly infectious disease preparedness should be required for accreditation and the CMS funding that comes with it. Any financing strategy must be realistic, but must also account for all contingencies and associated hospital planning requirements.

ACTION ITEMS:

a. **Adopt a disaster preparedness portfolio.** The Administrator of CMS, in conjunction with ASPR, should seek the endorsement of the National Quality Forum and adopt, as part of its health delivery reform efforts, a disaster preparedness portfolio that includes Conditions of Participation, Interpretive Guidance, measures development for inclusion within value-based purchasing, and innovation projects. Preparedness measures should be included in the evolving Merit-Based Incentive Payment System program and link community, supplier, and provider resilience efforts to reimbursement and incentives.

b. **Link Centers for Medicare and Medicaid Services incentives and reimbursement to new accreditation standards.** Congress should authorize CMS to provide funding to those hospitals that meet these new accreditation standards for bioterrorism preparedness and preparedness for other highly infectious disease events.

NEED FOR A FORMALIZED STRATIFIED HOSPITAL SYSTEM

It is not necessary or prudent for every hospital in the United States to possess and maintain the same capability for treating patients affected by intentionally introduced and naturally occurring biological events.[86] Ebola demonstrated that this is an unrealistic expectation, prompting the CDC to introduce a three-tiered system to more strategically allocate resources and response efforts.[87] Today, Ebola patients can be treated at a hospital among the tiers deemed capable of providing necessary care in properly controlled environments, assuring the safety of the patient, health care workers, and anyone within and surrounding these hospitals.

A stratified hospital system similar to that utilized for Ebola and other specialized pathologies (e.g., trauma, stroke, cardiac care, burns, pediatrics) is needed for infectious diseases. Such a system would require all hospitals to attain the ability to assess patients in order to recognize bioterror agents, as well as emerging and reemerging infectious diseases. All hospitals would also be able to stabilize patients within 48 hours, and then refer patients quickly to higher-level hospitals for more definitive care. Other levels of hospitals would be able to provide increasingly specialized care, depending on the status of these patients. Biodefense responsibilities could also be added to Accountable Care Organizations, trauma centers, and hospital coalitions. Ebola funding available via the HPP can help establish this system, but more must be done to formalize it and increase its functionality. This could include exploration of reimbursement enhancements via the previously mentioned specialties.

Recommendation 21

Establish a biodefense hospital system. Hospitals are already stratified according to their abilities to treat patients according to various specialties. Applying this same approach to biodefense will result in better patient treatment, improved occupational health and safety, and more realistic expectations of hospitals.

ACTION ITEMS:

a. **Stratify hospitals.** The Secretary of Health and Human Services should establish a stratified system of hospitals with increasing levels of capability to treat patients affected by bioterrorism and other events involving highly pathogenic infectious diseases. A categorical rather than disease-specific approach should be used. Where possible, the Secretary should add biodefense responsibilities to Accountable Care Organizations, trauma centers, and hospital coalitions to expand their capabilities.

b. **Develop accreditation standards for each stratum.** The Administrator of CMS should develop accreditation standards by or with the Joint Commission, Det Norske Veritas, Health Facilities Accreditation Program, and Center for Improvement in Healthcare Quality, as well as certification and licensure associated with each level.

c. **Associate Centers for Medicare and Medicaid Services funding.** The Administrator of CMS should associate hospital funding with the ability to meet these accreditation standards for each stratum.

IV. ADVANCING PLANNING FOR MEDICAL COUNTERMEASURE DISTRIBUTION AND DISPENSING

The CDC manages the SNS, a cache of pharmaceuticals, medical supplies, and equipment stored to protect the American public in the event of a major chemical, biological, radiological, or nuclear (CBRN) incident severe enough to strain local resources. The MCM contained therein are only as good as our ability to provide them in a timely way to the people who need them. The CDC and a number of its federal, non-federal government, and private sector partners have worked hard to develop plans for distributing and dispensing SNS contents to the locales that need them. PHEP agreements require exercises toward these ends. Many experts, however, are unconvinced that SNS contents can reach massive numbers of people in the short time in which they are required (as few as 48 hours for certain infectious diseases).

NATIONAL MASS PROPHYLAXIS MUST DEPEND ON NON-FEDERAL INPUT, PLANNING, AND IMPLEMENTATION

The current distribution and dispensing system is insufficient and unacceptable. The likelihood that needed MCM could reach individuals in short timeframes on a mass scale is still not a reality. One study found as recently as 2012 that the MCM response architecture lacks clear, centralized leadership; clear and consistent directives for and coordination of state, local, territorial, and tribal

government plans; clear goals and objectives for response; sufficient imagination to consider alternative scenarios such as repeat or simultaneous attacks; and sufficient funding for health departments.[88] These remain unresolved problems. Additionally, certain logistical questions (e.g., how long it will take to break down pallets, how long until multi-dosage medications are resupplied) have not yet been addressed and are a concern for most localities.

A now-defunct program would have leveraged the delivery capacity of the USPS to deliver MCM to residences. Pilot programs showed a willingness on the part of certain locales and volunteer postal carriers to carry out this task. They also demonstrated that such a USPS delivery plan is highly complex, requiring hundreds of potential routes to be served; an enormous drain on law enforcement resources (a sworn officer would be required to chaperone each carrier); and dependent on high levels of training and exercising, as well as sustained, annual federal funding.

While some cities could benefit from this approach, an optimal national mass prophylaxis capability will have to reach far beyond the USPS and into private delivery companies, pharmaceutical chains, and volunteer healthcare worker coalitions. Various modalities (e.g., distribution by large employers, regional pharmacies, healthcare facilities, non-governmental organizations) have often been discussed, but our primary dependence still remains on the static open point of dispensing (POD) model, which cannot alone meet the need.[89]

Unresolved issues in the distribution and dispensing of MCM must be addressed. The Nation lacks a workable national MCM distribution system that can be activated quickly and counted upon to work in an emergency. One reason for this is that a national, stakeholder-driven MCM response framework is missing; such a framework would provide structure and guidance for local planning efforts. MCM distribution from the cache sites to local destinations is often addressed in federal hazard planning documents intended for use by local jurisdictions that do not adopt them, frequently because they are not really at the table during their development. It remains unclear how regional distribution and local dispensing operations can best be coordinated among federal, state, local, territorial, tribal, private sector, and nongovernmental partners. The federal government needs to assist PHEP grantees with integrating performance measures, processes, shared services, roles and responsibilities, technologies, and resources needed to implement a truly functional distribution and dispensing architecture for MCM into their plans.

In order for any distribution and dispensing plan to be successful, the CDC must issue clinical utilization guidance for the MCMs in the stockpile. Such guidance helps local health officials understand who should get which vaccine or treatment, which diseases they should screen for prior to dispensing, and who is at risk for complications. The CDC has delayed issuing clinical guidance for years in some cases. If an outbreak were to occur tomorrow, even if the assets were already in place, health officials would not necessarily know how to allocate them. This is a special concern for vulnerable populations (e.g., children, elderly, immunocompromised) who require guidance specific to their status. The Vice President should hold the CDC accountable for this extremely important component of MCM planning.

Recommendation 22

Develop and implement a Medical Countermeasure Response Framework. A stakeholder-driven framework for solving continued challenges in operational MCM response will provide greater assurance that distribution and dispensing can be achieved quickly, efficiently, and safely.

ACTION ITEM:

a. **Produce a comprehensive framework to guide medical countermeasure distribution and dispensing planning.** Together with non-federal partners, the ASPR, the Director of the CDC, and the Administrator of FEMA should identify requirements and capacities needed to achieve successful distribution and dispensing of MCM from the SNS as well as from local caches. The framework they develop must address unresolved issues. It should be a progressive and innovative approach that pushes the envelope beyond what a given agency might devise and beyond the bureaucratic impediments associated with a federal-only distribution system. If implementation would exceed funding available through current grant allocations, additional funding must be requested.

LACK OF MCM PLANNING PREVENTS FORWARD DEPLOYMENT OF THE SNS

While planning for the challenges described above can be resolved in the medium term with the advent of the framework called for in Recommendation 22, the CDC can institute near-term change in advance of that. Some localities have worked hard to demonstrate their ability to quickly and responsibly take charge of MCM distribution and dispensing. For example, New York City is now so well practiced in setting up PODs that responders would be ready to serve their populace hours before CDC assets even arrive. The CDC, however, has thus far been as unwilling to forward deploy assets to qualified cities. Given that the United States is already behind in developing a fully functional system for the distribution and dispensing of MCM, the government should support forward deployments to jurisdictions that prove themselves capable of handling SNS contents and dispensing them efficiently.

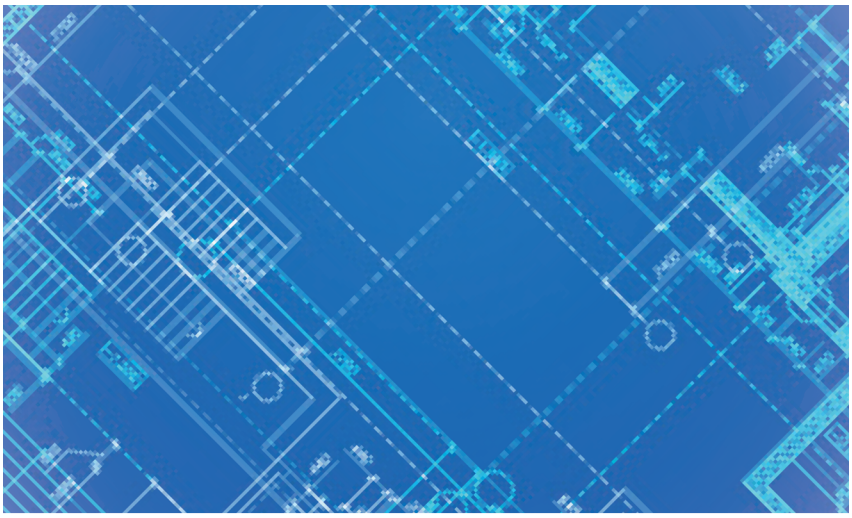
Recommendation 23

Allow for forward deployment of Strategic National Stockpile assets. Pre-deployment of SNS caches to those jurisdictions that have demonstrated the capability to appropriately handle SNS contents will vastly improve preparedness.

ACTION ITEMS:

a. **Determine logistics and funding needs.** The Director of the CDC should determine the necessary assessment, logistical, and funding requirements to forward deploy SNS assets.

b. **Implement forward deployments.** Once the requirements are established, the President should request funding in the next budget cycle to support forward deployments to cities that have demonstrated readiness. Deployments of reasonable quantities should go toward to high-threat, high-density urban areas that have demonstrated an ability to stand up PODs faster than SNS medications can be delivered to these jurisdictions and subsequently distributed to PODs. The Director of CDC should actively encourage leaders of other major urban areas to plan for and demonstrate ability to stand up PODs faster than SNS medications can currently be delivered.



V. DEALING WITH CYBER THREATS TO PATHOGEN SECURITY

Despite the overwhelming benefits that digital information technologies bring to biodefense, they simultaneously create portals for malicious intent.[90] The FBI, other federal departments and agencies, and the private sector are working to address vulnerabilities where biology meets cyberspace. But the work is nascent, and the United States is not yet well positioned to address cyber threats that affect the biological science and technology sectors.

Senator Sheldon Whitehouse told the Panel, "There is a considerable bank of information on biological warfare dating back to the biological warfare planning of the United States and the Soviet Union fifty years ago…Unlike a nuclear warhead, that information can travel very readily, and in the hands of terrorists or others who wish us harm, it can be very dangerous. So how do we control the proliferation of that bank of information our countries built back in those days?"[91] Not only does this historical information still pose a risk, but so does the body of knowledge about pathogens that has expanded since that time. In the modern day, the sharing of data via cloud computing, the growth of big data in the life sciences, and private and/or government networks that contain biotechnology know-how and/or pathogen information are a particular risk.

While a cyber attack on any health-related system could have enormous consequences to health security and care delivery, an area of particular relevance to biodefense and biosecurity is the vulnerability of pathogen-related data. Such information is commonly shared via the cloud or non-secure networks during the course of scientific business. Genetic sequences of pathogens (including those of the most serious threat agents) may be shared. The databases that contain this kind of information are as vulnerable to hacking as any other, and adversaries could

use their contents to gather intelligence on U.S. defensive capabilities, or even to engineer bioweapons. Life sciences research is also pushing further into big data analytics, a method by which enormous amounts of data are captured, integrated, and analyzed to reveal trends. The storage of any huge datasets, whether in the cloud or on secure servers, allows for scientific advancements, but also creates enormous vulnerabilities, as made clear in 2014-2015 with several attacks on health insurance provider databases.[92,93]

Additionally, biotechnology companies, universities, and government research laboratories store large amounts of networked information on biotechnology. This information includes advanced methods for genetic engineering, bio-manufacturing technologies, and emerging trends in biomedicine. These databases are targets for intellectual property crimes, industrial espionage, and intelligence gathering. Should these biotechnology databases fall into the wrong hands, rogue nations or other malefactors could use them to accelerate their biological terrorism and weapons programs.

Theft, misuse, or tampering with pathogen data should be considered a national security matter. If cloud-based data sharing, storage, and analysis are to be used for disease research, detection, and characterization, technical and non-technical security measures must be developed and implemented to ensure that no data stored or shared in the cloud are inappropriately manipulated or destroyed. A strategy for sharing information regarding cyber threats, securing pathogen data, and preventing national security breaches is needed. In addition, pursuant to President Obama's Executive Order on cybersecurity,[94] the federal government is in the midst of integrating cybersecurity risk assessments and obligations into all of its procurements. Federally-supported pathogen research projects, however, have not yet been included in that revised procurement model. Any time federal dollars are to be spent on pathogen and MCM research, cybersecurity concerns must factor into funding awards, and addressing these concerns should constitute an obligation for the funding recipients, much in the way select agent researchers are already obligated to comply with Select Agent Program (SAP) security regulations. The additional adoption of more stringent voluntary measures on the part of researchers should be encouraged and rewarded.

Recommendation 24

Harden pathogen and advanced biotechnology information from cyber attacks. The U.S. government, in partnership with the private sector, must innovate quickly to address the growing cybersecurity threat in this sector.

ACTION ITEMS:

a. **Develop and implement a security strategy for stored pathogen data.** The Vice President must ensure that the security of pathogen information is addressed by national U.S. cybersecurity strategy and policy, incorporating such deterrent and enforcement measures as oversight and inspection. Any policies promulgated pursuant to the strategy should set forth clear consequences for individuals or countries that undertake such actions. The measures developed should not imperil the legitimate sharing of scientific data and information.

b. **Provide the research community with tools and incentives to secure its data.** Federal departments and agencies should include federally-supported pathogen research projects in the revised procurement model under development. They should develop and establish voluntary standards in partnership with the members of the research community.[95] The Secretary of Agriculture and the Secretary of Health and Human Services should incorporate these standards into any new SAP regulations promulgated per Recommendation 32.

c. **Develop cyber-threat information-sharing mechanisms for the pathogen and advanced biotechnology communities.** The Vice President should elevate the priority of addressing cyber threats to these communities, including both virtual and physical infrastructure. The Secretary of Homeland Security, working with existing privately-led ISACs, should also address cyber threats to these communities. The Director of Immigration and Customs Enforcement (ICE) should direct the Intellectual Property Rights Center and the ICE Cyber Crimes Center to specifically address cyber threats to and vulnerabilities of the data possessed by these communities, and prevent intellectual property loss in this regard. The Vice President should also direct the Secretary of Health and Human Services to establish a formal pathogen and biotechnology subsector within the Healthcare and Public Health Critical Infrastructure Sector.

VI. REENGAGING WITH THE BIOLOGICAL AND TOXIN WEAPONS CONVENTION

The BWC is a legally binding treaty that entered into force in 1975. Signatory nations agree to never "develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes."[96] To date, 173 nations have become parties to the convention,[97] but at least five of these countries (China, Iran, North Korea, Russia, and Syria) are suspected of engaging in biological weapons activities despite BWC ratification.[98]

The BWC does not absolutely prohibit the use of biological agents or toxins, but instead prohibits their use as or in biological weapons. The BWC allows these agents and toxins to be used for peaceful purposes, including research and the development of MCM, protective equipment, and detection systems. Such peaceful work can cross the line into offensive work, and a well-known shortcoming of the BWC is that it lacks a verification system to sufficiently restrain countries from engaging in offensive biological weapons programs.

The United States has not been satisfied with any previously proposed verification and compliance (including sentencing) protocols because they neither adequately or realistically address prohibited activities nor allow for clear judgments on compliance to be made. The serious concerns about the development of an unsuitable verification regime caused the United States to withdraw from the fifth review conference in 2001, which threatened the viability of the BWC. The United States did rejoin the review conference when it resumed in 2002, but continues to harbor reservations about verification and compliance with the Convention.[99]

Despite concerns about BWC implementation, the United States remains a signatory to the BWC and continues to participate in BWC review conferences that occur every five years and annual Meeting of States Parties and Expert Meetings. Given their experience with the 2001 review conference, member nations tread lightly on the topic of verification and compliance, while hoping that such a regime can and will be developed eventually. When the United States withheld support of the verification protocol put forward in 2001, it left a leadership void that has never been filled adequately since.

Recommendation 25

Renew U.S. leadership of the Biological and Toxin Weapons Convention. Because the threat is real and growing, the United States must continue to engage in a biodefense program. However, the United States must not allow challenges associated with verification of, compliance with, and enforcement of the BWC to prevent it from exerting leadership in an arena that requires more than diplomatic support of the treaty.

ACTION ITEMS:

a. **Continue to strengthen implementation of the Biological and Toxin Weapons Convention where U.S. support is unequivocal.** The Secretary of State should lead U.S. efforts to revitalize the BWC by addressing topics such as universalization of the convention; calls for national laws and regulations concerning use, storage, and transport; and submission of complete annual reports by all member state parties. All U.S. federal agencies should press these issues in meetings with foreign counterparts.

b. **Set U.S. goals for the Biological and Toxin Weapons Convention and determine the conditions necessary to achieve them.** The Vice President should direct the NSC to use the period leading up to the December 2016 BWC review conference to determine desired outcomes. The Secretary of State should employ a high level emissary to press these issues with other parties to the treaty in advance of the next review conference.

c. **Develop three actionable recommendations for Biological and Toxin Weapons Convention verification.** Prior to the next BWC review conference, the Vice President and the Secretary of State should convene a series of meetings with representatives from all Cabinet and independent agencies with responsibilities for biological defense, as well as industry and academia, to discuss verification and compliance with the BWC. The result of this meeting should be the development of three recommendations for a verification protocol that would meet U.S national security needs as well as state-level compliance.

d. **Establish better biological weapons sentencing guidelines in statute.** Congress should amend the Biological Weapons Anti-Terrorism Act of 1989[100] and the USA PATRIOT Act[101] to include more specific sentencing guidelines, taking into better account the real and growing possibility that biological weapons will be used in the United States.

VII. BUILDING UPON DEFENSE SUPPORT TO CIVIL AUTHORITIES

DOD possesses resources and expertise that would be applicable in certain civilian contexts. Recognizing this, DOD has established some doctrine in support of civil authorities.[102] U.S. Northern Command has taken on a number of responsibilities for providing support to civil authorities and in executing those responsibilities, and has managed to foster some of the military-civilian collaboration needed for biodefense. Collaborative biodefense efforts (e.g., biosurveillance, pandemic planning) for the most part, however, are not formalized and there are no clear measures in place to ensure that they will be sustained. Additionally, these efforts do not reach far enough to address the needs of the entire Nation for biodefense.

Despite the importance of DOD's role in providing support to civilian authorities in response to domestic bioincidents, doctrinal clarity for this role is lacking. DOD has not established strong interfaces with the federal, state, local, territorial, and tribal agencies that would be involved in responding to a major biological attack against the United States. Should an event occur, while many suggest that the military should be called upon to assist civilians, there are no clear policies for the integration of military assets and the delegation of decisions to DOD decision-makers and the National Command Authority (NCA) that might be required.

DOD has significant knowledge that it could transfer to the civilian sector in the way of planning, logistics, response, operating in contaminated environments, science, technology, and many other matters. DOD and its civilian counterparts should engage in continuous transfers and exchanges of information to strengthen biodefense and the ability of the civilian sector to pull its own weight in a large-scale biological event – especially if military and other DOD personnel are called away to defend the Nation overseas.

DOD force protection and projection are imperiled by the threat of both bioweapons and naturally occurring infectious diseases. Yet U.S. warfighter preparedness for and protection against biological attacks is inadequate. DOD assets and force readiness overseas and within the homeland could be dangerously compromised by a major biological event. Scant consideration has been given to how operations would be conducted in biologically contaminated environments caused by a biological attack or by exposure to infectious disease when engaging in combat or providing humanitarian assistance.

Current military biodefense doctrine and policy falls short of adequately protecting the warfighter and ensuring that military operations continue unimpeded. Civilian policy also falls short of adequately protecting first responders and ensuring their activities continue unimpeded. Both civilian and military operators share many similar requirements for protection in biologically contaminated environments. However, mechanisms to encourage and develop collaboration between these communities are weak and are in need of greater support by both public and private sector leaders.

Recommendation 26

Implement military-civilian collaboration for biodefense. Civilian governmental and nongovernmental agencies would benefit from the experience, expertise, and technology resident in the U.S. military. Collaborative efforts should be institutionalized.

ACTION ITEMS:

a. **Conduct a review of military-civilian collaborative efforts.** The Secretary of Defense should conduct a review of previous and current efforts to collaborate with civilian counterparts and partners, including on biodefense. The Secretary of Defense should identify best practices from other efforts that could be applied to collaboration on biodefense, constraints that could prevent collaboration, potential solutions for removing these constraints, and recommendations for creating, implementing, and institutionalizing a formal program for ongoing military-civilian interaction and collaboration for biodefense. DOD should report the results of this review to the Vice President and the House and Senate Armed Services Committees.

b. **Establish military-civilian biodefense collaboration.** Congress should mandate military-civilian collaboration on biodefense, including research regarding force protection. Congress should include this requirement for ongoing collaboration in the National Defense Authorization Act and add it to the House and Senate Armed Services Committees' oversight agendas.

c. **Clarify parameters for military support to civilian authorities in response to a domestic biological attack.** The Secretary of Defense should clarify existing military doctrine to provide this support. The Vice President should develop clear policies addressing the integration of military assets when called upon to respond to a domestic biological attack. The Vice President should also direct the NSC to determine in what specific circumstances decision-making may need to be delegated to DOD leaders and the NCA in the event of a biological attack.

d. **Update and implement military biodefense doctrine.** DOD must produce technically feasible and politically acceptable doctrine for biodefense activities if it is to fulfill its primary responsibilities for force protection and projection. The Secretary of Defense should be held accountable by the Vice President for ensuring that this doctrine has been refreshed and/or developed with the input and full concurrence of the Joint Chiefs of Staff. DOD should base scientific R&D, training, and other activities necessary for biodefense on this doctrine.

CHAPTER 3: THE NEED FOR LEADERSHIP IN DRIVING INNOVATION

Governments are not known for taking innovative approaches to managing problems or to seeking high risk/high payoff scientific and technological solutions. The public sector has traditionally discouraged this kind of creative and cutting-edge thinking, in contrast to the private sector, which thrives on it.[103]

Scientific discovery is inherently fraught with uncertainty and policymakers have difficulty making enormous investments that may or may not result in viable scientific and technological solutions.[104] Innovation usually involves investment risk which, in turn, challenges policy makers. This is especially true with regard to low probability/high consequence events and in the absence of immediate threats.

It is reasonable for federal agencies to approach their missions with deliberation and well-established solutions. However, some problems call for greater urgency and innovation – because they are imminent threats, because the vulnerabilities underlying them have existed for too long, or because their complexity requires equally complex solutions. Biodefense falls into each of these categories. A problem like defending a nation from biological threats is inherently difficult to solve because it consists of overlapping subsets of problems, is addressed by diverse stakeholders with distinct agendas, and attracts problem solvers from a variety of organizations with different values – characteristics that can impede even a definitive statement of the problem.[105]

These complex problems require extraordinary coordination and collaboration, as well as innovative solutions. The government must be innovative in the very way it organizes to solve the problem (e.g., establishing agile and flexible procurement processes) and in developing requirements for the technologies it needs to solve the problem (e.g., progressive MCM that could redefine modern preparedness). Our leaders must give priority to innovative approaches to engaging industry and others toward needed solutions in areas like diagnostics, detection, biosurveillance informatics, personal and collective protection, remediation, and attribution. Recent guidance from OMB on FY 2017 science and technology priorities emphasizes that agency budget requests should include funding for innovative programs in biosurveillance and in countering WMD.[106] This guidance must be taken seriously by every agency with a role to play in these areas; and henceforth, funding for innovation in science and technology should be the norm. Innovation in technological solutions, regulatory approaches, and even operations is fundamental to solving the biothreats problem. Creative thinking must permeate the strategic visions of all agencies that fund biodefense, not only those with specific charges to be innovative. The United States should be the first to innovate in biodefense, as we have in so many other areas. The alternative is that we fall behind and become beholden to other nations, or that we are simply unprepared for the next attack, outbreak, or pandemic. Our leaders must internalize that forward and creative thinking and ensure its pervasiveness.

This chapter addresses innovation in the following areas:

I. Incentivizing Civilian Medical Countermeasure Development

II. Leaping Ahead to a Modern State of Biodetection

III. Removing Select Agent Program Impediments to Innovation

IV. Implementing New Approaches to Global Health Response

I. INCENTIVIZING CIVILIAN MEDICAL COUNTERMEASURE DEVELOPMENT

The WMD Commission argued that a nation prepared with MCM is one that can take threat agents off the table.[107] MCM development stands out as an area in which innovation can move biodefense along by leaps and bounds. But these advancements will not occur without bold leadership, strategic initiatives, creative thinking, and more disruptive advancements. While we must not ignore long-standing, successful technologies that have yielded useful tools (e.g., traditional vaccines) to address specific biological threats, we still must push the envelope on next-generation technologies, innovations to address genetically engineered pathogens, and tools that allow for rapid assessment of immune triggers and for extremely rapid vaccine and therapy development and production. All of these, furthermore, can be linked to innovative acquisition strategies.

A systemic risk-averse culture has emerged that is stifling MCM innovation. If this continues to evolve, progress on biodefense objectives will be curtailed and the still nascent biodefense industry will have little incentive to participate. Innovation must become ingrained in current policies and practices to take advantage of the technologies available today and in the future.

Government and industry have successfully partnered to innovate before, and they can do so again. For example, during Operation Desert Storm and later deployments in the mid 1990s, DOD needed to deploy vaccines and therapeutics for operational use under clinical investigational protocols to protect soldiers from biological and chemical warfare threats and endemic infectious diseases. This required alternative thinking and risk tolerance on the part of policy makers, program leaders, and the FDA to use investigational new drug (IND) products in combat environments. This experience spurred further innovative thinking and legislative solutions that culminated in the emergency use authorities provided in the Project BioShield Act of 2004.

More recently, when Ebola emerged in 2014, the only MCM candidates available were in very early stages of development. The U.S. government and industry partners rose to this challenge and rapidly transitioned three experimental vaccines and one therapeutic into clinical development in fewer than three months. Although the rapid development and collapsed clinical trial design and implementation are not the optimal way of doing business, this was nevertheless a remarkable achievement requiring forward thinking and risk tolerance. Some lessons and disruptive ideas are emerging that build on the most positive and useful aspects of that experience.

NEW MODELS FOR MCM DEVELOPMENT

The Nation remains unprepared for known, unknown, and unexpected threats. The collective experiences described previously suggest that non-traditional development and surge models are not only a plausible way to deal with this challenge, but should become the planned strategy. The foundations that would allow this kind of progressive approach already exist: for example, BARDA has a statutory mission to promote "innovation to reduce the time and cost of countermeasure and product advanced R&D."[108] And Congress recently demonstrated interest in a substantial shift at NIH when it proposed an NIH Innovation Fund at $2 billion annually.[109]

The risks and the subsequent approach needed vary by pathogen, and this must be thought through strategically on a detailed, case-by-case basis. Non-traditional development and surge models should be considered – not just for humans, but also for animals. A formal strategy is needed to operationalize the capabilities and capacities needed to rapidly

identify immunogenic components, deliver antigen payloads in platform technologies, quickly manufacture MCM using flexible and adaptable technologies, and rapidly distribute MCM to affected populations in response to unanticipated and new threats, while decreasing the need for expensive and inefficient stockpiling. The federal government should work closely with industry to develop new strategies that strike the right balance between stockpiling MCM against known high consequence/low probability threats, and surge manufacturing for emerging and unknown threats.

The DOD had a transformational medical technologies initiative that was paving the way to develop capabilities that would enable rapid pathogen characterization, antigen identification, and platform technology approaches. Despite early success, the initiative was reduced in scope largely due to criticism that it was too risky and funding could be better used on traditional CBRN equipment and technologies. The DOD should consider initiating a similar medical technologies initiative today, challenging the risk-averse culture and leading the way for other agencies to follow.

Recommendation 27

Prioritize innovation over incrementalism in medical countermeasure development. Leaders must not only prioritize funding for distinctly innovative programs, but must also decide that innovation is the solution to boldly meeting the biological threat.

ACTION ITEMS:

a. **Prioritize innovation in medical countermeasures at agencies with biodefense responsibilities.** Congress has proposed establishing an NIH Innovation Fund at $2 billion annually. Ten percent of this fund, if appropriated, should be dedicated to innovation at NIH in biodefense and emerging infectious disease MCM tied to BARDA requirements. The Director of BARDA should devote no less than ten percent of BARDA's annual budget to funding innovative technologies that can achieve progress across a broad spectrum of biological threats. Working groups should be established at all of these agencies to secondarily review proposals rejected as being too risky.

b. **Exploit existing innovation.** The Director of NIAID, the Director of BARDA, and the Deputy Assistant Secretary of Defense (DASD) for Chemical and Biological Defense should coordinate to identify at least five promising novel technologies (including platform technologies) that could ultimately be applied to MCM development for material threats. The most promising candidates (with sufficient safety and efficacy data to meet FDA standards) that enable using multiple antigens on an existing platform should be developed. If needed, FDA should develop a new approval pathway for these technologies.

c. **Revolutionize development of medical countermeasures for emerging infectious diseases with pandemic potential.** The Director of BARDA, in coordination with the Director of NIAID and the DASD for Chemical and Biological Defense, should establish a program to rapidly develop MCM for emerging infectious diseases with pandemic potential. They should develop a strategy to identify those candidates that would be most suitable for the program (while continuing to invest in more traditional pathways for other targets) and be as transparent as possible to academic and industry partners during this process. The Administrator of APHIS, in coordination with the DHS Under Secretary for Science and Technology and the Director of NIAID, should do the same for animal vaccine candidates, with similar transparency to academia and industry.

d. **Establish an antigen bank.** The Director of NIAID, the Director of BARDA, the DASD for Chemical and Biological Defense, the Administrator of APHIS, and the DHS Under Secretary for Science and Technology should identify and establish a bank of antigen payloads with supporting characterization data and standards to operationalize a plug-and-play strategy using proven platform technologies for use in an emergency for both human and animal pathogens.

FUNDING MCM INITIATIVES TO APPROPRIATE LEVELS

The development of any drug or vaccine candidate is a risky, lengthy, and expensive process. The challenges with MCM are even greater, because there is limited-to-no commercial market for these products and because the opportunity costs for doing this contract work for the government are too high for most experienced and innovative companies.

The federal government has, therefore, recognized that it alone can incentivize MCM development. It alone can account for intelligence, pathogen virulence, and the potential products already in development, and from there develop a plan for infectious disease threats that employs differing strategies and incentives. Given that some products may have viable commercial markets (e.g., antibiotics), limited commercial markets (e.g., acute radiation syndrome treatments), or no commercial market (e.g., pandemic influenza, tularemia, and Chikungunya MCM), a spectrum of strategies and incentives must be identified and leveraged to stimulate private sector development and manufacturing.

The legislative underpinnings for this are already present. Congress established Project BioShield and created BARDA to work with the biotechnology and pharmaceutical industry to plan and execute advanced development and procurement of MCM. The laws that established and funded Project BioShield and BARDA recognized that multi-year funding, transparent long-term strategies, and other incentives to include more flexible contracting mechanisms were required to garner industry's participation in solving biodefense problems. The Public Readiness and Emergency Preparedness (PREP) Act (P.L. 109-148) extensions to reduce tort liability are also very important statutory tools for incentivization, but the declarations under this Act for anthrax, smallpox, botulism, acute radiation syndrome, and pandemic influenza expire at the end of 2015 and must be reissued and extended by the Secretary of Health and Human Services before that time to ensure the continued participation of private sector partners.

BARDA was formed in 2006 and established a solid track record working with industry as a partner to develop and procure MCM for pathogens that DHS has determined pose material threats to the Nation.[110] Approximately $6 billion from FY 2004-2013 in advanced development and procurements allowed for the development and delivery of 12 MCM to the SNS. Another $6 billion was provided in emergency supplement funding in FY 2006 to support pandemic influenza preparedness in accordance with the National Strategy for Pandemic Influenza. Given that the cost of bringing a single drug to the commercial market can be in excess of $2 billion,[111] this investment is efficient and demonstrates the value of risk sharing through public-private partnerships (PPP). Twelve MCM, however, are not nearly enough considering the number and diversity of threats we face. This number could be doubled by 2018 if future congressional appropriations for the BioShield Special Reserve Fund (SRF) are adequate.

At the end of FY 2013, the original advanced appropriation for MCM procurements via the SRF[112] expired, and the supplemental pandemic influenza[113] balances were exhausted shortly thereafter. The SRF and pandemic influenza programs became subject to annual appropriations in FY 2014 and have experienced dramatic decreases in funding. Viewed against authorized levels, the project BioShield funding shortfall alone could be as much as $1.53 billion by 2018, eroding trust in the partnership model, resulting in fewer MCM, and leaving national security threats on the table. The shift from the advance-appropriated model to an annual appropriations process is highly questionable, given the relative success of the program, bipartisan support for it, and the lack of any decrease in the threat. It has even been questioned by the Director of BARDA.[114] The expiration of the SRF eliminated the guaranteed market that allowed companies and venture capitalists to more easily make the case for investing their own capital in innovative MCM development. It also diminished the flexibility of the U.S. Government to use these no-year funds to respond to an unexpected threat without the need for a supplemental appropriation.

The best way to incentivize industry to a level that allows it to participate in biodefense programs and pursue truly innovative ideas is to: 1) fund MCM development to legislatively authorized levels; 2) re-establish multiyear advanced appropriations through the SRF; and 3) eliminate bureaucratic hurdles within the partnership. To further enhance the environment for innovation, especially as the partnership model between government and industry evolves, many have urged Congress and BARDA to adopt other incentives that would invigorate MCM developers. Government, policy thought leaders, and industry have proposed a variety of incentives including success-based milestone payments and monetary prizes; minimum procurements/advanced market commitments; guaranteed pricing; patent extensions; orphan drug status expansions; wild-card exclusivity; transferable data exclusivity extensions; and priority review vouchers for pathogens that DHS has determined to be material threats.

These proposals vary in their cost to government, their political feasibility to authorize, and, critically, in their palatability to the companies for which they are designed. BARDA and industry should convene to determine and recommend the most effective incentives beyond congressional appropriations. Recommendations for incentives should be designed for small biotechnology companies, large pharmaceutical companies, and those in between. The array of business models necessitates a variety of incentives.

Recommendation 28

Fully prioritize, fund, and incentivize the medical countermeasure enterprise. Only through a firm and long-lasting commitment to MCM development can we successfully address the full spectrum of biological threats.

ACTION ITEMS:

a. **Fund the medical countermeasure enterprise to no less than authorized levels.** Congress should immediately fund MCM initiatives through BARDA, the SRF, and the SNS consistent with the bipartisan authorized levels for these programs. Longer-term appropriations should be reflective of needs identified in the National Strategy for Biodefense and associated budgeting and prioritization initiatives outlined in this report.

b. **Re-establish multi-year biodefense funding for medical countermeasure procurement.** The President and Congress should re-establish multi-year funding for Project BioShield, thus re-establishing the marketplace while building and maintaining capabilities. A 10-year advanced appropriation for the SRF is entirely appropriate.

c. **Address prioritization and funding for influenza preparedness.** At least every five years, the ASPR, in coordination with all government and non-governmental stakeholders, should review existing pandemic influenza assets, assess their ability to fulfill goals, and inform near- and long-term budget requests. The ASPR must more effectively engage and communicate with pandemic influenza industry stakeholders. Congress should consider providing complementary legislative authorization as appropriate to define and guide pandemic influenza programs.

d. **Improve the plan for incentivizing the private sector and academia.** The ASPR and DASD for Chemical and Biological Defense should convene non-governmental stakeholders to identify meaningful incentives which are independent of congressional appropriations for MCM developers and manufacturers. They should report findings and recommendations to Congress within six months, identifying those incentives that would improve industry and academic participation in MCM development, and requesting congressional authorization for those that would require it.

REMOVING BUREAUCRATIC HURDLES TO MCM INNOVATION

Improving federal government contracting practices will enable the federal MCM enterprise to meet mission requirements. Legacy and current contracting practices are still not sufficiently transparent, uniformly implemented, predictable, or flexible enough to accommodate efficient MCM development, or to optimize industry participation to achieve U.S. government biodefense preparedness objectives. The evolving government-wide, risk-averse culture is a contributing factor and a growing disincentive for the very companies that the government needs to meet its requirements.

For example, the DOD MCM program utilizes an acquisition system that has evolved over the years for weapons systems. This acquisition model has been modified to some degree to accommodate life science applications and FDA regulatory requirements, but its use for vaccines has mixed to poor results with at least two vaccine candidates lingering in advanced development for almost 15 years.

DOD and Army acquisition leadership recently acknowledged that traditional and legacy acquisition strategies are hindering progress and industry participation for all biodefense technologies, including medical. The Army is now implementing new and innovative acquisition strategies including the use of other transaction authority (OTA) for MCM.[115] Army leadership should be commended for implementing innovative acquisition and contracting strategies.

BARDA should similarly reduce unnecessary hurdles and implement innovative acquisition strategies, to include making greater use of OTA, as Congress originally intended when authorizing BARDA. The contracting authorities available to BARDA (like OTA) go beyond traditional Federal Acquisitions Regulation mechanisms, but these expanded authorities have only been used to establish one (non-Ebola) partnership to date. Additionally, BARDA should reestablish its own internal contracting authority, rather than rely on the separate ASPR Office of Acquisitions Management, Contracts and Grants. This would reduce unnecessary bureaucratic delays, improve efficiency and decision making, and enhance BARDA program effectiveness and accountability. Finally, when Project BioShield was created in 2004, its funding was derived from DHS while the program was administered by HHS, resulting in the need for OMB review. Now that all BioShield funds and procurement responsibilities are housed at HHS, an OMB review of contracts already approved and funded by HHS is unnecessary and slows MCM procurements.

Recommendation 29

Reform Biomedical Advanced Research and Development Authority contracting. A variety of statutory and organizational issues impede nimble and efficient contracting by BARDA, leading to delays in the availability of MCM.

ACTION ITEMS:

a. **Return contracting authority to the Biomedical Advanced Research and Development Authority.** Contracting authority should be the exclusive responsibility of BARDA. The ASPR should administratively reinstate BARDA as the sole authority to negotiate, award, and administer its own advanced research, development, and procurement contracts. If the ASPR fails to do so, Congress could mandate this.[116]

b. **Leverage previously provided authorities.** BARDA should prioritize the use of OTA and consider any other appropriate flexible contracting authorities for BioShield and advanced development contracts.

c. **Eliminate Office of Management and Budget review of BioShield procurements.** Congress should amend the Public Health Service Act to eliminate OMB review of BioShield procurement contracts.[117]

DEVELOPMENT OF RAPID POINT-OF-CARE DIAGNOSTICS LARGELY IGNORED

A rapid point-of-care diagnostic test would have significantly improved management of the Ebola outbreak abroad and in the United States – perhaps more than anything else. If it had been available, it would have significantly improved quarantine and isolation decisions at home and abroad, and saved countless lives. Ebola screenings of suspected patients were often based on little more than thermometer readings and a series of questions. While an assay was quickly fielded under an EUA, it was not a rapid and patient-side device of the kind that could exist by the hundreds or thousands in clinics and be used by anyone with limited training. The absence of such tests for many threats makes it difficult to ascertain the full scope of an incident, reliably distinguish infected from uninfected individuals, and determine appropriate intervention strategies.

Most physicians are not trained to recognize the early symptoms caused by emerging diseases or select agent pathogens. Initial symptoms (e.g., high fever, muscle aches, lethargy) that infected individuals exhibit for most biothreats are non-specific. Rapid recognition of illness caused by a novel biothreat against the background noise of more common and routine infections is, therefore, unlikely without access to definitive diagnostic tests for the new pathogen.

We must push hard to develop advanced molecular diagnostics in order to move beyond old technology and the incremental improvement of new technology. With the proper investment, we can get there. The technologies needed for the quick patient-side diagnostics of the kind used in doctors' offices to screen for influenza exist or are in development. However, their development has not been prioritized for Ebola and other threats on which the government and industry have spent billions on vaccines and therapeutics. From anthrax to influenza, the investment has been almost solely in drugs with a dearth of focus on diagnostics, and certainly not rapid point-of-care diagnostics.

This is extremely short sighted. These technological solutions require significant investment up front, but they can be highly leveraged when integrated into a biological response architecture. They spare vaccines, treatments, and the necessity for quarantine or isolation when they are not needed, saving valuable resources. Furthermore, increasingly sophisticated profiling of the molecular signatures of biothreat agents is also valuable in the event of a bioattack, potentially providing informative forensic clues for attribution and justification for actions based on this information.

Recommendation 30

Incentivize development of rapid point-of-care diagnostics. Advanced diagnostics are clearly needed, and BARDA must incentivize their development. Without these tools, the Nation remains vulnerable.

ACTION ITEM:

a. **Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases.** The Director of BARDA should determine the suite of rapid diagnostics that are needed for biological agents determined to be material threats and emerging infectious diseases. BARDA must prioritize their development and acquisition, and implement a plan to work with industry and academia to achieve success in this arena. The MCM incentive discussions per action item 28d apply and strong efforts should be made to provide companies with participation incentives.

II. LEAPING AHEAD TO A MODERN STATE OF BIODETECTION

Effective environmental surveillance improves pathogen identification and, most importantly, provides early warning. The federal government collects limited data on water and soil contamination, and lacks requirements that would incorporate any such data into a federal database. The biodetectors designed to inform biosurveillance of the air (commonly referred to as environmental detection) have not progressed significantly since their initial deployments.

The BioWatch program was launched in 2003 with great urgency, but its potential remains unrealized. As of 2015, BioWatch uses the same technology – manual filter collection and laboratory polymerase chain reaction testing – as it did twelve years ago. BioWatch is a DHS system of nationally distributed detectors that sample the air for a select number of bioterror pathogens in a few dozen cities. Non-federal public health laboratories then analyze the samples. The technological limitations of the system are many: 1) it relies on winds blowing in optimal directions; 2) it can take up to 36 hours to alert the possible presence of a pathogen; 3) specimens are inactivated, preventing determinations of whether live organisms were released; 4) it cannot differentiate between normal background bacteria and harmful pathogens; and 5) it cannot identify atypical threats. Beyond the scientific limitations are challenges in execution. For instance, federal agencies involved in determining what to do with test results often disagree as to what course of action should be taken and do not always consult non-federal public health and other leaders, even though many response decisions ultimately must fall to local leadership.

The entire BioWatch system is dying for lack of innovation. DHS attempted and failed to acquire next-generation BioWatch technology (Generation 3) that could have reduced time-to-detection to as few as six hours. Even if the acquisition had been successful, the system would still have been flawed: like the current system, it would have addressed only a small number of biological agents, inactivated them, and relied on non-random air currents. To date, no fully automated, tested, and evaluated autonomous detection system has been deployed that adequately addresses the airborne biological threat or sufficiently provides operational response information. Yet technological advances in sequencing and other relevant technology exist and could be fostered with clear requirements, meaningful PPP, and strongly focused innovation.

DHS R&D efforts are the responsibility of the S&T Directorate. OHA within DHS, however, pursued its own R&D activity in support of the Generation 3 effort, ultimately wasting time and funding. Congress should remind DHS leadership that DHS S&T and OHA have distinct – not overlapping – responsibilities. R&D efforts fall squarely and only in the purview of S&T per statute.[118] Simultaneously, DOD engages in its own biodetection research and acquisition programs. While the needs of civilians and warfighters are generally distinct, the science behind environmental detection is not. DOD and DHS must better coordinate their environmental detection efforts and leverage each other's advances. Together (and with congressional oversight) these departments can develop a detection system capable of meeting today's threats with 21st century ingenuity and replace the ineffective civilian system currently in place.

Recommendation 31

Develop a 21st Century-worthy environmental detection system. The Nation continues to lack a rapid and reliable environmental detection system for known and unknown biological threats, a situation that must be rectified.

ACTION ITEMS:

a. **Fund the development of advanced environmental detection systems to replace BioWatch.** Congress, through its appropriations to DHS and DOD, should fund an advanced environmental detection system capable of rapid agent characterization and confirmation. The system should be capable of recovering live agents from collection devices, determining geographical distribution, determining environmental persistence, and providing advanced molecular diagnostics at the laboratories that will support operational activities. The Vice President should call for a formal process between DHS, DOD, and all other federal agencies utilizing or developing biodetectors to share information regarding their biodetection successes and failures, up to and including a mandate to procure another agency's technology if it fits requirements. For domestic biodetection, DHS must work with end users in states, localities, territories, and tribes at the earliest stages of requirement development. DHS must also develop a standardized integration strategy and training requirements based on these discussions.

b. **Replace BioWatch Generation 1 and 2 detectors.** The Secretary of Homeland Security must replace these detectors within five years with the systems developed per action item 31a. If they cannot be replaced within that timeframe, the Secretary of Homeland Security should remove them from service.

III. REMOVING SELECT AGENT PROGRAM IMPEDIMENTS TO INNOVATION

The primary federal program to prevent the misuse of pathogens and toxins is the SAP, administered jointly by the CDC and USDA.[119] This program has functioned as an impediment to would-be attackers. Yet the regulatory regime of the SAP does not fully address underlying issues in pathogen safety and security, including how to prevent and deal with human error, how to ensure standards for safety and security awareness are met, and how to be more transparent within statutory confines about lapses and problems with the system. It is time for a complete review followed by a comprehensive overhaul.

Information, knowledge, and equipment to produce pathogens de novo (known as synthetic biology) have become increasingly available in the years since the SAP's establishment. Therefore, restriction of access to pathogens already secured in laboratories has decreased impact today. Furthermore, pathogens are not the only problem. Non-pathogens (e.g., bioregulators, small peptides) could also be used in biological weapons and yet fall outside of the current regulatory regime. SAP regulations can also reach burdensome levels that make the scientific workforce resistant to engaging in much needed biomedical research and provide minimal or no enhancement of biosafety or biosecurity.[120] SAP

regulations also fail to recognize the reality of select agents presenting in animal diagnostic samples, and the nature of the work that veterinary diagnostic laboratories must, therefore, do to keep the Nation and its animals safe and healthy.

Policymakers must address: discrepancies among the purpose of the SAP, rationale for its regulations, and criteria for determining which agents are added or removed from the list; barriers to full implementation of the SAP; the value of a dynamic characteristic-based approach for restricted agents and toxins versus the current, static list-based approach; challenges associated with inspections; whether federal and private investments in biodefense are maximized; and how to implement a restorative (rather than punitive) process for addressing problems.

The program has been reviewed, but the recommendations of the 2009 report of the Trans-federal Task Force on Optimizing Biosafety and Biocontainment Oversight were never fully implemented.[121] An undeniable problem with this task force is that it was co-chaired by HHS and the USDA, the very agencies that administer the program. A different approach to identifying problems and ensuring that solutions are implemented is needed. Hopefully, the results of a Request for Public Comment by OSTP regarding the impact of SAP regulations[122] will lead to a rigorous and comprehensive assessment of the program.[123] The focus of the overhaul should be less about whether we can secure stocks of pathogens and more about whether we can control the proliferation of information, predict the nature of the changing biological threat, and ingrain a culture of security awareness within the biomedical research community.

Recommendation 32

Review and overhaul the Select Agent Program. A comprehensive program assessment and overhaul is long overdue. Congress should ensure that these are initiated in the near term.

ACTION ITEMS:

a. **Undertake a major reassessment of the Select Agent Program.** Congress should direct the National Science Advisory Board for Biosecurity (NSABB, a federal advisory committee authorized in the Public Health Service Act) to undertake a systematic, evidence-based assessment of the SAP. This assessment should include extensive consultation with all stakeholders, including the regulated community and the law enforcement and intelligence communities. NSABB should evaluate all pertinent strategies, laws, and guidance related to the SAP; identify key drivers of safety and security lapses; and identify regulatory burdens in the SAP that stifle research and innovation. The report should include specific and actionable recommendations for revising SAP regulations and their implementation in order to improve security and safety and to incentivize laboratory certification under the program. NSABB should provide the assessment and recommendations for program overhaul to the Secretary of Health and Human Services, the Secretary of Agriculture, and the Vice President within six months. The report should also be made public and provided to Congress shortly thereafter.

b. **Overhaul the Select Agent Program.** Based on the recommendations of the NSABB and input from other sources as appropriate, the Secretary of Agriculture and Secretary of Health and Human Services should undertake a comprehensive overhaul of the program, to include development of a revised program strategy; notice of proposed rulemaking and public comment periods as necessary; and promulgation of new rules as necessary. Any new rulemaking must be undertaken to achieve optimal laboratory safety and security while minimizing bureaucratic burdens on the regulated community. Congress should provide oversight over all proposed rules for the program.

IV. IMPLEMENTING NOVEL APPROACHES TO GLOBAL HEALTH RESPONSE

International cooperation is a key element in implementing global health strategies.[124] Through the Global Health Security Agenda (GHSA), the United States and its international partners collaborate to prevent and mitigate the biological risk and to promote global health security as an international priority.[125] The GHSA was formally announced in 2014, setting a five-year agenda for prevention, detection, and response. It represents an ambitious plan to meet global gaps in surveillance, detection, and MCM availability. U.S. activities include establishing emergency operations centers, strengthening laboratory biosecurity in developing nations, partnering with international animal health authorities to rapidly detect and manage animal diseases, and implementing and strengthening the International Health Regulations and OIE reporting capacities.

Although the United States has helped build biosurveillance infrastructure in nations throughout the world where emerging diseases are likely to arise, Ebola proved that current efforts failed to achieve adequate surveillance capacity, and warning signs went unheeded. While there is disagreement over where exactly the failure occurred in terms of detecting Ebola and communicating that detection, health officials did seem to underestimate the timing and scope of the disease's transmission and were blinded by preconceptions that Ebola was a disease of the jungle and would not spread to cities.[126,127] Senator Richard Burr characterized the Ebola outbreak as a "total breakdown of global detection."[128]

Nowhere is the fragility of the human-animal disease boundary more pronounced than in developing nations, from where the majority of new infectious agents are emerging.[129] Urban areas are nucleation points for infectious disease risk and their populations are dramatically increasing in many of these countries. Because these nations often lack both public health and animal health infrastructures, their capacity for early and effective surveillance and mitigation efforts is challenged. Multilateral bodies like WHO and OIE must, therefore, support the development of in-country activities and capabilities to meet international standards, prevent cross-border spread of disease, and reduce the risk of accidentally or intentionally introduced biological threats. As a voting member of and major donor to both the WHO and OIE, and as a resource-rich nation with enormous public health expertise, the United States has an obvious role to play at the forefront of these efforts.

Investment in prevention would reduce the much higher cost of outbreak response and MCM. When prevention efforts fail, early detection and rapid response systems are needed to quickly resolve outbreaks before they spread. Global prevention and response capacity will not come from the WHO; it must come from nations who agree to make it a priority. The geographic hotspots at highest risk for these disease events have been identified[130] and further refined by recent analyses.[131] What remains desperately needed is an off-the-shelf logistical enterprise at the ready to insert public health resources into areas where infectious diseases with pandemic potential are percolating after local resources have been overwhelmed.[132] It was widely thought before the 2014 Ebola outbreak that the WHO was sufficiently equipped for this kind of rapid and large-scale response. It is not.

Logistical expertise and resources are critical enablers for quick and effective outbreak response. WHO does not possess sufficient logistical assets to fulfill this requirement. While other public sector (e.g., U.S. Transportation Command, the North Atlantic Treaty Organization) and private sector (e.g., Federal Express, DHL) organizations are proven logistical powerhouses, they are not regularly called upon to help. No individual organization or nation should take on this task alone. Rather, a PPP that incorporates a variety of logistical organizations, as well as others that would support such an effort (e.g., pharmaceutical companies) is clearly necessary.

The recent Ebola outbreak happened not because any single institution or nation failed, but because they failed collectively.[133] Together with their partners, the United States should leverage the GHSA to develop a global public health response capacity and build international threat awareness, reach consensus on priorities, improve regional and cross-border surveillance, and increase regional MCM stockpiling and distribution plans. The effectiveness of the effort will be only as good as the strategy by which it is implemented and the level of funding it receives. If we fail to aggressively fund and implement multilateral activities such as these, we risk something potentially much worse than Ebola.

Recommendation 33

Lead the way toward establishing a functional and agile global public health response apparatus. The United States should harness its considerable diplomatic clout to forge development of a response system with partner nations that can meet the need for rapid public health and animal response.

ACTION ITEMS:

a. **Convene human and animal health leaders.** The Secretary of State should convene human and animal health leaders from throughout the world to evaluate current mechanisms and develop a strategy and implementation plan for global public health response. This cooperation should be multilateral and could be achieved through GHSA and bilateral and multilateral agreements.

b. **Establish the response apparatus.** Through the multilateral efforts described above, the United States should implement the plan and lead the establishment of a functional public health response system based on PPP. The President should request any required new funding via the unified biodefense budget.

APPENDIX A: PROPOSED CONGRESSIONAL OVERSIGHT HEARINGS

The value of congressional oversight in ensuring that federal departments and agencies are meeting congressional and other mandates, and doing so in a coordinated fashion, cannot be overstated. These proposed hearing topics reflect major recommendations outlined in the report, as well as additional ideas for consideration.

ISSUE	SUMMARY	HOUSE COMMITTEE(S)	SENATE COMMITTEE(S)
The Threat	Four commissions and the Blue Ribbon Study Panel on Biodefense have expressed concern about the threat and the inability of the IC to modify or develop new methods to collect, analyze, and disseminate biological intelligence. What has changed since the release of the Robb-Silberman Commission report? Has the IC redirected resources to address this growing threat? If so, to what extent? What has the IC done to increase information sharing with state and local governments regarding the biological threat? (See Recommendation 16.)	• Permanent Select Committee on Intelligence • Judiciary • Homeland Security	• Select Committee on Intelligence • Judiciary • Homeland Security and Governmental Affairs
Animal Disease Reporting	A nationally notifiable animal disease system akin to the existing system for human disease would enhance surveillance and detection of biological threats. A proposed National List of Reportable Animal Diseases has been offered by the USDA, but not yet implemented. What diseases should be on such a list? How could the list be part of a larger system by which states and other owners of disease information could willingly and comfortably report disease incidence? (See Recommendation 14.)	• Agriculture • Homeland Security • Natural Resources	• Agriculture, Nutrition and Forestry • Environment and Public Works • Homeland Security and Governmental Affairs
BARDA's Mission Space	BARDA's scope is being expanded to include development of MCM for antimicrobial resistant pathogens irrespective of ties to bioterrorism. How might this expansion require diversion of BARDA funding away from its original mission and force it to compete for additional funding? What level of funding is necessary to ensure that BARDA's statutory mission space in CBRN and emerging infectious disease is fully met?	• Appropriations • Energy and Commerce • Homeland Security	• Appropriations • Health, Education, Labor and Pensions • Homeland Security and Governmental Affairs
Biodefense Strategy	The United States lacks a unifying biodefense strategy. The unification of myriad federal biodefense mandates into a coherent strategy could serve as a backbone for progress and accountability. What should the elements of a unified national strategy for biodefense be? (See Recommendation 3.)	• Agriculture • Armed Services • Budget • Energy and Commerce • Homeland Security • Oversight and Government Reform	• Agriculture • Armed Services • Budget • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs

ISSUE	SUMMARY	HOUSE COMMITTEE(S)	SENATE COMMITTEE(S)
Biosurveillance	The United States lacks a comprehensive biosurveillance and detection capability. An integrated biosurveillance function exists in statute, but has been difficult to realize. What would it take to bring the agencies with biosurveillance responsibilities together in a trusted, information-sharing environment? What is the needed end state for a continuous capability to detect, validate, and warn of any biological threat within U.S. borders? How would the participation of data owners be incentivized and ensured? (See Recommendations 11, 12, 13.)	• Agriculture • Energy and Commerce • Homeland Security • Natural Resources • Oversight and Government Reform • Veterans' Affairs	• Agriculture • Environment and Public Works • Energy and Natural Resources • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs • Veterans' Affairs
Budgeting	Lacking a unified approach to budgeting, biodefense budget requests are spread across a dozen departments and agencies. What is the best way to consolidate biodefense programs into a cross-cutting analysis? What would a unified biodefense budget look like and how could it best be utilized? (See Recommendation 4.)	• Budget	• Budget
Cyber Vulnerabilities to the Life Sciences	Laboratory and research databases, as well as the expanding use of biotech information technology (e.g., monitors, sensors) within and outside of the government, contain information about pathogens that allows for great advances in biomedical science. It also creates a serious vulnerability. Where are the weak links in storage of life science information? What technologies exist or need to be developed to protect them? How can federal grant agreements and procurement contracts create a driving force for incentivizing protection of this information? (See Recommendation 24.)	• Energy and Commerce • Homeland Security • Oversight and Government Reform • Science, Space, and Technology • Permanent Select Committee on Intelligence • Transportation and Infrastructure	• Health, Education, Labor and Pensions • Commerce, Science, and Transportation • Homeland Security and Governmental Affairs • Select Committee on Intelligence
Food Supply Protection and Response	The Food and Agriculture critical infrastructure sector is a distributed and highly complex system. Many efforts have been made to reduce the vulnerabilities of this system to terrorism and other insults. HSPD-9 (2004) and DHS's sector specific plan (2010) provide a foundation for the protection of this sector. Have the plans been updated, exercised, and sufficiently funded? Are they integrated with related efforts in biosurveillance, attribution, and decontamination standards? How will federal agencies (including the FDA and CDC) respond if there is a terrorist attack affecting the food supply? How can PPP in this area be improved? What efforts and funding are still required in biosurveillance and MCM to protect livestock? In decontamination and remediation to bring food processing plants back on line after an incident?	• Agriculture • Energy and Commerce • Homeland Security • Natural Resources	• Agriculture, Nutrition and Forestry • Environment and Public Works • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs

ISSUE	SUMMARY	HOUSE COMMITTEE(S)	SENATE COMMITTEE(S)
Global Health Response	A global public health response apparatus that can react quickly and insert public health teams to respond to human and animal outbreaks is lacking. What is the current capacity and in what ways is it not meeting the need? How can international efforts be evaluated and better coordinated? What is the status of current global health reserve programs and how can they show more progress? What level of funding would be necessary? What lessons can be learned from the 2014 Ebola outbreak? (See Recommendation 33.)	• Agriculture • Armed Services • Foreign Affairs • Energy and Commerce • Natural Resources	• Agriculture • Armed Services • Foreign Relations • Health, Education, Labor, and Pensions
MCM Innovation	The Ebola outbreak demonstrated that being caught in an outbreak situation without MCM puts us at serious risk. And yet, there were some signs that our MCM apparatus could at least partially rise to the occasion with alacrity. What is a good strategy for mustering needed resources rapidly enough to get some candidates off the shelf and into clinical trials? How can the U.S. government catalyze development of MCM for naturally emerging infectious diseases with pandemic potential? (See Recommendations 27, 28.)	• Armed Services • Energy and Commerce	• Armed Services • Health, Education, Labor, and Pensions
Military-Civilian Biodefense Collaboration	The military provides support to civil authorities in accordance with established doctrine. However, it is unclear how much of this occurs in regard to biodefense. Military-civilian collaboration on biodefense would be beneficial to both sectors, especially as regards force protection (for the military sector) and responder protection (for the civilian sector). To what extent is collaboration between these sectors occurring now? What barriers and opportunities exist for collaborating on biodefense? What is needed to make this collaboration happen? (See Recommendation 26.)	• Armed Services • Agriculture • Energy and Commerce • Homeland Security • Permanent Select Committee on Intelligence • Science, Space and Technology • Transportation and Infrastructure	• Armed Services • Agriculture, Nutrition and Forestry • Commerce, Science, and Transportation • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs • Select Committee on Intelligence
Origin of Active Pharmaceutical Ingredients (API)	By some reports, 80% of API is manufactured outside of the United States, with the majority of these coming from India and China. Increasingly, critical products are made with API sourced outside of the United States. Does foreign sourcing of such material from developing countries improve U.S. ability to stockpile, or does it create vulnerability? What lessons can be learned from the current oncology drug shortage? Are there ways to develop U.S. opportunities for manufacturing the kinds of materials these nations currently supply, while aligning with free trade agreements and fostering innovation? Are existing agreements like the Trade Agreements Act being fully enforced? Could U.S. companies be incentivized to innovate toward this end?	• Armed Services • Energy and Commerce • Foreign Affairs • Homeland Security • Judiciary • Veteran's Affairs	• Armed Services • Foreign Relations • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs • Judiciary • Veteran's Affairs

ISSUE	SUMMARY	HOUSE COMMITTEE(S)	SENATE COMMITTEE(S)
PHEMCE Coordination of MCM Efforts	Investment strategies for MCM must match product development goals. In what ways are the members of the PHEMCE still uncoordinated, from budget submissions to priority setting to procurements? Are funding allocations for participants appropriate to meet the need? What should be included in a NIAID biodefense spend plan to ensure its utility? How can Congress ensure that PHEMCE priorities and agencies meet requirements to address biological agents that have received MTDs and emerging and reemerging infectious diseases that are on the proposed priority list per Recommendation 7? (See Recommendation 8.)	• Appropriations • Energy and Commerce • Homeland Security	• Appropriations • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs
Select Agent Program (SAP)	The SAP was established by Congress to better secure pathogens that, if stolen, could enable enemies to more easily develop biological weapons. Since its inception, however, SAP requirements seem to have become increasingly burdensome. How difficult is it to obtain necessary permissions to conduct research with select agents? How long does it take on average to receive permission (how many months, years)? How effective have USDA and the CDC been in administering the program? What efforts have been made to harmonize these rules with those of foreign countries to account for select agent use outside of the United States? (See Recommendation 32.)	• Energy and Commerce • Armed Services • Judiciary	• Health, Education, Labor, and Pensions • Armed Services • Judiciary
Vulnerable Populations	The needs of vulnerable populations must be considered in all biodefense planning. Children, the elderly, the disabled, the immunocompromised, and other at-risk groups require unique planning and resources, in everything from risk communication to MCM development and dispensing. Has the vision of the PAHPA for leaders to recognize and address the health security needs of children and other vulnerable populations been met? Where are continued gaps in planning and implementation?	• Homeland Security • Energy and Commerce • Veterans' Affairs	• Homeland Security and Governmental Affairs • Health, Education, Labor, and Pensions • Veteran's Affairs

APPENDIX B: METHODOLOGY

The Blue Ribbon Study Panel on Biodefense was established in 2014 to inform U.S. biodefense and provide recommendations for change. The Panel – supported by a suite of ex officio members; institutional hosting through Hudson Institute and the Inter-University Center for Terrorism Studies at Potomac Institute for Policy Studies; and funds from academia, foundations, and industry – set out to determine where the United States has fallen short of addressing bioterrorism, biological warfare, and emerging and reemerging infectious diseases.

RESEARCH QUESTIONS

In order to address the gaps in the biodefense enterprise and the biodefense body of knowledge, the following research questions were developed:

1) Are our priorities correct?
2) Are our investments commensurate with the challenge?
3) Can we benefit by rebalancing investments or is new funding required?
4) What have we done that has brought a significant return on investment?
5) What else should we be doing that we are not?

PRELIMINARY RESEARCH

The Panel reviewed previous research efforts; scientific studies; reports by congressional and presidential commissions (including the U.S. Commission on National Security/21st Century, Commission on Terrorist Attacks on the United States, Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, and Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism); presidential directives; statute and proposed legislation; GAO reports; and federal strategies, plans, budgets, organizational constructs, and programs related to defense against deliberately introduced and naturally occurring biological events with catastrophic potential. This review: 1) allowed for an assessment of the comprehensiveness of efforts to address the postulated and actual biodefense challenges they were intended to meet; and 2) determined how the understanding of the threat, the knowledge base, and elements of the biodefense enterprise should change in light of this assessment. This review also informed the structure and topics of the four formal meetings of the Panel.

FORMAL PANEL MEETINGS

The four formal meetings were organized around the pillars of U.S. national biodefense policy (as articulated in National Security Presidential Directive 33 and Homeland Security Presidential Directive 10) – threat awareness, prevention and protection, surveillance and detection, and response and recovery. During each of these day-long meetings, members of the Panel, ex officio members, and study staff received: 1) information regarding current relevant national policy, legislative issues, and departmental and agency programmatic activities; and 2) statements from current and former Members of Congress, current and former federal officials, state and local representatives, thought leaders, and subject matter experts. Panel staff summarized the major insights, areas for improvement, and recommendations articulated by meeting speakers, and conducted preliminary high-level analysis of each day-long meeting for Panel and ex officio review.

SATELLITE WORKSHOPS

The activities of the Panel were enhanced by four meetings held by biodefense stakeholders. Four groups agreed to hold satellite workshops at which they convened experts and discussed key biodefense issues in-depth. They presented their findings at the third public meeting of the Panel. These meetings were hosted by the: MESH Coalition in Indianapolis, Indiana (on hospital preparedness); New York City Department of Health and Mental Hygiene in New York, New York (on major urban area concerns, ranging from environmental detection to MCM dispensing); the Texas A&M University Health Sciences Center in College Station, Texas (on the human-animal interface in biodefense); and the Alliance for Biosecurity in Washington, DC (on MCM research, development, and procurement). These groups identified specific areas in need of policy, legislative, programmatic, and resource improvement for the Panel to consider.

ANALYSIS

Qualitative methods were used to analyze all of this information. The Panel examined the oral and written statements provided by meeting speakers and developed a table that mapped their findings and recommendations to the capabilities required in HSPD-10. Each finding and recommendation was then further evaluated by various means, including additional policy research and interviews with subject matter experts and former high level officials, as well as in light of the Panel's own experience. Throughout the process, the five questions defined previously provided the basis for assessment. This approach allowed the Panel, ex officio members, and staff to identify continuing organizational, legal, policy, and programmatic issues and recommend specific near-, medium-, and long-term solutions. Statistical and other quantitative methods were not used for this study. The study is not considered pseudo-qualitative/quasi-quantitative.

STUDY LIMITATIONS

Funding and other resource constraints prevented the Panel from performing site visits. In addition, a number of biodefense programs and policies; intelligence, raw data, and documents; appropriations and budget documents; and other sensitive pieces of information are classified or otherwise unavailable, and were not reviewed by the Panel as this was a wholly unclassified endeavor.

APPENDIX C: MEETING AGENDAS AND SPEAKERS

All meetings were held at Hudson Institute, Washington, D.C.

MEETING 1: THREAT AWARENESS DECEMBER 4, 2014

Congressional Perspective

- The Honorable Richard Burr – United States Senator, North Carolina and Chairman, Senate Select Committee on Intelligence

Panel One: WMD Commission Perspectives

The relevance of the WMD Commission's past work, its assessment of the potential threat, and its evaluation of U.S. preparedness efforts

- Senator James M. Talent, J.D. – Senior Fellow, American Enterprise Institute
- Colonel Randall Larsen, USAF (ret.) – Former Executive Director, Congressional Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism

Lunch Keynote

The threat

- The Honorable Richard J. Danzig, J.D. – Director, Center for a New American Security

Panel Two: Executive Branch Perspectives

Contemporary insights on the nature of the chemical and biological threats, and the ability of the Department of Homeland Security, Intelligence Community, and Congress to define the risks

- The Honorable Tara O'Toole, M.D., M.P.H. – Executive Vice President, In-Q-Tel
- The Honorable Michael Moodie, M.A. – Former Assistant Director for Multilateral Affairs, U.S. Arms Control and Disarmament Agency
- George Poste, D.V.M., Ph.D. – Director, Complex Adaptive Systems Institute, Arizona State University

Panel Three: Non-Governmental Perspectives

The potential enabling role that modern technology affords states, non-states, and individuals to conduct biological and chemical terrorism

- Peter J. Roman, Ph.D. – President, WIT Consulting LLC
- W. Seth Carus, Ph.D. – Distinguished Research Fellow, National Defense University
- Keith H. Wells, Ph.D. – Senior Consultant, BioProcess Technology Consultants

MEETING 2: PREVENTION AND PROTECTION JANUARY 14, 2015

Panel One: Biological Arms Control, Cooperative Threat Reduction, the Global Health Security Agenda, and Quarantine

International challenges and opportunities in reducing the risk from biological threats

- Daniel M. Gerstein, Ph.D., M.S.N.S.S., M.M.A.S., M.S.O.R. – RAND Corporation
- David R. Franz D.V.M., Ph.D. – Former Commander, United States Army Medical Research Institute of Infectious Disease
- Elizabeth E. Cameron, Ph.D. – Director, Countering Biological Threats, National Security Council staff
- Michael A. Stoto, Ph.D. – Professor of Health Systems Administration and Population Health, Georgetown University

Lunch Keynote

First responder protection

- William F. Raub, Ph.D. – Public Health Consultant

Panel Two: Biosecurity, the Select Agent Program, and Synthetic Biology

Understanding the challenges of laboratory research in the context of modern threats, regulatory regimes, and new technologies

- Timothy Lu, M.D. Ph.D. – Associate Professor, Massachusetts Institute of Technology
- Thomas G. Ksiazek, D.V.M., Ph.D. – Professor, Department of Pathology, University of Texas Medical Branch

Panel Three: Resilience, Biodeterrence, First Responder Vaccination, and Agricultural Defense

Means of creating a society resilient to biological threats through deterrence, public health and animal health measures, and protections for first responders

- Jeffrey Levi, Ph.D. – Executive Director, Trust for America's Health
- Bruce E. Miller, O.E., M.S. – Assistant to the Vice President for Homeland Security, Office of the Vice President (2001-2009)
- Sgt. Mark R. Landahl, Ph.D. – Supervisor, Frederick County (MD) Sheriff's Office
- Curt J. Mann, D.V.M. – Principal, Empryse Group

Panel Four: Insights on Ebola and Pandemic Influenza Response

Real-world outbreaks and the ways in which they have demonstrated U.S. strengths and weaknesses, particularly with respect to medical countermeasures

- Robin Robinson, Ph.D. – Director, HHS/Biomedical Advanced Research and Development Authority (BARDA)
- Monique K. Mansoura, Ph.D., M.B.A. – Head, Medical Countermeasures & Government Affairs, Americas, Novartis Influenza Vaccines
- Daniel Lucey, M.D., M.P.H. – Adjunct Professor Georgetown University Medical and Law Centers, & School of Foreign Service

MEETING 3: SURVEILLANCE AND DETECTION MARCH 12, 2015

Congressional Perspective

- The Honorable Sheldon Whitehouse – United States Senator, Rhode Island

Panel One: The Biosurveillance and Detection Landscape

Key elements of effective biosurveillance and detection, and continued challenges in the effectiveness of ongoing efforts

- Julie Louise Gerberding, M.D., M.P.H. – Executive Vice President, Strategic Communications, Global Public Policy, & Population Health, Merck & Co., Inc.
- Julie E. Fischer, Ph.D. – Associate Research Professor of Health Management and Policy, The Milken Institute School of Public Health, The George Washington University
- Norman M. Kahn – Former Director, Intelligence Community Counter-Biological Weapons Program

Panel Two: Environmental Surveillance and Detection

Technological and policy challenges to early and reliable detection of environmentally dispersed biological and chemical agents

- The Honorable Jeffrey Runge, M.D. – Former Assistant Secretary for Health Affairs and Chief Medical Officer, U.S. Department of Homeland Security
- Denise Pettit, Ph.D. – Assistant Director, North Carolina State Laboratory of Public Health
- Eric Joseph Van Gieson, Ph.D. – Senior Director, Diagnostics and Biosurveillance Innovation, MRIGlobal

Lunch Keynote

The human-animal interface

- William B. Karesh, D.V.M. – Executive Vice President for Health and Policy, EcoHealth Alliance

Panel Three: Clinical Surveillance and Detection

Key elements of an effective clinical surveillance and detection architecture, and impediments and opportunities to increase situational awareness for early and accurate disease detection and clinical diagnosis

- Dan Didier, M.D., Ph.D. – Head of Public Health, Thermo Fisher Scientific
- Daniel P. Desmond – Founder, The SIMI Group, Inc.
- Deborah G. Rosenblum, M.A. – Executive Vice President, The Nuclear Threat Initiative
- Robert W. VanDine – Chief Government Affairs, RPS Diagnostics, Inc.

Panel Four: Law Enforcement, Attribution, and the Lone Wolf

Law enforcement activities, attribution of deliberate acts, and the problem of the lone wolf

- Randall S. Murch, Ph.D., M.S. – Professor in Practice, School of Public and International Affairs, Virginia Polytechnic Institute and State University (Virginia Tech)
- Yonah Alexander, Ph.D. M.A.– Professor and Director, Inter-University Center for Terrorism Studies
- Edward H. You, M.S. – Supervisory Special Agent, Biological Countermeasures Unit, Weapons of Mass Destruction Directorate, Federal Bureau of Investigation

Panel Five: Read-outs from Study Panel Satellite Meetings

Presentation of findings and recommendations from satellite meetings held in support of the Study Panel

- Elizabeth G. Posillico, Ph.D. – President & CEO, Elusys Therapeutics, Inc.
- Gerald W. Parker, D.V.M., Ph.D., M.S. – Vice President for Public Health Preparedness and Response, Texas A&M University Health Science Center
- Beth Maldin Morgenthau, M.P.H. – Assistant Commissioner, Office of Emergency Preparedness and Response, NYC Department of Health and Mental Hygiene
- Timothy Stephens, M.A. – CEO, MESH Coalition

MEETING 4: RESPONSE AND RECOVERY APRIL 1, 2015

Congressional Perspective

- The Honorable Mike Rogers – Former Chairman, House Permanent Select Committee on Intelligence (2011-2015), and Distinguished Fellow, Hudson Institute

Panel One: Pre-event Activities and Emergency Response

Pre-event and post-event planning, including the challenges faced by first responders and hospitals, and the role of DOD and other federal agencies

- Chief G. Keith Bryant – President and Chairman of the Board, International Association of Fire Chiefs
- Matthew Minson, M.D. – Senior Advisor for Health Affairs, Texas Engineering Extension Service, Texas A&M University
- Carter Mecher, M.D. – Senior Medical Advisor, Office of Public Health, Department of Veterans Affairs

Panel Two: Public Health Response

Challenges of real-time epidemiology and other tools for characterizing the spread of disease or a large-scale chemical event throughout United States and elsewhere

- James Terbush, M.D., M.P.H. – Senior Partner, Martin, Blanck and Associates
- Suzet M. McKinney, Dr.P.H., M.P.H. – Deputy Commissioner, Bureau of Public Health Preparedness and Emergency Response, Chicago Department of Public Health
- Melissa S. Hersh, M.A. – Principal, Hersh Consulting, LLC

Lunch Keynote

Thinking about readiness at scale, and with imagination

- Irwin Redlener, M.D. – Director, National Center for Disaster Preparedness, Columbia University

Panel Three: Pharmaceutical Response

Response requirements for medical countermeasures, including the need for extremely rapid development, distribution, and dispensing

- Anne S. De Groot, M.D. – EpiVax, Inc. CEO/CSO
- Daniel J. Abdun-Nabi, J.D. – President & Chief Executive Officer, Emergent BioSolutions Inc.
- Michael W. Chervenic, M.B.A. – Managing Director, Stokes Evans
- Jude M. Plessas – Executive Manager, Countermeasures Delivery and Distribution, United States Postal Service

Panel Four: Recovery and Mitigation

Recovery and mitigation, including the challenges posed by cutting edge technology, lack of agreement regarding agency responsibilities, resilience, and implications for future preparedness

- Kavita M. Berger, Ph.D. – Scientist, Gryphon Scientific
- Michael J. Hopmeier, M.S.M.E. – President, Unconventional Concepts, Inc.
- Kenneth W. Staley, M.D., M.P.A. – Former Director for Biodefense Policy, Homeland Security Council

Panel Five: Leadership

The unique challenges and opportunities for leaders in biodefense, and the need to expand the ranks

- RADM Kenneth Bernard, M.D., D.T.M&H, USPHS (Ret.) – Adviser on Security and Health, Former Special Assistant to the President for Biodefense
- Lisa E. Gordon-Hagerty, M.P.H. – President, Tier Tech International, Inc.
- Colonel Robert Kadlec, M.D., USAF (Ret.) – Former Special Assistant to the President and Senior Director for Biodefense Policy, Homeland Security Council

APPENDIX D: ACRONYMS

API	active pharmaceutical ingredients
APHIS	Animal and Plant Health Inspection Service
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
BWC	Biological and Toxin Weapons Convention
CBRN	chemical, biological, radiological, and/or nuclear
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
DASD	Deputy Assistant Secretary of Defense
DHS	U.S. Department of Homeland Security
DNI	Director of National Intelligence
DOD	U.S. Department of Defense
DOI	U.S. Department of the Interior
DOL	U.S. Department of Labor
DOS	U.S. Department of State
EPA	U.S. Environmental Protection Agency
EUA	Emergency Use Authorization
FBI	Federal Bureau of Investigation
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
GAO	Government Accountability Office
GHSA	Global Health Security Agenda
GPRA	Government Performance and Results Act
HSPD	Homeland Security Presidential Directive
HHS	U.S Department of Health and Human Services
HIV	human immunodeficiency virus
HPP	Hospital Preparedness Program
HSC	Homeland Security Council
IC	Intelligence Community
ICE	Immigration and Customs Enforcement
IND	investigational new drug
IOM	Institute of Medicine
ISAC	Information Sharing and Analysis Center
ISIL	Islamic State of Iraq and the Levant (also known as Da'esh)
JCAT	Joint Counterterrorism Assessment Team
MCM	medical countermeasure(s)
MTD	Material Threat Determination
NAHLN	National Animal Health Laboratory Network
NBIS	National Biosurveillance Integration System
NBFAC	National Bioforensics Analysis Center
NCA	National Command Authority
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIM	National Intelligence Manager
NSABB	National Science Advisory Board for Biosecurity
NSC	National Security Council
NSDM	National Security Decision Memorandum
OHA	Office of Health Affairs
OIE	World Organization for Animal Health
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
OTA	other transaction authority
PAHPA	Pandemic and All-Hazards Preparedness Act
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP	Public Health Emergency Preparedness program
POD	point of dispensing
PREP	Public Readiness and Emergency Preparedness
PPE	personal protective equipment
PPP	public-private partnership(s)
R&D	research and development
S&T	Science and Technology
SAP	Select Agent Program
SNS	Strategic National Stockpile
SRF	Special Reserve Fund
WHO	World Health Organization
WMD	weapon(s) of mass destruction
USDA	U.S. Department of Agriculture
USPS	U.S. Postal Service
VA	U.S. Department of Veterans Affairs

APPENDIX E: FINANCIAL SPONSORS

The Panel received financial support from many organizations. Each of these contributors enthusiastically provided the funding needed to promote the efforts of the Panel. Without their substantial support, the Panel and its report would not have been possible. For this and for their commitment to biodefense, we thank them.

- Bavarian Nordic
- Biotechnology Industry Organization (BIO)
- Dalrymple & Associates, LLC
- Elusys Therapeutics, Inc.
- Emergency Services Coalition for Medical Preparedness
- Emergent BioSolutions Inc.
- HWC (formerly Hassett Willis and Company)
- Luminex Corporation
- MESH Coalition
- The Nuclear Threat Initiative (NTI)
- Open Philanthropy Project
- PharmAthene, Inc.
- REGENXBIO Inc.
- SIGA Technologies, Inc.
- Smith Richardson Foundation, Inc.
- Texas A&M University

ACKNOWLEDGMENTS

The Blue Ribbon Study Panel on Biodefense exists because of the foresight, forbearance, and perpetual optimism of Dr. Robert Kadlec. Bob understood that as much progress as had been made in the national effort to prevent and prepare for biological threats, it is not yet enough. He knew that with the right impetus, we could do much more, and he envisioned this Panel as a means to that end. We are glad he did.

Two institutions quickly stepped up to host the initiative: Hudson Institute provided an excellent venue for the Panel's public meetings, deep subject matter expertise, and an administrative home base that allowed the day-to-day activities of the Panel to proceed efficiently; and the Inter-University Center for Terrorism Studies at the Potomac Institute for Policy Studies offered their space, financial resources, and profound expertise in the roots of terrorism to lend further credential to the initiative. The Panel and its report came to fruition because of the willingness of these organizations to support this endeavor.

We thank our financial sponsors for the outstanding support they provided to make this initiative a reality. They are listed in Appendix E.

The many speakers who graciously and enthusiastically accepted invitations to address the Panel are listed in Appendix C. Their contributions were invaluable. Their perspectives (based on years in public service, the field, and elsewhere) helped the Panel identify areas in which efforts were lagging and informed the Panel's recommendations for action. Enthusiastic Capitol Hill staff juggled their Members' schedules to ensure that congressional input was received. Many Hill staff also encouraged us to establish the Panel from the very beginning, came to its public sessions, facilitated informal meetings with their bosses, and worked with the Panel in hopes that its final product would be received by a Congress willing to act upon it. Similarly, many individuals in the Executive Branch were supportive of the Panel's activities and helped inform our findings and recommendations. We thank them for their dedication to this cause.

Several organizations hosted workshops to delve deeply into specific issue areas. Representatives presented their findings to the Panel and contributed substantially to the report. These organizations were the Alliance for Biosecurity, MESH Coalition, the New York City Department of Health and Mental Hygiene, and the Texas A&M University Health Science Center.

Many other individuals and organizations unable to participate in the public meetings also provided information to the Panel for consideration. Ms. Megan Reeve Snair and many others reviewed and provided feedback on the draft report. Input from subject matter experts and stakeholders helped shape the report in many ways. There are far too many contributors to name, but we thank them all for their exceptional commitment to biodefense.

ENDNOTES

1 Franz, D.R., Parrott, C.D., & Takafuji, E.T. (1997). The U.S. Biological Warfare and Biological Defense Programs. In F.R. Sidell, E.T., Takafuji, & Franz, D.R. (Eds.), Medical Aspects of Chemical and Biological Warfare (p. 426). Washington, DC: Office of the Surgeon General of TMM Publications.

2 From 1943 to 1969, the United States learned how to weaponize, distribute, combine, manipulate, and counteract many biological agents (e.g., Bacillus anthracis, Clostridium botulinum, Coxiella burnetii, Francisella tularensis, Germiston virus, Puccinia graminis, Sendai virus, Staphylococcal Enterotoxin B, Venezuelan equine encephalitis virus, and Yersinia pestis), as well as anti-materiel organisms.

3 Schram, M. (2003). Russian Bio-Shock: Soviet Secrets Dumbfound U.S. Intelligence. In Avoiding Armageddon: Our Future, Our Choice: Companion to the PBS series from Ted Turner Documentaries (pp. 186-196). New York, NY: Basic Books.

4 Miller, J., Engelberg, S., & Broad, W. (2001). Germs: Biological Weapons and America's Secret Wars (p. 150). New York, NY: Simon & Schuster.

5 Inter-University Center for Terrorism Studies. (2014). Reassessing the WMD Challenges: The Next Phase. Washington, DC: Potomac Institute for Policy Studies.

6 Discussions of the threat in this report have been informed not only by experts who presented to the Study Panel, but also by classified and unclassified intelligence information. No classified information is discussed. Unclassified information that may have otherwise been useful to the discussion was not actually included if doing so would result in classified statements, particularly regarding the activities of the Intelligence Community. Discussions of the threat and of intelligence actions related to it are, therefore, necessarily high level and not highly specific.

7 U.S. Department of State. (2015). Adherence to and Compliance with Arms Control, Nonproliferation, Disarmament Agreements and Commitments. Retrieved from http://www.state.gov/t/avc/rls/rpt/2015/243224.htm

8 For example, an estimated 100-200 tons of weaponized anthrax were buried by Russia on Vozrozhdeniye Island in the Aral Sea in 1988, incompletely destroyed, and never properly secured after the island came under the control of Kazakhstan and Uzbekistan. Even if only 50 tons of the weaponized anthrax on Vozrozhdeniye Island remains, this one source of anthrax unaccounted for is 45 million times larger than the 5 grams used in the U.S. anthrax attacks of 2001. Pala, C. (2003, March 22). Anthrax Buried for Good. The Washington Times.

9 The smuggling of biological agents and weapons from poorly secured, previously established stockpiles – such as areas where the Soviets buried anthrax – is of concern, particularly through those countries surrounding the Middle East. Nations containing smuggling routes; inadequate border control systems, export laws, and export controls; and groups or individuals that could help to smuggle biological agents and weapons are all at risk, including the United States.

10 Advances in and diffusion of biological expertise, technology, and information have accelerated and led to the democratization of the capabilities and capacity necessary to produce biological agents and weapons throughout the world.

11 Advanced science and technology are necessary for the production of biological weapons, as are laboratories, physical space in which to conduct necessary experimentation and production, personnel trained in laboratory science, and military and other planners who know how best to utilize such weapons.

12 Resources and intent alone do not result in the immediate capability to produce biological agents or weapons. See Vogel, K.M. (2008). Framing Biosecurity: An Alternative to the Biotech Revolution Model? Sci Pub Pol, 35(1):45–54.

13 Rogers, M. (Speaker). (2015, April 1). Meeting 4 of the Blue Ribbon Study Panel on Biodefense: Response and Recovery.

14 Alexander, Y., & Swetnam, M. (2012). Al-Qa'ida: Ten Years After 9/11 and Beyond. Arlington, VA: Potomac Institute for Policy Studies.

15 Nothing prevents U.S. citizens who are bioscience professionals from joining domestic militia groups, although U.S. laws do prohibit these professionals from removing biological agents from laboratories and developing biological weapons in the United States. U.S. domestic militia members have produced ricin and sarin on a larger scale than they had previously, demonstrating increasing capabilities. Valla, E.J. & Comcowich, G. (2008). Domestic Terrorism: Forgotten but Not Gone. In J.H. Norwitz (Ed.), Armed Groups: Studies in National Security, Counterterrorism, and Counterinsurgency (p. 176). Washington, DC: U.S. Government Printing Office.

16 Lone wolves are individuals who do not operate within the organizational constructs offered by militias, domestic violent extremist groups, or terrorist groups. Lone wolves are more difficult to track than domestic militia groups. As with members of ISIL, lone wolves have left social mores behind. A lone wolf who obtains biological agents or weapons should be expected to use them with little hesitation. Additionally, U.S. citizens who sympathize with ISIL and likeminded groups may present an equal or even greater danger than terrorist groups.

17 Kuntz, C. (2012). Biodefense: When Technology Goes Global. Washington, DC: Center for Strategic and International Studies.

18 Potomac Institute for Policy Studies. (1991). Conference on Countering Biological Terrorism: Strategic Firepower in the Hands of Many? Arlington, VA: Potomac Institute for Policy Studies.

19 For example, the influenza season takes an estimated 3,000-49,000 U.S. lives annually. Thompson, M.G., Shay D.K., Zhou, H., Bridges, C.B., Cheng, P.Y., et al. (2010). Updated Estimates of Mortality Associated with Seasonal Influenza through the 2006-2007 Influenza Season. MMWR, 59(33), 1057-1062.

20 Extremely drug resistant tuberculosis is just one example of a reemerging disease that we had hoped to eradicate, but which is evading the medicines currently at our disposal. Our inability to prevent the misuse of antimicrobials, combined with the ability of organisms to mutate and outpace development of new countermeasures, means that diseases we thought we had conquered remain with us. Organisms can also be intentionally manipulated to worsen their effects. Intentionally over-using antimicrobials to produce drug-resistant diseases, purposely convincing people to avoid vaccination, and deliberately spreading infectious diseases will weaken any population, making them easier to control and defeat.

21 Anthrax was accidentally released in 1953 and 1979 from laboratories in Russia when a maintenance worker neglected to replace an air filter.

22 Chappell, B. (2015, May 28). Live Anthrax Was Mistakenly Sent to 9 States and a U.S. Military Base. The Two-Way: Breaking News from NPR. Retrieved from http://www.npr.org/sections/thetwo-way/2015/05/28/410220914/live-anthrax-was-mistakenly-sent-to-9-states-and-a-u-s-military-base

23 Centers for Disease Control and Prevention (2015, March 13). Conclusion of Select Agent Inquiry into Burkholderia pseudomallei Release at Tulane National Primate Research Center [Press release]. Retrieved from http://www.cdc.gov/media/releases/2015/s0313-burkholderia-pseudomallei.html

24 Biosecurity builds on biosafety rules and procedures, adding other requirements to ensure that those disease agents that could be used to produce biological weapons are properly secured.

25 Centers for Disease Control and Prevention. (2014, July 8). CDC Media Statement on Newly Discovered Smallpox Specimens [Press release]. Retrieved from: http://www.cdc.gov/media/releases/2014/s0708-NIH.html

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27 The United States Commission on National Security/21st Century. (1999). New World Coming: American Security in the 21st Century, Major Themes and Implications, Report on the Emerging Global Security Environment for the First Quarter of the 21st Century (p. 63). Washington, DC: U.S. Department of Defense.

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33 The National Performance Review was a task force on government performance.

34 The National Strategy for Biosurveillance is an example.

35 Determinations of the number of departments and agencies that contribute to biodefense depend on how biodefense is defined. See: Sell, T. K., & Watson, M. (2013). Federal Agency Biodefense Funding, FY2013-FY2014. Biosecur Bioterror, 11(3), 196–216, which describes nine departments and agencies based on an analysis of budget documents. See also H.R. 2356, Sec. 104, 112th Congress, which called for the inclusion of 12 departments and agencies in a biodefense budget analysis.

36 Larsen, R., Boddie, C., Watson, M., Gronvall, G.K., Toner, E., et. al. (2015). Jump Start (pp. 56-7). Baltimore, MD: University of Pittsburgh Medical Center, Center for Health Security.

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38 In addition to the Biological Incident Annex of the National Response Plan, other annexes related to the response to biological incidents are the Public Health and Medical Services Annex, Oil and Hazardous Materials Response Annex, and Agriculture and Natural Resources Annex.

39 The behavior of weaponized pathogens differs from naturally occurring biological agents in terms of incubation rates, disease severity, and other characteristics.

40 Many of these are discussed in: Polin, D. (2009, May 15). A U.S. Biodefense Strategy Primer. LLNL-TR-413042. Livermore, CA: Lawrence Livermore National Laboratory.

41 For example, the Office of Science and Technology Policy can work through each document to identify gaps in capabilities that could be mitigated by innovations in science and technology.

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43 For proposed elements of the cross-cut, see H.R. 2356, Sec. 104, 112th Congress.

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59 An advisory panel to the CDC recognized this gap in 2011, when it reported that the White House must provide robust policy oversight and coordination, to include the establishment of goals and priorities for biosurveillance. The Panel also found that the government must invest in new biosurveillance technologies. See National Biosurveillance Advisory Subcommittee. (2011, April). Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: Second Report of the National Biosurveillance Advisory Subcommittee.Atlanta, GA: Centers for Disease Control and Prevention.

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81 For proposed language, see H.R. 3299, Sec. 2, 114th Congress.

82 For proposed language, see H.R. 3299, Sec. 3, 114th Congress.

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98 U.S. Department of State. (2015). Adherence to and Compliance with Arms Control, Nonproliferation, Disarmament Agreements and Commitments. Washington, DC: U.S. Department of State.

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100 The Biological Weapons Anti-terrorism Act of 1989, P.L. 101-298, 18 U.S.C. chapter 10 § 175 et seq. (2006).

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108 Section 401(c)(2)(d) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417, 5, 6, 10, 15, 18, 21, 31, 38, 41, 42, and 50 U.S.C.

109 H.R. 6, Sec. 1002, 114th Congress.

110 As of the publication of this report, DHS has made 13 chemical, biological, radiological, and nuclear Material Threat Determinations.

111 Tufts Center for the Study of Drug Development. (2014, November 18). Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion. Retrieved from: http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study

112 The Department of Homeland Security Appropriations Act of 2004, P.L. 108-90.

113 Unlike WMD threats, pandemic flu is singled out as a separate appropriations stream but not authorized.

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115 The Other Transactional Authority (OTA) can offer increased flexibility and be less onerous than traditional Federal Acquisitions Regulations contracting, making it particularly appealing to companies that do not have experience with more typical government contracting requirements.

116 For proposed language, see H.R. 3299, Sec. 6, 114th Congress.

117 For proposed language, see H.R. 3299, Sec. 5, 114th Congress.

118 Title III of the Homeland Security Act of 2002, P.L. 107-296, 6 U.S.C. §195b (2006).

119 The Public Health Security and Bioterrorism Preparedness Act of 2002, P.L. 107-188, 42 U.S.C., defined and authorized the regulation of select agents and toxins.

120 For example, laboratory personnel currently spend many hours engaged in the bureaucratically tedious process of inventory control of select agent pathogens, but this has little security meaning when applied to biological organisms. While it is important to know that a laboratory stores a particular pathogen, it is of little meaning to know that the laboratory stores either two tubes or three of a replicating biological organism.

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122 Impact of the Select Agent Regulations; A Notice by the Science and Technology Policy Office, FR Doc. 2015-05906 (March 16, 2015).

123 This assessment should address research investment, governance policies, and the challenge of conducting biodefense research in a continuously changing regulatory environment. It should also assess other problematic areas, including the process for adding and removing pathogens from the list, lack of pathways for appeal of SAP decisions, and the destruction of samples for security reasons.

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THE FEDERAL INTERAGENCY RESPONSE TO THE CORONAVIRUS AND PREPARING FOR FUTURE GLOBAL PANDEMICS

THURSDAY, MARCH 5, 2020

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 9:32 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Ron Johnson, Chairman of the Committee, presiding.

Present: Senators Johnson, Romney, Scott, Hawley, Peters, Carper, Hassan, Harris, Sinema, and Rosen.

OPENING STATEMENT OF CHAIRMAN JOHNSON

Chairman JOHNSON. Good morning. This hearing will come to order.

I want to thank the witnesses first and foremost for your efforts as they are related to the current—I guess we have to call it a "pandemic" at this point in time, right?—with coronavirus disease 2019 (COVID–19). I do think it is important we put everything in perspective, and I would ask my Committee Members to include my written statement in the record.[1]

I think we oftentimes fail to recognize and put this in proper perspective, so let me just rattle off a couple figures here.

Ebola, total cases worldwide ended up being less than 29,000. I remember in the midst of that crisis we were talking about this thing spreading and it could be a million people, which obviously would have been a huge problem because Ebola had a mortality rate of 40 percent. But in the end, because of really effective action on the part of the World Health Organization (WHO) and the Obama Administration, we surged resources in there, and we prevented that from spreading. So less than 29,000 people actually contracted that; about 11,000 people died.

Now, we have had other outbreaks of Ebola, but we are getting better at it. We have developed, I think, some relatively effective vaccines that certainly helped protect our health workers, and we will talk a little bit about that. Mr. Cuccinelli in our Senate briefings pointed out that that is a finite resource.

The next deadliest virus that we have been dealing with is the 2012 Middle East Respiratory Syndrome (MERS) outbreak. Total

[1] The prepared statement of Senator Johnson appear in the Appendix on page 361.

cases were less than 2,500; 815 people died, so that was a mortality rate of 34 percent.

In 2003, we dealt with Severe Acute Respiratory Syndrome (SARS); 8,000 people affected, 774 people died, a mortality rate of 9.6 percent.

The average flu, the seasonal flu—and these numbers are a wide dispersion of what happens—9 million to 45 million people a year catch it; 140,000 to 810,000 people are hospitalized with it. Obviously, anybody with underlying health conditions and the elderly are most affected by it, and we will lose—there will be 12 to 60 some thousand fatalities per year with just seasonal flu.

Another virus that certainly reached pandemic levels that sure sounded scary was the H1N1 virus. The actual stats on that, about 60 million Americans caught H1N1. Worldwide, I think it was over 200 million. Worldwide, 150,000 to 575,000 people died from H1N1 globally. But the fatality rates were not that high. I mean, thousands died in the United States, but we have dealt with these things in the past.

So the current stats, as far as I have them, that we know about, 81,000 individuals have contracted and tested positive for COVID–19, close to 3,000 deaths. The latest mortality rate is about 3.4 percent, which is serious. The normal flu mortality is about 0.1 percent. So this is definitely more virulent, a higher mortality rate, but I would caution everybody in terms of that mortality rate. This is just deaths from people that we have tested, and we do not have the types of test kits or the numbers yet. We are developing them rapidly, thanks to, I think, reducing government regulatory burdens in terms of the testing. Again, we will talk a little bit about that. We definitely do want to clarify that situation. But my guess is the mortality rate, when all is said and done, once we actually do have a sense of how many people actually contract this, where they either do not display symptoms or they are very mild, particularly in younger people, I think that mortality rate, I would think, would probably come down. But, again, nobody knows. There is an awful lot about this disease that nobody knows.

So what I am hoping we can accomplish in today's hearing is talk about this administration's response—which, by the way, I think has been almost immediate. From what I have seen, my interaction, the accessibility of whether it is Acting Secretary Chad Wolf, Mr. Cuccinelli, members of the Centers for Disease Control (CDC), the National Institute of Health (NIH), I have had access to them. Now, I have not abused that access because I really want you working to mitigate this problem. But they have been very accessible. I do not know how many briefings I have already attended. I appreciate we have two individuals here. You may say, well, why don't we have everybody representing every agency? I want them to work. They have a job to do. I know there have been a lot of hearings, so you have been very accessible. I think you have taken a whole-of-government approach.

As I have said repeatedly, I certainly do not see the administration underresponding. In fact, you have taken unprecedented steps: travel bans, quarantines, I think—is this correct?—for the first time in 50 years?

Mr. CUCCINELLI. Over.

Chairman JOHNSON. Unprecedented steps. So we have not underreacted, but I think this administration is fully aware and cognizant of the costs of overreacting. So the basic fact of the matter is the chances of the administration getting it just right, reacting perfectly, is zero. It will not happen. But, again, from my own knowledge, my own interaction, what we have seen in terms of the interaction with the Senate and the House, this is an all-government approach; this is all hands on deck. This is not being ignored. You can just see, the $8 billion response as opposed to the $2.5 billion funding request. Funds are not going to be an issue. Congress will make sure that the administration has the funds.

In terms of priority of action, it is important that we are able to test so we know the extent of what the outbreak is. I really want to talk about the regulatory issues, just the basic science issues. I was talking to Dr. Kadlec in the front room. There is a reason they call it "medical practice." This does not just happen overnight. This is a whole new virus. It just became known to mankind, what, 3 months ago, Mr. Cuccinelli, you were saying?

Mr. CUCCINELLI. Less, less.

Chairman JOHNSON. So it takes time to develop the tests to make sure that the tests do not produce false positives. Then you have to manufacture them.

So I am heartened by what I am basically hearing. I will not tell the figures now. I want to hear about those, and we want to delve into those, so we know what we are really talking about in terms of what testing kits are available, how they are going to be distributed throughout the Nation, kind of what the priority is for that distribution, so we really do get a sense by being able to test as many individuals as doctors want to test, because right now it has been limited. There are a limited number of tests, so there is pretty high criteria to test any patient.

I want to talk about current travel restrictions. Obviously, this is the Homeland Security Committee. We want to talk about Customs and Border Protection (CBPs) role, the Transportation Security Administration (TSAs) role, how you are cooperating with CDC, what the screening measures are, what data we are collecting. Mr. Cuccinelli, we talked about that, and you reacted to our conversations reflecting more data so we can trace travelers that may have come in contact with people that are infected. So we want to talk about all those issues as it relates to the Department of Homeland Security (DHS).

Again, testing is a top priority, but then we also want to talk about the current issues with the supply chain, but also in the future. Once we have this all stabilized and we know where we are at—and hopefully this will prove to be somewhat seasonal, although there are indications it may not be. Once we have taken care of this and vaccines are developed and are accessible to the public, which will be quite some time in the future, we really do need to take a look at the Strategic National Stockpile (SNS). We need to take a look at the supply chains. We need to really ask ourselves in a manufacturing process that is not labor intensive, why are so many of these precursor chemicals for drugs produced in India, which is now, according to news reports, blocking export of some of these chemicals as well.

I see no reason for manufactured drugs approved by the Food and Drug Administration (FDA) for the United States use that those things should be manufactured overseas. I just do not. We have to learn from these types of situations and put in place either regulations or laws so that we are better prepared for the next pandemic, because there will be a next pandemic. I have just rattled off the ones we have already had to deal with.

So, again, I really want to thank the witnesses. I am hoping this is a really good discussion. I hope it is a clarifying discussion. This is about transparency, recognizing that you do not have all the answers because there are just things right now that are unknowable. But thank you again for your work in this. Thanks for appearing before our Committee.

With that, I will turn it over to our Ranking Member, Senator Peters.

OPENING STATEMENT OF SENATOR PETERS[1]

Senator PETERS. Thank you, Mr. Chairman. Thank you to our witnesses for being here today.

The top priority of this Committee and of your agencies, is quite simple: keep Americans safe. To be clear, this coronavirus outbreak in the United States is not currently widespread, but, nevertheless, it does pose a significant threat to our public health and our homeland security, and we have to take it seriously.

I am grateful for the efforts of your agencies and public health officials across the country to limit the spread of this contagious virus.

While we have seen growing numbers of cases in the United States, we have thankfully not yet seen widespread outbreak yet in this country.

It is the job of this administration to work with Congress and our State and local governments to do everything we can to limit the spread of this virus. It is clear to me that we should also prepare for a worst case scenario and widespread infections.

Assessing clear information about coronavirus has been a significant challenge for the public to date. The American people have a lot of questions. They want accurate, reliable information about the virus's spread and what the government is actually doing to protect their health and safety.

As we have learned from past epidemics and pandemics, outbreaks like this require an aggressive, coordinated, and comprehensive response as well as timely and trusted, useful guidance from public health officials as well as security officials.

In the coming weeks and months, your agencies will play a critical role in containing the outbreak, educating Americans about this virus, and protecting public health.

Whether your response is timely and effective will truly be a matter of life and death. With that in mind, I appreciate you joining us today. My constituents in Michigan and the American people want clear answers to some of the most pressing questions that they have right now.

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[1] The prepared statement of Senator Peters appear in the Appendix on page 363.

I look forward to hearing about what steps your departments are taking to ensure that we have the right plans and that you have adequate resources to actually execute those plans in order to stop the spread of this highly contagious disease.

Thank you again for taking time to be with us today.

Chairman JOHNSON. Thank you, Senator Peters.

It is the tradition of this Committee to swear in witnesses, so if you will both stand and raise your right hand. Do you swear that the testimony you will give before this Committee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. CUCCINELLI. I do.

Dr. KADLEC. I do.

Chairman JOHNSON. Please be seated.

Our first witness is Ken Cuccinelli. Mr. Cuccinelli is the senior official performing the duties of the Deputy Secretary at the U.S. Department of Homeland Security. Mr. Cuccinelli most recently served as the Acting Director of U.S. Citizenship and Immigration Services (USCIS). He previously served as the Attorney General (AG) for the Commonwealth of Virginia. Mr. Cuccinelli.

TESTIMONY OF THE HONORABLE KEN CUCCINELLI II,[1] SENIOR OFFICIAL PERFORMING THE DUTIES OF THE DEPUTY SECRETARY, U.S. DEPARTMENT OF HOMELAND SECURITY

Mr. CUCCINELLI. Chairman Johnson, Ranking Member Peters, and distinguished Members of the Committee, it is my honor to appear before you today to testify about the work of DHS and what we are doing to respond to the outbreak of Coronavirus Disease 19.

Let me first say I am very proud of the work that the men and women of DHS and our partners at the Department of Health and Human Services (HHS) and across the government are doing to contain the spread of the disease, slow the spread of the disease, and to prepare for a domestic response. The Department's top priority is the safety and security of the American people, and we are committed to an aggressive, proactive, and preemptive whole-of-government response in fulfilling that mission. As required by Congress, in 2018 President Trump signed the first ever "National Biodefense Strategy" to build upon our ability to rapidly respond to and limit the impacts of bioincidents like the one we are facing now. We are seeing that strategy pay dividends as we implement a whole-of-government response to this disease.

DHS is taking action at airports of entry to support HHS in slowing the spread of the novel coronavirus. DHS is working to decrease the workload of public health officials, expedite the processing of U.S. citizens returning from China, and, above all, ensure that resources are focused on the health and safety of the American people.

DHS, including Customs and Border Protection and the Transportation Security Administration, continues to work very closely with our partners at CDC to route all admissible persons who have been in Mainland China and Iran in the previous 14 days to one of 11 designated airports of entry where the Federal Government has focused public health resources.

[1] The prepared statement of Mr. Cuccinelli appear in the Appendix on page 364.

Any admissible person who has been in Hubei Province, China, in the previous 14 days is subject to up to 14 days of mandatory quarantine where CDC has made arrangements with State and local authorities to ensure they are provided proper medical care and health screening. Any admissible person who has been in the rest of Mainland China or Iran within the previous 14 days undergoes proactive entry health screening at one of the airports and, if they are asymptomatic, up to 14 days of self-monitoring to ensure they have not contracted the virus and do not pose a health threat.

DHS continues to facilitate enhanced health screening of travelers entering the United States who have recently been in China or Iran. Travelers identified by CBP officers during their primary inspection are then referred to Countering Weapons of Mass Destruction (CWMD) medical screeners. We have 500 of them, over 500 contracted, and about 95 on duty at any given time. For those that through medical screening are identified as particularly at risk, they are then referred to CDC personnel who are onsite and have made arrangements with local health authorities. This has involved over 53,000 air travelers to date.

We realize these actions could prolong travel times for some individuals; however, public health and security experts do agree these measures are necessary to contain the spread of the virus and protect the American people.

To minimize disruptions, CBP and the air carriers are working to identify qualifying passengers before their scheduled flights.

DHS CWMD is currently supporting the enhanced screening efforts through agreements with State, local, or private sector Emergency Medical Services (EMS), public health, and first responder personnel. That is where those 500 contractors come from.

CWMD established this capability in response to the Ebola virus threat that was emerging last summer, and these actions ensured a trained, vetted, and badged workforce was ready to rapidly deploy to support CDC with airport screening operations. DHS was able to adapt this capability to quickly address the COVID–19 threat.

CWMD is also providing direct support to CDC's effort to collect passenger information at all 11 airports, allowing CDC to provide direct information to public health officials to facilitate contact tracing efforts. CWMD's efforts have significantly increased the accuracy of the data collected.

CBP and the U.S. Coast Guard (USCG) continue their work to recognize, detect, and assist individuals arriving through our land ports and waterways who may be carrying the virus, all in coordination with CDC. The Coast Guard continues to review all Advance Notices of Arrival (ANOA). This is a notice they get 96 hours before any ship comes to an American port. It gives a full accounting of the medical status of everyone on the ship. The Captain of the Port will communicate any concerns stemming from sick or deceased crew or passengers to their Coast Guard chain of command and the cognizant CDC quarantine station, who will coordinate with local health authorities.

To ensure continued facilitation of international trade, non-passenger commercial vessels that have been in China or Iran or embarked crew members who have been in China or Iran within the

previous 14 days, with no sick crew members, may be permitted to enter U.S. waters and offload their cargo, reload, and depart the port.

My time is up. I will go ahead and stop with the opening statement that we submitted covering a lot of this territory, and I am happy to answer your questions.

Chairman JOHNSON. Thank you, Mr. Cuccinelli.

Our next witness is Dr. Robert Kadlec. Dr. Kadlec is the Assistant Secretary for Preparedness and Response (ASPR) for the U.S. Department of Health and Human Services. Prior to joining the Department in 2017, he served as Staff Director for the U.S. Senate Select Committee on Intelligence and as Special Assistant to President George W. Bush for Biodefense Policy. Dr. Kadlec served in the U.S. Air Force (USAF) for over 20 years and was named U.S. Air Force Flight Surgeon in the year 1986.

In a more expanded biography—I want to read a little bit more—Dr. Kadlec was instrumental in drafting the Pandemic and All-Hazard Preparedness Bill which was signed into law to improve the Nation's public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural. He served in the White House from 2002 to 2005 as the Director for Biodefense on the Homeland Security Council, where he was responsible for conducting the biodefense end-to-end assessment, which culminated in drafting the National Biodefense Policy for the 21st Century. He served as the Special Adviser for Counterproliferation Policy at the Office of the Secretary of Defense, where he assisted Department of Defense (DOD) efforts to counter chemical, biological, radiological, and nuclear (CBRN) threats in the wake of 9/11 and contributed to the Federal Bureau of Investigation (FBI) investigation of the anthrax letter attacks.

I felt it was important to point out just really how extensive your experience is in this and, as a result, what an appropriate witness you are for this particular hearing. Dr. Kadlec.

TESTIMONY OF THE HONORABLE ROBERT KADLEC, M.D.,[1] ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. KADLEC. Thank you, Mr. Chairman. I appreciate it very much. That is a very nice way of saying I am one-trick pony.

Chairman Johnson, Ranking Member Peters, and distinguished Members of this Committee, thank you for the opportunity to testify before you today on how HHS is supporting the whole of HHS and U.S. Government response to the 2019 coronavirus outbreak.

This morning, I just want to take a few minutes to discuss how we are addressing this issue from a point of strategic anticipation. Working with my colleagues at CDC, FDA, the Centers for Medicare and Medicaid Services (CMS), and NIH across the U.S. Government supporting State and local authorities, we are working hard to contain and mitigate this virus outbreak to save lives and protect Americans.

ASPR has a four-pronged approach to manage and support domestic response. This includes medical countermeasure develop-

[1] The prepared statement of Mr. Kadlec appear in the Appendix on page 370.

ment, supporting the health care system, incident management, and direct support to State and local entities.

In the area of medical countermeasure development, we are rapidly establishing an Interdepartmental Medical Countermeasure Task Force that includes partners across HHS, Department of Defense, and other Federal agencies and the private sector to identify therapeutics, diagnostics, and vaccines that could be rapidly brought through the pipeline to address the coronavirus threat. Specifically, we are looking at point-of-care diagnostics to aid public health in rapid detection and guide treatment. We are also identifying potential therapeutics to aid and support the treatment of infected persons. Last, we are also working very closely with NIH concerning multiple potential vaccine candidates. Combined, all of our efforts are pushing platforms and candidates forward as fast as possible to aid the overall response.

Turning to how do we support the public health system through ASPR's Hospital Preparedness Program and in coordination with CDC's Public Health Emergency Preparedness Program (PHEP), we have improved coordination and collaboration between hospitals in the public health sector and other entities like Emergency Medical Services. We have also leveraged the National Ebola Treatment Network, which was an idea that was created by Congress and established as a response to the 2014 Ebola outbreak, to support the treatment of repatriated persons. As the health care system prepares for possible spread of the coronavirus, this network has and will continue to link technical experts with quarantine and isolation experience to aid transport and treatment efforts at the State and local level.

Shifting to our overall response structure, since repatriation efforts began, we have been working with the Federal Emergency Management Agency (FEMA), to put in place an active incident management network that is based on the National Response Framework (NRF). This is the first time we have formally implemented this structure. Though we had practiced activating this such structure during previous exercises, we are doing it for real now, and it means that we can leverage the capacities of FEMA and all the emergency support functions that may be necessary to deploy responders to assist States and local authorities in responding to the coronavirus outbreak if and when asked.

I want to end with just a few brief updates how we are providing direct support to State and local entities.

First, I mentioned our repatriation efforts early in my statement where we successfully brought back approximately 1,100 Americans from Wuhan and from the Diamond Princess cruise ship under very difficult circumstances. Currently there are no additional planned repatriation efforts at this time, but should the need be raised, we are standing ready to support the State Department or any other authority. We have shifted our efforts now to provide direct support and aid to States. In the State of Washington, we have used the Strategic National Stockpile to deploy personal protective equipment (PPE) to protect health care workers, and a second shipment is arriving today to augment what we have already sent earlier this week. We are also planning to send 28 of our Commission Corps Public Health Service officers and our National Dis-

aster Medical System (NDMS) team members to support them as well.

We are concerned about health care entities like long-term and elder-care facilities where we know the most vulnerable populations reside and are working proactively with CMS and with CDC to provide information on best practices and, when possible, help them shield our elder populations from the impact of the coronavirus.

With that, I would be happy to yield the rest of my time and be happy to answer any questions you may have. Thank you, sir.

Chairman JOHNSON. Thank you, Dr. Kadlec.

I do want to ask some questions. Normally I yield and ask later, but I just want to get some clarity on a few things because I know this has been confusing. Let us talk about the test kits.

My understanding is that 2,500 test kits will be distributed they say the end of this week, which is like tomorrow. Each test kit can perform 500 tests. So if you do the numbers on that, that is 1.25 million individual tests. Senator Hassan was remarking yesterday that each patient really, to be sure, should be tested twice, so that is about 600,000 Americans.

Is that an accurate assessment? Or where are we at in terms of——

Dr. KADLEC. Yes, sir.

Chairman JOHNSON [continuing]. Tests, because this is—so who is manufacturing this? Is it a private sector manufacturer?

Dr. KADLEC. Sir, CDC started initially manufacturing some of these test kits, and within a week or 10 days of when the sequence of the virus was posted by the Chinese, began to work on a polymerase chain reaction test, which is really a genetic test, to look for the presence of ribonucleic acid (RNA) from this virus. They were able to basically do a proof of concept and develop a prototype and then began to produce that there at CDC and then have shifted it to a commercial manufacturer called Integrated DNA Technologies (IDT). They are the individuals that basically are making the 2,500 test kits, which include 500 tests per kit, to your point of 1.2 million tests.

Chairman JOHNSON. Those will be going out to how many different centers?

Dr. KADLEC. They will be going out to 190 places around the country, but, quite frankly, the CDC has already distributed 75,000 tests already, of their tests, if you will. The intent of the Secretary and the Vice President is really to maximize the number of tests that can be performed.

Now, to just kind of put some reasonable expectations behind this, these are test kits that are going to be sent out to labs around the country. They are going to have to basically validate these labs for their test procedures and train their personnel. So they will not become immediately available, but they will become increasingly available over the next week or two to basically test Americans, which is another part of this critical function, which is there have been several things to do to basically enhance our testing posture. One is make more test kits, distribute them, train the people who need to do that, but also ensure that they are validated. But there have also been things that have been done to increase the use of

these tests by indicating that people who fit the case definition for possible coronavirus can be relaxed so we can test more people, and that has significantly enhanced the ability of doctors and first-line primary care physicians and nurses to judge when their patients should get tested if they suspect coronavirus.

So there are a lot of things that are in play here, regulatory, definitional, as well as manufacturing and distribution.

Chairman JOHNSON. So, obviously, I think there is oftentimes unrealistic expectations. It is a new virus. We just found out about this literally 3 months ago. It takes time to first develop the test. It takes time to validate it in the CDC, because you do not want false positives.

Dr. KADLEC. With the FDA.

Chairman JOHNSON. Then it takes time to manufacture the first test kits. Then it takes time in the labs to validate the labs so the personnel—they need to be trained. But you are thinking within a couple of weeks there will be a capability for testing, about 1.25 million tests, and then my guess is that manufacturing can ramp up pretty quick.

Dr. KADLEC. Yes, sir. In fact, I think there is the expectation for this particular company to expand their manufacturing, and there is also a parallel effort that is being done by the Biomedical Advanced Research and Development Authority (BARDA) to basically engage commercial laboratory testers—the Quests, the LabCorps—to basically introduce the test in their systems so that would proliferate it across the domain.

I think the thing is where there has been maybe a lack of test kits, there will be plenty of opportunity for testing. I think the key thing and what we are focusing on is being able to do point-of-care diagnostics to support physicians on the front line in their offices and to basically test people in their offices to decide whether or not someone has coronavirus. What will happen at this point is it is going to be hospital-based, public health laboratory-based, and then commercial laboratory-based, and we are trying to push it out as far and as far as we can. It will take us some time, but we are on the way.

Chairman JOHNSON. Again, as a former manufacturer, I realize this takes time. You wish it would not, but it does take a little bit of time. I think this has actually been proceeding pretty rapidly. But everybody recognizes how incredibly important this is because we really cannot get a game plan until we really know the extent of the problem.

Let us just quickly talk about the vaccine time because, again, I want to have people's expectations be reasonable. It sounds like we are developing a vaccine at pretty much a rapid pace. So it will go into Phase 1, which is just the safety, make sure the vaccine is safe, when, approximately?

Dr. KADLEC. So I think Dr. Fauci is the best in the world in this, and he basically believes it can be done in a couple of months. Even then after that is done, there will be a period of time to evaluate the safety data and then enter into the next phase.

Chairman JOHNSON. OK. So, again, let us talk about the approximate period of time. Nobody is going to hold you to this, but I want

to create the expectation. So a couple months to develop one. Then we are going to have to validate the safety.

Dr. KADLEC. Right, a Phase 1 study.

Chairman JOHNSON. Validate that. That will take?

Dr. KADLEC. Another couple months.

Chairman JOHNSON. OK. So now we are at 4 or 5 months out.

Dr. KADLEC. Then Phase 2.

Chairman JOHNSON. Then is it effective?

Dr. KADLEC. That is the Phase 2 study that will actually look at that.

Chairman JOHNSON. That will take how many months?

Dr. KADLEC. Another 6 months.

Chairman JOHNSON. A year before we really have a vaccine that we think is safe and that will be effective. Then you have to manufacture it, right?

Dr. KADLEC. I think the reasonable expectation is between a year and 18 months, honestly. I think Dr. Fauci has said up to a year and a half, again, to moderate expectation.

Chairman JOHNSON. So let us say everything goes swimmingly well, and after a year we actually have a vaccine that we know is safe and effective. But you are not going to be able to mass produce that yet. But will you be able to produce enough to provide to our first-line responders, to doctors, to nurses? I would think that would be—you would prioritize who is going to have access to this before the general population.

Dr. KADLEC. Yes, sir. That is an area that, quite frankly, is I think recognized in the supplemental, the generous funding that you all provided. Our domestic manufacturing for a vaccine for this particular virus is limited. Typically—and, again, a lot of our plans are based on pandemic influenza where we could use eggs and much of our capacity, domestic capacity, is egg-based production. For these newer technologies like synthetic RNA or recombinant genetic vaccines or cell culture vaccines, we have a limited capacity. So we will be somewhat constrained to get a vaccine for everyone, but to your point, it would be prioritized to those who would need it most, health care workers and——

Chairman JOHNSON. So we already know this vaccine will use one of those more sophisticated techniques as well as the egg-based?

Dr. KADLEC. Yes, sir.

Chairman JOHNSON. So if you are talking about 18 months before you are really starting to manufacture it for the general population, we will miss next year's flu season, and you are really not going to have a vaccine available until really the 2022 flu season. Correct? Is that the right year?

Dr. KADLEC. So that is conceivable, and, again, that is why we are putting a lot of emphasis on diagnostics and therapeutics to basically look at it. I did not mention it in my opening statement, but screening existing FDA-approved drugs and they have activity to basically do that, and the supplemental has helped us basically actualize that. We are looking at thousands of compounds that may be available that we could be using that could be—as well as the candidates that Dr. Fauci has talked about, Rendesivir and some other drugs, an anti-human immunodeficiency virus (HIV) drug.

But, quite frankly, right now the only thing we really have is really kind of 18th century public health as well as things like N95 respirators.

Chairman JOHNSON. OK. So, again, the vaccine is in the future as a solution, so now you really, again, turn to how do you mitigate this, and that will be how do you screen, how do you get your arms around exactly where this is, quarantines—and we will talk further about other contemplated actions should this thing really spread and become a far more significant outbreak.

My time is up. Senator Peters.

Senator PETERS. Thank you, Mr. Chairman.

This information is very important that you are providing, and as I mentioned in my opening comments, it is just so important for us to get this information out to the American people and in a trusted source.

One thing I have called for and handed information to the Vice President yesterday is that, as I have looked and our folks have looked to find out where information is for the public through the Federal Government, there is good information. CDC has some information. But there is additional information that DHS needs to have. There is no one coordinated place where people can go to find out exactly what the government is doing with all of the agencies, a whole-of-government kind of approach coming forward. So, my suggestion is we have a dot-gov website. Dot-gov is trusted by everybody, that really talks about not just what the CDC puts out but what travel restrictions are, what the Homeland Security Department is doing, all of this where people can go to, because right now people are just actively searching—and I get this back home all the time. They are actively searching for information. There are all sorts of websites that are not accurate. There are folks that are trying to peddle products and create fear in order to make money. There is a lot of stuff happening right now. We have to tamp that down. To me, to have one coordinated site makes sense.

Does that make sense to both of you gentlemen, that we have a place where all the agencies, and it is trusted, a dot-gov site? Mr. Cuccinelli.

Mr. CUCCINELLI. It does. Obviously at DHS we have used our websites for each agency and at the departmental level to describe what we are doing. But this is, as Dr. Kadlec described it, a whole-of-government approach. It is a complicated interaction at the government level.

I would also note—and we will talk more about it, I am sure—the preponderant role that local and State officials play in this response and then coordinating between different levels of government as well. So, yes, and I saw your letter, Senator, was glad to see it, and I believe that it makes an awful lot of sense, particularly in a circumstance like this where, while Dr. Kadlec, for instance, has the lead Federal agency, there is an awful lot of us working on this subject, which is why the President convened the task force and so forth. So it is definitely something—we heard you loud and clear in your letter and we are taking it back to the task force to talk about it.

Senator PETERS. I appreciate that, and I would just say we just saw another incident. I am looking at the CDC website, putting out

facts about the disease. I know last night the President was being interviewed, and some of the comments that he made have caused some confusion. So I want to take an opportunity at this hearing. It says here: "If you are sick, to keep from spreading respiratory illness, you should stay at home when sick." Is that accurate, you should stay at home when sick? I know there is some confusion now.

Dr. KADLEC. Yes, sir.

Senator PETERS. Which is why it is important that we have one trusted source.

Dr. KADLEC. Yes, sir, I think that is part of the best thing is self-isolation if you have a respiratory illness and you are not sure what it is, if it is flu, good reason to stay home. It is coronavirus, better reason to stay home. But it is a good practice.

Senator PETERS. Right. Thank you.

Mr. Cuccinelli, there are some reports that some foreign nationals that have traveled to China in the past 14 days are actually coming into Canada, which does not have those same restrictions, and they are crossing the land port of entry (POEs) from our Northern Border—obviously, Michigan has a very active Northern Border, but all across the Northern Border. Are you aware of these reports? Is CBP conducting any screening of the Northern Border to try to intercept folks who may be using Canada as a port of entry and then using a land port to come to the United States?

Mr. CUCCINELLI. Yes, Senator. To broaden the context even further, it has not been uncommon for Chinese nationals to fly to Tijuana, Vancouver, or Montreal—that is not the limit, but by way of example—and then cross into the United States. The three largest land ports of entry for Chinese nationals are Blaine, Washington, Buffalo, New York, and San Ysidro in California. As you know, of course, with Detroit, they are not the only ones.

Senator PETERS. Right.

Mr. CUCCINELLI. At those three ports, the numbers are sufficiently high that we staged, in cooperation with HHS, medical personnel there much like we have at the airport. It was not widely advertised, necessarily.

I would note that the 212(f) Proclamation applies at land as well as airports, and we have excluded over 300 foreign nationals. Some people may find it ironic, but the largest excluded group are Canadians, and it is Canadians who had traveled to China in the previous 2 weeks. The next largest group were Chinese nationals, and then it dropped substantially from there. I want to say 90 Chinese nationals.

So the challenge you pose is real. We have been very aware of it and confront it head on and turning those folks back, frankly.

Senator PETERS. So do you screen passengers in vehicles? Because it is a different screening process, clearly, when you are coming across the land border. It is easier in an airport as you are walking by CBP folks. How do you deal with passengers who are in the vehicle and have an opportunity to really screen them?

Mr. CUCCINELLI. So the first screen and the most important screen that CBP is best at is a travel screening. So, for instance, I described turnaways, people who are not allowed in the United States because of their travel history. So CBP does have some ac-

cess to this at the border, depending on how the individual or family perhaps in front of them came to be there. If they came through air travel recently, that is a fairly straightforward determination. But they are also doing interviews, essentially, of people at the ports of entry in addition.

So if you think of the airport arena, the CBP folks do a travel interview: Where have you been? Who did you encounter? et cetera. Then the next layer, you get more of a medical interview. But that first one, it is the location where they have been that is the first and biggest flag. Predating this virus situation, CBP has always had direct access to CDC when people present in front of them with the appearance of illness.

Now, of course, the danger here is you can be asymptomatic with this particular virus, but that process has been vigorously engaged in on both borders, north and south.

Senator PETERS. You are talking about airports. It is even more complicated when someone is coming across——

Mr. CUCCINELLI. Yes.

Senator PETERS. Address that. You are coming across in a vehicle. Two of the three busiest border crossings in North America are in Michigan. Lots of vehicle traffic. How are you doing that?

Mr. CUCCINELLI. So the main screen that is our first filter and our biggest filter is the travel screen. We are using the data systems we have available to our officers and that interview which, while they were always doing it, there is obviously a heightened focus on China, on Iran, but also Korea, Italy, Japan, et cetera. There is not a proclamation barring those, but if you get a "yes" answer to those areas of the world, you are still going to pay closer attention. These are not medically trained individuals, but if there is anything they suspect, then those individuals will be pulled to secondary screening, contact will be made with CDC, and it essentially becomes a consultation at that point with genuinely medically trained folks but who are not physically present.

Senator PETERS. Right. Thank you so much.

Mr. CUCCINELLI. Yes, sir.

Chairman JOHNSON. The bottom line is it is a far from foolproof system. Again, that is just the nature of the beast.

Mr. CUCCINELLI. If I could, that is a really important point, Mr. Chairman. This has never been from day one intended to be a hermetically sealed process. We are trying to reduce and delay the biggest peak in the virus wave hit on the United States of America. All of these steps reduce and delay; they do not stop the virus. We have never suggested we were capable of doing that, and viruses do not care about boundaries, right? So it is an obvious point for us to try to provide extra safety to the American people, but it is by no means foolproof.

Chairman JOHNSON. Again, my comment is not a criticism. It is just trying to create realistic expectations, OK? Because if it was hermetically sealed, we would not have trade at the border. It would just be—again, overreacting here would be unbelievably costly.

Senator PETERS. Right, and I am just saying the ability of that is just to slow it down, to buy time, to have more testing kits out there.

Chairman JOHNSON. To mitigate it.

Senator PETERS. To be able to mitigate it. You are buying us time at the border, so thank you for doing that.

Chairman JOHNSON. Which, again, is what Dr. Fauci said in a private briefing. The travel ban definitely delayed this, definitely helped mitigate this, reduce the——

Mr. CUCCINELLI. It was contrary to the models. It was not necessarily predicted to work that way. Our analysis of the task force, we came to a different conclusion, and now we can Monday morning quarterback ourselves. That has clearly been effective. It does not mean perfectly, as you point out, Mr. Chairman, but it bought us time.

Chairman JOHNSON. Senator Carper.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Thanks, Mr. Chairman. Welcome. Thank you for joining us today and for your testimony and for your work.

Dr. Kadlec, given the potential for fairly rapid spread of this virus, we cannot afford for our patients to delay screening because of concerns of affordability with respect to insurance deductibles and co-pays. Recently the news media has documented one short-term health insurance plan in Florida, I believe, billing a patient more than $3,000 for his coronavirus screening and flu test. Three thousand dollars.

What are you and your staff doing to ensure that coronavirus screenings and treatment are low cost and affordable? Have you asked health insurers and employers to lower or remove financial barriers to coronavirus screenings?

Dr. KADLEC. Sir, that was appreciated, and that is why Dr. Seema Verma, who is a head of CMS, is now part of the task force, to really focus in on that part of the problem. One is about the accessibility of health care for people who may have the coronavirus and how that is being covered, as well as the affordability issue. She has been engaging with insurance companies, and it is not surprising that someone may be taking advantage of this. But she is not someone to be fooled with, and I clearly have confidence that she is going to engage on this fully. But we can certainly have her available for a briefing for members, if that would be helpful, to talk more about what CMS is doing to address that concern, accessibility and affordability.

Senator CARPER. I think that would be well received. Thank you.

There is a Bipartisan Commission on Biodefense. I think, Dr. Kadlec, you might have been the founding Staff Director of that Commission.

Dr. KADLEC. Yes, sir.

Senator CARPER. I think it is co-chaired now by Tom Ridge, former Governor, former Secretary, and Joe Lieberman, who was once the Chairman of this Committee, as you may recall.

Dr. KADLEC. Yes, sir.

Senator CARPER. In 2015, that group issued a report. I think that report included 33 recommendations to improve our Nation's preparedness for intentional or naturally occurring biologic threats. I am pleased to know that the President has filled one of those recommendations, and that is centralizing response efforts at the

highest level of government, in this case with the Vice President. Many of the recommendations, however, remain unfulfilled.

As the founding Staff Director of that Commission, could you just speak for a minute or so about the recommendations that still remain to be completed and what stands in our way for completing them?

Dr. KADLEC. Thank you, sir. I think just broadly there was a second one that was completed. That was the National Biodefense Strategy, which was really the foundational document or effort to really understand what as a whole of government we need to do. There was a lot of great work that Congress did with the administration back in 2005 and 2006, and, quite frankly, that is unfinished business. I think that was the intent of that study panel, to basically evaluate what needs to be done.

So broad strokes in the health care system. We have a health care system that is about 95 percent privatized, that is running on very limited margins in terms of profitability, limited surge, and that surge capacity or lack of surge capacity is going to be tested to the limit here. So that is one area in terms of health or hospital health care system preparedness' major vulnerability.

The other one critical infrastructure is the public health infrastructure, which is really about the people at the State and local level, and there are serious issues there in terms of the numbers of people who are willing to get involved in that business. I call it the "Rodney Dangerfield of medicine." They get no respect, because when they do everything right, nothing happens. It is a circumstance, I think, there that really does require a little more nuanced effort to promote and incentivize that.

The third is a different kind of infrastructure, and that is what I would say is the infrastructure for medical countermeasure development. We talked a little bit about the domestic production of vaccines, and that is a good thing, because if we can expand that, that is not only making sure we have the right vaccines but we have great jobs for Americans in many parts of the country and really enhance innovation in health care. That is the fourth element where we are doing some of that to address maybe some issues that would be related to supply chain that have to be addressed, things like active pharmaceutical ingredients (API), the precursors for that, and where that is manufactured. Much of it is overseas and a great vulnerability as we all learned through this experience.

So there are four quick things in broad strokes that I would suggest that that study panel has done to raise our awareness and focus our efforts to do that.

Senator CARPER. You may have answered this, but I am not sure. Just take another minute and talk to us about steps, additional steps that the administration is taking to fill other recommendations. You mentioned four that have been fulfilled. The other 30-some that maybe have not been.

Dr. KADLEC. Yes, sir, and I will put it in broad strokes, because we have talked about the Biodefense Strategy. The one thing was the Executive Order (EO) on pandemic influenza which really talks about, relevant to this issue, quite frankly, how do we basically manage a potential pandemic of flu. Again, a lot of that is really about speed, speed of action, which I think is a fundamental issue

in this event. The virus is moving faster than sometimes we can even think and act.

Then the second thing is really about domestic capacities and supplies, things like the Strategic National Stockpile that have to be maintained over time. I will just point out that one of the findings out of the Biodefense Strategy was we invest about $8 billion in this kind of activity each year. It sounds like a lot of money, but when you consider that an aircraft carrier costs $17 billion and we have 12 of them as a country, that gives you some kind of scale of what we invest in one arm of our national defense that we probably want to invest in our national health security.

Senator CARPER. All right. Thank you.

As you know, pharmaceutical companies that exist, maybe that were founded and operate exclusively in this country, oftentimes partner with pharmaceutical companies in other parts of the world in order to try to solve Alzheimer's disease, Parkinson's disease, and Multiple Sclerosis (MS). What kind of collaborations are being encouraged, should be encouraged with respect to shortening the development time for the vaccines to address this virus?

Dr. KADLEC. Senator, some examples. Coalition for Epidemic Preparedness Innovations (CEPI) is a group that is kind of an international consortium that involves the Wellcome Trust, the Gates Foundation, the U.S. Government is involved, several European governments are involved, to focus on major disease areas. Coronavirus is one of them, quite frankly, as well as Marburg virus, a hemorrhagic fever. I think those kinds of initiatives are valuable because they can, if you will, consolidate small resources and give bigger opportunities, and, again, tap into the wealth of innovative thinking around the world to address some of these hardest problems, and also understand that in many of these cases, the underdeveloped world is probably the greatest at risk, and so to make it affordable and more accessible. So those kinds of models are very helpful.

The Global Health Security Agenda is another thing that was created in the Obama Administration, perpetuated in the Trump administration, to address how we can build capacity in countries so they can be better positioned to help themselves. That was the success of the western Congo outbreak of Ebola where small amounts of money helped build the infrastructure, as well as the availability of an effective vaccine. Obviously, eastern Democratic Republic of the Congo (DRC) is a different story, but those are some examples I would use, sir.

Senator CARPER. Great. Thank you so much.

Chairman JOHNSON. Senator Hassan.

OPENING STATEMENT OF SENATOR HASSAN

Senator HASSAN. thank you, Mr. Chair, and thanks to both of our witnesses not only for your presence here this morning, but to you and your teams, thank you for your service and theirs, and please take our thanks back to everybody on the front lines.

Dr. Kadlec, I wanted to just start with following up on Senator Johnson's line of questioning about what we can be communicating to our constituents about the timing of increased testing availability. You went through—we have tests at public health labs.

Now we are surging up on the commercial side. We have talked about a million-plus test capacity. But part of the process here is going to be once the commercial labs get these testing kits, they have to validate them, right? So how long does the validation process take? I am just trying to get to a timeline——

Dr. KADLEC. Sure.

Senator HASSAN [continuing]. So people understand when this surge will really be making a difference in their experience.

Dr. KADLEC. I think the key thing is, based on what is the availability of these tests now in terms of delivery, they are being delivered now.

Senator HASSAN. Right.

Dr. KADLEC. In the public health labs, they will be increasingly—by the end of next week, you will probably see very high capacity and capability, so about a week. Then you can imagine that the commercial laboratories will be lagging about a week behind them.

Senator HASSAN. Then how long does the validation process take?

Dr. KADLEC. It takes a couple of days to do that.

Senator HASSAN. For each kit?

Dr. KADLEC. No, it is the machine and basically validating the test itself on the machine.

Senator HASSAN. OK.

Dr. KADLEC. The people who have to basically work the machines and the test kits.

Senator HASSAN. I think it would be very helpful—and I want to move on to some other questions. I do not want to belabor this. But if the administration would put down a timeline so that people could see in writing on a website when to—you do not have to promise an exact date, but when it would be reasonable to expect commercial labs to be able to perform this test if your doctor suggests you get it, I think that would be very helpful.

I wanted to move on to another issue. As you know, Dr. Kadlec, the National Disaster Medical System and other programs play a critical role in ensuring that uninsured and underinsured patients can receive care during emergencies by helping reimburse hospitals. I know that you mentioned earlier in the week that this issue was under discussion within the administration. Can you provide an update on those conversations and, more broadly, what the administration is doing to help ensure that underinsured and uninsured patients can receive the emergency care that they need?

Dr. KADLEC. Ma'am, I am probably not the best one to answer that. I think Dr. Verma may be.

Senator HASSAN. OK.

Dr. KADLEC. But I do know that in the supplemental there is money to basically support that; that would basically expand it. I think it is about $1 billion, so you were very generous in that allocation. I think that will be money that will be used for that purpose, to basically ensure that we can take care of everyone, literally everyone who is afflicted with this.

Senator HASSAN. All right. I will follow up with Dr. Verma to be sure, but it is going to be an important issue, and if we need more resources to make sure that people are not only getting the care

they need, but, getting the test they need so that they will not be infecting other people.

Earlier this week, Dr. Kadlec, I met with New Hampshire's public health officials. They have in-State stockpiles of protective equipment such as masks, but they recognize that their stockpiles may be quickly used up, and we have already had at least one confirmed case in New Hampshire. Public health officials in my State have attempted to order more supplies, but they were told such supplies are on backorder until May.

Based on your testimony earlier this week, I am concerned that the National Strategic Stockpile will not be sufficient to meet the demand. What is the timeline for getting the equipment in the field? How will you advise people to protect themselves in the interim?

Dr. KADLEC. Ma'am, we have taken a multi-pronged strategy to basically address what I think is your point, which is unless you have it on hand immediately, you are going to face some challenges. One is that we have a stockpile, a limited stockpile right now of masks—when I say "masks," surgical masks—N95 respirators, and we are in the midst of procuring more immediately, meaning tens of millions, and then have introduced or released as of yesterday a request for proposals for 500 million N95 respirators to basically be provided over the next 6 to 12 months.

Senator HASSAN. OK.

Dr. KADLEC. So the intent is that that will ramp up.

Senator HASSAN. The supplemental provides funding for that——

Dr. KADLEC. Yes, ma'am.

Senator HASSAN [continuing]. So that the manufacturers know they will get paid. OK. So do you have a plan in place to ensure that firefighters, public health officials, and other first responders are appropriately prioritized for receiving the equipment?

Dr. KADLEC. We met with the manufacturers yesterday, and I think that is one of the conversations we are having. They are making allocations on their own, but—and then realize that in the course of, let us say, just these N95 masks, in a given year, only 10 percent is used by the health care professionals and lump in the first responders. And so much of it is used by construction, mining, and manufacturers. The FDA has given an emergency use authorization (EUA) to allow non-medical masks to be used by a broader population, first responders included, and we are going to try to work to see if we can get an allocation to make sure that those first responders are covered.

Senator HASSAN. OK. So that is helpful to know. In addition to States needing these supplies, it is going to be important to provide training to any responders or providers who will be tasked with assisting or treating coronavirus patients. What efforts are underway at the Federal level to ensure that responders and providers can access training on the use of personal protective equipment?

Dr. KADLEC. Thank you, ma'am. One of the critical things—and, again, a product of Congress' work has been the National Ebola Treatment Network that was created post the 2014 Ebola event.

Senator HASSAN. Right.

Dr. KADLEC. With that, there was more generous monies then than now to basically address not only ten regional centers, three

national centers of excellence, but we have also, like in the north New England area, started a regional Disaster Health Response Network with Mass. General Hospital that is working with your catchment area to basically train and prepare people. So that will be one mechanism. We can get training out and specific information on how to manage these coronavirus experts, and, actually, we used some of the people from Mass. General in the repatriation of the people from Diamond Princess.

Senator HASSAN. OK. I think it is going to be important, something that I asked Acting Secretary Wolf about yesterday, too, because in the proposed DHS budget there are actually cuts to programs that train first responders in this kind of work. So I want to make sure we are focused on that.

I am just about out of time, so I thank you both, and I thank you, Mr. Chair.

Chairman JOHNSON. Senator Rosen.

OPENING STATEMENT OF SENATOR ROSEN

Senator ROSEN. Thank you, Mr. Chairman. Thank you for being here. I know you have been in a lot of hearings. We appreciate your around-the-clock work.

As no surprise to anyone, the virus is moving fast. Nevada has just reported its first case of the virus today. I have been in close contact with our State officials, our Governor's office, and I want to emphasize, really stress the importance, just like the other Senators have here, how important it is to keep those clear lines of communication open with really good data that they can respond; they are our boots on the ground.

But what I would like to address is Federal assistance for the impacted individuals. If larger quarantine measures are needed and medically justified, what plans are in place to provide relief to those Americans who may miss work due to government-impose quarantine but not necessarily to their illness? Many folks live paycheck to paycheck. The loss of a few days' work is a major hardship, let alone staying home for a few weeks. This could lead to people losing their homes, not being able to afford food or other essentials.

If we have disaster-like situations on the ground, what can FEMA do to help alleviate this in the short term? What do you need from us to help with that?

Mr. CUCCINELLI. FEMA has been in place with ASPR at HHS for almost a month now and assisting them, bringing the expertise FEMA brings to disaster response to this effort, still with ASPR as the lead Federal agency, of course. People naturally look to Stafford Act, and this is a disaster of sorts, but the response mechanisms are not the same. It is not currently anticipated that you would see a Stafford Act declaration. The intensity of the problem will be different in Nevada than it will be in Virginia, for instance. There is the base fund where Governors can make requests when elements of their systems are overwhelmed for funding. There is a $5 million cap that is waivable for that, and this is not the Disaster Relief Fund (DRF), the $34 billion disaster—this is a base fund that has about $640 million or so in it.

Senator ROSEN. Would they be able to use this? We know that around the country some places are reporting school closures. We could anticipate maybe closures of senior centers. So we have many kids across this country, many in my State, kids on free or reduced lunch, free breakfast. We have senior centers where those seniors reliant on those meals every day. How do we ramp up and give the ability, if there is a school closure, a senior center closure, to use Meals on Wheels or give brown bags to these kids and their families? Can you speak to that?

Mr. CUCCINELLI. Yes, but it is a belief. I believe Secretary Azar has some authority to expand aid, welfare programs, under these circumstances. But FEMA nor DHS do not have dollars available that would legally fit the description of the relief you are describing, Senator. So that is something that I believe is being covered and addressed in the supplemental, and that is the appropriate vehicle.

I would just note more generally that Dr. Kadlec referred to the planning efforts that have gone before this all arose, and we operate off the Pandemic Crisis Action Plan (PANCAP) 18 plan, and in that plan it was envisioned that the financial vehicle to deal with an outbreak of this nature was via a supplemental. So we are sticking with that plan, and as was said 6 weeks ago, if we need dollars, we will come to the Congress. We are here now, of course, and that discussion is going on. It is including the kind of things you are describing?

Senator ROSEN. So our Governors would be able to request this and funnel it to communities that need it, is what you are saying?

Mr. CUCCINELLI. No. I think you are mixing two things. If the supplemental includes monies to address the types of shortcomings, financial shortcomings you are describing, then the answer would be yes.

Senator ROSEN. OK.

Mr. CUCCINELLI. There is nothing currently legally in place that FEMA has available that would fulfill the needs you are describing. I want to make sure that——

Senator ROSEN. So we may have to look to that in the future and see what we——

Mr. CUCCINELLI. Yes, ma'am.

Senator ROSEN [continuing]. Have to do to take care of those vulnerable populations.

The next thing I would like to ask you is about immigrants that are seeking care. Nevada's diversity is its strength, with about one in five Nevadans born outside the United States, many more living in households with immigrants, some of whom are undocumented. As we work to contain the coronavirus, we have to ensure that there is timely access to medical care for everyone who needs it, regardless of their status. This is a public health and safety issue. Anything less puts all of our communities at risk.

So, Mr. Cuccinelli, no one should be afraid to seek care as the coronavirus spreads, placing our communities at risk. Will the Department refrain from apprehending individuals based solely on their immigration status while they are in the process of seeking care?

Mr. CUCCINELLI. So much like the CDC–CBP relationship preexists this virus, it is something that has stood before, U.S. Immigration and Customs Enforcement (ICE) also has an already-in-place policy, their sensitive locations policy. They do not do enforcement in health care facilities absent single case exigent circumstances. So there is no reason anyone should expect that law enforcement take place——

Senator ROSEN. But would they refrain from potential intimidation factors such as placing vans outside of community centers or health centers where people may go to seek these tests?

Mr. CUCCINELLI. That would be consistent with the policy, Senator.

Senator ROSEN. Thank you. I yield back.

Chairman JOHNSON. Mr. Cuccinelli, very quickly, because we discussed this. Senator Portman brought this up yesterday. He had a chance to look at the supplemental. Zero dollars for DHS. We talked a little bit about this in the cloakroom. Can you describe what the thinking of Congress is on that and how DHS is going to get the funding to do the things you need to do in this situation?

Mr. CUCCINELLI. So the easiest starting point on that is what is already going on. So FEMA is in the office every day with Dr. Kadlec assisting HHS. That is financed by HHS. So there are interagency agreements in place, so dollars that flow to HHS to address the virus challenge, as the source of the lead Federal agency, do flow to DHS when we are providing those sorts of supportive efforts from any of our agencies or components, the most obvious one day to day being FEMA at the moment.

Chairman JOHNSON. So there is a mechanism in place between agencies, so you are not concerned when you look at that supplemental, well, where is our support, where are our resources? You are going to get those through HHS and, again, the administration requested $2.5 billion. We are going to give them $8 billion. Resourcing should not be a problem.

Mr. CUCCINELLI. That is exactly how this will work going forward, as it has, as I noted, for the last month or so.

Chairman JOHNSON. OK. Senator Hawley.

OPENING STATEMENT OF SENATOR HAWLEY

Senator HAWLEY. Thank you, Mr. Chairman. Thanks to both of you for being here. Thanks for the excellent work that you are doing to address this outbreak. I have to say it is very concerning. I am concerned about the spread of the virus nationwide. I am also concerned about what this has exposed. One of the things is I think the fragility, the vulnerability of our medical supply chains. You referenced this a moment ago, Dr. Kadlec, the fact that for medical devices too many of our drugs or pharmaceuticals themselves are manufactured in whole or in part in other places, China in particular. Now we have already seen early reports about potential drug shortages because of Chinese factory closures. This is something that we have to scramble to address now to make sure that, as this outbreak continues, we are not caught with severe medical shortages in key drugs, antibiotics, antivirals, but also going forward that we take necessary action.

So, Dr. Kadlec, let me just start with you on this. Can you describe the actions that ASPR and the task force are taking or have taken to ensure that our health care providers have uninterrupted access to personal protective equipment like masks and gloves?

Dr. KADLEC. Sir, I think the key thing is we have been working with the manufacturers, the key manufacturers, all the manufacturers in the United States, with the distributors. Again, it is kind of a delicate balance to ensure that what is made available is available into the stockpile, and not only our stockpile but to distributors so they can provide for private health care workers as well as institutions. Many States do have a limited supply, a limited stockpile, and our intent is to basically provide—support the States by providing them materials as we did in the State of Washington, to basically supplement what they already have on hand, what is available commercially, to ensure that they do not run out in an emergency of this nature.

Senator HAWLEY. In your written testimony, you wrote about the Strategic National Stockpile and that it is working hand in hand with commercial supply chain partners to monitor shortages. Can you just elaborate on that?

Dr. KADLEC. Sir, basically, again, if not daily, weekly conversations with the major suppliers of, let us say, overgarments, Dupont; respirators, 3M, Honeywell, all the others; to basically understand what their allocations are to the private sector and what are the needs for the Federal Government as well. There are many departments and agencies that have needs as well, and we are monitoring that so that we can moderate what is perceived needs versus actual needs to ensure that we have enough in the pipeline for the private sector to meet their first-line needs.

Senator HAWLEY. It is my understanding that the FDA is currently working with manufacturers to monitor potential shortfalls for drugs and devices. To what extent are manufacturers complying, to your knowledge, with requests from the FDA in this regard?

Dr. KADLEC. Sir, the FDA does this through a confidential kind of business arrangement with them, so I do not have visibility entirely, as appropriate in this case, to know exactly what the particulars are. But Dr. Hahn would be an excellent source to come in and brief you all on what they are doing.

At this point, however, there is only one drug, prescribed drug that has really been identified as being potentially in a shortfall. There are alternative products available in the U.S. market that could be substituted. So the impact of that limitation does not seem to be great. But he is kind of monitoring that like a hawk with his team to ensure that they cannot only identify near-term but longer-term risks to our medical pipeline.

Senator HAWLEY. My own view is that we need to give the FDA more authority to look under the hood, find out exactly where our drugs and medical devices come from, what the supply chain vulnerabilities may be, and then give them the authority to backfill by speeding up approval of alternative devices or drugs manufactured in other areas. I have introduced legislation to do just that.

Mr. Cuccinelli, let me turn to you. Do we need to be considering expanded travel restrictions as the virus spreads? How do you evaluate that?

Mr. CUCCINELLI. The short answer is yes, but it is yes because we have literally been considering them on a daily basis. The driving factors would include—and they vary how they weigh in each country—first, the transparency of the Nation under consideration. You compare, say, China's transparency to Korea. It is a rather dramatic difference. The ability of their own health care system to respond to the outbreak in their country; and the capacity remaining after they do so.

So, for instance—I will give you an example—the State Department's warnings early on about China were not just because of the outbreak. They were also directed to keeping all of our U.S. employees safe, because if you got in a car accident, completely unrelated to the coronavirus, in Hubei Province, there was not a doctor to take care of you. So their systems in parts of their country were and are overwhelmed, so that is another consideration.

Now, China, on the other hand, would be a very different consideration than, say, their neighbor Mongolia, which, you compare the health care systems, Mongolia closed their border very fast, and part of the rationale was that they do not have the ability to respond. We are talking in this Committee about our strengths and weaknesses and what we could better in the future, but they have no ability. So those sorts of factors weigh in on those other countries.

Senator HAWLEY. You are reevaluating, your testimony is that you are reevaluating this on a daily basis.

Mr. CUCCINELLI. Daily basis.

Senator HAWLEY. Is that an interagency process?

Mr. CUCCINELLI. It is an interagency process, and we are using two scales to warn Americans: both the State Department's Travel Advisory Scale, which is a 1 to 4, and the CDC Health Scale, which is alert to 3. Their numbers naturally are off by one as we go up and down, so 4 and 3 are the tops, respectively. But we have found, as Steve Biegun, the Deputy Secretary who sits on the task force, would tell you, I am sure, they I do not think have ever seen such responsiveness to their travel advisories. We have never seen such consumption by the American public, much like CDC, I believe, had 500,000 downloads of their business advice, their business guidance in the last 24 to 48 hours. So that is all having a real meaningful effect without government mandates.

Of course, there is a 212 Proclamation with China. The TSA issued security directives yesterday, effective yesterday, with respect to Korea and Italy, but really a very minimal legal impact, more advice and weight of the value and credibility of the government advice.

Senator HAWLEY. Very good. Dr. Kadlec, let me just come back to you before my time completely expires. I am sure that you are aware of news reports I have seen of the other countries like South Korea, for instance, is performing over 10,000 diagnostic tests per day. They have even set up drive-through clinics in South Korea where citizens can go and be tested.

Why are we not at scale and able to do something like that? While we are on this topic, can you explain the precise reason for the defective kits that we saw earlier?

Dr. KADLEC. Sir, I cannot provide the exact reason for the defective kits. We probably need to have CDC come and brief you on that. But in terms of the scaling, earlier conversations by the Chairman were that we are scaling up now by commercialization of not only test kits that could be used in public health laboratories, but really engaging the private sector, the commercial labs that can do large-volume testing. That is going to be kind of rolling off the line here in the next week or two that would significantly expand the opportunity to not only do testing in public health labs, hospitals, and clinics, and even doctors' offices that use these commercial laboratories. That will rapidly be turned around.

Again, we may not get to drive-through swabbing, if you want to call it that, but also I just want to comment on that point alone. You have to do it with some precision how you take those naso-oral pharyngeal swabs. The risk is you can swab somebody if you are not careful and get a false negative. It does take a little bit of training, so I would not think that Jack in the Box will be swabbing here in the United States any time soon.

Chairman JOHNSON. Senator Scott.

OPENING STATEMENT OF SENATOR SCOTT

Senator SCOTT. Dr. Kadlec, we have a lot of information at NIH and CDC. I have not seen anything where everyone is talking about the risk for pregnant women. Is there increased risk? Are there any precautions they have to take?

Dr. KADLEC. Sir, little data on that. Honestly, at this point in time I think there needs to be a better understanding of that. That is a particularly vulnerable population for a variety of reasons, two lives, as well as the different physiological effects of pregnancy on women and the baby. And so that is an issue.

The earliest report has been a coronavirus report or a case in a newborn in China, but that is the only thing. That is an anecdotal case, but certainly that is a major issue and concern.

Senator SCOTT. So nothing has come out of South Korea or Japan or——

Dr. KADLEC. Nothing as of yet, sir. We are getting high-level statistical data, but not case reports that are vital for this purpose.

Senator SCOTT. OK. Thank you.

Secretary Cuccinelli, I am from Florida. We have 150 million-plus passengers through our airports. Then we have all the millions and millions of people who go through our cruise ships. What advice are you giving to both our airports and our seaports to deal with? We have so many people coming from now all over the world that we know these countries have coronavirus. What advice are you giving them? What precautions are you putting in place?

Mr. CUCCINELLI. So a few things. First of all, the Coast Guard, TSA in particular, have very regular communication with the cruise lines and the airlines. In fact, I have been doing that as well. You will have noticed that for the first time ever—we were talking about travel advisories with Senator Hawley—we issued a travel advisory, the Department of State specifically, related to cruise

ships—not a country, not a location, but to cruise ships, because they have proven to be such a risky venture from a health standpoint. That was unique. It was effective in terms of the responses. That is not economically good for the cruise ship industry, but we have also see—I mean, the Diamond Princess was a viral disaster, and avoiding a repeat of that series of mistakes that really are going to take a long time to even understand completely has driven a lot of that response.

On the airline front, we are seeing point-to-point declines in traffic. I have data on some of that if you would like. Needless to say, China's flights have gone through the floor, and Korea has declined maybe by half, Japan by about 25 percent, just by way of example. There are good reasons for that.

The cruise ships themselves, in my discussions with some of the representatives, are themselves trying to avoid bringing on passengers from these hot zones and to avoid a repeat of the result of essentially quarantining a ship. As it works in the ports—and you do have many of those in Florida—the Captain of the Port, the Coast Guard person in command of that port, is in absolute control of that port. We hold ships offshore when needed, and we have done that throughout this entire time. That has primarily been associated with cargo shipping because we have tried very hard, to some of the discussion about supply chain, to keep the cargo flowing—not for dollar reasons but because of the interconnected nature of our supply chains. We have taken special steps, for instance, keeping ship crews on ships, allowing offloading and reloading of ships and they leave without the usual coming ashore.

In a passenger context, that is much more difficult, and we continue to contend with these. You are sitting next to Senator Harris. We are dealing with one coming in San Francisco, and literally as we speak that is being dealt with directly. The Captain of the Port will work directly with the regional CDC head to address these on a case-by-case basis in terms of how to deal with passengers. As you might imagine, of course, having been Governor of Florida, you can appreciate if we were to try to use the health care facilities in one port to deal with an entire cruise ship, we would immediately swamp the health care system locally. That is our counterbalancing challenge that we rely on CDC to make those State-local arrangements, though they are conversations that the Coast Guard has all the time.

So we really are handling them one at a time, but it is with an eye to not bringing ashore virus spread. That is the priority, and it is part of why we have warned Americans not to go on them in the first place.

Senator SCOTT. Particularly airports, we all have lots of international flights. We have a lot in Florida. So what is it going to take for you to do the same thing you did restricting travel out of China? What do we have to have?

Mr. CUCCINELLI. Of course, that step was taken in literally the world's epicenter there in Hubei Province, still the largest number of cases in the world. We do not see anything like that developing to that scale, though Korea and Italy are kicking case numbers up very fast. It is important to remember when you take a snapshot of today's cases, that is a week, 2-week, 3-week lagging indicator

of what was already there. We are operating on dealing with this virus that has not been known to exist in humans for 3 months yet, lots of areas we lack knowledge. We are trying to err on the side of conservativeness. If you are in the cruise business or airline business, that is hurting you right now, and that is going to keep hurting you for a little while. We do not know how long. But, obviously, our challenge is to try to keep Americans safe.

Senator SCOTT. I do not trust any of the information coming out of China. I do not believe they are a transparent country. It is Communist China run by the Communist Party. So do you have any inclination to open up travel from China any time soon?

Mr. CUCCINELLI. That is not on the discussion table. We are not even talking about it right now.

Senator SCOTT. OK. I think it would clearly be important for my State, but on the cruise industry, do you think you are going to get to the point where you are going to say you are going to start testing everybody that is going to come off?

Mr. CUCCINELLI. Again, that would be a case-by-case. We will not be able to for a few weeks at least. However, we are right now literally as we speak flying test kits out to a cruise ship off San Francisco—off California, I should say; it is moving up to San Francisco—with Coast Guard helos and Parajumpers (PJs) basically dropping onto the ship and bringing kits. We are going to test, if not everybody, a very large number of individuals relative to the ship. That we have full information, when the Captain of that Port in San Francisco is talking to their local CDC authority—and they have already been working as an action group with the cruise line themselves, so this is not popping on us. We have been working it for days.

Senator SCOTT. All right. Thank you. Thanks to both of you.

Chairman JOHNSON. Thank you, Senator Scott.

Just real quick, on the cruise industry, I would think in terms of availability of testing kits, because it is such a unique situation, that would be one of the priorities in terms of getting test kits so that is a capability. Senator Harris.

OPENING STATEMENT OF SENATOR HARRIS

Senator HARRIS. Thank you, Mr. Chairman.

As you know, my State is home to 40 million people, and we have the largest number of cases, 62. Yesterday our Governor declared a State of emergency for the entire State. The coronavirus I think presents an interesting convergence between public health concerns and pay equity concern. Specifically, two-thirds of low-income workers in the United States do not have paid sick leave, and as we know, we have been encouraging people who are sick to stay at home. Often people who are in that pay category also are in the service industry. They work in restaurants; they work in hotels; they work in child care. They have contact with a lot of people. For them to stay at home in the interest of public safety means they may not be able to put food on their table.

So my question is: Understanding this is a very real issue. What is the administration planning to do to encourage employers to provide paid sick leave for sick employees so that they will stay at home and not have to face that awful decision about whether they

stay at home in the interest of public safety or do not put food on the table of their family?

Mr. CUCCINELLI. So I will speak first to the communications we have had with people across the private sector. In addition to our accelerated communications with local and State-level officials, we have also been talking to non-health care private enterprises and encouraging them in this direction as well, recognizing the burden that asking employees to stay home imposes both on the business and on the employee. You identified, Senator, certain businesses where it is important for everyone else, not just co-workers, for that person to stay home.

Senator HARRIS. Right.

Mr. CUCCINELLI. If you are serving food and the customers in that restaurant——

Senator HARRIS. Like a fast-food restaurant.

Mr. CUCCINELLI. Yes. They do not want you to come to work, right.

Senator HARRIS. So what can we do to support you talking with the private sector about providing paid family leave during this concern?

Mr. CUCCINELLI. So Cybersecurity and Infrastructure Security Agency (CISA) has already standing sector consortiums that they are talking to, and this is one of the subjects that they have talked to them about, about supporting employees who are asked to stay home.

Obviously, we are also asking businesses in those lines of work where it is possible to make the telework arrangements so people can keep working and they can keep getting paid. You do not function as well, but they can still earn money for their families.

Senator HARRIS. But my concern is that for the majority of low-income workers who do not have paid sick leave, they are in the service industry, so teleworking is not an option for them. So perhaps we can follow up to determine how we can support what sounds like is your effort to figure out ways that we can make sure that these employees do not have to make a decision between paying their rent or contributing to what we know is in the interest of public health.

Mr. CUCCINELLI. There actually is more money available, and I would defer to Dr. Kadlec because that is out of HHS.

Dr. KADLEC. Just one other area, ma'am, on the White House task force, Secretary Mnuchin, Mr. Kudlow, and the National Economic Council are involved in this, and they are looking at ways—and the conversations I have heard have been about small businesses and, again, a very critical part of supporting individuals and how they can do that. So I am sure they will welcome the opportunity to work with Congress to figure out ways to basically support individuals who are facing this problem, who are challenged.

Senator HARRIS. Thank you. Federal employees. So we have many Federal employees who, again, their job does not allow them to telecommute, TSA, for example, postal workers. What is the administration's plan for those workers in terms of what—also, soon-to-be enumerators for the 2020 census, which, of course, starts April 1. What is the administration's plan for dealing with those

Federal workers who do not have the ability to telework and do their job?

Mr. CUCCINELLI. So one of the sub-groups in the task force is dealing with the Federal workforce, and, of course, to use the Department of Homeland Security as an example, we have a building in Washington State where we, unfortunately, have had an employee test positive. That is an office building setting. That is one setting that DHS operates. It is a lot different than a Border Patrol station or a TSA desk where a bunch of people are going by you in close proximity each day.

For those folks, people like the TSA example you used, Senator—and it would apply to CBP and others—we have made PPE available to them. The medical guidance on how to use it, it does require appropriate training to use correctly in a way that is advantageous to the wearer. I have been out to Dulles Airport myself when China flights were coming, and I observed the difference in the employees, for instance, the CBP's Office of Field Operations (OFO) employees, who, when I arrived at the airport with no flights, had their uniform on and otherwise looked like you and me. When the China flights were arriving, gloves and masks were on.

Senator HARRIS. That is great.

Mr. CUCCINELLI. That is available to all of our employees, and that is true for the front-line folks across the Federal Government. But that is being closely studied, and we are doing things like pulling down unnecessary travel, other things where we do not create risks for either our employees or the general public.

Senator HARRIS. Thank you. In follow-up to Senator Rosen's question about immigrants and undocumented immigrants, the reality is that we have many undocumented immigrants who are in America's workforce. We also recently had an announcement from ICE that they were going to increase enforcement. So it is a legitimate and real concern that undocumented immigrants in particular and their family members are in fear of and certainly discouraged from going to public health facilities to receive treatment if they are sick.

I heard what you said about the policy. Would you be willing, Mr. Cuccinelli, to issue a public statement that during the crisis that we are now facing around the coronavirus, there will not be ICE enforcement at these public health facilities, be they hospitals, medical clinics, or things of that nature?

Mr. CUCCINELLI. We actually issued a statement yesterday in response to similar inquiries. Obviously, our statement was based off the existing policy, but we did restate that publicly just yesterday.

Senator HARRIS. OK. That is great. Then for both witnesses, there has been a lot of discrimination against Asian Americans and Asian immigrants, and public health experts agree that the coronavirus does not focus on or target any group by race or ethnicity, yet we are seeing many reports and hearing many reports of intimidation, of profiling, and threats in particular to our Asian American community and friends.

So what is the administration prepared to do in terms of committing to actively dispelling misinformation about this issue? Because it is very real, and we already have enough fear about the public health crisis, but to compound that, that our friends and relatives

and neighbors would have fear about being profiled is something very real.

Mr. CUCCINELLI. Obviously, we are trying to convey calmly lots of different information about a virus about which much is unknown, and we have woven into remarks really at every level of government the very same concern you have just voiced, because periodically—and we typically do it, candidly, when we have instances brought to our attention, so that in our—"our" now is the Department of Homeland Security, and the same would apply in other places—in our soon thereafter public statements is when we try to knock that back. That is when we talk about that. We want to be very clear, as you said and I will say it clearly, the task force, there is without question no difference that this virus shows whether you are black, white, Asian, Hispanic, anything else. The dangers are to the same people regardless of race, ethnicity, et cetera, and our responses should be irregardless of people's skin color or ethnicity. Obviously, that is how the Federal Government and how we are responding to it. At the same time—I used the Northern Border with the China 212(f) Proclamation. More Canadians have been barred from the United States on the Northern Border than Chinese, 113 to 90, because of that proclamation, and it is because it was travel-based. It was not that you are Chinese. It is that you have been in the hot zone in the targeted time period of 14 days. We will continue to operate that way and continue to make efforts to knock down story lines or narratives that say anything different from that.

Senator HARRIS. Thank you.

Chairman JOHNSON. Senator Sinema.

OPENING STATEMENT OF SENATOR SINEMA

Senator SINEMA. Thank you, Chairman Johnson, and thank you to Ranking Member Peters and our witnesses for participating in today's important hearing.

I represent Arizona, a State with confirmed coronavirus cases, and I would like to acknowledge the Arizona Department of Health Services, the Arizona State Lab, the Maricopa County Department of Public Health, and Arizona State University for their swift actions to care for those individuals and to mitigate potential exposure to those in the community. We need to see that same level of cooperation and coordination on the Federal level. I have constituents who were quarantined at Lackland Air Force Base who received little to no information about when they would be able to go home after another individual who had been released later tested positive for the coronavirus.

While many of them are now on their way home to their loved ones, some are still in quarantine, and this lack of communication is simply unacceptable. Our constituents deserve straight answers from the Federal Government on both quarantine guidelines and efforts to develop a coronavirus vaccine and treatments. These answers must be driven by evidence-based public health expertise.

My first question is actually directed to both of you. Innovative companies, both large and small, are working to develop vaccines, therapeutics, better diagnostics, and are lending their expertise from previous pandemics. Moderna, Johnson & Johnson,

GlaxoSmithKline (GSK), Takeda, Sanofi, Merck, Gilead, Regeneron, Roche, and others are included in this all-hands-on-deck effort. Newer innovators like Arizona's own Phoenix Biometrics have also submitted information to the CDC to evaluate their biosensor technology to detect airborne viruses.

But once a vaccine is approved, what will the prioritization strategy be for its deployment, specifically targeting vulnerable populations such as seniors and those with underlying health conditions? Also, what about front-line workers at our Border Patrol stations, our ports of entry, or health care workers, and our servicemembers who are stationed abroad in hard-hit countries?

Dr. KADLEC. Ma'am, I will take the first shot at this, and, quite frankly, we have actively been reaching out to innovative companies, and at BARDA and ASPR, we actually have met with over 1,500, engaged 1,500 commercial entities and universities and the like. So we would be delighted to receive a white paper or any suggestions from your folks on this, and I will be very happy to provide that information as well.

I think the key thing here is we are looking across the domain. BARDA yesterday put out—and my Director of BARDA is behind me, if I am right; still behind me. Basically, they put out a broad area announcement to basically look for innovative ideas across the spectrum of medical countermeasures. So, again, there is a way to both physically and, if you will, electronically engage in that area.

Subject to the issue of the vaccine, clearly that is not an imminent possibility. From earlier conversations, it is 12 months to more like 18 months when we would have something, and the scale of that availability will be dependent on the kind of vaccine that will be developed. Right now there are primarily three candidates that are being considered: Moderna is one, Johnson & Johnson is another, and then there is Sanofi as well as the third. So much of what will be available will be determined on the prioritization you identify. Clearly, there is a national security component of this, what would we need to protect our forces. There is also the criticality of how do we protect the people on front lines like health care workers. Then as you highlighted, the vulnerable populations, which are significant in our country, but still—and so that all has to be factored into that. Again, those are, I think, answers yet to be determined based on, like you said, the best evidence and scientific answers that we can come up with in the time that we have.

Senator SINEMA. OK.

Mr. CUCCINELLI. With respect to the prioritization, you can expect to see, when we reach that point, what I would call a "traditional prioritization," and you mentioned it yourself, Senator. High-risk categories, the mortality rate if you are over 60 and have a secondary condition is much higher than if you are under 50. And so limited supply will be funneled to the priority categories as typically happens already.

We are also going to have to work through exactly the kind of challenges you describe, the force protection as well as front-line law enforcement and first responders, the people who come face to face—and health care workers. I am sure you are familiar with the sort of—the first doctor in China to really speak publicly about this has now passed away. He was an otherwise healthy 34-year-old.

But health care workers are a limited resource in the sense that nothing any of us are going to do here will make more health care workers to fight this battle. So they get priority to care for them because we need them to care for everyone else. And that priority will go forward, and it will be similar for first responders. So you can fully expect to see that play out, and in your State, as a border State, that will include Border Patrol agents and so forth who man those posts and deal with people who do not come in with documentation, who do not come in with medical histories.

Senator SINEMA. Right.

Mr. CUCCINELLI. And we have to be very cautious in those circumstances. And, frankly, one or two people in a facility like that can wipe that facility out for utility purposes.

Senator SINEMA. All right. Thank you.

Mr. CUCCINELLI. Yes, ma'am.

Senator SINEMA. My second question is for Dr. Kadlec. The FDA recently announced it will allow more types of respirators to be used by health care personnel as part of the coronavirus response to address shortage concerns. This week, Senator Deb Fischer and I introduced the Health Care Workforce Protection Act. It addresses manufacturer liability concerns by amending the Public Readiness and Emergency Preparedness (PREP) Act to include respirators that are certified by the National Institute for Occupational Safety and Health.

Could you talk a little bit about some of the coordination efforts that your office is leading to ensure adequate supplies of protective equipment, including efforts to incentivize manufacturers to increase production?

Dr. KADLEC. Thank you, ma'am, for that question. That is a critical issue that has to be addressed. I happened to be on the Health, Education, Labor and Pensions (HELP) Committee at the time when the PREP Act was originally considered and enacted, so I have firsthand experience. And one thing that we did not consider at that time, quite frankly, is the situation we have here right now, which is then we thought a pandemic of influenza would be the principal threat we would have to confront. And with that we focused a lot on the idea of medical countermeasures that would be necessary to protect our front-line health care workers and vulnerable populations—vaccines, therapeutics like antivirals, and diagnostics and the like. And, again, and with that, the PREP Act was focused on those particular things and did not include respirators.

So that was 15 years ago, a little bit of oversight, but has significantly implications today. I want to thank you for introducing that bill with Senator Fischer and acknowledge that in the House there is a companion bill with Representatives Bacon and Tonko, and I would hope that Congress would make action on it. We did try to make an effort to have it included in the supplemental language but were unable to. But this is vital, I think, for the producers of these products who, as you pointed out, the Food and Drug Administration gave an Emergency Use Authorization which allows nonmedical N95 respirators to be used by the health care industry. That is vital to do that.

We have a requirement that for health care workers, depending on how severe this outbreak is, for a billion to a couple of billion N95 respirators, and there is no physical way that we can produce those respirators, particularly the medical ones, which are important particularly in the use in the operating room, intensive care units, that are splash resistant. But we can use other ones that are used by industry which are not splash resistant that could be used in other health care settings that would incredibly expand our ability to protect front-line health care workers, because right now the only thing we have is that personal protective equipment to protect our front-line health care workers and first responders, so thank you.

Senator SINEMA. Thank you.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator Sinema.

Senator Hassan has a couple extra questions.

Senator HASSAN. I appreciate this very much, Mr. Chair, and I appreciate our witnesses' stamina because I know you started at 8 o'clock this morning with an all-Senators briefing.

Look, I just wanted to circle back, Mr. Cuccinelli, to something you had talked about on the cruise ship issue. We learned some lessons from the Diamond Princess, right? The first positive test I think was February 1 on that ship. It took several days, at least, before a quarantine was implemented. At the end of the day, there were 3,700 people on board; 700 tested positive, 6 deaths. And so we determined, I thought, that it was not a good idea, if there is a positive result on a cruise ship, to keep everybody on that cruise ship together.

Now, apparently, from news reports and a little bit of what you said in response to Senator Scott, we are hearing that there is a cruise ship off California, which, to Senator Harris' point, has 40 million people, lots of military bases, lots of hospitals, lots of health care and public health facilities, and yet we do not seem to have a protocol to get those folks off the ship into quarantine in a way that would minimize the spread of infection.

So I am just curious and concerned that, given the example of the Diamond Princess and what we thought we learned, we do not seem to have a protocol in place right now that is clear.

Mr. CUCCINELLI. So, first of all, let us be clear about what we learned. That was a bad quarantine. That was not a successful quarantine situation, and not just because the virus spread. That was a secondary effect of a bad quarantine. So the lessons we learned there were negative lessons. I am sure that does not surprise you.

Senator HASSAN. No, but that is my point. And it is sounding from news reports that what happened on the Diamond Princess is being repeated on this ship off the coast of California.

Mr. CUCCINELLI. So the initial assessment with the Diamond Princess before the spread accelerated was that the safest thing for all the passengers was to hunker down.

Senator HASSAN. Right.

Mr. CUCCINELLI. It was to isolate in place. And because the quarantine was not maintained effectively, that did not hold. Had it been done well, it would have been the right course. And so we do

not want to obviously use one bad example to set the rule for everything else, and that is why we have flown test kits out to the ship. Literally as we are speaking, that is going out, so that we have greater clarity on exactly what we are contending with. And we will do, as we did—you may remember the cruise ship that went out of Bayonne, New Jersey. It seems like a long time ago now. But when that one came back, we basically investigated the circumstances on the ship and designed an offload strategy for that ship under those circumstances, and this was the Captain of the Port working very smoothly with the regional head for CDC there, and then last, but not least, brought those who were suspected of infection off the ship separately to prearrange the local health care facilities.

Now, we could do that because it was four people. If you start putting zeros on that number with a heavy suspicion they are positive, you can overwhelm local health care capacity.

Senator HASSAN. Understood, and I do not want to belabor the point except to say this: It is not as if we have to take all of the people who have tested positive on a cruise ship off and send them to one local health care facility. We are the United States. We have lots of them. Some States are being hit a lot more than others. And I just think it is important that we have protocols in place. I understand the importance of factual, case-based determinations.

Mr. CUCCINELLI. Sure.

Senator HASSAN. But it seems like there is some confusion going on here. So that is just an observation. I appreciate the response. But we have the whole country available to us, and we do not have to worry about overwhelming a single point.

Mr. CUCCINELLI. If I just could, we do not. There is a misconception about the capacity we could put together for quarantining, and, frankly, Dr. Kadlec is better positioned than I, but this is an important misconception that I think would be helpful for this Committee——

Senator HASSAN. Why do we not address that, Dr. Kadlec? Because if we do not have the capacity, knowing now for at least a couple of months that a highly contagious virus, not as lethal as some but a highly contagious virus, was heading our way in all likelihood, what is our quarantine capacity then and what do we need to do to increase it? I know that in my State we have the capacity on a State level to quarantine when we need to. So why don't you address that?

Dr. KADLEC. Ma'am, we do not have the quarantine or isolation capabilities or even the treatment capabilities to kind of manage these things. Even though we have made investments for Ebola, for example, it has been really on the single-digit kind of events. And, fortunately, we had that capacity, as modest as that is, where we had only a couple dozen of isolation beds that we could use for an Ebola-like disease that we could use here, and we maxed out that capacity, particularly at the University of Nebraska, where they have 12 beds and they expanded it to 16 beds for us to basically help take care of the most seriously at-risk personnel from the Diamond Princess.

So I think there is another area for, I think, Congress to consider. How do we do this in the future given the nature of what

we experienced? And to the Chairman's point, this is not the last one. There will be another one behind it as——

Senator HASSAN. How do we ramp up now if we need to is the other thing, because, again——

Dr. KADLEC. Yes, ma'am.

Senator HASSAN. We are Americans. We know how to do things. And we do hard things, and we can ramp up capacity. We have a lot of resources, and we have a lot of smart and able people, and we are good people who want to take care of each other. So let us figure this out.

One other question, just to follow up on something Senator Harris was touching on. As we know, a lot of people who should stay home if they get sick, to Senator Harris' point, cannot stay home and still feed their families and pay the rent. So I wanted, Dr. Kadlec, just to follow up with you on a question I posed earlier this week in one of our briefings. Sometimes the Federal Government invokes authorities to help those in need during a natural disaster by, for instance, providing Supplemental Nutrition Assistance Program (SNAP) benefits and Temporary Assistance for Needy Families (TANF) to go beyond those typically eligible. Since we know many of our citizens cannot afford to miss a day of work and they face very real financial burdens, have you considered providing similar support during a public health emergency?

Dr. KADLEC. Ma'am, HHS, and Secretary Azar, is exploring all these options honestly to ensure those who need care or assistance can receive it. And assuming funding, potentially through a supplemental, HHS does have authorities to not only reimburse hospitals but potentially do these other things. So I think——

Senator HASSAN. So when are we going to have a determination then about whether you are going to do it? Because, again, we have a virus spreading in our country. If people know that they could get SNAP benefits or TANF if they need to stay home, they are more likely right now to self-quarantine when we need them to. So when is the answer going to come?

Dr. KADLEC. Ma'am, I will have to get you a firm answer on that. I will take the question back.

Senator HASSAN. It is a question that has been asked already this week. It is a question that needs an answer. They sent you here to us today, so I would appreciate it as quickly as possible, please.

Dr. KADLEC. Yes, ma'am.

Senator HASSAN. Thank you.

Dr. KADLEC. Thank you.

Chairman JOHNSON. Before I turn it over to Senator Peters, I want to go back to the definition of "quarantine capacity." My guess is we are talking about something pretty strictly defined in terms of its capabilities, medical facility, for very sick people, that type of thing. If we have to, again, if this thing becomes more and more significant, there are things we can do. It may not be a perfectly defined quarantine facility, but you can still do things. Can you just define—when you are saying we have limited capacity, I am not denying that. But in what way is it limited?

Dr. KADLEC. Sir, for institutional quarantine we have limited capacities, and, in fact, DOD was vital, instrumental to basically ac-

commodate individuals and disrupt some of their activities, training and otherwise, to——

Chairman JOHNSON. Again, do you know what "institutional quarantine"—what does that mean?

Dr. KADLEC. It is basically having dorm rooms or places where you can put people. Probably the best place you can quarantine people is in their homes. And in the cases of Wuhan and the Diamond Princess, that was not necessarily feasible when you are basically trying to move a large group of people who are representative across the Nation and realize they are at risk and potentially could be at risk to society, you have to put them in one place at one time and monitor them over time. I think if you talk about a distributed approach, the best place to do it—and, again, CDC has been working with State and local authorities to do this—is for people who are particularly being identified in travel screenings at airports is try to get them to maybe their home of record and have them self-quarantine or isolate so that they can be in familiar settings and not put a burden on everyone else.

Chairman JOHNSON. And, again, this discussion, all is dependent on this thing ramping up to a certain level of significance where we would start doing these things. One of the issues of home quarantine is: Will people actually do it? I just read a case of some kid who went out to a party, should have been self-quarantined and here he is out someplace where a lot of people are coming in contact with him.

Mr. Cuccinelli, do you have——

Mr. CUCCINELLI. Yes, so in the Ebola experience, what experts told us is they use this tactic, smaller numbers but it was over 98 percent effective. I just want to give you a sense of scale. I am sorry the Senator left, but, if you just look at the number of people who have been referred by the medical screeners at the 11 funneling airports, and that is it, for home quarantining, that is over 32,000 people in only 11 communities. They are all big cities, but they are not unlimited in their health care capacity. And the logistics of just getting that person safely—and that means the people getting them to the next point must remain safe—from Point A to Point B are very substantial. You just look at the repatriation flights. They were enormously expensive, they were enormous logistical undertakings, and just moving a single person from Point A to Point B becomes a real challenge. And you get local authorities who say, "No, do not move them through here" because of the fear factor.

Chairman JOHNSON. And that is just the beginning of this event. So that would contemplate, if you are really—the only solution might be self-quarantining. I guess there would have to be some kind of penalties at least threatened. Is that something you already have the authority to do? Is that something that Congress would have to pass?

Mr. CUCCINELLI. It is really——

Chairman JOHNSON. Again, this is assuming something becomes far more significant. We are not suggesting it now.

Mr. CUCCINELLI. Yes, but you noted earlier, Mr. Chairman, that we used Federal quarantine here on a scale not used in over 50 years. The last time was smallpox in 1969. Remember smallpox? It

has been that long. The real authority and day-to-day expectation is that local and State authorities are going to make these sorts of decisions because they have the most knowledge about their communities.

Now, I will say the legal authorities vary rather dramatically from State to State and with home-rule States locality to locality. But that is where we expect those to take place, and I will give you an example that one of your colleagues has talked to me about—it is at an airport—and wonders about the economic exceptions, cargo pilots and so forth going into town. Their equivalent of Secretary Alex Azar, the State equivalent—I talked to their Attorney General—has the legal authority to keep them in the plane and to force that company effectively to use two crews, fly in, turn it around, fly out, like we are doing with the Coast Guard with ships frequently. And that is a State authority, and they have the sensitivity to make that decision in the case of their community, because it also has economic impacts, it has all these other impacts that we would rather not impose at the Federal level, being Federalist respecters, on local authorities, but we obviously want them to be engaged. We want them to make those well-informed decisions. We stand with them shoulder to shoulder in walking through those. That is why I was talking to an Attorney General. That is why we were talking to their health commissioner.

Chairman JOHNSON. So the Federal Government's role will be robust in this, but so will the State and local governments' role. And we will certainly be providing resources. We will be advising; we will be providing information, accumulating all that information. But in some of these cases, this will really be dependent on local and State authorities to—OK. That is helpful. Senator Peters.

Senator PETERS. A question regarding the air travel and tracking folks that are traveling. This is both to Mr. Cuccinelli and Dr. Kadlec. Airlines indicate that they do not have all the requisite information that the CDC needs to help trace the spread of viruses. I think it is primarily because passengers only provide a phone number or email when they purchase airline tickets, so it is difficult to track if someone was on that plane and who they were sitting next to and where they have gone.

My question to both of you: Are you aware of the holes in the data between what is provided by travelers when they purchase tickets and what the CBP and airlines provide to the CDC? And should we be looking at that?

Mr. CUCCINELLI. So, yes, and I think we both have elements to speak to on this. There has been a 15-year battle going on with the CDC and the airlines, with CDC trying to get a regulation in place to get what they would say are the five key pieces of data they need to effectively do contact tracing if the need arises. And the airlines have successfully fought it off for 15 years.

The task force dealt with an interim final rule that CDC, in fact, has issued directing the airlines to provide these pieces of information. There is now a logistical gap between right here as we sit here together and when they can have the systems in place to actually do this, because it has to happen at the point of ticket purchase. And, of course, many people have already bought tickets already.

I would also note that airlines are not the only ones that sell us our tickets. We will go to Orbitz or Travelocity and so forth, and they provide even less information to the airline than you or I would provide them if we went to their website or called their sales folks.

So it is very widely varying, and when this broke out, CBP went through their databases, pulled manifest information going back 2 weeks from the then previously existing Wuhan flights. So we are talking about 7,000 passengers over the course of 2 weeks, roughly. And it took CDC time to process through using that information to try to contact those individuals, and what they found is they could only actually ultimately reach about 25 percent of them. And when I say "they," their partners in this were the local and State public health officials. We mentioned already how important they are. This is one of the roles they play, is the investigation.

So what has happened is we evolved, and Senator Johnson and I were talking. In the midst of the changes we were making, only as a practical matter not as a legal matter, where we used that secondary screening, we brought on more contractors and got CDC to give us, meaning the DHS personnel there, their computers, and we started just manually entering this information one person at a time, straight into their system.

Now, since that time, they have been able to contact well over 95 percent of the people they have been trying to contact. And, again, "they" in this situation is heavily weighted to local and State public health authorities. That is who gets this information. CDC works with them, but they are the ones really pulling the oars on this work. So that has changed dramatically, and you can expect, Senator, that when the Instrument Flight Rules (IFR) is functionally in place, not merely legally in place, but the airlines are collecting and delivering this information immediately, we should maintain that level of performance, above 95 percent contact rates.

Chairman JOHNSON. Let me quickly interject because this is from my standpoint one of the prime examples of how responsive the administration has been here. In some of our briefings, I was not getting satisfactory answers out of the CDC. Remember the all-Senator briefing. We talked about that. I am talking to Ken and really in a very rapid period of time—again, you are already on the case—you changed that procedure so you could capture that information. So, again, that is what I am saying. From my own personal experience, this administration has been on top of these issues, grappling with gaps, and then trying to correct them as rapidly as they can correct these issues.

So, anyway, Senator Peters.

Senator PETERS. As we are talking about the cooperation between industry and government and sharing that information, it is also critical that we are doing that in the supply chain as we have talked about here in the hearing throughout the day, that we have to have data as to where things are in the chain.

Dr. Kadlec, information sharing is important, and my question is: Are you receiving the information that you need from interagency counterparts, such as data from manufacturers collected by the FDA to adequately assess supply chain security and where those vulnerabilities are? And if not, what more should we be doing?

Dr. KADLEC. Sir, the way we have organized this—and, again, since FDA has authorities to have that kind of commercial proprietary information, I look to Dr. Hahn to basically provide me his kind of analysis of what is necessary and not getting into the details. So he is part of our team. FDA is embedded in what we are doing. They have the insight authorities to do that kind of work, and we look to them to provide the guidance as well as awareness as to anything that may be awry or at risk.

Senator PETERS. So my understanding is the pandemic influenza plan did not formally address drug delivery devices, such as needles and syringes, which would be important for vaccines, mass vaccines, for example. What steps is HHS taking to ensure that these types of supplies are available to respond to this outbreak?

Dr. KADLEC. Sir, there are a couple of ways. Obviously, you can do it the old-fashioned way and buy it. However, a lot of that material is kind of just-in-time, so the ability to provide, for example, for a pandemic influenza, you may need 600 million or more, more like 800 million needles and syringes to do that. Now, that is a lot of needles and syringes, right?

Mr. CUCCINELLI. Right.

Dr. KADLEC. And so whether or not that can be stockpiled, we have been looking to innovate around that. We have worked with a very innovative company called "Abboject" that is looking to be able to just-in-time mass manufacture a very simplified one-dose, non-reusable needle and syringe. It is quite elegant in its design, and it would be something that could be used not only here domestically during a pandemic, but it could be used around the world, particularly in developing countries.

So what we are looking at is a joint public-private partnership to address that, and with the benefit of the supplemental monies, we intend to actually kind of work to build some capacity to do that using that kind of innovative approach, as well as other innovative approaches like transdermal application or administration of vaccines.

Dr. Bright, who leads BARDA here, has been very successful in their endeavors. There are 53—is that right, 53? Fifty-four. As I was here testifying, we have probably got 54, so my apologies. But the point is really trying to look at innovation to basically help solve some of these very difficult supply chain issues. We do not just have to do it the old way. We can find new ways to do it just as effectively and likely more cheaper as well.

Senator PETERS. Great. Thank you. A final question, Mr. Cuccinelli. Is the Department now considering issuing an emergency declaration under the Stafford Act given what happened, or do we have to wait to see what happens as it develops—maybe you could walk me through that a little bit—to issue an emergency declaration under the Stafford Act that would allow the government to deploy disaster medical teams, incident management teams, mobile hospitals, or transportation support? We have done that in a variety of times in the past with West Nile virus and Ebola, et cetera. Walk me through that, your thinking about that.

Mr. CUCCINELLI. So the answer to the first part of the question is no, but that does not foreclose the use, for instance, of the Incident Management Assistance Teams (IMAT). So just to give you an

idea of some of the work we have been doing, with the time we bought with the strategies we have been using, you are familiar with our IMAT teams at FEMA, Senator, and they are sizable numbers of people. We have reshuffled them down to four-and five-person teams who we provided some additional training to deal with a virus situation versus, say, a hurricane, a tornado in Tennessee that we are dealing with right now. And the reason we did that is because the impact of a virus, unlike a weather event, can be everywhere at once in a worst-case scenario, we created enough stand-alone teams that we could help all 50 States in smaller degree with the kind of support that FEMA brings in terms of experience and so forth. So, again, not sitting idly, those are the kinds of changes we have been making to our structure so we are responsive to what is out there today.

But the Stafford Act does not envision a circumstance like this. I mentioned earlier the availability of the base fund, not the Disaster Relief Fund that really I think you have to go back to the 1990s, and I think it was West Nile. It was New York and New Jersey, if memory serves, that made requests of the base fund to get ahead of, alleviate—the easier example is a forest fire. Hey, if you help us now, we can keep this thing from getting bigger. Same idea. But it has a $5 million cap. It is a waivable cap. And it is designed to avoid rolling damage to a system. In this circumstance, you are probably looking at when a community or a State has its health care system threatened to be overwhelmed because they are getting hit harder than other parts of the country.

So there is some money available for that purpose. I would say the Stafford Act is not really designed for this, and not surprising to you, we have analyzed it for these purposes sort of backwards and forwards. So you are seeing—even those IMAT teams would typically be deployed alongside HHS here and in support of them, and HHS would reimburse us—that is how the budget piece would work—for their deployment, just as they are for the FEMA team that is supporting them at the State Operations Center (SOC) right now.

Senator PETERS. Great. Thank you.

Chairman JOHNSON. Thank you, Senator Peters.

Just real quick, I really need to close this out here pretty quick, but, Dr. Kadlec, who is in control of the Strategic Stockpile?

Dr. KADLEC. Sir, I have operational control, and the Secretary is really the overall—I will not say incident manager, but he is the person in charge at HHS to basically manage this event.

Chairman JOHNSON. So how many items are inventoried in the stockpile?

Dr. KADLEC. Sir, it is about an $8 billion enterprise with——

Chairman JOHNSON. 8 or 80?

Dr. KADLEC. $8 billion.

Chairman JOHNSON. An $8 billion enterprise. How many items? How many SKUs?

Dr. KADLEC. Hundreds of vaccines, therapeutics, all kinds of supplies, masks.

Chairman JOHNSON. So who and how are the inventory levels set?

Dr. KADLEC. Sir, we have requirements that are set that are based on a requirements process. Some of it has been fixated on the basis of what can we buy or can we afford to buy as much as what we may need, particularly——

Chairman JOHNSON. So how close are we to actually having the required levels in inventory now?

Dr. KADLEC. Sir, I would have to give you a detailed kind of answer back on that——

Chairman JOHNSON. OK. Again, that is——

Dr. KADLEC [continuing]. But I think the thing is—it is something—we have a multi-year budget that looks at what we would need to do it, so I think you can look back over the last 5 years as what should be those levels of funding that reflect many of those requirements.

Chairman JOHNSON. So, again, the point was not to get the answer to my question, but to just raise the issue. From my standpoint, in terms of the supply chain and what we need in the stockpile, we have the short-term situation about what we need now and how are we going to procure it, so that if this thing continues to get worse and worse, we have the supplies. And recognize, again, not to create unrealistic expectations, it takes time to manufacture things. And if it is not in the stockpile right now, those are going to be some issues. But, again, I really appreciate your pointing out that our first Strategic Stockpile is the number of doctors and nurses and health care professionals, and that is a finite amount, and so we need to protect them first.

But then long term, I told Senator Hawley on his way out, we do need to take a look at how we fill that stockpile, based on our experience of how this all ends up, what inventory levels should be there, what things should be inventoried, how much money should we spend. Again, I think somebody pointed out the aircraft carrier. This is $8 billion versus $17 billion. Hopefully we learn from this, and I certainly want to use this Committee—and I would imagine you are the person to deal with—in terms of what we need to pass legislatively to make sure that we are better prepared next time. So learn the lessons from this episode and be better prepared.

I will also say to me it is ridiculous—I am a manufacturer. OK? I am all for global supply chains. But when we have an FDA approving drugs for use in America, the fact that we have really put ourselves in a position where—I think it is about 70-some percent of the API comes from India, correct?

Dr. KADLEC. Yes, sir. A lot of it comes from overseas.

Chairman JOHNSON. A lot of stuff comes from China. But, a lot of—that is not a labor-intensive manufacturing process, I would not believe. So there is no reason, I do not believe, that the FDA—OK, if it is an approved drug here, it needs to be manufactured here. We do need to take a look at these things and be smart about this. The way you do it in industry, we need to do the same thing from the standpoint of government as well.

So I really want to work with you. When the dust settles on this, when we get by this event, we have to prepare better, and I think that is going to require legislation and appropriation, but it is going to require thoughtful analysis.

So to close this out, I want to thank all the Committee Members that are not here, but hopefully they will hear it, for their respectful questions, for their attendance. And I want to thank you. I hope the press, I hope the American people are listening to the thoughtful responses. It would give them a fair amount of confidence. This is uncertain. We do not know where this is going to go. But from my standpoint, having dealt directly with members of the administration and people throughout these agencies, first of all, thank the men and women of your agencies, but this is being carefully considered. We are thoughtfully working our way through this process in a very uncertain situation.

So, again, thank you, thank the men and women in your agencies. Again, I really do appreciate the Members of this Committee being very respectful and thoughtful in their questions as well.

The hearing record will remain open for 15 days until March 20th at 5 p.m. for the submission of statements and questions for the record. This hearing is adjourned.

[Whereupon, at 11:38 a.m., the Committee was adjourned.]

APPENDIX

"The Federal Interagency Response to the Coronavirus and Preparing for Future Global Pandemics"
Opening Statement of Chairman Ron Johnson
March 5, 2020

As prepared for delivery:

On December 31, 2019, China first alerted the World Health Organization of a cluster of abnormal health cases in the central Hubei province. What at first appeared to be cases of pneumonia were later revealed to be the emergence of a novel coronavirus, now identified as COVID-19.

In early January, the U.S. began tracking the virus and notifying U.S. clinicians, and established an incident management system. On January 17, the Department of Homeland Security implemented targeted airline passenger health screenings at three airports to detect ill travelers on flights arriving from (or connecting through) Wuhan, China. The Centers for Disease Control and Prevention activated its Emergency Operations Center on January 21, and the President created a Coronavirus Task Force on January 29. On January 31, the President issued an emergency declaration paving the way for DHS to begin funneling all incoming flights from China to eight U.S. airports for entry health screenings and expanding that number to eleven by February 3. Also pursuant to the emergency declaration, on February 2 the U.S. began denying entry into the United States to most foreign nationals who have traveled in China within 14 days of their arrival. The U.S. has continued to adjust travel restrictions as conditions change: it expanded its ban to travel related to Iran, continues to update its guidance and screening for passengers returning from Italy and South Korea, and is monitoring for any necessary changes for other significantly impacted countries.

The World Health Organization states the total number of global COVID-19 infections is 93,090—spanning 77 countries and territories—and 3,198 deaths. As of this morning, the CDC reported 126 cases and 9 deaths across 13 states. To date, the global mortality rate for COVID-19 stands at 3.4 percent, compared to 40 percent for the 2014 Ebola outbreak, 34 percent for the 2012 MERS outbreak, 9.6 percent for the 2003 SARS outbreak, and 0.1 percent for the average U.S. seasonal flu.

The continued spread of the virus should focus us on addressing top priorities. First, we must ensure that we are protecting our medical responders: doctors, nurses, and other medical staff, as well as, first responders at Customs and Border Protection and the Centers for Disease Control.

Second, we need a sufficient supply of testing kits to diagnose persons that have potentially been infected by COVID-19. On February 4, the FDA issued an Emergency Use Authorization for the CDC to develop test kits to be used by qualified public health labs. I hope that we can clarify the administration's strategy for the supply and distribution of testing kits during today's hearing.

Finally, we need to address the insecurity of our medical supply chain, both in the short term to address COVID-19 and in the long term. The virus has produced demand for personal protective equipment approximately 100 times higher than normal, resulting in extremely high

prices and a supply that may be insufficient to meet our needs. Experts have also warned that COVID-19 could result in potential shortages of drugs, as we are over-reliant on active pharmaceutical ingredients manufactured outside the U.S. We will want to hear what actions are being taken to address the current shortage.

Although unique, COVID-19 is not the first disease outbreak that has spread globally and it will certainly not be the last. Our response to each outbreak should help us prepare and protect against the introduction and spread of future global pandemics. It should also help us reflect on the consequences of our reliance on drugs manufactured outside of the U.S. and provide us an opportunity to think long-term about what we need to improve our strategic stockpile and what, if any, steps Congress should take to help increase U.S.-produced, FDA-approved drugs and other necessary medical devices and supplies.

I thank our witnesses for joining us today look forward to addressing these and other questions.

U.S. Senate Committee on Homeland Security and Governmental Affairs
"The Federal Interagency Response to the Coronavirus and Preparing for Future Global Pandemics"

OPENING STATEMENT OF RANKING MEMBER GARY C. PETERS
March 5, 2020
AS PREPARED FOR DELIVERY

Thank you, Mr. Chairman, and thank you to our witnesses for joining us today.

The top priority of this committee, and of your agencies, is very simple: keeping Americans safe. To be clear, this Coronavirus outbreak in the United States is not currently widespread, but it does pose a grave threat to our public health and our homeland security and must be taken seriously.

I am grateful for the efforts of your agencies and public health officials across the country to limit the spread of this contagious virus.

While we have seen a growing number of cases in the United States, we have thankfully not yet seen a widespread outbreak in our country.

It is the job of this Administration to work with Congress and our state and local governments to do everything we can to limit the spread of this virus. We must go above and beyond to prepare for the less likely, but worst case scenario, of more widespread infections.

Accessing clear information about Coronavirus has been a significant challenge for the public. The American people have a lot of questions. They want accurate, reliable information about this virus's spread and what the government is doing to protect their health and safety.

As we have learned from past pandemics, outbreaks like this require an aggressive, coordinated and comprehensive response as well as timely, trusted, and useful guidance from public health and security officials.

In the coming weeks and months, your agencies will play a crucial role in containing the outbreak, educating Americans about the virus, and protecting public health.

Whether your response is timely and effective will truly be a matter of life and death. With that in mind, I appreciate you joining us today to give my constituents in Michigan and the American people clear answers to the pressing questions they have about this virus.

I look forward to hearing about what steps your departments are taking to ensure that we have the right plans and resources in place to limit the spread of this highly contagious virus and keep Americans safe.

TESTIMONY

OF

KEN CUCCINELLI II

SENIOR OFFICAL PERFORMING THE DUTIES OF THE DEPUTY SECRETARY

U.S. DEPARTMENT OF HOMELAND SECURITY

REGARDING A HEARING ON

"THE FEDERAL INTERAGENCY RESPONSE TO THE CORONAVIRUS AND PREPARING FOR FUTURE GLOBAL PANDEMICS"

BEFORE THE

UNITED STATES SENATE COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

March 5, 2020

Washington, D.C.

Introduction

Chairman Johnson, Ranking Member Peters, and distinguished Members of the Committee. It is my honor to appear before you today with my interagency partners to testify about the work the Department of Homeland Security (DHS) is doing to respond to the current outbreak of Coronavirus Disease 19, known as COVID-19.

Let me first say that I am very proud of the work that the men and women of DHS and our partners at the Department of Health and Human Services (HHS) and across the government are doing to contain the spread of the disease, slow the spread of the disease, and to prepare for a domestic response. The Department's top priority is the safety and security of the American people, and we are committed to an aggressive, proactive, and preemptive whole-of-government response in fulfillment of our mission. As required by Congress, in 2018, President Trump signed the first ever "National Biodefense Strategy" to build upon our ability to rapidly respond to and limit the impacts of bioincidents like the one we are facing now. We are seeing that strategy pay dividends as we implement a whole-of-government response to this disease.

Additionally, the operational coordination and cooperation between HHS and DHS dates back to a 2005 Memorandum of Understanding (MOU) enhancing preparedness against the introduction, transmission, and spread of quarantinable and serious communicable disease into the United States. Our combined experience and long-standing relationship, continues to be beneficial today. Across the air, land, and maritime domains, DHS has taken and continues to take proactive measures to address COVID-19.

Protecting Americans through our Efforts at Air Ports of Entry

DHS is taking action at airports of entry to support HHS in slowing the spread of the novel coronavirus. DHS is working to decrease the workload of public health officials, expedite the processing of U.S. citizens returning from China, and, above all, ensure that resources are focused on the health and safety of the American people.

On January 31, 2020, the Secretary of Health and Human Services declared COVID-19 a public health emergency in the United States, and the President signed a Presidential Proclamation using his authority pursuant to Section 212 (f) of the Immigration and Nationality Act to suspend the entry into the United States of foreign nationals who pose a risk of transmitting the virus. As of 5 p.m. Eastern Standard Time on February 2, 2020, foreign nationals, other than immediate family of U.S. citizens and lawful permanent residents and other individuals falling within narrow exceptions to the Proclamation, who were physically present in the People's Republic of China, excluding Hong Kong and Macau, within the previous 14 days will be denied entry into the United States. On February 29, 2020, President Trump expanded this Proclamation to also include most foreign nationals who have been in Iran within the previous 14 days.

DHS, including U.S. Customs and Border Protection (CBP) and the Transportation Security Administration (TSA), continues to work very closely with our partners at the Centers for Disease Control and Prevention (CDC) to route all admissible persons who have been in

mainland China and Iran in the previous 14 days to one of 11 designated ports of entry where the Federal Government has focused public health resources.

Any admissible person who has been in Hubei province, China in the previous 14 days is subject to up-to-14 days of mandatory quarantine where CDC has made arrangement with state and local authorities to ensure they are provided proper medical care and health screening. Any admissible person who has been in the rest of mainland China or Iran within the previous 14 days undergoes proactive entry health screening at one of these airports and, if they are asymptomatic, up-to-14 days of self-monitoring to ensure they have not contracted the virus and do not pose a public health risk.

DHS continues to facilitate enhanced health screening of travelers entering the United States who have recently been in China or Iran. Travelers identified by CBP officers during their primary inspection are referred to a secondary screening area, where contractor personnel (through agreements by the DHS Countering Weapons of Mass Destruction Office (CWMD)) conduct enhanced entry screening. Travelers who have been in Hubei province, China within the previous 14 days or who exhibit symptoms consistent with COVID-19 are sent to CDC for tertiary screening and consideration for quarantine. Between February 2 and March 2, CBP referred 53,012 air travelers for secondary screening by the CWMD contract personnel at the 11 funneling airports. Of these, 74 individuals required referral to the CDC for medical evaluation. At all airports of entry, CBP officers continue to remain alert and notify CDC and other public health officials when encountering passengers exhibiting signs of overt illness, regardless of their travel history.

We realize these actions could prolong travel times for some individuals; however public health and security experts agree these measures are necessary to contain the spread of the virus and protect the American people. To minimize disruptions, CBP and the air carriers are working to identify qualifying passengers before their scheduled flights.

DHS CWMD is currently supporting CDC's enhanced entry screening efforts through agreements with state, local, or private sector Emergency Medical Services, public health, and first responder personnel at all 11 designated airports of entry for passengers who have been in China or Iran within the previous 14 days. CWMD established this capability in response to the Ebola virus threat that was emerging in the Democratic Republic of the Congo last summer. These actions ensured a trained, vetted, and badged workforce was ready to rapidly deploy to support the CDC with airport screening operations. DHS was able to adapt this capability to quickly address the threat of COVID-19 and support CDC's enhanced health screenings in the national interest.

CWMD is also providing direct support to CDC's effort to collect passenger information at all 11 airports, allowing CDC to provide direct information to state and local public health officials to facilitate contact tracing efforts. CWMD's efforts have significantly increased the accuracy of the data collected.

Protecting Americans through our Efforts at Land and Sea Ports of Entry

CBP and the United States Coast Guard (USCG) continue their work to recognize, detect, and assist individuals arriving in the United States through our land ports and waterways who may be carrying the virus. In coordination with the CDC and USCG, CBP has measures already in place at all ports of entry to identify travelers with overt signs of illness who may be potentially infected with a communicable disease and to minimize the risk to the traveling public.

USCG continues to review all "Advance Notice of Arrivals" 96 hours in advance of the scheduled arrival of a ship in port in accordance with its current policies. The Captain of the Port will communicate any concerns stemming from sick or deceased crew or passengers to their Coast Guard chain of command and the cognizant CDC quarantine station, who will coordinate with local health authorities. This process has been working smoothly across the country.

To ensure continued facilitation of international trade, non-passenger commercial vessels that have been to China (excluding Hong Kong and Macau) or Iran or embarked crewmembers who have been in China (excluding Hong Kong and Macau) or Iran within the previous 14 days, with no sick crewmembers, may be permitted to enter the U.S. and conduct normal operations, with restrictions. Crewmembers on these vessels will be required under Captain of the Port authority to remain aboard the vessel except to conduct specific activities directly related to vessel cargo or provisioning operations.

At and between land ports of entry, CBP is identifying persons with recent (within 14 days) travel to China or Iran and making appropriate referrals to CDC or the local health system. Between February 13 and February 24, CBP referred 2,019 travelers from China for potential screening at the three largest U.S. land ports of entry with recent travel history to China - Blaine, WA, San Ysidro, CA and Buffalo, NY.

Monitoring the Disease

DHS and its Components were well-prepared to take proactive and preemptive action to mitigate the threat, minimize risk, and slow the spread of the virus by working closely with CDC and other interagency partners as cases of the virus in China began to increase. The National Biosurveillance Integration Center (NBIC) within DHS CWMD began tracking an outbreak of unidentified viral pneumonia in Wuhan, China on January 2, providing early situational awareness on what we now know is COVID-19. NBIC continues to generate and distribute daily updates to thousands of federal, state, and local partners to apprise them of the situation. NBIC further supports CDC and CBP operations by analyzing passenger travel data relevant to the movement of persons out of the impacted area. These interagency analyses of flight data, in conjunction with operational considerations, helped inform the selection of U.S. airports for enhanced health screening for coronavirus.

COVID-19 is an emerging disease and there is much more to learn about its transmissibility, severity, and other characteristics. The DHS Science and Technology Directorate's National Biodefense Analysis and Countermeasures Center has received a stock of the virus and is collaborating with CWMD on a research effort to address critical information gaps regarding the environmental stability of the virus and its susceptibility to common disinfecting agents. This augments the important work and research that others across the government and within the health community are doing to achieve better understanding of this new and emerging threat.

DHS Workforce Protection

The DHS workforce is our greatest asset, and every precaution is being taken to keep our workforce safe, especially for our USCG, TSA, CBP, and U.S. Immigration and Customs Enforcement officers and agents on the front lines. Ensuring that these individuals, and all DHS personnel remains safe and healthy is critical, and immediately upon the onset of COVID-19 as a global concern, the Department proactively took action.

The DHS Management Directorate has established a workforce protection command center to ensure that protective procedures are in place for the front-line workforces who may regularly encounter potential disease carriers and is working with all DHS components to assess their readiness. Some current precautionary measures for these officers include providing gloves, masks, and hand sanitizer.

Although the most recent CDC guidance does not recommend changes to routine security screening operations or respiratory protection, TSA is authorizing frontline personnel, whose security screening tasks require routine, close contact with the traveling public, to wear surgical masks if they choose to do so. CBP personnel have access to personal protective equipment (PPE) as part of their normal operations at all ports of entry and have been provided guidance in case of exposure to a contagion. CBP issued an updated Job Hazard Analysis on February 5, 2020, to all employees that outlines the current comprehensive PPE guidance, which includes guidance about wearing masks under the appropriate circumstances.

DHS continues to share information with the workforce on an ongoing basis. Our workforce protection command center is in close coordination with federal health partners and Component health and safety officials. Furthermore, the Chief Medical Officer (CMO) in DHS CWMD continues to advise DHS leadership on the ongoing health threat and its impact on workforce health.

Supporting the Interagency

As the lead federal agency for coronavirus response, HHS leads outreach to state, local, tribal and territorial public health and safety officials on the outbreak status and the U.S. public health response. In support of HHS, DHS provides information to ports of entry on the risks of COVID-19, advising that front-line personnel be alert for individuals who may have come from

an infected region. TSA has been working with select airlines to notify travelers on the risks of potentially contracting the communicable disease in Wuhan. CBP has posted travel notices at land border crossings informing passengers about the virus. Finally, the USCG has issued a Marine Safety Information Bulletin to maritime industry partners advising of required reporting of illnesses or deaths onboard arriving commercial vessels and delineating conditions whereby vessels may be denied entry into the United States.

CWMD, which includes the DHS CMO, continues to work with the USG interagency, state/local public health agencies, non-governmental organizations, the Governments of Mexico and Canada, and private industry partners/stakeholders on medical and public health coordination and information sharing.

Additionally, the Cybersecurity and Infrastructure Agency (CISA) has been assessing the National Critical Functions for potential impacts to infrastructure and systems from COVID-19 and is working closely with private sector owners and operators to identify issues of concern and ensure continuity of these critical assets in the event that COVID-19 reaches pandemic levels and the United States sees significant community spread.

As of February 12, DHS has been augmenting the HHS Secretary's Operations Center with personnel from FEMA, DHS HQ, USCG, CWMD, and CISA, who are assisting the HHS-led interagency response through increased support and coordination.

FEMA is providing support to HHS as the lead federal agency in the areas of incident management, resource planning, and Federal interagency coordination. Additionally, FEMA remains postured to support HHS with consequence management to anticipate any potentially necessary mitigation actions. This ongoing planning effort is similar to the experience with past outbreaks of Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), caused by similar viruses.

Conclusion

The American public can be assured that DHS and its component agencies are taking decisive action to analyze the threat, minimize risk, and slow the spread of the virus by working closely with CDC health professionals and interagency partners involved in this whole-of-government effort.

I want to thank you, Chairman Johnson, Ranking Member Peters, and the members and staff of this committee for the support you have shown the Department and the government's effort to respond to COVID-19.

I look forward to your questions.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Federal Interagency Response to the Coronavirus and Preparing for Future Global Pandemics

Witness appearing before the
Senate Homeland Security and Governmental Affairs
Committee

Robert Kadlec, M.D., Assistant Secretary for Preparedness and Response

Testimony of the Department of Health and Human Services on COVID-19

Since President Trump took office, his work to protect the health and safety of the American people has included a specific focus on monitoring, preparing for, and responding to biological threats, such as infectious disease outbreaks. As soon as the United States became aware of a novel coronavirus at the end of 2019, the U.S. Government was tracking its spread and began preparing necessary responses.

Within the first two weeks of China's initial report of the outbreak in December 2019, China reported 45 pneumonia cases and two deaths. . More recently, there has been an increase in cases outside of China.

COVID-19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans. This new disease, officially named Coronavirus Disease 2019 (COVID-19) by the World Health Organization (WHO), is caused by the SARS-COV-2 virus, which is in the same family of viruses as that cause the common cold, There are many types of human coronaviruses including some that commonly cause mild upper-respiratory tract illnesses. Coronaviruses are a large family of viruses. Some cause illness in people, and others, such as canine and feline coronaviruses, only infect animals. Rarely, animal coronaviruses that infect animals have emerged to infect people and can spread between people. This is suspected to have occurred for the virus that causes COVID-19. Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) are two other examples of coronaviruses that originated from animals and then spread to people.

The potential global public health threat posed by this virus is high, but right now, the immediate risk to most Americans is low. The greater risk is for people who have recently traveled to an affected country or been exposed to someone with COVID-19.

On January 29, 2020, President Trump announced the formation of the President's Task

Force on the Novel Coronavirus, which is chaired by the Secretary for Health and Human Services and coordinated through the National Security Council. The President's Task Force is composed of subject matter experts from the White House and several United States Government agencies, and it includes some of the Nation's foremost experts on infectious diseases. The Task Force is leading the Administration's efforts to monitor, contain, and mitigate the spread of COVID-19 while ensuring that the American people have the most accurate and up-to-date information to protect themselves and their families.

The President's top priority is the health and welfare of the American people, and his Administration has made it a priority to prepare for infectious disease outbreaks that can cross borders. In 2018, President Trump launched the National Biodefense Strategy, which lays out a framework for coordination among agencies, with the Secretary of the U.S. Department of Health and Human Services (HHS) as Chair of the Biodefense Steering Committee, and helps identify gaps in preparedness and response. As the situation around the new coronavirus evolves, the Administration will continue its coordinated response, in collaboration with state and local governments and the private sector, and adjust its positioning as needed.

Within HHS, the Centers for Disease Control and Prevention (CDC), the Assistant Secretary for Preparedness and Response (ASPR), the National Institute of Allergy and Infectious Diseases (NIAID), and the Food and Drug Administration (FDA) play critical roles in responding to COVID-19 by preventing and slowing the spread of the disease, assisting repatriated Americans, protecting the supply of food, drugs, and devices, and developing diagnostics, therapeutics, and vaccines.

Centers for Disease Control and Prevention

In late December 2019, Chinese authorities announced a cluster of pneumonia cases of unknown etiology centered on a local seafood market in Wuhan, China, with an estimated case

onset in early December. CDC immediately began monitoring the outbreak, and within days – by January 7, 2020 – had established a Center-led Incident Management Structure. On January 21, 2020, CDC transitioned to an Agency-wide response based out of its Emergency Operations Center. This allows CDC to provide increased operational support to meet the outbreak's evolving challenges and provides strengthened functional continuity to meet the long-term commitment needed to curb the outbreak.

CDC is assisting ministries of health in countries in every region of the globe with their most urgent and immediate needs to prevent, detect, and respond to the COVID-19 outbreak.

CDC's most expert and practiced infectious disease and public health experts are dedicated to this response 24/7 to protect the American people. CDC is a disease preparedness and response agency, and this work is fundamental to our mission both domestically and internationally. The Agency's approach to COVID-19 is built upon decades of experience with prior infectious disease emergencies including responses to SARS, MERS, and Ebola, and to pandemic influenza.

To mitigate the impact of COVID-19 within the United States, CDC is working alongside Federal, state, local, tribal, and territorial partners, as well as public health partners. This public health response is multi-layered and includes aggressive containment and mitigation activities with an objective to detect and minimize introductions of this virus in the United States so as to reduce its spread and impact. It is impossible to catch every single traveler returning from an affected country with this virus – given the nature of this virus and how it's spreading. Our goal continues to be slowing the introduction of the virus into the United States as we work to prepare our communities for more cases and possible sustained spread

To accomplish this, CDC is also working with multiple countries, in collaboration with U.S. Agency for International Development (USAID) and other federal agencies and WHO to

support ministries of health around the globe to prepare and respond to the outbreak. For example, the U.S. Government is helping to support countries to implement recommendations provided by WHO related to the identification of people who might have this new infection, diagnosis and care of patients, and tracking of the outbreak. CDC staff are also starting to work together with interagency colleagues in those countries to conduct investigations that will help inform response efforts going forward.

The Agency is using its existing epidemiologic, laboratory, and clinical expertise to gain a more comprehensive understanding of COVID-19. CDC is leveraging prior programmatic investments in domestic and global public health capacity and preparedness to strengthen the Agency's response to COVID-19. Thus far, this response has been built largely on the foundation of our seasonal and pandemic influenza program's infrastructure. The ongoing response to COVID-19 also demonstrates CDC's continued commitment to strengthen global health security. CDC has been engaged in global health security work for over seven decades. Thanks to investments in Global Health Security, the U.S. Government's work has helped partner countries build and improve their public health system capacity. This global effort strengthens the world's ability to prevent, detect, and respond to infectious diseases like this new coronavirus.

This outbreak also underscores the need for the United States to continue to play a leadership role on the global stage, and to strengthen global capacity to stop disease threats at their sources, before they spread. Furthermore, the outbreak demonstrates the importance of continued investment in our nation's public health infrastructure. Despite years of progress in domestic disease prevention and response, efforts to help modernize our federal, state, and local capability and health systems that are crucial to responding to and understanding unprecedented threats continue.

The U.S. Government has taken unprecedented steps to prevent the spread of this virus and to protect the American people and the global community from this new threat and allow State, local, territorial, and private partners time to prepare for any necessary response and mitigation activities. Since February 2, 2020, pursuant to arrival restrictions imposed by the Department of Homeland Security, flights carrying persons who have recently traveled from or were otherwise present within mainland China or other affected countries have been funneled to designated U.S. airports with CDC quarantine stations. At these airports, passengers are subject to enhanced illness screening and self-monitoring with public health supervision up to 14 days from the time the passenger departs the affected country. This enhanced entry screening serves two critical purposes. The first is to detect illness and rapidly respond to symptomatic people entering the country. The second purpose is to educate travelers about the virus and what to do if they develop symptoms.

These measures are part of a layered approach which includes our other core public health efforts, including aggressively tracking COVID-19 around the globe, building laboratory capacity, and preparing the national healthcare system for community spread. These core capabilities and expertise are essential to CDC's comprehensive approach to addressing this outbreak.

While CDC believes that the immediate risk of this new virus to the American public is low, CDC is preparing the nation's healthcare system to respond to identification of individual cases and potential person-to-person transmission of COVID-19 in the community, at the same time ensuring the safety of its patients and workers. CDC has developed guidance on appropriate care and infection control for patients with COVID-19 and is engaging regularly with clinical and hospital associations to confirm that its guidance is helpful and responsive to the needs of the healthcare system.

Furthermore, understanding the current constraints of the global supply of personal protective equipment (PPE), CDC is working with industry and the U.S. health system to comprehend possible effects on facilities' abilities to procure the needed levels of PPE, and to provide strategies to optimize the supply of PPE.

Effective disease surveillance enables countries to quickly detect outbreaks and continuously monitor for new and reemerging health threats. CDC continues to monitor the COVID-19 situation around the world.

CDC has begun working with domestic public health laboratories that conduct community-based influenza-like illness surveillance and leveraging our existing influenza and viral respiratory surveillance systems so that we may begin testing people with flu-like symptoms for the SARS-COV-2 virus. HHS is developing plans to expand this effort.

This collaboration with domestic public health labs is another layer of our response that will help us detect if this virus is spreading in a community. All of our efforts now are to prevent the sustained spread of this virus in our communities, but we need to be prepared for the possibility that it will spread. Results from this surveillance could necessitate changing our response strategy.

CDC has issued guidance for people at high risk of exposure to the virus, including flight crews, recent travelers to China, and healthcare workers. Through its extensive Health Alert Network, CDC shared guidance for clinical care for healthcare professionals and state and local health departments. Health departments, in consultation with healthcare providers, can evaluate patients and determine whether someone may have the illness and should be subjected to additional diagnostic testing.

CDC has a demonstrated record of innovative science and evidence-based decision-making, and an experienced and expert workforce that is working 24/7 to combat this public health emergency. The COVID-19 outbreak is evolving rapidly, and the U.S. Government is constantly making adjustments to respond to the changing nature of this public health emergency. Our goal continues to be slowing the introduction of the virus into the United States and preparing our communities for more cases and possible sustained spread. While leaning forward aggressively with the hope that we will be able to prevent community spread, CDC remains vigilant in confronting the challenges presented by this new coronavirus.

Assistant Secretary for Preparedness and Response

Currently, there are no vaccines or therapeutics approved by the FDA to treat or prevent novel coronavirus infections. The Biomedical Advanced Research and Development Authority (BARDA), part of ASPR, is working with counterparts across the government, including within HHS and with the Department of Defense (DOD). The team is reviewing potential vaccines, treatments, and diagnostics from across the public and private sectors to identify promising candidates that could be developed to detect, protect against, or treat people with coronavirus infections. BARDA is working closely across the U.S. Government to assess and identify potential partners and technologies suitable to address the COVID-19 outbreak – both for

prevention and treatment.

This has allowed BARDA to leverage existing partnerships, accelerating the development of COVID-19 medical countermeasures, including diagnostics, therapeutics, and vaccines. Established partners, including Regeneron, Janssen, and Sanofi Pasteur, have shown success in developing both prophylactic and therapeutic medical countermeasures for emerging infectious diseases.

BARDA is collaborating with Regeneron to leverage their partnership agreement to develop multiple monoclonal antibodies that, individually or in combination, could be used to treat this emerging coronavirus. Regeneron's monoclonal antibody discovery platform, called VelocImmune, was used to develop a promising investigational three-antibody therapeutic which was deployed to treat Ebola in the most recent outbreak in the Democratic Republic of the Congo, and an investigational two-antibody therapeutic to treat MERS. The technology shortened multiple aspects of the product development timeline for therapeutics to treat MERS and Ebola from years to months. The technology helped shorten certain stages of drug development, including the process of antibody discovery and selection, preclinical-scale manufacturing, and clinical-scale manufacturing. BARDA and Regeneron are working to utilize these monoclonal antibodies, produced by a single clone of cells or a cell line with identical antibody molecules, which will bind to certain proteins of a virus, reducing the ability of the COVID-19 virus to infect human cells.

BARDA is working with Janssen to leverage their Ebola, Zika, HIV vaccine platform to expedite development of vaccines that protect against the SARS-CoV-2 virus. Using existing resources, BARDA will share research and development costs and expertise with Janssen to help accelerate Janssen's investigational COVID-19 vaccine into clinical evaluation. Janssen will also scale-up production and manufacturing capacities required to manufacture the candidate vaccine.

This same approach was used to develop and manufacture Janssen's investigational Ebola vaccine with BARDA support; that vaccine is being used in the Democratic Republic of the Congo as part of the current Ebola outbreak response. Additionally, BARDA and Janssen are working together to help develop treatments for coronavirus infections. Janssen will conduct high throughput screening on thousands of potential antiviral compounds in order to identify medicines that could safely and effectively be used to reduce the severity of illness and treat COVID-19 infections, as well as identify compounds that have antiviral activity against SARS-CoV-2 as an initial step in developing new treatments. These products include those in development to treat and prevent MERS or SARS, which are caused by coronaviruses also related to COVID-19.

Finally, in their work with Sanofi Pasteur, BARDA is able to leverage a licensed recombinant influenza vaccine platform to produce a recombinant SARS-CoV-2 vaccine candidate. The technology produces an exact genetic match to proteins of the virus. DNA encoding the protein will be combined with DNA from a virus harmless to humans, and used to rapidly produce large quantities of antigen which stimulate the immune system to protect against the virus. The antigens will be separated and collected from these cells and purified to create working stocks of vaccine for advanced development.

BARDA has initiated early steps of medical countermeasures development with partners and will continue to work to accelerate this process. Availability of these medical countermeasures is essential to save lives and protect Americans against 21st century public health threats.

Our nation's healthcare system is better prepared than it has ever been. For example, all 50 states have Pandemic Plans, as a requirement of CDC's Public Health Emergency Preparedness Program (PHEP) and ASPR's Hospital Preparedness Program (HPP). HPP was

established after the September 11, 2001, terrorist attacks, with the goal of improving the capacity of local hospitals across the country to deal with disasters and a large influx of patients in an emergency. Using HPP funding, state grantees initially purchased equipment and supplies needed for emergency medical surge capacity. Over time, the program has successfully evolved to support local, coordinated healthcare coalitions, including hospitals, public health facilities, emergency management agencies, and emergency medical services providers. Investments administered through PHEP and HPP have improved individual health care entities' preparedness and have built a system for coordinated healthcare system readiness. HPP is the only source of federal funding to prepare the nation's mostly private health care system to respond to emergencies, including COVID-19.

Beginning in 2018, ASPR has been supporting Regional Disaster Health Response Systems (RDHRS) pilot projects. The RDHRS concept aims to provide funding directly to hospitals and healthcare systems to establish multi-state regional partnerships to increase preparedness and response capability and capacity for hospitals and healthcare facilities in advance of, during, or immediately following incidents, including emerging infectious diseases. Two sites were selected in September 2018 to begin development of RDHRS pilots. In 2019, two grants were awarded to support new centers of excellence pilots focused on pediatric disaster care. The RDHRS and Pediatric Disaster Care Center of Excellence cooperative agreement requirements are intentionally aligned to ensure synergy between the programs and collaboration between all sites and facilities. Ultimately, these efforts inform best practices to help ready healthcare delivery systems for disasters and emergencies and are critical in aiding response and limiting the impact of disaster. As you all are aware, the United States is in the middle of influenza season. Many emergency departments are at 90 percent capacity. If influenza worsens, or if COVID-19 intensifies domestically, emergency

departments would be severely strained, which is why supporting models such as the Hospital Preparedness Program healthcare coalition network is so important.

The National Ebola Training and Education Center (NETEC) combines the resources of healthcare institutions experienced in treating Ebola to offer training, readiness consultations, and expertise to help facilities prepare for Ebola and other special pathogens. The regional Ebola and other special pathogen treatment centers, of which ASPR and CDC funded 10 across the country, all have respiratory infectious disease isolation capacity or negative pressure rooms for at least 10 patients, including pediatric patients. The NETEC and the regional Ebola and other special pathogen treatment centers have been used to support recent quarantine efforts. Should the coronavirus infections increase domestically, these centers will become critical in isolating infected persons and providing adequate treatment.

ASPR and CDC also work to enhance medical surge capacity by organizing, training, equipping, and deploying Federal public health and medical personnel, such as National Disaster Medical System (NDMS) teams, and providing logistical support for federal responses to public health emergencies. NDMS was originally created during the Cold War to take care of military casualties from overseas in U.S. civilian hospitals. Today, NDMS teams are deployed to strategic locations across the country, caring for U.S. citizens who may have been exposed to SARS-CoV-2, effectively providing medical care and limiting the potential spread of the disease.

Recently, to assist in the repatriation effort, ASPR stood up a National HHS Incident Management Team (IMT) located in Washington, DC. The IMT serves as the national command and control element, deploying Public Health Service Commission Corps Officers and NDMS personnel.

In addition, HHS provided cache equipment, (e.g., medical supplies and resources) to Travis AFB, Marine Corps Air Station Miramar, Lackland, Air Force Base, and Camp Ashland to support evacuees quarantined at these facilities. HHS deployed one Disaster Medical Assistance Team (DMAT) and one IMT on February 12, 2020, to support American citizens in Japan on the Diamond Princess cruise ship, as well as the
U.S. Embassy, to provide medical care, prescriptions, and behavioral health support.

Many active pharmaceutical ingredients and medical supplies, including auxiliary supplies such as syringes and gloves, come from China and India. This outbreak demonstrates why ASPR is seeking innovative solutions and partnerships to better protect national security. ASPR is working to increase access to personal protective equipment (PPE) by:

- Coordinating with CDC and other Federal agencies to share information about optimization of PPE, to prevent overbuying and overuse of existing supplies

- Engaging private sector partners who manufacture and distribute PPE to share information and concerns, and to explore options to anticipate and meet the needs of the U.S. healthcare sector more effectively. During recent discussions, for example, distributors informed us that they have implemented allocations to help prevent stockpiling at healthcare facilities. The allocation is a percentage of a customer's previous orders and is designed to help protect the healthcare supply chain and ensure the right supplies are available for those who need it.
- We are also partnering with other Federal agencies such as DHS, DOD and the U.S. Department of Veterans Affairs who are large buyers of PPE, to develop acquisition strategies that incentivize industry to expand PPE production while not exacerbating supply challenges.

The Strategic National Stockpile (SNS) holds thousands of deployable face masks, N95 respirators, gloves, and surgical gowns that could be deployed if state and local supplies are diminished due to the current COVID-19 response and commercial supplies are exhausted. The SNS is working hand-in-hand with commercial supply chain partners and other Federal agencies to continue monitoring supply levels and to prepare for a potential deployment of SNS personal protective gear if it is needed.

The National Institutes of Health

The National Institutes of Health (NIH) is the HHS agency leading the research response to the global health emergency of COVID-19. Within the NIH, the National Institute of Allergy and Infectious Diseases (NIAID) is responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID-19.

NIAID is well-positioned to respond rapidly to infectious disease threats as they emerge by leveraging fundamental basic research efforts; a domestic and international research

infrastructure that can be quickly mobilized; and collaborative and highly productive partnerships with industry. NIAID provides preclinical research resources to scientists in academia and private industry throughout the world to advance translational research for emerging and re-emerging infectious diseases. These research resources are designed to bridge gaps in the product development pipeline, thereby lowering the scientific, technical, and financial risks incurred by industry and incentivizing companies to partner in the development of effective countermeasures including diagnostics, therapeutics, and vaccines.

NIAID also supports the Infectious Diseases Clinical Research Consortium, which includes a network of Vaccine and Treatment Evaluation Units (VTEUs). The VTEUs conduct clinical trials to investigate promising therapeutic and vaccine candidates when public health needs arise. NIAID collaborates with other Federal agencies, including through the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), to help advance progress against newly emerging public health threats. In addition, partnerships with academia, the biotechnology and pharmaceutical industries, domestic and international researchers, and organizations such as the World Health Organization (WHO) are integral to these efforts.

NIAID has a longstanding commitment to coronavirus research, including extensive efforts to combat two other serious diseases caused by coronaviruses: SARS and MERS. This research has improved our fundamental understanding of coronaviruses and provides a strong foundation for our efforts to address the challenge of SARS-CoV-2, the novel coronavirus that causes COVID-19. NIAID has responded to the newly emerging COVID-19 outbreak by expanding our portfolio of basic research on coronaviruses. NIAID scientists have rapidly identified the human receptor used by SARS-CoV-2 to enter human cells. In addition, NIAID investigators and their collaborators recently identified the atomic structure of the spike protein, an important SARS-CoV-2 surface protein that is a key target for the development of vaccines

and therapeutics. NIAID scientists also are evaluating the stability of SARS-CoV-2 on various ordinary surfaces and in aerosols to better understand the potential for viral spread throughout the community.

NIAID-supported researchers are assessing the risk of emergence of bat coronaviruses in China, including the characterization of bat viruses and surveys of people who live in high-risk communities for evidence of bat coronavirus infection. Such research is necessary to better understand this emerging infection and to investigate optimal ways to diagnose, treat, and prevent COVID-19.

The NIAID Centers of Excellence for Influenza Research and Surveillance (CEIRS), which conduct influenza risk assessments in multiple sites throughout the world particularly in Asia, have responded rapidly to the COVID-19 outbreak. CEIRS researchers at the University of Hong Kong are evaluating the epidemiology, transmission dynamics, and severity of COVID-19. These scientists also have performed environmental sampling of the Wuhan market where the first COVID-19 cases were reported.

NIAID is working with CEIRS collaborators and the CDC to obtain additional virus and biological samples from patients to further advance research efforts on COVID-19. Recently, the NIAID-funded BEI Resources Repository made samples of SARS-CoV-2 available for distribution to domestic and international researchers at Biosafety Level 3 laboratories. In addition, CEIRS researchers and other NIAID-supported scientists are developing reagents, assays, and animal models that can be used to evaluate promising therapeutics and vaccines. These research resources also will be shared with the domestic and international scientific community as soon as they become available.

On February 6, 2020, NIAID issued a *Notice of Special Interest regarding the Availability of Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus*. This notice encourages existing NIAID grantees to apply for supplements for research project grants focused on the natural history, pathogenicity, and transmission of the virus, as well as projects to develop medical countermeasures and suitable animal models for preclinical testing of COVID-19 vaccines and therapeutics.

NIAID has responded to public health concerns about COVID-19 by increasing ongoing coronavirus research efforts to accelerate the development of interventions that could help control current and future outbreaks of COVID-19. These activities build on prior NIAID research addressing other coronaviruses, such as those that cause SARS and MERS.

The CDC has developed a real-time Reverse Transcription-Polymerase Chain Reaction (rRT-PCR) test that can detect COVID-19 using respiratory samples from clinical specimens. NIAID is accelerating efforts to develop additional diagnostic tests for COVID-19, and NIAID-supported investigators are developing PCR-based assays for SARS-CoV-2 to facilitate preclinical studies and aid in the development of medical countermeasures. NIAID scientists also are developing reagents for an enzyme-linked immunosorbent assay for SARS-CoV-2. CEIRS researchers at the University of Hong Kong have developed a separate RT-PCR test and made their protocol publicly available through the WHO. These NIAID-supported investigators also have distributed assay reagents to 12 countries to facilitate the diagnosis of COVID-19.

NIAID is pursuing the development of antivirals and monoclonal antibodies for potential use against SARS-CoV-2. NIAID has launched a multicenter, randomized controlled clinical trial to evaluate the safety and efficacy of the antiviral drug remdesivir for the treatment of

COVID-19 in hospitalized adults with laboratory-confirmed SARS-CoV-2 illness. The adaptive design of this trial will enable the evaluation of additional promising therapies. NIAID plans to assess other existing antivirals for activity against SARS-CoV-2, and NIAID scientists are working to identify monoclonal antibodies with therapeutic potential from COVID-19 patient samples as well as historical SARS patient samples. NIAID-funded scientists also aim to delineate new viral targets to facilitate the development of novel therapeutics with broad activity against coronaviruses. Finally, NIAID is expanding its suite of preclinical services to add assays that investigators can use to accelerate research and development of therapeutics for COVID-19.

A safe and effective vaccine for SARS-CoV-2 would be an extremely valuable tool to stop the spread of infection and prevent future outbreaks. Public and private entities across the globe have announced plans to develop SARS-CoV-2 vaccine candidates following the release of the SARS-CoV-2 genetic sequence. NIAID is supporting development of several SARS-CoV-2 vaccine candidates, and is utilizing vaccine platform technologies that have shown promise against the coronaviruses that cause SARS and MERS.

The NIAID Vaccine Research Center (VRC) is collaborating with the biotechnology company Moderna, Inc., on the development of a vaccine candidate using a messenger RNA (mRNA) vaccine platform containing the gene that expresses the VRC-designed spike protein of SARS-CoV-2. NIAID anticipates the experimental vaccine will be ready for clinical testing in the NIAID VTEUs within the next two months and will conduct preclinical studies as well as a first-in-human study of this COVID-19 vaccine candidate. The Coalition for Epidemic Preparedness Innovations (CEPI) will fund the manufacture of the first clinical production lot of this mRNA-based vaccine candidate using the Moderna rapid manufacturing facility.

NIAID Rocky Mountain Laboratories (RML) scientists are collaborating with Oxford University investigators to develop a chimpanzee adenovirus-vectored vaccine candidate against SARS-CoV-2; in addition, they have partnered with CureVac on an mRNA vaccine candidate. RML investigators also have launched a collaboration with the University of Washington and have begun early-stage testing of an RNA vaccine candidate against SARS-CoV-2. In addition, NIAID-supported scientists at Baylor College of Medicine and their collaborators are evaluating an experimental SARS-CoV recombinant protein vaccine to determine if it also provides protection against SARS-CoV-2. NIAID is exploring additional collaborations with extramural research and industry partners on other vaccine concepts. NIAID also is supporting the development of standardized assays and animal models that will be utilized to evaluate vaccine candidates.

With all these efforts, NIAID is coordinating closely with colleagues at the CDC, BARDA, FDA, DOD, and other federal and international partners.

To achieve the ultimate goal of having a SARS-CoV-2 vaccine available to the public, it is important that NIAID and the entire biomedical research community pursue a range of vaccine strategies in order to be better positioned to overcome the scientific or technical challenges associated with any particular vaccine approach. In this regard, NIAID has dedicated resources toward preclinical research to advance a robust pipeline of vaccine candidates into Phase 1 clinical evaluation. Further vaccine research, including Phase 2 clinical trials, will then be required. Additional research also is needed to better understand the fundamental biology of coronaviruses and to facilitate the design of vaccines that elicit optimal immune responses and protect against infection.

While ongoing SARS-CoV-2 vaccine research efforts are promising, it is important to realize that the development of investigational vaccines and the clinical testing to establish their safety and efficacy take time. Although we plan to begin early-stage clinical testing of an NIAID-supported vaccine candidate in the next few months, a safe and effective, fully licensed SARS-CoV-2 vaccine will likely not be available for some time. Currently, the COVID-19 outbreak response in the United States remains focused on the proven public health practices of containment – identifying cases, isolating patients, and tracing contacts.

NIH is committed to continued collaboration with other HHS agencies and additional partners across the U.S. government and international community to advance research to address COVID-19. As part of its mission to respond rapidly to emerging and re-emerging infectious diseases throughout the world, NIAID is expanding our efforts to elucidate the biology of SARS-CoV-2 and employ this knowledge to develop the tools needed to diagnose, treat, and prevent disease caused by this virus. NIAID is particularly focused on developing safe and effective COVID-19 vaccines. These efforts also help to expand our knowledge base and improve our continued preparedness for the next inevitable emerging disease outbreak.

Food and Drug Administration

The FDA plays a critical role in overseeing our Nation's FDA-regulated products as part of our vital mission to protect and promote public health, including during public health emergencies. Our work primarily focuses on four key areas: first, actively facilitating efforts to diagnose, treat, and prevent the disease; second, surveilling product supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary; third, conducting inspections and monitoring compliance, including of facilities that manufacture FDA-regulated products overseas; fourth, helping to ensure the safety of consumer products.

A key focus area for the FDA is helping to expedite the development and availability of

medical products needed to diagnose, treat, and prevent this disease. We're committed to helping foster the development of critical medical countermeasures as quickly as possible to protect public health. We provide regulatory advice, guidance, and technical assistance to sponsors in order to advance the development and availability of vaccines, therapies, and diagnostic tests for this novel virus.

On February 4, 2020, the FDA issued an emergency use authorization (EUA) to enable immediate use of a diagnostic test developed by the CDC, facilitating the ability for this test to be used in CDC-qualified laboratories.[1] The FDA is dedicated to actively working with other COVID-19 diagnostic developers to help accelerate development programs and requests for EUAs. We have developed an EUA review template for tests to detect the virus, which outlines the data requirements for a Pre-EUA package that is available to developers upon request. To date, we have shared the EUA review template with more than 100 developers who have expressed interest in developing diagnostics for this virus.

The medical product supply chain is always potentially vulnerable to disruption, which makes our surveillance work and collaboration with industry critical and why the Agency takes a proactive stance on any potential impact or disruption to the supply chain. An outbreak of this global scale has an impact on the medical product supply chains, including potential disruptions

[1] FDA. 2019 Novel Coronavirus Emergency Use Authorization. February 4, 2020. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019.
FDA. FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic: Critical Milestone Reached in Response to this Outbreak. https://www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first.

to supply or shortages of critical medical products in the United States. We are in contact with manufacturers; global regulators, like the European Medicines Agency; health care delivery organizations; and other participants in the medical product supply chains to quickly identify and address any supply concerns that come from issues related to China and other locations in Southeast Asia sourcing raw materials for manufacturing drugs.

We are also tracking reports of increased ordering of some essential medical devices through distributors, such as personal protective equipment (PPE) (e.g., respirators and surgical gowns, gloves and masks). FDA is working proactively to stay ahead of potential shortages or disruptions of medical products. The agency will use all available authorities to react swiftly and mitigate the impact to U.S. patients and health care professionals as these threats arise.

Monitoring the safety of FDA-regulated product supply chains is one of the FDA's highest priorities. The FDA utilizes risk-based models to identify firms for inspection and prioritizes inspections based on specific criteria. Because of travel restrictions to China, the Agency has postponed planned inspection activities in China. However, we are currently continuing inspection and enforcement activities as normal for the rest of our operations. Inspections of facilities in China remain prioritized in our site selection model and, when travel restrictions are lifted, inspections of facilities in China will resume. Any travel to China that is deemed to be mission-critical is being assessed on a case-by-case basis in close coordination with other HHS components and with the Department of State. FDA is committed to maintaining its scheduled inspections around the globe to the extent possible, while maintaining the safety of the staff involved. We will revisit this approach and adjust as necessary as this outbreak continues to unfold. In the meantime, FDA is working with our partner government

agency, U.S. Customs and Border Protection (CBP), to evaluate and adjust our risk-based targeting strategy to ensure FDA-regulated products are safe when entering the United States.

While the outbreak is impacting our ability to conduct inspections in China, it's important to underscore that the FDA's regular risk-based process of surveillance testing of imported products, including those from China, continues.

Inspections are one of many tools that the Agency uses to inform its risk strategy for imported FDA-regulated products and to help prevent products that do not meet the FDA's standards from entering the U.S. market. Other tools include: import alerts, increased import sampling, and screening. Inspections are also part of, among other things, the new and generic drug approval process. While such pre-approval inspections are on hold in China, we are working to mitigate the impact on new and generic drug approval decisions by requesting records that may be used in lieu of an inspection, depending on the circumstances. Based on our evaluation of previous FDA inspection history, a firm's previous compliance history and information from foreign health authorities with which we have mutual recognition agreements, we determine if the totality of the information would suffice in lieu of such a pre-approval inspection.

All products offered for entry into the United States, including items for personal use, are subject to the regulatory requirements of CBP. Imported shipments of FDA-regulated products referred by CBP, including those from China, are then reviewed by the FDA and must comply with the same standards as domestic products. At this time, we want to reassure the public that there is no evidence to support transmission of COVID-19 associated with imported goods, including food and drugs for people or pets, and there have not been any cases of COVID-19 in the U.S. associated with imported goods.

We established a cross-agency task force to closely monitor for fraudulent FDA-regulated products and false product claims related to COVID-19 and we have already reached out to major retailers to ask for their help in monitoring their online marketplaces for fraudulent products with coronavirus and other pathogen claims.

FDA is utilizing all our existing authorities to address COVID-19 and we welcome the opportunity to work with Congress to strengthen our response capabilities. There are four specific proposals included in the President's Budget that would better equip the Agency to prevent or mitigate medical product shortages.

(1) Lengthen Expiration Dates to Mitigate Critical Drug Shortages

Shortages of critical drugs can be exacerbated when drugs must be discarded because they exceed a labeled shelf-life due to unnecessarily short expiration dates. By expanding FDA's authority to require, when likely to help prevent or mitigate a shortage, that an applicant evaluate, submit studies to FDA, and label a product with the longest possible expiration date that FDA agrees is scientifically justified, there could be more supply available to alleviate the drug shortage or the severity of a shortage.

(2) Improving Critical Infrastructure by Requiring Risk Management Plans

Enabling FDA to require application holders of certain drugs to conduct periodic risk assessments to identify the vulnerabilities in their manufacturing supply chain (inclusive of contract manufacturing facilities) and develop plans to mitigate the risks associated with the identified vulnerabilities would enable the Agency to strengthen the supply chain by integrating contingencies for emergency situations. Currently, many applicants lack plans to assess and address vulnerabilities in their manufacturing supply chain, putting

them, and American patients, at risk for drug supply disruptions following disasters (e.g., hurricanes) or in other circumstances.

(3) Improving Critical Infrastructure Through Improved Data Sharing: Requiring More Accurate Supply Chain Information

Empowering FDA to require information to assess critical infrastructure, as well as manufacturing quality and capacity, would facilitate more accurate and timely supply chain monitoring and improve our ability to recognize shortage signals.

(4) Device Shortages

FDA does not have the same authorities for medical device shortages as it does for drugs and biological products. For instance, medical device manufacturers are not required to notify FDA when they become aware of a circumstance that could lead to a device shortage or meaningful disruption in the supply of that device in the United States, nor are they required to respond to inquiries from FDA about the availability of devices. Enabling FDA to have timely and accurate information about likely or confirmed national shortages of essential devices would allow the Agency to take steps to promote the continued availability of devices of public health importance. Among other things, FDA proposes to require that firms notify the agency of an anticipated meaningful interruption in the supply of an essential device; require all manufacturers of devices determined to be essential to periodically provide FDA with information about the manufacturing capacity of the essential device(s) they manufacture; and authorize the temporary importation of certain devices where the benefits of the device in mitigating a shortage outweigh the risks presented by the device that could otherwise result in denial of importation of the device into the United States.



March 6, 2020

The Honorable Ron Johnson
Chairman
U.S. Senate Committee on Homeland Security & Governmental Affairs
342 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Gary C. Peters
Ranking Member
U.S. Senate Committee on Homeland Security & Governmental Affairs
342 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Johnson and Ranking Member Peters:

The Healthcare Leadership Council (HLC) appreciates the opportunity to submit this letter regarding the U.S. Senate Committee on Homeland Security & Governmental Affairs hearing on "The Federal Interagency Response to the Coronavirus and Preparing for Future Global Pandemics."

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

As the 2019 Novel Coronavirus (COVID-19) outbreak continues to spread rapidly across the globe, HLC members share your concerns over this significant threat to public health and remain vigilant during this public health emergency. Our members recognize the importance of public-private partnerships, especially during emergency preparedness and response, and have been engaged on all fronts to contain and to prevent further spread of COVID-19.

To date, HLC members have contributed their scientific expertise to research and development efforts and have partnered with agencies within the U.S. Department of Health and Human Services, such as the Biomedical Advanced Research and Development Authority, to accelerate the development of a COVID-19 vaccine and treatments for the infection. Additionally, our members have provided monetary and in-kind contributions (surgical masks, ventilators, disinfectants, etc.) for COVID-19 relief, taken steps to protect the healthcare supply chain, and have screened and treated

patients that have recently traveled to China for COVID-19. HLC recognizes the importance of disaster preparedness and response and is holding ongoing discussions with agencies within the federal government including the Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, and the Department of Homeland Security to discuss collaboration on improving the nation's readiness to respond to disasters and catastrophic events.

As a diverse, multisector organization with representation from all disciples within American healthcare, we stand ready to be a resource for you as this public health emergency continues to evolve. Thank you for examining this important issue and please feel free to contact Tina Grande, at (202) 449-3433 or tgrande@hlc.org with any questions.

Sincerely,



Mary R. Grealy
President

ROUNDTABLE COVID–19: HOW NEW INFORMATION SHOULD DRIVE POLICY

WEDNESDAY, MAY 6, 2020

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 2:19 p.m., via video conference, Hon. Ron Johnson, Chairman of the Committee, presiding.

Present: Senators Johnson, Portman, Lankford, Romney, Scott, Hawley, Peters, Carper, Hassan, Harris, Sinema, and Rosen.

OPENING STATEMENT OF CHAIRMAN JOHNSON

Chairman JOHNSON. Hello, everybody. I want to welcome everybody to this roundtable, the first one we have ever done that is completely on the internet via video. We tested out this capability yesterday. It looks pretty slick, but I would anticipate a few hitches. But, everybody, I think we can handle this if we just kind of follow the rules, and so let me quickly go over some of the rules here.

First of all, if you will take a look at the circles on the bottom of your screen there, if you have a mouse and you get your little arrow up and going, there are two icons. On the far left, there is a microphone and a video. If you are in attendance as a member or a witness, keep your video unmuted. I just muted mine, just unmuted it there, so you can see how that works.

Do not touch your audio. Everybody is muted until it is your turn to speak, and we are doing that not to be cruel but just because it makes an awful lot of sense in terms of being able to not have a bunch of chaos during this roundtable. Again, because that is a disruption, sensitive, multiple microphones, do not touch that mute button.

If you would like to speak at another time, there is on the attendee list at the very bottom, if you take a look, it is very small. There is a little hand. There are three little squares and a little hand. If you click on that—I am clicking on mine right now—that will signal either the witnesses or me that you want to make a point.

Certainly, I do not have a problem with the witnesses doing it. I am hoping Members do it sparingly. Again, this is not going to be like a normal hearing. So it is not quite the same kind of free flow that we normally have.

What I would urge all the Members, direct your questions at a particular witness because it is going to be pretty hard to have this wide open. So if you have a particular question, ask it to a particular witness or possibly witnesses, but be very specific.

And we are going to be very mindful of the time. I want both Senators and the witnesses to be watching that 7-minute clock run down. A favorite technique of Senators is to ask about a question that requires about a 5-minute answer right after the 6:59 mark. I do not want to really allow that. We can take those types of questions under advisement for questions for the record.

So, with that, Dan, if you can quickly put it up, I have just got four little charts. It should really surprise nobody, but I just want to start out with some basic information because what this hearing really is, from my standpoint, all about is as we develop data.

Let us face it. When we found out about coronavirus disease (COVID), a brand-new virus, nobody had ever heard about it, pretty darn scary. You see folks in China in moon suits, and so it is that fear of the unknown that is driving so much of policy right now. I have not been critical of really any policymaker who has had to make very tough decisions with very limited information.

But as we were gathering that data now—and that is what this hearing is all about—we should take that new information, that new data into account in terms of how do we modify our policy as well as what I have been advising for quite some time. We have to look at the totality of the harm being done, not only just the tragedy from the standpoint of lives lost and lives destroyed, but also the economic destruction, the human toll that that is taking as well.

So I have just got four quick slides, just some basic information to try and keep everything in perspective. The first one is the one on the screen, "Causes of Death, 2018."[1] You will notice 2.8 million Americans died that year. That is pretty typical. It is almost 8,000 people per day. I think the largest number of per-day deaths per COVID is slightly over 2,000. So you can understand how significant an issue, the significant tragedy that COVID really is.

Next slide. This is just the 9-year history off the Centers for Disease Control (CDC) website of seasonal flu.[2] I think it is important to point out the magnitude of that problem. I think the figure is only 40 percent of Americans get vaccinated for this. The vaccine is not 100 percent effective, and you can see how many Americans die on an annual basis over the last 9 years. In total, 337,000 Americans have lost their lives due to seasonal flu over the last 9 years. That is an average of a symptomatic-case fatality rate of 0.13 percent.

You can see in the past years. The lowest level is about 0.1 percent. A really bad flu season is almost 0.18 percent. I think those numbers are important to keep in mind as we take a look and we eventually find out not only the case infection rate is with COVID, but what is the actual infection fatality rate, which as the denominator grows and that infection fatality rate decreases, hopefully some of the fear will be reduced. Again, I am not saying the fear

[1] The Causes of Death chart appears in the Appendix on page 483.
[2] The Influenza in U.S. chart appears in the Appendix on page 484.

is not irrational. It absolutely is legitimate, but in order to really regain our economy and open it back up, we do need people looking at this from a proper perspective and hopefully with effective therapy and cure.

We are going to have Dr. Kory on to talk about some pretty hopeful signs in terms of therapies in the hospital. Hopefully, we can also bring down that fear level so people can go back to a more normal type of life. You can see 337,000 deaths over the last 9 years just due to seasonal flu.

Next. These are up-to-date figures as of this morning. Here is a State and Territory comparison.[1] Unfortunately, for New York, it leads the pack in terms of number of cases, in terms of number of deaths, in terms of percent of the population that are known cases, 1.7 percent, percent of deaths of the population, 0.13 percent. The lowest percent of population in terms of cases is Hawaii and Montana at about 0.043 compared to New York which is 1.7. In terms of percent deaths, there are a lot of States, fortunately, that are only 0.001.

On average, America is about 0.36 of the population is reported as a case, and 0.02 of the population has actually died from COVID.

The final chart. These are country comparisons.[2] I have 12 countries on here that I have been tracking pretty much on a daily basis. I am going to throw Russia and China out in terms of actual comparisons because I am, quite honestly, not sure how accurate their reporting is.

Let us face it. Everybody is going to have different standards on how they report these cases and how they collect information, but I think it is important to point out when you take a look at cases as a percentage of population, the United States ranks No. 3 in terms of worst, in terms of highest percentage of the population that has been infected, but we rate seventh when it comes to percentage of population of the deaths at 0.02.

I want to point out Sweden because Sweden definitely took a different approach to responding to COVID. They basically took the approach of we will quarantine the sick, we will protect the vulnerable, and the rest of us will basically go about our lives, obviously following the guidelines of social distancing, sanitizing, personal hygiene, that type of thing.

Again, these numbers, we do not know where they will eventually turn out, but Sweden in the scheme of things is not going that badly. In terms of percentage of their population that have a confirmed case, they rate eighth at 0.26. In terms of the percent of the population that have died, they rate sixth on this list of these 12 countries at 0.03.

So, again, that is just some basic information. I have tried to get that to all the witnesses and Senators to, again, put all this in perspective.

With that, I will turn it over to Senator Peters, my Ranking Member, for his opening comments.

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[1] The States compared chart appears in the Appendix on page 485.
[2] The Countries compared chart appears in the Appendix on page 486.

OPENING STATEMENT OF SENATOR PETERS[1]

Senator PETERS. Thank you, Mr. Chairman.

The coronavirus pandemic has certainly profoundly altered our world. It is putting millions of people out of work, threatening the future of small businesses, exposing serious inequities in our health care system, and it is taking the lives, to date, of more than 71,000 Americans.

Like so many of us, I am ready to start getting America back to work, but we need a clear plan, backed by science and by data, that will give us a roadmap to safely reopening our economy in stages.

While cases in some parts of the country appear to be plateauing, we know that there are other communities that are experiencing rising numbers right now.

We currently do not have enough tests to fully understand how many people have contracted or succumbed to the virus.

We are still struggling to get enough masks, gloves, and other personal protective equipment (PPE) to our frontline workers, and we do not yet have the supplies needed to prevent a resurgence of this virus.

We need a robust contact-tracing plan to identify possible exposure to coronavirus and prevent further spread that could result in another wave of cases, hospitalizations, and unfortunately, tragic deaths.

We need to protect and grow the capacity of our hospitals to deal with these localized outbreaks, and we need to take back production of life-saving drugs and medical supplies. We need to take back that production from China.

We need to develop and deploy a vaccine to inoculate Americans who have not contracted the virus, and we need clear data and metrics that are backed by science to tell us what is working and what is not. And we need to push these best practices to help our small businesses out so that they can keep their employees safe and their customer's confidence.

This critical information and the lessons we have learned will help create a plan for how we can safely reopen.

Without this data-driven plan, we risk undermining the progress that we have made and a repeat the unbearable loss of human life and economic shock that we are experiencing.

Despite all this hardship, I am encouraged every day by the workers and the entrepreneurs in my home State of Michigan that are finding ways to keep their workplaces safe and, as we speak, are retooling their businesses to meet the needs of frontline responders.

I have talked to many of them over the last few months, and they all are saying they need clear guidance by reliable data to back up their actions.

We also must remain focused on the unequal impact of this virus and how it inflicts and impacts communities of color. In Michigan, black residents make up 13 percent of the population but represent 40 percent of the deaths from COVID–19. This disparity is rooted in systemic inequity, and we must change our plans in response to

[1] The prepared statement of Senator Peters appear in the Appendix on page 451.

the data and protect these communities, not simply accept the inequity of the inevitable.

These decisions are a matter of life and death, and we cannot accept tens of thousands more coronavirus deaths as unavoidable, just as we cannot accept that reopening our economy while minimizing risks is not possible.

We must have a clear plan that provides people with guidelines that are backed by science to help us reopen.

I look forward to today's discussion and to continuing to work with my colleagues to ensure that we are taking the appropriate steps necessary to allow us to safely reopen our economy while protecting our most precious resource, the American people.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thanks, Senator Peters.

I would really like to thank all of our witnesses for the time you have taken out of your day just to participate in this but also the time you have spent, first of all, speaking to these issues. I think all but one of you, I have seen on some television (TV) show in the last couple weeks, but you have put your lives and you have done a lot of work to try and educate the public. And I truly appreciate that.

Our first witness will be Dr. Pierre Kory. I just spoke with him last week. He is affiliated with the University of Wisconsin, Madison, but he is a New Yorker, and he is currently on the frontlines in New York. And the reason I wanted to put him first is to give us a little bit of hope.

What he is talking about in terms of effective therapy once individuals have been hospitalized, I think, is very encouraging, and I wanted to give him enough time to kind of speak to that before we kind of open up into sort of the main purpose of what this hearing was all about, which is really taking a look at the data and taking a look at the policy choice and decisions that we have made and that we need to make based on what that information and what that data tells us and instructs us.

Again, our next witness is Dr. Pierre Kory. He is the Chief of Critical Care Service, the Medical Director of the Trauma and Life Support Center, and Associate Professor of Medicine at the University of Wisconsin School of Medicine and Public Health. He is board-certified in critical medicine, pulmonary diseases, and internal medicine. He previously served as Director of the Advanced Courses sponsored by the American College of Chest Physicians. Dr. Kory received a Doctor of Medicine (MD) at the St. George's University School of Medicine. Dr. Kory.

TESTIMONY OF PIERRE KORY, MD, MPA,[1] CRITICAL CARE SERVICE CHIEF, ASSOCIATE PROFESSOR OF MEDICINE, UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE AND PUBLIC HEALTH

Dr. KORY. All right. Thank you. I believe I am unmuted. So thanks for the invitation. I really appreciate the opportunity to talk about COVID.

[1] The prepared statement of Dr. Kory appears in the Appendix on page 453.

I do want to start out by saying that I am speaking today as part of a group. I have bonded with five colleagues of some of the most well-known and highly published and most impactful critical care experts in the world, and I do want to make sure that I mention them.

One is my colleague, Dr. Paul Marik. He is from the Eastern Virginia Medical School, very well known in our specialty; also Dr. Umberto Meduri, who is from the University of Tennessee in Memphis; and then also Dr. Joe Varon in Houston and then Dr. Jose Iglesias from Hackensack.

Now, the five of us, we came together early on in COVID, and we have been trying to figure out this disease. I got to tell you, we came up with a protocol, and I want to talk about that protocol but with some other issues that I think the health care system needs to be aware of.

First of all, let me just tell you about some of the results of our protocol. Members of our group have now treated in excess of 100 hospitalized patients with our treatment protocol, and we are going to report that nearly all survived. The two that died were in their 80s and had advanced chronic medical conditions. None of the patients had long stays in the ventilators. None are ventilator-dependent, and most of them had short hospital stays and were discharged in general good health.

I am going to say that is good news. Many people are going to be skeptical and ask about that, but let me talk a little bit more about why we are seeing that.

The first thing is I just want to say how troubled we were. I appreciate your comments, Senator Johnson, about how we are all doing the best we can with the data we have, and so it is hard to point fingers. But I have to say that we are dismayed by the lack of proposal for an effective treatment protocol.

There are three critical things that we have seen over the last month that we really want to talk about. So No. 1—and, again, I do not want to diminish the value and the expertise of our national health care societies and international health care societies like the World Health Organization (WHO) and the CDC; however, I think those are bodies that are built for peacetime and not for war. And we are at war right now with this virus.

One of the main issues that we have seen is that they initially came out—all of the national health care societies came out with recommendations that focus on supportive care only, which is generally you give Tylenol for a fever. You treat symptoms. You might give a little hydration nutrition, and you give oxygen and ventilators for support when they cannot breathe. That is reasonable for a viral syndrome, but this thing is different, No. 1.

No. 2, that strategy is failing. I do not think I need to spend a lot of time showing how badly that is failing. The mortality and morbidity rates of this disease are unprecedented. I have been doing critical care for a decade and a half. I do not see mortality rates associated with any severe illness that I see in this one.

Supportive care is not working. We are just trying to put a call out to the world to rethink this supportive care-only strategy. So that is one major concern we have had.

The second is we want to call attention to the world to what we think is a tragic error in analysis of medical data, and that is the fact that all societies from the beginning of COVID have advised against the use of corticosteroids in COVID–19. We think that is a fatal and tragic flaw.

And I will tell you why. One of the members of my group, Dr. Umberto Meduri, who is probably the world expert on corticosteroid therapy and critical illness, 3 weeks ago, he published a paper along with five other internationally known experts. They published a paper in Critical Care Explorations, which essentially reviewed the role and impact of corticosteroid therapy in all the prior pandemics, including the coronavirus pandemics of severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and H1N1.

Contrary to the conclusion of the reviews done by all those national societies, they showed that in the two largest and most carefully executed studies of all of the impacts of corticosteroids that corticosteroids are actually lifesaving in these severe viral syndromes. They showed drastic reductions in mortality in anyone who had anything beyond mild disease. You should not use it early as an outpatient, but once you hit the hospital, it is lifesaving, and just this week, we are starting to get even more really impressive data showing the importance of corticosteroid therapy in these syndromes.

So, for instances, just this week, Sorin Draghici—he is the Chief Executive Officer (CEO) of Advaita Bioinformatics. And this is fascinating stuff, and this is about as cutting-edge and futuristic medicine that you can imagine. They have the sophisticated artificial intelligent platform called iPathwayGuide. What they did is they cultured human cells, and they infected them with coronavirus. They were able to analyze the genes that were activated by the coronavirus. They were able to do this with multiple viruses, and what they saw is that in the coronavirus cell types, the types of genes that were activated, they were able to match that against medicines that suppress that activation of those genes. And the one drug that they found that perfectly met the ability to counteract that gene activation was methylprednisolone, which is a corticosteroid.

At the same time that they did that, Dr. Mayer Ramesh, at the Henry Ford Hospital—he is a transmit infectious disease expert and immunologist. He implemented a methylprednisolone protocol. Their study just came out this week, and what they showed—and I even talked to him in a personal communication—is once they started using methylprednisolone, their needs for ventilators went down. Their mortality went down. They are reporting this in a study that is right now in just prepublication, but in over 200 patients, they saw dramatic effects.

He said the entire environment changed. There were less codes, less need for ventilators. Their ventilators peaked and decreased. They came out of a mass casualty environment to a much more controlled condition.

Then right now we are also getting word that there is a paper under review from our colleagues in Spain, critical care experts, all of them, who are now reporting that when they used

methylprednisolone therapy earlier and longer than in the Henry Ford study, they are showing absolutely dramatic reductions in mortality.

So those mortality rates that you are seeing, we think that there is a really strong answer to that, and we need to change our treatment strategy, which was one where we did not use corticosteroids, which we think are critical and we want to use them.

Again, the standards of medical evidence have changed a little bit in this crisis, and so I am going to use some Facebook posts. But these were posts that were posted anonymously by doctors who are in the middle of this surge, and this is what one of them posted 2 weeks ago. This is a hospital that is in Southeast Michigan, and he wrote, "We floundered for 2 weeks, lots of codes, intubations, and death, maybe 15 discharges. We started steroids and discharged 250 patients, less intubations, less codes, and the ones that ended up on a ventilator not as serious. If they have chest x-ray or computerized axial tomography (CAT) scan changes, start steroids. If they are hypoxic, start steroids. If they are ambulatory and hypoxic, start steroids. This completely changed our trajectory.

Steroids are a game changer. This critical efficacy is being noticed more and more around the world. We are seeing it pop up in new protocols and guidelines.

Another post from a doctor in New Orleans who also got inundated in the surge. They found and he writes, "I am here in New Orleans. Since we started using steroids, we were able to free ventilators and get elderly patients out of the hospital without needing a ventilator. Patients that were obviously crashing quickly who we had to have end-of-life talks with were able to walk out of the hospital. At no point did any of our patients worsen because of steroids. These patients shed viruses 4 weeks later with or without steroids. The virus does not kill anybody; it is the inflammation that does."

So those two things that I just reviewed which is, one, the fact that the supportive care only is failing; two, the lack of steroids may be a critical absence in the treatment strategy of these patients.

And then No. 3, the other thing that we have seen all around the world in many institutions and medical journals and editorials is this constant cry for randomized control trials or prospective trials.

Listen, we in our group, we all know the critical need for data and trials, but we think there is an overemphasis. And we are forgetting some of the ethics of doing research in a pandemic when patients are dying and they are very sick, and I want to remind us of a few ethical principles that the world has agreed on.

So, No. 1, the Declaration of Geneva of the World Medical Association (WMA), binds the physician with the words "The health of my patient will be my first consideration."

No. 2, the International Code of Medical Ethics declares that "A physician shall act in the patient's best interest in providing medical care."

And then most importantly, this is where everyone is getting confused is that this idea that what we are doing is unproven or experimental therapies. I want to call particular attention to Article 37 of the World Medical Association Declaration of Helsinki, for

approved in 1964 and most recently approved in 2013. In that Article 37, which is titled "Unproven Interventions in Clinical Practice," it reads—and I paraphrase—In the treatment of an individual patient, where proven interventions do not exist, a physician may use an unproven intervention if in the physician's judgment it offers hope of saving life, reestablishing health, or alleviating suffering.

Having said that, let me just talk about what our group did, and I am sorry if I am going a little bit overtime. But this is what we did. So myself, Dr. Marik, Dr. Meduri, Dr. Iglesias, and Dr. Varon, we got together early on, and all we did is talk COVID 24 hours a day. We exchanged emails and papers and clinical discussions.

Probably, my biggest contribution to the group is I am a New Yorker. I have trained with, I have been trained by, and I have trained almost every person in every intensive care unit (ICU) in New York City, and from the beginning, while I was in Madison preparing for the surge, I got to talk to them each and every day. The accumulating clinical experiences, the impressions, the responses of different treatment strategies, we all got to observe, and we convened a group. And we came up with a treatment protocol. It is based on decades of our experience of taking care of patients, our research, as well as hundreds of publications.

What we noticed was three things that I think people are not recognizing is that the way that this virus is killing people and causing all these organ failures is there are three major pathologic processes that were seen, which is this stage of extreme hyper and dysregulated inflammation. Some people are calling it a cytokine storm. That is No. 1. No. 2, we are seeing hypercoagulability with frequent and excessive clotting; and No. 3, we are seeing this outside hypoxemia, which approaches to treating that have sort of been evolving. But I think we failed in the beginning.

So based on those three processes and based on our knowledge of therapies and therapeutics, we came up with what we call Methylprednisolone Ascorbic acid Thiamine Heparin (MATH+) protocol. It is on our website. It so covid19criticalcare.com, but I am going to go through it really quickly.

No. 1, the three critical medicines is methylprednisolone—I just gave you some of the evidence and some of the rationale why that is critical. We know it worked in SARS, MERS, and H1N1. The fact that we are not using it here, I think, is causing some of this needless death. So methylprednisolone, No. 1, it is a powerful anti-inflammatory drug that we use to suppress the immune system and prevent organ damage. This condition on COVID–19, which is the cytokine storm, a corticosteroid is the standard recommended treatment accepted around the world for cytokine storm.

Ascorbic acid, although known as vitamin C, everyone dismisses that as a vitamin. Those of us who use it and know its physiology and its potency, it is not only a vitamin. It acts as a stress hormone in fighting off infections. It is critical. It has synergistic capabilities along with steroids, and so we strongly promote that. It prevents the development of leaky blood vessels within the lung, and it avoid the development of lung failure. It should always be used when paired with corticosteroids.

Heparin is another one. It is a blood thinner. We are seeing excessive blood clotting. Almost all centers and institutions around that have promoted the use of some amount of blood thinners. Some have been more cautious than others. Some are more aggressive than others, but we all recognize the critical need.

Then the last thing is what a lot of us got wrong. I am going to say at the University of Wisconsin, we did not. I am going to toot my own horn here, but we avoided the early intubation. Early intubation with these patients is harming them. The machine makes the disease worse, and so we should try to avoid intubating until last resort. And as we do that, we are seeing that we are able to alter the trajectory of these patients away from the ventilators, and we are seeing lives saved.

So I am just going to summarize by saying our treatment is not unique. We are starting to see it pop up in centers and protocols and countries around the world. The most recent Italian guidelines were extremely aggressive. They are mandating an overall focus on treating inflammation with tocilizumab and mandatory steroid use early on in the disease. They are saying to do it as soon as someone's oxygen level drops.

And this is what I want to say. This is the last tragedy, and I know that probably what I have said is a little bit heated. I am emotional, but this is absolutely a calamity that is going on in medicine. I have been in New York City for 2 weeks trying to treat these patients with COVID. Either I have been inundated with patients who are chronically on the vent and who are dying of end-stage fibrotic lung disease, or I am seeing patients who are crashing into my ICU. But as opposed to a month ago where they were coming in with these mild abnormalities on chest x-ray and maybe mild abnormalities in their oxygen intake, now we are seeing floridly abnormal x-rays with very advanced disease. I am throwing the book at them, and it is not working.

I have to emphasize that the timing of initiation of this therapy is critical. The world needs to know this.

What happened here in New York is that initial surge caused so many terrible reports of patients being unattended to, running out of resources, not enough physicians and nurses, and now the population is scared. They are not coming to the hospital early enough, and now when they are coming, they are so far advanced that the medicines do not work as well, and so we need to get the word out that things are better on the ground. We are definitely much more stable in the hospitals. We are much more resources. We are regrouped. We are ready to take care of patients, but the patients have to come. If they wait at home with these symptoms, we are not going to be able to save them.

So I just want to finish by saying, finally, our group and what we have tried to do is put effective, sound, physiologic, and evidence-based protocol, and we have been trying to disseminate it. We have sent it. It has gone to the White House three times now.

A month ago, it was given to a member of, I think, Kushner's team and brought to the White House. They apparently liked it; however, they got pushback from the National Institute of Health (NIH) and the CDC, who I think were cautious on the steroids.

Then 2 weeks ago, Dr. Marik was interviewed by former Speaker Newt Gingrich, who also brought it to the White House. We still have not heard.

Then this week, our protocol and our group's efforts were published in the American Spectator, and the editor of the American Spectator also brought it to the White House. We still have not heard anything.

We do think that we need to develop a national effective treatment strategy, and with that, I think I am just going to end there and just say we are experts in our field. This is what we do. We know how to take care of patients. Let us take care of these patients. We know that these medicines are sound. We know the safety profile. Everything in our protocol is safe, Food Drug Administration (FDA)-approved, has been used for decades. Yes, it is off label, but we do off-label stuff every day.

With that, I probably took too much time. I am done. Thank you.

Chairman JOHNSON. First of all, thank you, Dr. Kory, for just being a doctor, for your passion. I can tell you, now your protocol has been sent to the White House four times. I sent it to Mark Meadows today with a text that I pray somebody in the White House will pay attention to this and give it very serious attention. So, again, thank you for that. Again, thank you.

Our next witness is going to be Dr. David Katz. Dr. Katz is the president of the nonprofit True Health Initiative; CEO of Diet ID, Inc.; and a board-certified specialist with 30 years of experience in preventive medicine and public health, having trained and later taught at Yale University School of Medicine. Dr. Katz is the founding director of the Yale University's Yale-Griffin Prevention Research Center, received an MD from the Albert Einstein College of Medicine and Master's in Public Health from the Yale University School of Public Health. Dr. Katz.

TESTIMONY OF DAVID L. KATZ, MD, MPH,[1] PRESIDENT, TRUE HEALTH INITIATIVE

Dr. KATZ. Senators, I greatly appreciate the privilege of addressing you, the opportunity to share my perspective. I deeply regret doing so without recourse to a professional haircut. If someone had told me I was going to be addressing a committee of the U.S. Senate and doing so sporting my hairdo from 1978, I am not sure which of those two things I would have found harder to believe, but here we are.

I would like to make five quick points about COVID, and I will quickly note that I am addressing this primarily as someone schooled in epidemiology, public health, scrutinizing the global data and the data here in the United States. But I did volunteer in New York, did several shifts in an emergency department in the Bronx. This was part of the Montefiore system, and, Dr. Kory, you will be pleased to hear everything you just mentioned was standard procedure when I was there 2 weeks ago. It had not been the week before. Steroids were being used routinely. Apixaban was being used routinely, and on it goes.

[1] The prepared statement of Dr. Katz appear in the Appendix on page 458.

So the word is getting out. Whether or not the White House got the memo, others have.

The first point, this is different diseases in different populations. We heard about the population landing in the hospital, needing intensive care, but the global data clearly show that elderly people and people with a significant burden of prior chronic illness are at high risk of severe COVID infection, life-threatening infection.

But the global data showed at the very beginning and appear to show to this day that 98 to 99 percent of all cases are mild. Younger people, certainly people under 50, maybe under 60, people free of major chronic disease like heart disease, diabetes, this tends to be a relatively mild infection and may often be asymptomatic.

Mr. Chairman, you showed us the data out of New York and talked about the fatality rate there, but a seroprevalence study in New York showed that maybe 20 percent of the population of New York City and perhaps the whole State has already had this infection. That would be 4 million people, and when the denominator swells to that degree, the percent of severe cases drops precipitously.

It is actually quite interesting that 20 percent is the same number we got from the Diamond Princess cruise ship. Maybe a significant portion of the population is just natively resistant to this bug, but it is different diseases in different populations. There is a high-risk group—elderly, chronically ill. There is a low-risk group—younger, generally healthy.

Second point, from the start, it has been clear there were two ways for COVID–19 to hurt people, damage health, and ruin lives. One was by infecting them, but the other basically was the unintended consequences of our interdiction efforts. If we were protecting people who did not need to be protected from this virus because it was not acutely dangerous to them, then causing them to lose their livelihood, putting them in a position of food insecurity and potential poverty was more likely to hurt them than the virus.

I think a humanist, a public health person needs to look at that and say both ways that the situation can hurt people are bad, and that leads to my third point.

We really need to have one national policy objective, and it has nothing to do with trading lives against dollars. That objective is total harm minimization. We acknowledge that people can be hurt by losing their jobs, and that hurt reverberates through public health and something we call social determinants of health. Food insecurity hurts people. Desperation hurts people—depression, addiction. We have seen spikes in everything from gun sales to domestic violence to suicides since the advent of this pandemic, and those are real families. Those are real people. All of that warrants our attention too.

By the way, it is not clear how much of the toll of COVID in New York, in the United States, we mitigated with our interdiction efforts, because we may have closed the barn door after all the horses were out. It seems clear now that COVID was circulating in the United States before we knew about it. We have evidence to suggest from seroprevalence studies that millions and millions of people in New York and around the Nation have already been infected. So a lot of what we are saying may be what we would

have seen even with significantly less draconian interdiction efforts.

The other thing we want to do, of course, is restore key elements of our society because those are crucial to services, good, and supply chains, and ultimately become limiting in terms of people's health.

We also need to worry about people staying away from the hospital who have other important conditions because of the fear of going where COVID is that Dr. Kory described so beautifully.

And then one other critical issue that I think is often overlooked and that is we do need an all clear. Frankly, I think about people like my parents who are 80 years old. My mother worries that she could get COVID and die because she is in the high-risk group at that age. She also worries, though, if we are on an indefinite timeline waiting for a vaccine, that she could die of something else before she ever again gets to hug her grandchildren. So I do think important segments of the population are waiting on a plan back, and the most likely proximal route to an all clear is herd immunity. And that does not mean putting people in harm's way; it means risk stratifying the population. So we are able to say who can encounter this infection safely because they are overwhelmingly likely to have a mild bout of it, get over it, make antibodies, and it is fairly clear from the global data, we do make antibodies. We do become immune. There was some communication on that topic that I think was a bit misleading.

Point No. 4 is we need data to inform a risk-stratified approach back to life as we knew it before, protect the vulnerable, but allow many of us who are not prone to severe infection back. And in order to inform a risk-stratified approach, two things. First, we do not need millions of tests. We need a representative random sample. That could be 20,000 people, 30,000 people, or 50,000 people. We could make it a fairly big and robust number, but as long as it traverses urban, suburban, rural, all the different ZIP codes, all the different age groups, all the different health status, it would be enough to extrapolate to the population of 330 million of us and tell us what we need to know, who is at risk, who is likely to be hospitalized, who might need the ICU, who is at risk of death, and for whom is the risk of COVID infection commensurate with many other risks associated just with living routinely, and I think that is a critical element.

Frankly, this is something CDC does routinely, and it is the work of several days, at most a week, and it does not require millions of test kits.

Then, finally, in speaking with colleagues, some of whom are joining as witnesses today, others like Dr. Mike Osterholm at the University of Minnesota, arguably the Nation's greatest pandemic response expert, we do need a bracing does of humility.

Previous pandemics have fooled us. When we thought we were most of the way through the woods, we would get a second wave. We do need supplies of PPE. We do need to know we will have hospital beds if this come back in the fall. We need to know that the ventilators are available. So we have been forewarned we need to be forearmed, and it is possible that there will be additional waves.

I am hopeful there will not be. I am hopeful this has actually already been quite widespread in our Nation. Many people have had this that did not even know. Many people may be natively resistant, and maybe we are well on our way to herd immunity.

Sweden is an encouraging example, but I think we could do even better than Sweden by more carefully protecting the high-risk groups and using American data to inform that effort.

Then, finally, there has never been a better time for a Get Healthy America campaign. The things that place people at risk for severe COVID infection are things that were taking years from lives and life from years before: heart disease, diabetes, hypotension, obesity. These are all fixable, and they are fixable with lifestyle. We can use risk calculators to identify someone's individual risk. We can take advantage of the fixation on this condition and the acuity of concern to suddenly get people to care about those long-term risk issues, which have been a threat to people's lives, a threat to people's livelihoods, a drain on the economy, all the bad stuff associated with COVID. That was going on before, but I would encourage you to think about basically making lemonade from the lemons here.

We do not just have COVID to deal with. We were especially vulnerable to a higher percentage of severe cases because the health of the Nation was in peril before from chronic disease, and if we address that effectively now, we will both lower people's acute risk for COVID and create a gift that keeps on giving, a healthier America.

Thank you.

Chairman JOHNSON. Thank you, Dr. Katz.

Our next witness is Dr. Tom Inglesby. Dr. Inglesby is the Director of the Center for Health Security at the Bloomberg School of Public Health within Johns Hopkins University. Dr. Inglesby is also a professor in the Department of Environmental Health and Engineering at the Johns Hopkins Bloomberg School of Public Health. Prior to that, he was chair of the Board of the Scientific Counselors, Office of Public Health Preparedness and Response, U.S. Centers for Disease Control and Prevention from 2010 to 2019. Dr. Inglesby received an MD from Columbia University College of Physicians and Surgeons. Dr. Inglesby.

TESTIMONY OF TOM INGLESBY, MD,[1] DIRECTOR, CENTER FOR HEALTH SECURITY, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

Dr. INGLESBY. Good day. COVID–19 has done great damage to our country, first in terms of people sickened and lives lost and second in terms of the terrible economic consequences and job loss. As a sign of the speed of its spread, as of 2 months ago on March 6, there were 200 people diagnosed with COVID–19 in the United States. As of yesterday, 1.19 million Americans have been diagnosed with COVID, and more than 71,000 people have died. In the absence of social distancing, this epidemic doubles in size approximately every week. That is the data that we have up until social distancing began.

In the last month, more than 200,000 new American COVID cases have been diagnosed every week. We have a national plateau of about 25,000 to 30,000 new cases daily. We had more than 2,000 deaths yesterday from this virus, and a great majority of U.S. deaths have occurred in the last 30 days.

Yesterday 33 U.S. States reported more than 150 new cases of COVID in their States. Seventeen States have daily case counts that are still on the rise. On the other hand, 10 States do have a 2-week decline in numbers, which is encouraging, and States that have 2-week declines and meet other conditions for a safe reopening could be the least risky places for initiating reopening process. States reopening without safe conditions could be at risk for a rapid acceleration of cases.

Our team worked with colleagues at the American Enterprise Institute to publish a report recommending four conditions that should be in place before a State eases social distancing.

The first is sustained reduction in cases for at least 14 days. The second is capacity for hospitals to give all patients with COVID the full standard of care. The third is the capacity to test all people with COVID–19 symptoms, whether they are mild, moderate, or severe; and the fourth is capacity to conduct active monitoring and quarantine of cases and their contacts. These conditions are largely consistent with the criteria and core State preparedness capabilities in the White House guidance report called "Opening Up America Again."

Thirty-eight percent of adults in the United States, or 92.6 million people, are at higher risk of serious COVID infection, given their age of 65 or older or underlying health conditions.

Some have called for focusing social distancing and mitigation efforts only on this high-risk group, but there are no feasible approaches to separate off this one-third of American adults. Most estimates of the infected mortality rate by epidemiologist and public health organizations are that this virus causes something on the order of 0.5 to 1 percent infected mortality rate. If this virus transmitted widely without social distancing and high numbers of people got sick with COVID in the same period in a given city or State, there would be the potential of overwhelming health care facilities, outstripping available ventilators, and/or the people needed to run them.

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[1] The prepared statement of Dr. Inglesby appear in the Appendix on page 466.

We came very close to this scenario in New York City last month. If that did happen and there were not enough ventilators to go around for the people with COVID, the infected fatality rate, which I just noted, could go up substantially, as it appeared to do both in Wuhan and in Lombardy, Italy. It is very important to look at the experience of Wuhan and Lombardy and New York City in dealing with COVID. In each of them, this virus was rapidly able to go from being nearly invisible to causing a complete health crisis in a period of weeks. That pattern is absolutely nothing like influenza or any disease we have dealt with in modern times.

In the time ahead, we have to find a way to cope with the severe potential public health toll and the severe economic toll of this virus in the United States. Some States are in a safer position than others to cautiously start to move ahead on easing social distancing. Any State that does should recognize that COVID could rebound, rebound sharply, in the time that follows easing social distancing, and those States should track hospitalization rates, ICU bed rates, ventilator rates, and deaths very carefully and be prepared to change course if numbers substantially worsen.

Leaders in those State should communicate clearly to the public that individual physical distancing measures, distancing between people, mask use in public, avoiding gatherings will all remain critically important throughout this entire period until we have a vaccine.

Even the epidemic from rebounding and causing new waves will take collective great action on the part of the American public.

Thank you.

Chairman JOHNSON. Thank you, Dr. Inglesby.

Our next witness is Avik Roy. Mr. Roy is the President of Foundation for Research on Equal Opportunity, a think tank focused on expanding economic opportunity for those who least have it. From 2011 to 2016, Mr. Roy was a Senior Fellow at the Manhattan Institute for Policy Research. Prior to that, Mr. Roy was a financial analyst and portfolio manager at several investment firms. Mr. Roy writes for Forbes and has advised numerous candidates for public office on health care policy. Mr. Roy was educated at the Massachusetts Institute of Technology and Yale University School of Medicine. Mr. Roy.

TESTIMONY OF AVIK ROY,[1] PRESIDENT, FOUNDATION FOR RESEARCH ON EQUAL OPPORTUNITY

Mr. ROY. Chairman Johnson, Senator Peters, and members of the Homeland Security and Government Affairs Committee, thanks for inviting me to speak with you today.

As Chairman Johnson mentioned, I am Avik Roy. I am the President of the Foundation for Research on Equal Opportunity (FREOPP), a nonpartisan, nonprofit think tank focused on expanding economic opportunities to those who least have it. All research conducted by FREOPP considers the impact of public policies and proposed reforms on those with incomes or wealth below the U.S. median.

[1] The prepared statement of Mr. Roy appears in the Appendix on page 471.

It is for this reason that I am gravely concerned about the profound economic destruction that the COVID–19 lockdowns have caused.

You know that 30 million Americans have lost their jobs, and that the Congressional Budget Office (CBO) estimates that second quarter gross domestic product (GDP) will be 40 percent lower than it was at this time last year. Jobs for hourly wage earners, the most vulnerable workers in our economy, are down 60 percent relative to pre-pandemic levels. These are hairdressers and line cooks. They work at doctors' offices and on assembly lines. They are, in President Clinton's words, "those who work hard and play by the rules,"

The good news is that the lockdowns have done what they were supposed to do, ensure that our hospitals and our ICUs were not overwhelmed, Italy style, with severely ill COVID–19 patients. The bad news is that the shapers of conventional wisdom now claim that we must continue lockdowns for as long as we cannot test the entire population for COVID–19 and have an effective treatment and develop herd immunity and produce a vaccine. All of this, we are assured, can take place in the next 12 to 18 months.

But what if it takes us 12 to 18 years to develop a vaccine? We have never developed a coronavirus vaccine before. The best scientists in the world have been trying to develop a vaccine for human immunodeficiency virus (HIV) for nearly 40 years, and we still do not have one. Effective non-vaccine treatments may arrive sooner, but when? And is it realistic to stick 6-inch swabs up the nostrils of millions of Americans every day until that happens?

The question of when is of urgent importance. Every week matters. The average small business holds less than 4 weeks of cash in reserve. For urban small businesses, it is more like 2 weeks. Some have been able to take advantage of the Paycheck Protection Program, but as you know, it is actually medium-sized businesses, not small businesses, that have been organized enough and savvy enough to maximize that opportunity.

Shapers of the conventional wisdom argue that these devastating economic costs are necessary and acceptable because we must do everything possible to protect people from COVID–19.

Let me explain why this thinking is flawed. First, the costs of the lockdown are not merely financial. The closure of schools has only widened educational disparities between the haves and have-nots. There is considerable evidence that high unemployment rates are associated with higher mortality, including deaths of despair. And there is a cost in lives and health among those who have been unable to seek non-COVID-related health care, including unmanaged chronic disease, missed cancer diagnoses, untreated heart attacks, and unavailable organ transplants.

Second, one-site-fits-all lockdowns are not based on actual evidence or science regarding COVID–19 but are instead based on fear and on off-the-shelf playbooks designed for influenza, a meaningfully different disease.

The risk of death due to COVID–19, as we have discussed, is very low for those under the age of 55, and yet our restrictions on economic activity apply equally to people of all ages.

Roughly half the deaths from COVID–19 have taken place in the tri-State area around New York City, and yet we are treating Oklahoma, Utah, and Wyoming no different than Manhattan.

According to an analysis by my FREOPP colleague, Gregg Girvan, that we will be publishing this week, nearly half of all U.S. deaths due to COVID–19 are taking place in nursing homes, and yet we are not incorporating that fact into our assessment of the risks outside of nursing homes.

Similarly, the risk of outdoor transmission appears to be much lower than for indoor transmission, and yet many States are applying equally onerous restrictions to indoor and outdoor activity.

Third, we have forgotten how we deal with risk in other aspects of our society. 100,000 Americans die of hospital-acquired infections each year, and yet we do not shut down the hospital industry. 37,000 Americans die each year in traffic fatalities, and yet we do not shut down the roads.

Indeed, traffic fatalities is a good mental framework for thinking about how to live with COVID–19. Instead of abolishing cars, we enforce traffic laws and speed limits and prohibit drunk driving. We set a minimum standard for car safety. But, most of all, we expect individual drivers to be responsible for their own conduct and the conduct of passengers.

Something similar can work for COVID–19. Businesses can deep-clean their surfaces and provide hand sanitizer and masks to their workers and customers. People can wash their hands regularly and minimize close contact with strangers. This is, in fact, what East Asian countries did after the——

[Pause.]

Chairman JOHNSON. We have lost him. We seemed to have lost Mr. Roy.

We will come back to Mr. Roy to have him finish up his testimony. I guess in the meantime, we will move on to our fifth witness, Dr. John Ioannidis.

Dr. Ioannidis is a professor of Disease Prevention at the Stanford School of Medicine. He is the Director of the Stanford Prevention Research Center and a Co-Director of the Meta-Research Innovation Center at Stanford (METRICS). Prior to joining Stanford, Mr. Ioannidis chaired the Department of Hygiene and Epidemiology at the University of—I cannot pronounce that one—Ioannina Medical School and was an adjunct professor at several other schools of medicine. Dr. Ioannidis received his MD from the University of Athens School of Medicine and trained in internal medicine and infectious disease at Harvard Medical School and Tufts University School of Medicine.

Sorry for all the mispronunciations, but Dr. Ioannidis.

TESTIMONY OF JOHN P.A. IOANNIDIS, MD,[1] C.F. REHNBORG PROFESSOR IN DISEASE PREVENTION SCHOOL OF MEDICINE, STANFORD UNIVERSITY

Dr. IOANNIDIS. Thank you for the kind invitation and the honor to join this hearing and to share some thoughts with our Senators.

[1] The prepared statement of Dr. Ioannidis appear in the Appendix on page 476.

COVID–19 represents a major crisis with major loss of life. There is no doubt about that. We should use the best science in a data-driven, evidence-based approach to minimize human loss from this pandemic. We need to consider both the benefits and harms of each of our policy interventions and to adjust our interventions according to continuous feedback with reliable data.

Shelter-in-place and lockdown orders were justified initially when announcements declared a new contagious virus with 3.4 percent fatality rate and no asymptomatic infections. Prospects of 60 million deaths worldwide led to comparisons against 1918 influenza. However, currently we know that asymptomatic or mildly symptomatic infections that people are not even aware of and do nothing about are very common. The number of people infected are actually far, far more than those documented to date with polymerise chain reaction (PCR) testing.

Infection fatality rate is accordingly much lower than the crude fatality rates derived from dividing the number of deaths by the number of documented cases. The exact infection fatality rate will vary from one place to another, depending on whether hospitals have crashed or elderly care nursing homes have been widely contaminated or not, but in places that do not see these disasters, it is very comparable to seasonal influenza.

While this is a very contagious virus and many people can be infected, to date person-years of life lost from COVID–19 worldwide is probably in the range of a hundred- to a thousandfold less than the person-years of life lost from influenza in 1918. At a global level, the number of person-years lost this year from COVID–19 is comparable or less than that of seasonal influenza around the world.

Of course, a second wave cannot yet be excluded, and we need to be very cautious about that. Its occurrence and potential magnitude can only be speculated with mathematical models, but unfortunately, models have not been successful so far in making COVID–19 predictions. Therefore, we need to proceed with caution in lifting lockdown and monitor the impact of any changes in policy measures with real data as opposed to just using models.

The fatality rate from COVID–19 is highly dependent on age, and it is modulated by the presence of comorbidities. For children and young adults, it appears that infection fatality rate is lower than seasonal influenza, and for middle-age adults, it is about the same. Infection fatality rate can increase sharply, however, when nursing homes are massively infected and when unprepared hospitals are running close to full capacity even on a regular season are overwhelmed and the infection spreads to hospitalized patients or what we call nosocomial infections. This explains the paradox why COVID–19 is typically a very mild benign infection, but at the same time, it also has the potential to become devastating in specific settings.

While lockdowns were justified initially, their perpetuation may risk many lives. Unemployment may create more marginalized citizens without health insurance. Mental health can be affected with increases in depression, suicides, domestic violence, and child abuse. Gun sales have increased drastically. Starvation is becoming a global threat. Moreover, deaths from common chronic diseases

and treatable conditions such as heart attacks may increase as patients avoid hospitals from fear, as interaction with their caregivers is disrupted and hospitals become financially devastated.

Excess deaths accruing during COVID–19 weeks may reflect both COVID–19 itself but also deaths from health care disruption. COVID–19 overwhelmed a few dozen hospitals, while COVID–19 measures may jeopardize services and multiple health outcomes in thousands of hospitals.

Moving forward, we need to defend hospitals and nursing homes with strict infection control and hygienic measures. We need to have universal and periodic testing of all personnel. We need to have quarantine for infected and exposed personnel. Conversely, we should reassure most citizens, those of younger ages and, of course, all of those without serious preexisting conditions, but also many that just have hypertension or some mild condition that they are at extremely low risk.

Reopening efforts require great caution with continuous feedback to identify and limit any potential surge of hospitalizations and deaths upon reopening. Reopening should be gradual, with continuous feedback on epidemic activity. This includes data on seroprevalence, which means the proportion of people already infected, and incidence of new infections. These data should be balanced against bed capacity reserves. It is unrealistic to expect that new PCR-detected cases to disappear before reopening. PCR remains positive for a while in many patients who are no longer infectious.

Moreover, with increased testing and with a large pool of previously undetected infections, numbers of PCR-positive samples may seem to remain quite high, even though the epidemic wave has largely passed.

It is also unrealistic to expect COVID–19 deaths to stop accruing before reopening. Deaths may happen 3 weeks after infection, and modern medical technology can maintain some people on mechanical support even for months.

Finally, it is unrealistic to expect that complete contact tracing will need to be feasible before reopening. In most locations, the number of people infected is already too large, and their casual contacts may include a large portion, if not the large majority of the entire population, thus, making complete contact tracing infeasible. Complete contact tracing can be more feasible when the epidemic activity has ceased, for example, in the future when trying to catch early and extinguish potentially new waves.

The pace of the reopening may differ across locations, depending on their evolving levels of infection, hospital capacity, and population vulnerability structure. While treatment advances and vaccine efforts may be successful eventually, lockdown measures cannot be prolonged until we find treatments and vaccines that save many lives, since such breakthroughs may take a long time or may even never happen. For example, remdesivir has shown promising results in shortening disease duration, but no conclusive evidence yet for saving lives.

Thank you for listening.

Chairman JOHNSON. Thank you, Dr. Ioannidis.

Before we go back to Mr. Roy, we will have our last witness, Dr. Scott Atlas, testify.

Dr. Atlas is the David and Joan Traitel Senior Fellow at the Hoover Institution at Stanford University and a member of the Hoover Institution's Working Group on Health Care Policy. Prior to joining the Hoover Institution, Dr. Atlas was Professor and Chief of Neuroradiology at Stanford University Medical Center for 14 years. He received an MD from the University of Chicago's School of Medicine. Dr. Atlas.

TESTIMONY OF SCOTT W. ATLAS,[1] DAVID AND JOAN TRAITEL SENIOR FELLOW, HOOVER INSTITUTION, STANFORD UNIVERSITY

Dr. ATLAS. OK. Thank you. Thank you, Mr. Chairman, and thank you for inviting me to speak here today.

As we all know, the consequences of the COVID–19 pandemic, of course, have been enormous. That said, the direct daily toll from the infection has markedly declined, including in the epicenter of New York. The curves have been flattened. The stated goal of the isolation has been accomplished for both hospitalizations per day and deaths per day, the two curves that needed to be flattened.

We now, though, have an even greater urgency specifically due to the extension of the severe single-minded policies already implemented. Treating COVID–19 at all costs is severely restricting other medical care and instilling fear in the public, creating a massive health disaster in addition to the severe economic harms that could generate a world poverty crisis with incalculable consequences.

Half of neurosurgery patients still today refuse to come in for treatment of the disease that if left untreated risk brain hemorrhage, paralysis, and death, even when their doctors directly reassure them because of the fear. Transplants from living donors are down 85 percent from last year. In the United States alone, 150,000 new cancer cases arise every single month. These patients are not being seen. Biopsies of unknown, undiscovered possible cancers number thousands per week. They are not being done. That does not include the latest reports of skipping two-thirds to three-fourths of cancer screening tests, most childhood vaccinations, and treatments for emergency new strokes and known cancer chemotherapy.

One more thing we absolutely know is that this total isolation policy prevents broad population immunity. We know from decades of medical science that the population develops immunity while acquiring antibodies. Indeed, that is the main purpose of widespread immunization, to assist with herd immunity.

In the COVID epicenter of New York, undoubtedly muted by the extreme policies, we still see that more than 24 percent of those tested have antibodies, and a similar finding was reported in Boston. That fact has been incorrectly portrayed to the public as an urgent problem requiring mass isolation, but on the contrary, infected people are the immediately available vehicle for establishing widespread immunity among low-risk groups. While we do not know

[1] The prepared statement of Dr. Atlas appears in the Appendix on page 479.

with certainty that antibodies stop infection, it is expected based upon decades of virology science, including with other coronavirus respiratory viruses. That is exactly why scientists are hopeful about using COVID–19 antibodies to treat the sickest patients. That is the basis for the drive to generate a vaccine.

Reassuring the public about reentry is critical, and it requires repeating the facts, what we know about the threat and who it targets. By now, as Dr. Ioannidis implied, multiple studies from all over the world suggest that the overall fatality rate is far lower than early estimates, and those were the estimates that motivated the extreme isolation.

We also now know who to protect because this disease by the data is not equally dangerous across the population. For example, in Detroit's Oakland County, 75 percent of deaths were those over 70, 91 percent over 60, similar findings of New York. Again, healthier younger people have virtually no risk of death and almost no risk of serious disease and, similarly, highly unlikely to be hospitalized.

Here, specific science-based logical steps strategically and safety restore the pathway to normal life.

First, we must finally focus on protecting the known most vulnerable. That specifically is nursing home patients. Given that older people with underlying conditions were always the obvious setups for serious complications from respiratory diseases like this, it is difficult to even excuse policies that allowed almost 30 percent of U.S. deaths to die in nursing homes, more than half in some States, particularly when they already live under controlled access. This is an urgent need and probably too late to help for most people, but targeted strict regulation of all who enter, including mandatory testing for these people must be done. We must continue to educate and inform the public about what they have already learned regarding at-risk age groups and how to deal with them.

In addition to the standards of hygiene and appropriate social distancing that we already know, that has to be reinforced, and we know that people can do it. That is what is being done.

Second, those with mild symptoms of the illness should strictly self-isolate for 2 weeks. It is absolutely not urgent to test them. We assume they have the infection at this point. That includes confinement at home, having the highest concerns for sanitization, wearing masks when others in their homes enter their room.

Third, K through 12 schools should be opened. If under 18 and in good health, you have virtually no risk of serious illness. Exceptions exist, as they do with every single clinically encountered infection, but that does not outweigh and cannot outweigh the overwhelming evidence to the contrary. Again, standards for consciously protecting elderly and other at-risk family members and friends, including the teachers in high-risk groups, should still be employed.

Fourth, most businesses can be opened, including restaurants and offices, but of course, we require new standards for hygiene and sanitization, with more stringent regulations than we have had. It is reasonable to post warnings for customers who are older or in other ways at risk, and indeed, we already see businesses and workplaces setting up such environments because they already un-

derstand the obvious need to allay fears of workers and customers in order to regain function. However, it is not logical that younger age groups must somehow be isolated or maintain a 6-foot spacing from each other. If infection in low-risk groups is still prevalent, which it is, socializing represents the opportunity for developing the widespread immunity eradicating the threat to the vulnerable.

Fifth, public transportation, which is the lifeblood of much of the workforce, should resume. In addition to the standards of cleanliness and hygiene that passengers would welcome, of course, regional authorities could require things like barrier masks for passengers. Given the state of our fearful public, it is highly likely that most people will choose to wear them. Similarly, air travel hygiene has already been improved, and further changes are likely, regardless of any requirement, because travelers will simply not have the confidence to fly.

Sixth, parks and beaches should be open. There is no scientific reason to insist that people remain indoors. Given now that we know who to protect and how to protect them, even inside our homes, outdoor activities can resume with smart, considered limits on large-group gatherings.

Finally, prioritized testing is important, but it is important in three specific groups: nursing home workers, health care workers and first responders, and patients in hospitals with respiratory symptoms or fever. Widespread testing for the entire population is not a predicate for reopening as above with these guidelines, and contact tracing, although an important part of the overall preparation for potential future outbreaks, is not critical right now and is not as valuable after a disease is already widespread, infecting tens of millions of people.

In summary, targeted protection for the known vulnerable, standards and commonsense recommendations for individuals and businesses and prioritized testing are the basis of an urgently needed, strategic reentry plan that would save lives, prevent overcrowding of hospitals, and limit what are the enormous harms compounded by continued total isolation.

Smart, safe reentry cannot be delayed by fear or hypothetical projections. We have direct data on risk, and we have now experience with managing it. The goal of the strict isolation has been accomplished. We need to stop underemphasizing the actual empirical data and established medical science while instead somehow doubling down on hypothetical models. Science and logic must prevail over fear and worst-case scenarios.

Thank you.

Chairman JOHNSON. Thank you, Dr. Atlas.

Mr. Roy, you are back. I think we heard most of your testimony. Do you want to finish off, though? Do you know where you blinked out?

Mr. ROY. I am happy to finish up.

Chairman JOHNSON. OK. Go ahead, Mr. Roy.

Mr. ROY. Thank you.

So I was mentioning that something similar can work for COVID–19 in terms of the analogy I made to traffic fatalities and responsibility for the roads. businesses can clean their surfaces and provide hand sanitizer and masks for their workers and customers.

People can wash their hands regularly and minimize close contact with strangers. This is, in fact, what East Asian countries did during the original SARS outbreak in 2003, and it enabled them to gradually return to normal life, despite the absence of a vaccine or effective treatments.

We discuss this and many more opportunities for strategies for reopening in our coherent, bipartisan, evidence-based plan for reopening the economy called "A New Strategy for Bringing People Back to Work During COVID–19," coauthored by Lanhee Chen of the Hoover Institution; Bob Kocher of Stanford University; and Bob Wachter, Chair of the Department of Medicine at the University of California, San Francisco. The report is available at our website freopp.org.

I look forward to discussing these ideas during today's conversation. Thank you very much, and again, apologies for the interruption.

Chairman JOHNSON. Not a problem. Thank you, Mr. Roy.

Just out of respect for everybody's time, I will hold off on my questioning until the very end. I will just warn everybody—not warn, but give you a heads-up in terms of witnesses. I think during my questioning, I will ask each of you, if you have something, if you disagree with another panel member—I do not want to get heated arguments, but I do want this to be a discussion and challenge other people's assumptions or conclusions as well. So that will be kind of what I will go after at the very end.

Otherwise, we will go down in order of basically seniority. I will again remind the Members. I will let you during your 7 minutes pretty well control the little hand thing. If you see one of the witnesses that you did not call on that puts up his hand and actually wants to speak to your question, I will let you determine whether or not you want to call on that individual or just move on to your next question.

So if you do, as a witness, get your little hand up there and it does not get called on, I do not want you to be offended. People may not be noticing it, or they may want to direct their question to another witness.

With that, Senator Peters.

Senator PETERS. All right. Thank you. Thank you, Mr. Chairman, and thank you to all of our witnesses. A fascinating testimony and certainly, really a range of ideas for us to be thinking about.

My first question is to Dr. Inglesby. I have been speaking to a lot of our businesses all across Michigan over these last few weeks, and certainly, everyone is anxious to try to find whatever that new normal is and to try to open up their businesses. A number of the very large businesses in Michigan have developed very detailed plans. Our auto industry, for example, has put together elaborate plans to keep their workers safe as they open up production in the future, to keep them safe, spacing folks out, making sure certain exist and egresses are used and traffic flows, temperature testing, et cetera. All these basic guidelines are being put in place, and some of the major auto suppliers will be able to do that as well.

However, I am concerned that many small businesses simply do not have the resources on their own to put together that kind of plan for their business and will have to figure out how do they op-

erate to keep their employees safe and, equally as important, make sure customers feel comfortable coming into those places that are open.

So my question to you is, What more could the Federal Government do to help those small businesses really understand what they need to do in order to keep their employees and their customers safe? How should we be thinking about it?

Dr. INGLESBY. Senator Peters, I have heard from big businesses and small businesses that what business really wants is some kind of very clear and detailed guidance from the Federal Government to help them set their own standards.

They worry about their own employees not feeling confident in coming back to the workplace. They worry about customers not feeling confident that businesses have necessarily taken all the right steps.

So for them, at least what I have heard, is that they really would like detailed guidance from CDC or Occupational Safety and Health Administration (OSHA) that would help them measure themselves. They are not necessarily asking for new regulations, but they are asking for a lot of clarity about what a safe environment looks like in different kinds of work, both retail, construction, office space, a variety of different settings, really tailored to those industries.

So for the industries you are talking about in Michigan, both in the automotive industries but also in agriculture, the more detailed guidance that employers can get, that workers can see, I think the better.

I think the other thing, for places that are large indoor facilities, they definitely are going to need access to the right kind of protective equipment. Now we have seen countless meatpacking facilities get very large outbreaks. We have seen outbreaks in prisons. We have seen outbreaks in nursing homes, in cruise ships. Indoor congregate settings are really among the highest-risk places.

We do think, fortunately, that smaller businesses are probably at lower risk. There is less people coming in and out of those organizations. They are less dense, but certainly, I think many of them would like to get either from a State agency or even probably for many who work in multiple States, they would like some kind of Federal clarity about what they should be doing.

Senator PETERS. Thank you, Dr. Inglesby.

I want to actually pick up on a point you mentioned about having personal protection equipment and how important that is going to be outside of just medical settings, where clearly that is where their priority is.

But if we look at what has transpired over these last few weeks, it has been a real challenge to get the masks, the respirators, the gloves just to our critical frontline folks, our doctors and nurses and med technicians. But as we start looking at opening up the economy, the demand for PPE is going to go up dramatically.

So my question to you is, Do you believe that the current supply chain is prepared to meet these needs right now in your assessment? I know Johns Hopkins has done some assessment of that.

Dr. INGLESBY. It is difficult to know because there are not any clear metrics that I think are being put out by the Federal Govern-

ment or State governments on this. I think if you speak to hospitals, it is a patchwork. Some hospitals feel like they have been able to get the PPE that they need. Other hospitals clearly do not feel that way, and we have not been able to really extend PPE supplies to industry in the way that industry seems to be seeking. And I think it is quite important.

My colleague at our center calculated that over a 100-day period in COVID, so a 3-month period, the country would need an additional 3.3 billion gloves, 57 million N95 masks above normal usage, and 179 million surgical masks for use around the country in health care facilities. This is exclusive of the need for business or for the need to use those masks in other settings.

So I think that is a very high demand. I do not know whether we have met it. There is no real way to measure that, and that was for the first 3 months of this illness. So as COVID goes on, we will need to reassess, see where we are in the outbreak, see how it has responded to the coming changes in our social distancing policy, and then make decisions about that.

Senator PETERS. Those are big numbers, and when you multiply it by all of the businesses that are going to need it, they are astronomical numbers in terms of what we are going to need.

Given our supply chain that we have now is primarily overseas, most of all this equipment is produced in China and other places. Give me your sense of how important it is for us to be thinking about bringing back production from China or actually taking it back. A lot of it has gone over there, but take it back and how we really need to source this type of manufacturing capability in the United States, not only to deal with this pandemic, but future pandemics.

Dr. INGLESBY. Yes. I completely agree with that. I think, unfortunately, both for PPE but also for antibiotics, a majority of what we get is from overseas, and that has been done for kind of commodity, again, the cheapest pricing over the years, but at this point, I think given the experience we have lived through, it have been searing and terrible. I think we should be very dedicated in bringing back those kinds of industries that we will need in future emergencies, and that does not mean we need to bring back the production of every medicine in America, but bring back the medicines that we believe we will need in the first months of a crisis, the PPE that we will need in the first months of a crisis, that we cannot afford to have cutoff from overseas productions. I think that should be a strategic goal of ours coming out of this pandemic.

Senator PETERS. Great. Thank you. Thank you for those answers.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thanks, Senator Peters.

I want to apologize to everybody for how we started late, and I realize some of you are going to have to go. We will not be offended if you have to go to other things. It is perfectly understandable.

What I will do is I will alternate between parties now based on seniority of who is actually in the WebEx seminar right now. I do not see Portman, Paul, or Lankford. So I think I will go next to Senator Romney. I see you are on, if you are ready, Mitt.

OPENING STATEMENT OF SENATOR ROMNEY

Senator ROMNEY. Yes. Thank you. I am.

I have just a couple of comments first. I appreciate the work that each of these individuals has provided and their testimony today.

A couple of comments first. Mr. Roy's comment that comparing, if you will, the number of deaths with 1918 as well as from the standard flu, I would note that, yes, they are much lower numbers than one might associate with this pandemic, but the President just last night said that without the actions he had taken to close down the economy, we would have had 2 million dead. So I think we have to recognize that while the numbers we are looking at are consistent with the normal influenza year, at least so far, we have taken pretty dramatic action, and that is, perhaps, one of the reasons why they are not as high as they could have been.

Dr. Atlas also indicated that the COVID infection rate has declined, that the curve is now aiming downward. I think that is true if you include the tri-State area or, frankly, just New York, but if you look at the national figures, excluding New York, why, the numbers continue to go up. I think we have 19 States that are actually seeing the number of infections and the number of deaths going up.

But my question that I am going to pose to Dr. Ioannidis or anyone else who would like to comment on it is this. I feel, as you do, that, gosh, this is very much like a standard flu. Maybe we have overestimated the mortality rate associated with this, and it is very dangerous for people who are older or who have underlying conditions. I look at the data that came from Massachusetts and from New York and from the prison study in the South as well, and it all suggests that there are a lot of asymptomatic people, and that perhaps this does not have the mortality rate that we feared.

On the other hand, I look at the data that comes from the meatpacking facilities, the number of people who died that just work in the meat processing area, likewise grocery store stocking clerks, a normal flu, you do not have dozens of people die that are stocking clerks. You do not have dozens of people die that work in meatpacking processes. What accounts for that phenomenon that you are seeing a lot more deaths than you would normally see were this just like a standard flu for people, under 50 years of age?

Dr. IOANNIDIS. I think that the reason for that paradox, which is indeed very prominent, is that there is a very steep gradient of risk. Influenza has less steep of a gradient of risk across age, even though it also has an age gradient, and also a less gradient of risk across people who are at high risk in facilities like those that you mentioned, even more so in nursing homes or in hospitals that you may get hospitalized, people getting infected with nosocomial infections.

In contrast to influenza, we do not have a vaccine. So staff in nursing homes, for example, typically have very high rates of vaccination, same thing for personnel in hospitals, in acute care hospitals. So it is really different when it hits these locations where you have a lot of vulnerable individuals clustered together, and you do not have the same background of vaccine protection that we have for influenza.

However, this being said, we have the means to protect these specific locations that can be the places where disaster can happen, and the vast majority of the population that are at risk would be the same or even less compared to influenza.

Influenza, for example, kills thousands of kids around the world every year. This does not happen with COVID–19. It gives lots of very young, completely healthy people—this does not happen with COVID–19.

We need to be smart. We need to avoid the disasters. We need to protect very carefully all the settings where we can get a disaster and at the same time mobilize something like 85, 90 percent, perhaps more of the population who would be at minimal risk or very low risk.

Senator ROMNEY. Yes. I do understand that, although people who are working in food processing and working in grocery stores are not a population that we would think we need special care for. I mean, I understand certainly nursing homes and the like, yes, we really need to make a very special effort there. But these are normal Americans that are seeing a very high level of mortality, which is inconsistent with the idea that this is just sort of the normal flu-type mortality.

Another question that I had for you, Dr. Ioannidis, is this. I really wonder how many people are asymptomatic. There are some studies. The prison study in the South, for instance, in five States in the South, I think it was, suggested that like 93 percent of the people that tested positive for COVID–19 had no symptoms, and if that were the case, you would say, well, there is no way to stop this from spreading rampantly through a society. You could not possibly get people who were asymptomatic to know that they need to isolate.

But on the other hand, you have a place like South Korea, which has pretty well snuffed out the extent of the disease, and there are other places, Australia, New Zealand, and so forth. So if there were massive numbers of asymptomatic people, how would they have been able to snuff out the number of severe cases that we are seeing in the rest of the world?

It is hard for me to square some of the data. That is the challenge I have. I look at some data that says all sorts of asymptomatic people, and then I look at the others, and I say that is impossible. Where do you come down on that? What do you think the proportion of our population is that is really asymptomatic and is still spreading the disease?

Dr. IOANNIDIS. I think that all the studies point to the fact that asymptomatic infections or mildly symptomatic infections that do not reach the level of attention that people would want to be tested are the vast majority.

If you retrospectively ask people, of course, if you ask them, "Do you have any cough or any symptoms in the last few months?" probably most of us will say, "Oh, yes, I can remember something." Maybe—who knows?—2 weeks go or 4 weeks ago or 2 months ago. But the vast majority of infections are not at a level that would draw attention, either asymptomatic or very mildly symptomatic.

What happened in South Korea and also in Taiwan is that they were very aggressive in testing very early on and in tracing con-

tacts of people who were infected. Taiwan is a country that has practically one large international airport. They were very aggressive to just test everyone who would be suspicious and then quarantine and then test all the contacts and again quarantine, and this worked. It worked very nicely, and if we have a new wave or, let us say, a new pandemic, this is a way to go, especially if you get it very early on. You have that intense testing and tracking.

Senator ROMNEY. Thank you.

Dr. IOANNIDIS. It is not going to work in a situation where you have 30 percent of New York already infected at the moment or 5 percent in other States or 10 percent or 12 or who knows. It is very difficult to contract trace when you have a sizable portion of the population already infected. They have been exposing almost everyone else to the infection.

Senator ROMNEY. Thank you.

Dr. IOANNIDIS. South Korea had more cases, but actually, they had a very big outbreak in a religious sect.

Senator ROMNEY. Right.

Dr. IOANNIDIS. So they knew how to limit and how to contain the boundaries of their testing, and they also were very aggressive in asking people to come in and get tested right away.

Senator ROMNEY. Thank you.

Chairman JOHNSON. Thanks, Senator Romney.

Again, I want to just draw everybody's attention to the 7-minute limit. I am mindful that three of the witnesses put up their hand, but that is up to the Senators to call on those individual witnesses if they choose to.

Our next Senator up to the plate is Senator Carper.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Thank you. I used to have the privilege of chairing this committee, and I am now the senior Democrat on the Environment and Public Works (EPW) Committee, which reported out unanimously today major legislation on infrastructure. Sometimes people think we cannot find anything to agree on, but every now and then, we do. What do they say about a blind squirrel that can easily find an acorn? We are going to look for some acorns right here with all of you.

I am going to ask Dr. Inglesby, if you will. Dr. Inglesby, I am going to ask you to just go back and think about what each of our other witnesses have said. We will start with Dr. Atlas. Let us pick something that Dr. Atlas said that you agree with. It does not have to be profound. If we were actually doing a real hearing, what I would do would be to ask you, go down line and ask each of you to say what are all the points where you agree. I do not know that works today, but I will just pick on you, Dr. Inglesby.

Dr. IOANNIDIS. Sure.

Senator CARPER. Just something that Scott Atlas from Stanford—our son went to graduate school there. Nice to see you.

But something he said that you think, yes, absolutely.

Dr. INGLESBY. I agree with Dr. Atlas about the critical importance of doing better with nursing homes and how it has been, I would say, so far a collective failure across the country to be able

to prevent so much sickness and death in nursing homes. I think that is very important.

Senator CARPER. All right. Thank you.

So I am going back to Dr. Katz. Can you recall something that Dr. Katz might have said that you said I agree with that?

Dr. INGLESBY. Yes. Let us see. I think Dr. Katz is right that many people are deferring hospital care, and that is creating its own secondary large problem. And we need to communicate better with people that they should be coming to the hospital and getting their regular medical care.

Senator CARPER. All right. Thank you.

And, Dr. Ioannidis, has anyone ever mispronounced your name?

Dr. IOANNIDIS. I think that there is 80 variances, and all of them are equally fine.

Senator CARPER. All right. Dr. Inglesby, how about something that Dr. Ioannidis said that maybe——

Dr. INGLESBY. I think Dr. Ioannidis said something along the lines of how important it will be to measure very carefully as we begin the next phase and to be very carefully monitoring how our social distancing changes are affecting the disease rate. I think he said that.

Senator CARPER. All right. And how about something that Dr. Roy said? I can see the faces of all these people as you mention——

Dr. INGLESBY. Yes. And I am trying to remember. I think Dr. Roy——

Senator CARPER. They can always say, "I never said that."

Dr. INGLESBY. Dr. Roy talked about the profound economic hardship that this disease is causing across the country, and I absolutely agree with all that he said about the hardship that Americans are going through, the job loss, the importance of considering strategies now that we can to reverse that.

Senator CARPER. All right. Dr. Kory. Dr. Kory did not have much time to talk to today, but do you think anything he said in his remarks that——

Dr. INGLESBY. Oh, I am sorry. I think——

Senator CARPER. Conflated? You conflated?

Dr. INGLESBY. I think I mixed up two of the speakers.

I think the speaker who was speaking—Dr. Roy was speaking about—I think Dr. Kory was speaking about medical interventions, and I thought his discussion about how the conditions in New York City and the urgency with which we needed to deal with the onslaught or the incoming numbers of patients who need critical care, I thought that was very important.

Senator CARPER. All right. And now back to Dr. Roy.

Dr. INGLESBY. I think that was what I said before about the economic losses and the hardships. I agree completely with his assessment of the economic implications of what is happening.

Senator CARPER. We do not have many doctors who have served here in the U.S. Senate. We just lost a former Ranking Member, Ranking Member Tom Coburn, who died last month, very sadly. He was a great member.

But if you were serving on this Committee, let me just go through the list. I will start with Dr. Roy. If you were serving here with us in the U.S. Senate, what would be the one thing that you

would focus on in getting out of this and getting back on the right track? Very brief from Dr. Roy, please.

Mr. ROY. A great question, Senator. In the plan, I would say the things that we would highlight are—particularly for what Congress can do is give safe harbor to businesses that can reopen, but the one thing I would just amplify what has been said before about guidance from OSHA and CDC, it is also important to give liability protection to businesses that reopen but also give aid to workers who do not feel confident to go back to work, some sort of paid sick leave or some analogy to that, so that businesses can get back to work and workers can feel confident and have relief if they do not.

Similarly, aid to schools——

Senator CARPER. Hold it right there.

Mr. ROY. Yes.

Senator CARPER. I see Senator Harris has joined us. I think she has asked me if I would yield my last minute. Do I have 30—I have 90 seconds. If you have time, will she be recognized, Mr. Chairman? Otherwise, I will yield what is left of my time.

Chairman JOHNSON. That is fine. If you want to give her 90 seconds, go ahead. Senator Harris.

OPENING STATEMENT OF SENATOR HARRIS

Senator HARRIS. Can you hear and see me?

Senator CARPER. We can hear you now.

Chairman JOHNSON. We can hear you now. Yes, go ahead.

Senator HARRIS. OK. Hopefully, you can also see me. Can you see me?

Senator CARPER. No.

Chairman JOHNSON. There you go.

Senator CARPER. Yes.

Chairman JOHNSON. We got all of you.

Senator HARRIS. OK, great.

Thank you, Senator Carper.

It is very brief and very to the point. Chairman, it has been 2 months since our Committee last met to remotely discuss COVID–19, and at the time that we last met, the number of coronavirus cases were about 200, and now they are 1.2 million. The death count in the country has gone from low double digits to over 70,000, and of course, these are our neighbors and our friends and family members. And then let us not talk about the global crisis around the world that is now affecting 186 countries.

I said at our roundtable in February—and I will repeat it—that we must hear from the officials who are currently responsible in the administration, who are currently responsible for addressing this pandemic.

Our Congress has passed four consecutive relief bills totaling at least $3 trillion, and there have been a multitude of problems with the way that that money has been disbursed, be it PPEs to frontline workers, be it small businesses and minority-owned businesses who are not going to gain the relief of the Paycheck Protection Program, be it the fact that we do not have enough testing to reasonably reopen our country.

It is in our job as our Committee—given that the Federal Emergency Management Agency (FEMA) is responsible for organizing

and coordinating all of the Federal agencies, and of course, our Committee has the responsibility for oversight of FEMA—that we bring current administration officials in to discuss with us what their plan is for the administration of taxpayer dollars. And at the Health Committee, they are having Dr. Fauci come. They are having the point person at the top level of the administration. We should do no less. We should not have low-level officials. We should have those folks who have the responsibility and the authority for the administration of the American taxpayer dollars to come in and be accountable to our Committee and our responsibility of oversight.

So that is my request of you, which is that immediately we bring those to administration officials in to be accountable to the American people, to get the American people through this pandemic and through this crisis in the most efficient and productive way possible.

Chairman JOHNSON. Thank you, Senator Harris. We will absolutely be doing oversight.

I have certainly been participating in multiple hour-long conference calls with officials across the administration. I know Senator Hassan has been on a lot of those calls. I think those things are pretty wide open to Members. The administration certainly has been briefing us. We will do the oversight. Those folks are working like 24/7. So I want them to concentrate on the job before they start testifying before Congress. They are briefing us quite regularly.

What we will do now is we will move on to——

Senator HARRIS. That logic would suggest that we do not have them come in before there is a vaccine, which, of course, is unacceptable.

Chairman JOHNSON. I do not——

Senator HARRIS. It is our responsibility to engage in oversight, Mr. Chairman, and I have registered my request of you and what I believe to be the mission and the responsibility of our Committee.

I appreciate you giving me this time. Thank you.

Chairman JOHNSON. OK. I understand.

Senator Lankford is now online. So, Senator Lankford.

OPENING STATEMENT OF SENATOR LANKFORD

Senator LANKFORD. Jumped in between you there.

It is good to get a chance to be able to hear all of the testimony. I appreciate all the folks that are here. Let me bounce a couple of questions.

Dr. Kory, I want to go back to some of the statements you made at the very beginning. Thanks for your description of what you have already done and the process you have gone through and the different ways that the disease itself is presenting, and it has changed pretty dramatically, the shortness of breath and everyone talking about this being a lung issue. It is now being blood, heart, and all the different aspects that are coming up now.

You made a comment about intubation of patients. I want to be able to follow up on that a little bit. Are you suggesting that we are using too many ventilators, that we are using the wrong proc-

ess, that we are using intubation too often? What has changed in what you have seen in the process of taking care of patients?

Dr. KORY. Terrific. That is a terrific question. OK. So let me tell you what I have understood, and again, I do not want to claim to be the world expert, but I will tell you I have been talking every day for 6 weeks to people all around the world and mostly in New York.

Here is the issue. It is that when this disease first presented, all the doctors were quite intimidated because there was so many reports of like this acute respiratory failure where patients could not breathe on their own. So a lot of systems and a lot of institutions, they decided to adopt these early intubation protocols. Whereas, traditionally, when we see someone who is having difficulty breathing or in respiratory distress, it is a challenge.

I am a pulmonologist and a critical care doctor. I have never in my career been able to decide when to intubate someone. It is a chronic challenge because you do not want to intubate too early and you do not want to intubate too late, because if you intubate too late, sometimes at least a cardiac arrest and it leads to very poor outcomes of the patients. If you intubate too early, you might put someone on a mechanical ventilator in which the harms of mechanical ventilation will be profound. Whereas, you could have avoided that if you did not intubate. So I just want to say that is the core challenge of my specialty.

When COVID came along, it was just weird, the reports coming out of China and Italy about how noninvasive ventilation and other respiratory support structures were failing. Many people in this country, around the country, said, "You know what? The best thing is to intubate them early. They are going to fail. Let us intubate them early and protect them," and that is what happened a month and a month and a half ago.

I fought against that. I thought it was going to be harmful to intubate the patients too early, although the severity and the acuity of this disease and how rapidly it progresses, we really did not know. But I was on the phone every day talking to patients, talking to my colleagues around the country, asking them what they were seeing.

So all I am going to do—and I am going to finish with this is that most centers around the country, I believe, adopted early intubation protocols in which they put patients on ventilators probably and they thought safely before they needed to, but that led to untold harms.

Now what I am seeing in New York City is unbelievable. I am seeing in my hospital here that I am working at is we have a tolerance to avoid intubation to the extremes. These patients are being supported with oxygen support, noninvasive ventilation, and we are avoiding intubation because the outcomes after you put them on an invasive mechanical ventilator are really dismal. So we are trying to avoid that at all costs.

So it is really a moving target, and we are evolving in how we approach this. But it is a challenge. I do not know that we are getting it right, but all I can tell you is I think we got it wrong in the beginning. But we are doing much better now.

Senator LANKFORD. OK. That is extremely helpful. I really do appreciate the insight on that because you got a chance to be able to see, obviously, a lot of patients and a path that you are seeing for care, and I am grateful for folks that early on trying to be able to work through to be able to solve this, because you are going to be able to share a lot of wisdom and insight to a lot of other folks.

Let me shift to something that Dr. Katz had mentioned before. Dr. Katz, you had mentioned something about unique moments to deal with the health of Americans. If you could drill down on that. Obviously, there is a lot of conversation about diabetes and being oversight and be able to have greater heart strength through exercise and such. Is that what you are talking about as a part of being preventative on this disease? Are you suggesting that what you are seeing on COVID–19, you are less likely to be able to face the severity of the symptoms of COVID–19 if you are doing exercise, if you are taking vitamins, if you are eating healthier, if you get your weight down? Is that what you are suggesting?

Dr. KATZ. All of the above, Senator, and thank you.

Actually, I think this relates back to a question Senator Romney raised a little bit ago: Why were we seeing higher rates of severe disease among people working in a meatpacking plant?

Senator LANKFORD. Right.

Dr. KATZ. There really is a perfect storm of confluence where the portion of the population most harmed by unemployment, because they were living hand to mouth, and struggling most, perhaps, to access the medical system and most burdened with those chronic diseases that sadly are all hyper endemic in the United States vis-a-vis type 2 diabetes, heart disease, all occur in the same population.

So I think among the strategies we have to adopt—and there really is an opportunity here at the Federal level to provide leadership—I think we have been relatively, if I may say it, contemptuous of chronic disease simply because it is chronic. The human nervous system is sort of hardwired to perceive threats that come at us fast. The fighter flight response, right? It is something that is coming at you in seconds, minutes, hours, maybe days, activates your adrenal gland and get your attention. COVID has it. Everybody is fixated on this.

But a large segment—I actually shared via the chat function of a paper that colleagues and I just pre-published today looking at the prevalence in the United States of these chronic disease liabilities that increase the acute risk for severe COVID infection. So that is exactly what I am saying. These things are hyper endemic, but the good news is dietary practices can modify immune function, improve immune balance in a matter of hours, significantly in a matter of just days, and profoundly in weeks. Control of type 2 diabetes could be improved significantly with lifestyle intervention over a very short period of time. Blood pressure can be lowered. Inflammatory states can be mitigated.

So the very same things we maybe should have been thinking about before to make America healthier now really becomes a matter of acute defense against COVID.

I think we can also use—in addition to representative random sampling to get a good understanding of the national data, we ac-

tually can use risk calculators[1] to determine what is the risk of severe infection, hospitalization, ICU need, or even at the individual level, and then offer up resources to individuals by various means, some via the internet, but all the resources that are collected, disposal, to empower people while they are sheltering in place as we transition to the next phase of policy, actually acutely lower their risk.

A sizable portion of our population could shift from the higher-risk group because of their current state with regard to chronic disease and weight and inflammation and migrate down to a lower-risk group by using lifestyle as medicine. I do not think there has ever been a better opportunity, and frankly, we think about the health of the population, both acutely and chronically. This is clearly a homeland security issue. So this is a great place to take up that mantle.

Senator LANKFORD. Thank you.

Mr. Chairman, thank you for the time, and thanks for pulling the hearing together.

Chairman JOHNSON. Thanks, Senator Lankford. Senator Hassan.

OPENING STATEMENT OF SENATOR HASSAN

Senator HASSAN. Thank you very much, Mr. Chairman and Ranking Member Peters, for having this hearing, and it is good to hear agreement about the importance of population health to our homeland security because that is one of the reasons that so many of us want to make sure that every American has access to good health care, all up and down the spectrum.

I also wanted to thank all of the witnesses for your participation today and just comment on the fact that what I would like to focus on is not a binary choice between opening our economy and having more people get COVID–19, some of whom will terribly and tragically die from it, or stay in a lockdown forever. I think there is another path, and it is the path that public health experts have been talking to us about, which is how do we implement public health tools, use the right kind of public health tools to reopen safely, protecting life as well as livelihood.

Dr. Inglesby, I would like to start with a question to you, please. First of all, thank you for your work during this pandemic to help provide medical and scientific expertise about what we need to be doing to keep Americans safe and our country strong.

There has already been some mention in our discussion today and in some of the testimony about the need for more daily testing, but I want to return to that topic because I think it has to be a focal point of any conversation about reopening the economy.

As you know, there are a variety of reports from public health experts projecting how many tests per day will be required nationwide as a part of a safe reopening strategy.

The Center for Ethics at Harvard recently put out a blue ribbon report stating that as a Nation, we may need 5- to 20 million tests per day. Other estimates have been even higher.

So, Dr. Inglesby, while I realize that modeling can vary and is dependent on a variety of factors, based on your research, have you

[1] COVID Age Risk Calculator appears in the Appendix on page 487.

determined how many tests we need to perform on a daily basis in order to fully reopen the economy nationwide, and are we at that level currently?

Dr. INGLESBY. So right now, we are testing somewhere on the order of 250,000 people a day, give or take, and we have been focusing primarily on people who have severe illness, people who are hospitalized, people who are in nursing homes, and then to some extent, the outbreaks that we have talked about, meatpacking, et cetera.

We know they were missing a large number of people with that strategy because we have not had testing to be able to reach out to them. So people who have mild to moderate illness, they could be COVID. We are not easily able to test them. They either cannot get a test, or they cannot get it quickly. So our estimate at our center is given the number of people that we believe have been infected in the country that have not been counted, we believe we need to scale up testing by an order of five times or so daily. So that would be about a million tests a day to get the full complement of everyone who has COVID symptoms on a daily basis in the country.

That might go down if the epidemic gets better, but for now, given the numbers that we have, we think that would be an approximate number.

I was just going to say the one thing it does not include, which the Harvard Center also tried to get to and others, is the second category of organizations that want testing, which is business in America and institutions, universities. They want to include testing as part of their reopening strategy. They want to incorporate screening. They want to incorporate sentinel testing. So if you include that, that is another additional set of testing which there is no real estimate yet that has been created by big business in America, but I think that would add millions of tests a day if we actually are able to do that.

Senator HASSAN. Do you have an idea of when we could reasonably expect to get to the point where we are doing the level of daily testing that you are talking about? Let us start with the million that would be testing people with symptoms or on the front lines and the most ill. What will it take to get there?

Dr. INGLESBY. I talked to a representative from the diagnostic industry earlier this week, and their sense is that they are getting close to that number in terms of being able to manufacture that number of tests, a million tests a day. But, clearly, that number is not actually happening, and part of the reason for that is maldistribution in the country. Part of that is lack of reagents. They might have a test kit, but they do not have the right reagent. They may not have swabs. We may have actual kits for that many people presently, but we do not have the full package or the operational planning to be able to deliver those tests to where they need to get.

Senator HASSAN. What could we do as Congress to help us get there?

Dr. INGLESBY. I think continued monitoring of industry and a commitment to the industry that this market is secure, that if they make tests for COVID–19, they will be purchased by the U.S. Gov-

ernment for this process. This is probably something that they are aware, but I do not think they have a sense of what market size the U.S. Government wants or U.S. industry wants. So there is some uncertainty. Should they make capital investments? Should they shut down other lines in favor of this one? Are they going to be crowded by other diagnostic developers? I think it is a complicated calculus for them, and the more that the U.S. Congress and the administration can say we intend to purchase these, we intend this market to be secure, it will grow over time because we need it for business, university, institutional purposes, as well as public health. I think that could help.

Senator HASSAN. OK. Thank you.

I have one other question for you, Doctor, and it follows up really on the line of questioning that Senator Peters had.

In recent weeks, even with social distancing measures in place, we have seen outbreaks of the disease at businesses and at gatherings across the country. For example, 81 employees tested positive at a Walmart in Massachusetts last week. It is unknown how long the virus was spreading within that store or how many people those employees had contacts with.

In order to reopen in a way that keeps employees, customers, and families safe, we need to be able to contain these types of outbreaks before they become widespread, and that requires support beyond diagnostic testing for people with symptoms.

We talked with Senator Peters some about the things businesses can do to open up safely, the kind of guidelines they need, but could you focus a little bit on the importance of robust contact tracing to contain community spread and immunity or vaccine registries that could be used to protect high-risk individuals?

Dr. INGLESBY. So all countries in the world that have done well against COVID–19 so far have had very strong public health capacity and the ability to do contact tracing and to isolate cases and then quarantine contacts and track them over 2 weeks. We saw that in places around Asia. We have seen it in New Zealand, Iceland, countries in Europe, and places that are succeeding have very strong contact tracing programs.

And we are beginning to move in that direction. States have announced programs to hire many contact tracers. Congress has done a number of things moving in that direction. The reason why that is so important is because that is the way to cutoff the chains of transmission. That is the way to get people isolated so they are no longer infecting others, and that gets people out of commission a bit at home, and it begins to drive down the numbers of infection. We have seen this in many and great detail in places around the world.

So we need to build that. It is not complicated to do it, but it takes some time. It takes resources for States to hire people. It does not need to be a commitment for 10 years, but it needs to be a commitment for the course of this pandemic.

Senator HASSAN. Thank you. I think it also would be very important in terms of giving the public confidence that when they do go out and they do engage in commerce or any other activity of their daily lives that the likelihood of them being in a safe place is much

greater, and I think that goes to the concerns that the public understandably has about this disease.

Thank you, Doctor, for your work and your testimony.

Dr. INGLESBY. Agree. Thank you.

Senator HASSAN. Thank you, Mr. Chair, for this hearing.

Chairman JOHNSON. Thanks, Senator Hassan.

We do not have a Republican teed up. What I would like to do is I see three witnesses with their hands kind of up, if they want to say something. So I will give them each a shot. I would appreciate succinctness before we go to Senator Rosen.

We will start with Dr. Atlas. Then we will go to Mr. Roy and then to Dr. Katz. Dr. Atlas.

Dr. ATLAS. Great. Thank you for allowing that.

Just a couple of points of clarification, and these are things that keep being repeated, but they are just misconceptions.

Senator Romney said that the curves are not coming down because the number of cases are actually going up in certain States. That is really not a curve to really watch at this point. We know that the more testing we do, the more cases we have. That is not a relevant curve. That was never a direct goal of the policy. The only curves that count are the number of hospitalizations per day and the number of deaths per day, not the number of cases.

Second point that again really needs to be clarified, there is somehow a false narrative that is being perpetrated that the people who do not want to total lockdown are saying there should be wide-open economic—and the isolation. That is actually not true. No one here is saying that. I do not know anyone who believes that. Everything is about targeted, protecting the at-risk people and allowing people to get out who are not in those groups, particularly so that we can increase herd immunity.

And then one more point, if I can, about testing. The role of testing is important, but it is very different at various time points in a pandemic. The role of testing in the beginning for South Korea and the urgent needs were very different than it is right now, especially for contact tracing. We have tens of millions of people who have had the infection here. Contact tracing, that seems sort of absurd to me unless it is for preparation of the next pandemic.

And then the final point, we keep discarding the massive harms. We are killing people with total isolation and lockdown. I do not know how many times this has to be said, but hundreds of thousands of people have serious diseases that are not being treated and not just that the economics alone is causing a massive catastrophe that is, in terms of health and poverty, throughout the world, because many economies are linked, in fact, the whole world for those in the United States and the western world.

Thank you.

Chairman JOHNSON. Thank you, Dr. Atlas.

By the way, is it Mr. Roy or Doctor? I do not want to——

Mr. ROY. Mr. Roy is fine. That is fine. Thank you very much, Senator.

Chairman JOHNSON. How about Avik?

Mr. ROY. Yeah, that works.

Chairman JOHNSON. Mr. Roy, go ahead.

Mr. ROY. So, similarly, I want to clarify a couple things.

First, quickly, Senator Romney, I think, misunderstood my comments of comparing to other types of fatalities. I was not comparing to the flu. COVID–19 is clearly more serious than the flu, especially for people over 65 and those with cardiovascular chronic disease.

My point was to analogize to traffic fatalities and hospital-acquired infections to say we do not shut down hospitals because 100,000 people die of hospital-acquired infections. We try to manage and mitigate and reduce those deaths. Similarly, with traffic fatalities, we have a whole regulatory system in place and impress upon people they need to be responsible. Those kinds of tools can be relevant here, just as they were in the East Asian countries that recovered from SARS in 2003.

I want to make one other comment about the testing discussion we were just having.

It is very important. I think a lot of people are under a false impression about just if we have X number of tests, then everything is going to be fine. We have to remember that antibody-based testing or serology testing does not generally measure an active infection. The antibodies only generate in a patient 3 weeks or 4 weeks after they have been infected.

So for testing the population to see if they have been infected or they have a current infection, it is not going to work, and the deoxyribonucleic acid (DNA) or viral ribonucleic acid (RNA)-based testing, Reverse Transciption Polymerase Chain Reaction (RT–PCR) tests, those are much more invasive at the moment, much more cumbersome, and very difficult to scale up.

So when we talk about the number of testing, I think it is unrealistic to expect massive population-wide testing, and people who are interested in more details about that, we can either get into it in this hearing, or you can review the freopp.org paper I mentioned earlier, where we delve into this topic at length.

Chairman JOHNSON. Thank you, Mr. Roy. Dr. Katz.

Dr. KATZ. Thank you, Senator.

I also wanted to comment on testing, which I have seen up close and personal in the emergency department, and it is cumbersome. One of the issues we have to overcome is the unreliability of a lot of the tests we are using. There still is a high false-negative rate.

But it does seem to me we are setting up a Catch-22 if any semblance of return to normalcy is predicated on a number of tests we know we cannot do and will not be able to do for the foreseeable future.

I think we need to ask ourselves what do we need the data for. We want to know what percent of the population is likely to get this infection. Is it everybody who is exposed, or is it one in five? So far, it really looks to be one in five on Navy ships, on cruise ships, and contained populations.

Of the group that gets this, how many develop symptoms? Of those, how many need to be hospitalized? Of those, how many are likely to need the ICU? Of those, how many are at risk of dying? On the basis of what antecedent risk factors? How does that shift with the presence or absence of hypertension, coronary disease, type 2 diabetes, body mass index (BMI), and those factors?

When we think about the utility of data, we really are not bogged down with testing millions of people. We need a representative random sample large enough to give us that actionable information. That is much more doable. We have the resources to do it now. It is proximal. It is the work of several days, and if the goal of getting data is not just to say look how much data we have, but look what we now understand to inform policy, representative random sampling will do.

The other thing I wanted to say is that there is an alternative to contact tracing, and that is to say we identify people at higher risk, and we carefully protect them from exposure to the virus. People at low risk, we actually expect the virus to circulate. So contact tracing in that group almost defeats the purpose of saying low-risk people, if we are ever going to get our lives back and not be on the indefinite timeline of maybe there will be a highly effective vaccine mass produced, we actually need the virus to circulate among people who can safely get it, get over it, make antibodies, which historically, before the advent of highly effective vaccines, it was how pandemics ended. Immunity developed.

But what we can do now artfully is say there are people who cannot safely get through this infection, we will protect them. There are people who can. They can go back to the world. I think contact tracing at scale in that group is not likely to be helpful, and I think we should do better than contact tracing for the high-risk people over 70, people over 80, people with a large burden of chronic disease. We need to double down on protecting them so they are not exposed, until we can document with ongoing at least random sampling, that viral transmission is near zero, and a high level of protective immunity has been achieved, and then basically everybody's grandparents can hug their grandchildren safely again.

Chairman JOHNSON. OK. Thank you, Dr. Katz.

I feel bad because I lost Senator Rosen. I know Senator Sinema is available. So, Senator Sinema, why do not you go, and then I see Dr. Inglesby as well as Dr. Kory have some points to make. But let us go to Senator Sinema first.

OPENING STATEMENT OF SENATOR SINEMA

Senator SINEMA. Thank you so much, Senator Johnson. Can you all hear me fine?

Chairman JOHNSON. We can.

Senator SINEMA. Great. So thank you, Chairman Johnson and to Ranking Member Peters, for holding today's roundtable and for everyone's flexibility during this time of coronavirus.

We have made some hard-fought progress in my home State of Arizona in flattening the curve by adhering to social distancing and other guidance from the CDC. It has not been easy, of course, and everyone has made sacrifices. I do not want those actions to be in vain by reopening too quickly and triggering a second surge of cases that will further harm our hospitals and our economy.

As you all may know, Arizona ranks dead last in the Nation in terms of coronavirus tests administered per capital. This is from the latest data from the Kaiser Family Foundation that ranked all 50 States and Washington, DC. They found Arizona was 51st in the Nation. So the data clearly shows that Arizona has work to do be-

fore it is safe to get back to normal, and public messages need to reflect that.

Ensuring Arizonans have the information they need to safe is my highest priority, but too many Americans are still confused about what is best practices to keep themselves and their families safe.

We have already lost too many lives, and I have serious concerns based on consistent data and analysis from the CDC's infectious disease experts that opening too quickly or softening social distancing without a better understanding of the prevalence of the virus will lead to spikes in infections and deaths.

We want the economy to open as quickly and safely as possible, but in my regular calls with mayors, county officials, health care providers, and small business owners, I hear directly from Arizonans who want to reopen and get back to normal. But they want to do it safe, and they want to do it smart. Moving too quickly or taking on too much risk could lead to a resurgence of the virus, a greater loss of life, and longer-lasting economic harm.

So I have heard from business leaders that continually reopening and closing the economy could be an economic disaster for them. So we have a long way to go to get through this crisis, and I know that if we are safe and smart, we can bounce back from this.

So I hope that this Committee will also consider a future hearing when it is safe to do so with relevant members of the White House Coronavirus Task Force to provide oversight over our Federal response as well.

So, with that, I have a couple of questions for Dr. Inglesby. The administration has included contact tracing as one of the critical components involved in safely and slowly reopening localities following the guidance of infectious disease experts. How can States determine if their contact tracking model is robust enough to move forward with what is commonly known as Phase two, when a community is shifting away from slowing the spread and into opening and public places reopening?

Dr. INGLESBY. So one measure is just the measure of contact tracers per population, and I think, in general, at this point, it seems like with early stage, the numbers of contact tracers per 10,000 people is somewhere in the order of one, two, or three contact tracers per 10,000 people. That seems to be a growing consensus around that. We do not have evidence around that, but it seems consistent with other efforts in other parts of the world which have been successful around contact tracing.

The second thing is for a State to be able to say can our State actually trace—can we isolate the people that are getting sick on a given day, and can we trace those contacts, in many States in the country, there are numbers that are low enough for—starting today if a contact tracing effort began, they would be able to isolate those cases and trace their contacts and put them in quarantine.

So while we have to acknowledge the stuff that has gone on before, those people are out there in the community, starting now we could begin to trace and isolate those contacts.

But there are some States in the country where the numbers are so high, and the number of contact tracers is so low that there would be no chance of trying to be able to identify and trace contacts and get them in quarantine. So, partly, it is a function of the

size of the State and the number of cases that they have. If they have many cases on a given day, then they are going to have more challenges. If they have few cases, then their contact tracing force on hand may be able to cope with that as they hire others.

Senator SINEMA. So a follow-up question on contact tracing, as you know, in Arizona, the hardest-hit community we have is the Navajo Nation where technology and access to technology and broadband can be very difficult to rely on. So apps or phone calls may not work effectively in those communities. What should contact tracers do, and how can they do it effectively to help reduce the spread and hopefully contain before a second wave comes for the Navajo Nation?

Dr. INGLESBY. Yes. I think that is particularly important because my understanding is that in the town of Gallup, outside Navajo Nation, it is a new hotspot. It shows that hotspots can arise in places that are not kind of traditional major urban centers. It sounds like a really serious situation.

I have also heard that Navajo Nation is having a lot of difficulty getting diagnostic tests and has really appealed to the administration to get more testing. So I hope that can happen soon.

I think for places without access to high technology, human capital really is the most important thing in contact tracing, people who can call people up, understand who their contacts were, call them back the next day, make sure things are going well, make sure they have not developed symptoms, make sure they understand what is going on.

So even before we had any technology, contact tracing has been part of public health for a long time. It has not been needed on this scale ever in this country, but I think if we get the right people in place and do kind of relatively just-in-time training for those people, that can make an enormous difference. And then it can be supplemented by technology.

Senator SINEMA. Oh, I appreciate that.

A follow-up question for you. You are trained as an infectious disease physician, and you are still seeing patients at a clinic. So my question for you is, How does your training in your practice impact how you approach the testing, modeling, and development of strategies for reopening?

Again, I am concerned because Arizona is 51st in the Nation in terms of testing per capita. How do you see your approach as different from that of an economist or other medical professionals?

Dr. INGLESBY. It is hard for me to speak about the perspectives of others, but I will tell you from our perspective in our center and what I do, there has been a lot of development of diagnostic strategy within the hospital system. Hospitals very much need to know and want to know the status of a person that is coming in the front door. They want to know the status of all the people that are being treated as outpatients.

We need to know if someone in our clinic has a fever. It is not enough for us to know right now that they have a fever. We need to know whether they have COVID. We need to know what the threshold is for them coming into the hospital. People with COVID can deteriorate quickly. So we need to know how they are doing at home. We check in with them over time. So our hospital system

has developed kind of a sophisticated layered way of making sure that its patients when they get sick are able to get tested, and that is really important for everyone who has COVID symptoms.

Senator SINEMA. Thank you.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thanks, Senator Sinema.

I am looking at our participant sheet here, and it looks like it is just me and our witnesses. I want to thank, first of all, all the witnesses for hanging in there. I really appreciate it. This is, I am sure, longer than we all thought this was going to go.

I am going to have three questions. One is going to be directed to Dr. Kory. Two, I am going to ask all of you to get rid of your little hand signals there because I am going to ask you to put up your hand if you think you can really excellently answer the two questions, and then I am going to give all of you, in reverse order of original testimony, a chance to either refute something or just whatever is on your mind in terms of the last thing you want to say.

Let me start with Dr. Kory. I have been advocating quite some time publicly to really allow doctors to be doctors, to allow them to practice medicine, to explore different theories of the case, different therapies, and certainly, what you are doing into—once patients have been hospitalized.

Certainly, I have been trying to find, whether it is hydroxychloroquine—I noticed in your testimony, you are talking about potential benefits of that, once we have the studies on it. But that looks like it is only effective maybe in the first 5 days of symptoms, probably even before a test comes back.

You are talking about a therapy that once people are ill, to present themselves to a hospital. That is the problem.

Can you just kind of speak to the different stages of this disease, the different types of techniques, what will work early, what will not work very late? Just quickly address that.

Dr. KORY. Absolutely. I am really glad you brought this point. I have listened through the whole discussion. I understand this multifaceted parts of this disease in this epidemic, and I appreciate my colleagues. I am not in my league when we are talking about testing and opening the economy and social distancing. That is not what I do.

I know how to treat severe illness. Let us talk about that.

So what we understand about this disease, this is what we experts—is that there are two phases. One is the viral replicative phase, which is really in the outpatient. Those are those first symptoms of sore throat when the virus invades the soft tissues of the head and neck, where you get maybe some fevers. You do not feel well, and most of those patients actually do OK. If somehow this virus triggers this hyperinflammatory response when you go into organ failure or multi-organ failure, that is when you come to the hospital, and that is where I am an expert.

What we know about antiviral therapies and vaccines is that they are most effective early on in the disease. So things like hydroxychloroquine, which is purportedly an antiviral medication, should be given in the outpatient setting, in the early days of symptoms. It is not a hospital drug. I have seen too many patients

dying on hydroxychloroquine in the hospital. The idea that you should wait until they come and they fall so ill in the hospital, to me as a physician, does not make any sense.

Remdesivir is the same thing. Why would you give it if the patients are already in the hospital who are in severe stages of disease? We have to understand this as two stages.

So the early part, where you talk about vaccines, hydroxychloroquine or remdesivir, that should be focused in the outpatient setting. Come to me. I am a hospital doctor. Once you come to me, it is the hyperinflammatory phase.

We are talking about cytokine storm, multi-organ dysfunction, and that is why I try to talk about the fact that we really need powerful anti-inflammatory and anti-coagulant drugs, and if we employ them early and systematically, I really believe we are going to change the trajectory of the massive morbidity and mortality that we are seeing.

I understand all the public health experts, and I understand the impacts on the economy and how to manage all that. That is way out of my lane.

When you come to me in the hospital, I want to try to keep you alive. I want to prevent death, and I want to prevent the massive uptake of ventilator and ICU resources. I know I can do that, but you need to come to me. And I need to be able to use these medicines early and powerfully. I do what I do. I mean, I live in ICUs, and I want to take care of critically ill patients.

Chairman JOHNSON. We will come back to you.

So two, hopefully, quick questions, and again, get rid of your little hand because I want the person who really thinks they can answer this.

New York City. What was so unique about New York City? Why did it explode so much?

I saw Mr. Roy raise his hand right off the bat there. Mr. Roy?

Mr. ROY. Yes. Senator, we, of course, do not know for sure, but we have evidence about two things. One, a group of economists at Massachusetts Institute of Technology (MIT) traced subway stations in New York City to certain ZIP codes where there were outbreaks, and they found a high correlation. So there appears to be a lot of correlation between the use of the New York City subway system to outbreaks of COVID–19.

The other piece that is really important in New York State, which affects New York City as well, of course, is New York State and New Jersey both had policies of requiring that nursing homes accept patients who were discharged from the hospital with COVID–19, even if they still might have an active infection, and that may have contributed to the outbreak of COVID–19 in nursing homes in those States.

Chairman JOHNSON. OK. So I will take that as the answer. Again, if you want to refute that, the very last stage of questions.

The last one is the stated policy of all these economic shutdowns and safer-at-home policies, that type of thing, was to flatten the curve so we do not overwhelm our health care system, but in flattening the curve, is there any guarantee that it will actually reduce the ultimate number of infections or ultimate number of deaths, barring a cure?

Anybody want to really take that one?

Dr. KATZ. Yes. Senator, I am happy to address that.

I think in our discussion, I mentioned that I have been privileged to work with a number of experts in mathematical modeling, and in particular, I can cite a paper by Maria Chikina at the University of Pittsburgh and Wes Pegden at Carnegie Mellon. They work collaboratively and published a pop culture piece calling for honesty in pandemic modeling.

The problem with an interdiction strategy that starts and ends with flattening the curve is you can never stop. Everybody has been kept away from the virus. Everybody has been sheltering in place. Nobody has immunity.

So if there is any level of viral circulation, asymptomatic carriers, for example, everyone remains vulnerable. The minute you release those clamps, you get the spike you thought you had prevented. You just make it happen on a different day.

So flattening the curve makes good sense while you devise a strategy for the next phase, and again, I think most of us collectively are arguing for that transition to a phase where we risk stratify, get better data, identify who is at risk, protect them, but allow for viral circulation in the portion of the population at very low risk of needing a hospital bed or getting very sick.

But if all you do is flatten the curve, you can never stop. You can never stop until for some reason that you do not necessarily understand, seasonality, the virus goes away, maybe to come back, or you not only have a highly effective vaccine, but mass produce it and give it to everybody, or you have to allow the virus to circulate, and those who can safely get through it develop their immunity. But that is the problem with flattening the curve.

Absolutely a critical tactic to avoid overwhelming a medical system at a given placed in a given time, but it really can only be phase one of a multiphase plan.

Chairman JOHNSON. OK. I am glad to see Senator Rosen came back. I will switch it over to you, Senator Rosen, and then when we close out the hearing, anybody wants to stick around, I will go in reverse order. You can make your closing comment. Senator Rosen.

OPENING STATEMENT OF SENATOR ROSEN

Senator ROSEN. Thank you for having this hearing.

I want to thank the witnesses for being here today.

I do want to mention before my questions that Senator Rubio and I have requested a longitudinal study on COVID from NIH and CDC, a 10-year study to be reported initially every 3 months, 6 months going forward. I do believe that that will help us. That data will point us in some direction as to what policies work and where we might need to fund or put our efforts going forward. Data is very important, and I hope to be doing some more studies. I think the data matters and can really, like I said, point us in the right way to a policy and legislation.

But today I want to talk about worker safety. Dr. Inglesby, I want to ask you a question in your capacity as someone on a recovery team. You are charged with helping the Governor reopen the

economy of a State. A big part of reopening, of course, is the workers returning to their physical workspaces.

So, in Nevada, we are known, of course, for a hospitality industry, from Lake Tahoe to Lake Mead, Reno, Las Vegas, hotels, gaming, entertainment, outdoor tourism, everything in between. Our hospitality workers cannot do their jobs remotely. They are all so eager to go back to work, and some are concerned that they might put their families at risk if they do return.

So what can you recommend to the hospitality industry, which is a huge portion of Nevada's base, as they reopen slowly in the coming months? What are our best practices for hotel rooms? And we want to protect our workers and our tourists that come. So how do we balance that, customer safety and employee safety? Because we want everyone to come back and enjoy Las Vegas and Reno, their conventions and vacations.

Dr. INGLESBY. Yes. I think the tourism industry is probably one of the most challenging industries to consider as we think about reopening, given the density of many of the activities and the closeness of people interacting.

My understanding is that the travel industry is really also seeking lots of guidance from the Federal Government about what would be the most safe practices. I think those practices will include things like trying to increase spacing in places where people are gathering, which will be difficult, especially in many of the settings that you just mentioned.

They will talk about hotel rooms and things like that. Terminal cleaning of hotel rooms, that is much more intense than you might have considered before, giving employees personal protective equipment where relevant. It is one thing to consider the customer that is coming into a facility, but I think the experience of the workers there, where they are actually on the receiving end of lots of interaction, I think they have special concerns about not getting infected on their jobs.

And then information to employees in languages that they speak in so they understand the low bar, where they have a range of symptoms that could be COVID and getting very early medical intervention and the possibility of including testing in some of this, the regime, or the workplace, either return to work or regular testing on the job to make sure, to give people confidence in those workforces, that there are not people who are sick at work.

I think I hear many employers asking about the possibility of testing in those settings, so that combination of things.

And then I think that it will be useful for that industry to have guidance from the Federal Government that they can lean against and say to both their customers and to their own employees, "We have done what the government believes is the most safe as we have reopened."

Senator ROSEN. Thank you. That was actually my next question. What role does the Federal Government—because we have so many of our companies, they want a clear standard for everyone to kind of follow as best they can, at least a broad standard. So I think that is our role, and it is really important that we have that, basic standards to meet.

We have also been focused, of course, in Nevada, not just our tourism and the Las Vegas Strip and Reno, but we have a booming outdoor tourism, if you have been to our mountains and Lake Tahoe and Lake Mead, skiing, hiking, and biking. But indoors is one thing for our hotels and conventions, but what do we do about our outdoor tourism or even our restaurants, things that can move outdoors with natural ventilation and no enclosed spaces? What kind of protections or guidance do you think we need there? Of course, it is going to be a little bit different. I want to be able to speak to our businesses that are in that outdoor recreation space as well. What can you tell me that you think we need to do there, kind of direction?

Dr. INGLESBY. I think what we know so far from studies, especially studies from China but other places as well, is that outdoor infections are much less common than indoor infections with COVID. So outdoor spaces will be safer and will have less risk than——

Senator ROSEN. You mean just the mask——

Dr. INGLESBY. Yes, when people are in close proximity, then masking is important, but then keeping people's space, if possible, when they are outside together, unless they are with people that they live with, that would be a safe practice that people could probably do in many of the outdoor environments that you are talking about.

Senator ROSEN. Thank you.

I think I have one more question for you on therapeutics and testing. Would you discuss in just the short time we have left what markers we need to reach regarding effective COVID—effective therapeutics that are widely available to treat the more serious cases before we are ready to fully lift those stay-at-home orders?

A lot of the people that I talk to, whether they are business owners, friends, family members, members of my church, community, they do not feel safe to go back out because they are worried that there is not any treatment for them. They are not thinking even about a vaccine, that if I go, there is no treatment to make me better. So can you talk a little more broadly about the markers we might need to reach on that, on therapeutics before people can feel safe?

Dr. INGLESBY. Yes. Unfortunately, I think it is going to be difficult to get to those markers sometimes soon.

I think there are a number of therapies that are in development, and they should be studied. I think there are very sophisticated trials going on around the country and people working on those issues with NIH and independently, but I do not see—even remdesivir, which did have a promising result, it is not going to make them sick. It is going to make them get out of the intensive care unit perhaps a bit more quickly, but we do not have a medicine that is close on the horizon that is kind of a cure-all.

So I think for people who are at high-risk——

Senator ROSEN. Right.

Dr. INGLESBY [continuing]. Older people, people with underlying conditions, at this point, if there is community spread in their community—and many places in the country, there are and do con-

tinue to be number of cases in those States or those communities—then I think there is a level of risk to being out and interacting.

There are places in the country where the numbers have come down very low, and that would be different in those places, but I think for people in communities where there is community spread, I do not think we are going to have a therapeutic solution anytime soon.

I hope we do, and there are things that are being studied, but I do not think that should be probably a marker for reopening broadly, because I do not know that we are going to get there.

Senator ROSEN. Thank you. I appreciate your time.

Chairman JOHNSON. Thank you, Senator Rosen. Sorry we missed you your first time around.

Here will be the final round. We will go in reverse order. I would ask you to keep your comment relatively succinct, if you can do it in a minute. I will interrupt you probably around the 2-minute mark, but try and be respectful for the other witnesses' time.

Again, I just want to thank all of you. You have hung in there. You have been incredibly patient. I have warned you all, this would be frustrating, but again, this was, I think, incredibly valuable testimony from everybody.

So we will start with Dr. Atlas.

Dr. ATLAS. Yes. Thank you for allowing me to participate.

I just want to make sure everybody understands we are not at the same place we were when this all started. We have learned a tremendous amount. We have a tremendous amount of evidence. We do not need at this point to start doubling down on hypothetical models because we have empirical data. We have decades of established medical knowledge, and now we use logic applying the data. We know who to protect. We know who is not at risk for hospitalization and who is, and we need to make those protections very strong while making sure we are not interfering with the actual pathway to establishing population immunity and safety. And that is the idea of allowing low-risk groups to set up these immune-based population immunity result of so-called "herd immunity."

There are artificial barriers being set up that are obstacles for allowing ending the massive destruction from total isolation. We really need to be very cognizant of that. A strategy of stopping COVID–19 infection is not an appropriate strategy.

Chairman JOHNSON. Thank you, Dr. Atlas. Dr. Ioannidis.

Dr. IOANNIDIS. To be at this hearing, I really feel that I learned a lot hearing my colleagues and also getting some excellent questions from Senators.

We need to realize, as Dr. Atlas said, that this is a crisis that we have almost gone through at least for this season, and even though we lost many lives, we have every reason to be optimistic.

We know very well who are the people and what are the settings that we need to protect. We can reassure the vast majority of the American population that their risk is extremely low in the range of other activities that they do routinely every day, like driving a car. They do not even give it a thought, a second thought, of whether they should do it or not.

At the same time, we know where are the devastating settings. We know that nursing homes, we know that hospitals with

nosocomial infection, we know that particular occupations are susceptible to outbreaks, and we know how to protect them. We know how to focus our efforts in securing a safe environment in these places and not allowing major outbreaks to happen.

I am pretty optimistic that we need to move forward with relieving shelter-in-place orders and lockdowns, because currently, the risk-benefit balance is clearly against our continuation, even if we get a resurgence of a second wave, by lifting some of the measures.

We need to try with science, with continuous feedback of information on incidence and prevalence and bed capacity, but hopefully, we will do very well. And if one of our steps is not the one that we should take, we can always backtrack and correct it.

Chairman JOHNSON. Thank you, Dr. Ioannidis. Mr. Roy.

Mr. ROY. Thank you, Mr. Chairman, again for having us all here.

I want to emphasize that the detailed version of our plan is at freopp.org. I am more than happy to brief any Members of this Committee or staff on some of the recommendations we have for Congress on how to reopen the economy.

A question that came up at an earlier part of the hearing was why is it that New Zealand and South Korea and some of these other countries have done well. I want to emphasize this. They have very disparate or heterogeneous reactions from a policy standpoint, very different health care system. The common element in all those Pacific Rim countries is they dealt with SARS-CoV–1 in 2003, and that meant the populations as well as the policymakers knew how to react to this serious threat in a way that those of us in the West did not. And I think that made the biggest difference in their ability to get out in front of SARS-CoV–2 and COVID–19 in a way that I think a lot of us have not appreciated.

And that leads to this point about the second wave. There is a lot of talk about a second wave. We should remember that there was no second wave with SARS-CoV–1. SARS-CoV–1 happened, and then it flamed out. Those economies re-bounced or bounced back in about 6 months. People still remained scared and alert and wore masks to work when they had got sick, but life eventually did return to normal without massive testing regimes, without a cure or a vaccine.

I will mention Sweden very quickly. Sweden is a model that I think we should look at more closely. The one thing that we can improve on relative to Sweden, though, is they did not do a good job of protecting their nursing homes. A lot of their deaths proportionately have happened in nursing homes. We can do a lot to restrict visitations and make sure that staff stay local within a particular nursing home. Do not go to multiple nursing homes and spread disease that way.

Finally, I want to mention the fiscal crisis. We have not talked about the fiscal crisis at all that has come out of the economic crisis. We have spent about $4 trillion and increased the debt. As you all know, that is a huge long-term national security problem along with everything else that a fiscal crisis can be. That is what increases the urgency of getting the economy back in place because the more we accelerate our fiscal crisis, the more long-term problems we have across all the things that Congress has to think about.

Thank you again very much.

Chairman JOHNSON. Thank you, Mr. Roy. Dr. Inglesby.

Dr. INGLESBY. Yes. First of all, thank you so much for having me today. I have really appreciated this discussion.

A couple of points. The first is that there has been some discussion about how this disease might be already widely prevalent in the United States. I do not agree with that. I do not think we have evidence for that yet. It may prove to be the case, but at this point, I think the evidence is more consistent with single-digit prevalence in the United States.

And that relates to the second point, which is it seems like some of the other witnesses are encouraging us to move toward a herd immunity strategy, and I just want to lodge my disagreement with that strategy. I think it is pretty clear that we need to get up to 60 to 70 percent or more of the population to begin to develop herd immunity. That is a long way from where we are now, which may be as low as 3 or 4 percent in much of the country.

We have had 70,000 deaths from this disease with seroprevalence, which I believe is low. We will find out when studies get better. So I do not agree with that, and I think that would be dangerous.

I think it is also dangerous to say that young people are at zero risk with this disease. It is true they are at much lower risk, but we are seeing young people get strokes in New York City. We do see some young people that are quite ill from this. I am not saying it is a grave threat as compared to other threats, but it is also not correct to say that there is zero risk to young people.

Then the other thing people have been talking about is whether there will be a new wave or not. We are already still in the middle of a rise in cases in this country, and I do not think it will be the fall before we have further undulations of cases across the country. I think we are at risk of having small waves throughout the summer. I do not see any evidence yet that there will be major seasonal change. I hope there is, but we have not had strong evidence of that. So I think we should be prepared for recurrence of cases in the summertime, right now, as people begin to do social distancing changes.

I am in favor of easing social distancing carefully in places which are ready for that, but in general, I do not think there will be a normal economy when people feel and see that cases are rising around them until they feel like there is control of this epidemic. And I think the way to get control is through diagnostics, hospital capacity, and contact tracing.

Chairman JOHNSON. Thank you, Dr. Inglesby. Thank you. Dr. Katz.

Dr. KATZ. Senator, thank you so much for including me. I have appreciated listening to the questions, listening to my colleagues.

I think there is a lot of agreement. In particular, I think we would all agree we do want to minimize the total harms of this, even if there are some disagreements so far based on the best ways of doing that.

We have also posted a lot of materials online at my nonprofit, truehealthinitiative.org. We have risk models. We have arguments there for this total harm and immunization approach, and I think

it allows for a range of opinions about what is the best way to get there.

I largely agree with my colleagues that we have the needed information to risk stratify the population, but I would argue it is crude risk stratification at this point. We know elderly people with chronic disease are at high risk. We know young healthy people are at lower risk.

But is a 40-year-old with mild obesity or mild hypertension at higher or lower risk than a 50-year-old without those conditions? There are a lot of combinations where I think we really do need representative random sampling.

So a particular plea to you in your capacity as Chair of this Committee that the Federal Government implement a policy of representative random sampling. We do not need millions of tests. Let us do 50,000 tests, but let us make sure we do them in a population that represents all of the United States.

Second thing is we do need a health promotion campaign because we cannot modify age, we cannot modify sex, but we can modify many of the chronic disease risk factors and many of the lifestyle practices that are influencing the acute risk for COVID. So these chronic liabilities that really were a huge drag on health and vitality and, for that matter, the economy in America there were all along are now an acute threat as well.

And I think part of the return-to-normalcy policy ought to be we are going to help everybody get healthier, so you actually come out of this stronger. There is an acute benefit. There is a lasting benefit.

So those two requests really for the Federal Government, representative random sampling so we are flying through a less dense fog and a nationally coordinated focus on helping to alleviate the burden of chronic disease that is now an acute liability too.

Chairman JOHNSON. Thank you, Dr. Katz.

Before we go to our final witness, I just want to point out, I was the guy that Championed Public Law 115–176, Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right To Try Act of 2017. I am a big believer in letting doctors be doctors to practice medicine. There is nothing that is universal, and certainly, in this case, one of the reasons I have been pushing that so hard is an effective therapy, an effective cure will break the back of this disease almost overnight. It will end the economic crisis.

So that is why I really did invite Dr. Kory because I was very encouraged by the work he and his colleagues were doing once people became hospitalized, but again, I really want to make sure that we are also pushing the envelope, allowing doctors to prescribe off label. Let us not restrict their use. It is what we have done with hydroxychloroquine. Again, I do not know it is going to, for sure, work. There is an awful lot of anecdotal evidence.

But, again, I really want to make sure that we continue to support doctors like Dr. Kory and others that are, again, practicing medicine, exploring different theories of this case. The sooner we can end up with the effective therapy or a cure, again, we break the back of this disease, this crisis, this horror almost overnight.

So, again, I will turn it over to you, Dr. Kory. Give us a little bit more hope, and keep practicing medicine.

Dr. KORY. Yes. No. Thank you, Senator Johnson, and you and I have an affinity on this. I totally agree the gloves need to come off.

This disease is wicked. I get confused when people are comparing this to the flu. I have been a doctor in an ICU for 15 years. There is nothing like this disease. Let us stop comparing it to other ones.

I have patients filling ICUs with fibrotic lung disease who I cannot ventilate without deep sedation and paralytics because their lungs are destroyed. This is not what the influenza does. This is a completely different disease in the sense that its acuity, its severity, and its rapidity is unlike any other that I have seen.

It does not mean I cannot handle it. I know I can treat this, but you have to let me do it. We have to get it earlier.

My problem is that everybody looks at the ICU doctors to solve this. It is not the ICU doctors. We just need to move more powerful therapies a little farther out. We need to get it in the emergency department (ED) and the hospital wards.

I promise you, we can avert this tragedy of fibrotic lung disease and ventilators. I know we can do it. We need to have a much more robust treatment strategy.

The other issue, I have to say I totally agree with Dr. Inglesby. Again, I do not want to be outside of my lane, but the prevalence in this her immunity stuff, I do not know about that. That is not what I am an expert at. I get the whole thing about balancing between saving lives and continuing life, which is an economic activity and financial activity and all of that. I do not really know the answer to that.

But I really do believe that if we can find effective solutions to prevent the deadliness of this disease, it would mitigate and it would help everything else, and that is what I am just trying to promote. I think we can do this. We have effective therapies. I am getting increasing reports of really good responses to treatments.

And like you said, Senator, we just need to be able to treat these things. Everybody has to stop thinking that we need to do everything in randomized control trials and this is experimental and dangerous. We know what we do. I do not know. If we come up with an effective medical therapy, this would mitigate a lot of the harms of everything that you guys are talking about, which is opening or closing or not—which I just got to say I am a doctor. I work in a hospital, and I really believe that the world needs to think about and the health societies need to think about what they are proposing for treatment. I really think we got this wrong.

We have to be stronger, hit harder, faster, and earlier, and we will do better. This will change the economy. That is all I am saying as a doctor.

Chairman JOHNSON. Listen, I appreciate that. I am so afraid that we are letting the bureaucracy—and, again, these are good people that are trying to do the right thing. They want to have safe drugs, but——

Dr. KORY. I agree.

Chairman JOHNSON [continuing]. We have safe drugs. Let doctors practice medicine and use off label, explore different theories of the case, develop that therapy, and to me, that is the solution.

Dr. KORY. I agree.

Chairman JOHNSON. It will be available, hopefully, far sooner than a vaccine, which may never come, which has also been brought up in testimony.

So, again, I want to thank all of you for your patience, for your testimony, for what you are doing, for being a doctor, for saving lives. God bless all of you.

The record will remain open for 15 days until May 21 at 5 p.m. for the submission of statements and questions for the record.

This roundtable is adjourned. God bless all of you. Take care.

[Whereupon, at 4:59 p.m., the Committee was adjourned.]

APPENDIX

U.S. Senate Committee on Homeland Security and Governmental Affairs
"How New Information Should Drive Policy"

OPENING STATEMENT OF RANKING MEMBER GARY C. PETERS
May 6, 2020
AS PREPARED FOR DELIVERY

The Coronavirus pandemic has profoundly altered our world – putting millions out of work, threatening the futures of small businesses, exposing serious inequities in our health care system, and taking the lives, to date, of more than 70,000 Americans.

Like so many of us, I am ready to start getting America back to work. But we need a clear plan, backed by science and data, that will give us a roadmap to safely reopening our economy in stages.

While cases in some parts of the country appear to be plateauing, we know there are other communities experiencing rising numbers.

We currently don't have enough tests to fully understand how many people have contracted or succumbed to the virus.

We are still struggling to get enough masks, gloves and other personal protective equipment to our frontline workers, and we don't yet have the supplies needed to prevent a resurgence of the virus.

We need a robust contact-tracing plan to identify possible exposure to Coronavirus and prevent further spread that could result in another wave of cases, hospitalizations and tragic deaths.

We need to protect and grow the capacity of our hospitals to deal with localized outbreaks.

We need to take back production of life-saving drugs and medical supplies from China.

We need to develop and deploy a vaccine to inoculate Americans who have not contracted the virus.

We need clear data and metrics that are backed by science to tell us what is working and what's not. And we need to push these best practices out to our small businesses so that they can keep their employees safe and give their customers confidence.

This critical information, and the lessons we have learned, will help create a plan for how we can safely re-open.

Without this data-driven plan, we risk undermining the progress we have made and a repeat of the unbearable loss of human life and economic shock we are experiencing right now.

Despite all this hardship, I'm encouraged every day by the workers and entrepreneurs in my home state of Michigan that are finding new ways to keep their workplaces safe and retooling their businesses to meet the needs of frontline responders. I've talked with many of them over the last few months. They need clear guidance driven by reliable data to back up their actions.

We also must remain focused on the unequal impact this virus inflicts on communities of color. In Michigan, black residents make up 13% of the population but represent 40% of the deaths from COVID 19.

This disparity is rooted in systemic inequity. We must change our plans in response to the data and protect these communities – not simply accept the inequity as inevitable.

These decisions are a matter of life and death. And we cannot accept tens of thousands more Coronavirus deaths as unavoidable – just as can't we accept that reopening our economy while minimizing risks isn't possible. We must have a clear plan that provides people with guidelines that are backed by science to help us re-open.

I look forward to today's discussion and to continuing to work with my colleagues to ensure that we are taking appropriate steps that will allow us to safely reopen our economy while protecting our most precious resource: the American people.

Pierre Kory, MD, MPA
Medical Director, Trauma and Life Support Center
Critical Care Service Chief
Associate Professor of Medicine
University of Wisconsin School of Medicine and Public Health

I want to start by saying that I am part of a group of physicians which include several of the most highly published and well-known critical care experts in the country and world (Drs. Paul Marik, Umberto Meduri, Joseph Varon and José Iglesias). In response to the COVID crisis we formed the Front-Line Critical Care Working group, our protocol can be found at covid19criticalcare.com

Members of our group have now treated in excess of 100 hospitalized patients with our treatment protocol. Nearly all survived, The 2 that died were in their eighties and had advanced chronic medical conditions. None of the patients have jad long stays on the ventilator nor become ventilator dependent The patients generally have a short hospital stay and are discharged in good health.

<u>Absence of Effective National and International treatment recommendations.</u>

Before I go into the process and rationale for our treatment protocol, I want to highlight three critical factors that we feel are contributing to the COVID-19 crisis which we call upon the health societies to address:

1) The fact that nearly all national and international health societies such as the WHO, CDC, ACP, ATS, and many others have issued treatment recommendations focusing almost solely on "supportive care only" strategies, things like Tylenol for fever, gentle hydration/nutrition then oxygen or a ventilator to support breathing.. This strategy is clearly failing as evidenced by unprecedented death rates and widespread and life-threatening shortages in ventilators, ICU beds, and ICU physicians and nurses. Our early recognition of the failure of this treatment approach is what prompted us to form our group
1) The 2nd factor is these same health societies dissemination of recommendations *against* the use of corticosteroids in COVID-19. We want to immediately call the worlds attention to this tragic error, based on the following emerging data:
    a. A senior member of our croup, and an international expert in corticosteroid therapy in critical illness, Dr. Umberto Meduri, along with 5 other international critical care experts published, 3 weeks ago, a comprehensive analysis of corticosteroid therapy during the prior pandemics of SARS, MERS, and H1N1 and their analysis found, contrary to the WHO recommendations, that corticosteroids were life-saving in those prior pandemics when given to anyone beyond mild illness.

b. Sorin Draghici, CEO of Advaita Bioinformatics just reported that their incredibly sophisticated Artificial Intelligence platform called iPathwayGuide, using cultured human cell lines infected with COVID-19 is able to map all the human genes which are activated by this virus, as they have done for other viruses such as influenza. Note almost all the activated genes are those that express triggers of inflammation. With this knowledge of the specific COVID inflammatory gene activation combined with knowledge of the gene suppression activity of all known medicines they were able to match the most effective drug for COVID-19 human gene suppression.. and that drug is methylprednisolone (this must be recognized, as the ability of other corticosteroids to control inflammation in cOVId-19 was much less impactful. This is, we believe, an absolutely critical and historic finding. Many centers are using similar but less effective agents such as dexamethasone or prednisone..

2) See this link for the full report https://engineering.wayne.edu/news/wayne-state-spinoff-advaita-bioinformatics-identifies-generic-drug-shown-to-be-effective-against-covid-19-39569

a. Around the same time of this discovery, Dr. Mayur Ramesh, an Infectious disease specialist and Immunologist at Henry Ford Hospital rapidly performed a study of methyprednisolone therapy in over 200 COVID-19 patients and they found that early methylprednisolone reduced LOS, ventilator needs and mortality

b. Finally, in a study that is currently under review from a group of Spanish critical care experts that we are in contact with, they found that an early and longer course o methylprednisolone therapy led to a massive reduction in mortality

c. Now, let me read some reports posted on Facebook by some anonymous doctors in Michigan:

"We floundered for two weeks. Lots of codes, intubations and death. Maybe 15 discharges. We started steroids and discharge 250 patients. Less intubations, less codes. And the ones that ended up on vent, not as serious. CXR/CT Changes = steroids Hypoxia on admission = steroids Ambulatory hypoxia = steroids Completely changed our trajectory Steroids are a game changer" Hospitalist, SE Michigan - our group is taking care of 700 plus COVID+ patients

John DP –

"I'm here in New Orleans , since we started using steroids, We were able to free ventilators and get elderly patients out of the hospital without needing a ventilator. Patients that were obviously crashing quickly, who we had to have end of life talk with were able to walk out of the hospital. At no point did any of our patient worsen because of steroids. These patients shed viruses 4 weeks later, With or without steroids. The virus doesn't kill anybody, it's the inflammation that does. Let the virus replicate however slow down the inflammation"

3) The third alarming factor we have witnessed, many of us firsthand, is the increasingly widespread insistence within institution, medical journals, and health societies that any proposed medical therapies for COVID-19 only be given to patients who participate in clinical trials. We are aware of instances whereby "restrictions" were proposed and placed against commonly used FDA approved medicines if used off-label in COVID-19, a practice that all doctors do every day.

Our group also supports the need for and execution of clinical trials in COVID-19, however, we want to remind everyone in regards to medical research in this pandemic that
1 - The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration,"
2- International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
3- Article 37 of the WMA declaration of Helsinki, titled: "Unproven Interventions in Clinical Practice"
It reads, and I paraphrase: "In the treatment of an individual patient, where proven interventions do not exist, a physician **may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering.**

In response to these three factors, Our group rapidly and collaboratively reviewed emerging literature from China, Italy and the US, while also systematically gathering the clinical observations and treatment results obtained with various therapeutic strategies from a large group of national and international colleagues. One of my main contributions to this effort came from my large network of

ICU colleagues in NYC where I trained, trained with, and was trained by many NYC ICU leaders. Basically, From the early days when I was in Madison, WI frantically helping lead preparations for the expected surge of patients to now where I am running an ICU in NYC full of dying COVID patients, many in their 2nd to 3rd week on ventilators with end-stage fibrotic lung disease, I was able to have repeated, daily clinical discussions with ICU leaders from multiple New York City area hospitals The time they gave me and the rich clinical conversations we had were invaluable to us.

Based on these clinical impressions, an exhaustive review of the early literature, our decades of clinical experience as well as the career research by members of our group we identified the three core disease processes in COVID-19 and then collaboratively developed our MATH+ protocol. This protocol is based on hundreds of peer reviewed medical publications and uses three readily available, SAFE and FDA approved medicines to target these disease processes. And the treatment is working.

The three core pathologic processes in COVID-19 are:

1) Hyper-Inflammation-
2) Hyper-coagulability
3) Hypoxemia

Front Line Covid-19 Critical Care Working Group "MATH+" PROTOCOL:

All three medicines must be started within 6 hours of admission to the hospital:

1) **METHYLPREDNISONE –** a powerful anti-inflammatory drug that we use to suppress the immune system and prevent organ damage. COVID-19 is causing a condition called the "cytokine storm" for which this drug, a corticosteroid, is the standard recommended treatment accepted around the world.
2) **ASCORBIC ACID–** although known as Vitamin C, when delivered intravenously, this substance acts as a powerful "stress hormone" that controls inflammation and prevents the development of leaky bloody vessels in the lung, thus avoiding the development of lung failure which is the condition causing death in almost all COVID-19 patients.
3) **HEPARIN -** COVID-19 is causing widespread blood clotting, preventing blood flow to vital organs such as the brain, lungs, and extremities. Heparin is a blood thinner which prevents the formation of these blood clots and thus preserves blood flow to these vital organs. We recommend the subcutaneous form of heparin, called enoxaparin, which has a long safety record and is easy for nurses to administer.
4) **OXYGEN SUPPORT** – In addition to the 3 medications listed above, we have found that maximizing the use of a high-flow nasal oxygen delivery devices allows the avoidance of invasive mechanical ventilation, which itself damages the lungs and is associated with a mortality rate approaching nearly 90% in some centers.

We are not claiming to be unique in our treatment approach, but rather that our approach is comprehensive and has an over-riding focus on the timing of initiation. This point cannot be over-emphasized, namely that almost the entire efficacy is dependent on the early delivery of these medicines to the hospitalized patient. **Having treated patients in NYC for the past tweo weeks, it is my very strong insight that** This "window for intervention" in COVID-19 appears to be wickedly short and fleeting, it will require all the hospitals and health care systems to be prepared to implement the protocol, quickly and without hesitation

I am seeing treatment fail here in NYC for a frightening reason – namely that based on the experiences

during the first surge of patients which overwhelmed many hospitals in NYC and led to horror stories of shortgaes in critical staff, ventialtors, medcines and beds with all associated with patients spending weeks on mechanical ventilators leading to the death of most, these reports have ***created a second catastrophe — the now widespread reluctance of patients to seek care in the hospital. Consequently, many new cases are arriving in hospitals in the more advanced phase of the illness, with often irreversible organ failure (lung) that poorly respond to any treatment protocol, even ours.*** We must place all focus on immediately reeducating the population and physicians alike. They must know that an effective treatment strategy exists, but that it only works if initiated ***early*** in the course of COVID-19.

Several of our ***Frontline COVID-19 Critical Care Working Group*** have seen firsthand how this simple treatment protocol can reduce the devastating complications of this disease and return patients to a quality of life that they value.

Finally, we want it to be known that ith the support of several physician colleagues and members of the media, we have tried to share our protocol widely. In fact, we know that it reached the White House for review on at least two, and soon to be three, occasions — the first a month ago via a member of Jared Kushner's COVID response team. We understand that it generated considerable interest until supposedly the N.I.H. and C.D.C. pushed back against it, instead seemingly favoring anti-viral and vaccine therapy. Later, Dr. Paul Marik was interviewed by former Speaker Newt Gingrich on his weekly podcast, Mr. Gingrich asked me and Dr. Marik to write a document outlining the rationale behind the therapy so that he could bring it to the White House for review. Still no response. Now this week, the editor of the American Spectator, Emmett Tyrrell, after publishing an article about our group and our protocol, asked us to write a letter to President Trump. We hope it gets to him.

SUMMARY/CONCLUSION

Our protocol has been out over 4 weeks. It is not unique, in fact, we are not alone in what we propose or have been trying — as you can read in the experiences posted above by doctors. In fact, we are seeing an increasing number of similar protocols with nearly identical therapeutics come out from various institutions and countries, including the Italian guidelines, Chinese Guidelines, Yale protocol, Montefiore protocol and others.

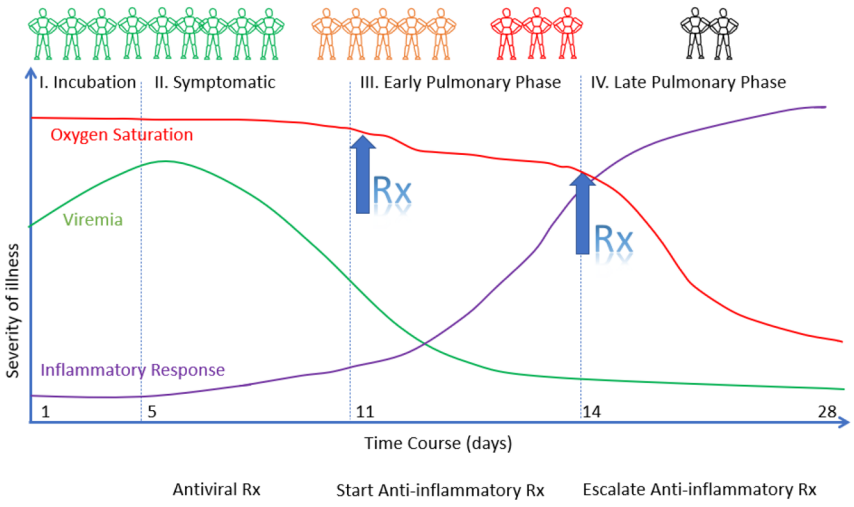
We are doctors, trained to diagnose and treat illness, we are experts in our field with decades of experience and hundreds of publications. However, we most pride ourselves by the skills we have gained at the bedside in caring for patients. We have clearly devised an effective treatment for use, prior to the publication of randomized controlled trials. Those trials are critical for sure, as they will help us further refine and/or perfect our treatment doses, durations, and indications, but waiting for the **perfect** is and will be the enemy of the **good,** which we are already achieving and will continue to achieve for many. We just want to save lives, and we know how to do it.

As for the timing:

Figure 1 below, illustrates the importance of understanding the two distinct, yet overlapping, phases of this disease.

1. The viral replicative phase — this occurs early, largely in outpatients. Mild symptoms: fevers, fatigue, body aches, and sore throat are felt as the virus directly invades the tissues and causes systemic symptoms (but no organ dysfunction)
    i. This is the phase anti-viral therapies should be focused on, i.e. before patients reach the hospital where medicines like hydroxychloroquine or Remdesivir would have the greatest impact to keep the patient away from the hospital and ICU
2. The hyper-inflammatory, immune response phase (what brings patient to the hospital) is a state of immune system dysregulation whereby immune cells exit the blood vessels into tissues, causing massive inflammation within and failures of the major organs, most commonly the lungs, brain, heart, and kidneys.

It is this later, hospitalized "hyper-inflammatory" phase that our protocol is designed to treat and where experts in hospital and ICU medicine are needed.



COVID-19: How New Information Should Drive Policy

Senate Committee on Homeland Security and Governmental Affairs

May 6, 2020
Written Testimony of **David L. Katz, MD, MPH**
President, True Health Initiative

Chairman Johnson, Ranking Member Peters, and members of the Committee- I thank you for this opportunity, and your kind attention.

I am an Internist with a 30-year history of patient care (and several volunteer shifts in a hard-hit emergency department in the Bronx during the COVID19 crisis). I am a board-certified specialist in Preventive Medicine/Public Health, completing that training at Yale University, where I have held faculty positions in Medicine and Public Health. I founded Yale's Yale-Griffin Prevention Research Center in 1998, and directed that facility- focused on chronic disease prevention- for over 20 years. I have co-authored five editions of a leading textbook on epidemiology, public health, preventive medicine, and biostatistics- and directed courses on all of those topics at the Yale University School of Medicine for well over a decade. I am a past president of the American College of Lifestyle Medicine; President of the non-profit True Health Initiative; and founder/CEO of my own start-up company, Diet ID, Inc. I have a native penchant for the big picture that all too often seems to hide in plain sight.

- ***Synopsis:***

We should adopt "**total harm minimization**," aimed at mitigating the direct harms of COVID19, and the indirect harms of societal upheaval and economic collapse, as our national policy objective. This is best pursued by means of **risk-based (i.e. vertical) interdiction** policies that shelter/protect those most vulnerable to severe infection and grave outcomes, while **phasing back** to relative normalcy those in lower risk groups. Sequencing back to normalcy can also be informed by the relative importance of different business sectors and activities. The overlap of "high societal importance" and "low risk population" is the ideal, initial wave back to relative normalcy.

Risk-stratification should be **informed by data**, notably **representative random sampling** at the population level and the construction of a **data pyramid**. Policy should remain nimble, adaptable, and responsive to empirical data that accrue over time. Phased returned to degrees of normalcy should culminate in **herd immunity** and the "**all clear**," abetted by the advent of a **vaccine** when available.

Since many of the factors that elevate risk for severe COVID19 infection are modifiable (i.e., obesity, heart disease, type 2 diabetes, etc.), and are major, chronic burdens on the nation's health, economic vitality, and productivity- there has never been a better time for a **nationally mediated "get healthy" campaign**. There is both immediate and lasting potential benefit in this; risk of severe COVID19 infection can be attenuated in a matter of weeks, days, and to some degree, even hours. Because COVID19 translates chronic risks to which we have become complacent into acute risks evoking both rapt attention and anxiety, this situation is classically a "**teachable moment**" in the parlance of Preventive Medicine. A crisis, in other words, is a dangerous opportunity.

- ***Details of platform:***

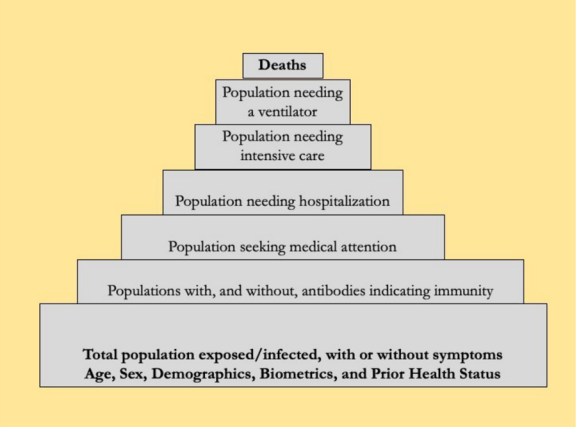
1) **The national policy objective should be *total harm minimization*** (1-3) **and establishment of a safe "all clear" for all population groups**
    a. Total harms of the pandemic encompass the direct toll of SARS-CoV-2 infection; immediate, indirect health effects related to neglect of other medical conditions; and longer-term indirect effects related to interdiction efforts, including but not limited to: unemployment; financial hardship; poverty; food insecurity; depression, anxiety, and other mental health disorders; addiction; domestic violence; suicide; homelessness; etc. (aka, social determinants of health; 4-8)
    b. The "all clear" is a state of sufficient safety that people may resume all desired activities without any specific prohibitions imposed by COVID19.
        i. A population-wide "all clear" is predicated on herd immunity
        ii. A highly effective, mass produced, universally administered vaccine is one path to herd immunity
        iii. Circulation of the virus among those most prone to mild infection and recovery, with subsequent, sequential exposure among those at incrementally higher risk of more severe infection is the alternative path to herd immunity
        iv. Evidence to date suggests that immunity does develop following infection with SARS-CoV-2 (9); and if it did not, an effective vaccine would certainly prove elusive (10)

2) **Primary means to the objective: vertical interdiction** (11) **and sequential herd immunity**
    a. Vertical interdiction refers to protecting those most vulnerable to severe infection with a concentrated allocation of all relevant resources, while phasing back to relative "normalcy" those least vulnerable
        i. In contrast, a one-size-fits-all approach to interdiction is "horizontal" and comes at a much higher cost in societal disruption and economic ruin
        ii. Vertical interdiction must be data-driven (see below)
    b. Flattening the curve: purpose and limitations
        i. Purpose
            1. Avoid medical system overwhelm
            2. Buy time for advancements
        ii. Limitations (12)
            1. Postpones, does not prevent, severe cases and deaths
            2. Requires a "subsequent" phase
    c. Herd immunity
        i. This is how pandemics end, whether mediated by infection and recovery, or immunization
        ii. Herd immunity = collective protection

iii. Herd immunity can be achieved while protecting those who cannot encounter the native infection by means of sequencing exposure for maximal safety based on risk stratification (13)
iv. Use immunity in others to defend the most vulnerable by creating a "dead end" for viral transmission

3) Required inputs for informed policy: constructing a data pyramid (14)

a. Structure of data pyramid, **FIGURE 1**



b. Data sourcing; site specificity
   i. The distribution of risk factors and outcomes of COVID19 infection will vary by population, so policy should be informed by population-specific (i.e., U.S, and/or state-level) data
   ii. Relevant data do not require whole-population testing, but can be acquired by means of representative random sampling
c. General risk assessment (15)
   i. Representative data are needed for infection and immunity
   ii. Corresponding data are needed for known and suspected risk factors for severe infection to determine how outcomes vary by risk classification
   iii. To date, available evidence indicates young (<50) and generally healthy equates to low risk (i.e., a small fraction of a percent for fatality) whereas as older (>70) and/or with major chronic disease burden (e.g., heart disease, kidney failure, type 2 diabetes) equates to high risk (i.e., something greater than 5%)

4) Refined risk stratification

a. Quantified risk calculation
    i. Risk calculation tools are available and being refined
    ii. Use of such tools can translate risk stratification from the population level to the individual level
b. Site specific applications
    i. Risks may vary by location
    ii. On-line risk calculators can adjust for geographic inputs

5) Ancillary opportunity: health promotion campaign

a. Modifiable risk factors for COVID19
    i. Poor diet, lack of physical activity, smoking, obesity, and chronic diseases related to these- heart disease, diabetes, COPD, etc.- constitute the major health burden in the United States, causing hundreds of thousands of premature deaths annually (16-18)
    ii. These chronic risks have been made "acute" by COVID19
b. Confluence of acute and chronic health risks
    i. This confluence of acute and chronic risk creates a unique opportunity to address both
    ii. Acute concern for COVID19 engenders a "teachable moment" (19)
    iii. This is an ideal time for a national "get healthy" campaign (20)

6) Specific challenges: prevailing fear, opposition, unknowns

a. Message clarity
    i. Must overcome polarized opposition
    ii. Consistent case for total harm minimization
b. Commensurates (21) should be a communication priority (e.g., the average risk of death from driving a car for two years; based on total US cases to date, more likely to be injured in a car crash this year than to get COVID)
    i. Compare unavoidable risks to familiar risks
    ii. Population specificity as warranted (e.g., kids in schools)

7) The case for humility and policy implications

a. Prior pandemics, and the vagaries of this one, call for humility about the important gaps in our knowledge (22)
b. There are known knowns
    i. Detected cases
    ii. Hospitalizations
    iii. Deaths
    iv. Risk factors (23)
    v. Unemployment figures
c. There are known unknowns
    i. Actual total cases (24)
    ii. Immunity prevalence, duration
d. There are unknown unknowns
    i. Pandemic "waves"
    ii. Viral mutations

e. We can, and should devise national policy despite uncertainties based on the best available data; however, this also calls for a nimble approach and willingness to adjust policy in response to empirical data that result from any given policy initiative. COVID19 will be "educating" us for some to come, and we should remain willing to learn, and to apply each new lesson to maximal advantage.

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United States Senate

Committee on Homeland Security and Government Affairs

COVID19: How new information should drive policy

Tom Inglesby, MD

Director, Center for Health Security

Johns Hopkins Bloomberg School of Public Health

May 6th, 2020

Chairman Johnson, Ranking Member Peters, and distinguished members of the Committee, thank you for the chance to speak with you today about COVID 19. My name is Tom Inglesby. I am the Director of the Center for Health Security of the Johns Hopkins Bloomberg School of Public Health and a Professor of Public Health and jointly in Medicine at Johns Hopkins University. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.

This virus has already done great damage to our country, firstly in terms of people sickened and lives lost, and secondly in terms of the terrible economic consequence and loss of jobs around the country. As a reminder of the speed of how quickly this has spread, on March 6, two months ago, there were about 200 people diagnosed with COVID-19. As of yesterday, 1.19 million people have gotten sick with COVID, and more than 70,000 people had died in the US.

This virus has a reproductive rate of about 2-4, which means the average person with this virus would spread it to 2-4 others, with each new generation of cases occurring every 5-7 days. Without having put social distancing measures in place, the virus would have continued to spread far more rapidly and widely, and it could have doubled weekly during this time period.

Principles for and steps toward reopening

Colleagues at our Center worked with colleagues at the American Enterprise Institute to publish the report called: "National Coronavirus Response: A Roadmap to Reopening". That report advised that four conditions were necessary to reopen states with low risk. These conditions can be summarized as: the state has a sustained reduction in cases for at least 14 days; hospitals in the state are safely able to treat all patients requiring hospitalization without resorting to crisis standards of care; the state is able to test all people with COVID-19 symptoms, mild or severe; *and, t*he state is able to conduct active monitoring and quarantine of confirmed cases and their contacts. These conditions are largely consistent with criteria and key capabilities outlined by the White House report on "Opening up America Again", though in that report some of those metrics were considered Gating Criteria and some were considered Core State Preparedness Responsibilities.

As of last evening, as per the NYT summary of data, 33 US states reported 150 new cases or more each day, and of those, 15 US states had an average of more than 500 new cases each day. 17 states in the country have daily case counts that are continuing to rise. On the other hand, 10 states have had 2 week declining numbers of cases, though two of them had high daily new case numbers of 250 and 2500 respectively. But there is no easy way to gauge independently whether those or other states have met the other 3 criteria above. States that have had 2 week declines and do meet the other 3 above reopening conditions would be the least risky places to move ahead on re-opening businesses first. States reopening without meeting those conditions will be at higher risk of acceleration of COVID spread in those states.

In all places where decisions to reopen are happening, political and public health leaders should continue to strongly advise all individuals to maintain their own physical space of 6 feet or more from persons outside their homes. All persons should be strongly encouraged to wear cloth masks when they will be around other people outside their home. People should be encouraged to continue to telecommute wherever that is possible. And people should be strongly discouraged from attending gatherings which have resulted in many reported outbreaks of COVID.

Once decisions are made to reopen, it will be critical for workplaces to follow guidelines for how to reopen with as little risk as possible. CDC and OSHA both have guidance, and CDC is developing more detailed guidance which I hope will be shared publicly soon. Industries themselves are developing their own guidance which will be helpful, but I have heard that American businesses want federal government guidance that they can compare themselves to in order to assure their employees and customers they will be operating as safely as possible. Based on public health principles, workplaces that have higher density, more people, closer personal interaction, indoor spaces will all be at higher risk of generating transmission than those with the opposite conditions. All workplaces should take places to mitigate risks within their operations. Our Center made recommendations regarding these issues in a recently published report.

There will need to be special precautions put in place for workers in places where there is particularly high density or congregate living. One particularly clear example of this is in meatpacking facilities around the country where there have been many outbreaks. There will need to be changes to meatpacking facilities to lower the risks to the employees. Workers in those facilities should have access to PPE, and operations should be modified in whatever way possible to diminish close interaction and increase spacing. There should also be regular testing and screening in those facilities, with close cooperation with local public health officials so that contract tracing and quarantine can take place as rapidly as possible. Information on signs and symptoms of COVID should be available to all employees in their native languages, as should be direction regarding what should be done if they develop illness. CDC and OSHA have put out clear guidance on this, and it should be carefully followed.

Special precautions should of course be taken to protect nursing home residents, including the restriction of visitors and provision of PPE to staff in those facilities.

Minority populations have also been disproportionately sickened and killed by COVID19. Special efforts should be made to ensure they are getting ready access to testing and medical care as the rest of the population, esp if reopening efforts are initiated in states, when the risk will rise regarding transmission in those communities.

As soon as it can be safely done, in states where cases are not increasing, consideration should be made for resuming elective procedures. Those decisions should ultimately be left to hospital systems who know best what capacity they have in their system. But if hospitals do have good capacity in their systems, it would be reasonable to consider beginning to open up elective procedures again. Of course, if high numbers of COVID pts begin to appear in hospitals and ICUS again, then those procedures may have to again be put on pause to deal with the those patients.

Impact in illness and mortality

In the last month, there have been more than 200,000 new American COVID cases diagnosed each week, and this is despite stay at home orders in place in most of the country. It took us about one month to go from very small numbers of cases nationally, to the number of 25-30,000 new cases daily. For this past month we have been at around those numbers in a prolonged national plateau. It is not clear yet when those number will go down. The great majority of the 70,000 deaths that took place occurred in the last 30 days.

An additional way to look at the number of deaths that could be attributed to COVID19 is to look at excess deaths. In the weeks ending Mar 28 through April 18, the CDC National Health Statistics website shows excess deaths for that period nationally of 54080. If we extrapolated forward from the week ending April 18 through to May 6 (basing it on the deaths per day the week of April 18 since average daily deaths per day from COVID have not gone done in that time), that would be an additional 42,431 deaths between April 18 and May 6. That would be a total of more than 96,000 excess deaths since the week ending March 28th. That number is already considerably higher than the approximately 70,000 deaths that have been confirmed by COVID diagnostic testing. I think that is a conservative estimate because death reporting lags by 1-8 weeks, so that number would likely grow when all the data is entered into the CDC database.

A Kaiser Family Foundation report concluded that 37.6% of adults 18 and older in the U.S. (92.6 million people) have a higher risk of developing serious illness if they become infected with coronavirus, due to their older age (65 and older) or health condition. Strategies designed to focus social distancing efforts only on older Americans and those with underlying conditions, at the same time letting society completely return to as it was before COVID with no further mitigation or distancing efforts, would need to recognize that this group represented a 1/3rd of adult Americans. There are no feasible paths to isolating one third of American adults from the other 2/3rds.

Its important to acknowledge as well, that while the disease has a much lower fatality rate in younger adults than older adults, there is still a lot we are learning about this disease. For example, just last week we started learning that it is causing strokes in people in their 30s and

40s. We learned this week that it is likely leading to the dangerous Kawasaki's disease in some number of children – 50 children in NY state reported to have this illness. If COVID19 were to spread quickly and widely in the US population, will not be entirely benign for younger adults and children. There will be hospitalizations, critical illness and deaths that will occur. It is important that CDC publish more detailed information on the full range of illness and death that is occurring in the US population.

Well designed serosurveys with tests that have been received FDA Emergency Use authorization are getting done now and we will soon have a more clear sense of what percent of the population has been infected by COVID. Until then it is difficult to put high confidence in the results of serology tests that have not been formally evaluated. FDA has given an EUA to 10 of the as many as 275 antibody tests that are reported to have been developed or are in development. Even when we have confidence in a serosurvey, others challenges with serology are that we don't know yet whether it will cause immunity, and if it does we don't know long that immunity will last. More scientific research is needed to answer those questions.

Some have proposed allowing the disease to spread until the point where the country has achieved "herd immunity". Epidemiologic estimates are that it will require on the order of 70% of the population to be infected to achieve herd immunity. 70% of the US population is about people 233 million people. Most studies that have been done calculate the infected fatality rate to be in the .5 to 1% range. For example, this Lancet analysis concluded that there was an infected fatality rate of .66% in China. If .5% of 233 million people were to die from this illness in the US, that would be 1,165,000 deaths.

Beyond that, it is likely that the infected mortality rate would go up substantially under conditions where the virus were allowed to spread rapidly in the US with no social distancing. We have lost 70,000 people to this virus in conditions where no patients were denied a ventilator because of shortages. If substantially higher numbers of people got sick with COVID in the same time period in a given city or state, there would be the possibility of overwhelming the health care facilities in that place, outstripping the number of available ventilators and/or the people needed to operate them. If that were the case, the infected fatality rate could go up substantially. We have to work to prevent that from happening.

Its important to look at the experience of Wuhan, Lombardy in Italy, and New York City in dealing with their COVID crises. Each of those places are considered to have strong hospital systems. And in each of them, this virus was rapidly able to come rapidly from causing no disease to causing complete health care crisis in a period of weeks. That pattern is nothing like influenza, or any other disease we have dealt with in modern times.

Conclusion

COVID19 has caused terrible illness and economic impact in the US over the recent months. It will continue to be a major public health threat until a safe and effective vaccine becomes available and is made available to the general public. Dr Fauci said this week that he believes that might start as soon as January 2021, which is more encouraging news than we had heard about a potential COVID vaccine until now.

In the meantime, we have to find a way to balance the severe potential public health impact and the severe economic toll that social distancing and the concern and fear about this virus has caused. Some states are in a better position than others to cautiously start to move ahead on easing social distancing. All states that do move forward on social distancing should do so with eyes wide open and recognition that the disease could rebound sharply in the weeks that follow those changes. They should monitor hospitalization rates, ICU bed rats, ventilator usage and deaths very carefully, and be prepared to change course if the epidemic in that state substantially changes for the worse. For businesses that are allowed to reopen they should do so with great care, mitigating their risks through changes to operations and processes and physical changes wherever needed and possible. And throughout all of this, political and public health leaders should communicate clearly to the public that individual physical distancing measures will remain critically important throughout all of this, and the public should continue to take these measures with the greatest seriousness. Keeping the epidemic from rebounding and causing new waves will take great collective action on the part of the America public.

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The Foundation *for* Research *on* Equal Opportunity

ROUNDTABLE OF THE UNITED STATES CONGRESS

Senate Committee on Homeland Security & Governmental Affairs

COVID-19

How New Information Should Drive Policy

AVIK S. A. ROY

President
The Foundation for Research on Equal Opportunity

May 6, 2020

The Foundation for Research on Equal Opportunity (FREOPP) is a non-partisan, non-profit, 501(c)(3) organization dedicated to expanding economic opportunity to those who least have it. FREOPP does not take institutional positions on any issues. The views expressed in this document are solely those of the author.

ORAL STATEMENT

Chairman Johnson, Senator Peters, and members of the Senate Homeland Security & Governmental Affairs Committee: thanks for inviting me to speak with you today.

I'm Avik Roy, and I'm the president of the Foundation for Research on Equal Opportunity, or FREOPP, a non-partisan, non-profit think tank focused on expanding economic opportunity to those who least have it. All research conducted by FREOPP considers the impact of public policies and proposed reforms on those with incomes or wealth below the U.S. median.

Figure 1. Percentage Change in Hours Worked by Small Business Hourly Employees (vs. January 2020)

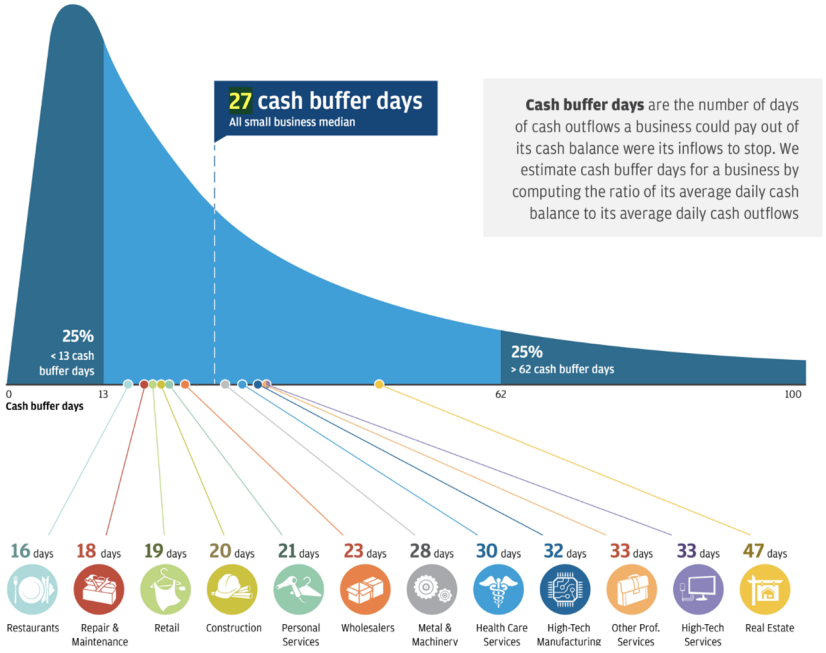


Work by hourly employees has collapsed. An analysis by Homebase, a timecard platform, indicates that the number of hourly-wage employees in small businesses going to work dropped by two-thirds between January and March 2020. All sectors have been affected, but especially those related to travel and retail-facing businesses such as beauty, personal care, leisure, and entertainment. Even the least-affected sectors, like home and repair, have seen drops of 50%. *(Sources: Alexander Bartik et al., University of Chicago; Homebase)*

It is for this reason that I am gravely concerned about the profound economic destruction that the COVID-19 lockdowns have caused.

You know that 30 million Americans have lost their jobs, and that the CBO estimates that second quarter GDP will be 40 percent lower than it was at this time last year. Jobs for hourly wage earners—the most vulnerable workers in our economy—are down 60 percent relative to pre-pandemic levels. These are hairdressers and line cooks. They work at doctor's offices, and on assembly lines. They are, in President Clinton's words, "those who work hard and play by the rules."

Figure 2. Median Cash Buffer Days for Small Businesses, by Sector



Small businesses are running out of time. The median small business has 27 days' worth of operating cash in reserve, with 75% of businesses holding fewer than 62 days' worth. *(Source: JPMorgan Chase Institute)*

The good news is that the lockdowns have done what they were supposed to do: ensure that our hospitals and our ICUs were not overwhelmed, Italy-style, with severely ill COVID-19 patients. The bad news is that the shapers of conventional wisdom now claim that we must continue lockdowns for as long as we can't test the entire population for COVID-19, *and* have an effective treatment, *and* develop herd immunity, *and* produce a vaccine. All of this, we are assured, can take place in the next 12 to 18 months.

But what if it takes us 12 to 18 *years* to develop a vaccine? We have never developed a coronavirus vaccine before. The best scientists in the world have been trying to develop a vaccine for HIV for nearly 40 years, and we still don't have one. Effective non-vaccine treatments may arrive sooner, but when? And is it realistic to stick 6-inch swabs up the nostrils of millions of Americans, every day, until that happens?

TIME IS OF THE ESSENCE

The question of "when" is of urgent importance.[1] Every week matters. The average small business holds less than four weeks of cash in reserve. For urban small businesses it's more like two weeks. Some have been able to take advantage of the Paycheck Protection Program, but as you know, it is medium-sized businesses, not small businesses, that have been organized and savvy enough to maximize that opportunity.

Shapers of the conventional wisdom argue that these devastating economic costs are necessary and acceptable, because we must do everything possible to protect people from COVID-19. Let me explain why this thinking is flawed.

First, the costs of the lockdowns are not merely financial. The closure of schools has only widened educational disparities between the haves and have-nots. There is considerable evidence that high unemployment rates are associated with higher mortality, including deaths of despair. And there is a cost in lives and health among those who have been unable to seek non-COVID-related health care, including unmanaged chronic disease, missed cancer diagnoses, untreated heart attacks, and unavailable organ transplants.

Second, one-site-fits-all lockdowns are not based on actual evidence or science regarding COVID-19, but are instead based on fear, and on off-the-shelf playbooks designed for influenza, a meaningfully different disease. The risk of death due to COVID-19 is very low for those under the age of 55, and yet our restrictions on economic activity apply equally to people of all ages.

Roughly half of the deaths from COVID-19 have taken place in the tri-state area around New York City, and yet we're treating Oklahoma, Utah, and Wyoming no differently than Manhattan. According to a soon-to-be-published analysis by my FREOPP colleague Gregg Girvan, at least one-third of all U.S. deaths due to COVID-19 are taking place in nursing homes.

And yet we are not incorporating that fact into our assessment of the risks outside of nursing homes. Similarly, the risk of outdoor transmission appears to be much lower than for indoor transmission, and yet many states are applying equally onerous restrictions to indoor and outdoor activity.

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[1] Roy A, Reopening the U.S. Economy Even if the Pandemic Endures. *The Wall Street Journal*. 2020 Apr 24; https://www.wsj.com/articles/reopening-the-u-s-economy-even-if-the-pandemic-endures-11587740529.

THE AUTO SAFETY PARADIGM

Third, we've forgotten how we deal with risk in other aspects of our society. 100,000 Americans die of hospital-acquired infections each year—and yet we don't shut down the hospital industry. 37,000 Americans die each year in traffic fatalities—and yet we don't shut down the roads.

Indeed, traffic fatalities is a good mental framework for thinking about how to live with COVID-19. Instead of abolishing cars, we enforce traffic laws and speed limits, and prohibit drunk driving. We set a minimum standard for car safety. But, most of all, we expect individual drivers to be responsible for their own conduct.

Something similar can work for COVID-19. Businesses can deep-clean their surfaces and provide hand sanitizer and masks to their workers and customers. People can wash their hands regularly, and minimize close contact with strangers. This is, in fact, what East Asian countries did after the original SARS outbreak in 2003, and it enabled them to gradually return to normal life, despite the absence of a vaccine or effective treatments.

For a more detailed set of recommendations, please read FREOPP's report, *A New Strategy for Bringing People Back to Work During COVID-19*, co-authored by Lanhee Chen of the Hoover Institution, Bob Kocher of Stanford, and Bob Wachter of UCSF.[2]

I look forward to discussing these ideas during today's conversation. Thank you.

[2] Chen L, Kocher B, Roy A, and Wachter B, *A New Strategy for Bringing People Back to Work During COVID-19*. The Foundation for Research on Equal Opportunity. 2020 Apr 14; https://freopp.org/a-new-strategy-for-bringing-people-back-to-work-during-covid-19-a912247f1ab5.

John P.A. Ioannidis, MD, DSc

Professor of Medicine, of Epidemiology and Population Health, and (by courtesy) of Biomedical Data Science, and of Statistics and Co-Director, Meta-Research Innovation Center at Stanford (METRICS), Stanford University, Stanford, CA

COVID-19 represents a major crisis with major loss of life. We should use the best science, in a data-driven, evidence-based approach to minimize human loss from this pandemic. We need to consider both the benefits and harms of each of our policy interventions and to adjust our interventions according to continuous feedback with reliable data.

Shelter-in-place and lockdown orders were justified initially, when announcements declared a new, contagious virus with 3.4% fatality rate and no asymptomatic infections. Prospects of 60 million deaths worldwide led to comparisons against 1918 influenza. However, currently we know that asymptomatic or mildly symptomatic infections are very common. The numbers of people infected are far more than those documented to-date with PCR testing. Infection fatality rate is accordingly much lower than the crude fatality rates derived from dividing the number of deaths by the number of documented cases. While this is a contagious virus and many people can be infected, to-date person-years of life lost from COVID-19 worldwide is probably in the range of 100- to 1000-fold less than the person-years of life lost from influenza in 1918. Of course, a second wave cannot yet be excluded. Its occurrence and potential magnitude can only be speculated with mathematical models, but models have not been very successful so far in COVID-19 predictions. Therefore, we need to proceed with caution in lifting lockdown and monitor the impact of any changes in policy measures with real data, as opposed to just using models.

The fatality rate from COVID-19 is highly dependent on age and modulated by the presence of comorbidities. For children and young adults, it appears that infection fatality rate is

lower than seasonal influenza, and for middle age adults it is about the same. Infection fatality rate can increase sharply, however, when nursing homes are massively infected and when unprepared hospitals are overwhelmed and the infection spreads to hospitalized patients (nosocomial infection). This explains the paradox why COVID-19 is typically a very mild, benign infection, but it also has the potential to become devastating in specific settings.

While lockdowns were justified initially, their perpetuation may risk many lives. Unemployment may create more marginalized citizens without health insurance. Mental health can be affected with increases in depression, suicides, domestic violence and child abuse. Gun sales have increased. Famine is becoming a global threat. Moreover, deaths from common chronic diseases and treatable conditions such as heart attacks may increase, as patients avoid hospitals, interaction with their care-givers is disrupted, and hospitals become financially devastated. Excess deaths accruing during COVID-19 weeks may reflect both COVID-19 itself but also deaths from health care disruption. COVID-19 overwhelmed a few dozen hospitals, while COVID-19 measures may jeopardize services and multiple health outcomes in thousands of hospitals.

Moving forward, we need to defend hospitals and nursing homes with strict infection control and hygienic measures; universal and periodic testing of all personnel; and quarantine for infected and exposed personnel. Conversely, we should reassure most citizens – those of younger ages without serious preexisting conditions - that they are at very low risk.

Re-opening efforts require great caution, with continuous feedback to identify and limit any potential surge of hospitalizations and deaths upon re-opening. Re-opening should be gradual, with continuous feedback on epidemic activity. This includes data on seroprevalence (proportion of people already infected) and incidence of new infections. These data should be balanced against bed capacity reserves. It is unrealistic to expect new PCR-detected cases to disappear before re-opening. PCR remains positive for a while in many patients who are no longer infectious.

Moreover, with increased testing and with a large pool of previously undetected infections, numbers of PCR-positive samples may seem to remain quite high, even though the epidemic wave has largely passed. It is also unrealistic to expect COVID-19 deaths to stop accruing before re-opening. Deaths may happen 3 weeks after infection, and modern medical technology can maintain some people on mechanical support even for months. Finally, it is unrealistic to expect that complete contact tracing will need to be feasible before re-opening. In most locations, the number of people infected is already too large and their casual contacts may include a large portion, if not the large majority of the entire population, thus making complete contact tracing infeasible. Complete contact tracing can be more feasible when the epidemic activity has ceased, e.g. in the future when trying to catch early and extinguish potentially new waves.

The pace of re-opening may differ across locations, depending on their evolving levels of infection, hospital capacity, and population vulnerability structure. While treatment advances and vaccine efforts may be successful eventually, lockdown measures cannot be prolonged until we find treatments and vaccines that save many lives, since such breakthroughs may take a long time (or may even never happen). For example, remdesivir has shown promising results in shortening duration of disease, but no conclusive evidence yet for saving lives.

How To Re-Open Society Using Evidence, Medical Science, and Logic

Scott W. Atlas, MD, is the David and Joan Traitel Senior Fellow at Stanford University's Hoover Institution and the former Chief of Neuroradiology at Stanford University Medical Center.

The consequences of the COVID-19 pandemic have been enormous. As of the first week of May, more than 70,000 Americans have died. If it were compared as a separate country, the New York area would rank, by far, as number one for deaths per capita. Given that three to four weeks typically elapses before death, thousands more already infected will also succumb to the virus. That said, the direct daily toll from the infection has markedly declined throughout the United States, including the epicenter of New York. The curves have been flattened – the stated goal of the isolation has been accomplished – for both hospitalizations per day and deaths per day.

We now have an even greater urgency, due to the severe and single-minded policies already implemented. Treating Covid-19 "at all costs" is severely restricting other medical care and instilling fear in the public, creating a massive health disaster, in addition to severe economic harms that could generate a world poverty crisis with almost incalculable consequences. Half of neurosurgery patients still refuse to come in for treatment of diseases that if left untreated risk brain hemorrhage, paralysis, and death, even when their doctors directly reassure them. Transplants from living donors are down 85 percent from the same period last year. Missed biopsies of now undiscovered cancers number thousands per week. That doesn't include the latest reports of skipping two-thirds to three-fourths of cancer screenings, most childhood vaccinations, and treatment for new strokes and known cancer.

We also know that total isolation *prevents* broad population immunity and *prolongs* the problem.
We know from decades of medical science that infection causes individuals to generate an immune response – antibodies – and the population later develops immunity. Indeed, that is the *main purpose* of widespread immunization in other viral diseases – to assist with "herd immunity". In the Covid-19 epicenter New York City, higher immunity is likely, although undoubtedly muted by the extreme isolation policies, as more than 20 percent of those tested had antibodies. A similar finding was reported in Boston. That fact has been *incorrectly* portrayed as an urgent problem requiring mass isolation. On the contrary, infected people are the immediately available vehicle for establishing widespread immunity. By transmitting the virus to others in lower-risk groups who then generate antibodies, pathways toward the most vulnerable people are blocked, ultimately eradicating the threat. While we do not know with certainty that antibodies from Covid-19 stop infection, it is

expected, based on decades of virology science, including other coronavirus respiratory viruses, where immunity post-infection is thought to last for a year or more. That's why scientists are hopeful about using Covid-19 antibodies to treat the sickest patients; that's the basis for the drive to generate a vaccine.

There are two critical aspects of this urgently needed, targeted re-entry plan. First, policymakers must apply logic and critical thinking to the data we have acquired, instead of continuing to prioritize hypothetical projections – projections that need to be readjusted every few days, highlighting their inaccuracy - and then combine that evidence with decades of established medical science. Second, we must demonstrate and fully convey the logic underlying the plan to reassure a public that has become almost paralyzed with panic and fear.

Reassuring the public about re-entry requires repeating the facts – what we know - about the threat and who it targets. By now, multiple studies from Europe, Japan, and the US all suggest that the overall fatality rate is far lower than early estimates, perhaps below 0.1 to 0.4%, i.e., ten to forty times lower than estimates that motivated extreme isolation. And we also now know who to protect, because this disease - by the evidence - is not equally dangerous across the population. In Detroit's Oakland County, 75 percent of deaths were in those over 70; 91 percent were in people over 60, similar to what was noted in New York. And younger, healthier people have virtually zero risk of death and little risk of serious disease – as I have noted before, under one percent of New York City's hospitalizations have been patients under 18 years of age, and less than one percent of deaths at any age are in the absence of underlying conditions.

Here are specific, science-based, logical steps to strategically end the lockdown and safely restore the pathway to normal life:

First, let's finally focus on protecting the most vulnerable – that means nursing home patients. Given that older people with underlying conditions are obvious set-ups for serious complications from respiratory infections, it is difficult to excuse policies that allowed 20,000 nursing care residents to die - 30 percent of all deaths in the US, more than half of the total in some states, particularly when they already live under controlled access. Urgently needed, targeted protection would include strictly regulating all who enter and care for nursing home members by requiring testing and protective masks for all who interact with these highly vulnerable people. Moreover, nursing home workers should be tested for Covid-19 antibodies, and if

negative, for virus to exclude infection, to ensure safety of senior residents. No Covid-19-positive patient can resume residence until definitively cleared by testing.

We must continue to educate and inform the public about what they have already successfully learned regarding the at-risk group. That means issuing rational guidelines advising the highest standards of hygiene and appropriate social distancing while interacting with elderly friends and family members at risk, including those with diabetes, obesity, and other chronic conditions.

Second, those with mild symptoms of the illness should strictly self-isolate for two weeks. It's not urgent to test them – simply assume they have the infection. That includes confinement at home, having the highest concern for sanitization, and wearing protective masks when others in their homes enter the same room.

Third, open all K-12 schools. If under 18 and in good health, you have nearly no risk of serious illness from Covid-19. Exceptions exist, as they do with virtually every other clinically encountered infection, but that should not outweigh the overwhelming evidence to the contrary. Again, standards for consciously protecting elderly and other at-risk family members or friends, including teachers in higher-risk groups, should still be employed.

Fourth, open most businesses, including restaurants and offices, but require new standards for hygiene, disinfection, and sanitization via enforceable, more stringent regulations than in the past. It is reasonable to post warnings for customers who are older or in other ways vulnerable. Avoid unnecessary requirements for spacing of customers, though – it is not logical that otherwise healthy adults, especially younger age groups, should be isolated or maintain a six-foot spacing from each other. If infection is still prevalent, socializing among these low-risk groups represents the opportunity for developing widespread immunity and eradicating the threat.

Fifth, public transportation, the lifeblood of much of the workforce in cities, should resume. In addition to new standards of cleanliness and hygiene that passengers would welcome, regional authorities could require barrier masks for passengers. Given the state of our fearful public, it seems highly likely that most people will choose to wear them.

Sixth, parks and beaches should open. The closure policy was aiming to prevent all social mingling. There is no scientific reason to insist that people remain indoors. Given now that we know who to protect and how to protect them, even inside our homes, outdoor sports activities can resume. Smart, considered limits on large group gatherings should be advised.

Finally, implement prioritized testing for three groups: nursing home workers, health care workers and first responders, and patients in hospitals with respiratory symptoms or fever. Widespread testing for the whole population is not a predicate for reopening as above. And contact tracing is not as valuable after a disease is already widespread, even though it would be an important part of the overall preparation for potential future outbreaks.

Targeted protection for the known vulnerable, standards and commonsense recommendations for individuals and businesses, and prioritized testing form the basis of an urgently needed, strategic re-entry plan that would save lives, prevent overcrowding of hospitals, and limit the enormous harms compounded by continued total isolation. Smart, safe re-entry cannot be delayed by fear or hypothetical projections, because we have direct data on risk and experience with managing it. The goal of the strict isolation has been accomplished. Let's stop underemphasizing empirical evidence and established medical science while instead doubling down on hypothetical models. Science and logic must prevail over fear and worst-case scenarios.

Causes of death, 2018

	deaths	% total
Heart disease	655,381	23%
Cancer	599,274	21%
Accidents	167,127	6%
Chronic lower respiratory diseases	159,486	6%
Stroke	147,810	5%
Alzheimer disease	122,019	4%
Diabetes	84,946	3%
Influenza, pneumonia	59,120	2%
Kidney disease	51,386	2%
Suicide	48,344	2%
All other causes	744,312	26%
All causes	**2,839,205**	
Average per day:	**7,779**	
Average per week:	**54,600**	

Source: CDC

Influenza in U.S.

estimated figures

	hospitalized	symptomatic	deaths	fatality rate
2010-11	290,000	21,000,000	37,000	0.176%
2011-12	140,000	9,300,000	12,000	0.129%
2012-13	570,000	34,000,000	43,000	0.126%
2013-14	350,000	30,000,000	38,000	0.127%
2014-15	590,000	30,000,000	51,000	0.170%
2015-16	280,000	24,000,000	23,000	0.096%
2016-17	500,000	29,000,000	38,000	0.131%
2017-18	810,000	45,000,000	61,000	0.136%
2018-19	491,000	35,500,000	34,000	0.096%
9y total:	**4,021,000**	**257,800,000**	**337,000**	**0.131%**
9y avg:	**446,778**	**28,644,444**	**37,444**	

Source: CDC

States compared

	population	cases	% of pop	deaths	% of pop
New York	19.5 m	326,659	1.679%	25,028	0.129%
New Jersey	8.9 m	130,593	1.470%	8,244	0.093%
Massachusetts	6.9 m	70,271	1.020%	4,212	0.061%
Illinois	12.7 m	65,889	0.520%	2,843	0.022%
California	39.5 m	58,853	0.149%	2,386	0.006%
Pennsylvania	12.8 m	53,967	0.422%	3,206	0.025%
Michigan	10 m	44,333	0.444%	4,179	0.042%
Florida	21.5 m	37,431	0.174%	1,470	0.007%
Texas	29 m	34,283	0.118%	955	0.003%
Connecticut	3.6 m	30,621	0.859%	2,633	0.074%
Louisiana	4.6 m	29,996	0.645%	2,042	0.044%
Georgia	10.6 m	28,927	0.272%	1,277	0.012%
Maryland	6 m	27,217	0.450%	1,390	0.023%
Indiana	6.7 m	21,423	0.318%	1,326	0.020%
Ohio	11.7 m	20,969	0.179%	1,135	0.010%
Virginia	8.5 m	20,256	0.237%	713	0.008%
Colorado	5.8 m	17,256	0.300%	901	0.016%
Washington	7.6 m	16,081	0.211%	863	0.011%
Tennessee	6.8 m	13,615	0.199%	234	0.003%
North Carolina	10.5 m	12,283	0.117%	477	0.005%
Iowa	3.2 m	10,111	0.320%	207	0.007%
Rhode Island	1.1 m	9,933	0.938%	355	0.034%
Arizona	7.3 m	9,305	0.128%	395	0.005%
Missouri	6.1 m	8,919	0.145%	408	0.007%
Wisconsin	5.8 m	8,566	0.147%	353	0.006%
Alabama	4.9 m	8,437	0.172%	315	0.006%
Mississippi	3 m	8,207	0.276%	342	0.011%
Minnesota	5.6 m	7,851	0.139%	455	0.008%

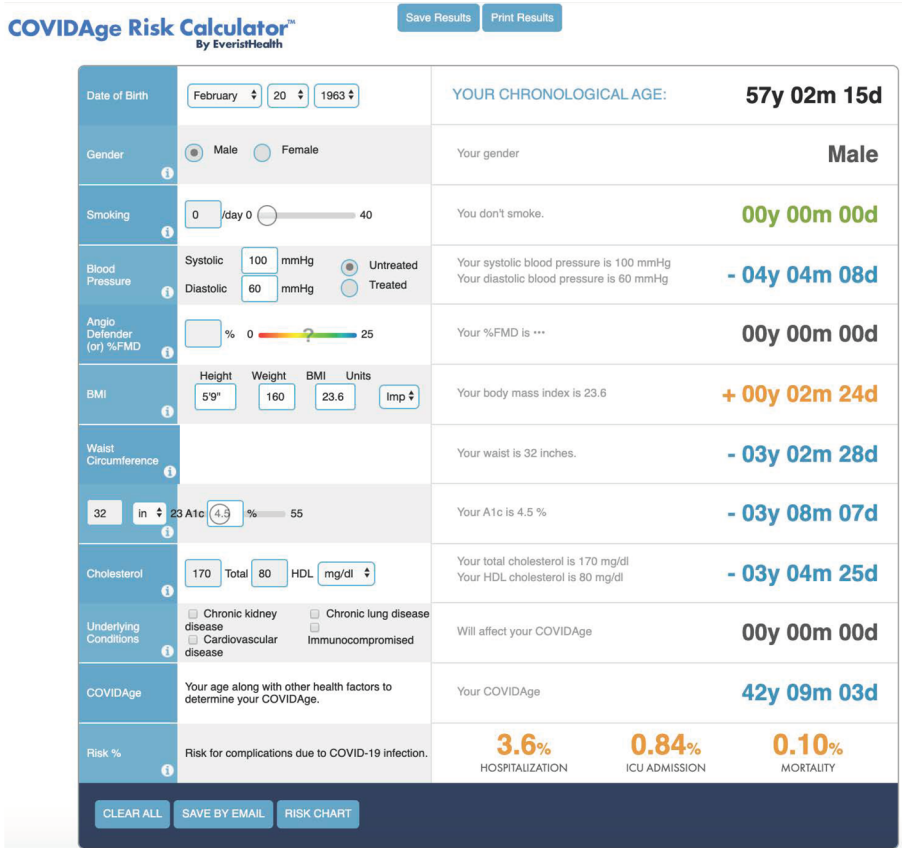
	population	cases	% of pop	deaths	% of pop
South Carolina	5.1 m	6,841	0.133%	296	0.006%
Nebraska	1.9 m	6,446	0.333%	82	0.004%
Kentucky	4.5 m	5,822	0.130%	278	0.006%
Nevada	3.1 m	5,695	0.185%	276	0.009%
Kansas	2.9 m	5,629	0.193%	160	0.005%
Utah	3.2 m	5,449	0.170%	56	0.002%
Delaware	1 m	5,371	0.552%	187	0.019%
DC	0.7 m	5,322	0.754%	264	0.037%
New Mexico	2.1 m	4,138	0.197%	162	0.008%
Oklahoma	4 m	4,127	0.104%	247	0.006%
Arkansas	3 m	3,525	0.117%	83	0.003%
Oregon	4.2 m	2,839	0.067%	113	0.003%
South Dakota	0.9 m	2,721	0.308%	24	0.003%
New Hampshire	1.4 m	2,636	0.194%	92	0.007%
Idaho	1.8 m	2,127	0.119%	66	0.004%
Puerto Rico	3.2 m	1,924	0.060%	99	0.003%
North Dakota	0.8 m	1,266	0.166%	25	0.003%
West Virginia	1.8 m	1,242	0.069%	50	0.003%
Maine	1.3 m	1,226	0.091%	61	0.005%
Guam	0.2 m	1,118	0.668%	6	0.004%
Vermont	0.6 m	907	0.145%	53	0.008%
Hawaii	1.4 m	615	0.043%	17	0.001%
Wyoming	0.6 m	604	0.104%	7	0.001%
Montana	1.1 m	457	0.043%	16	0.001%
Alaska	0.7 m	369	0.050%	7	0.001%
U.S. Virgin Isl.	0.1 m	66	0.063%	4	0.004%
N. Marianas Isl.	0.1 m	15	0.026%	2	0.003%
U.S. total	**331.8 m**	**1,210,749**	**0.365%**	**71,077**	**0.021%**

Source: New York Times, May 6, 2020. https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html

Countries compared

	population	cases	% of pop	deaths	% of pop
United States	328.2 m	1,204,475	0.37%	71,078	0.022%
Spain	46.8 m	219,329	0.47%	25,613	0.055%
Italy	60.3 m	213,013	0.35%	29,315	0.049%
United Kingdom	67.9 m	196,243	0.29%	29,501	0.043%
France	65.3 m	170,694	0.26%	25,538	0.039%
Germany	83.8 m	167,007	0.20%	6,993	0.008%
Russia	145.9 m	165,929	0.11%	1,537	0.001%
Iran	84 m	101,650	0.12%	6,418	0.008%
Belgium	11 m	50,781	0.46%	8,339	0.076%
Switzerland	8.6 m	30,009	0.35%	1,795	0.021%
Sweden	8.9 m	23,216	0.26%	2,854	0.032%
Norway	5.4 m	7,955	0.15%	215	0.004%

Source: Johns Hopkins Coronavirus Resource Center dashboard, May 6, 2020


COVIDAge Risk Calculator™
By EveristHealth
Save Results
Print Results
Date of Birth
February 20 1963
YOUR CHRONOLOGICAL AGE:
57y 02m 15d
Gender
Male
Female
Your gender
Male
Smoking
0 /day 0 40
You don't smoke.
00y 00m 00d
Blood Pressure
Systolic 100 mmHg
Diastolic 60 mmHg
Untreated
Treated
Your systolic blood pressure is 100 mmHg
Your diastolic blood pressure is 60 mmHg
- 04y 04m 08d
Angio Defender (or) %FMD
% 0 25
Your %FMD is •••
00y 00m 00d
BMI
Height 5'9"
Weight 160
BMI 23.6
Units Imp
Your body mass index is 23.6
+ 00y 02m 24d
Waist Circumference
Your waist is 32 inches.
- 03y 02m 28d
32 in 23 A1c 4.5 % 55
Your A1c is 4.5 %
- 03y 08m 07d
Cholesterol
170 Total 80 HDL mg/dl
Your total cholesterol is 170 mg/dl
Your HDL cholesterol is 80 mg/dl
- 03y 04m 25d
Underlying Conditions
Chronic kidney disease
Chronic lung disease
Cardiovascular disease
Immunocompromised
Will affect your COVIDAge
00y 00m 00d
COVIDAge
Your age along with other health factors to determine your COVIDAge.
Your COVIDAge
42y 09m 03d
Risk %
Risk for complications due to COVID-19 infection.
3.6% HOSPITALIZATION
0.84% ICU ADMISSION
0.10% MORTALITY
CLEAR ALL
SAVE BY EMAIL
RISK CHART

Sign in Join now



Out of the Blight of Contagion, into the Light: of Pandemic and Pyramid



David L. Katz, MD, MPH, FACPM, FACP, FACLM

CEO, DietID; President, True Heal...

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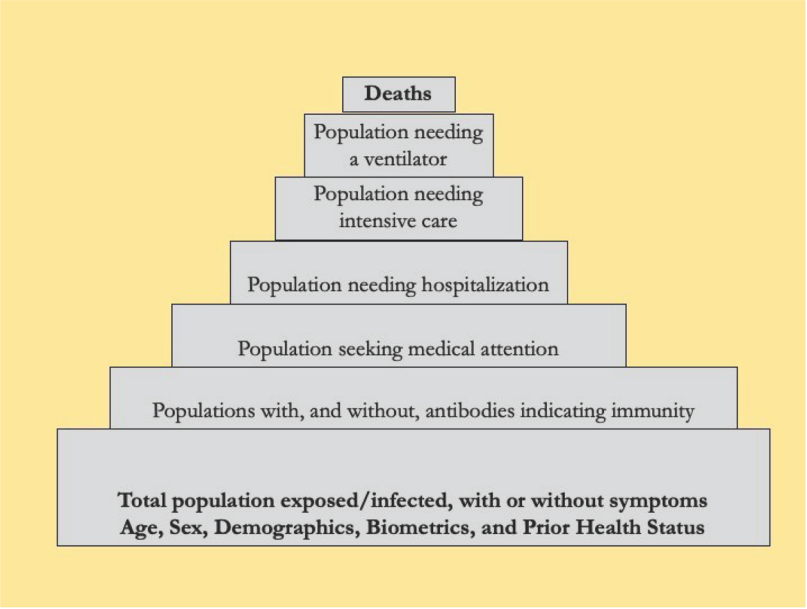
We are, no doubt, all comparably eager to consign this blighted interval- of coronavirus contagion, social upheaval, recrimination and fear - to the history books. One day, this will all just be a reference in a tale told to grandchildren, an episode stripped of its visceral impacts and neatly archived.

Before living through COVID19, though well-schooled in the great flu pandemic of 1918, I never paused to wonder what it felt like to be a family caught up in it, waiting for fate to play out that century ago. Textbooks on epidemiology and public health preserve the facts, but are very antiseptic to feeling and the human experience. Now I know.

Sign in Join now

light. It waits not at the end of a tunnel, but at the top of a pyramid. The pyramid in question is made of data, and we need to build it.

The pyramid we need looks like the below, and is responsive to our urgent needs for illumination.



We talk about the virulence, or severity, of SARS-CoV-2 infection, but the blunt reality is- we don't know. We certainly know that some cases are severe, that some cases are lethal. But we just don't know the denominator: how many people in the United States (or world) have been infected? The overall severity of this infection derives from the ratio of severe cases to total, and we simply can't know that without knowing the total.

We talk about the *case fatality rate*, but that, too, is unknowable without the denominator. That figure is the ratio of deaths from a given cause- coronavirus infection in this case- to the total number exposed. We don't know the total number exposed.

A pyramid constructed of the data highlighted above would answer all of our most pressing questions. *Who is at risk of severe infection, and who is not? Can we safely achieve herd immunity by* ***loosening interdictions in phases, based on risk stratification****? How much of this contagion has been asymptomatic? Is it infection, or* ***haphazard interdiction****, that is hurting more people?*

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us- as the CDC does routinely- and then extrapolate. This is not perfect, it's just very, very good- and monumentally better than the dense fog of ignorance from which policy proposals are emanating now.

We are not limited to only extreme and dire choices: ***expose everyone to the risk of infection for the sake of normalcy***, or ***abandon all hope of life as we knew it for the sake of one-size-fits-all interdiction***.

With the guidance of data, we can determine who can encounter this pathogen at very low risk, and who must be kept away from it. A **data-informed pivot to vertical interdiction** remains possible. We still have the opportunity to protect the vulnerable; resume living, learning, and work in phases; make our safest possible way **to herd immunity**; achieve the "all clear" that lets grandparents hug their grandchildren once more; **minimize the total harms of infection and societal collapse alike**; resurrect life much as we knew and loved it, before all this.

Or at least, we might have that opportunity. To know for sure, we need to rise above the fog down here and get to the light. To know for sure, we need to build, and climb, a pyramid of data. We can; we should.

As I've hastened to note before, the numbers used in that construction cannot substitute for, and should never obscure, **the experiences of individual patients and families**. If you are a family who has lost a loved one to this scourge, I doubt you care all that much what the accurate case fatality rate is. You only care about the hole the pandemic punched into your lives, and rightly so. My heartfelt condolences to you.

I truly understand this challenging juxtaposition, of the one and the many. I write this under some time pressure: I leave tomorrow for a deployment of several days to a New York City hospital as a volunteer physician. I am doing that because while I think striving to exert a beneficial influence on public policy is important, it is not more important than rendering care to a person in acute need. Writing about policy today, departing to a hospital tomorrow, makes me reflect, as I have across **the span of my career**, on how clinical medicine and public health are both greater and lesser than the other. For impact at scale, public health – both its practice, and contributions to salutary policy decisions -is the greater. But for immediacy, intimacy, and the indelible impressions of human interaction- nothing rivals the privilege of clinical care.

We all must strive to bridge that divide. The seemingly sanitized, dispassionate, anonymizing statistics of public health veil the stories of real people, real families, real feeling. We can honor that, while still allowing for the value intrinsic to those numbers, what they reveal about patterns. Only by knowing the patterns of this pandemic- from denominator through numerator, from the base of the pyramid to its peak- can we know the path to **total harm minimization**.

If there is a light after COVID19, it's not at the end of a tunnel. It's at the top of a pyramid. The pyramid is made of data. If we climb that pyramid, we have the best possible opportunity to get up, over, and beyond this- and lay it to rest as a historical episode of singular challenge and memorable cost.

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place we bury the dark days of COVID19. First, good data. Then, good understanding. Then, good policy. And then, good riddance.

-fin

Dr. David L. Katz is a board-certified specialist in Preventive Medicine/Public Health.

New York Times OpEd by Dr. Katz

New York Times OpEd by Thomas L. Friedman

Click here to access the one-page summary of #TotalHarmMinimization

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Updated estimates of comorbidities associated with risk for COVID-19 complications based on US data

Mary L Adams, Joseph Grandpre, David L Katz

doi: https://doi.org/10.1101/2020.05.02.20088781

This article is a preprint and has not been certified by peer review [what does this mean?]. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.

Abstract | Info/History | Metrics | Preview PDF

Abstract

We updated previous estimates (wwwnc.cdc.gov/eid/article/26/8/20-0679_article) of adults with any underlying condition increasing risk of complications from COVID-19 using recent US hospitalization data instead of mortality data from China. This substitutes obesity for cancer in the definition and increased the percentage of adults reporting more than 1 condition to 56.0% (95% CI 55.7-56.4). When controlled for all measures listed, factors increasing odds of reporting any of the underlying conditions include being male, older, African American, American Indian, household income <$25,000, < high school education, underinsurance, living in the South or Midwest (vs. West), plus the risk factors of ever smoking, sedentary lifestyle, and inadequate fruit and vegetable consumption. Population-attributable risk for the listed risk factors was 13.0%, 12.6%, and 15.0% respectively. Results have potential implications for policies based on risk-stratification of the population and for improvement of risk status through lifestyle change. National support for a health promotion campaign would be timely.

Competing Interest Statement

The authors have declared no competing interest.

Clinical Protocols

https://wwwnc.cdc.gov/eid/article/26/8/20-0679_article

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Author Declarations

All relevant ethical guidelines have been followed; any necessary IRB and/or ethics committee approvals have been obtained and details of the IRB/oversight body are included in the manuscript.

Yes

All necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived.

Yes

I understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).

Yes

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

Yes

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Drawing the line for risk stratifications:
Designing return-to-work policies that consider diagnostic error, costs, benefits and COVID-19

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Reopening Communities Affected by COVID-19 is a Risk Management Issue

Governor Andrew Cuomo, April 15, 2020 NY (D)

"It's over when people know I'm 100% safe and I don't have to worry about this. When does that happen? When we have a vaccine...Until you have a vaccine, until you have the medical treatment, what do you do? How are you building the bridge? Well, it's going to be a phased reopening."

Governor Charlie Baker, April 22, 2020 MA (R)

"If we move too quickly, we risk moving the progress that we've made so far... We'll get through this and we will come out stronger on the other side but everyone needs to do their part and understand that we need the facts on the ground to drive our decision making."

Governor Gavin Newsom, April 15, 2020 CA (D)

"Let's not make the mistake of pulling the plug too early, as much as we all want to...I don't want to make a political decision that puts peoples' lives at risk and puts the economy at even more risk by extending the period of time before we can ultimately transition and get people moving again."

Governor Kim Reynolds, March 25, 2020 IA (R)

"While we'll look at it from a regional perspective and we'll talk about collectively the metrics we're using, each individual governor is going to look at their own state's metrics."

Governor Larry Hogan, March 25, 2020 MD (R)

"You can't put a timeframe on saving people's lives. We're going to make decisions based on the scientists and the facts."

Executive Summary

What this Paper Provides

This paper outlines an easy to implement toolbox that clinicians can use to help develop local risk policies to minimize the total harm from COVID-19.

How to Use this Paper

Use this paper to help develop and evaluate risk stratification policy options:

- **input information about a test, model or risk stratification policy rule, and your assumptions about the community needs and priorities**
- **receive back a customized risk stratification policy for that community.**

Key Points

1. Any policy to risk stratify individual involves implicit or explicit trade-offs, footnotee.g., harm to health from infection with COVID-19 vs. harm to health from economic losses regardless of how risk stratification is done.[a]

2. Policies can be designed to achieve maximum value for the trade-offs by making simple calculations, and this analysis provides a coherent, concise communication tool for and explaining policies to constituencies and the media.

3. Policies can be designed to take advantage of whatever information is available at a given time, and can incorporate different testing protocols within a single framework (e.g., virology tests where they are available; age-based criteria when they are not).

[a] e.g.,using diagnostic test, predictive model, expert judgement, or some other way.

Importantly, clinicians do not need to be mathematicians to use these techniques. The calculations may be done in a few lines of a spreadsheet or even on a hand calculator.[1] Most of the main content is delivered through real-world examples.

Templates provide guidance on how to make better decisions about reopening economies, screening patients, and other decisions and policy questions.

A **web-based tool** for exploring this analysis is publicly available at no charge at:
`http://www.rogermstein.com/covid-19-resources/`. (*see the Quick-reference Guide.*)

[1] Though not required, mathematical detail and technical references are provided in the Appendices.

Where to Find Techniques for Some Common Policy Questions

- How can policies be designed to minimize total harm, while also maximizing benefits, given economic and related health concerns?[a]
- What are the potential dangers of using risk stratification methods to stage the end of self-isolation?[b]
- How do these dangers change if tests and data are less or more reliable?[c]
- If different regions have different access to different tests, can these be combined within a single policy?[d]
- How can risk stratification using a single measure be made more flexible to allow for prioritization of specific community and economic objectives?[e]
- Is it worth it to spend extra money on better data or testing, and if it is, how much?[f]

---

[a] By doing a few calculations. See Example 5.
[b] It varies. See Example 3.
[c] It can make a BIG difference. See Example 4.
[d] Often, yes. See Example 8.
[e] Yes, by adjusting a few numbers for each objective. See Example 7.
[f] Sometimes. The decision can be explicitly structured however. See Example 6.

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Abstract

The COVID-19 pandemic of 2019 and 2020 has brought to a standstill normal life and commerce in many parts of the world. This has left clinicians challenged to determine when and how to return workers to the workforce while also balancing critical public health issues and minimizing additional harm. A number of recent proposals have suggested using risk stratification strategies to classify members of the public into "higher" and "lower" risk tiers. This article describes practical methods for creating risk stratifications using currently available information which can be updated over time. In this context, we discuss three key observations: (1) Any policy to risk stratify individuals involves implicit or explicit trade-offs (e.g.,harm from morbidity/mortality vs. harm from economic impact on health due to self-isolation), regardless of whether risk is measured using diagnostic tests, predictive models, or expert judgement. (2) Policies can be designed to minimize the harm caused by such trade-offs and failing to do so will directly result in unnecessary harm for the population. (3) Policies can be designed to take advantage of whatever information is available at a given time, and can incorporate different testing protocols within a single framework (e.g., virology tests where they are available, and age-based criteria when they are not). We demonstrate each of these points.

We provide a set of simple *calculation templates* that clinicians can use to discuss risk stratification policies with the objective of developing *Total Harm Minimization* policies. We have also provided a *web-based* tool-set that implements these methods, and which is available publicly.

Using these approaches, for example, a policymaker can input assumptions about risk stratification needs and community priorities, and get as output a risk stratification policy that minimized health and economic harm, given the community priorities. This allows clinicians to assess the advisability of a range of important options for bringing communities back on-line, as well as for making decisions, such as whether to invest in more accurate tests or gather more detailed data.

Keywords *COVID-19; health policy; health economics; cost-benefit analysis; total harm minimization; base rate; Bayesian probability; ROC analysis*

1 Introduction

At the time of this writing, the vast majority of the U.S. population has been quarantined or is under a self-isolation or shelter-in-place order. This is the result of a set of strategies, implemented at the state level to reduce the immediate transmission of the novel novel coronavirus, and to slow its progression. In addition to public heath concerns, a key objective of these strategies is to reduce the risk of overwhelming the healthcare infrastructure of individual states and cities.

These drastic measures, while showing promise in reducing the spread of COVID-19, have also had the effect of severely depressed both local and global economies. Furthermore, a number of health advocates have observed that a prolonged period of attenuated economic and social activity has, itself, the potential to increase substantially negative health outcomes.

Recent quantitative models have suggested the merits of have advocated performing "risk stratification" in order to to classify members of the workforce and broader public into "higher" and "lower" risk tiers, to potentially allow some to return to work in advance of the introduction of an effective novel novel coronavirus vaccine. Recent recommendations (see, e.g., Katz et al., 2020; Stein et al., 2020) have also advocated this strategy.

The basic premise of such proposals is that, at the very least, many "low risk" individuals would not themselves be at severe health risk, even were they to be exposed to and contract COVID-19.[2]

These proposals assert that these "low risk" individuals should return to the workforce to re-energize the economy and reduce unnecessary harm from the negative health impacts of self-isolation. Under these proposals, those individuals who are at "high risk" for severe health outcomes if exposed to the novel coronavirus, in contrast, would remain in isolation pending the development of widespread screening programs and/or vaccines that reduce health risks to the levels of more common viral infections such as seasonal flu.

NY Governor Andrew Cuomo summed-up this concept up succinctly: "*Until you have a vaccine, until you have the medical treatment, what do you do? How are you building the bridge? Well, it's going to be a phased reopening.*"

It is inevitable that some people who are infected will end up being allowed to "cross the bridge" too early while some other healthy people will just as inevitably end up being asked to "stay back" by mistake. In the setting of a pandemic and the resulting lock-down, there are few easy decisions and **there are no attractive options** for managing the risks of infection, on the one hand, and the health and economic conse-

[2] There is often discussion as well about the risk to high risk individuals of low-risk individuals transmitting the disease while themselves showing no or mild symptoms.

quences of self-isolation and quarantine, on the other.

> ***All options currently before clinicians for managing the COVID-19 lockdown involve risks that may harm segments of the population. The charge of clinicians is to minimize this potential harm to the highest degree possible, given the risks that must be taken. Policy approaches that do this are called***
>
> ***Total Harm Minimization (THM) strategies.***

Most risk stratification approaches to policy rely implicitly on a policymaker's (PM) ability to segment individuals into different risk groups using some form of a "test," which may be a diagnostic test, a statistical analysis, a heuristic, etc. (see Section 1.1.1 for a discussion of the many forms that such tests may take). For example, a policy might consider only two risk groups, "high" and "low." The coarse test might be related age and medical status: all individuals above the age of 65 with certain comorbidities would be stratified into the "high risk" group, while those those below 65 or with no comorbidities would be stratified into the "low risk" group.

Risk-stratification recommendations, by construction, assume the widespread availability of some form of diagnostic instrument or predictive model that can be used as a test to grade the risk of individuals to classify them into risk groups (tiers). As a matter of practice, any current test criteria that clinicians must use to defining such stratifications are not perfect, in that the test may erroneously classify some COVID-19 infected individuals as "low risk," while also erroneously classifying some non-infected individuals as "high risk." [3]

1.1 Risk stratification

The techniques described in this paper are meant to be applied in cases in which a policymaker wishes to implement a **policy**: a set of criteria and a plan for allowing subsets of individuals, or specific segments of the population, to enter some venue or to return to some specific activity before an effective COVID-19 vaccination has been introduced.

Some examples are given below:

[3] For example, anecdotal evidence suggests that at the time of this writing, the COVID-19 viral tests that are used to determine whether an individual is infected or not have a false negative rate of about 15% meaning that in about 1 out of 7 cases in which an individual is infected, the test will give a negative result indicating that the patient is healthy.

Activity/Venue		*Policy Maker (PM)*
◦ End self isolation	→	National/local officials
◦ Reopen elementary schools	→	School admins; National/local officials
◦ Enter press conference	→	Political administration
◦ Enter factory	→	HR executives; National/local officials
etc.		etc.

The goal of a policy is to balance the health **risk** to the individual and public at large of contracting and spreading COVID-19, against the health and other risks to the individual and public at large of reduced economic capacity and other non-COVID-19-related morbidities that result from keeping individuals isolated unnecessarily.

In forming such policies, clinicians will consider two types of information about how widespread the COVID-19 is. For questions of capacity, epidemiologists typically consider **prevalence** which is the current number of active cases or the number of active cases as of a specific point in time. For considering contagion, the **incidence rate** describes the number of new cases that develop during a specific time.

For example, the prevalence of COVID-19 in New York on January 1, 2020 represents the total proportion of New Yorkers who were sick with COVID-19 in on January, 1, while the incidence rate of COVID-19 in New York in the month of January describes the rate at which healthy New Yorkers were contracted COVID-19 during that month. Prevalence is often useful for considering issues of capacity and health burden, while the incidence rate describes how quickly COVID-19 is spreading.

1.1.1 Tests and other forms of screening

The techniques we present are designed for cases in which a policy is anticipated to use some form of **test** to determine which individuals will be allowed to enter (do) the target venue (activity) and when. We use the term **screening** to describe the process of administering the test and then using the result as a decision criterion.

Tests may take a number of forms. Some examples include:

- A virology diagnostic
- A serology diagnostic
- Heuristics based on Age, travel, comorbidities, etc.
- Predictive analytics based on epidemiological data
- etc.

Such tests are generally **administered at the individual level** and the result of a test applies to an individual.[4]

Some tests produce **binary** outcomes while others produce results in a **continuous range** of possible outcomes. For example, the answer to a "yes/no" question such as, "Do you live alone?" is (generally) binary as are certain serology tests, while certain RNA-based virology test may return the number of amplicons or the viral load, with higher levels indicating more virus present. Another example of a test with continuous range outcomes would be the use of *Age* as a crude "test," with a different expected health outcomes associated with ages.

A **test result** may be delivered in a number of forms. Examples include:[5]

- RNA concentration level in a specimen
- The presence of IgG antibodies to SARS-CoV-2 in the blood
- Travel to a COVID-19 "hot-spot" within the past two weeks
- Absence of a fever above 98.7° F (37.0° C)
- An estimate of the probability of current infection
- etc.

In some cases, the preferred test may not be available to all individuals given limited availability or differences in test protocols at different facilities. This makes it necessary for a policymaker to integrate different types of tests into a single policy (see, Section 3.4).

There are many forms of **risk** related to COVID-19 for which a policymaker may wish to screen in order to implement some form of harm mitigation. Among the **risks** that may concern a policymaker may consider are:

- individuals who are *currently infected* with COVID-19 entering the general population;
- individuals who are *more likely to become infected* with COVID-19 becoming exposed;
- individuals who might experience *more severe prognoses were they to be infected* becoming infected with the coronavirus (e.g., older individuals or those with comorbidities);
- individuals who are *more likely to transmit* COVID-19 if infected, even if they themselves do not experience severe symptoms circulating in the general population;

[4] Note that although the results are given at the individual level, it is possible, in some cases, to administer the test itself to a group by, e.g., pooling individual specimens (see, for example, (Bilder and Tebbs, 2012)).

[5] These, and all examples in the paper are provide purely for illustrative purposes.

- individuals who do not meet the above criteria, being unnecessarily kept from working and conducting other daily activities;
- etc.

For purposes of our discussions, we generally use examples involving the first and last risks. For our examples, we primarily assume the goal of the policymaker is to isolate currently infected individuals and permit uninfected individuals to leave isolation).

However, we do this for exposition not because we suggest this to be or not to be main purpose of current policies. In fact, the techniques we discuss are quite general and can be applied to any of the risk stratification problems listed, as well as many others.[6]

In what follows, we use the term **risk** to mean the risk of that a policy decision will cause causing individuals who would otherwise have remained healthy to become infected with COVID-19. This may be refined, in some settings to contemplate cases in which the average prognosis for an exposed individual becomes worse as the result of a policy decision.

> An individual may be *at risk* for infection or at risk because if they were to become infected, their prognosis would likely be severe, perhaps resulting in significant hospitalization or death. Even if an individual were not personally likely to become severely ill if exposed to the novel coronavirus, that individual may still put others at risk if they are likely to spread COVID-19.

In what follows, we use the term **harm** to mean the consequences of policy decisions which result in reductions of health and economic security for an individual.

> An individual may be *harmed* if they suffer a reduction in the quality or duration of their health, as the result of either direct morbidity from COVID-19 or other conditions resulting from prolonged isolation, the effects of food insecurity, lack of access to medical services due to high utilization by COVID-19 patients, psychological trauma, domestic abuse, and loss of economic security.

1.1.2 Risk stratification systems, staging and test errors

For purposes of policies based on **risk stratification**, individuals may be grouped into **risk levels** (**risk tiers**) by assigned each individual or group a **risk score** based on the results of one or more tests.

[6] This is also not intended to imply that each of the challenges (concerns) we listed is equally easy to analyze. Assessing the impact of transmission by asymptomatic individuals is more complicated than screening individuals for the presence of the novel coronavirus RNA.

Each risk tier is defined by a set of **criteria** based on the results of one or more types of tests.

Importantly, it is not necessary for the inclusion criteria for a specific risk tier to be based on a single test, and not all tests must necessarily be required for inclusion in a specific tier. For example, a coarse "high risk" class might include individuals who are over 80 years old *or* have recently come into contact with an individual with a confirmed case of COVID-19 *or* who have tested positive for the novel coronavirus.

Risk tiers can be particularly useful for implementing **staging** strategies, designed to enable some segments of the population to "enter" earlier, while others do so at later points. For example, all else equal, individuals in a company that do similar jobs may be staged such that those who are deemed to be lower risk are the first to return to work, followed later by those who are deemed to be higher risk.

Risk stratification involves defining one or more **cutoffs**: threshold values for test results that determine into which of two adjacent risk tiers a result would place an individual. Returning to the earlier examples of various forms of test results, we can see that the criteria implicitly include cutoffs:

Test criterion	*"high" risk cutoff*
RNA concentration in a specimen	concentration $>x$
The presence of IgG antibodies	No antibodies found
Travel to a COVID-19 "hot-spot"	Two weeks & on "hot-spot" list
Fever	body temp >98.8° F
A model estimate of a probability of infection	probability>1%

Finally, for practical purposes, all tests have some level of **test error**. An error occurs when a test result disagrees with the truth. This most often occurs because most tests cannot be exactly tailored to each individual and may miss key information that determines an individual's risk, even if they do identify differences between individuals along more typical dimensions. In some cases, there may also be instances of testing error that go undetected.

By convention, we label those test results that erroneously classify a sick person as healthy, **false negatives** – high risk individuals who are erroneously stratified as "low risk" and reenter the general population. These are sometimes called **Type I errors**.

We label those results that erroneously classify a healthy person as sick **false positives** – uninfected or immune individuals who are erroneously classified high risk and thus prevented from reentering the general population and workforce. These are sometimes called **Type II errors**.

We call correct test results the **truth**, and we label a test result that correctly identifies a sick individual "positive," a **true positive**, Similarly, we label a result as a **true negative** if the test correctly identified an uninfected individual as "negative."

Collectively, we call the set of the true negative rates, true positive rates, false negatives rates, and false positive rates for a test, the test's **performance**.

It is worth noting that the terms "negative" and "positive" can sometimes cause confusion. In common usage, we think of negative outcomes as bad and positive outcomes as good. However, in our context, these terms refer to the outcome of a test for, e.g., the presence of COVID-19. In this case, if the test "comes back" negative, it means that no virus was found.

Continuing the "age test criterion" example, a policymaker may conclude that individuals above 40 years old are at higher risk than those at below 40. Indeed, if *"Age is lower than 40 years"* were used as a criterion to allow individuals to return to work, many infections might be avoided (true positive). However, in addition, many healthy individuals would be unnecessarily kept from returning to work (false positive). Furthermore, some individuals below age 40 will also contract COVID-19, despite passing through the screening (false negative), thought the many more healthy people would also correctly be able to return (true negative).

The *risk* is of infecting ones-self or others others, while the *errors* are any mis-stratification of high risk individuals into low risk tier, or the low risk individuals into the high risk tier. Figure 1 gives an example of how risk and errors related.

For clarity, we distinguish between the risk of COVID-19 infection and transmission, and the **costs** of errors that result from imperfect stratification. Costs relate to the **harm** caused by a policy with respect to test errors.

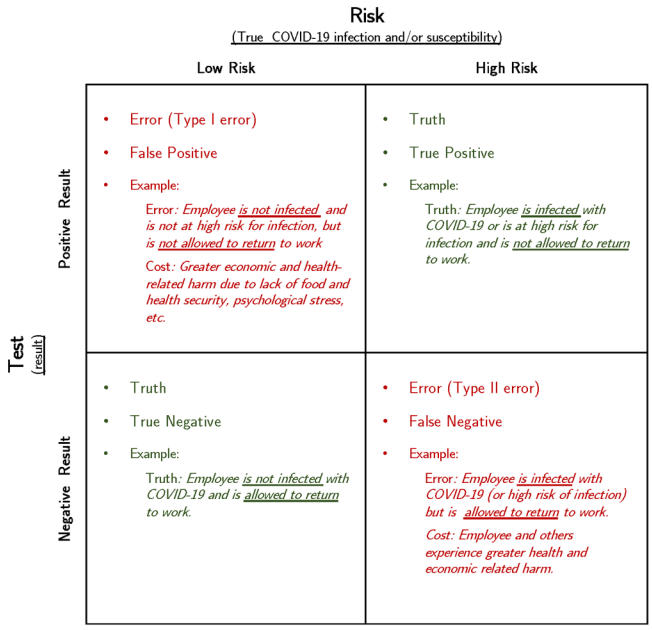


Figure 1: An example of the relationship between outcome risk (true outcome) and error (test result)

This table shows both the kinds of errors a diagnostic test may make in the context of COVID-19 screening, as well as correct (true) test results. Each cell notes whether the outcome is the truth or an error, the name of the type of error if applicable, and gives an example. An error occurs if when the test result (vertical) disagrees with the truth (horizontal). Benefits are not shown, though we discus these later on.

Returning again to the example of the "age test criterion,"

- The "errors" would be the mis-classifications (mis-stratifications) of high and low risk individuals (e.g., under-40-year-olds who actually are or become infected and gravely ill: false true negatives; and uninfected over-40-year-olds who are asked to continue self-isolating: false positives).
- The "costs" would be the harm that results from the mis-classifications (e.g., additional infections to others increasing morbidity and mortality from COVID-19; and additional health and financial problems due to extended self-isolation and economic loss, respectively).

The cells of Figure 1 give examples of the the costs of each type of error. (Also see Section 4.)

Note that later on, we will also discuss **benefits** that may be associated with correct classifications in the same way that costs are associated with errors.

1.2 Trade-offs in risk stratification: Painful questions and limited data

Implicit in any risk stratification proposal is an acceptance that there will be some number false negatives and that there will also be some number of false positives.

A common question that clinicians struggle with is therefore:

What level of health and economic of risk is acceptable?

Said differently, one may ask:

How should a policymaker determine what level of risk is "too high," given the needs of their community?

Determining such a cutoff (e.g., everyone under the age of 65 with no preexisting conditions may return to work) requires consideration of a number of factors relating to the overall risk and severity of infection:

- the costs to the healthcare system (in both financial and health terms) implied by severe infections;
- the benefits of workers returning to work;
- the costs (in both financial and health terms) of individuals remaining in isolation;
- the error rate of whatever test is used;
- the speed at which COVID-19 is spreading;
- etc.

These factors are often hard to assess, and the data available to clinicians is often limited, noisy, inconsistent, and anecdotal. However, regardless of whether a policy is explicit in how it trades off these factors or is silent, and regardless of whether the policymaker introduces them them deliberately or incidentally, these trade-offs are present and can often be inferred by observers simply by using public data.

Policy makers evaluate such trade-offs routinely.

Example 1. Routine trade-offs in policy

The U.S. FDA approves a drug's safety based on its analysts judgement that the adverse effects of the drug are outweighed by the benefits to the patients that respond well (as supported by data from clinical trials).

In general, this is the case. However, many patients are still harmed by these drugs. The The Agency For Healthcare Research and Quality, which is part of the US HHS, estimates that in 2017, there were over *720,000 adverse drug events while patients were under close medical supervision within a hospital* (AHQR, 2019). This does not include the adverse drug reactions that non-hospitalized individuals experienced. In 2017, adverse drug reactions accounted for about 3% of all visits to hospital emergency departments (Rui and Kang, 2018).

The experience of clinicians with drug approvals is not intended as a normative observation.[7] Rather, it is serves to highlight that much of policy making involves risk management, that risk management involves trade-offs, and thus trade-offs are inevitable in policy making.

Despite this, a policymaker's constituents may have little transparency into or appreciation of what these trade offs involve, or how they are determined.

[7] To the contrary: The Agency for Healthcare Research and Quality has instituted a program to aggressively reduce ADRs through a number of initiatives, including more transparent reporting and data collection. The incidence of ADRs declined by 25% between, 2010 and 2016.

The techniques that follow can also provide a language for communicating to constituents, rather than leaving the interpretation of policy priorities to community members,policymaker who may have less context than the policymaker.

1.3 An approach to making flexible, rational decisions with incomplete data and tools

clinicians are charged with responding quickly in crisis situations. Their charge requires them to use of whatever data and tests are available, regardless of the quality. In this context, it is logical that a policymaker should use these data and tests to minimize the total harm caused by imperfect information when determining how best to make required trade-offs.

A policymaker should seek to minimize the total harm the the highest degree possible for the incidental risk that accompanies the use of imperfect test, criteria and data.

Example 2. How not to choose an irrational policy

Imagine that a policymaker is asked to determine a policy for determining which individuals will be able to return immediately to their jobs and which individuals will remain in isolation. The definition of such a policy involves a trade-off between the benefits to workers of workers returning to the workforce, on the one hand, and the costs of the harm harm that will result from some of those workers becoming infected or infecting coworkers, on the other.

The policymaker is considering three policy proposals. Each policy will return some workers to the workforce, but will also l also likely create additional harm by causing an increase in COVID-19 cases in the community, because to some of the infected workers will not be screened out due to test error.

For simplicity at this point, we assume that the only information that the policymaker has to inform this decision relates to the number of cases of COVID-19 that each policy is likely to produce due to test error and the number of workers that will be permitted to return to work.

	Expected # employees back to work	Expected # additional cases of COVID-19
Plan A	15,000	500
Plan B	10,000	500
Plan C	15,000	400

The three proposals listed above are the policy choices plans available to the PM.

Under any state of the world, the PM should prefer Plan A to Plan B (assuming he wishes to maximize the number of employees returning to the workforce and minimize the number of additional COVID-19 infections).

He would deliver more benefit with Plan A, for the same cost of additional harm. (More benefit, same cost.)

By similar reasoning, the PM should prefer Plan C *even more* than Plan A: Plan C gives the same benefit as Plan A, but with lower cost. (Same benefit, less cost.)

In this case, these preferences will hold regardless of how he values the harm of additional COVID-19 cases relative to the benefit of additional employees returning to work.[8]

If these were the only factors in his decision, it would be irrational to choose any plan other than Plan C. ♢

In what follows, we discuss issues related to choosing policies when errors in risk stratification are to be expected due to imperfect information and imperfect tests.

We examine

- the impact of the error rate of a diagnostic instrument on the real-world population of COVID-19 susceptible individuals; and
- the potential impacts on policy evaluation that data and risk stratification errors may precipitate; and
- a set of methods for evaluating potential policies that are designed to minimize the total harm to the population, given the economic, social and health costs and benefits.

The specific costs of different types of errors (infected employees returning to work or healthy employees being asked not to), and benefits of true test results (economic security, access to services, social well being; mitigating the spread of COVID-19) will vary greatly across communities and domiciles. We are not qualified to opine on these quantities, and do not address their determination in this paper.

[8] This ignores in the improbable case that he views the harm as irrelevant.

However, the leadership of a community (country, state, city, firm) *is* well positioned to opine on these topics. Assuming that leaders are able to determine, even in broad terms, these factors and costs, the techniques we describe can provide them with a mechanism for choosing the "best" risk tiers and cutoffs in order to minimize total harm.

To be useful, these methods must be accessible. To make this paper accessible, most of the main body of each section is given over to examples, rather than detailed mathematical derivations. (However, for those interested in the technical details, more in-depth mathematical results are available in the Appendices.)

This paper is not intended be theoretical. It is meant to be used by non-mathematicians. To that end, most of the main results may be calculated on a hand calculator or in a few cells of a spreadsheet.

In many cases the results may also be calculated online at no charge at:
http://www.rogermstein.com/covid-19-resources/

The remainder of this paper is organized as follows:

The Organization of the Paper

- **Section 2** (the next section) discusses the policy implications of model and test error and of sparse or unreliable data. Some of these implications are surprising to readers not familiar with probability theory, but are nonetheless directly relevant to the issues that can arise, even when a test has a high reported accuracy, as well as some potential solutions.
- **Section 3** describes how a policymaker can use even imperfect tests and data to determine risk stratification policies, given a set of priorities, costs, and benefits. This section is divided into a number of sub-sections, that demonstrate:
  - how to coherently incorporate different decisions and priorities into a policy;
  - how observers can infer a policy's trade-offs by examining the policy and doing a few calculations;
  - how clinicians can assess whether more expensive or extensive tests or data collection efforts are justified and, if so, what their impact could be;
  - how to create flexible risk stratification policies to adjust for different priorities and community objectives
  - how to tailor such policies to different groups by considering things like the criticality of an individual's job function or the risk of harm that their return to the workforce may pose to the community or to themselves.
  - how to incorporate tests given to different individuals, using different testing tools, can be coherently incorporated into a single consistent policy.
- **Section 4** discusses some implications of the results, and also discusses:
  - some of the challenges in developing local cost and benefit assessments;
  - how more advanced, flexible and efficient risk stratification policies may be constructed;
- For those who are interested, a number of technical Appendices provide mathematical details that are used in the main paper, including the main formulae.

2 Risk policy in an imperfect world: Bad options + Rational Analysis = Total Harm Minimization

Consider a test that produces a score: $\mathcal{HIGH}$ or $\mathcal{LOW}$, indicating that an individual is either in a "high" or "low" risk tier, respectively, for serious COVID-19 morbidity. This test could be a medical diagnostic, a simple rule (e.g., everyone over 65 is at high risk), the prediction of a machine learning algorithm, etc.

If the test were perfect, then given a risk score of $\mathcal{HIGH}$, the probability of actually belonging to the high risk tier[9] would be 1.0. Similarly, for a risk score of $\mathcal{LOW}$, the probability of belonging to the low risk tier[10] would be 1.0 as well. In this idyllic setting, there would be no model error and *every* high risk individual tested would be stratified into $\mathcal{HIGH}$ category and *every* low risk individual tested would be stratified into $\mathcal{LOW}$.

However, if the risk scoring system were not perfect, then the probability of being at high risk, given a score of $\mathcal{HIGH}$, would not be 1.0 and/or the probability of being low risk, given a score of $\mathcal{LOW}$, would not be 1.0. Furthermore, for an imperfect scoring system, the probability of getting a score of $\mathcal{HIGH}$ if the disease were actually present may also not be 1.0, so some results would not correctly stratify individuals into their appropriate risk tier.

The probability of getting a *correct* test result of $\mathcal{HIGH}$, when the subject is indeed at high risk is the **true positive rate**. The probability of getting an *incorrect* test result of $\mathcal{HIGH}$, when the subject is really at low risk, is the **false positive rate** (or the **Type I error rate**). We can define the *true negative* rate and **false negative rate** (or the **Type II error rate**) in the same way. In what follows, we label these $\mathcal{TP}$, $\mathcal{FP}$, $\mathcal{TN}$ and $\mathcal{FN}$, respectively.[11] The next example shows how these rates affect risk stratification.

[9] i.e., $p(\mathbb{H} \mid \mathcal{HIGH})$.

[10] i.e., $p(\mathbb{L} \mid \mathcal{LOW})$.

[11] Note also that it is not necessary to explicitly specify all of the accuracy and error rates, because of the following identities:

$$\mathcal{TP} = 1 - \mathcal{FN} \quad (1)$$
$$\mathcal{TN} = 1 - \mathcal{FP} \quad (2)$$
$$\mathcal{FP} = 1 - \mathcal{TN} \quad (3)$$
$$\mathcal{FN} = 1 - \mathcal{TP} \quad (4)$$

Example 3. How many infected reporters get into a press briefing? Imagine that a policymaker were worried about infected reporters spreading the novel coronavirus at a press conference, but she also worried about restricting reporters' access to the press conference.

The policymaker might consider screening each reporter as they enter the briefing room. In this case, we would be concerned about infected individuals entering the briefing room and possibly infecting others.

Using either Equation (B.1) or Equation (C.8), we can calculate the expected number of infected reporters who will enter the briefing room after being screened.

Assume for purposes of this example that

- the test is 97% effective at detecting COVID-19 when an individual is infected;
- the test is 90% effective at detecting the absence of an infection when an individual is not infected; and
- the prevalence of active infections is 20% at the time of the briefing.

If the press corps for the briefing includes 300 reporters then we have:

$$\begin{aligned} n_T &= 300 && \textit{(the number screened)} \\ \mathcal{TP} &= 0.97 && \textit{(true positive rate)} \\ \mathcal{TN} &= 0.90 && \textit{(true negative rate)} \\ \mathcal{FP} &= 0.10 && \textit{(false positive rate)} \\ \mathcal{FN} &= 0.03 && \textit{(false negative rate)} \\ p(\texttt{COVID-19}) &= 0.20 && \textit{(prevalence of COVID-19)} \end{aligned}$$

With this information, we can calculate the expected outcomes of the testing using only counting and basic arithmetic:

$$\begin{array}{rlrll} \boldsymbol{n_{\mathbb{C}}} = \mathbf{60} & \textit{(\# with COVID-19)} & \equiv & p(\texttt{COVID-19}) \times n_T & = 0.2 \times 300 \\ \boldsymbol{n_{\mathbb{W}}} = \mathbf{240} & \textit{(\# who are well)} & = & n_T - n_{\mathbb{C}} & = 300 - 60 \\ \boldsymbol{n_{\mathcal{N}}} = \mathbf{218} & \textit{(\# negative results)} & = & \mathcal{FN}(n_{\mathbb{C}}) + \mathcal{TN}(n_{\mathbb{W}}) & = 0.03(60) + 0.9(240) \\ \boldsymbol{n_{\mathcal{P}}} = \mathbf{82} & \textit{(\# positive results)} & = & n_T - n_{\mathcal{N}} & = 300 - 218 \\ & & & & \\ \boldsymbol{n_{\mathbb{W}\mathcal{N}}} = \mathbf{216} & \textit{(\# true negatives)} & = & \mathcal{TN} \times n_{\mathcal{N}} & = 0.90 \times 240 \\ \boldsymbol{n_{\mathbb{C}\mathcal{P}}} \approx \mathbf{58} & \textit{(\# true positives)} & \approx & \mathcal{TP} \times n_{\mathbb{C}} & = 0.97 \times 60 \\ \boldsymbol{n_{\mathbb{C}\mathcal{N}}} \approx \mathbf{2} & \textit{(\# false negatives)} & \approx & n_{\mathbb{C}} - n_{\mathbb{C}\mathcal{P}} & \approx 60 - 58 \\ \boldsymbol{n_{\mathbb{W}\mathcal{P}}} \approx \mathbf{24} & \textit{(\# false positives)} & \approx & n_{\mathcal{N}} - n_{\mathbb{C}\mathcal{P}} & \approx 240 - 216. \end{array}$$

Thus, a total of 240 reporters would test negative and be admitted to the press briefing ($n_{\mathcal{N}}$). Within this group, about 2 reporters would be infected with novel coronavirus and presumably contagious (false negatives, ($n_{\mathbb{C}\mathcal{P}}$). In addition, 24 reporters, who should have been permitted to participate, would be excluded (false positives, $n_{\mathbb{W}\mathcal{P}}$).

To rely on this test, given the conditions at the time, the administration would need to be comfortable trading off the "cost" both of allowing 2 infected reporters to circulate among the press corps and leadership, while also excluding 24 reporters who should have been allowed to participate, in exchange for the benefit of preventing another 58 infected reporters from participating.[12] ♢

Application Template - Estimating the number of infected people erroneously cleared using a specific test for screening

All calculations may be done on a hand calculator or simple spreadsheet. Example 3 can be used as a template.

Input: Test accuracy
prevalence of COVID-19

Result: Expected number of infected individuals missed
Expected number of uninfected denied

2.1 Model error, data error, and risky risk-stratification policy

Up until this point, we have assumed that the population prevalence was known. However, it could be the case that prevalence rate is different from the estimate that the administration used for screening. This would be the case if, for example, the incidence rate were estimated using only patients that presented at hospitals and requested a test, but who were only tested if they were symptomatic.

In the case of COVID-19, it has been suggested that asymptomatic patients may also be contagious. However, due to shortages in testing, these asymptomatic patients would not have been unlikely to present at hospitals for testing, and their cases would not be counted in calculating the prevalence, so the population estimate of the prevalence of COVID-19 would be understated.[13]

[12] It could be the case, however, that clinicians are more concerned about COVID-19 cases that will become severe and require hospitalization than about COVID-19 cases that are likely to be mild. In this case, we may apply Equation (B.2 to combine the probability of contracting COVID-19 with the probability of requiring hospitalization given contracting COVID-19, and proceed as before, but now including the error rates for the model (or other stratification approach) used to stratify the risk that a COVID-19 patient will require hospitalization.

[13] This would also affect probability estimates from statistical models, such as those developed by applying machine learning algorithms to data collected on *recorded* COVID0-19 cases or on patients hospitalized for COVID-19. The next example demonstrates this.

2.2 What does a positive test result really mean?

To motivate this next section, imagine that there is a condition that has an incidence rate of zero among some subset of the population. For our purposes, we consider prostate cancer as the condition, and female individuals as the subset.[14]

Imagine further that there is a diagnostic blood test for this condition that is very, very accurate at detecting the disease, i.e., has a very low false positive rate (e.g., a Type II error rate of 0.01% or less than one false positive per 10,000 tests. Thus, the probability a subject with prostate cancer of receiving a positive result is 1-0.01% = 99.99%).

If the test were given to a female individual, even considering the very low Type II error, there is still a small chance that this particular test will return a result that is positive positive.

In this case, even the subject received a positive result, and even though the tests is 99.99% "accurate," we would still know that the probability that the subject in fact had prostate cancer, would be zero. In fact, regardless of how many female individuals tested positive, we would *always* know that their probability of having prostate cancer is zero because the overall population prevalence among the female population for that condition is zero. Female individuals do not have prostates.

If instead there were another condition that were slightly more common among the female population (e.g. the condition was very rare, but still occurred occasionally, say 1 case per 1000 individuals), a positive test result for a female individual would still be surprising, and although we would no longer think that the probability of the individual having this condition were zero, we might suspect that it was still very low.

Finally, if the incidence rate across all sexes were equally likely, and a very accurate test returned a positive result, we might become more concerned.

Note that in each of the preceding cases, the error rate of the test remained the same. However, our intuition about what a positive result implied changed based on our sense of the probability of an individual *ever* having the disease. The less likely this were, the less likely we were to accept a negative result as truth.

On the other hand, imagine that we were considering a test result for a very common disease, but that the test itself had a very high Type II error ($\mathcal{FP}$ is large) and frequently produced many alarms. In this case, again, we might be cautious in interpreting a positive test result, given the high levels of test error.

[14] Some of the particulars of hypothetical narrative, not necessarily accord with the pathology of prostate cancer. We ignore this for exposition.

The observation that the probability of an individual acquiring a disease impacts the interpretation of test results error rates explains why it is so challenging for clinicians to *develop policies* for public health without adequate prevalence data, on the one hand, or to *implement policies* without accurate tests, on the other.

2.3 Adjusting test results as better data comes in

The actual probability, given a positive test result, that a patient has contracted a disease like COVID-19 is a simple form of risk stratification.

We argued informally in the last section that even with a positive test result, the reliability of the stratification is still a function both the error of the test (the and the prevalence (or incidence rate, depending on context) of COVID-19.

However, it is generally understood that, for a variety of reasons (including shortages in test kits and selection bias in testing), data on the true prevalence of COVID-19 is of poor quality and incomplete, likely understating the true prevalence of the virus among the population.[15] In cases where the data used to estimate the prevalence of a disease is of poor quality, this uncertainty may critically affect the effectiveness of risk stratification.

We can make our earlier intuition more formal (see, Appendix C). Doing so results in a simple adjustment that we can make to a test result, as new data comes in about infection rates, etc.

The probability transformation converts a "bad" estimate of the probability of having COVID-19 given a positive test result (such as an estimate that was made using a "bad" estimate of the COVID-19 prevalence) into a more accurate real-world estimate of having COVID-19. This allows clinicians to begin risk stratification using the best estimate available of the real-world prevalence, but to continually update their policy guidelines in a consistent fashion as new information comes in.[16]

[15] A recent study reported by Andrew Cuomo, the Governor of New York, supports this understanding. The study randomly tested 3,000 New Yorkers across the state, and found that 13.9% of them had signs of the virus, which is about ten times higher than prior estimates, which were based primarily on patients presenting with symptoms (LaVito et al., 2020).

[16] While this specific adjustment works in some settings, it is not appropriate in many others. See important caveats discussed in Appendix C.

Example 4. How many infected reporters really get into the press briefing?

Using Equation (C.2) (or Equation Equation (C.8)), we return to Example 3, which involved using a test with known accuracy to screen reporters for COVID-19 prior to allowing them to enter an official press briefing.

Recall that the hypothetical the press corps for the briefing includes 300 reporters and the test accuracy is:

$$\begin{aligned} n_T &= 300 \\ \mathcal{TP} &= 0.97 \\ \mathcal{TN} &= 0.90 \\ \mathcal{FP} &= 0.10 \\ \mathcal{FN} &= 0.03. \end{aligned}$$

If the true prevalence were →	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**
	(A)	(B)	(C)	(D)	(E)	(F)	(G)
Individuals allowed in/barred							
Total admitted	217.8	191.7	165.6	139.5	113.4	87.3	61.2
Total barred	82.2	108.3	134.4	160.5	186.6	212.7	238.8
Wrongly barred	24.0	21.0	18.0	15.0	12.0	9.0	6.0
Contagious people allowed in	***1.8***	***2.7***	***3.6***	***4.5***	***5.4***	***6.3***	***7.2***
True risk after screening							
Chance of COVID-19 if admitted	**0.8%**	**1.4%**	**2.2%**	**3.2%**	**4.8%**	**7.2%**	**11.8%**
Chance of no COVID-19 if barred	11.0%	11.0%	10.9%	10.8%	10.6%	10.3%	9.8%

Table 1: The impact of test error varies greatly with the assumptions/data on the true prevalence

This table compares various measures of risk in Example 4, given different COVID-19 prevalence. For this example, we assume that 300 reporters are seeking entry into an official press briefing. In order to enter the press room, a reporter must be screened using a test with the following performance: of $\mathcal{TP} = 0.97, \mathcal{TN} = 0.9$. However, we assume that the observed prevalence is unknown, due to a lack of testing kits.

This time, however, we assume that the policymaker believes that the data that has been collected on the prevalence of COVID-19 is currently unreliable, due to under-sampling. She she wishes to understand how her policies would will be impacted if the prevalence is higher than the current assumptions.

As before, the administration screens each reporter and, based on the test result, admits or denies access to the reporter based on the outcome of the testing. However, now we examine the realized outcomes, given different levels of the unknown prevalence rate (which actually still remains uncertain as of the date of this writing).

The results of this sensitivity analysis are shown in Table 1.

From the table, it is clear that the increase in prevalence leads to an increase in the number of individuals erroneously admitted to the press conference. For example, recall from Example 3 that screening with the diagnostic test would result in about two infected reporters being admitted into the press room if the real prevalence were 20%. This is roughly equivalent to one infected reporter out of every 121.

In contrast, that would rise to about 7 infected reporters erroneously admitted if the prevalence were 80% (column (G)). Because fewer non-infected reporters are admitted when the prevalence is higher, this would be roughly equivalent to one infected reporter every 9 seats. Furthermore, the realized error rate increases at an increasing rate in the prevalence.

Similar behavior occurs for non-infected population, but inversely. When the prevalence is 20%, 24 out of the 82 reporters denied access should not have been, or about 1 out of every 3.5 or so barred reporters (column (A)). This compares to only about 6 out of about 239, or only about 1 out of every 40 reporters barred wrongly (column (G)) when prevalence is 80%.

Figure 2 shows these relationships graphically. ♢

In evaluating Table 1 and Figure 2 from Example 4, we observed that given a fixed test error rate, the number of infected individuals admitted is proportional to the real prevalence in the population, while the number of individuals wrongly barred is inversely proportional.

There are two ways that we can think about the results in Example 4. On the one hand, Table 1 emphasizes how important accurate data on prevalence is for making sound decisions. In the example, using the same test, say the real prevalence were 50% rather than the 20% we assumed in the first example. In that case, rather than

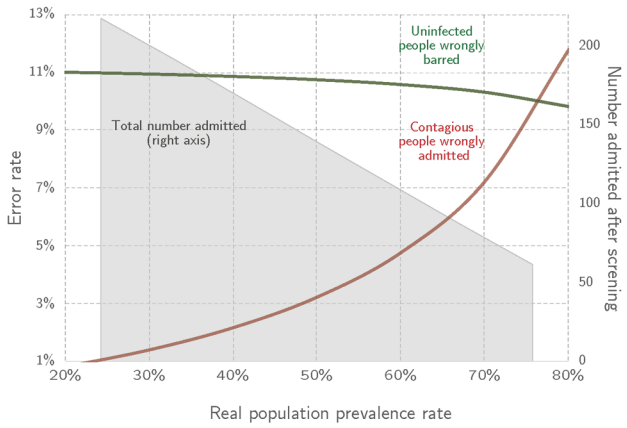


Figure 2: The impact of test error varies greatly with the assumptions/data on the true prevalence

This figure shows the impact of differing prevalences (x-axis) on the percentage of infected individuals allowed to enter and the percentage of uninfected individuals wrongly prevented from entering (y-axis), using a test with fixed error rate. For this example, we assume that 300 reporters are seeking entry into a press briefing. In order to enter the press room, a reporter must be screened using a test performance of $\mathcal{TP} = 0.97, \mathcal{TN} = 0.9$. However, we assume that the observed prevalence is unknown, due to a lack of testing kits. (See: Table 1).

erroneously admitting one infected individual for every 121 or so reporters, the policy would allow one infected individual in for every 30.

Another way to think about these results is to use these insights, and the recognition that information on prevalence will be updated from time to time as data collection and testing become more common. In this case, test results for individuals, or test thresholds for communities or sub-populations, could be updated dynamically to reflect the most current information available.

Application Template - Updating individual/group risk or updating policy thresholds based on new or localized data

All calculations may be done on a hand calculator or simple spreadsheet. Example 4 can be used as a template.

Example applications:

- Updating individuals' test results as new prevalence (or incidence) information becomes available in real-time.
- Use their policymaker's specific knowledge or assumptions about local prevalence to interpret general test results for policy purposes.
- Adjust risk cutoffs dynamically for communities or sub-populations as new data arrives.

Input: Test result (described as a probability)
Initial estimate of COVID-19 prevalence
(or incidence rate, depending on application)
Updated (or local) COVID-19 prevalence or incidence rate

Result: Updated estimate of probability of having the condition

3 Setting policy cutoffs to minimize total harm

> Although clinicians can update their assumptions about or information on prevalence or incidence rates, they have little control over the actual levels. This is also true of the accuracy of a given test.
>
> *However, clinicians do have control over how tests are applied and test results are interpreted for policy purposes.*

For example, a very basic risk stratification approach might be to simply use a person's age as an indicator of risk. Age is continuous, and there is no natural point at which crossing over a given age threshold makes someone suddenly much older (or riskier) than they were the day before.[17]

In such settings, the policymaker may choose a *cutoff score*, above which a test subject would be considered to be "high risk" and below which she would be considered "low risk."

For a test with given performance, it is this cutoff that determines the false negative and false positive error rates, $\mathcal{FN}$ and $\mathcal{FP}$.

As another example, consider that if *all* scores were deemed by the policymaker to be "high risk" (the "EVERYONE-IS-HIGH-RISK" policy) there could be no false negatives ($\mathcal{FN} = 0$), since there would be *no* negatives. Similarly if all scores were considered by the policymaker to be "low risk" (the EVERYONE-IS-LOW-RISK policy), there could be no false positives ($\mathcal{FP} = 0$), since there would be no positives, and everyone would pass the screening.

Were a policymaker to believe that even a single false negative (an infected individual admitted into the public) were untenable, he would be forced to adopt the EVERYONE-IS-HIGH-RISK policy. Similarly, were the policymaker to believe that even a single unfairly barred individual would be unacceptable, he be forced to choose the EVERYONE-IS-LOW-RISK policy.

In general, there are costs to mistakes, both false positives and false negatives.

- Most clinicians would reject the EVERYONE-IS-HIGH-RISK policy, due to the unacceptably high cost to the health and economics of uninfected people forced to stay home.
- Most clinicians would similarly reject the EVERYONE-IS-LOW-RISK policy because the cost to public health of widespread COVID-19 infections would be too

[17] The current discussion of age buckets such as "65 and over" is more reflective of the manner in which data is collected and reported, than of some natural measure of overall health or susceptibility.

high, both in terms of lives lost (especially given finite health system capacity) and in terms of the social and economic disruption that would result.

This means that most policies will not be all-or-nothing strategies, and will necessarily involve a trade-off between

(a) **the benefits** of allowing some lower risk individuals to return to the workforce and general public, while preventing some higher risk ones from doing so, and

(b) **the costs** of erroneously allowing some infected individuals to enter the workforce and general public, while also erroneously preventing some uninfected members from entering.

We generalize this notion in what we call:

The Law of Risk-Based Decision Making

Any policy based on less than perfect risk stratification, will involve trading off competing objectives involving harm in one form or another.

Although this "law" seems obvious, a surprising number of policies avoid any discussion of these trade-offs explicitly. In the particular case of COVID-19, the Law of Risk-Based Decision Making implies:

Until an effective COVID-19 vaccine is available widely, any policy for returning workers to the workforce that is based on risk stratification must involve trading off the cost of infecting more individuals, some of whom will die, against the costs of lost economic activity, food insecurity, and health insecurity, and unemployment.

This does not imply that policy cannot proceed unless models are perfect. Rather, it implies that clinicians can explicitly develop policies that cause the least harm by determining how best to stratify risk, and how to subsequently select cutoffs for risk tiers. Given the imperfect nature of the information and tests that form the basis of policy decisions, if a PM does not choose a policy that minimizes harm, conversely, any alternative policy is causing unnecessary harm.

3.1 Setting a policy cutoff

In its most fundamental form, harm "minimization" involves setting cutoffs for defining the risk tiers that achieve the best possible trade-offs, given the current error rates of

diagnostic tools and models and data available, and the expected costs and benefits of errors and good risk stratifications, respectively.

We will assume that there is a set of benefits and costs that a policymaker can calculate, at least approximately. The costs represent the real-world harm that errors in assessing an individual's risk incorrectly, while the benefits represent the positive outcomes associated with correct assessments.

Imagine that a policy there is a test that produces a score for each individual ranging from s_1 ("lowest risk") through s_K ("highest risk"). This score could be the propensity score of a machine learning algorithm or the concentration level of SARS-CoV-2 RNA (cp/μL) detected using an assay or a medical authority's assessment of at what age morbidity increases significantly for those exposed to the novel coronavirus, etc.

The abstract goal of the policymaker is to determine which score cutoff to use for stratifying the risk of the individuals into "high risk" (scores worse than the cutoff) and "low risk" (scores equal to or better than than the cutoff). Because the test is not perfect, any cutoff selected other than will result in some errors. If a policymaker chooses the k^{th} score as the cutoff, then the corresponding performance measures would be $\mathcal{TN}_k, \mathcal{TP}_k, \mathcal{FN}_k$ and $\mathcal{FP}_k$.

If the policymaker has an estimate of the prevalence, then, given this information (performance at the cutoff, costs, benefits and prevalence), we can calculate the total value, V_k, of a policy that uses this test and sets the cutoff at score s_k. (see: Appendix A).

It turns out that V_k is simply the weighted net value of two trade-offs: a correct vs. an incorrect classification of a test result as low risk; and the weighted value of a correct vs. incorrect classification of an individual as high risk. The weighting is done based on the prevalence and the probability of being correct or incorrect, which depends on the model accuracy ($\mathcal{TP}_k$, etc.).

The goal of the policymaker can now be seen more concretely as to maximize the value of the policy, which will minimize unnecessary harm. This is done by selecting a cutoff that results in the largest value of V_k.

In practice, there are a number of approaches for maximizing V_k.[18]

For many real world problems involving risk stratification objectives that may have a variety of attributes, it is sometimes convenient to simply calculate $\mathcal{TP}_k, \mathcal{FP}_k$, etc. for a range of k values, and to then use the cutoff that results in the maximum value of V_k.[19]

[18] See, Stein (2005) for details.

[19] The Risk Stratification Workbench app does this type of calculation automatically. See Appendix E

The following example shows an application of this approach.

Example 5. Which screening threshold to use for entry to the press briefing?

Imagine now that a new COVID-19 test is developed and has the performance shown in Table 2, and that the administration now wishes to use this new test to determine which reporters are permitted to enter a press briefing.

Risk level	s_k	$\mathcal{TP}$	$\mathcal{FP}$
Lowest Risk	R1	99%	62%
·	R2	99%	49%
·	R3	98%	20%
·	R4	96%	14%
·	R5	91%	10%
·	R6	85%	8%
Highest Risk	R7	65%	4%

Table 2: Performance of hypothetical COVID-19 diagnostic tool

This table shows the hypothetical performance of a new test (e.g, an assay, a data-driven predictive model, etc.) for screening individuals in order to stratify them into risk tiers, based on the likelihood that they are infected. $\mathcal{TP}, \mathcal{FP}$ are true positive (correct high risk) and false positive (low risk that is erroneously stratified as high risk) rates, respectively. s_k is the candidate cutoff.

The test results take the form of one of seven risk scores R1 through R7 with R1 being the lowest risk and R7 being the highest risk. The last two columns of the table show the accuracy of the test at identifying infected and non-infected individuals, $\mathcal{TP}$ and $\mathcal{FP}$, respectively, if the individuals were split into two risk tiers using that risk score.

This information can also be presented in the form of an **ROC curve**, as shown in Figure 3. An ROC (receiver operator characteristic) curve is an analytic tool for evaluating diagnostic and decision tools (e.g., Green and Sweats, 1966; Provost and Fawcett, 2001). An ROC curve plots a diagnostic tool's Type II error (false positive rate) on the x-axis error against one minus the Type I error (1-$\mathcal{FN}$= $\mathcal{TP}$, the true positive rate). In the case of novel coronavirus detection, an ROC curve describes the percentage of non-infected individuals tested that will be inadvertently stratified as high risk, given each possible cutoff k, in order to correctly screen out a specific percentage of infected individuals when using a specific test.

In general, the better a test is at differentiating between infected and virus-free individuals, the farther up and to the left the curve will be placed. If one test's ROC is above that of another test's at every point, then there are no situations in which using the diagnostic with the lower ROC will result in better decisions than using the diagnostic with the higher one ROC. The 45° line represents the ROC curve for a random decision tool. since the tool is effectively not providing any information (to eliminate y% of the COVID-19 cases, one must also eliminate y of the non-COVID-19

cases; i.e., using the random test, the only way to block y of the infected individuals is to just eliminate y of *all* individuals.

We have annotated Figure 3, to identify where on the ROC curve for the new COVID-19 test, each of the risk scores falls. For example, we can see from the figure that setting a cutoff at risk score R7 would screen out 65% of the infected individuals tested, but at the cost of erroneously mis-classifying 4% of the virus-free individuals, and calling them high risk.

In order to choose a cutoff for admitting or barring individuals, the policymaker must determine how best to trade off the effects of the errors. For example, if the policymaker believed that it was much, much worse to have an infected individual enter the press conference than to wrongly deny a virus-free reporter access, she might choose to use risk class R1 as a cutoff, since doing so would ensure that almost all infected individuals would be screened out, albeit at the cost of unfairly denying more than 60% of all reporters access.

In order to determine the "best" cutoff the policymaker explicitly assigns costs and benefits to the errors and correct stratifications, respectively:

$$
\begin{aligned}
c_{\mathcal{FN}} &= 20 \equiv \text{cost of false negative (infected allowed in)} \\
b_{\mathcal{TP}} &= 0 \equiv \text{benefit of true positive (correctly stopped infected)} \\
c_{\mathcal{FP}} &= 4 \equiv \text{cost of false positive (non-infected is kept out)} \\
b_{\mathcal{TN}} &= 3 \equiv \text{benefit of true negative (non-infected allowed in)} \\
p_{\mathbb{C}} &= 20\% \equiv \text{probability of COVID-19 (prevalence)\%}
\end{aligned}
$$

Using this set of assumptions, the policymaker can now apply Equation (A.1) to the compute the value of of a policy that would use that each. Table 3 shows the results of this analysis. In the table, V_k represents the value of a policy that allows all individuals with risk scores equal to or better (lower risk) than the corresponding score to return to work, while barring all of those with worse scores than the corresponding score.

	Score (s_κ)	V_k	**Decision**
Lowest Risk	**R1**	-1.11	OK
·	**R2**	-0.40	OK
·	**R3**	1.20	OK
·	**R4**	1.46	OK
·	**R5**	**1.48**	OK
·	**R6**	1.35	NOT CLEARED
Highest Risk	**R7**	0.78	NOT CLEARED

Table 3: Risk stratification by a hypothetical test and associated "values" (Equation (A.1))

Based on this analysis, the policymaker would choose to use risk score **R5** as a cutoff since this score maximizes the benefit with the lowest costs.

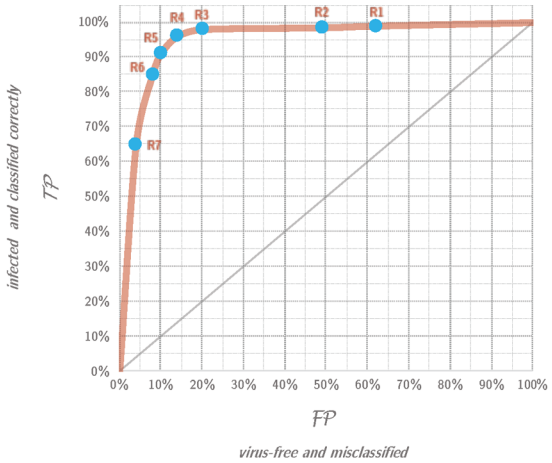


Figure 3: ROC curve for test performance in Table 2

This figure an provides an example of an ROC plot. The x-axis is the Type II error ($\mathcal{FP}$) as a percentage of all non-infected individuals. The higher the error rate, the larger percentage of non-infected individuals is excluded unintentionally. The y-axis shows the $\mathcal{TP}$: the percentage of infected individuals that is correctly screened out at a given cutoff. The points on the ROC are labeled to correspond to the error rates associated with each risk stratification level from the least risky (the smallest percentage of infected individuals missed) at R1 to the most risky, R7, which screens out the smallest percentage of infected individuals out (See: Table 2).

Said differently, using this test, there is no other risk score that would have as high a benefit (allowing reporters into the press conference) at a lower risk or, conversely, that would minimize the risk more for the same number of reporters admitted. ♢

Application Template - Determining a risk stratification policy (Basic)

All calculations may be done on a hand calculator or simple spreadsheet. Example 5 can be used as a template.

The basic strategy assumes a single cutoff for the entire population that is chosen to minimize total harm to the community (maximize the value of the policy), given the community priorities, needs, costs and objectives.

Input: Test accuracy
prevalence of COVID-19
Cost of $\mathcal{TN}$ and $\mathcal{FP}$ based on community objectives, economy and needs
Benefit of $\mathcal{TP}$ based on community objectives, economy and needs

Result: Risk stratification threshold (cutoff) that optimizes community objectives

3.2 Costs, benefits, and the Law of Risk-Based Decision Making

In setting up Example 5, we implicitly assumed that a policymaker would be comfortable making trade-offs among competing outcomes and the errors that accompany them. Is this reasonable?

The short answer in many cases is "No." Most people are, in fact, extremely *uncomfortable* considering trade-offs such as *"How many long machinists will I bring back to work if the expected harm is that an additional 55 year old individual will need to be admitted to ICU for a month?"*

However, whether a policymaker is comfortable with such a trade-off or not, The Law of Risk-Based Decision Making ensure that any policy that relies on risk stratification and screening using a test (assay, algorithm, age-based heuristic, etc.) that has error rates greater than zero, *is* making trade-offs, regardless of whether the PM evaluates these trade-offs explicitly or not.

Importantly, in addition to depending on the accuracy of the diagnostic, the risk stratification cutoff will also depend on the prevalence in the target population, and the various costs and benefits assigned to different errors and correct predictions. Table 4 demonstrates this by calculating the best cutoff using the same model as described in Examples 3 - 5, but then varying the assumptions about prevalence and costs.

In this Table 4, we allow the policymaker to make different assumptions about the prevalence of COVID-19, and the costs and benefits of different errors and accurate predictions. As can be seen from the "Risk cutoff" row, the range of selected cutoffs

	Base Case	Prevalence ▼	Prevalence ▲	Prevalence ▲▲	Cost of $\mathcal{FP}$ ▼	Cost of $\mathcal{FP}$ ▲	Benefit of $\mathcal{TN}$ ▼	Benefit of $\mathcal{TN}$ ▲	Cost of $\mathcal{FN}$ ▼	Cost of $\mathcal{FN}$ ▲
Best risk cutoff	***R5***	↕ ***R6***	↕ ***R4***	↕ ***R3***	↕ ***R4***	↕ ***R6***	↕ ***R4***	↕ ***R6***	↕ ***R7***	↕ ***R4***
	← ..... V_k ..... →									
R1	-1.11	-1.23	-0.88	-0.4	0.4	-9.05	-1.72	4.1	-1.08	-1.2
R2	-0.40	-0.42	-0.38	-0.3	0.8	-6.68	-1.22	6.5	-0.36	-0.5
R3	1.20	1.40	0.80	**0.0**	1.7	-1.36	-0.08	12.1	1.26	1.0
R4	1.46	1.74	**0.89**	-0.2	**1.8**	-0.34	**0.08**	13.2	1.58	**1.1**
$\mathcal{S}_\kappa$ **R5**	**1.48**	1.89	0.66	-1.0	1.7	0.26	13.7	13.7	1.75	0.8
R6	1.35	**1.90**	0.26	-1.9	1.5	**0.33**	-0.12	**13.9**	1.80	0.2
R7	0.78	1.75	-1.17	-5.1	0.9	0.26	-0.76	12.0	**1.83**	-2.0
	← ..... *Cost and Benefit assumptions* ..... →									
$c_{\mathcal{FN}}$	20	20	20	20	20	20	20	20	**5**	**60**
$b_{\mathcal{TP}}$	0	0	0	0	0	0	0	0	0	0
$c_{\mathcal{FP}}$	4	4	4	4	**1**	**20**	4	4	4	4
$b_{\mathcal{TN}}$	3	3	3	3	3	3	**1**	**20**	3	3
$p_{\mathbf{C}}$	20%	**5%**	**40%**	**80%**	20%	20%	20%	20%	20%	20%

Table 4: Risk stratification cutoffs depend on prevalence, costs and benefits

This table shows the differences in lowest permissible risk score policy, given changes in prevalence, costs and benefits. *Best risk cutoff* is the cutoff that minimizes harm. Below that score, individuals will be considered "high risk" so the cutoff represents the worst acceptable risk score for an individual to still be considered low risk, given the costs and benefits (i.e., risk scores from that risk score up to **R1** would be labeled "low risk.")

KEY:

▲, ▼ : a negative upward or downward change in the parameter

▲, ▼ : a positive upwards or downwards change

↕, ↕ : standards to became looser or tighter relative to the baseline.

ranges from a fairly conservative R4, to the most aggressive R7 depending on the assumptions made by the policymaker.

This variability may be seen as both a bug *and* a feature for clinicians.

On the one hand, Table 4 highlights the importance of having good information on which to base policy. For example, if the *true* prevalence rate is higher than a policymaker believes, but she has no data on this, she will make policy decisions based on the "bad" prevalence rate, but the policy will be executed in the world of the true prevalence rate. In many cases, that difference will make a material differences in risk cutoffs which in turn will affect which and how many workers are scheduled to return to work at different points in time.

On the other hand, the Table also highlights the great flexibility that clinicians can use in designing different risk stratification cutoffs for different demographics and job types, since different cutoffs may be determined for each segment using different costs and benefits in each case. We discuss this point in more detail in Section 3.4.

We have developed enough of the machinery on risk stratification to design a basic risk stratification system and to decide which risk tiers are cleared to return and which are not.

The basic algorithm is as follows:

Selecting a Risk Stratification Policy

1. Identify a test that can be practically administered in the target setting (e.g., that has costs and throughput speed that meet the needs of the application).
2. Determine $\mathcal{TP}_\kappa$, etc., for each of the possible results of the test, making use of the identities in Eqs. (1) - (4) as needed.[a]
3. Determine the appropriate cost and benefit functions for the community.[b]
4. Using the performance information from (2) and the cost and benefit information from (3), calculate V_κ for each candidate stratification level, κ.
5. Use the cutoff risk level, κ_{best}, that has the highest value of V_κ, for the test, given the prevalence information and costs and benefits.

[a] Most FDA approved tests, for example, publish this information, while most good quality quantitative models also disclose similar information.

[b] This is typically non-trivial and will form the core of a clinicians expertise. We discuss this in more detail in Section 4.

3.3 Are more expensive tests worth the expense?

In addition to getting better information, and making more rational policies based on that information, a policymaker may also, in some cases, have access to better quality tests. However, given the large number of tests that a community may be required to administer, it is reasonable for clinicians to analyze the value of more expensive vs. less expensive tests.

Using the machinery of the previous section, a PM can evaluate this value explicitly. This is done by calculating the best cutoff to use for each model, and then comparing the values of V_k.

If the difference in the value of using the more expensive tests exceeds the additional costs of those tests, a policymaker may be more likely to opt for the more expensive tests.

Example 6. Deciding whether to purchase more expensive tests

Assume that a policymaker has access to two different COVID-19 tests with the performance shown in Table 5. The policymaker needs to decide whether to mandate use of the less expensive, less accurate test, or the more expensive, more accurate test.

		Lower cost test		**Higher cost test**	
Risk level	s_κ	$\mathcal{TP}$	$\mathcal{FP}$	$\mathcal{TP}$	$\mathcal{FP}$
Lowest Risk	R1	99%	62%	99%	60%
·	R2	99%	49%	99%	50%
·	R3	98%	20%	98%	19%
·	R4	96%	14%	97%	10%
·	R5	91%	10%	92%	9%
·	R6	85%	8%	87%	6%
Highest Risk	R7	65%	4%	70%	4%

Table 5: Performance of two different hypothetical COVID-19 diagnostic tools

This table shows the hypothetical performance of two tests for screening and risk stratifying individuals, based on the likelihood that they are infected with COVID-19. For each test, $\mathcal{TP}$ and $\mathcal{FP}$ are the true positive rates (correct high risk detection) and false positive rates (low risk erroneously stratified as high risk), respectively. s_κ is the candidate cutoff.

We assume that the costs, benefits, and prevalence are:

$$
\begin{aligned}
c_{\mathcal{FN}} &= 20 \equiv \text{cost of false negative (infected allowed in)} \\
b_{\mathcal{TP}} &= 0 \equiv \text{benefit of true positive (correctly stopped infected)} \\
c_{\mathcal{FP}} &= 4 \equiv \text{cost of false positive (non-infected is kept out)} \\
b_{\mathcal{TN}} &= 3 \equiv \text{benefit of true negative (non-infected allowed in)} \\
p_{\mathbb{C}} &= 20\% \equiv \text{probability of COVID-19 (prevalence)\%}
\end{aligned}
$$

All else equal, we can see by examining Table 5 that there is no cutoff that can be chosen for which the less expensive test will perform better than the more expensive one, since, at each cutoff, the $\mathcal{TP}$ rate is higher and the $\mathcal{FP}$ rate lower for the more expensive test.

However to determine the whether the value of this difference is worth the expense, the policymaker calculates the best cutoff for each test and compares these:

Less expensive test:	$V_k = 1.48$	at cutoff **R5**
Less expensive test:	$V_k = 1.72$	at cutoff **R4**

As expected, the more expensive test is more valuable ($1.48 > 1.72$). However, the determination of whether or not the difference in value of 0.24 is substantial enough to justify the added cost will depend on the policymaker's assessment of the difference in value and the difference in cost. (Note that here we deliberately avoid using specific units to denominate the value, as each policymaker may use different calculations in determining value. See Section 4.) $\diamondsuit$

Application Template - Deciding whether to invest in better tests and data

All calculations may be done on a hand calculator or simple spreadsheet. Example 6 can be used as a template.

To determine whether a proposed investment in additional resources is cost effective, clinicians can use the templates developed so far, along with information on the expected performance of each model to calculate value that would be realized if the new investment were made.

In principle, this may be done using any scale for costs and benefits, however, it is most easily done if the scale of the expense of the new test, and the scale of the benefits and costs, are the same.

Input: Accuracy of current risk stratification approach
Accuracy of current risk stratification approach if investment made
prevalence of COVID-19
Cost under current approach of $\mathcal{FN}$ and $\mathcal{FP}$
Cost under proposed new approach of $\mathcal{FN}$ and $\mathcal{FP}$ (if different)
Benefit under current approach of $\mathcal{TN}$ and $\mathcal{TP}$
Benefit under proposed new approach of $\mathcal{TN}$ and $\mathcal{TP}$ (if different)

Result: "Optimal" risk stratification thresholds (cutoffs) for each approach
Relative (or absolute) value of new and current approaches

3.4 Flexible risk stratification policies for different needs across communities

Recently there has been heightened interest in formulating strategies and policies that would permit some "low risk" workers to return to work sooner than other "high risk" workers. For example, (Stein et al., 2020) proposes a *Total Harm Minimization* framework that prioritizes the timing of returning workers by both economic and health-risk factors, as well as by the degree to which a worker may productively work remotely, and thus continue to self-isolate if needed, during the first phases of the process.

Such strategies explicitly recognize that the risks faced by different segments of the population vary considerably. For example, while two individuals may have similar age and health profiles, if one of them has already been exposed to the novel coronavirus and the other has not, the exposed individual may be at lower risk than the one who has not been exposed.

Table 4 provided a preview of how clinicians can tailor risk stratification cutoffs to different situations. In the next example, we allow a policymaker to assume that for certain functions returning to work urgent than it is for others, and that keeping certain

employees away from their place of employment may be more or less costly than it is for others.

Example 7. Fact-based, flexible risk stratification for returning to the workforce

In this example, we consider a policymaker who is working towards bringing as many workers back into the workforce as possible, without undertaking unreasonable risk to the public.

The policymaker has consulted his economic advisors, and together the team has determined which industries are more critical to the region than others and which workers may work from home for a longer period with less loss to the economy and low health risks.

Furthermore, new serology tests now permit the identification of individuals who are expected to have acquired immunity because they have either been confirmed to have had COVID-19 and have recovered, or because they tested positive for protective antibodies. (We assume here that the scientific community has guided the policymaker in this regard.)

The group also has access to a fairly accurate test that can be used assign initial risk grades to individual workers. The performance of the test is known. as well as the effective accuracy and error rates for that procedure. (For convenience in this example, we assume that this test has the same accuracy, etc. as the one we have been using in the last example.

What remains is for the policy group to draft the costs and benefits associated with different policies. However, rather than draft a one-size-fits-all cost function, the group takes advantage of the work it has done with economic advisors and medical professionals and creates a set of cost functions that can be used with different segments of the workforce, depending on their characteristics. Table 6 shows the result.

The table shows how different segments of the population could be triaged for returning to work. As the risks and costs go down, or the benefits go up for a worker's return, the worker is given a more lenient threshold for returning to the workforce.

For example, the cost of keeping a worker who can work from home is much lower than the cost of keeping a worker at home who cannot work from home. In this case, the first worker who can work remotely would be permitted to return to work only with a relatively good test score of (low risk tier) **R4** or better (i.e., **R1** - **R4**. In contrast, the policy would take more risk in the case of the worker who can only work at his place of business. This worker would be allowed back with a much poorer risk score of **R7** (i.e., any risk score from **R1**-**R7**). ♢

	Base Case	Recent exposure		Can work remotely		Industry		Immunity	
		No	Yes	No	Yes	Critical	Non-critical	Yes	No
Best risk cutoff	***R5***	↕ ***R6***	↕ ***R3***	↕ ***R6***	↕ ***R4***	↕ ***R6***	↕***R4***	↕ ***R7***	***R5***
	← ..... V_k .....→								
strict ← POLICY → loose									
R1	-1.11	-1.23	-0.66	-9.05	0.97	2.54	-1.72	-1.33	-1.11
R2	-0.40	-0.42	-0.35	-6.68	1.36	4.49	-1.22	-0.43	-0.40
R3	1.20	1.40	**0.40**	-1.36	2.27	8.88	-0.08	1.59	1.20
R4	1.46	1.74	0.33	-0.34	**2.37**	9.71	**0.08**	2.01	1.46
R5	**1.48**	1.89	-0.16	0.20	2.27	10.12	0.04	2.29	**1.48**
R6	1.35	**1.90**	-0.82	**0.33**	2.05	**10.18**	-0.12	2.43	1.35
R7	0.78	1.75	-3.11	0.26	1.26	9.99	-0.76	**2.71**	0.78
	← ..... *Cost and Benefit assumptions* ..... →								
$c_{\mathcal{FN}}$	20	20	20	20	20	20	20	**▼0**	20
$b_{\mathcal{TP}}$	0	0	0	0	3	0	0	0	0
$c_{\mathcal{FP}}$	4	4	4	**▲20**	**▼1**	4	4	4	4
$b_{\mathcal{TN}}$	3	3	3	3	3	**▲15**	**▼1**	3	4
$p_{\mathbf{C}}$	20%	**▼10%**	**▲60%**	20%	20%	20%	20%	**▼0%**	20%

Table 6: A flexible back-to-work policy based on information on economic and health risks

This table shows how the same test may be used to risk stratify different groups of workers for prioritizing back-to-work stages for different health and economic profiles. This is done by adjusting the costs, benefits and prevalence. The hypothetical factors are only considered in isolation here, but a more robust approach would consider combinations. *Best risk cutoff* is the cutoff that minimizes harm. Below that score, individuals will be considered "high risk" so the cutoff represents the worst acceptable risk score for an individual to still be considered low risk, given the costs and benefits (i.e., risk scores from that risk score up to **R1** would be labeled "low risk.")
KEY:

▲, ▼ : a negative upward or downward change in the parameter

▲, ▼ : a positive upwards or downwards change

↕, ↕ : standards to became looser or tighter relative to the baseline.

Application Template - Determining a flexible risk stratification policy (Intermediate)

All calculations may be done on a hand calculator or simple spreadsheet. Example 7 can be used as a template.

To develop a more flexible risk stratification policy that permits different segments to be evaluated differentially using segment-specific criteria, the basic approach discussed in Section 3.1 may be used with parameters tailored to each subgroup's specific roles and health characteristics.

Input: Accuracy of risk stratification approach
Prevalence of COVID-19 for each subgroup
Cost for each subgroup of $\mathcal{TN}$ and $\mathcal{FP}$ in context of community
Cost for each subgroup of of $\mathcal{TN}$ and $\mathcal{FP}$...
Benefit for each subgroup of $\mathcal{TP}$ and $\mathcal{FP}$...

Result: Risk stratification policy for each subgroup enabling looser/tighter risk as warranted by the community's needs

3.5 Unified risk stratification: incorporating disparate types of tests

Example 8. Incorporating different kinds of tests into a single policy

In this final example, consider a policymaker who has decided on the appropriate costs and benefits for each community but must rely on a variety of tests, depending on the test availability and capabilities at different testing facilities.

Imagine that there is a virology test that has fairly high accuracy, but which is only available in limited supply. Because of the limited supply, only about 10% of the community will be able to be tested using it. A second virology test, which is not as accurate, will be available for about a third of the remaining community. a small percentage of the of the community can be screened with a predictive model developed with machine learning techniques that has good accuracy, but which is only applicable to small subsets of the general population. For the remainder, a less accurate simple heuristic test will be administered (e.g., based on an individual's age and whether they live alone or with others).

For simplicity, we assume that the costs and benefits are the same in all regions of the community:

$$
\begin{aligned}
c_{\mathcal{FN}} &= 20 \equiv \text{cost of false negative (infected allowed in)} \\
b_{\mathcal{TP}} &= 0 \equiv \text{benefit of true positive (correctly stopped infected)} \\
c_{\mathcal{FP}} &= 4 \equiv \text{cost of false positive (non-infected is kept out)} \\
b_{\mathcal{TN}} &= 3 \equiv \text{benefit of true negative (non-infected allowed in)} \\
p_{\mathbb{C}} &= 20\% \equiv \text{probability of COVID-19 (prevalence)\%}
\end{aligned}
$$

The tests' results use different scales, which range from having seven risk tiers to having just two, and the quality is variable across the tests and between grades. Table 7 displays the performance for each test.

Risk level	s_κ	**Higher accuracy viral test** $\mathcal{TP}$	**Higher accuracy viral test** $\mathcal{FP}$	**Lower accuracy viral test** $\mathcal{TP}$	**Lower accuracy viral test** $\mathcal{FP}$	**Low accuracy heuristic test** $\mathcal{TP}$	**Low accuracy heuristic test** $\mathcal{FP}$	**Machine Learning predictions** $\mathcal{TP}$	**Machine Learning predictions** $\mathcal{FP}$
Low Risk	R1	99%	60%	95%	18%	**60%**	**11%**	93%	24%
·	R2	99%	50%	**85%**	**14%**	-	-	90%	18%
·	R3	98%	19%	-	-	-	-	**85%**	**14%**
·	R4	**97%**	**10%**	-	-	-	-	73%	10%
·	R5	92%	9%	-	-	-	-	65%	8%
·	R6	87%	6%	-	-	-	-	-	-
High Risk	R7	70%	4%	-	-	-	-	-	-

Table 7: Performance of two different hypothetical COVID-19 diagnostic tools

This table shows the performance of four different hypothetical tests for stratifying individuals into risk tiers, based on the likelihood that they are infected. $\mathcal{TP}$ and $\mathcal{FP}$ are true positive rates (correct high risk) and false positive rates (low risk erroneously stratified as high risk), respectively. The rows in bold indicate the test's performance at their best cutoffs, given the costs and benefits described in the example. This is the cutoff that minimizes harm. Below that score, individuals will be considered "high risk" so the cutoff represents the worst acceptable risk score for an individual to still be considered low risk, given the costs and benefits (i.e., risk scores from that risk score up to **R1** would be labeled "low risk.").

The policymaker would like screen as many individuals as possible using whatever tests are available. However, they are concerned that the test all have different performance and that each also use a different number of risk tiers to report test results. Table 7 makes it clear that an "R1" from one test does not communicate the same information about the probability of an individual being infected with COVID-19 as another, and thus two "R1" risk tiers cannot be compared directly.

However, given the scarcity of tests, the policymaker must find a way to use whatever

tests they can offer to community. Said differently, they need to *integrate* all of the disparate tests into a single scale.

To do this, the policymaker can first determine the best cutoff for each test, and then determine the probability that an individual who is screened has COVID-19.

This transformation may be done using the techniques developed earlier. In particular, using either Equation (C.2)) or Equation (C.8), each tests' performance at its best cutoff can be mapped to a probability, and the probabilities can then be directly compared.

Table 8 shows the result of performing these calculations for each test.

	Probability of COVID-19 infection if...		*Healthy but...*		
	...test result is negative	*...test result is positive*	*...test result is positive*	$\mathcal{TP}$	$\mathcal{FP}$
Viral test - H (R4)	**0.8%**	70.8%	**11.0%**	97%	10%
Viral test - L (R2)	**4.2%**	60.3%	**15.6%**	85%	14%
ML test (R3)	**4.2%**	60.3%	**15.6%**	85%	14%
Heuristic test (R1)	**10.1%**	57.7%	**11.1**	60%	11%

Table 8: Converting to probabilities to compare individuals tested with different tests [Equation (??), (C.8)]

This table shows how individuals tested using four different types of tests, each with different performance and each with a different scale, can be compared and integrated into a single coherent policy for risk stratification. The tests are a higher accuracy virology test, a lower accuracy virology test, a heuristic rule, and predictive algorithm developed using machine learning (ML) techniques; the best cutoff for each test is shown in parentheses after the test name. $\mathcal{TP}$ and $\mathcal{FP}$ are true positive rates (correct high risk) and false positive rates (low risk erroneously stratified as high risk) , respectively. The columns in bold show the percentage of negative (positive) results for which a the subject was actually COVID-19 infected (healthy), and thus increased the total harm for the community.

The results in Table 8 illustrate a number of useful points. First, note that the hypothetical high accuracy viral test dominates all other tests in terms of stratification, with uniformly lower percentages of erroneous risk scores for both healthy and infected individuals. If it were possible to use *only* that test, the reduction of harm would be substantial.

Second, notice that two of the tests, the lower accuracy viral test and the test developed using machine learning, produced identical performance, even though they used different methods and different scales. Thus, under theses assumptions about costs and incidence, the policy should treat results of the the tests as equivalent, when their best cutoffs are used.[20]

[20] This is not strictly true for a variety of reasons. For example, the variance of the estimates may be different, etc.

Finally, the "mislabeled" rates in the two bold columns appear to show three distinct risk stratifications: high (around 10% risk of COVID-19 infection), medium (about 4%) and low (about 1%).

Furthermore, the actual risk grades can now be used to calculate other quantities of interest, such as the expected number of new cases, under the policy and so forth.

Note also that, were the policymaker to move to an entirely probability-based scoring system, there would no longer be a need to create cutoffs at all: each risk grade in each test's scale can be mapped directly to a probability and these probabilities can be used to manage the staging of the return more effectively (see, Section 4).

Application Template - Integrating disparate risk stratification methods in a single policy

All calculations may be done on a hand calculator or simple spreadsheet. Example 8 can be used as a template.

Example applications:

- Map all testing protocols and tests to a unified risk stratification scale
- Map test results to probabilities of exposure, morbidity, mortality, etc.
- Calculate, e.g., expected number of new cases under policy, etc.
- Create a single risk stratification policy that can be used irrespective of any current or new tests that are selected by the policymaker.
- Use as input to more advanced risk management approaches that consider clustering of incidence (not discussed here)

Input: Accuracy of each risk stratification approach
Prevalence of COVID-19 for the community
Cost of $\mathcal{TN}$ and $\mathcal{FP}$ in context of community
Cost of $\mathcal{TN}$ and $\mathcal{FP}$...
Benefit of $\mathcal{TP}$...

Result: A common probability scale for directly comparing and ordering the results of all testing approaches that may be in use; quantitative information that can be used to manage and monitor staging.

4 Discussion

There are a number of open issues and extensions that may be considered to the basic framework we outlined in Section A. Here we discuss two of these: coming to terms with how best to intentionally assign cost and benefit values (rather than doing so unintentionally by implication), and potential improvements that allow more precise and customized risk stratifications.

4.1 The difficulty in assessing costs and benefits

In this paper, we have assumed that clinicians are able to explicitly state approximate values for cost and benefits. This is extremely challenging and, realistically, may only be possible very coarsely. In the case of novel coronavirus, this assessment is made more complicated by several factors, including:

- generally poor data on true prevalence, contagion rates, mortality rates, hospital admission rates (given infection), ICU admission rates (given hospitalization), etc. Without better data on these parameters and others, it will be exceedingly difficult to properly form policy.;
- complexity in both the pathology and evolution of the novel coronavirus, and how these are impacted by interventions, prior medical histories, genotype and phenotype information, etc.
- complexity in relating epidemiological phenomena to economic phenomena;
- complexity in understanding supply chain dynamics, and the many interrelationships between different economic sectors (e.g., retail and trucking), as well as the degree of modularity in any particular business or industry, and how these relate back to individuals.;
- the need to execute short-term policy within the context of long-term economic and health planning objectives

It is both outside of our knowledge and beyond the scope of the current paper to undertake this analysis in any detail for any specific case. Indeed such decisions require information on the economic and health impacts of different outcomes within a community, as well as information on the demographics of the population. These analyses also require a normalization and prioritization of outcomes that are measured on different scales, such as the health costs of self-isolation vs. the risk of overloading hospitals vs. the cost to the community and individuals of lost wages and economic output.

However, these need not be exceedingly refined or comprehensive in some cases. It may be the case, for example, that clinicians, economists, and health officials can easily

agree on the extreme cases, and then work backwards using, e.g., a point system for different costs and benefits.

Examples of costs and benefits could include a wide variety of global, national and local factors. Table 9 provides examples of some of the hypothetical factors that might go into a discussion with health and economic policy advisors while formulating a policy.

In some settings, decision makers can agree more easily on relative value than on absolute levels. In such cases, valuing factors in terms of points, rather than dollars and health outcomes may be more tractable. This is particularly so given the complexity, co-dependence, and tight coupling of the systems and actors in question.

Hypothetical examples of...

...potential costs of erroneously keeping uninfected people isolated ($c_{\mathcal{FP}}$)	**...potential benefits of getting uninfected people out of isolation ($b_{\mathcal{TP}}$)**	**...potential costs of erroneously returning infected people to population ($c_{\mathcal{FN}}$)**
▲ psychological illness	▲ economic output	▲ infection rate
▼ economic participation	▲ ability to care for others	▲ hospital loads
▲ expenses	▲ national security	▲ spread of COVID-19
▲ food/medical insecurity	▲ services and product availability	▲ mortality due to COVID-19
▲ domestic abuse	▲ resources for community support	▲ reduced health svcs. access
▲ disruption of supply chain	▲ quality of life	▼ resilience of community
▲ lifestyle-related morbidity	▲ lifestyle-related health	▼ prolonged population lock-down
etc.	etc.	etc.

Table 9: Some hypothetical factors for discussing a return-to-work policy. (*Example only*)

This table shows some of the dimensions that clinicians might consider in a hypothetical discussion of return-to-work policy construction. It is intended as an example only. The actual dimensions will differ and be weighted differently in various real settings. (▲, ▼indicate a negative increase or decrease as the result of an error; ▲ indicates a positive increase as the result of a benefit.)

4.2 Risk stratification without cutoffs: More refined tests minimize harm

While cutoffs can be chosen by clinicians to maximize overall benefits to a community these are only "best" when the options are restricted to designating a single cutoff. If the clinicians and the community have access to more refined tests, these may be used to create much more flexible screening procedures.

In such cases, particularly if the test is calibrated to produce a continuous scale and can be calibrated to produce probability estimates, a policy can be designed to accommodate a wide range of individual situations. This permits highly customized assessments of specific sub-populations, and even of individuals.

Furthermore, such tools can be explicitly designed to incorporate multiple dimensions of risk (e.g., age AND health status AND recent exposure, etc.) rather than assessing each independently, as in Example 7. Doing this allows risk stratification to be informed by a fuller picture of the individual or sub-population, and also reduces double-counting substantially.

It can be shown (Stein, 2005) that such approaches are generally superior to simple cutoff-based approaches. Furthermore, as better empirical data on COVID-19 becomes available, this type of more refined analysis and prediction is likely to become increasingly available.

The question of how to best determine a scale and to then calibrate involves a number of dimensions and may be done in several ways, each offering different advantages and limitations, depending on the applications (see, (Bohn and Stein, 2009, , Chapter 4) for a discussion.

5 Conclusion

In this note we have tried to provide guidance for clinicians on ways to make more informed decisions as part when developing risk stratification approaches for bringing individuals back to work and the general public prior to the introduction of an effective vaccine for COVID-19.

Our discussion was framed in this context and our examples focused on COVID-19 entirely. However, the techniques we used in this context are general, as are their mathematical formulations.

These general techniques can provide a grounding in facts and science for clinicians to draw on in evaluating the challenging policy decisions that now face many national and local governments.

These methods perform better with more accurate data, and as a result, they can also help clinicians understand how best to collect this information, and up until what point the benefits of data collection continue to outweigh the costs.

Finally, the methods are flexible and can be readily adapted to local needs, using whatever information is available.

Many discussions of policy were initially focused on emergency tactics to prevent healthcare systems and communities from being overrun with COVID-19 outbreaks. As these discussions now turn towards longer-term strategies to manage how communities might start to return to more "normal" activities, when the threats of COVID-19 begin to abate, we hope that this type of analysis will inform better, more effective, and less costly policies for total harm minimization.

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A Appendix: Setting a policy cutoff

Assume that there is a set of benefits and costs that we can calculate for a correctly and incorrectly stratifying an individual.[21] Denote these costs and benefits as follows:

$$
\begin{aligned}
b_{\mathcal{TN}} &\equiv \text{benefit of correctly stratifying a disease-free individual as low-risk} \\
b_{\mathcal{TP}} &\equiv \text{benefit of correctly stratifying of an infected individual as high-risk} \\
c_{\mathcal{FN}} &\equiv \text{cost of incorrectly stratifying of an infected individual as low-risk} \\
c_{\mathcal{FP}} &\equiv \text{cost of incorrectly stratifying of an disease-free individual as high-risk}
\end{aligned}
$$

Imagine further that the diagnostic produces a score, s_i for each individual, that ranges from s_1 ("lowest risk") through s_K highest risk. This score could be the propensity score of a machine learning algorithm, the concentration level (cp/μL) of SARS-CoV-2 detected using an assay, a person's age, etc.

The goal of the policymaker is to determine the score cutoff κ to use for stratifying the risk of the population into "high risk" (scores higher than κ) and "low risk" (scores lower than κ). Without a loss of generality, let k be the percentile of s_κ in the population. [22] Because the diagnostic is not perfect, any κ selected other than s_1 or s_K will produce accuracy and error rates $\mathcal{TN}_k, \mathcal{TP}_k, \mathcal{FN}_k$ and $\mathcal{FP}_k$.

Given this information, the total value of a policy, V_k, that uses this diagnostic with the cutoff k is:

$$
V_k = p^*_{\mathbb{F}} \left[b_{\mathcal{TN}} \times \mathcal{TN}_k - c_{\mathcal{FP}} \times \mathcal{FP}_k \right] + p^*_{\mathbb{C}} \left[b_{\mathcal{TP}} \times \mathcal{TP}_k - c_{\mathcal{FN}} \times \mathcal{FN}_k \right], \tag{A.1}
$$

where, as before, $p^*_{\mathbb{C}}$ and $p^*_{\mathbb{F}}$ are the true prevalence and one minus the true prevalence, respectively.

This is simply the weighted net value of a correct vs. incorrect classification of an individual as low risk plus the weighted value of a correct vs. incorrect classification of an individual as high risk. The the weighting is done based on the probability of being virus-free or infected and the probability of being correct or incorrect depends on the model accuracy ($\mathcal{TP}_k$, etc.).

In order to maximize the value (equivalent to minimizing the negative value) we can V_k to zero, differentiating with respect to k and rearrange terms. This gives the slope of a line with marginal cost equal to zero.

This gives:

[21] It is beyond the scope of this note to discuss the many factors that must go into such determinations. However, regardless of whether clinicians explicitly make these calculations or not, by the Law of Risk-Based Decision Making the costs and benefits will be implied in any risk stratification policy.

[22] For completeness, $k = \#\{s_i < \kappa\}/N,\ i = 1...N$, where N is the size of the total population and $\#\{x\}$ is the count of the number of cases in which x is true.

$$S = \frac{(1 - p_{\mathbb{C}}) \times [c_{\mathcal{FP}} + b_{\mathcal{TN}}]}{p_{\mathbb{C}} \times [c_{\mathcal{FN}} + b_{\mathcal{TP}}]}.$$

The point at which a line with slope S, as defined above, forms a tangent to the ROC curve for a stratification method, defines optimal cutoff, given a particular set of costs and benefits: this point will be the one at which marginal payoffs (costs) are zero. (Green and Sweats, 1966) provides a discussion of this approach and an analytic formulation of the problem as applied to ROC analysis.

The goal of the policymaker is to maximize the value of the policy, which is done by selecting a value of k that maximizes V_k. This may be done graphically using ROC curves or analytically, as above. (see: (e.g., Stein, 2005) for details and exertions).

As noted earlier, for real-world problems involving risk stratification systems that may have a variety of attributes, and for which there may only be a small number of potential cutoff values, it may be convenient to calculate $\mathcal{TP}_k, \mathcal{FP}_k$, etc. for the range of k values, and to then use the cutoff that results in the maximum value of V_k.

B Appendix: A general analytic result using Bayes' Rule

Bayes' Theorem gives:

$$p(A \mid B) = \frac{p(B \mid A)p(A)}{p(B)}, \tag{B.1}$$

where, as usual,

$p(x)$: the probability of event x occurring; and
$p(x|y)$: the probability of event x occurring given that y is observed.

For more involved calculations, we note that the chain rule permits calculation of joint probabilities based on their conditional products:

$$p(A_n, \ldots, A_1) = p(A_n | A_{n-1}, \ldots, A_1) \cdot p(A_{n-1}, \ldots, A_1). \tag{B.2}$$

For example, if we were worried about spreading the novel coronavirus at a press conference, but also worried about restricting reporters' access to the press conference, we might consider screening each reporter as they enter briefing room. In this case, we would be concerned about infected individuals entering the briefing room and possibly infecting others. If we wished to determine the probability that an individual had COVID19, given that she got a negative test result, $\mathcal{N}$, Equation (B.1) becomes:

$$p(\texttt{COVID-19} \mid \mathcal{N}) = \frac{p(\mathcal{N} \mid \texttt{COVID-19}) \times p(\texttt{COVID-19})}{p(\mathcal{N})}.$$

If there were n_T total test given, (negative test result, $\mathcal{N}$ indicating no COVID19 and positive result $\mathcal{P}$ indicating COVID-19 present), Equation (B.1) becomes:

$$p(\texttt{COVID-19} \mid \mathcal{N}) = \frac{(n_{\mathbb{C}\mathcal{N}}/n_{\mathbb{C}}) \times (n_{\mathbb{C}}/n_T)}{(n_{\mathcal{N}}/n_T)}. \tag{B.3}$$

where

$$\begin{aligned}
n_{\mathbb{C}} &\equiv \text{total number of COVID-19 infected individuals} \\
n_{\mathbb{W}} &\equiv \text{total number of individuals tested who are well (no COVID19)} \\
n_T &\equiv \text{total number of individuals tested} = n_{\mathbb{C}} + n_{\mathbb{W}} \\
n_{\mathcal{P}} &\equiv \text{total number of individuals who test positive} \\
n_{\mathcal{N}} &\equiv \text{total number of individuals who test negative} \\
n_{\mathbb{C}\mathcal{P}} &\equiv \text{total number of individuals with COVID-19 who test positive} \\
n_{\mathbb{C}\mathcal{N}} &\equiv \text{total number of individuals with COVID-19 who test negative}
\end{aligned}$$

which (of course) simplifies to

$$p(COVID19 \mid \mathcal{N}) = \frac{n_{\mathbb{C}\mathcal{N}}}{n_{\mathcal{N}}} \equiv \mathcal{FN}. \tag{B.4}$$

The false positive rate may be calculated similarly.

It is useful at times to recall that $\mathcal{TP}, \mathcal{FP}$, etc. do not depend on $p_{\mathbb{C}}$, the incidence rate. (See Appendix D for a proof.)

C Appendix: Calibrating the probability of a COVID-19 infection as new information arrives

In some cases, we can make simple adjustments, using the Bayesian framing, in order to adjust for differences between the noisy population prevalence estimates and (perhaps new) true population prevalence to better characterize the effectiveness of a diagnostic or model. In the simplest case, a straightforward adjustment to the "bad" probability, using a new "better" estimate of prevalence may suffice (see, e.g., Bohn and Stein, 2013; Khozin and Stein, 2020, for details).[23]

It can be shown, for example, that absent systematic selection bias (see: footnote 23).

One such fix-up is:

$$p(\mathbb{S} \mid \mathcal{R})^{tru} \equiv p_{\mathbb{S}\mathcal{R}}^{tru} = p_{\mathbb{S}}^{tru} \left[\frac{p_{\mathbb{S}\mathcal{R}}^{bad} \times \left[1 - p_{\mathbb{S}}^{bad}\right]}{p_{\mathbb{S}}^{bad} - (p_{\mathbb{S}}^{bad} \times p_{\mathbb{S}\mathcal{R}}^{bad}) + (p_{\mathbb{S}}^{tru} \times p_{\mathbb{S}\mathcal{R}}^{bad}) - (p_{\mathbb{S}}^{tru} \times p_{\mathbb{S}}^{bad})} \right]. \tag{C.1}$$

where

$$\begin{aligned}
\mathbb{S} &\equiv \text{the true disease status (} \texttt{COVID-19} \text{ or } \texttt{well}\text{)} \\
\mathcal{R} &\equiv \text{the result of the diagnostic test } \mathcal{P} \text{ or } \mathcal{N} \\
p_{\mathbb{S}} &\equiv \text{the true prevalence of } \mathbb{S} \\
p_x^{tru} &\equiv \text{is the correct estimate of the probability of } x \text{ if correct data were used} \\
p_x^{bad} &\equiv \text{is the bad estimate of the probability of } x \text{ using unreliable data, and} \\
p_{\mathbb{S}\mathcal{R}} &\equiv p(\mathbb{S} \mid \mathcal{R}).
\end{aligned}$$

So, for example, the true probability of a person who tested positive actually having COVID-19, can be computed from an estimate, $p_{\mathbb{C}\mathcal{P}}^{bad}$, that was originally made based on unreliable data:

$$p(\texttt{COVID-19} \mid \mathcal{P})^{tru} \equiv p_{\mathbb{C}\mathcal{P}}^{tru} = p_{\mathbb{C}}^{tru} \left[\frac{p_{\mathbb{C}\mathcal{P}}^{bad} \times \left[1 - p_{\mathbb{C}}^{bad}\right]}{p_{\mathbb{C}}^{bad} - (p_{\mathbb{C}}^{bad} \times p_{\mathbb{C}\mathcal{P}}^{bad}) + (p_{\mathbb{C}}^{tru} \times p_{\mathbb{C}\mathcal{P}}^{bad}) - (p_{\mathbb{C}}^{tru} \times p_{\mathbb{C}}^{bad})} \right]. \tag{C.2}$$

The above equations **can only be used in certain special settings**, we introduce them here only to demonstrate the magnitude of the impact that unreliable data may have on a risk stratification, and because certain intermediate results of the proof[24] are useful for calibration.

[23] The adjustment shown here assumes that there is no systematic sampling bias, i.e., that the actual missing cases are MCAR. Clearly, in the case of the COVID-19 testing discussed here, this is not the case. However, in such settings, more detailed analysis may also be used to adjust probabilities (see, e.g., Khozin and Stein, 2020, and references therein).

[24] Much of the proof of this result follows closely a version given in (Elkan, 2001), though the one given here contains more of the details, and contains extensions.

Proof of Eq. (C.2)

We begin with Equation (B.1):

$$p(A \mid B) = \frac{p(B \mid A) \times p(A)}{p(B)},$$

from which it also follows that,

$$p(B \mid A) = \frac{p(A \mid B) \times p(B)}{p(A)}. \tag{C.3}$$

For convenience, let

$$\begin{aligned} p(A \mid B) &= p(\texttt{COVID}-\texttt{19} \mid \mathcal{P}) \equiv p_{\mathbb{C}\mathcal{P}}, \text{ and} \\ p(B \mid A) &= p(\mathcal{P} \mid \texttt{COVID}-\texttt{19}) \equiv p_{\mathcal{P}\mathbb{C}}. \end{aligned}$$

$$p_{\mathbb{C}\mathcal{P}} = \frac{p_{\mathcal{P}\mathbb{C}} \times p_{\mathbb{C}}}{p_{\mathcal{P}}}$$

and let $p_{\mathbb{W}} = 1 - p_{\mathbb{C}}$ be the probability of not having COVID-19 (being *well*), and

$$\begin{aligned} p_{\mathcal{P}} &= p_{\mathbb{C}} \times p_{\mathcal{P}\mathbb{C}} + p_{\mathbb{W}} \times p_{\mathcal{P}\mathbb{W}} \\ &= p_{\mathbb{C}} \times p_{\mathcal{P}\mathbb{C}} + (1 - p_{\mathbb{C}}) \times p_{\mathcal{P}\mathbb{W}} \end{aligned} \tag{C.4}$$

If our estimate of $p_{\mathbb{C}}$ is based on a "bad" estimate, then, $p_{\mathbb{C}\mathcal{P}}$ will also be "bad." Using the notation above, the erroneous ("bad") estimate of $p_{\mathbb{C}\mathcal{P}}$, $p^{bad}_{\mathbb{C}\mathcal{P}}$, is then:

$$\begin{aligned} p^{bad}_{\mathbb{C}\mathcal{P}} &= \frac{p^{bad}_{\mathcal{P}\mathbb{C}} \times p^{bad}_{\mathbb{C}}}{p^{bad}_{\mathcal{P}}} \\ &= \frac{p^{bad}_{\mathcal{P}\mathbb{C}} \times p^{bad}_{\mathbb{C}}}{p^{bad}_{\mathbb{C}} \times p^{bad}_{\mathcal{P}\mathbb{C}} + (1 - p^{bad}_{\mathbb{C}}) \times p^{bad}_{\mathcal{P}\mathbb{W}}} \\ &= \frac{p^{bad}_{\mathbb{C}}}{p^{bad}_{\mathbb{C}} + (1 - p^{bad}_{\mathbb{C}}) \times \theta} \end{aligned} \tag{C.5}$$

where $\theta^{bad} = p^{bad}_{\mathcal{P}\mathbb{W}}/p^{bad}_{\mathcal{P}\mathbb{C}}$. Note that because θ is equivalent to $\mathcal{FP}/\mathcal{TP}$, it does not depend on $p_{\mathbb{C}}$ (see, Appendix D), and therefore

$$\theta^{bad} = \theta^{tru} = \theta,$$

so we also have

$$p^{tru}_{\mathbb{C}\mathcal{P}} = \frac{p^{tru}_{\mathbb{C}}}{p^{tru}_{\mathbb{C}} + (1 - p^{tru}_{\mathbb{C}}) \times \theta}, \tag{C.6}$$

where the superscript tru indicates the true value of the parameter, which is the equivalent to Equation (C.5), but using the good estimate $p^{tru}_{\mathbb{C}}$.

Although theta does not depend on $p_{\mathbb{C}}$, $p^{bad}_{\mathbb{C}\mathcal{P}}$ and $p^{tru}_{\mathbb{C}\mathcal{P}}$ do depend on $p^{bad}_{\mathbb{C}}$ and $p^{tru}_{\mathbb{C}}$, respectively. Thus, in order to accomplish the adjustment, we can solve for θ in terms of $p^{bad}_{\mathbb{C}\mathcal{P}}$. This gives

$$\begin{aligned} \theta &= \frac{p^{bad}_{\mathbb{C}} \times (1 - p^{bad}_{\mathbb{C}\mathcal{P}})}{p^{bad}_{\mathbb{C}\mathcal{P}} \times (1 - p^{bad}_{\mathbb{C}})} \\ &= \frac{p^{bad}_{\mathbb{C}} - (p^{bad}_{\mathbb{C}} \times p^{bad}_{\mathbb{C}\mathcal{P}})}{p^{bad}_{\mathbb{C}\mathcal{P}} - (p^{bad}_{\mathbb{C}\mathcal{P}} \times p^{bad}_{\mathbb{C}})} \end{aligned} \tag{C.7}$$

Plugging Equation (C.7) back into Equation (C.6) gives

$$
\begin{aligned}
p_{\mathbb{C}\mathcal{P}}^{tru} &= \frac{p_{\mathbb{C}}^{tru}}{p_{\mathbb{C}}^{tru} + (1 - p_{\mathbb{C}}^{tru}) \times \frac{p_{\mathbb{C}}^{bad} - (p_{\mathbb{C}}^{bad} \times p_{\mathbb{C}\mathcal{P}}^{bad})}{p_{\mathbb{C}\mathcal{P}}^{bad} - (p_{\mathbb{C}\mathcal{P}}^{bad} \times p_{\mathbb{C}}^{bad})}}, \\
&= \frac{p_{\mathbb{C}}^{tru}}{p_{\mathbb{C}}^{tru} + (1 - p_{\mathbb{C}}^{tru}) \times \frac{p_{\mathbb{C}}^{bad} \times (1 - p_{\mathbb{C}\mathcal{P}}^{bad})}{p_{\mathbb{C}\mathcal{P}}^{bad} \times (1 - p_{\mathbb{C}}^{bad})}}, \\
&= \frac{p_{\mathbb{C}}^{tru} \times p_{\mathbb{C}\mathcal{P}}^{bad} \times (1 - p_{\mathbb{C}}^{bad})}{p_{\mathbb{C}}^{bad} + (p_{\mathbb{C}\mathcal{P}}^{bad} \times p_{\mathbb{C}}^{tru}) - (p_{\mathbb{C}}^{tru} \times p_{\mathbb{C}}^{bad}) - (p_{\mathbb{C}}^{bad} \times p_{\mathbb{C}\mathcal{P}}^{bad})}, \\
&= p_{\mathbb{C}}^{tru} \left[\frac{p_{\mathbb{C}\mathcal{P}}^{bad} \times [1 - p_{\mathbb{C}}^{bad}]}{p_{\mathbb{C}}^{bad} + -(p_{\mathbb{C}\mathcal{P}}^{bad} \times p_{\mathbb{C}}^{bad}) + (p_{\mathbb{C}}^{tru} \times p_{\mathbb{C}}^{bad}) - (p_{\mathbb{C}}^{tru} \times p_{\mathbb{C}}^{bad})} \right] . \blacksquare
\end{aligned}
$$

Importantly, because θ is a the ratio $\mathcal{FP}/\mathcal{TP}$ does not involve $p_{\mathbb{C}}$, Equation (C.2) may be simplified substantially if we know the performance ($\mathcal{FP}$ and $\mathcal{TP}$) of the test, which can be convenient:

$$
p_{\mathbb{C}\mathcal{P}}^{tru} = \frac{p_{\mathbb{C}}^{tru}}{p_{\mathbb{C}}^{tru} + (1 - p_{\mathbb{C}}^{tru}) \times \frac{\mathcal{FP}}{\mathcal{TP}}}, \tag{C.8}
$$

since any specific test result will be associated with a specific $\mathcal{FP}$ and $\mathcal{TP}$, which, in turn, will result in a specific probability estimate(see, Appendix sec:bayes). For tests that produce a range of test values, any specific test value will still have a specific $\mathcal{FP}$ and $\mathcal{TP}$ and resulting probability associated. (See Figure 3).

D Appendix: Proof that $\mathcal{TP}$ (and $\mathcal{FP}, \mathcal{FN}, \mathcal{TN}$) do not depend on the prevalence $p_{\mathbb{C}}$

We wish prove that $\mathcal{TP}$ and $\mathcal{TN}$ do not depend on $p_{\mathbb{C}}$. It is sufficient to prove that $\mathcal{TP}$.

We begin by proving that $\mathcal{TP} = 1 - \mathcal{FN}$.

$$\begin{aligned}
\mathcal{TP} \;=\; p(\mathcal{P} \mid \mathbb{C}) \quad &= \quad \frac{p(\mathbb{C} \mid \mathcal{P}) \times p_{\mathcal{P}}}{p_{\mathbb{C}}} \\
&= \quad \frac{\frac{n_{\mathbb{C}\mathcal{P}}}{n_{\mathcal{P}}} \times \frac{n_{\mathcal{P}}}{n_T}}{\frac{n_{\mathbb{C}}}{n_T}} \\
&= \quad \frac{n_{\mathbb{C}\mathcal{P}}}{n_{\mathcal{P}}} \times \frac{n_{\mathcal{P}}}{n_T} \times \frac{n_T}{n_{\mathbb{C}}} \\
&= \quad \frac{n_{\mathbb{C}\mathcal{P}}}{n_{\mathbb{C}}} \\
&= \quad \frac{n_{\mathbb{C}} - n_{\mathbb{C}\mathcal{N}}}{n_{\mathbb{C}}} \\
&= \quad \frac{n_{\mathbb{C}}}{n_{\mathbb{C}}} - \frac{n_{\mathbb{C}\mathcal{N}}}{n_{\mathbb{C}}} \\
&= \quad 1 - \mathcal{FN}. \;\blacksquare
\end{aligned}$$

It can similarly be shown that

$$\mathcal{TN} = 1 - \mathcal{FP}.$$

It now remains to show that that $\mathcal{TP}$ does not depend on $p_{\mathbb{C}}$, which, by exertion of the first proof, establishes the result for $\mathcal{FN}, \mathcal{TP}$ and $\mathcal{FN}$ as well.

$$\begin{aligned} \mathcal{TP} &= \frac{n_{\mathbb{C}\mathcal{P}}}{n_{\mathbb{C}}}, \\ n_{\mathbb{C}\mathcal{P}} &= n_{\mathbb{C}} \times n_T \\ \\ n_{\mathbb{C}\mathcal{P}} &= (p_{\mathbb{C}} \times n_T) \times \mathcal{TP}. \end{aligned}$$

Now let $p_{\mathbb{C}}^{new}$ be an alternative value of $p_{\mathbb{C}}$ such that

$$\begin{aligned} \frac{p_{\mathbb{C}}}{p_{\mathbb{C}}^{new}} &= \lambda. \\ p_{\mathbb{C}}^{new} &= \lambda \times p_{\mathbb{C}} \qquad \text{(D.1)} \\ n_{\mathbb{C}}^{new} &= \lambda \times p_{\mathbb{C}} \times n_T \\ &= \lambda \times n_{\mathbb{C}} \qquad \text{(D.2)} \end{aligned}$$

Now

$$\begin{aligned} n_{\mathbb{C}\mathcal{P}}^{new} &= p_{\mathbb{C}}^{new} \times n_T \times \mathcal{TP}. \\ &= \lambda \times p_{\mathbb{C}} \times n_T \times \mathcal{TP}. \\ n_{\mathbb{C}\mathcal{P}}^{new} &= \lambda \times n_{\mathbb{C}\mathcal{P}} \qquad \text{(D.3)} \end{aligned}$$

The new value of $\mathcal{TP}$, $\mathcal{TP}^{new}$ is the value of $\mathcal{TP}$ based on the new prevalence rate $p_{\mathbb{C}}^{new}$:

$$\mathcal{TP}^{new} = \frac{n_{\mathbb{C}\mathcal{P}}^{new}}{n_{\mathbb{C}}^{new}}, \qquad \text{(D.4)}$$

Substituting Equation (D.2) and (D.3) into Equation (D.4) gives

$$\begin{aligned} \mathcal{TP}^{new} &= \frac{n_{\mathbb{C}\mathcal{P}}^{new}}{n_{\mathbb{C}}^{new}} \\ \\ \mathcal{TP}^{new} &= \frac{\lambda \times n_{\mathbb{C}\mathcal{P}}}{\lambda \times n_{\mathbb{C}}} \\ &= \mathcal{TP}. \ \blacksquare \end{aligned}$$

E Risk Stratification Workbench: Staging, cutoff, and policy evaluation

In order to facilitate education regarding the techniques discussed in this article, we have implemented a web-based tool called *Risk Stratification Workbench* for performing these analyses.[25]

Risk Stratification Workbench is publicly available at no charge, and can be found at:

http://www.rogermstein.com/covid-19-resources/.

Risk Stratification Workbench is intended to be used in conjunction with this article, however, the following two pages provide a "Cheat Sheet" for quick reference.

[25] Although the software is available at no cost, some caveats are in order: This software is only intended for educational purposes and there is no express or implied warranty regarding the use of this tool or its outputs. Although we believe the code to be free of errors, the user should note that the accuracy of the software and results are not guaranteed, and the applicability of the analysis may or may not be appropriate for any specific purpose. In light of this, any decisions that may or may not result from the use of this software are the responsibility of the user. (Also note, that the author has no medical training.)

Risk Stratification Workbench Cheat Sheet

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Enter information about community priorities on a scale of 1-100 (see, e.g. Section 3.1)

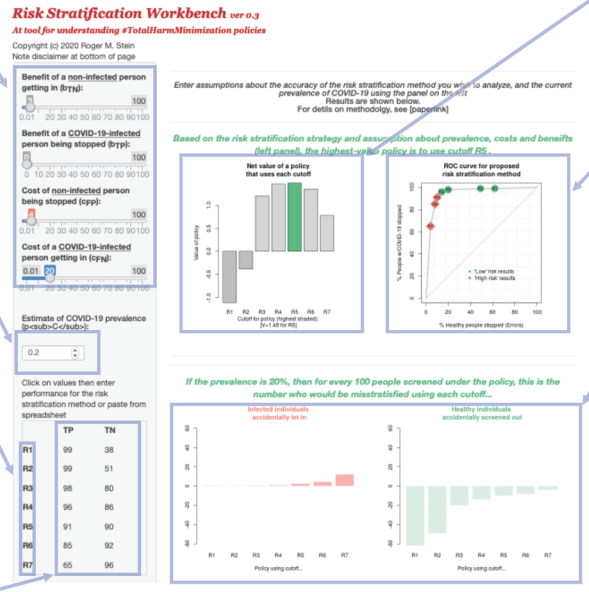
Enter the prevalence of COVID-19 based on the best information available using a probability scale [0.0 - 1.0] (see, e.g. Section 2.3)

Note the scale for risk stratification system; K1 is lowest risk…K7 is riskiest. (See Section 2.1)

If there are fewer than seven levels in the risk stratification system, start with the riskiest levels (bottom to top) until all levels are entered; then fill the rest of the table by repeating performance for the least risky.

Enter data on the accuracy of the risk stratification method. (see, e.g. Section 3.1)

(e.g. TP = % of COVID-19 infected person is classified as being "high risk"



View plot showing the relative value of a policy using each risk stratification as a cutoff (see, Section 3.1)

View plot showing the ROC curve for the stratification method (see, Section 3.1)

View plots showing how policies based on each possible risk cutoff level in the system would perform. (see, Section 2).

The height of the bars indicates the number infected individuals who should not have been approved but were allowed to "enter" (left) and the number of uninfected individuals who should have been approved but were not allowed to "enter" (right).

For details, see: Stein, R. M (2020), "Where to draw the line for risk stratifications: Designing return-to-work policies that consider diagnostic error, costs, benefits and COVID-19."

Risk Stratification Workbench Cheat Sheet

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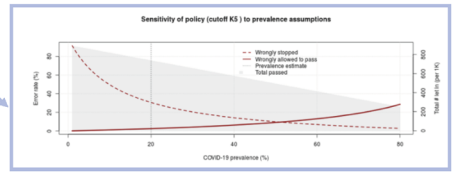


View the graph showing the how the true probability of having (not having) COVID-19 varies for the risk stratification system at the best cutoff would change if updated (or more accurate) information on the prevalence becomes available. (see, Section 2.3)

The graph shows the percentage of individuals who tested negative ("low risk") would actually be COVID-19 infected and allowed to "enter" and the number of individuals who tested positive ("high risk") who would actually be non-infected, but prevented from "entering."

In addition, the total number of individuals (per 1,000 screened) who would be allowed to "enter is shown in gray.

Using the cutoff K5 (that maximizes value under the assumptions in the left panel), for every 100 people screened under the policy, this is the number who would be misstratisfied at different prevalences...



(Each row shows a different assumption about the population prevalence)

prevalence	passed.with.COVID.19	stopped.but.healthy
1.00	0.10	91.58
10.00	1.10	49.72
20.00	2.44	30.53
30.00	4.11	20.41
40.00	6.25	14.15
50.00	9.09	9.90
60.00	13.04	6.83
70.00	18.92	4.50
80.00	28.57	2.67

DISCLAIMER: This software may be used at no cost. It is intended for educational purposes. That the author of this tool is not a medical professional. That there is no express or implied warranty regarding the use of this tool or its outputs. The author is not responsible for any policy decisions that may or may not result from the use of this software, and makes no representations regarding the accuracy of the code, output or analysis, or with respect to the appropriateness of this analysis for any specific purpose.

View the table showing the numerical values implied by the figures in the graph, per 1,000 individuals screened. (see, e.g. Section 2.3)

All values are calculated based on the risk stratification profile entered, and assuming that the policy continued to use the best cutoff as determined by the current prevalence assumption.

Note that were the prevalence rate to be different than the current assumption, different cutoff might be implied.

For details, see: Stein, R. M (2020), "Where to draw the line for risk stratifications: Designing return-to-work policies that consider diagnostic error, costs, benefits and COVID-19."

Anyone can publish on Medium per our Policies, but we don't fact-check every story. For more info about the coronavirus, see cdc.gov.

A New Strategy for Bringing People Back to Work During COVID-19

It's imperative that we responsibly restore the economy while working to flatten the coronavirus curve.



Avik Roy Follow
Apr 14 · 29 min read



Photo by Taylor Grote on Unsplash

By Lanhee Chen, Bob Kocher, Avik Roy, and Bob Wachter; with additional contributions

from Mark Dornauer, Gregg Girvan, and Dan Lips

Executive Summary

A quasi-consensus has emerged among many policymakers and commentators that the U.S. should continue to close schools and non-essential businesses until coronavirus testing and immunity is widespread. But there is a significant possibility that we are many months, if not years, away from meeting these thresholds. Time is of the essence, given the severe human cost of a prolonged economic shutdown.

The good news is that policymakers have an opportunity to strategically reopen the economy, by taking into account a unique feature of COVID-19: its heavy skew toward bad outcomes in the elderly and the near-elderly who also have other chronic diseases. With the proper precautions, and the deployment of tools like contact tracing, self-quarantines, and telemedicine, we can continue to protect the most vulnerable, while returning as many Americans as possible to work.

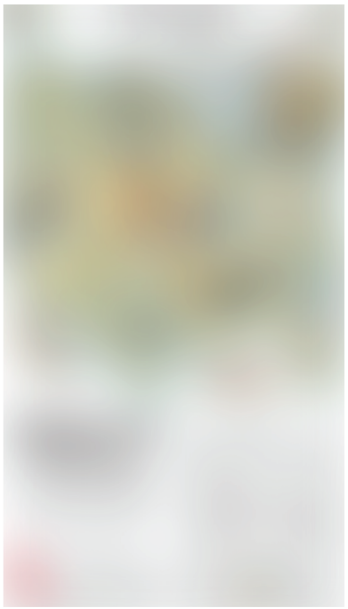
We will still need to address high-risk populations, like those in nursing homes, rehabilitation facilities, jails, and prisons. But we are persuaded that much more can be done to reopen the economy today, thereby improving the lives of hundreds of millions of low-to-middle income Americans.

(Authors' note: This is a working paper that will be continuously updated with new evidence and policy ideas. Revisions will be noted at the end of the paper. Please check back frequently.)

Introduction

Deaths and hospitalizations are continuing to rise in the United States from COVID-19, the disease caused by the novel coronavirus SARS-CoV-2, albeit more slowly than before. Many policymakers and members of the public have expressed the

hope that life will be "back to normal" by May or June. But it won't be. Indeed, life may never return to exactly the way it was before 2020.



A summary of this paper, authored by Avik Roy, appears in the April 25, 2020 edition of the Wall Street Journal.

And that is the *optimistic scenario* most widely articulated by public health commentators, in which the U.S. successfully "flattens the curve," establishes nearly ubiquitous testing, and succeeds at rapidly developing treatments and vaccines for SARS-CoV-2. A recent paper published by former FDA Commissioner Scott Gottlieb and others at the American Enterprise Institute outlines this scenario.

This optimistic scenario leaves us concerned that the public, the media, the business community, and policymakers are largely unprepared for a *pessimistic scenario* in which accurate, near-ubiquitous testing is difficult to achieve; infected individuals' antibodies

do not lead to immunity; anti-viral treatments take longer to develop; and vaccines never arrive.

> We are concerned that the public, the media, the business community, and policymakers are largely unprepared for a pessimistic scenario in which near-ubiquitous testing is difficult to achieve, infected individuals' antibodies do not lead to immunity, anti-viral treatments take longer to develop, and vaccines never arrive.

Under the present policy paradigm, many commentators and policymakers argue that something resembling the pessimistic scenario will require a prolonged shutdown of six months or longer, or an indefinite series of on-and-off stay-at-home orders that could go on for years.

As Morgan Stanley biotechnology research analyst Matthew Harrison put it in an April 6 op-ed, "Hope that…the U.S. has not reached crisis levels…will be shortlived, as the reality sets in that the path to reopening the U.S. economy is going to be long, and marred by stops and starts. It will be fully resolved only when vaccines are widely available in spring 2021, at the earliest."

But the U.S. economy cannot sustain a shutdown of that magnitude, nor the permanent closure of tens of thousands of businesses that will accompany it.

Several features of SARS-CoV-2 and the COVID-19 disease lead us to believe that there is at least a 30% chance that the pessimistic scenario unfolds instead of the optimistic one, or — more precisely — that the optimistic scenario will take too long to play out.

Hence, it is essential that we develop a strategy to reopen the economy for both the optimistic and pessimistic scenarios, as well as for a spectrum of intermediate scenarios:

that is to say, *even if* we fail to achieve near-ubiquitous testing, effective anti-viral treatments, and a vaccine. In this working paper, we discuss a plan to do that.



Two main categories of tests for SARS-CoV-2 infection. RT-PCR tests that examine levels of viral RNA in a patient are very accurate, but only detect current infections, not past ones, and are cumbersome to administer. Antibody tests can detect past infections, but not always current ones, and are less accurate than RT-PCR. (Graphic: Patel et al., mBio 11:e00722–20.)

Ubiquitous testing may be difficult to achieve in the near term

There are two principal kinds of tests for SARS-CoV-2: antibody-based or *serology* tests that detect if a patient has developed antibodies to the virus; and reverse transcriptase polymerase chain reaction (RT-PCR) tests, which measure viral RNA levels in a patient's nasal secretions. Both forms of testing have significant technical limitations.

Statistically speaking, most antibody-based tests currently yield too many *false negative* cases, in which infected people go undetected, to be useful for population-wide surveillance.

Most patients only begin developing detectable levels of antibodies between 7–11 days *after* exposure to SARS-CoV-2. Hence, people who have yet to test positive on serology can in fact be infected and be infecting others.

For example, the latest IgG antibody test from Abbott Laboratories is best at detecting the presence of antibodies two weeks after a patient complains of COVID-19 symptoms, but can yield a high false negative rate, or low *sensitivity*, before then, dropping down to 50% three days after COVID-19 symptoms. On top of that, there is some evidence that many people infected with SARS-CoV-2 do not ever develop detectable levels of anti-coronavirus antibodies.

SARS-CoV-2 antibody tests will also need to reach a specificity, or true negative rate, above 99.5% to be useful on a mass scale. That is to say, for every 100,000 uninfected people, the test will correctly identify all but 500 of them.

RT-PCR, which measures viral RNA levels in a patient's nasal secretions, has more accuracy, especially at detecting active infections. But RT-PCR is more difficult to scale up quickly, because RT-PCR is more labor-intensive to administer, and is much more expensive than a conventional blood test.

On March 27, Abbott Laboratories announced the emergency use authorization of a PCR-based SARS-CoV-2 test that it can manufacture at a rate of 50,000 per day. That would be a meaningful boost to U.S. testing levels—at the end of April, the U.S. was testing around 200,000 individuals per day, counting both serology and PCR. PCR tests,

however, generally must be administered in clinical settings like a doctor's office or an urgent care clinic. On April 21, LabCorp announced emergency use authorization for an at-home RT-PCR COVID-19 test kit, but due to scalability issues, LabCorp stated that they are only offering the kit to first responders and health care professionals for the time being.



The U.S. is a long way from a comprehensive and accurate testing regime. Total tests—including both antibody and PCR tests, have reached 200,000 per day. Importantly, the total number of tests does not indicate the quality or accuracy of those tests. (Source: The COVID Tracking Project.)

And in order to reach South Korean levels of coronavirus testing, Matthew Harrison estimates that the U.S. will need to administer 1 million tests per day. In order to repeatedly screen the entire population, Nobel laureate economist Paul Romer estimates that the U.S. will need to reach 22 million tests per day.

Antibodies may not be protective

Many commentators are assuming that, for the subset of infected patients who develop antibodies, those antibodies will protect people from being re-infected with SARS-CoV-2. In fact, little is known about whether anti-SARS-CoV-2 antibodies are *neutralizing*; i.e., protective against subsequent infection. "Right now, we have no evidence that the use of a serological test can show that an individual has immunity or is protected from reinfection," said Maria van Kerkhove, the COVID-19 technical lead for the World Health Organization, at an April 17 press conference.

In South Korea, for example, 51 patients who have recovered from COVID-19 have tested positive for possible reinfection. This is not unprecedented; individuals infected with HIV often possess large quantities of anti-HIV antibodies in their serum that have no effect on the HIV virus or the progression of AIDS. People often develop antibodies to the common cold, which is also a coronavirus, but those antibodies rarely confer immunity beyond one year, if at all.

Based on experience with the 2003 SARS pandemic, many experts believe that anti-SARS-CoV-2 antibodies are likely to be at least partially protective. But an absence of complete protection would make it challenging to put workers into high-risk situations. An equally large challenge is that most Americans are unlikely to have been infected by May or June of 2020; hence, over the near- to mid-term, most Americans will remain highly susceptible to this very contagious virus.

Effective anti-viral treatments may take longer to develop

Historically, anti-viral medicines have proven much more difficult to develop than anti-bacterial medicines (a.k.a. antibiotics). While we now have effective medicines for HIV and hepatitis C, these took decades of research to commercialize.

According to the Milken Institute's COVID-19 Treatment and Vaccine Tracker, there are over 150 treatments for COVID-19 in preclinical or clinical trials. While there is great reason to hope that some of these trials will eventually deliver us an effective treatment against the COVID-19 disease, there is no guarantee that such a treatment will arrive soon.

There is preliminary evidence that convalescent serum exchange could help some patients, but there is no definitive evidence at this time, and even if properly randomized trials show benefit, serum exchange will be costly and difficult to scale.

Kevzara, an anti-arthritis agent also known as sarilumab, has been studied in COVID-19 patients, with the hopes that the drug could mitigate the inflammatory process that seems to make COVID-19 worse in many patients. But Kevzara manufacturers Regeneron and Sanofi announced on April 27 that the drug failed to demonstrate a benefit to patients.

Direct anti-viral treatments also have their drawbacks. On April 16, Adam Feuerstein and Matthew Herper of STAT obtained a confidential recording from a videoconference among University of Chicago clinicians who are participating in a clinical trial of remdesivir, a potential anti-viral treatment for SARS-CoV-2 developed by Gilead Sciences. The physicians expressed hope that remdesivir was helping to rapidly resolve COVID-19 symptoms in their patients. But optimistic reports from physicians at a single site of a clinical trial do not necessarily translate into full-fledged success for the broader study.

Indeed, a fuller picture of the remdesivir trial showed no benefit for severe COVID-19 patients. A greater proportion of remdesivir patients died at 28 days (13.9 percent) than placebo patients (12.8 percent), though this was not a statistically significant finding. A National Institutes of Health study of less severe patients found a modest but statistically significant benefit in recovery from hospitalization, with remdesivir patients recovering in 11 days on average vs. 15 for placebo.

On the basis of this somewhat positive result, the FDA issued an Emergency Use Authorization for remdesivir, and Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, declared remdesivir the "standard of care" for COVID-19 hospitalizations. Paradoxically, deploying remdesivir in all hospitalized COVID-19

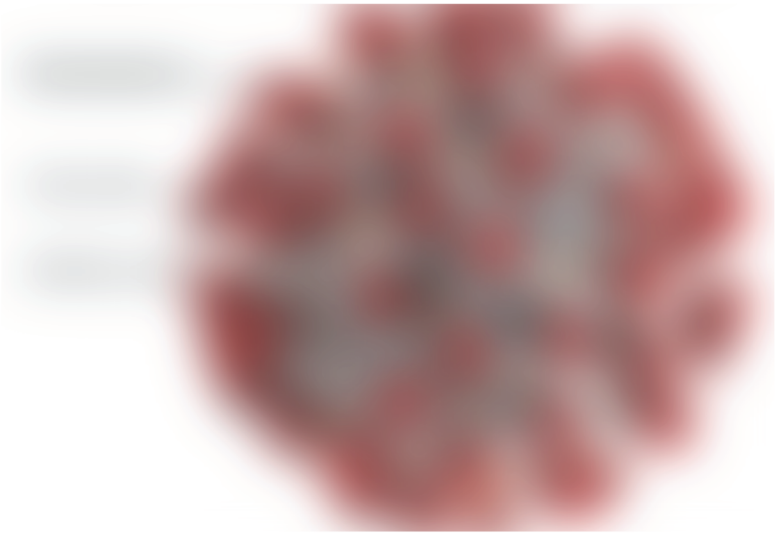
patients will make it harder to conduct clinical trials of more effective agents that will no longer be compared to placebo.

Vaccines may never arrive

While there have been several attempts, a successful vaccine has never been developed against a deadly coronavirus, including SARS-CoV-2 predecessors MERS (2012) and SARS-CoV-1 (2003). And while the biopharmaceutical industry is placing an extraordinary effort into developing a SARS-CoV-2 vaccine, effort alone is no guarantee of success; witness our failure to develop vaccines for HIV or hepatitis C. Indeed, the fastest viral vaccine development program ever was for the Ebola vaccine, which took five years.

A 12 to 18 month timeline for a SARS-CoV-2 vaccine is highly unrealistic. 12 to 18 years is more typical. After nearly 40 years of effort, we have failed to produce a vaccine to the human immunodeficiency virus (HIV). No one has ever developed a vaccine against a deadly coronavirus. (Graphic: The New York Times.)

Most SARS-CoV-2 vaccine developers are targeting the *spike glycoproteins* that dot the surface of the spherical coronavirus particle. But glycoproteins—a combination of sugar and protein molecules—are especially good at evading the human immune response.



It may prove difficult to develop a vaccine for SARS-CoV-2. Coronavirus vaccine developers are primarily targeting spike glycoproteins (S) that reside on the surface of SARS-CoV-2. But viruses deploy glycoproteins because they are better at evading the human immune response. (FREOPP graphic adapted from the Centers for Disease Control and Prevention.)

Americans are optimistic by nature, and the public is well within its rights to hope for the best. But policymakers must prepare for the worst. And that means that we must consider options for reopening the economy in a world in which we have not completely controlled the COVID-19 pandemic.

Time is of the essence

Moody's Analytics estimates that in only a few weeks' time, stay-at-home orders have reduced U.S. economic output by 29 percent. Congress has spent over $2 trillion, and the Federal Reserve even more, to prop up the economy merely through the month of April.



More than one-third of the U.S. economy is already off-line. Research by Moody's Analytics indicates that as of April 6, 29 percent of U.S. GDP was off-line solely due to business closures. Economic output has decreased further due to second-order effects of those closures and stay-at-home policies. (Graphic: The Wall Street Journal.)

A 2016 study by the JPMorgan Chase Institute found that "most small businesses hold a level of cash reserves that would provide an insufficient cushion in the face of a significant economic downturn or other disruption," with the median small business holding 27 days' worth of cash in reserve.





Small businesses are running out of time. The median small business has 27 days' worth of operating cash in reserve, with 75% of businesses holding fewer than 62 days' worth. (Source: JPMorgan Chase Institute.)

The lockdown has profoundly impacted hourly-wage workers, the most vulnerable workers in our economy. An analysis of timecard data from Homebase by researchers at the University of Chicago's Rustandy Center for Social Sector Innovation has found that hourly workers in all sectors have seen significant declines in available work, with beauty, personal care, leisure, and entertainment nearing zero.



Work by hourly employees has collapsed. An analysis by Homebase, a timecard platform, indicates that the number of hourly-wage employees in small businesses going to work dropped by two-thirds between January and March 2020. (Source: Homebase).

All hourly-wage sectors have been affected by the lockdown. All sectors have been affected, but especially those related to travel and retail-facing businesses such as beauty, personal care, leisure, and entertainment. Even the least-affected sectors, like home and repair, have seen drops of 50%. (Source: Alexander Bartik et al., University of Chicago.)

The good news is that there are ways to get more of the economy back on line while we continue to fight to flatten the COVID-19 curve.

Some commentators have propagated a dichotomy in which we can only improve public health through a total shutdown of the economy, and we can only improve the economy —in the near term—by sacrificing public health. This dichotomy is false. New technologies and emerging evidence regarding the epidemiology of COVID-19 will enable Americans to adopt a new strategy which can restore much of the U.S. economy without overly endangering public health.

Some commentators have propagated a dichotomy in which we can only improve public health through a total shutdown of the economy, and we can only

improve the economy — in the near term — by sacrificing public health. This dichotomy is false.

Healthy Americans under 65 face lower mortality risks

While people of all ages have succumbed to COVID-19, there is considerable preliminary evidence that infection by SARS-CoV-2 is especially lethal in the elderly, especially in those who have preexisting conditions, such as cardiovascular disease, high blood pressure, diabetes, obesity, kidney failure, and immunodeficiency. Those between the ages of 40 and 65 appear to also be at risk if they have preexisting conditions.

According to the Centers for Disease Control and Prevention, the risk of death from COVID-19 is far greater in the elderly than it is for younger individuals. As of April 17, there have been 129 deaths associated with COVID-19 among Americans below the age of 35, and only 16 deaths among those below the age of 15. By contrast, there have been over 10,000 deaths associated with COVID-19 among those over 65: 78 percent of the U.S. total.



The risk of death from COVID-19 is far higher in the elderly than in younger Americans. According to data from the Centers for Disease Control and Prevention, there have been 9 deaths associated with COVID-19 per million people among those aged 25 to 54, whereas there have been 194 deaths per million among those over 65: a 22-fold difference. Note that not all COVID-19 deaths reported elsewhere are counted by CDC, and that not all CDC-counted deaths were caused by COVID-19; some of these individuals died from other causes, but tested positive for SARS-CoV-2 antibodies. (Graphic: A. Roy / FREOPP.)

This pattern has been found consistently all over the world, and suggests that we can do more than we are doing right now to bring low-risk populations back to work: in particular, healthy people of working age. It should soon be possible to study carefully the attributes of higher-risk patients on dimensions other than age and health status, in order to increase the number of people who can safely work. For example, there appears to be evidence that men are more at risk than women, and over time, we may find that certain genetic profiles confer higher or lower risk.

To be clear, this is not to say that there is no risk to younger individuals from COVID-19, but rather to suggest that the human benefits of reopening the economy with younger individuals is likely worth that risk. An April 9 survey by Data for Progress found that 52 percent of American voters under 45 have "already lost their job, been furloughed, placed on temporary leave, or had [their] hours reduced." While the elderly are disproportionately affected by the COVID-19 disease, the non-elderly have been disproportionately affected by the economic consequences of our policy response.

Controlling the spread of COVID-19

In combination with targeted quarantines of infected individuals, "contact tracing," a long-standing public health technique, can help us slow the spread of COVID-19 while we still have limited testing capacity.

Contact tracing involves interviewing a known infected patient; identifying all of the people whom that patient has been in contact with; alerting those individuals that they may be at risk; and then testing, treating, and/or isolating these other at-risk individuals.

Asian countries like Singapore, Taiwan, and South Korea have substantially upgraded contact tracing by incorporating geolocation data from patients' Bluetooth and/or GPS-enabled smartphones.

On April 10, Apple and Google announced that they had agreed to collaborate on "application programming interfaces (APIs) and operating system-level technology to assist in enabling contact tracing" and also a "Bluetooth-based contact tracing platform." The Apple-Google effort could dramatically accelerate the ability of third parties, including public health authorities, to develop smartphone apps that can establish nationwide contact tracing.

It will be important to ensure that contact tracing adheres to U.S. privacy laws, including the California Consumer Privacy Act. The American Civil Liberties Union has described the Apple-Google effort as one "that appears to mitigate the worst privacy and centralization risks," because of its Bluetooth-based approach. But while Bluetooth is a

superior approach from a privacy standpoint, it is not completely accurate, because two individuals could be defined as "connected" via Bluetooth even if they are in separate rooms without any contact with each other.

We estimate that if 50 percent of the population uses these apps, we can achieve sufficiently robust contact tracing. We believe that the government should create powerful incentives to make it very easy for infected contacts to participate and self-quarantine, by providing income relief and accommodation when necessary in order to break the chain of transmission. Federal and state authorities can supplement technology-based contact tracing by also increasing funding for the traditional personal interview-based approach.

Effective contact tracing may only require a modest ramp-up of testing from current levels. An April 7 paper published by Mark McClellan and colleagues at the Duke Margolis Center for Health Policy estimates preliminarily that "a national capacity of at least 750,000 tests per week [will] allow for isolation and contact tracing." 750,000 per week is only slightly above mid-April U.S. levels of 100,000 per day, although present testing capacity relies too heavily on antibody assays instead of RT-PCR.

A new strategy for reopening the economy

This combination of factors—(1) the significant possibility of a pessimistic scenario, in which the spread of the virus cannot be completely contained in the near term; (2) the heavy skew of poor health outcomes and death from COVID-19 disease toward the elderly and those with chronic disease; and (3) new tools for contact tracing and quarantines—lead us to propose a new strategy for bringing Americans back to work and restoring as much of the U.S. economy as possible:

- ***Reopen pre-K and K-12 schools.*** While COVID-19 hospitalization and death rates among school-aged children are greater than zero, they are sufficiently low to justify the reopening of schools, preschools, and child care centers. Students who live with high-risk individuals, such as the elderly and those with chronic disease, and/or are in regular close contact with high-risk individuals, should remain at home, as should high-risk teachers and staff. Schools should administer deep-cleaning techniques on a daily basis in order to minimize the spread of SARS-CoV-2, and adopt other public health best practices, such as routine hand-washing. Schools should consider

grouping cohorts of students together, and reorganizing staff so as to reduce contacts per student per day. Reopening schools will help us avoid widening educational inequities in the U.S., and enable more parents of school-aged children to work productively. Public primary and secondary schools should consider making up for lost time by completing the spring semester in the summer months. California Gov. Gavin Newsom, for example, is considering starting the 2020–21 school year in July. For children who must remain at home, due to their relationship with high-risk individuals, state and local governments should ensure access to high-quality learning options, including reliable internet access and options for virtual instruction, such as the "inverted classroom" model in which lectures are recorded, and teacher time is invested in interactive tutoring. In particular, states should take the lead in planning virtual curricula for all K-12 students in their districts who need to stay home. Schools should also establish continuity plans in case the 2020–21 school year is disrupted by a prolonged outbreak.

- ***Lift stay-at-home orders for most non-elderly individuals.*** Healthy individuals under the age of 65 who are not in regular contact with high-risk individuals should be allowed by state governments to return to work, even if they work at "non-essential" businesses. Individuals between the ages of 40 and 65 should consider continuing to stay home if they have any underlying conditions that make them more susceptible to death or hospitalization with COVID-19, such as cardiovascular disease, high blood pressure, diabetes, severe asthma, chronic obstructive pulmonary disease (COPD), kidney failure, severe liver disease, immunodeficiency, and malignant cancer. It is worth noting that a large percentage of the over-40 population has one of these conditions, and so it will be essential to monitor COVID-19 cases over time for evidence that helps us narrow the categories of risk, and also evidence regarding the relationship between positive antibody tests and immunity. State officials should strongly encourage individuals returning to work to download and deploy contact tracing apps that meet U.S. privacy standards and have the potential for sufficiently widespread use.

- ***Reopen safe, but "non-essential" businesses.*** For example, car washes may not be "essential" in the way that hospitals are, but drive-through car washes require no social interaction and do not facilitate person-to-person viral transmission. States and localities should be responsive to businesses that can operate safely in a

pandemic environment, regardless of whether or not their workforce includes elderly or at-risk populations.

- ***Incentivize employers to deploy RT-PCR testing at work.*** Congress should offer a $300-per-test tax credit — roughly equivalent to the cost of an RT-PCR test — for businesses that administer RT-PCR tests to their workers, and grant employers safe harbor from liability for administering these tests. Workplace testing will accelerate re-employment, and also increase consumer confidence in retail businesses that institute universal testing. A fixed-dollar tax credit will incentivize employers to shop for the most cost-effective testing platform, and incentive price competition among test suppliers.

- ***Incentivize consumers to use contact tracing apps.*** Similarly, Congress could offer a $50 tax credit to consumers who download a certified contact tracing app that meets agreed-upon standards of privacy and robustness.

- ***Continue to prohibit large group gatherings.*** To reduce risk of the U.S. relapsing into rampant transmission, states should continue to prohibit large group gatherings like sporting events, concerts, conventions, and theme parks. High risk locations like bars, nightclubs, and gyms should remain closed until infection reproduction rates, as measured by Ro, decline below 1. States and localities should allow restaurants to reopen, but with seating arrangements that enable physical distancing, and actively estimate Ro in localities and counties.

- ***Carefully reopen passenger air and Amtrak travel.*** In order to reduce the risk of spreading the novel coronavirus to other individuals on passenger flights and Amtrak trains, Amtrak and all airlines should be required to keep middle seats unoccupied, so long as they are receiving aid from Congress to maintain their operations. Airlines should supply passengers with masks and alcohol wipes, and deep-clean each plane after each flight, as some airlines are already doing. Those wishing to engage in air and Amtrak travel should be required to participate in a certified contact tracing app, and airlines should test their flight crew as often as possible—at least once or twice weekly—by RT-PCR to confirm the absence of active infections. Once scaled-up testing is feasible, passengers should be required to demonstrate at check-in that they have tested negative for SARS-CoV-2 with an FDA-approved RT-PCR test and attest that they have not had any symptoms within the

last two weeks. If antibodies are ultimately shown to be protective, proof of anti-SARS-CoV-2 antibodies could also suffice for boarding. Localities could deploy these measures for subways, buses, and commuter rail, where feasible. Since carriers will have an economic incentive to increase their passenger loads, Congress should appropriate funds to help them facilitate passenger testing. As a supplemental testing measure, the Transportation Security Administration should work with airports to ensure that airport scanners are configured to detect passengers with unusually high temperatures, as fever can be a sign of SARS-CoV-2 infection.

- ***Grant safe harbor to states that restrict interstate travel.*** It may become necessary for state governments to restrict Americans from entering their jurisdictions by car from a bordering state where a COVID-19 outbreak has occurred. For example, on March 29, in response to a COVID-19 outbreak in New Orleans, Texas Gov. Greg Abbott signed an executive order requiring those entering Texas by road from Louisiana to enter quarantine for 14 days while in Texas. Under the U.S. Constitution, regulation of interstate commerce is the domain of the federal government; hence, it may be worthwhile for Congress to grant a temporary safe harbor to states that restrict travel due to COVID-19, so as to ensure that such measures are not overturned in litigation.

- ***Prioritize testing in high-risk sectors.*** As testing ramps up, it will be essential to ensure that people working or living in high-risk settings have access to FDA-approved tests. These include health care workers; hospital patients; those working at essential businesses; and those working or living in high-risk settings such as nursing homes, rehabilitation facilities, jails, and prisons. In addition, the FDA should do everything it can to make home-based RT-PCR testing feasible, so that we can quickly diagnose acute infections, minimizing the number of exposed contacts.

- ***Contract with empty hotels to house COVID-19 patients.*** State governments should contract with hotel owners to house coronavirus-infected patients who have no alternative to living at home. Quarantined housing can especially help those who live with someone in a high-risk cohort, or in a nursing home.

- ***Minimize non-essential inpatient admissions.*** There is considerable evidence, compiled here by Jonathan Tepper, that *nosocomial infections*—those spreading within a hospital—are a significant contributor to the COVID-19 outbreak. Federal

and state authorities should work with clinicians and acute care facilities to ensure that as many patients as possible are cared for through virtual visits and sent to outpatient facilities.

- ***Develop community testing strategies.*** As the Santa Clara serology study demonstrated, it is essential to understand the true prevalence of SARS-CoV-2 infection rates in the community, so as to understand the true danger of infection. Public health officials should build on strategic plans for broad-based RT-PCR and antibody testing so as to fully understand seroprevalence rates. Such testing might involve community drive-in sites, workplace sites, or physician offices and pharmacies. Insurers and physicians should work together to ensure that every patient that goes in for an annual physical exam is tested for coronaviral RNA and antibodies, with no cost-sharing for the patient.

- ***Incentivize states to grant reciprocity to physicians with out-of-state licenses, and liberalize scope-of-practice regulations.*** Each U.S. state has its own system for licensing physicians, which creates artificial barriers to the movement of physicians to areas of need: a barrier that becomes a crisis during pandemics. Congress should reserve some portion of federal health care aid to states that enact laws that enable any physician licensed in another U.S. state to practice under that license within its jurisdiction. Removing these barriers should be simple; health care startup Merit, for example, has created a verified identity platform that can enable cross-state reciprocal licensure. Similarly, Congress should reward states that allow nurse practitioners, physician assistants, nurse anesthetists, and other physician extenders to practice to the top of their licenses without supervision from a physician. Today, many states have "scope of practice" laws that arbitrarily restrict these health care professionals from performing services they are well-trained to do.

- ***Continue to build up ICU, ventilator, personal protective equipment (PPE), and N95 mask capacity.*** The U.S. should continue to build up its capacity to treat patients with acute respiratory syndromes, in order to ensure that a second wave of infections does not destabilize our health care infrastructure.

A new multi-risk susceptible-infected-recovered model (MR-SIR) developed by four MIT economists finds that "semi-targeted policies that simply apply a strict lockdown on the oldest group can achieve the majority of the gains from fully-targeted policies," while

roughly halving the economic damage. "The reason is that, once the most vulnerable group is protected, the other groups can be reincorporated into the economy more quickly." And low-density localities with plenty of excess ICU capacity may find that even targeted lockdowns need not be strict, so long at-risk individuals continue to practice basic safety measures such as hand washing and physical distancing.

Repairing the damage already done

Central to the new strategy we are proposing is the fact that the lockdown has caused staggering economic and human damage in just a short time. The stimulus bills passed by Congress may achieve some good, especially those elements that help small businesses pay their workers during the stay-at-home period. But others are poorly targeted, such as the indiscriminate $1,200 checks being sent to most Americans, regardless of COVID-related need.

Still others—like costly employer mandates that make it even more difficult to retain workers—are actually counterproductive. For example, on March 13, Congress passed the Families First Coronavirus Response Act, which contains a poorly-designed requirement that employers offer workers 12 weeks of paid sick leave, partially offset by a complex and cumbersome tax credit on the back end. Most large businesses already offer paid sick leave, but smaller businesses with limited cash cushions will face additional pressure under the mandate to lay off workers and close their doors.

Policymakers in Washington are actively considering additional stimulus bills, and state governments continue to look for ways to aid their communities. These additional vehicles could be used to consider the below policies:

- ***Health reinsurance to fund the cost of care for the sick.*** Reinsurance, which works like an invisible high risk pool, can be used to directly fund the costs of caring for sick individuals such as those with COVID-19. Congress should fund a reinsurance pool of $20 billion per year for the individual insurance market, so that those who have lost their jobs have the opportunity to find affordable premiums in these alternative markets.
- ***Reduce seniors' out-of-pocket exposure to prescription drug costs.*** The Senate Finance Committee has reported out a package of reforms that would cap out-of-pocket costs in the Medicare prescription drug benefit, while also reducing overall

Medicare spending by $100 billion over 10 years. These savings would help offset increased spending on reinsurance and other programs.

- ***Provide additional support to high-risk populations.*** Unless we successfully develop a vaccine or population-level immunity, people over 65 and the other high-risk populations discussed above will not be able to work and participate fully in society. Congress should provide income relief for non-retired individuals who cannot safely work, and authorities should facilitate social support through mechanisms like touchless food delivery, telemedicine, and virtual mental health care.

- ***Rescind mandatory discharges of COVID-19 patients to nursing homes.*** In March, the New York State Department of Health issued a directive forcing nursing homes to accept patients who had been discharged from hospitals after being infected with SARS-CoV-2. This mandate exacerbated the outbreak of COVID-19 in New York and neighboring states. Such mandates should be rescinded, and replaced with methods that help seniors recover without putting nursing home residents at risk.

- ***Invest in health care data exchanges among—and within—states.*** COVID-19 has revealed enormous gaps in health care information, hindering our ability to respond effectively to the pandemic. Most states have built homegrown spreadsheets to track hospital occupancy, resources like ventilators and PPE, and population-level infection and diagnostic data. These spreadsheets should be converted into lasting connections, APIs, and data feeds, so that when future outbreaks occur, the health system will be far more responsive and adaptable. In 2010, the HITECH Act created requirements for electronic health records to be able to exchange hospital occupancy data as well as funding to create state information exchanges, but many states still lack this connectivity.

- ***Large states with major metropolises should build independent emergency medical stockpiles.*** Congress never intended for the Strategic National Stockpile (SNS) to address a prolonged nationwide pandemic. Instead, the SNS was designed to serve as a resource for more regionalized bioterror attacks and natural disasters, and as a "fallback" once private sector and state supplies were exhausted. Alarmingly, nearly 90 percent of the SNS's personal protective equipment (PPE) became depleted by early April. States with large urban centers, such as New York,

Florida, California, Pennsylvania, and Illinois, should consider building independent stockpiles of ventilators and PPE based on their own needs.

- ***Re-envision management of the Strategic National Stockpile and federal contracts for emergency preparedness.*** Reporting from ProPublica and the *New York Times* revealed how myriad missteps and red tape led to a national shortage of ventilators. In 2006, federal officials sought to procure 70,000 private-sector ventilators over ten years; in March 2020, only 12,700 were available for distribution. It will be important for the executive branch to objectively assess these bureaucratic barriers, and facilitate interagency cooperation regarding emergency preparedness contracts.

- ***Accelerate highway infrastructure projects.*** States and localities should take advantage of reduced vehicle traffic to accelerate highway infrastructure projects. Acceleration could provide a near-term economic stimulus, by employing more people, and also the mid-term recovery, by reducing traffic congestion.

- ***Provide resources and support to schools and education providers that remain open during the summer.*** Disparities in educational outcomes are at risk of widening during this period of school closure, because low-income parents lack the resources to provide educational opportunities to their children outside of school. Congress and state governments can help financially support schools and education service providers that elect to remain open in the summer to make up for lost time, or to otherwise ensure that children have equal access to high-quality learning options outside of school where needed. If teacher union contracts prevent schools from remaining open during the summer months, federal and/or state COVID-19 relief funding could be applied to Education Savings Accounts that families could use to purchase online learning services.

- ***Address the potential humanitarian crisis in America's jails and prisons.*** As Jonathan Blanks has described, correctional facilities were not built to enable physical distancing. Congress should provide additional funding to ensure that federal, state, and local facilities have the means to test inmates and workers for the novel coronavirus; quarantine those who test positive; and consider early parole or release for SARS-CoV-2-negative individuals who meet criteria for non-violence and risk.

Who benefits from partially reopening schools and the economy?

Our plan is designed to maximize America's ability to reopen our economy while protecting public health. But the path we recommend has important limitations.

For example, our proposal to reopen schools to children who do not live with elderly or at-risk individuals means that some children will have to stay home. Chronic diseases are more highly prevalent among low-income populations and African-Americans. On the flip side, today, there are single mothers who cannot work because it would force them to leave their children at home, alone.

We believe that the benefits to those children and parents outweigh the disadvantages of a partial reopening of schools. However, it is important for states and localities to do everything they can to facilitate virtual learning for those who remain home.

A partial reopening of the workplace may involve similar temporary disparities. A broad-based program of workplace testing can help mitigate this problem. And, again, continuing the economic lockdown with no effort at reopening will have even worse effects on disadvantaged communities and low-income households.

There is ample evidence that significant increases in unemployment lead to an increase in death. A 1 percentage-point rise in the U.S. unemployment rate is associated with a 6% increase in the chance of dying within the next year. In heart failure patients alone, unemployment is associated with a 50% higher risk of death.

These economic effects are separate from the direct effects on the health care system of neglecting or avoiding needed care. We do not yet know how many Americans have foregone health care unrelated to COVID-19, but the preliminary evidence is significant. Organ donations and transplantations have decreased precipitously, harming those with end-stage liver disease. In North Carolina, far fewer people are visiting emergency rooms, which may be an indication that ordinary conditions like heart attacks are not being adequately treated. Disruptions in cancer care may significantly increase mortality. Many clinical trials for new treatments have ground to a halt. To date, no one has attempted a systematic analysis of these costs.

Learn from history, but rely on new evidence

Much of the traditional paradigm for managing pandemics comes from our historical experiences, especially the 1918 Spanish flu pandemic. But COVID-19 is not the flu, and those whose policy recommendations are primarily based on the 1918 experience will ignore important options for reopening the economy.

SARS-CoV-2 may not as easily lend itself to vaccine production as influenza does. And, relative to the flu, the COVID-19 disease far more heavily impacts the elderly and those with chronic diseases. The primary reason for the lockdown was a fear that COVID-19 would overwhelm U.S. hospital capacity; instead, today, most U.S. hospitals are seeing unusually low utilization.

In other words, while we must learn from our history, we must not be wedded to it. Instead, we must focus on the specific biology of the virus at hand, and the specific evidence of the disease at hand. If we do these things, we will find that we have better options to improve public health and reopen the economy than many have believed.

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About the authors

Lanhee Chen, Ph.D., is a member of FREOPP's Board of Directors. He is the David and Diane Steffy Research Fellow at the Hoover Institution, and Director of Domestic Policy Studies and Lecturer in Stanford's Public Policy Program. In 2012, he served as Mitt Romney's policy director, and was a senior adviser to Marco Rubio's 2016 presidential campaign. During the George W. Bush administration, Chen served as a senior official at the U.S. Department of Health and Human Services.

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Avik Roy is the co-founder and President of FREOPP. He is also the Policy Editor at *Forbes* and a Senior Advisor to the Bipartisan Policy Center. He has advised three

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About FREOPP

The Foundation for Research on Equal Opportunity (FREOPP) is a non-profit, non-partisan think tank focused on expanding economic opportunity to those who least have it, using the tools of individual liberty, free enterprise, and technological innovation. All research conducted by FREOPP considers the impact of public policies and proposed reforms on those with incomes or wealth below the U.S. median. For more information, please visit our Mission page.

FREOPP does not take institutional positions on any specific policy issues, and the views expressed in this paper are solely those of the authors.

Revision history

- ***April 20***: Added minor edits and revisions; added Robert Wachter as a co-author; expanded sections on testing and treatment; added discussion of anecdotal remdesivir data; added CDC data on mortality by age bracket, and a discussion of the Santa Clara County and Los Angeles County serology studies; expanded discussion of air & train travel and public transit; deleted recommendation to

establish temporary hospitals; added section on inequality; added discussion of hospital capacity.

- ***April 26***: Removed discussion of Santa Clara County and Los Angeles County serology studies; revised and expanded proposal to re-open passenger air travel and Amtrak to include subways, buses, and commuter rail.
- ***April 27***: Added supplemental content from the *Wall Street Journal* and *American Wonk*; incorporated latest data on remdesivir and Kevzara.
- ***April 28***: Added figure from the COVID Tracking Project on the number of daily tests completed in the U.S.; added discussion of California's consideration of an expanded 2020–21 school year.
- ***May 5***: Removed recommendation for supplementing Medicare Advantage reinsurance funds; added discussion of NBER paper on targeted lockdowns by Daron Acemoglu *et al.*; updated discussion of remdesivir to include NIAID study and EUA; removed asthma and COPD as risk factors associated with COVID-19 morbidity and mortality (cardiovascular risk factors appear to be more important than pulmonary ones); added analysis of Homebase hourly wage data.

Thanks to Lanhee Chen.

Policy Covid 19 Coronavirus Infectious Disease Economics

Relying on Foreign Drugs Is Dangerous

Atlas, Scott W; McMaster, H R . Wall Street Journal , Eastern edition; New York, N.Y. [New York, N.Y]29 Apr 2020: A.19.

ProQuest document link

FULL TEXT

Health security is critical to national security. The Covid-19 pandemic is a moment to re-evaluate U.S. dependence on China for pharmaceutical ingredients and to solidify the pharmaceutical supply chain in advance of proliferating threats.

Americans filled the equivalent of 5.8 billion 30-day prescriptions in 2018. That doesn't count the hundreds of millions of vaccinations administered annually. In 2019 the Food and Drug Administration estimated that 40% of finished medications and 80% of active pharmaceutical ingredients were manufactured overseas, mainly in China and India.

While U.S. pharmaceutical companies may preserve redundancy in their sources for patented drugs, the generic drug business, which accounts for more than 90% of all U.S. prescriptions, prioritizes low cost over supply-chain resiliency. Most generics, including antibiotics, are imported from India -- and India imports some 70% of its active ingredients from China. America needs to understand and diversify sources of supply, as well as maintain a strategic reserve of antibiotics and the key drugs for the most prevalent serious diseases.

Beyond scale and complexity, details on drug manufacturing are opaque and complex. The Food and Drug Administration requires country-of-origin markings, but the U.S. Court of Appeals for the Federal Circuit ruled in February that processing ingredients into tablets in the U.S. is enough to constitute "manufacturing." A drug made into tablets in the U.S. with active ingredients from India may list only the U.S. as "principal place of business" for FDA purposes. Labeling should be straightforward, but not at the sacrifice of security.

Protecting the drug supply also requires guarding against poor-quality and counterfeit medications, a repeated problem of medications from China in particular. Although the FDA conducts 3,500 inspections of generic plants a year, additional measures are necessary. More than half of FDA inspections are conducted on foreign manufacturers, but only a small minority are done unannounced in China and India. The U.S. government should require far greater on-site access and increase the funding and staff to implement that policy. It is also time to stop viewing the reimportation of drugs as a potential solution without serious downsides.

A strategy to diminish supply-chain risk must also take account of China's dependence on U.S. drugs. The U.S. is the world's predominant source of pharmaceutical innovation, including new cancer drugs, next-generation biopharmaceuticals and tests that determine which patients will benefit from those drugs. China is highly reliant on foreign sources of more-expensive brand-name drugs, which make up 90% of overall drug revenues, exporting only 1.2% of all medications in total value; the U.S. is among the top five exporters.

China is deeply dependent on U.S. cancer drugs in particular. Of those launched world-wide from 2013 to 2017, 51 of 54 were available within two years in the U.S. Only two were available in China. Cancer survival in China is only half that in the U.S. The Communist Party recognizes this problem. Its Healthy China 2030 Plan exempts most drugs from taxes and omits U.S. cancer drugs from tariffs placed on other medications in 2019.

China has emphasized generating new pharma patents. China now exceeds the U.S. in published applications, even though the U.S. still leads by a wide margin in patents that are ultimately granted. Mutual dependence on uninterrupted access to critical drugs, among both allies and adversaries, is a vital part of risk mitigation. Leaders should make clear that the U.S. will never withhold pharmaceuticals from other nations for coercive or punitive

purposes, except when faced with hostile actions, such as acts of war.

Perhaps most important, policies must encourage pharma innovation and production. Reducing vulnerability to health threats such as Covid-19 rests on American discovery and competitiveness. While the U.S. leads the world in health-care innovation, this is no reason to be complacent. Congress should strengthen tax incentives for high-risk investments in early stage medtech and life-science companies, including drug development, and target additional incentives to domestic drug manufacturing.

Developing a new drug typically costs more than $2.5 billion and takes more than a decade. Safety standards shouldn't be compromised, but lengthy clinical trials can be streamlined. The FDA should continue the impressive work it began in 2016 to expedite drug approvals. During 2017 and 2018, yearly new drug approvals increased by around 70% relative to the eight years under the Obama administration. Finally, legislators must avoid the temptation to impose price regulation and limit patent protections. These measures delay drug launches, reduce access and crush research and development.

A secure drug supply chain couldn't have made up for the Chinese Communist Party's decision to conceal the threat of Covid-19. But it is essential for mobilizing resources to mitigate the crisis. And the stakes are high, even in normal times. More than 15 million American seniors, or 1 in 3, take five or more medications daily. As the U.S. population ages, society will become even more dependent on drugs indispensable to treating the biggest killers -- heart disease, cancer and stroke. Preventing an interruption of the supply of vital medications that save lives and treat diseases, whether during pandemics or in routine care, is a matter of national security.

Dr. Atlas is a physician. Lt. Gen. McMaster, a retired Army officer, served as White House national security adviser, 2017-18. Both are senior fellows at Stanford University's Hoover Institution.

Credit: By Scott W. Atlas and H.R. McMaster

DETAILS

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LINKS

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EVALUATING THE FEDERAL GOVERNMENT'S PROCUREMENT AND DISTRIBUTION STRATEGIES IN RESPONSE TO THE COVID–19 PANDEMIC

TUESDAY, JUNE 9, 2020

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in room SD–562, Dirksen Senate Office Building, Hon. Ron Johnson, Chairman of the Committee, presiding.

Present: Senators Johnson, Portman, Lankford, Romney, Scott, Hawley, Peters, Carper, Hassan, Harris, Sinema, and Rosen.

OPENING STATEMENT OF CHAIRMAN JOHNSON

Chairman JOHNSON. Good morning. This hearing will come to order.

I want to thank our witnesses, Admiral Brett Giroir, Administrator Peter Gaynor, and Rear Admiral John Polowczyk, first of all, for your service to this Nation. Also, I think on behalf of the Committee, if you can thank the men and women that have worked with you in this, what I think is a pretty tremendous effort, trying to deal with an overwhelming situation. I think as a Nation we all need to be very grateful for all your efforts. I realize you probably have not had too many days off much less hours off, pretty much dealing with this 24/7, and I really truly do appreciate that.

I want to ask for consent to have my written statement entered in the record,[1] and I just want to go through just a couple facts, a little timeline here, just to kind of lay out really how extraordinary and overwhelming this effort has been.

But back on January 21st, not that long ago, we had the first case reported of coronavirus disease 2019 (COVID–19). Eight days later, on January 29th, the administration established the Coronavirus Task Force. At that point in time, we only had five cases, zero deaths. From my standpoint, I am thinking that is pretty forward-looking.

Two days later, President Trump announced travel restrictions on China. That was not a very popular decision, but as Dr. Fauci said, that probably saved many lives and certainly bought us time to be able to flatten the curve to hopefully save additional lives.

[1] The prepared statement of Senator Johnson appears in the Appendix on page 631.

Ten days later, on February 10th, the Federal Emergency Management Agency (FEMA) began assisting the Department of Health and Human Services (HHS). At that point in time, there were 12 cases, still zero deaths. Again, I would think that is pretty forward-looking. February 10th, FEMA is already recognizing this is going to be a real problem here and providing the types of expertise and capability that really only FEMA has in support of HHS' efforts.

About a month later, on March 13th, President Trump declared a national emergency, and basically FEMA was put in charge of the effort. By that time, we had over 2,000 cases and, unfortunately, 47 deaths.

Six days later, on March 19th, Vice President Pence designated FEMA to lead the Federal response to this. At that point we had about 12,000 cases, a couple hundred deaths.

Eleven days later, on March 30th, FEMA announced the Supply Chain Stabilization Task Force. By that time it started exploding. We had 160,000 cases and 3,000 deaths.

I point that out because it is awful easy to sit up here at the dais and Monday morning quarterback. The easiest thing in the world is to be a Monday morning quarterback or armchair quarterback. But when I look through the testimony and I see what has been accomplished, in light of how overwhelming the situation was, how many unknowns there were, how this was a brand-new virus—it was never on Earth; no human had ever experienced it. We had no tests for it; we had to develop all these things from scratch. Again, I just have to say, Well done, you guys did an extraordinary job. Not perfect. We passed $2.9 trillion of financial aid. Far from perfect. Had to be done. We did the best we could do. But I think you guys have really done a tremendous job. As of June 2nd, FEMA has spent $6.3 billion on COVID–19 from the Disaster Relief Fund (DRF).

I was talking to Administrator Gaynor earlier. Probably close to 100,000 employees, and that includes about 40-some thousand National Guard troops, 100,000 people involved in this effort. I had a tough time managing a couple hundred people in my manufacturing plant much less 100,000. So, again, this was a task force, an effort assembled in a very short period of time and really performing pretty well.

We can talk about this later in terms of the data, the charts, but I do appreciate some of the charts you have supplied the Committee. I think you really need to, as much as possible, make that information public. I realize a lot of this is preliminary and you hate publishing data that was not quite right. I get that. I know I have to be able to restrain, but when I look at the five types of personal protective equipment (PPE) that is really vital—N95 masks, gowns, surgical masks, gloves, and face shields—you look at that and it is anywhere from 1.6 to 3.2 times the normal demand as a result of this, because, supply and demand in a normal economy is pretty evenly matched. All of a sudden we had a requirement for double to triple that amount overnight. Coming from a manufacturing base, I realize that that is not very easy. I think what we have been able to do, recognizing that so much of this equipment is sourced overseas, and those countries are grappling with this as well, and there is a global demand for these supplies.

What you were able to do in terms of, for example, sterilizing N95 masks, the airlift operation, really some pretty innovative rapid response, pretty extraordinary effort. I just take my hat off to you. I am not going to Monday morning quarterback.

But I will just conclude by kind of asking the questions that I think need to be asked. As we will see in Administrator Gaynor's testimony, he will talk about, as in any Federal disaster, the proper course of action is local effort first, supported by the State, finally supported by the Federal Government. This was so overwhelming. The Federal Government had to take in many respects a real lead, and I think they have. But I think the questions we need to be asking, particularly in this hearing, which is about the National Stockpile. We will also be holding hearings on our supply chain vulnerabilities, whether it comes to medical devices, medical equipment, PPE, and certainly pharmaceuticals. That is a big subject but an incredibly important subject. This one I think is really going to be more targeted on your response, what we need to be doing to respond to potentially a fall surge or a future pandemic when it comes to the National Stockpile, because let us face it, we were not ready. We just were not ready. Again, blame us all. As a government, as a Nation, we were not ready for this. We need to learn the lessons we need to be ready in the future.

So the questions we have to ask: What should the items in the National Stockpile, what should those be? Who should hold them? Should it be at the local level? Should it be at the State level? Should it be the Federal? Should this be going through normal general commercial distributors supported by Federal or State or local funding?

So what should those inventory levels be of those items? Who should hold them? How do we take care of the inventory turns? You cannot just buy a billion N95 masks, walk away for 10 years, and expect that those things are not going to degrade. So we have to have some process of keeping a stockpile. Maybe we use private sector warehouses, and we just say, in the regional warehouses we maintain an inventory that you continue to turn. So if your standard inventory is a million masks, maybe we support financially a 2 million inventory level. Those are the types of things. And then, of course, it always gets down to who should pay.

But as is always the case when I discuss FEMA, I will continue to emphasize it starts at the local level. When the locals cannot handle it, the State steps in. When the State is overwhelmed, the Federal Government has to be ready to assist and support, and I do believe in this case you truly were.

So, again, I thank you and the men and women that serve in your agencies.

With that, I will turn it over to Senator Peters.

OPENING STATEMENT OF SENATOR PETERS[1]

Senator PETERS. Thank you, Mr. Chairman, and thank you to our witnesses for being here today and for your service to our country in this urgent time of need.

[1] The prepared statement of Senator Peters appears in the Appendix on page 632.

In our lifetimes, we have encountered few, if any, challenges of the size and scope of the coronavirus pandemic. Addressing this pandemic is clearly a monumental task, and the Federal Government's failure to adequately prepare and quickly respond to this crisis has led to costly and tragic missteps.

We have now lost more than 110,000 Americans to this pandemic—loved ones whose lives will never be replaced. As families across the country grieve these unimaginable losses, we must make every effort to examine how we reached this heartbreaking point and ensure that we are better prepared to protect Americans from the challenges of the future, including a potential second wave.

My home State of Michigan has been hit especially hard among our State's minority communities, in particular, in cities like Detroit. This pandemic has highlighted longstanding disparities and health inequities facing minority communities. And when disasters strike, minority communities often suffer some of the most severe impacts but are among the last to receive assistance.

This crisis has served as a chilling reminder that we must do more to protect our most vulnerable and underserved communities going forward.

A rigorous examination of the Federal Government's response will help ensure that successes can be replicated and any shortcomings can be addressed. These efforts are critical to containing this deadly virus and to continuing the safe reopening of our economy.

In Michigan and across the country, Americans are eager to get back to work. But many industries are still struggling to access the personal protective equipment that they need to reopen safely. Americans need these items so that they have the confidence that they are safe when visiting a restaurant or a store.

I warned in a 2019 report that we faced a grave national security risk because of our overreliance on foreign manufacturers for medical supplies, including those manufactured in China. The pandemic only intensified those vulnerabilities.

I have heard from manufacturers in Michigan who want to do their part to help produce these critical supplies. Yet the White House was reluctant to fully use its authorities to mobilize private industry. There is no doubt in my mind that this hesitation slowed our response efforts, damaged our economy, and cost American lives.

I greatly appreciate the hard work so far to obtain and distribute supplies to those in great need.

But as our economy continues to reopen, we must redouble our efforts to secure the resources to keep workers and customers safe.

Effectively addressing this pandemic will also require widespread testing. But months into the most severe public health crisis of our lifetimes, we still have more questions than answers about our national testing capability.

Every State in the country has encountered challenges securing the resources to test people. Even now, my home State of Michigan only has the resources to conduct 15,000 tests per day.

Without sufficient testing, we cannot fully understand the extent of the catastrophe or take the necessary precautions to protect our

communities. Moving forward, we must adopt and implement a clear, effective, and comprehensive national testing strategy.

These are just a few of the issues that I hope to discuss with you today. The loss and the heartbreak that we have experienced in this crisis are simply immeasurable, and we must do everything in our power to prevent a return to our most difficult days. The hearing is long overdue, but I am eager to work with you on this vital mission.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator Peters.

It is the tradition of this Committee to swear in witnesses, so if you will all stand and raise your right hand. Do you swear that the testimony you will give before this Committee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Admiral GIROIR. I do.

Mr. GAYNOR. I do.

Admiral POLOWCZYK. I do.

Chairman JOHNSON. Please be seated.

Our first witness is Admiral Brett Giroir. Admiral Giroir currently serves as the Assistant Secretary for Health at the Department of Health and Human Services. In his capacity as Assistant Secretary, he is the principal medical and science adviser to the HHS Secretary. Admiral Giroir has served as a member of the Unified Coordination Group (UCG) and was designated as the Federal Coordinator for COVID–19 testing. Prior to joining HHS, he served as Chief Executive Officer (CEO) of ViraCyte, LLC, and executive vice president and CEO of Texas A&M's Health Science Center. Admiral Giroir.

TESTIMONY OF THE HONORABLE ADMIRAL BRETT P. GIROIR, M.D.,[1] ASSISTANT SECRETARY FOR HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Admiral GIROIR. Thank you, Chairman Johnson, Ranking Member Peters, and distinguished Members of the Committee. I am honored to be here to update you on our Nation's progress regarding COVID–19 testing and to provide details about the close coordination between HHS and FEMA during the pandemic response.

On March 12th, Secretary Azar requested that I lead COVID–19 testing efforts within HHS, including oversight and coordination of the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) with regard to testing. Since then, the Nation has performed more than 20 million COVID–19 tests, now on pace to perform at least 3 million per week. The Nation's capability will continue to increase so that we will have the capacity to perform 40 to 50 million tests per month by September.

To meet the complex public health challenges, we implemented a phased approach that enabled the Nation to meet the specific testing needs at each stage of the pandemic, especially now during reopening, when the need for testing is the greatest.

In early March, HHS and FEMA developed and implemented 41 community-based drive-through testing sites in locations prioritized by the CDC in collaboration with State and local partners. These

[1] The prepared statement of Admiral Giroir appears in the Appendix on page 634.

sites have tested over 245,000 high-risk individuals and served as prototypes that have been duplicated multifold.

Next, building on these prototypes, we leveraged trusted pharmacies to further implement community-based testing. This Federal program is now providing testing at 437 locations in 49 States, and 70 percent of these locations are in communities with moderate to high social vulnerability by the CDC's Social Vulnerability Index. This program has tested over 516,000 individuals.

To further expand safe access to COVID–19 testing, we authorized all licensed pharmacists to order and administer COVID–19 testing under the Public Readiness and Emergency Preparedness (PREP) Act. Over 90 percent of Americans live within 5 miles of a pharmacy.

To meet the truly unprecedented demands, as the Chairman pointed out, for testing supplies, reagents, and laboratory platforms, we secured the global supply chain through a military airbridge. We worked directly with manufacturers to increase domestic production. We collaborated with the private sector and the FDA to validate multiple technologies that expanded existing testing capacity while minimizing the need for PPE. The government secured and prioritized scarce point-of-care testing assets to supply State public health laboratories, the Indian Health Service, and other critical needs. Finally, we used Title III of the Defense Production Act (DPA) to further invest in domestic manufacturing.

These and many other efforts culminated in the current partnerships to support State reopenings and to provide early warning of any new outbreaks. Together we are working with States, territories, and tribal communities to support their testing plans and goals that are evidence-based and adaptable.

Before this experience, I only knew of FEMA as the agency that quite literally rescued my family's future after hurricanes and flooding in Louisiana. Now I have even more respect for the agency, and especially for the people who make it great.

HHS has integrated seamlessly into the FEMA process, working closely with all of our Federal, State, and local partners truly on a daily basis. The National Response Coordination Center (NRCC) has provided invaluable and unparalleled infrastructure, communications, process methodology, and personnel upon which to build an integrated and effective pandemic response, the scale of which has been unequaled in modern history.

I am a member of the Unified Coordinating Group, led by Administrator Gaynor. The UCG meets daily to provide strategic direction, leadership, and collaborative decisionmaking and ensures that all levels of government work together in response to COVID–19. My primary role on the UCG is to advise on and operationalize the full spectrum of public health and science issues and to help prioritize deployment of the U.S. Public Health Service Commissioned Corps, the uniform service that I lead.

And in this regard, I will close by recognizing and expressing my heartfelt gratitude to my fellow officers in the Commissioned Corps; 4,329 men and women have deployed to directly support this response, including to the Diamond Princess cruise ship in Japan, to our military bases repatriating Americans, to our community-based testing sites in international airports, to FEMA and our

task forces, to nursing facilities, and to field hospitals in hard-hit communities across our Nation. I thank each and every one of these officers and their families and on their behalf thank all of you in Congress for supporting our training needs and the establishment of a ready reserve to supplement our ranks during inevitable future national emergencies.

Thank you for the opportunity to provide these remarks.

Chairman JOHNSON. Thank you, Admiral.

Our next witness is Pete Gaynor. Mr. Gaynor currently serves as the Administrator of FEMA. In his capacity as Administrator, he is the principal adviser to the President, Homeland Security Council, and the Secretary of Homeland Security for all matters related to emergency management. He has over a decade of experience at the local, State, and Federal levels in emergency management. Prior to his experience as an emergency manager, he served for 26 years in the United States Marine Corps (USMC). Mr. Gaynor.

TESTIMONY OF THE HONORABLE PETER T. GAYNOR,[1] ADMINISTRATOR, FEDERAL EMERGENCY MANAGEMENT AGENCY, U.S. DEPARTMENT OF HOMELAND SECURITY

Mr. GAYNOR. Good morning, Chairman Johnson, Ranking Member Peters, and distinguished Members of the Committee. My name is Pete Gaynor. I am the FEMA Administrator. Thank you for this opportunity to discuss the actions taken by FEMA to protect the lives of and lessen the impact on the American people during this pandemic.

On behalf of the men and women of FEMA, I would like to begin today by acknowledging and offering my condolences to the loved ones of the exactly 110,949 Americans who have lost their lives to COVID–19. One life lost is one life too many, and our hearts go out to all those who have been affected by the pandemic.

This has been a trying time for our country, and FEMA has been working around the clock to help our Nation respond to this historic and unprecedented global pandemic. As the FEMA Administrator, it has been an honor to work alongside the dedicated men and women of FEMA. Today I want to acknowledge that workforce and our many partners for their commitment to the Nation during this response. This response continues to be one that is locally executed, State managed, and federally supported.

When President Trump made the unprecedented decision to declare a nationwide emergency on March 13th, the entire team has worked tirelessly to make a positive impact, many risking their own health and safety to do so. For the first time in American history, we have a major disaster declaration in every State, territory, the District of Columbia, and one tribe concurrently. Today FEMA is responding to 104 active disasters.

The magnitude of this pandemic has required us to reexamine our past practices, to keep the risk to our staff as low as possible, while refusing to fail in meeting our mission. COVID–19 has been a global crisis with most countries competing for the exact same medical supplies.

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[1] The joint prepared statement of Mr. Gaynor appears in the Appendix on page 645.

Every government across the Nation has been competing for the same resources, such as PPE. To complicate matters further, most PPE is made in Asia, where the virus significantly slowed manufacturing and where U.S. law and authorities only matter so much.

During national disasters FEMA typically manages abundant resources for disasters that are limited in geographic scope and impact. In responding to COVID–19, FEMA has had a much different and difficult task of managing the lack of critical medical supplies and equipment. Rather than managing resources, we are managing shortages.

We have worked tirelessly to find medical supplies and equipment across the globe and rapidly move them to America. We quickly prioritized resources to ensure that locations with the highest risk of COVID–19 cases and deaths would not be in danger of running out of supplies and lifesaving equipment. Using the HHS Strategic National Stockpile (SNS) early on, it quickly became clear the scope and scale of this pandemic went far beyond what the stockpile was designed for. It could not be relied upon as the single solution for pandemic supplies in the United States.

To address these widespread shortages, the Supply Chain Stabilization Task Force was swiftly created by FEMA and its Federal partners, and in less than 10 days, we established an airbridge to expedite critical supplies already purchased and owned by some of the Nation's largest medical distributors, with the goal of providing temporary relief through stabilizing supply chains. This airbridge cut international shipments from 37 days on a ship to just 1 day by air. Since March 29th, we have completed over 200 flights carrying lifesaving supplies to the American public.

In addition to expediting supplies into the United States, the Federal response focused on stabilizing the lives of Americans in many impactful ways. I would like to provide you with a few facts that illustrate FEMA's commitment and speed of delivery to the COVID–19 mission.

Since March 13th, we have provided $6.8 billion in obligations to States for COVID–19-related activities, with the first $1 billion obligated in just 11 days; $27 million in commodities, including emergency food; $17 million in crisis counseling; over $1 billion each to the States of New York and California; $1.4 billion in support of the National Guard and Title 32; the deployment of 5,600 Department of Defense (DOD) Title 10 medical professionals, afloat and ashore, providing critical medical support to numerous hospitals under stress; and supporting the Testing Blueprint, the procurement, and delivery of 13 million swabs and 9 million units of media in just 1 month; the procurement of 16,000 new ventilators with a goal of 110,000 ventilators; through mission assignments to the U.S. Army Corps of Engineers (USACE), built 38 alternative care facilities and deployed 41 Federal medical stations; and, finally, conducted nearly 500 informational engagements with Congress, Governors, mayors, and tribal leaders.

While we continue to respond to COVID–19, we recognize the risk for future outbreaks exist, and we want to ensure we are all using available resources to address these critical shortfalls. To do so, we are utilizing the Defense Production Act to increase the amount of medical equipment manufactured domestically to ensure

our Nation's future preparedness is not overly reliant on foreign producers. This transition will allow FEMA to pivot toward focus on hurricane season and other natural disasters. As part of this pivot, FEMA recently released planning guides for the 2020 hurricane season to help local officials best prepare for disasters within the context of a pandemic.

The Nation continues to count on FEMA to accomplish our mission, and we will do so in accordance with our core values of compassion, fairness, integrity, and respect. This historic response and our preparations for the future will continue to require a whole-of-America effort, and FEMA looks forward to coordinating closely with Congress as we work together to protect the lives of the American people.

I would like to thank the Committee for providing FEMA with the resources to meet these complex mission requirements, and I look forward to any questions you may have. Thank you.

Chairman JOHNSON. Thank you, Administrator Gaynor.

Our final witness is Rear Admiral John Polowczyk. Rear Admiral Polowczyk currently serves as the Vice Director for Logistics for the Joint Chiefs of Staff. In this role he oversees a portfolio of work focused on core logistics capabilities such as supply, distribution, and health services support. He has served in the United States Navy for more than 30 years, largely focusing on managing logistics. Since March, Rear Admiral Polowczyk has led the Federal Government's Supply Chain Stabilization Task Force. Rear Admiral.

TESTIMONY OF REAR ADMIRAL JOHN POLOWCZYK,[1] VICE DIRECTOR FOR LOGISTICS, JOINT CHIEFS OF STAFF, U.S. DEPARTMENT OF DEFENSE

Admiral POLOWCZYK. Good morning, Chairman Johnson, Ranking Member Peters, and distinguished members of the Committee. I am Rear Admiral John Polowczyk——

Good morning, Chairman Johnson, Ranking Member Peters, and distinguished Members of the Committee. I am Rear Admiral John Polowczyk, Vice Director for Logistics, Joint Staff. Thank you for the opportunity to discuss the Federal response to the COVID pandemic and strategies for future planning.

Let me start by offering my condolences to the families and friends who have lost loved ones to this pandemic.

On a personal note, let me share that this pandemic hits close to home, as it did for many Americans. I have two family members working on the health care front lines. My sister is a nurse in Westchester, and my niece is a nurse on Long Island. Through daily communications I am very cognizant of the needs of health care workers and if they are being met.

On March 19th, I was asked to support the management of critical medical supplies needed to combat the pandemic, specifically ventilators, personal protective equipment, and equipment for testing. It was clear the global demand for critical medical supplies could not be met domestically as U.S.-based manufacturing was limited. Upon arrival, I quickly realized the Strategic National Stockpile could not address the Nation's requirement as the bulk

[1] The joint prepared statement of Admiral Polowczyk appear in the Appendix on page 645.

of the stockpile was already being allocated. On March 20th we established the Supply Chain Stabilization Task Force to address the widespread shortfalls amidst the global competition for lifesaving equipment.

The task force consists of over a dozen departments and agencies across the U.S. Government and liaisons from the private sector. I also want to add that the support extended globally, with the Department of State helping track down viable manufacturers around the world. Our goal since the beginning has been to provide medical supplies to where it is needed when it is needed.

A strategy had to be developed and quickly executed to deliver the lifesaving supplies to COVID outbreaks popping up around the country. We made a decision to leverage the strengths of both government and private sector for a whole-of-America approach. To execute this strategy, we developed four lines of effort.

The acceleration and preservation lines of effort were designed for outcomes measured in hours and days while the allocation and expansion lines of effort focused on a longer time horizon. With the shortages in PPE, acceleration of the commercial market was required because we could not wait for shipments of critical resources. Normal distribution methods using maritime shipping could not meet the speed needed to immediately get critical supplies to the point of care.

Project Airbridge is a major focus of this effort and expedited the movement of critical supplies from the global market to locations across the United States. On March 29th the first flight landed in New York with gloves, masks, and respirators. By April 30th, the 100th flight, Airbridge had delivered nearly 800,000 N95 respirators, 825 million gloves, 75 million surgical masks, over 11 million surgical gowns, more than 2 million thermometers, 650,000 face shields. Using the airbridge, we cut the amount of time it takes to transport supplies from Asia to the United States from months to days.

The supplies I just listed would still have been at sea on April 30th and not available to our health care workers if normal shipping methods were used. At its core, the airbridge is a public-private partnership with six major medical distributors. The Federal Government covers the cost to fly supplies purchased by the private sector into the United States from overseas factories. As part of the agreement, 50 percent of the distributors' supplies in each plane are directed to points of care in geographic areas needed using CDC data along with inputs from Dr. Birx. Based on CDC data, prioritization was given to hospitals, health care facilities, nursing homes around the country to COVID hot spots such as New York, New Jersey, Chicago, and Detroit.

Beyond the airbridge, our acceleration efforts continue to source supplies with flights carrying over 55 million FEMA-procured masks and 2 million gowns into the United States. Working with CDC, we provided preservation guidance on how to extend the life of PPE and introduced options like decontamination systems that allow for multiple use of N95 masks.

You cannot run a supply chain if you cannot visualize it. Using data-driven decisions for allocation ensures the right quantities of critical medical supplies get to the right place at the right time. In

an unprecedented fashion, we consolidated business system data from the six major medical distributors into the cloud of FEMA, creating a data lake of information. For the first time, using a supply chain tool from DOD, we were able to see the health care supply chain from supplier to point of care, all done within a matter of 2 weeks. We could now see inventory held by competing companies for distribution in the United States and how the supply chain was filling those orders. We combined this supply chain data with CDC information, ensuring the commercial markets moved resources to the hot spots.

Looking at the longer time horizon, expansion is needed to align U.S. manufacturing with current COVID and future demands. Prior to COVID, the medical community procured the majority of supplies from cheap overseas markets. We need to change that.

American business leaders continue to respond. For example, with no financial incentive from the government, Walmart teamed with the medical supply chain and produced over 200 million hospital isolation gowns. Using the Defense Production Act, we are creating investment across manufacturers in the United States to make domestic production equal to the surge in COVID demand. We used DPA to raise the U.S. production of N95 masks and bring in 50 million N95s from 3M's overseas production. Another example is rated contracts for ventilator production under the DPA, including contracts for thousands of ventilators delivered to the stockpile.

Looking ahead, we are preparing America to be fully prepared for any future outbreaks, beginning with increasing our reserves, expanding our domestic capacity. We now have more ventilators in the Strategic National Stockpile than before the pandemic thanks to U.S. production. Pre-COVID, the stockpile had less than 18 million N95 masks. We are growing that to 300 million. The SNS had no ventilator drugs. We will now have at least five drugs in stock with 3 months' worth of supply. There were no swabs. The stockpile will now include swabs for testing.

This updated version of the stockpile will regularly refresh stocks, capitalize on our work to understand the whole supply chain for linkage with the private sector. A larger National Stockpile combined with more U.S. production will enable a continued Federal response.

Thank you for the opportunity to testify today. I look forward to answering any questions that you may have.

Chairman JOHNSON. Thank you, Rear Admiral.

I will defer my questioning to the end. The order of questioning will be Senators Peters, Lankford, Carper, Hassan, Rosen, Portman, Scott, and Romney. Senator Peters.

Senator PETERS. Thank you, Mr. Chairman.

Admiral Giroir, the first question is for you. The coronavirus pandemic, as we all know, has disproportionately impacted the African American community, yet reports suggest that diagnostic testing for coronavirus is disproportionately located in areas with higher incomes and lower minority populations. So could you walk me through the steps that the Department has taken to evaluate access to coronavirus testing for minority communities, including at

the individual and even neighborhood level for these communities, if we could get a better understanding as to how you approach it?

Admiral GIROIR. Yes, thank you, Senator. In my job before COVID, this was a major part of my job as Assistant Secretary for Health working on health disparities, so it is a topic that I feel fairly familiar with.

The first thing we did—and I mentioned this in my remarks—is the federally sponsored pharmacy sites. There are 437 of those. We made sure—this was by contract—that the majority of which are located in sites of high social vulnerability. Seventy percent of those 437 are there. The Social Vulnerability Index takes into account race and ethnicity, income, languages, disability, and other areas. So it is the way that we can target those resources.

Second, the federally qualified health centers—we now call them "community health centers"—they take care of 30 million primarily of the poor and under-or uninsured in our Nation. Ninety-two percent of them are offering COVID testing right now, so almost all of them, and they are located in the neighborhoods of need.

Last week, we released guidance—and this was a flaw in the system. There was no requirement for reporting of race, ethnicity, age, sex, even zip code or location, with lab reports. It was very difficult to understand what the data were, and we still do not have a good understanding of that. This was an authority that the Coronavirus Aid, Relief, and Economic Security (CARES) Act gave to the Secretary, and we enabled that last week. My office, the Office of Minority Health, has a funding announcement that is available right now to create an entire national infrastructure to focus on minority issues, primarily linkages to testing as well as linkages to services following that testing. I think you said in your remarks and something that we are focusing on more and more is health disparities have plagued this country for decades. The underserved minorities sometimes it really is true, your zip code matters more than your genetic code. And this was really not something new, but it was a magnification of the health disparities we see. I do not want to take up your time, sir, but we just saw what had occurred for decades just magnified because of this pandemic.

Senator PETERS. There is no question about that, and we have to lean in very heavily to deal with those, and that will be at a future time we can talk about that.

Just kind of the follow-up question. You talked about how these resources are in these different areas, and yet you also said we did not really have data until just recently. So how can you make that statement without data? How are you about to——

Admiral GIROIR. So what we do know is the Social Vulnerability Index is a published index to understand what communities are really vulnerable. So we placed our testing centers in those communities. What I do not have is the national data to say how many African Americans have been tested, how many Hispanics have been tested, because that is not a requirement, and the Federal Government does not get that. We have mandated that as part of the guideline from the Secretary last week, but we have very limited data. We just have very limited data to understand the percentage of those tested. We know how many are hospitalized, who

suffers the consequences, but testing, we are flying blind until this comes in, sir.

Senator PETERS. Right. And you agree that this data is essential, we have to have it?

Admiral GIROIR. It is absolutely essential. We cannot develop a national strategy to reach the underserved to know how well we are doing until we have the data that shows us if we are reaching them or not. So, yes, we are very anxious for that data, and I wish I could present that. But it was an authority that just gave to us in CARES, and it is a guideline now that people will have to report.

Senator PETERS. What steps are you taking to collaborate with other partners such as FEMA and the Housing and Urban Development (HUD) and others in these efforts?

Admiral GIROIR. So these are my brothers here. I mean, literally, since things moved to FEMA, we are informally probably meeting five times a day, but there is a formal meeting every single day where every task force reports to the Unified Coordinating Group. We hear from every region, so we really hear it where the boots on the ground are, because you cannot know everything in Washington, but we hear directly from HHS, the FEMA Regional Administrators, and then almost every day we have a Uniform Coordinating Group that really provides direction and decisionmaking. And then Admiral Polowczyk and I are not officially on the White House task force, but we are regular invitees. So, again, we are there along with the Administrator, who is. So every day we have multiple hours of contact with each other. It has been one of the great, I think, teams that have sort of self-assembled during this given FEMA's structure really allowed us to do that.

Senator PETERS. Administrator Gaynor, a just response requires leadership, as you know very well, at the highest level of the agency and a dedicated office to develop a proactive plan that can assist that leadership. And we have to ensure that aid and assistance is always delivered equitably.

I introduced the Achieving Racial Equity in Disaster Response, Recovery, and Resilience Act of 2020 which will basically establish an office of equal rights and community inclusion at FEMA that would refocus the agency's efforts on those communities that have been left behind, and as we mentioned, the disparities with communities of color in particular.

So my question for you, Administrator Gaynor, would you commit to working with me to move this legislation and bring greater focus within FEMA to communities that are particularly vulnerable?

Mr. GAYNOR. Yes, sir. And just for the record, FEMA already has an Office of Equal Rights and Civil Rights, and so we would be happy to work with you about what we have been doing, some of our successes, and I would be happy to offer technical assistance to you and your staff on that legislation.

Senator PETERS. I appreciate it, and I know you have that office, and we appreciate the work that that office does. But I think what we have seen transpire in the last few months, we should probably redouble our efforts and focus more on that. That is certainly the spirit behind the legislation, that we bring even greater focus. For

example, the lack of data, those are things that we should have been doing from day one, and we need to have lessons learned from the past as we move forward to make sure that we have more equitable responses in the future. So that is the spirit of the legislation.

Mr. GAYNOR. Yes, sir. If I could share just one thing to just tell you how early we were concerned about equal rights and civil rights. Early on in the process, in May, my Office of Equal Rights put out a bulletin to all FEMA employees working on COVID–19. I sent 25 civil rights advisers out to my ten regions across the country. They adjudicated 211 civil rights items before they became official. So we have been out there on the front line adjudicating civil rights, making sure that we stand up for what is right, what we believe in. And so, again, I would love to work with you and your staff on moving that forward to even a greater effort.

Senator PETERS. I appreciate it. Thank you. Thank you, Admiral, as well for your comments. Appreciate it.

Chairman JOHNSON. Thank you, Senator Peters.

Senator Lankford, by the way, I think I mentioned this to you. When I got home last night, my wife has C–SPAN on, and she said, "You have to watch what Senator Lankford had to say." I thought you did an extraordinary job, so I would recommend everybody go and get a clip of Senator Lankford talking about disparity. As Senator Carper always says, we do not have a perfect union. We are trying to form a more perfect union. But, excellent remarks. Senator Lankford.

OPENING STATEMENT OF SENATOR LANKFORD

Senator LANKFORD. Thanks, Chairman.

Gentlemen, thanks for your service, what you are doing. You do a lot of work behind the scenes that Americans do not have the opportunity to be able to say thank you, so from the people of Oklahoma, let me pass on my thanks because you have done quite a bit to be able to serve the folks in my State and across the country.

Let us talk a little bit about the National Stockpile, though. There was a lot of early engagement on expired N95 masks and expired prescriptions and such in the National Stockpile. Help me understand how we got to that point that things were expired, and how does it get better to be able to deal with the rotation so that we do not have expired materials in the future?

Admiral POLOWCZYK. Yes, Senator. I am going to refrain from talking previous to March 19th, so I cannot speak to those practices. But I will talk to you about what we are doing going forward. The National Stockpile should not be thought about as I buy it, I put it on a shelf, and I am done.

Working with the colleagues at Health and Human Services, I am trying to develop a National Stockpile next that uses practices that DOD has done, has used. DOD has a Warstopper Program where we buy inventory, we put it on the shelf with our commercial partners, and as the commercial partners make issues, they replenish and they manage shelf life for us. That is just one example. And so we are looking to change from a stagnant mentality of buy it, put it on the shelf, and then have to figure out how to rotate stock. It is not just N95 masks. Even simple things like needles

and syringes that are sterilized and wrapped, they all have a shelf life based on the sterilization.

So there is work to do there going forward, and it is going to change, and it is going to take a little bit of——

Senator LANKFORD. Do you need legislation to do that at this point or do you have the authorities you need to be able to do it right now?

Admiral POLOWCZYK. I believe Health and Human Services has the authorities, but it may take a difference in understanding of funding resources for them, and I will not be able to speak specifically for Health and Human Services. But I think they are going to need an annual appropriation that pays for different inventory management practices than they have had. You cannot just put it on the shelf and then walk away from it.

Senator LANKFORD. Right. We will look forward to getting a chance to be able to walk through that because obviously, if we buy a product and it sits on a shelf for a period of time and then it starts to get near expiration, it would be much better to be able to sell that and to be able to get it off or to be able to rotate it out and be able to keep that moving. Again, you were talking about the DOD process and what they are doing and storing it with commercial entities as well.

Are we at a point right now that if we had a vaccine, let us say in November, that we would have enough syringes and distribution to be able to get it out?

Admiral POLOWCZYK. Sir, to answer that specifically, we are on glide path to have approximately 400 million needles and syringes by, I will say, December. I do not have the numbers right in front of me, but it is at least 400 million as we get into the winter, and 700-some-odd million as we get into next year.

Senator LANKFORD. OK. Mr. Gaynor, let me ask you about this. FEMA is all about mitigation, storm mitigation, trying to prepare ahead of time and to be able to get communities prepared ahead of time. Have you started a list right now with what we can do to be able to help hospitals, States, local entities, for how they can prepare for the pandemic? Because it was not just the Federal Government that was caught flat-footed on this. A lot of hospitals and local entities had a 2-or 3-day supply of PPE knowing they could just reorder if they needed more. But no one could just reorder at that point, so everyone across the country was caught flat-footed in this.

Have you all started a process already to brainstorm what we can do to be able to help prepare local entities in mitigation efforts?

Mr. GAYNOR. Yes, sir. It is a great question, and I am going to start with the way this whole system works, and when it works the best, everyone is involved, so locally executed, State managed, federally supported, to include our citizens across the country.

We are probably going to have to readjust some grants. We put out about $2.4 billion in preparedness grants. Over the past couple of years, we have focused on cyber and terrorism and things like that. So maybe it is time to refocus what really is important or what we have learned from the past 90 to 120 days, what we have learned from that and how we are going to correct it so we do not fall into the same trap ahead. So, again, everyone needs to embrace

preparedness from the local, State, and Federal level, to include hospitals and everyone else.

I think we need to embrace preservation of PPE. There were moments over the past 90 days where it was dim when it came to having enough PPE. So we need to think about how we use PPE in a new way. So I think, we are all very—we like cheap 70-cent masks from China, disposable, throw it away after one time, and it keeps everybody happy. Maybe that is not the way we need to go forward. Again, the majority of PPE is not manufactured in the United States. I know we have a great effort to bring that back home, but we really need to change the culture about what really is important and make sure everyone is invested in all these things.

So, again, everyone needs to—if you are in the hospital, maybe you need to think about how you are going to manage your PPE and how you are going to manage surge and how you are going to make sure that it stays fresh over time. I think everyone owns a piece of this puzzle, not just the Federal Government.

Senator LANKFORD. That is great. Let me make a couple of comments, if I can, on this as well. I will do a quick question on it. One, we have to relook again—and it is something this Committee can continue to work on, and thank you, Mr. Chairman, for this Committee's work in this area—is dealing with domestic manufacturing. All of the things that we had to get with an airbridge to be able to ship over in a moment of a pandemic, I would suggest every one of those supplies we should reexamine what is our domestic manufacturing for those supplies that we were in such a desperate moment that we had to be able to move those things via an airbridge from Asia. Why are we not producing those domestically? And what can we do to create more domestic supply on those so that we can ramp up working nights and weekends rather than ramping up and to be able to move them over from Asia and a point where we are exposed on this?

I do want to ask one more question, though, on Veterans Affairs (VA), the current VA process for testing in particular. HHS makes the decision on what the need is across the VA. It gets to FEMA. FEMA then gets those supplies onto national VA and it gets down to hospitals. My numbers, if they are correct on it, about 300 testing units are getting to hospitals or most entities across the country, somewhere on average of that a month. The hospitals in my State are looking for about 700 tests a week to be able to test more people coming in and to be able to help evaluate that.

How do we bump up the numbers that are available to VA as we have a complicated process where HHS decides that FEMA distributes, it gets down to VA, then distributes down to the individual hospitals and clinics?

Admiral GIROIR. Sir, thank you for that question, and it is good to shed some light on that. Dr. Stone, who is the chief executive of the Veterans Health Administration (VHA), and I talk regularly. The VA makes a request, and we fulfill it. That is just that clear. If they need 100,000 swabs, we give them 100,000 swabs. We have had to tide them over with Abbott ID NOW rapid testing machines, the Cepheid cartridges in order to buildup their—so, quite simply,

for the VA and for the DOD, if they have asked for anything, we have supplied it to them.

Now, how the VA distributes that within their system is kind of behind the curtain to me, but we supply nationally to take care of our veterans because a lot of them were in the vulnerable age groups, as you know. They are co-morbid and they are elderly, and I will look specifically into Oklahoma. But at that level, the VA gets what they need.

Senator LANKFORD. Good.

Mr. GAYNOR. Sir, just in addition to that, the VA has a dedicated liaison officer at FEMA full-time, and so if there is a requirement, a request, a problem, we hear that directly, all three of us, and take immediate action. So they are on the inside of this process, and, again, we take immediate action on anything that we see.

Senator LANKFORD. That is great. We will try to follow up from there. Thank you.

Chairman JOHNSON. So let me answer the first part of your question. As a former manufacturer, in order to guarantee manufacturing in the United States, we have to guarantee orders at a reasonable price that guarantees a reasonable rate of return. It is that simple—not how exactly we do it, but that is what we have to do. And that will be a decision I think the Congress will have to make.

Senator Hassan. Just hold because we cannot hear you yet. There you go.

OPENING STATEMENT OF SENATOR HASSAN

Senator HASSAN. Folks, can you hear me?

Chairman JOHNSON. Yes, we can hear you now.

Senator HASSAN. OK. So I just wanted to add my thanks not only to the witnesses, but to all the men and women who work in the field for your agencies during this extraordinary time. We do know that this has been an unprecedented amount of work, and we are very grateful.

Having said that, I just want to add a caution because while the time for an after-action report on what was done well and what was not is for after the pandemic, I think there is general agreement that we needed to establish our goals earlier and that we still have some ways to go in terms of being transparent about what our goals for things like PPE and testing are.

There is a difference between saying we have worked really hard and done all these things and knowing that we have actually met our need. There is a difference between saying let us see what we can do and here is what we need to do. And so that is what my questions are really focused on.

I will start with Administrator Gaynor, and, again, I want to thank you and everybody at FEMA for all the hard work you have been putting in. But I have had a consistent frustration, and we have shared it with you, and I know it is shared by the Chairman and other Members of this Committee, about the administration's inability or refusal to publicly lay out clear numerical projections and goals for its COVID–19 response.

I have been asking for months now for the administration's estimates of how many N95 masks and pieces of other personal protective equipment our country needs. It took over a month of pressure

from this Committee to even get verbal answers to these questions, and it was not until late last Friday night that I got anything in writing. And even now that I have this document, which you all produced to my staff Friday night, the administration still says, "We cannot make it public."

There are real questions about this document, but I do not see the utility of asking about it if the public does not have access to it at the same time so they can follow our discussion. The American people deserve answers to these basic questions: how much personal protective equipment we need and what our plan is to get there.

So, Administrator Gaynor, why is the administration refusing to make this document public? Public scrutiny is critical to evaluate these projections, how they were developed, whether they account for real needs in nursing homes, hospitals, schools, and business. Why can't I share this document with my constituents?

Mr. GAYNOR. Yes, ma'am, thanks for the question. So I do not know of any prohibition about sharing the slides, so if you have an interest in sharing those slides publicly, go ahead and do so. We provided those slides to you and the Committee for your use, and if that includes sharing those with U.S. constituents, I do not see a prohibition against it.

When it comes to understanding PPE—and I will defer to the Admiral here in a minute, but when it comes to understanding PPE scarcity, a demand for things that some sectors have never had a use for before, it has taken some time for us to understand that. And so, early on we want to understand what usage was against what pre-COVID numbers look like. Now that we are moving into opening government, what do those numbers look like? Elective surgeries, dentists, all these things are new and additive to the problem.

So as we go, we learn more. We will update those slides. They will be more comprehensive.

Senator HASSAN. Director Gaynor, I thank you. But I will just say—and I have limited time—your staff explicitly told our staff that we could not share these documents publicly. So I am glad for your commitment today, but I just want to be clear on the record that we were told we could not share these documents.

Mr. GAYNOR. Yes, ma'am, and I apologize for that.

Senator HASSAN. Thank you.

I would like to move on to a question to Admiral Polowczyk, please, and I will just say again it would be better to forecast what you think the needs are as you have discussions with different sectors so that we can then develop a plan to meet the need.

Admiral Polowczyk, related to my question to the Administrator is the fact that critical facilities still face severe shortages. Federal data released last week showed that nursing homes around the country still do not have the personal protective equipment that they need to keep people safe. More than 500 nursing homes in our country lack any N95 masks, and more than 250 do not even have surgical masks.

Admiral, I appreciate that this is a challenging situation, but those numbers are completely unacceptable. About 40 percent of all U.S. COVID–19 deaths are residents or workers at nursing homes

or other long-term facilities. And in New Hampshire, over 80 percent of deaths are in long-term-care settings. The Federal Government has to do more.

What are you doing to remedy the lack of personal protective equipment available to nursing homes and other long-term-care facilities across the country?

Admiral POLOWCZYK. Thank you. That is a great question, and I appreciate your passion for the vulnerable. So we are doing several things. One, in our prioritization scheme, the first priority is public hospitals, then the VA, private hospitals, and then nursing homes. So nursing homes are one of our top priorities as we work to get items where it is needed and when it is needed.

Second, we have instituted a project to bring personal protective equipment to every single registered nursing home in America—that is 15,408 nursing homes—delivered directly to their front doors. That is millions of surgical masks, millions——

Senator HASSAN. And when is that going to happen?

Admiral POLOWCZYK. We started that project, building the volume of supplies necessary, in April. We started deliveries in May, and that will run through weekly—they will be getting deliveries of several weeks' worth of PPE as we go through August and into September, and we are——

Senator HASSAN. So, Admiral, what—and I realize that I am over time, but, Admiral, what I am looking for is a plan that tells every nursing home in America when they are getting the equipment they need——

Admiral POLOWCZYK. Yes, ma'am, so we give every Governor every Monday, when the Vice President has the Governors call, I give them a State breakout with every single nursing home in their State and the address, including the amount of supplies and when the item is being shipped and if it has been delivered. So we have a great communication with——

Senator HASSAN. As you know, we still do not have this equipment in many nursing homes.

Admiral POLOWCZYK. So, ma'am, one of the things that the Healthcare Ready network is now producing is an input of nursing home information, and they are working with Administrator Seema Verma, and I see regularly inputs from nursing homes where less than 2 percent of nursing homes that are reporting say that they do not have a week's worth of personal protective equipment. I would really love to sit with your staff to go through that information and understand what you are saying that there are hundreds of nursing homes that do not have——

Senator HASSAN. Well, it is——

Admiral POLOWCZYK [continuing]. Data being collected, and I am being—from the Healthcare Ready network is showing a very small amount. And once we see those numbers, we go work with each one of those nursing homes to make sure that they have PPE.

Senator HASSAN. I would appreciate following up with you on that. Mr. Chair, if there is a second round of questions, I would appreciate being able to ask them. Thank you.

Chairman JOHNSON. OK. Senator Rosen.

OPENING STATEMENT OF SENATOR ROSEN

Senator ROSEN. Thank you, Chairman Johnson, thank you, Ranking Member Peters. I want to thank all of our witnesses today for your service and your hard work.

I would like to address natural disasters and the pandemic because in Nevada we are about to enter wildfire season. In the past month, we have unfortunately experienced multiple earthquakes, including a 6.5 magnitude event that shook our entire State. Flooding and other disasters are also possible throughout the year. So I would like to hear more about what FEMA and HHS are doing to prepare for responding to the COVID–19 pandemic while we are also responding dynamically to these natural disasters. It is absolutely critical that we have a detailed concurrent plan, our planning going on right now, as we see the pandemic hitting, of course, across the country. We have to be nimble in order to respond, and, FEMA, for you to address a multiple-disasters situation simultaneously.

So, for Administrator Gaynor and Admiral Giroir, how are FEMA and HHS preparing for testing for COVID, treatment for COVID, and vaccine delivery if power is impacted by a natural disaster? Are there additional mobile generators for refrigeration systems? Are these being acquired? What type of equipment might you need in a remote scenario? We have very rural, remote areas that get the wildfires, have the earthquakes. What supply chains could be disrupted? What do you need from Congress to start doing this? Or have you started doing it? We will start with Administrator Gaynor, please.

Mr. GAYNOR. Yes, ma'am, thank you for the question. So if I can just zoom out a little bit and focus on some of the wider efforts that we have done at FEMA and across the country—and, again, with my many partners here, Admiral Giroir, DOD, and many others that are not here, early on, probably before the President declared a nationwide emergency in March, we knew that hurricane season was coming, and we wanted to make sure that we were prepared for hurricane season with the overlay of responding to COVID–19. And so along that way, my team and my partners collected best practices, lessons learned, the best resources for COVID–19, and we built in 27 days—I am not sure if you can see it, but I brought a prop with me here—the COVID–19 Pandemic Operational Guidance for the 2020 Hurricane Season.[1] Although it says "hurricane season," you could scratch that out and put in "wildfire" or "earthquake" or "flooding," because all the lessons learned in here apply to all hazards.

Senator ROSEN. Let me ask you this question, and I am going to take a look at that after this. But is there strong support in there for our State and local agencies, our first responders? Is that in your document as well?

Mr. GAYNOR. Yes, ma'am. Back to a line in my opening statement, "locally executed, State managed, and federally supported," and I will just give you an example about some of the challenges that we will face this year. It does not matter if it is hurricane or wildfire or an earthquake. It is about sheltering. In it, we want to

[1] FEMA Hurricane Plan appears in the Appendix on page 678.

make sure that we stimulate conversation at the State, local, tribal, and territorial level (SLTT), emergency managers, State health officials, to ask those questions. What does evacuation look like in your community under COVID–19? Do you have enough space? Do you have enough hygiene equipment? Can you screen people? If you have somebody that is positive, what do you do with that? Are you going to do testing?

So lots of prompting questions to have every emergency manager in the Nation go look at their plans and make sure that they are up to date for whatever hazard they may face and COVID–19. I have held conversations with every State emergency manager in the country on this. We have an exercise kits that we encourage all levels of government to use to exercise those plans with COVID–19. So pretty comprehensive. I will make sure that you and your staff have a copy, and I would be happy to answer any questions after that. When it comes to testing, I will turn it over to Admiral Giroir about what testing may look like in the future.

Admiral GIROIR. Yes, thank you, Senator, and thank you, Administrator. On the testing side—and I am so appreciative you brought this out—it is the reason why we are working directly with each State individually to make custom evidence-based plans for those States. My multidisciplinary team has met with the multidisciplinary teams from every State now three times to establish the initial State goals, and we did this in late April. So for Nevada, your team's goal was 120,000 tests. We concurred, 120,000 tests were very good for your State. We provided all the supplies that are needed to do those 120,000 tests. Not only was it numerical, but there are specific issues. Like your State is number 8 in relying on the public health laboratory, so you are very highly reliant on the public health laboratory, and that being the case, we supply more supplies to your public health laboratory than other States that are not so reliant on it. We also focus on any indigenous populations through the Indian Health Service.

So it really is a custom plan for your State, and, by the way, in May your State did really good, just about met your State goals, certainly within a stone's throw of it. So we look forward to that. And now we are reviewing every single State plan as required by the Paycheck Protection Program (PPP) legislation along with the $10.25 billion. We have a specific State plan that we are reviewing now for May and June, and then on June 15th, it will be the plan for the rest of the year.

Again, this is a cooperative agreement between the CDC and the States, meaning we are working together. It is not the State's responsibility; it is not a Federal responsibility. It is us to work together to make sure that that State plan is appropriate and can be executed.

Senator ROSEN. Admiral, I want to just follow up on something Senator Lankford asked about syringes and things that we are preparing for, for a vaccine. What about our vaccine vial supplies? Do we have enough borosilicate that is the special glass that we need for those vials to contain the vaccine? If we do not have enough, are there alternative material that we can consider using as we ramp up not just syringes but the vials that are needed as well?

Admiral POLOWCZYK. Ma'am, great question. So there is a little bit of a dividing line between my efforts and then Operation Warp Speed. I am working closely with them, but they have a plan for vials and syringes. There is also a secondary plan of a new technology, a blister-pack blown product where it will be pre-filled, and you will get the dosage in a blister pack, be able to open it, and inject it and squeeze it so it is one. We are actually using some investment money, the Defense Production Act, on that item.

But Operation Warp Speed has all the details there, but because it has something to do with the supply chain, prior to the stand-up of Operation Warp Speed, I dived into needles and syringes just because I thought that was what is next. But I will have to work with Operation Warp Speed to get you a specific answer on the vials, ma'am.

Senator ROSEN. Thank you. I appreciate it.

Chairman JOHNSON. Senator Portman.

OPENING STATEMENT OF SENATOR PORTMAN

Senator PORTMAN. Can you hear me?

Chairman JOHNSON. Yes, we can hear you now. OK. Great. We will reset you for 7 minutes.

Senator PORTMAN. I am almost out of my time. I apologize. First, I want to thank you——

Chairman JOHNSON. You are going to have to talk a lot louder, though.

Senator PORTMAN. Admiral Polowczyk, I want to thank you for your hard work on how to improve our supply chains in particular. I have had this conversation in person [inaudible] times. I know you are a sincere champion of American reshoring [inaudible] like China and——

Chairman JOHNSON. Rob, you have to put that microphone really close to your mouth. It is kind of fading in and out, and we can barely hear you.

Senator PORTMAN. OK. I do not think the microphone is working. Can you hear me?

Chairman JOHNSON. Yes, we hear real good right now.

Senator PORTMAN. OK. You just testified, Admiral Polowczyk, that we are ramping up domestic production to meet the COVID challenge. We are preparing America by increasing U.S. production. As you know, and, again, I know you are sincere about that, but this Joint Acquisition Task Force that is vetting contracts, because it has shifted now over to Defense Logistics Agency (DLA), they are vetting contracts to supply PPE over the next 90 days. And as Chairman Johnson said earlier, you have to have that demand signal. You have to have that long-term contract to make the investment to actually bring this PPE production back to America. And I just have not seen an indication that this Joint Acquisition Task Force and DLA are issuing these needed long-term contracts for PPE. These companies need the certainty to be able to make the investment. It is a huge investment. It is the right thing to do. And my question to you I guess would be about that. There is an Ohio company I have talked to you about that has an exciting plan to actually bring textile production back to America. They are already [inaudible] sheets and towels already, seeing Mitt Romney is

listening to us, they provided them to the Marriott Corporation, which then [inaudible] that can do this. They have U.S. sheets and towels and other linens. So they cannot do it unless they would like to make reusable gowns here in America, but they cannot do it unless they have these long-term contracts.

So I want to know, one, what your view is on that. On the record, do you agree that it is in the national interest to make [inaudible] in the United States?

Admiral POLOWCZYK. Sir, I had a little bit of a hard time hearing your question, but I get the genesis is a little bit about our plan to bring manufacturing back and the requirement——

Senator PORTMAN. Do you support bringing it back? Do you support reshoring——

Admiral POLOWCZYK. Yes, sir, right. I do not think we could be ready for any future pandemic, and so a little bit longer lens than just, say, for a second wave in the fall. I talked about a vignette from—unfortunately, I bring a lot of DOD with me, right? So, you cannot be resilient and ready if you are not managing your supply chains and managing the production of required resilient items. So let me give you an example.

While the Navy has full magazines of Tomahawk cruise missiles, we still buy Tomahawk cruise missiles every year and keep them on low-rate production. And that is so we can surge. That same mentality I believe has to happen in the health care area. We are working to aggregate demand, so the slides that the Committee got about demand, we are working to aggregate that long-term demand and bring that to industry to say, hey, look, this is the repeatable, long-term demand for health care items, not just personal protective equipment but——

Senator PORTMAN. Admiral, let me ask you a follow-up on that. Do you agree that in order to do that we need to have, in addition to the short-term contracts for immediate need—I get that—but do we need to have these long-term contracts to provide that demand signal for these U.S. manufacturers so that they do bring production back to these shores?

Admiral POLOWCZYK. Right. So I am busily in the process of aggregating demand across DOD, the National Stockpile, VA, and then in consultation with each State through their Regional Administrators, to understand what the States would desire to stockpile, kind of the three levels of inventory there, and bringing that national demand forward.

I would also say that there will be work that the administration must do on the right backstopping to make sure that the items do not go back overseas. But there is a need for having long-term demand with stable funding.

Senator PORTMAN. Great. Thank you. Could you tell us when DOD is going to issue long-term contracts to companies who are looking to bring PPE back to our shores?

Admiral POLOWCZYK. Sir, we are continuing to do that right now. We have asked the Defense Logistics Agency essentially for a first wave of items. I think that was 450 million. That ought to be followed up by several billion, and then as you bring forward DOD's requirement, the VA's requirement, and the States' requirements, that number will be quite large, and we will be sharing that with

industry as we go. And we continue to work the back stream, the raw materials pieces of these supply chains. So we have pending Defense Production Act investments to bring millions, additional millions of square feet of meltblown, the non-woven fabric to make either gowns or surgical masks here in America with American-made product.

Senator PORTMAN. Thank you, Admiral. I agree with you we need to have these long-term contracts to provide that demand, and I hope that you will get DLA to do that quickly.

Admiral Giroir, thank you for all of your help with Ohio. I have had the opportunity to work with you on a number of projects. Right now we need more testing in Ohio. We are the 43rd in the country in testing per capita even though we are the seventh most populous State. We have a real issue with testing. We need the help. We have the Thermo Fisher test, as you know. They are heavily reliant on people, on staffing. They do not have enough lab technicians necessary to be actually running these tests, and we have been trying to work with you all to get other tests into Ohio, particularly tests that require less of that staffing. My understanding is that you have been willing to work with Ohio on that, but we are still not there.

My question for you is: What can we do to get more testing into Ohio? The Hologic test in particular is one that you have access to that we need in Ohio. Seventy percent of our State's deaths looks like occurred in nursing homes. There are only a quarter of those deaths nationally, and that is an example where we just need more testing so that in congregate settings like that, we can be sure that the virus is not spreading, because we do not have insights into what is happening without testing.

Can you give us a sense of where we are in terms of getting those tests to Ohio?

Admiral GIROIR. Yes, thank you, Senator, and I really appreciated our calls that we have had multiple times during the pandemic. In addition to working with your State in the plan that we outlined, we probably a week ago had a special session with all of your leadership in Ohio because the Governor was concerned about the relatively lower performance of Ohio compared to other States.

The good news is that has changed pretty dramatically over the past couple of weeks, so when we met with your teams, your State health official, your State person who ran the laboratories, a whole multidisciplinary team, it looked like things were really on track, and I do think they are. You did very well with your May goals, really within a stone's throw of achieving exactly your May goals for testing. So that is excellent.

In terms of specific machines, I just wanted to clarify this, that like everything else, there is not enough of any single material to go around and, therefore, it really requires a couple different approaches. For things like swabs and media, the market was so fragmented with multiple small producers that literally the Federal Government buys the supplies, and we are committed to doing that through December at a rate of about 20 million of each—tubes, media, and swabs—and distributing those to the States, at least through December and maybe further.

For other markets that are more mature, what we are doing is matching the supplies that are in the market to the States. In other words, we are helping match what the capabilities are to what the States have. And that is where we are going to be for the next few months, and we will do well. We did almost 12 million tests in May, which is just an enormous milestone and very close to the State's full goals.

In terms of the specific questions you asked about Hologic, I do want to be clear that not everybody is going to be able to get the specific newest technology that they want the moment they want it. We are going to have to deal with the existing technologies. I call them the "Ford trucks." I have a Ford truck. I love my Ford Truck. It gets me places. But it is not, a sports car, right? So the sports cars in the laboratory environment like the Hologic Panther, they are new items. They are being ordered, and we tracked down—and Ohio is actually getting, I think, two or three of their machines within the next couple of weeks.

So that is kind of where we are. Ohio is doing much better, really moved up the charts in the last couple of weeks, and your team seems to be satisfied, and we will continue to work with them individually at any time. They are a really professional, highly skilled, and collegial team, and we really enjoyed working with them.

Senator PORTMAN. Thank you, Admiral. My time has expired, but we appreciate your service and the service of all of the folks who work with you.

Chairman JOHNSON. Senator Romney.

OPENING STATEMENT OF SENATOR ROMNEY

Senator ROMNEY. Thank you, Mr. Chairman. Can you hear me OK?

Chairman JOHNSON. Loud and clear. Yes, thanks.

Senator ROMNEY. Good. Thank you. Thank you, gentlemen, for your participation on this panel today. Thank you, Mr. Chairman and Ranking Member for calling this panel.

Some have hypothesized that Asia was able to respond more quickly than the Western nations in part because they had the experience with Severe Acute Respiratory Syndrome (SARS). They learned from that experience, the old, COVID–19, fool us once, shame on you; but fool us twice, shame on us. And so I do want to look back at some of the things that we did not do terribly well and try and understand why.

I know, Rear Admiral Polowczyk, you indicated you did not want to talk about things that happened before, I think, March 19th. But given where you are, you probably have some perspective on that. We did not have a very substantial stockpile then, as you pointed out. We now have what sounds like an ample and going stockpile that is going to be well rotated, it sounds ideal. But why were we so, if you will, short prepared with regards to our stockpile? Was it the bureaucracy? Was it the administration's—I am not look for any particular names. I am looking for where the problem was. Was it Congress? Did we not provide sufficient funds to actually—purchase the stockpile? Where was the problem? And how do we avoid that in the future?

Admiral POLOWCZYK. Sir, again, I have a pretty good working knowledge of the National Stockpile. I will tell you that the Health and Human Services team brought that up from the Centers for Disease Control in Atlanta to the Assistant Secretary for Preparedness about a year-plus ago, and so, again, I was moved from the Joint Staff as the Vice Director for Logistics in mid-March and had not worked with the Health and Human Services staff.

The National Stockpile has more in it than just pandemic-related supplies. It also has a chem/bio focus, so it——

Senator ROMNEY. Admiral, I have such a short period of time. If you do not have a good understanding of where the problem was with regards to medical supplies, that is fine. But is that something you want to address or should I move on?

Admiral POLOWCZYK. No, sir. Again, I am not a Health and Human Services employee. I was pulled to go forward and stabilize the supply chain, and so I have not spent a significant amount of time worrying about why they did or did not do things in the past. So I would ask that maybe——

Senator ROMNEY. That is fine. I think it would be helpful if there is some effort to understand. That is so we can avoid that in the future and be better prepared if needed.

Admiral Giroir, you spoke just momentarily ago about the fact that you are coordinating the swabs and I think the medium, which makes sense to me. When something is in short supply, there needs to be coordination of how that gets distributed throughout our country. But I think there is the perception that at the very beginnings of this crisis that the Federal Government said to the States, OK, Governors, you have to get your own stuff. I am not sure which things were included in that, but I did talk to more than one Governor who said that they were scrambling on their own to try and find protective equipment or try and find testing equipment, and they were competing with each other and in many cases asking for more than they actually needed because they knew they had to do that in order to get what they might need.

As we look forward, can you help us put together a model for what should be originated at the Federal level and what should be originated at the State level? And I do not know whether—I am sure it was not perfect in the past, but with the experience that we have had now, I think it would be very helpful if you in your role could say, hey, look, these things need to be done federally, these things have to be done at the State level. Is that appropriate?

Admiral GIROIR. Yes, sir, and thank you for the question. I think you are exactly on target. I will just make a comment that during the early parts of this, from mid-March to mid-April, we had absolute shortages. There was no question we had shortages of everything, and we were in a posture of getting requests through the FEMA system that is part of the organization that they brought in trying to adjudicate those requests as much as possible because we could not get prospective like we are now in terms of testing. So it was really down to how many new cases there were, what the hospitals were in allocating those limited supplies.

Moving forward, from mid-April through now, we have been able to be more prospective to provide States what they have asked for up front, but you are exactly right that an overall strategy and

framework of how we work together, particularly in diagnostics moving forward, is exactly what we need.

I think we have a working framework. It was built while we were flying the airplane. But I think now is a good time to look back and make sure that is precisely right and what we need.

Senator ROMNEY. Thank you, Admiral.

I am going to open this to all three of you, and I guess no one is going to want to respond to it, but I will ask it nonetheless. Do any of you see any gaps, any things we are missing? We are asking questions based on our perceptions, but you are right there. Are there some things we should be focused on to prepare for the next pandemic that we are really not thinking about? Or, for that matter, are there things we should be thinking about with regards to the distribution of vaccines through our country that we are not thinking about? Is everything ready for the next time this happens? Or could you direct us to places where we should be making a better effort?

Admiral GIROIR. I will just make a quick comment, and we are obviously working on this because when we see a gap, we try to fill it. I think there is a lot of work on what we are doing right now, and there is a lot of futuristic work through the Rapid Acceleration of Diagnostics (RADx) Program. And these are really fantastic things, but I think we have to work on magnifying networking, improving process flow of what we have right now, because we can get a lot more juice out of the squeeze we are doing right now, and I really want to focus on that, things like: Can we really pull samples so that we can use one test to test ten people? I think we need to be working with a lot more private partners, universities, Historically black colleges and universities (HBCUs), other groups, in order to make sure that we are reaching the populations we need to reach and we are addressing all the concerns that they have.

So it is not that this is not being done, but I think we have a lot of do it now and the futuristic things, but there is a lot in the middle that we really need to focus on, because that is where really the advantages are going to be reaped for September and October.

Senator ROMNEY. Thank you, Admiral. I see my time is up. Mr. Chairman, thank you.

Chairman JOHNSON. Thank you, Senator Romney. Senator Harris.

OPENING STATEMENT OF SENATOR HARRIS

Senator HARRIS. Thank you, Mr. Chairman. It is obviously impossible to conduct oversight when FEMA has not provided timely responses to critical questions on everything from disaster preparedness to addressing racial disparities. So I would first like to ask unanimous consent (UC) to enter into the record the four oversight letters[1] that I have sent to FEMA during this pandemic for which I have not received a response.

Chairman JOHNSON. Without objection.

Senator HARRIS. Thank you.

[1] The letters referenced by Senator Harris appears in the Appendix on page 661.

This is directed to the full panel. In the midst of this deadly epidemic, the President has stated that help from the Federal Government was a "two-way street," indicating that States would only get assistance if their elected officials were "nice" to him. There have been multiple reports that while FEMA and other administration officials sought to prioritize resources to States and localities most in need, the President sought to prioritize his personal allies instead.

Mr. Gaynor, Mr. Polowczyk, and Mr. Giroir—is that the correct—yes, thank you——

Admiral POLOWCZYK. No. It is Admiral Polowczyk, not "Mister."

Senator HARRIS. Thank you for that, Admiral. During the Federal response to COVID–19, has the President, Admiral, or any of the other panelists, or anyone at the White House directed, suggested, or implied that you direct or redirect resources to certain States or localities for political reasons? Admiral, why don't you start?

Admiral POLOWCZYK. Yes, ma'am. Thank you. I have received no direction from anybody over at the White House to tell me where to send anything. We have a prioritization cell at FEMA that takes CDC inputs and inputs from Dr. Birx to provide COVID communities most in need, and so anything that was distributed or sent was based on those priorities.

Senator HARRIS. And reports also suggest—this is a follow-up to you—that the White House has intervened in the Federal contracting process, which is designed, of course, to be devoid of political interference. Has the President or anyone at the White House ever directed, suggested, or implied that you should award or deny contracts to specific entities? And that is just a yes or no, please.

Admiral POLOWCZYK. I am not involved in the contracting process, so I have no knowledge of that. The FEMA organization has its own contracting staff, and they do not work for me, and I have no involvement in contracting.

Senator HARRIS. Thank you. Mr. Gaynor.

Mr. GAYNOR. What question do you want me to start on, ma'am?

Senator HARRIS. The first one, please, which is during the Federal response to COVID–19, has the President or anyone at the White House directed, suggested, or implied that you direct or redirect resources to certain States or localities for political reasons?

Mr. GAYNOR. Absolutely not.

Senator HARRIS. And has anyone at the White House or the President ever directed or suggested or implied that you should award or deny contracts?

Mr. GAYNOR. Ma'am, when it comes to contracting, there is—between a potential lead that comes from multiple different places, so from Governors to Senators, from Congressmen, those leads are generated, and they go into a validation system inside FEMA. Between that lead and a contract, that chasm is as wide as the Grand Canyon. Those things do not touch. I have the highest confidence in my contracting team, acquisition and procurement, that every contract was executed according to all the Federal regulations, without influence from anyone in government, no matter where they sit.

Senator HARRIS. Thank you. And, Admiral Giroir?

Admiral GIROIR. Thank you, ma'am. The answer to the first question is, no, ma'am, I have not been directed to put any resources anywhere. It has always gone through the prioritization cell or other HHS mechanisms. And for the second, I have no knowledge of that. Again, I am not a contracting officer either, so I am not involved in the contracting process. But I do not have any knowledge of that.

Senator HARRIS. OK. Thank you. And the Federal Government has a very bleak history, frankly, of failing to provide adequate resources like food, housing, financial support, and others to specific communities that have experienced a disaster, and I am referencing the administration's response to Hurricane Harvey in Texas and Hurricane Maria in Puerto Rico.

On April 24th, I led a letter with Ranking Member Peters demanding answers to how the administration is addressing racial disparities. I believe this has come up earlier in this hearing. I finally received a response yesterday evening. Unfortunately, it was inadequate, frankly, and referred to data that HHS and CDC are collecting. But in a House hearing last week, CDC Director Redfield acknowledged that HHS has not fulfilled its responsibility to collect racial data. As it relates to nongovernmental data, the ones that we have do not indicate the mortality rate for—or they actually do indicate that the mortality rate for black Americans is nearly 2½ times higher than for white Americans, and other minority populations, particularly Native and indigenous communities, are also disproportionately impacted.

So I asked this question of Admiral Giroir. I know HHS is using a Social Vulnerability Index, so I thank you for that. Mr. Gaynor, what specific action are you taking?

Mr. GAYNOR. Yes, ma'am, if I can just address the letters. So FEMA and my great partners are still responding to COVID–19 across the Nation, so that is an ongoing response. I have received in excess of 300 letters from Congress. These are numbers that we have not seen before, and we try to get to each and every one of them as fast as we can. I think FEMA has a great relationship with Congress about how fast we speed responses to the Congress. So we will get to every one of those, and so I apologize for the delay, but my effort and my focus has really been on response.

To offset that, to include myself personally and my staff, over 500 engagements with Congress, Governors, mayors on COVID–19, providing all the up-to-date data we can get, including——

Senator HARRIS. I appreciate that. I only have a few minutes left. But I would appreciate your attention to getting a response for us as soon as possible. I thank you for that.

Mr. GAYNOR. I will try to do that, ma'am.

Senator HARRIS. And my last question is: I had previously asked about how FEMA plans to address the wildfire season, and I have asked this a number of times to a number of different people at FEMA, and we have still not received what is the disaster preparedness response plan for wildfires, which disproportionately impact my State, in the midst of the pandemic. Can you tell me when we are going to get that?

Mr. GAYNOR. Yes, ma'am. You actually have it. Again, I want to step back. This whole system works locally executed, State man-

aged, federally supported. I was a local emergency manager. I have a responsibility to my mayor, to my top manager, to my tribal chief, to——

Senator HARRIS. I appreciate the chain of command, but, sir, this is my question: We actually have a hurricane plan.

Mr. GAYNOR. Yes, ma'am.

Senator HARRIS. Is that what you are referring to? Because that is very different by nature than wildfire.

Mr. GAYNOR. Although it does say "hurricane" on the cover, in the first paragraph of the opening statement, it says that the lessons learned in this can be applied to any disaster.

Senator HARRIS. Let me point out a distinction between hurricanes and fires and wildfires, and you can point my direction to where in that pamphlet this might be addressed. Hurricanes, we get forecasts. Thankfully, we have come to a point where we have science and technology (S&T) that gives us warning time. That is not the case with wildfires. So where in your report is that fact addressed? Because I have spent time with the families, the firefighters, in the midst of embers burning during the devastation of the wildfires, and there was no warning for the families that live in those communities, much less for the firefighters and the first responders.

So can you tell me in your report where the nature of that is addressed, including the fact that wildfires spread quickly? They are not regional. They will spread quickly. And where is that fact distinguished between wildfires and hurricanes?

Mr. GAYNOR. Yes, ma'am. So it is true that there is a difference in forecasting for hurricanes and wildfires, and so you do not need to forecast to do actually planning. And so what this encourages, every emergency manager across the country, from the lowest level to the highest level, take their existing plans. So if you have a fire evacuation planning in——

Senator HARRIS. Is there a reason you do not have a plan for fires, for wildfires, and you only have a plan for hurricanes? Because it is not addressed specifically in your report.

Mr. GAYNOR. Again, ma'am, the lessons in this guide can be applied to any disaster. We are an all-hazards agency, so specifically for this season, the hurricane season, it is named the "Hurricane Plan."[1] You can apply all the lessons learned and best practices and resources to local/State planning and disaster that——

Senator HARRIS. I am sorry, sir. The firefighters in my State would disagree with what you are saying in terms of applying the same principles and standards in response to a hurricane as to a wildfire.

Thank you, Mr. Chairman.

Chairman JOHNSON. Senator Carper.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Gentlemen, nice to see you all again. Thank you for your extraordinary service, and thank you for your leadership during one of the most challenging chapters in the history of this country, at least in the years that I have spent on this Earth.

[1] The FEMA Hurricane Plan appears in the Appendix on page 678.

My colleagues would tell you—you do not know me well, but my colleagues would tell you I am a glass-half-full guy. I take to my heart the words in the Bible, "In all things give thanks." Sometimes that is hard to do. In the words of Albert Einstein, "In adversity lies opportunity." And sometimes that is hard to realize, but this is adversity. God knows this is adversity, and there has to be some opportunity here as well.

I served in uniform—never made it to Admiral. I made it as far as captain. And I was, along with John—with the death of John McCain, I am one of the last Vietnam veterans serving in the U.S. Senate. I like to run down to the Lincoln Memorial. I usually go home at night, but I love to run from here down to the Lincoln Memorial. In fact, I always run by the Vietnam Veterans Memorial as well. And there are 58,000 names carved into that stone, and I think about them every time I run by them. That is 58,000 names.

We learned this week—I would say this to Administrator Gaynor: We learned this week, Pete, that the number of deaths is not 110,000 in this country. It is 117,000. I just learned that this morning. That is twice as many people who died from this virus has died in the entire Vietnam War from beginning to end. And that war was predicated on an untruth, and we paid a severe price for that.

We are in a different kind of war today, and we are in a war that you are trying to help us turn the corner on and turn the tide. I just want to say that the work that you have described, the efforts that you have described from men and women in uniform, folks who are medical professionals, folks who are in the private sector, who fly airplanes and move goods from all across the world, heroic efforts. Heroic efforts.

We have somebody who is really close to our family who is an anesthesiologist, and she is very special to us. She graduated from her anesthesiology training, 4 years as an about-to-be anesthesiologist, and finished last week. For months, she has worked in a hospital intubating people so that they could be placed into a coma and be placed on a ventilator and hopefully survive. Most did not. And she is a hero is well—a heroine as well. There are all kinds of people, hundreds, thousands, tens of thousands across the country. And I am inspired by them, and I am inspired by the efforts that you described here today.

But what I am not inspired by are these numbers. In a world where we in the United States have less than 5 percent of the world's population, we have recorded more than 25 percent of the world's deaths from COVID–19.

I have a friend who, when you ask him how he is doing, he always says, "Compared to what?" And I am just going to say I just want to compare the United States to what, and we are 117,000 and counting. New Zealand, 22; Singapore, 25; Taiwan, 7; Australia, 102; Canada, 7,800; South Korea, 274; Germany, 8,800; Japan, 916. China, and I do not know that I believe these numbers, but with 1.4 billion people they are reporting less than 10,000 deaths. Even if you doubled that, it is still only 20,000.

And the thing that I have a hard time getting my head around and understanding is how, by comparison, our deaths, how have they reached these kind of staggering numbers by comparison to

these other nations I just mentioned. I am not a real partisan guy, but I am just going to share with you what may sound partisan, but it is the truth. I want to use these words from our President. February 28, 2020, this is what he said. He said, "It is going to disappear. One day, it is like a miracle, it will disappear." That was February 28, 2020.

March 6th, the President's words: "Anybody that wants a tests can get a test. That is what the bottom line is." Really? March 6th.

Here is March 10th, the same President, he said, "This was unexpected, and we are prepared, and we are doing a great job with it." And he added, "And it will go away. Just stay calm. It will go away."

March 24th: "We have never closed down the country for the flu, so you can say to yourself, 'What is this all about?'"

And May 20th: "When you say that we lead in cases, that is because we have more testing than anybody else. I do not look at that as a bad thing. I look at it as a badge of honor." That just flies in the face of the truth.

You have been asked and handed an incredibly difficult challenge. And if truth be known, it is because we were really late out of the starting gate, realizing what we faced, and addressing it right up front.

A fellow who used to be the head of General Motors used to say, "Leadership is staying out of step when everyone else is marching to the wrong tune." The people that you have to lead have had to march a lot faster because of the lack of leadership that we had in February and March and into April.

So I just want to thank you for the Herculean effort to try to get us out of this crisis finally. And we are not there yet. But because of your efforts, we will be there someday.

A question: When I was a Member of the House of Representatives, I co-authored the reauthorization of the Defense Production Act, one of the things I was proud of. I have followed with interest the role that this administration has played with respect to using the Defense Production Act. But what is the role of this White House—this would be for you, Admiral and Administrator Gaynor. What is the role of the White House, if any, in steering Defense Production Act policy in response to COVID? And, specifically, what is the role of the President's Trade Adviser, Peter Navarro, in approving Defense Production Act requests or shaping DPA policy? And I would ask that of Admiral Polowczyk and Administrator Gaynor, please. Thank you. In that order.

Admiral POLOWCZYK. Administrator, I will go first.

So any use of the Defense Production Act, no matter where it may came from, so let me describe a little bit to you. As I do my work, we have figured out that, N95 masks were in incredibly short supply, a line on Asia. The first action that I put over to the Joint Acquisition Task Force was increase U.S. production of N95 masks. That work came back from the acquisition professionals at DOD, came back in through the Federal Emergency Management Agency, whose staff brought it to the Unified Command Group (UCG), where Administrator Gaynor, Dr. Kadlec and Admiral Giroir lead that, approved that item, and then sent it to the White House, the

NSC, to work through the staffing at the White House. And then it was again briefed to the White House Task Force for approval.

I would imagine that Mr. Navarro is in that management process, but I have no firsthand knowledge of a Mr. Navarro approval of something. It was all approved at the White House Task Force. Mr. Gaynor.

Senator CARPER. Just a brief response, if you would, please.

Mr. GAYNOR. Yes, sir. I wholly agree with the Admiral's recital of how that process works. That is exactly how it works. There is a function for that. We have used DPA, FEMA and my other partners, 15 times, Title I, Title III, Title VII, all those uses follow that process. And it is pretty straightforward from my point of view.

Senator CARPER. All right. Thanks very much.

Thank you, Mr. Chairman.

Chairman JOHNSON. Senator Hawley.

OPENING STATEMENT OF SENATOR HAWLEY

Senator HAWLEY. Thank you, Mr. Chairman.

Mr. Gaynor, let me start with you, if I could. I have appreciated your help in getting Missouri, my home State, the PPE and other resources that we need. I have written to you a number of times. You have been responsive, and your agency, so thank you for that. I want to ask you a question along these lines. We just spoke to my Governor today, and the Governor tells me that the State really wants to continue to buildup their supply of PPE because of the second-line personnel, and there we are thinking particularly of law enforcement, first responders, clinics, others who are having trouble getting PPE. The State wants to be able to resource them. Of course, they do not have the ability, these particular personnel do not have the ability to order directly themselves. They have to get resourced by the States, and the State really feels they need to continue to build their supply of PPE.

Would you be willing to work with me on that to make sure that Missouri gets fully resourced and that these responders, again, law enforcement, clinics, first responders, are able to get what they need?

Mr. GAYNOR. Yes, sir, and I just think for context—and I think this is some of the dynamics we are trying to understand. There are hospitals and nursing homes that had a pre-COVID use for PPE, medical grade PPE. Now that COVID is with us, there are other critical infrastructure factors that had no pre-COVID use for PPE, especially medical grade. So trying to understand exactly what some of these individuals or companies or private sector are looking for, we would want to understand that. So I would love to have a conversation about what exactly is the delta. Is it medical grade PPE for medical purposes? Or is it cloth facial masks? Because you need less than 6 feet to actually get back to work in some business.

I think between the Admiral and I, we can help solve that problem, identify the need, and then obviously identify a source.

Senator HAWLEY. Great. Good. I think that making sure that our law enforcement and first responders get appropriately resourced is a priority that I would hope would be a high priority, and I hope

that you would be able to work with me on that. So I will hold you to that.

Admiral Polowczyk, let me turn to you. Let us talk a little bit about supply chain questions, which you were just referencing in your answer to Senator Carper. I have been following the work that you have done to expedite imports of PPE. Project Airbridge, for instance, I applaud your work on this. And my own view is that we are going to need to reshore these critical supply chains for essential medical products as soon as possible to make sure that we do not find ourselves in a situation like the one we have confronted here in the last several months.

But let me just ask you, in your assessment, Admiral, how severely have export controls by other nations impeded the flow of PPE or impeded our ability to acquire PPE?

Admiral POLOWCZYK. Senator, that is a great question. There are a bunch of unsung heroes—the cargo pilots, the Federal Express (FEDEX), the United Parcel Service (UPS), the National Air Cargo. I could go on and on about those folks. China changed the rules multiple times, subjected our pilots to all sorts of tests, all sorts of other behavior, spraying them with disinfectant. So it is not just export controls which China has changed, as well as other nations have changed, that slowed down or tried to interrupt.

In my opening remarks, I mentioned how fully involved the Department of State was. I had great access to senior leaders within the Department of State to bring up all of these issues to them, and they continued to work great efforts to loosen controls. Every time China changed a process, the Department of State was able to work with the ministerials there, along with asking countries like Malaysia to put workers back in glove factories. So unsung heroes, the Department of State, you may not be thinking about all of the partnerships. This was a great partnership between FEMA, the Department of State, and others.

Senator HAWLEY. You mentioned China. Let me just ask you, lots of Chinese companies have no experience in producing medical equipment but retooled their factories to produce PPE during this crisis. Can you give us a sense of the quality of those Chinese products?

Admiral POLOWCZYK. Right. So one of the things we did, realizing that everybody said that they had or they could produce—I was very skeptical of those things. So very early on, I realized there was really nothing to buy that the health care supply chain already was not working to bring to the points of care needed.

So, again, we used the Department of State. They deployed members in country to go actually visit vendors, go look at warehouses. And then FEMA let a contract with Underwriters Laboratories to actually go do inspection for us so we would not bring inferior product back to the United States.

Senator HAWLEY. Very good. Broadly speaking, Admiral, how would you assess the State of our domestic productive capacity when it comes to PPE, the sorts of devices we have been talking about?

Admiral POLOWCZYK. So currently it is starting to ramp up. Let me just give you a slight metric. We essentially make zero nitrile gloves in the United States, and so we are working with one or two

companies—the Joint Acquisition Task Force has identified several manufacturers that could ramp up to make nitrile gloves, and so that will be a forthcoming DPA action.

N95 masks, we already had some U.S. production going into the middle of March. We used the Defense Production Act to ramp that up from 30, 40 million masks a month to 180 million masks a month, which I think will be sufficient.

Then there are other items such as ventilator drugs, which are going to be significantly more difficult because the advance pharmaceuticals come from multiple places across the globe. And so we are working a process to onshore those along with things like penicillin. My comment to you would be that is going to be a little bit more of a rheostat than a light switch because it is going to take a little bit more investment and process to go work, where it is going from very little to a lot more.

Senator HAWLEY. Give us a sense of what you think the delta is right now between our needs and our domestic productive capacity, if you had to spit ball one.

Admiral POLOWCZYK. N95 masks, I think we are ramping up to meeting our needs. Something like disposable gowns, we are in that process to start making more non-woven fabric, and so that one we have turned to our textile industry to make textile gowns, non-disposable gowns, and so that is 50 percent there, but on a ramp to be there by the fall.

Senator HAWLEY. Very good. Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator Hawley.

I have a 12:15 commitment, so I want to wrap this up before then. I have just got a couple quick questions.

Admiral Giroir, can you explain why is so important to have a less than 10 percent positivity rate in terms of testing and what is our current metric on that?

Admiral GIROIR. Yes, thank you, Senator. This gets to the question of how many tests are enough, and the number of tests that are needed in New Jersey and New York and Massachusetts and the Detroit area are going to be different than what is needed in Montana, Wyoming, and other areas just because of the overall disease.

One reasonable metric that everybody can sort of get their hands on is what we call the "percent positivity of tests." That means if you do 100 tests, how many of those 100 are positive? It is generally accepted that we should shoot for a rate of under 10 percent. So for 10 percent, that means you are testing ten people for everyone one positive. You can sort of understand if 80 percent of the people you test are positive, you do not have enough tests out there. So that is a general metric. It is one that the World Health Organization (WHO) says is an objective. It is generally accepted by most epidemiologists. It is not a magic number. It is not written on stone tablets.

Nationally right now we are at 5.8 percent positivity, which means, by that metric we are in a pretty good range. I follow this every morning per State. Right now there is only one State and the District of Columbia that is outside of that 10-percent range, and they are right on the margin. Again, we are not going to stop there, but that is a metric that we can look at to give us an idea about

how we are doing. You see when there is an outbreak in a certain State, like in a meat-processing facility or something, that percent positive goes up, and we need to ramp up our testing more.

Chairman JOHNSON. One thing that really drove a lot of this policy was the scary numbers coming out of China, for example, about 3.4 percent case fatality rate. I have been monitoring the Oxford Center for Evidence-based Medicine. Their current estimate is somewhere between 0.1 and 0.41 infection fatality rate. The 9-year average for seasonal flu is 0.13 percent; a bad year—2010, 2011—it was, I think, 0.18.

Currently, do we have an estimate in terms of what we think the infection fatality rate is going to be globally on COVID–19?

Admiral GIROIR. So several months ago, I came into the Senate and House—it was a joint session—and we made the estimate back then that the infection fatality rate was going to be about 0.1 to 0.5 percent. There was a lot of yelling and screaming that we were underestimating it, but it is going to be in the 0.1, 0.2 percent range. Again, whatever the rate is, 117,000 is——

Chairman JOHNSON. There is no doubt about it.

Admiral GIROIR. But it is going to be in that rate, and it is going to vary from country to country. I expect our infection fatality rate to be lower than many countries. It is going to be higher than some. But it will be in that range. I think in the spirit of this hearing, this could be considered one of the best of the worst cases because we could have had a virus where that fatality rate was much higher. So as godawful as this has been and how much suffering this has brought, I do consider us in one of the best of the worst cases, and we need to prepare for a lot worse.

Chairman JOHNSON. So we have talked about not having enough PPE for long-term-care facilities. New York, they forced long-term-care facilities to keep COVID patients—Florida said no hospitals, you keep them. Because there is a higher fatality rate, obviously, if you are particularly 75 and over, why wasn't there a game plan? Or should we have a game plan moving forward to transfer those that test positive for COVID out of elderly care and into some kind of segregated hospitalization system? Where, by the way, the PPE could be utilized far more efficiently and effectively than in a long-term-care facility.

Admiral GIROIR. So thank you for that. As was pointed out earlier, 40 or 45 percent of all our deaths occur in elderly, primarily in long-term-care facilities. In an ideal world—and we do not live in an ideal world. In the theoretical world, you could put an elderly person back into a long-term-care facility and do the appropriate isolation. That is very difficult to do given the amount and range of employees and all the interactions.

So Centers for Medicare and Medicaid Services (CMS) have put out some very specific guidelines about how we need to test, how we need to test weekly for workers in long-term-care facilities. And the CDC continues and will have more guidelines soon about how we really need to cohort. But I think in general it is a very dangerous practice to put actively positive patients back into an environment that you cannot contain it, particularly those of the highest vulnerability.

Chairman JOHNSON. It seems like we really ought to be moving them out of there into a different type of facility.

Admiral GIROIR. Into a different type of facility or into a long-term-care facility where everybody is positive so that they are cohorted. But, cohorting by room or even by hallway is just a very difficult thing to do. It is something that hospitals can do, but the 15,000 long-term-care facilities often with workers who have minimal training and low wages is just very difficult to make that happen. So I think you really need to apply the extra precautions that you are suggesting and that we are recommending.

Chairman JOHNSON. I see that Senator Sinema just joined us, so, Senator Sinema, are you ready?

OPENING STATEMENT OF SENATOR SINEMA

Senator SINEMA. Thank you.

I want to first start by thanking the Chairman and our witnesses for holding today's hearing. Arizona has been significantly impacted by the coronavirus. Over the weekend, we crossed the 1,000-death threshold, and the Navajo Nation continues to experience unrivaled per capita infection rates.

Last week, the University of California, Los Angeles (UCLA) American Indian Study Center made the illustrative point that if tribal nations were counted as States, the five States with the highest infection rates in the country would all be tribal nations. So our tribes are hurting badly, and they need our help.

My first question is for FEMA Administrator Gaynor. Unlike State and local governments, tribes do not have a tax base to generate revenue. Funding for essential tribal programs comes from the Federal Government or tribally owned enterprises. As a result of the COVID–19 pandemic, tribes are not generating revenue, which is leading to the closure of vital services. As a result, many tribal governments do not have the funding necessary to pay for emergency protective measures ahead of reimbursement.

Yesterday I and many of my colleagues sent a letter to FEMA requesting advance payments, possibly similar to Section 428 public assistance alternative procedures. Can you work with me to find an alternative pathway for tribal governments on this issue?

Mr. GAYNOR. Yes, ma'am. I cannot say I have seen the letter, but I would be happy to work with you and your staff on a way forward. And just again, for context, specifically with the Navajo Nation, a significant amount of effort from all our partners to include Health and Human Services, Indian Health Service, the States of Arizona, New Mexico, and Utah, all in support of the Nation. We have provided nearly $5 million of direct Federal support to the Navajo Nation, and, again, the Indian Health Service has provided an allocation of about $80 million, again, all to help the Nation deal with COVID–19.

So, again, I would be happy to work with you and your staff on a way forward.

Senator SINEMA. Thank you. I have a follow-up question for you. Many tribal governments contending with the coronavirus outbreak have not previously worked directly with FEMA. Tribes that elect to seek direct assistance from FEMA must overcome a number of administrative hurdles. These requirements include completing a

FEMA Tribal Agreement providing proof of an active emergency response plan and completing a public assistance administrative plan before they can apply for reimbursement.

Streamlining this administratively burdensome process would allow tribal governments expedited access to the funding necessary to save lives and protect their public safety.

How can FEMA streamline this process for the duration of the pandemic?

Mr. GAYNOR. Yes, ma'am, again, through our Regional Administrators across the country, there is a special relationship with the federally recognized tribes and the Federal Government. They can work through their State if they decide to do that, or they can come directly to us, and we will do either way. Again, we will provide technical assistance to any tribe who needs help, and, again, I do that through my ten regions. Again, if there is a specific tribe you are talking about that needs that technical assistance or more, we would be happy to provide that to them.

Senator SINEMA. Thank you. We are going to follow up with you because we do have some tribes that do need this direct technical assistance, so I appreciate that.

My third question: The Arizona Department of Emergency and Military Affairs has expressed concerns with FEMA's guidance that says that the agency will be the arbiter of duplication decisions between FEMA Category B and other Federal funding available to the State. And yet there has been little guidance to address the many areas where overlap in eligibility may exist. Could you explain how this process works in practice?

And then my second question would be: When can we expect to see complete written eligibility guidance to address those areas of potential overlap?

Mr. GAYNOR. Yes, ma'am. So no matter COVID–19 or any other natural disaster, we are always worried about—especially if we are competing with another Federal agency that may have jurisdictional like authority, we always want to make sure that we do not do a callback because we have duplicated benefits. COVID–19 has been a little more challenging mainly because of all the different kinds of COVID–19 supplemental money—CARES Act money. And so we want to work thoughtfully through that to make sure that the appropriate agency owns that problem and those that are trying to use that money derive the greatest benefit from that money, in some cases under the Stafford Act it is a 75–25 cost share. Maybe if you used another agency, like HHS, maybe it is 100 percent.

So we are working through all those variables, and, again, we would be happy to work with you and your staff about trying to untangle that so any jurisdiction can maximize the Federal benefit when it comes to whether it is Stafford Act or CARES Act.

Senator SINEMA. Thank you.

Thank you, Mr. Chairman. I yield back.

Chairman JOHNSON. Thank you, Senator Sinema.

I have just one final question, probably for either the Rear Admiral or the Administrator. We talked a little bit about this earlier, but, again, there is going to be a fair amount of complexity of really honing in on how to handle the Strategic National Stockpile mov-

ing forward. The question I have is: Who is going to be making those decisions? And when will those decisions be made?

Admiral POLOWCZYK. Senator, I will start. Those decisions on the National Stockpile will work its way through the Unified Coordination Group up to the White House Task Force. What I mean by that is levels of inventory—I have personally briefed the Vice President on where I think the high end is. We are working with Health and Human Services to bring to bear the resources Congress provided in the CARES Act to go do that. The administration, the President has already agreed with, more on the shelf, more items, like swabs were not there, the inventory practices of using the commercial marketplace potentially to rotate inventory. So I would say, sir, that the decisions have already been made, but as we get down to the actual resources being applied, the numbers, I hold that up through Health and Human Services, the UCG, to the White House Task Force.

Chairman JOHNSON. Administrator Gaynor.

Mr. GAYNOR. Yes, sir. There are plenty of lessons learned over the past 90 days when it comes to PPE and the National Stockpile. I know that the Admiral is on the next-generation SNS Task Force. We will take all those lessons learned, and we will make the best decisions to make sure that we are ready in the short term, over the summer and into the fall, if there is a second wave. And then, obviously, for the longer term, I think that is probably the greater challenge: How do we sustain all these great lessons learned over the long haul not to get put back in the position that we see ourselves in today?

So this is an ongoing working effort, and we will continue, again, to be part of that process. And we would love to have input from Congress on that on how to make it better, how to fund it, and, again, we would be happy to work with you and your staff on all those things.

Chairman JOHNSON. You will need not only input, but you will need consultation from Congress. This is going to be a long-term process. One of the things I have found a little frustrating, we set up about ten members of our staff on really oversight of COVID–19, National Stockpile, the supply chain vulnerability. For example, this Committee does not even get information on the National Stockpile. That goes to the United States Senate Committee on Health, Education, Labor and Pensions (HELP) Committee. Perfectly appropriate for that, but, really, this is a long-term process. We all need to take responsibility for this, which means we all need to be on a long-term basis involved in the process. So it has to be that collaborative effort. It cannot just be one administration, one time, or it sits on the shelf and it gets forgotten. This really ought to be an annual hearing out of this Committee to take a look at that, where we sit and what we anticipate in the future.

Again, I really do want to thank——

Admiral POLOWCZYK. Can I add something? I do not mean to interrupt you.

Chairman JOHNSON. Sure.

Admiral POLOWCZYK. I bring analogies of how we treat readiness in the Department of Defense, and the readiness of whether it be the stockpile, the health care supply chain, or the readiness of

health care in the Nation, I think this has shown that there is a potentially different way that we should be thinking about it. I echo your concerns that it should not be a one-and-done. I did not fully understand your question, I think, when you asked me. I do think there is a ton of collaboration that needs to happen to help change mind-sets of, hey, I just put some stuff on the shelf and I am good to go. How resilient are we? I think in things of great power competition, and I think you could see where great power competition may have led us in other areas of resiliency. And so I do think that there is—and I am just suggesting that maybe there is, like you said, an annual hearing on the readiness of those things that we desire to be resilient. I think you are on the right track, sir.

Chairman JOHNSON. I appreciate that.

Admiral GIROIR. I absolutely agree with that, and, just as the pediatrician in me, the pediatric Intensive Care Unit (ICU) doctor, it is not just being resilient for the event that we are facing but what have we had to give up in the normal health care system in order to achieve that. Childhood immunization rates have plummeted during the COVID pandemic. Our screening for colon cancer, breast cancer, cancer across the—has gone down. We have had many more cardiovascular attacks in the home and sudden deaths. So in terms of resiliency, I would even broaden the view even more, that it is not just about what we are attacking at that point, but what we have had to give up, and how do we have a total system resiliency, how do we meet that.

Chairman JOHNSON. I have always chafed when I hear people talk about we are going to cancel elective procedures, because one person's elective procedure is somebody else's lifesaving treatment or lifesaving diagnostic test, and we cannot forget that. The whole goal of the shutdown was to flatten the curve so we would not overwhelm our health care system. Fortunately, we did not overwhelm our health care system. What we did is we underwhelmed it in so many cases and, it has resulted in layoffs. There is a lot to be learned. There are a lot of tough decisions being made with imperfect information. I do not want to be critical of those, but we have to look back. We have to analyze what we did, what we did not do right, what we did do right, but we really need to be better prepared in the future.

I want to thank all three of you. I truly want to thank the men and women that work with you. I think it has been an extraordinary effort. Right, it has not been perfect. How could it possibly be? But what is always so true in America, when we face these crises, we really do see just the absolute best come out of our country, the doctors and nurses, the grocery store clerks. I mean, throughout our country people have stepped up to the plate to keep this country as together as possible during a crisis. Quite honestly, it does inspire me. So, again, thank you all for your service.

The hearing record will remain open for 15 days, until June 24th at 5 p.m., for the submission of statements and questions for the record.

This hearing is adjourned.

[Whereupon, at 12:13 p.m., the Committee was adjourned.]

APPENDIX

"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"
Opening Statement of Chairman Ron Johnson
June 9, 2020

As prepared for delivery:

In less than four months, the COVID-19 virus has infected more than 1.8 million Americans and tragically killed more than 100,000. The novel nature of the virus has presented significant challenges for the federal government and states in a number of areas, but particularly in procuring and distributing critical medical equipment and supplies. The focus of today's oversight hearing is to understand how the federal government has reacted to those challenges, and begin to evaluate what may be necessary to ensure we are better prepared in the future.

On March 13th, President Trump issued an emergency declaration nationwide to all 50 states, territories, and the District of Columbia. That action circumvented the need for state executives to formally request federal aid and expedited delivery of emergency protective measures across the country. The President also encouraged states to apply for a major disaster declaration. New York was the first state to request a major disaster declaration. By April 17th, the President had issued a major disaster declaration to all 56 states and territories.

On March 19th, Vice President Pence, as the head of the President's Coronavirus Task Force, designated the Federal Emergency Management Agency (FEMA) to lead the federal response to COVID-19. Following that announcement, FEMA activated the National Response Coordination Center to a Level 1 - its highest level. The Level 1 activation provides a centralized place for agency leads across the federal government to coordinate and facilitate a unified response, and provides a clearinghouse for states to process their requests for assistance.

It is evident that our preparedness enterprise, resources, and supply chains were stressed past the capacity required to meet a nationwide pandemic. We have faced challenges predicting the future demand of personal protective equipment, diagnostic tests, and other medically-necessary equipment, and to meet actual demand with timely, sufficient supply. The administration has worked to combat these challenges through a coordinated response focused on innovative and expedited procurement and distribution programs, including Project Airbridge.

But it is important to note that as with every disaster, the entities best positioned to serve Americans are at the state and local level. FEMA has maintained that the best delivery model for emergency management is one that is locally-executed, state-managed, and federally-supported, and I agree. Those at the state and local level know best how to craft a response, allocate necessary resources, and implement guidelines to protect their specific communities depending on their distinct characteristics, challenges, and requirements. We can and must find ways to encourage and assist states to be better prepared for pandemics and other disasters in the future.

The men and women of FEMA and the Department of Health and Human Services have worked tirelessly for many months to help save Americans' lives. We owe them and our witnesses here today a great deal of gratitude for their service.

U.S. Senate Committee on Homeland Security and Governmental Affairs
"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"

OPENING STATEMENT OF RANKING MEMBER GARY C. PETERS
June 9, 2020
AS PREPARED FOR DELIVERY

Thank you, Mr. Chairman. Thank you to our witnesses for being here today and for your service to our country in this time of need.

In our lifetimes, we have encountered few, if any, challenges of the size and scope of the Coronavirus pandemic. Addressing this pandemic is a monumental task and the federal government's failure to adequately prepare and quickly respond to this crisis led to costly and tragic missteps.

We have now lost more than 110,000 Americans to this pandemic – loved ones whose lives are irreplaceable. As families across the country grieve these unimaginable losses, we must make every effort to examine how we reached this heartbreaking point and ensure that we are better prepared to protect Americans from the challenges of the future, including a potential second wave.

My home state of Michigan has been hit hard, especially among our state's minority communities in cities like Detroit. This pandemic has highlighted longstanding disparities and health inequities facing minority communities. When disasters strike, minority communities often suffer some of the most severe impacts but are among the last to receive assistance. This crisis has served as a chilling reminder that we must do more to protect our most vulnerable and underserved communities going forward.

A rigorous examination of the federal government's response will help ensure that successes can be replicated and any shortcomings can be addressed. These efforts are critical to containing this deadly virus and to continuing the safe reopening of our economy.

In Michigan and across the country, Americans are eager to get back to work. But many industries are still struggling to access the personal protective equipment they need to reopen safely. Americans need these items so that they have confidence they are safe visiting a restaurant or a store.

I warned in a 2019 report that we faced a grave national security risk because of our overreliance on foreign manufacturers for medical supplies, including those in China. The pandemic only intensified those vulnerabilities.

I have heard from manufacturers in Michigan who want to do their part to help produce these critical supplies. Yet the White House was reluctant to fully use its authorities to mobilize private industry. There is no doubt in my mind that this hesitation slowed our response efforts, damaged our economy, and cost American lives.

I greatly appreciate the hard work so far to obtain and distribute supplies to those in great need. But as our economy continues to reopen, we must redouble our efforts to secure the resources to keep workers and customers safe.

Effectively addressing this pandemic will also require widespread testing.
But months into the most severe public health crisis of our lifetimes, we still have more questions than answers about our national testing capacity.

Every state in the country has encountered challenges securing the resources to test people. Even now, my home state of Michigan only has the resources to conduct 15,000 tests per day.

Without sufficient testing, we cannot not fully understand the extent of this catastrophe or take the necessary precautions to protect our communities. Moving forward, we must adopt and implement a clear, effective, and comprehensive national testing strategy.

These are just a few of the issues that I hope to discuss with you today. The loss and heartbreak that we have experienced in this crisis are simply immeasurable and we must do everything in our power to prevent a return to our most difficult days. This hearing is long overdue, but I am eager to work with you on this vital mission.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"

Witness appearing before the
Senate Homeland Security and Governmental Affairs Committee:

Admiral Brett P. Giroir, M.D., Assistant Secretary for Health,
U.S. Department of Health and Human Services

June 9, 2020

Introduction

COVID-19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans. This new disease, officially named Coronavirus Disease 2019 (COVID-19) by the World Health Organization (WHO), is caused by the SARS-CoV-2 virus. There are many types of human coronaviruses including some that commonly cause mild upper-respiratory tract illnesses. Coronaviruses are a large family of viruses. Some cause illness in people, and others, such as canine and feline coronaviruses, only infect animals. Rarely, coronaviruses that infect animals have emerged to infect people and can spread between people. This is suspected to have occurred for the virus that causes COVID-19. Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) are two other examples of coronaviruses that originated in animals and then spread to people.

The Department of Health and Human Services (HHS) has integrated seamlessly into the Federal Emergency Management Agency (FEMA) process, working closely with our Federal, state, and local partners on a daily basis. The Nation Response Coordination Center (NRCC) has provided invaluable and unequalled infrastructure, communications, methodology, and personnel upon which to build an integrated and effective pandemic response – the enormity of which has been unequalled in modern history. The interagency group meets daily to report results from each task force, department, and critical agency, and to hear reports from the individual FEMA/HHS regions. Leadership and decision-making are also structured and collaborative. Led by the FEMA Administrator, there is a Unified Coordinating Group (UCG) that meets daily to provide strategic direction and leadership. I am a member of that group, along with the Assistant Secretary for Preparedness and Response (ASPR).

We thank Congress for supporting our efforts through the passage of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020; the Families First Coronavirus Response Act; the Coronavirus Aid, Relief, and Economic Security (CARES) Act; and the Paycheck Protection Program and Health Care Enhancement Act. These laws have provided additional resources, authorities, and flexibility to our COVID-19 efforts. Within HHS, the Assistant Secretary for Health along with additional components not represented today, have critical roles in the response to this public health emergency as discussed below.

Diagnostics and Testing

Testing for the presence of SARS-CoV-2 is an essential component of our nation's response to the COVID-19 pandemic; its importance is now further magnified as states continue in their various stages of reopening. The indications for viral testing depend heavily on the stage of the pandemic and the extent of mitigation employed. In general, testing may be indicated for diagnosis of those who are symptomatic, tracing of those in contact with those who are infected, and surveillance testing of those who are asymptomatic or mildly symptomatic to achieve infection control and/or other public health objectives.

Currently, there are tests for the presence of the virus and tests for the presence of antibody to the virus. The former determines whether the individual ***is*** actively infected, and presumably infectious. The latter determines whether the individual ***has been*** infected, has developed an immune response, and may be protected from subsequent SARS-CoV-2 infections; however research is ongoing in determining if past infection confers immunity. Today I will focus mostly on widespread testing for the presence of the virus, which has represented the primary challenge the nation has faced since the onset of the pandemic.

It is useful to understand the overall testing strategy in terms of its chronology and sequential objectives, and to understand that this virus was a new human pathogen for which no diagnostic tests had previously been developed. In addition, the predominant type of test relies on sophisticated RNA amplification technology that can only be done in a laboratory certified to perform moderate or high complexity testing. New point-of-care (POC) tests are an exception in that they are low complexity; however, this class of test still represents a minority of available testing capability and has limited utility because of its low throughput and limited sensitivity especially very early or very late in the infection. Finally, the pandemic caused an unprecedented demand for all supplies and materials, such that overall demand in a single month approximated total annual demand of some essential supplies and materials. This reality represented substantial challenges, but federal leadership has guided efforts to combat these challenges in close collaboration with states, local jurisdictions, and the private sector. Our overall strategy for testing includes:

- Assuring that those who need testing, receive testing;

- Prioritizing testing to meet the stage of the pandemic;
- Increasing the number, diversity, and quality of tests;
- Enhancing states' ability to collect specimens through novel "front ends" like drive-through community-based testing sites;
- Organizing and galvanizing the industry on an unprecedented scale;
- Enhancing testing to underserved communities;
- Providing surge testing capacity during local outbreaks;
- Supporting critical infrastructure and national security needs; and
- Enhancing reimbursement for tests to stimulate the private sector, and providing additional incentives for testing in nursing homes and vulnerable communities

Stage 1: Launch: Engaging the Emerging Crisis

In the beginning stages of the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) was engaged in building the foundation for diagnostic testing in the United States. On January 10, 2020, Chinese researchers deposited the 2019-nCoV genome sequence to GenBank and CDC began development of the CDC 2019-nCoV Real-Time PCR Diagnostic Panel. On January 24, CDC publicly posted its assay for the CDC's newly developed diagnostic panel, allowing the global community to develop their own assays using the CDC design. On February 3, CDC submitted an emergency use authorization (EUA) request, and the U.S. Food and Drug Administration (FDA) issued an EUA on February 4, just 24 hours after receiving the complete package, enabling use of the CDC's COVID-19 diagnostic panel.

Understanding the importance of increased testing, the FDA engaged test developers from the beginning of the pandemic. Any developer, including labs, could always introduce tests through the EUA process, as they had during previous emergencies, and FDA encouraged labs and commercial manufacturers to do so swiftly, engaging with more than 550 test developers since January who indicated their intent to submit requests for EUAs. In mid-January, the Biomedical Advanced Research and Development Authority (BARDA) within ASPR convened a meeting of leading diagnostic companies from across America to encourage development of COVID-19 tests. In the ensuing months, multiple funding opportunities for the development of COVID-19 diagnostic tests were announced and the National Institutes of Health (NIH) provided

COVID-19 RNA to diagnostic companies to expedite private-sector test development. With a desire to ensure high quality diagnostic testing but also ensure rapid development and dissemination of COVID-19 tests, the FDA has provided voluntary EUA templates for laboratories and manufacturers in an effort to streamline the entire process, and works with developers who wish to use alternate approaches to the templates. FDA has issued a record number of EUAs for COVID-19 tests. This has contributed greatly to the dramatic increases in testing the nation has seen in the past months. The amount and expediency in which EUAs were issued for COVID-19 tests far exceed past viral outbreaks. For example, in response to the 2016 Zika Virus outbreak, FDA issued 20 test EUAs; in response to the 2009 H1N1 outbreak, FDA issued 17 test EUAs. Currently, FDA has issued more than 100 COVID-19 test EUAs. The timeliness and number of EUAs issued by FDA for COVID-19 tests is unprecedented and has been critical to improving the testing scale and capacity in our country, while providing enough oversight to assure patients can depend on the results of these tests.

Throughout the COVID-19 outbreak, the Administration has encouraged diagnostic test manufacturers, commercial laboratories, and professional societies to expand capacity and scale for existing nucleic acid testing platforms. Through the efforts of the Administration, the United States has developed a multilayered, multifaceted approach to testing that can provide the right test to the right person at the right time. This approach includes contributions from state public health labs, high-throughput commercial labs, academic and hospital labs, labs at CDC, the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs. In addition, the ecosystem now includes POC testing that can be done in rural areas at high risk without sophisticated supporting infrastructure, or as a tool to investigate outbreaks in nursing homes or other confined settings.

As of the end of May, our nation has performed nearly 17 million tests, and now at a rate of between 400,000 and 500,000 tests per day; and this number will continue to increase. Commercial laboratories are working more efficiently, processing tests in rapid succession, which ensures patients receive their results, on average, within three days. Hospital and academic laboratories typically provide results within 2 days, and often much sooner. POC tests provide results within 15 minutes.

To expand capacity and scale without impinging on the traditional health care system like emergency rooms and urgent care clinics, HHS worked closely with FEMA, interagency, and state and local partners to establish Community Based Testing Sites (CBTS). At the inception of this effort, the 41 federally supported sites were developed and established by the U.S. Public Health Service Commissioned Corps (Corps), in CDC-prioritized locations across the country and currently 13 sites remain open with Federal support. These sites remain operational in Colorado, Texas, Illinois, New Jersey, and Pennsylvania. The Corps had unique expertise in COVID-19 testing, since many officers had deployed to Japan and elsewhere to assist in infection control, diagnosis, and eventual repatriation of American citizens. The initial objectives of CBTS were to screen and test healthcare facility workers and first responders, as prioritized by local jurisdiction. The CBTS model has been a success, having tested over 236,000 individuals, and with an overall COVID-19 test positive rate of approximately 14 percent, meaning that the CBTS are testing the right individuals at the right time. This effort has also supported and co-evolved with technological advances such as the validation of the FDA authorized use of nasal self-swabbing, which minimizes the need for trained health professionals and personal protective equipment. The CBTS initiative was an early example to states and localities on how to conduct community based COVID-19 testing, and this model has been replicated throughout the country to screen and test hundreds of thousands more Americans.

And from the onset in January, and continuing to the present, the President, Vice President, and senior Administration officials have held numerous briefings with governors and their state leadership. Many of these briefings have focused on joint federal-state efforts to expand testing throughout the country. In addition to these calls with the Nation's governors, the White House and senior Administration officials have organized numerous calls to enhance state, local, territorial and tribal testing coordination efforts. The constant communication between the Administration and state leadership has helped provide guidance to states on how to best utilize testing capacity in their own states. Another product that was produced by the Administration to assist the states to leverage the full testing capacity at their disposal was a database of nationwide lab locations and capacity, including the specific testing platforms at each laboratory.

Stage 2: Scaling and Technological Innovation

The identification and expansion of public and private sector testing infrastructure has been, and continues to be, a priority. One example of expanding testing infrastructure through public-private partnerships is the engagement of the Administration with well-known retailers that have a regional or nationwide footprint. As of June 3, and with the assistance of the Federal Government, United States retailers have opened and are operating 437 testing sites in 48 states and the District of Columbia and they have tested over 484,000 individuals. To expand testing further, the federal Government is building upon the public-private partnerships to increase the number of testing sites offered at commercial locations across the country. The public-private partnerships with these retailers are being expanded to support many more testing sites that will be opened and operating in the coming weeks. These commercial testing locations are also uniquely situated to meet the testing needs of communities with moderate to high social vulnerability, which was the focus of the original sites. Going forward, retailers have indicated their intent to open at least one thousand more of these sites depending on local needs.

Another effort of the Administration to further support and expand the testing infrastructure in the United States has been strengthening the testing supply chain. The Administration has massively increased the availability of laboratory and testing supplies by engaging directly with distributers and manufacturers to increase production capacity through direct procurement, application of the Defense Production Act, formation of various public-private partnerships, and improved allocation criteria that ultimately help ensure that supplies meet the state's needs and reach the locations where the supplies are needed most. In addition, validation of additional supply types has led to a dramatic broadening of available supplies and reagents.

In May alone, working collaboratively with FEMA and utilizing their logistics, the Federal Government has procured and began to distribute to states – according to their needs and plans – over 12.8 million specimen collection swabs and more than 8.9 million tubes of transport media. To meet state needs, this procurement and distribution will continue in June and the following months, as necessary.

Stage 3: Support Opening Up America Again

Current efforts are focused on further scaling up testing capabilities to guarantee that each state has the testing supplies and capabilities they need to reopen according to their own individual state plans. For example, the Federal Government procured over 20 million swabs and tubes of transport media (or saline) in May. These supplies will be shipped out to states over the course of the next few months, starting in May. ThermoFisher, which has more than 3,000 lab machines across the country, will be producing more than 10 million laboratory testing extraction and PCR kits per month, enabling states to complete millions of additional tests starting in May. In mid-March, the FDA issued an EUA for Hologic's Panther COVID-19 test, which runs on more than 600 lab machines across the United States. Beginning in early May, Hologic began shipping several million test kits per month to labs across the nation.

The Administration will continue to work hand in hand with governors to support testing plans and rapid response programs. The Opening Up America Again guidelines, provided by the Administration, describe roles and responsibilities as well as elements of the robust testing plans and rapid response programs called for in the President's Guidelines.

The Laboratory Testing Task Force is providing technical assistance to all 50 states, tribes, and territories through calls with every state public health team to discuss their testing goals and the best mechanisms to achieve them. The federal government is assisting states to develop testing plans, supplying resources to help meet these testing plans, and deploying teams to states that need additional subject matter expertise.

On May 24th, HHS delivered a COVID-19 strategic testing plan to Congress. This Plan is a direct outgrowth of the work done by the Laboratory Testing Task Force and Community Based Testing Task Force, both under the leadership of HHS and supported by FEMA personnel within the NRCC. It outlines how HHS increased domestic testing capacity across the United States and provides additional guidance and information about diagnostic technologies, platforms and inventory that States, territories and tribes can utilize to develop flexible, adaptable, and robust COVID-19 testing plans. This report fulfills a requirement of the Paycheck Protection Program and Health Care Enhancement Act, signed into law on April 24th. Furthermore, HHS recently distributed $11 billion in support to states, territories, and tribes to support implementation of jurisdictional testing goals as well as a broad array of activities

associated with testing, as indicated in the Paycheck Protection Program and Health Care Enhancement Act.

Because of the Administration's success in rapidly scaling up of the testing ecosystem, states will be fully equipped to conduct more COVID-19 tests per capita each month than most countries have tested cumulatively to this date.

The federal government will continue to support Americans by providing expedited regulatory approvals for tests and equipment as necessary and appropriate, updating guidance for administering diagnostic testing, and catalyzing technological and scientific innovation. The process of reopening the United States will be one that is federally supported, state-led and locally executed.

We recognize that vulnerable populations in many underserved communities are among the highest risk of suffering devastating health and economic impacts of COVID-19. The Office of Minority Health issued a Notice of Funding Opportunity on May 1. The three-year initiative will include the development and coordination of a strategic and structured network of national, state, territorial, and local public and community based organizations that will help mitigate the impact of COVID-19 on racial and ethnic minorities as well as rural and socially vulnerable communities across the nation. The initiative also includes a national multi-media outreach and education effort. One of the primary goals of these information dissemination efforts is to provide additional education and community-level information on resources to help fight the pandemic to those who need it most. In addition, guidance was released on June 4 which will require that demographic data are collected and reported with COVID-19 lab results. The guidance standardizes reporting to ensure that public health officials have access to comprehensive and nearly real-time data to inform decision making in their response to COVID-19. This will ensure that underserved communities are benefitting from the Federal Government investments.

Role of the of the Assistant Secretary for Health on the Unified Coordination Group

On January 31, 2020, the Secretary of HHS declared a public health emergency for the United States in response to the COVID-19 pandemic. Also, in accordance with Presidential

Policy Directive 44 and section 2801 of the Public Health Service Act (as amended by the Pandemic and All-Hazards Preparedness Act), HHS assumed the role of Lead Federal Agency for Federal public health and medical services, under the National Response Framework. On March 13, 2020, the President declared a nationwide emergency under the Stafford Act. In the following days after the President's announcement, FEMA assumed the primary lead role under the White House Corona Virus Task Force in coordinating Federal support and operations in the Whole-of-America response to the COVID-19 pandemic.

Consistent with the National Response Framework, the Unified Coordination Group (UCG) takes action to ensure that all levels of government work together in response to COVID-19. Given the scope of COVID-19, the UCG considers and resolves (or elevates to the White House Coronavirus Taskforce, as appropriate) strategic operational and policy decisions. As suggested in the Biological Incident Annex, the UCG is comprised of principals based on the key operational areas of the response.

As part of the UCG, the Assistant Secretary for Health operationalizes the spectrum of public health and science issues related to COVID-19 response efforts, oversees the U.S. Public Health Service Commissioned Corps, providing it with strategic and policy direction. Additionally, the Assistant Secretary for Health serves as the HHS lead for diagnostic testing, with leadership authority over FDA and CDC.

United States Public Health Service Commissioned Corps

Since the early stages of the COVID-19 outbreak, the Corps has been an indispensable asset leveraged to address the public health needs of the nation in response to this crisis. The Corps is one of the eight uniformed services of the United States and the only uniformed service committed to protecting, promoting, and advancing the health and safety of the nation. Corps officers serve throughout the nation in communities that are most in need by providing essential healthcare services to underserved and vulnerable populations.

In January, the Corps deployed officers to provide expert outbreak response in direct support of CDC. Deployment expanded rapidly from 38 officers on February 1, 2020 to more than 4,100 officers as of May 25, 2020, with many of them undertaking multiple or consecutive

deployments. Corps officers have been deployed across our country and internationally to assist with the outbreak response, to support the return of American citizens, to assist in the management of hospitalized United States citizens with COVID-19 abroad, and to support clinical trials related to COVID-19. Corps officers provided critical assistance to community-based testing sites throughout the nation and their contributions to this effort are immeasurable. In response to the escalating crisis, the Corps established COVID-19 Clinical Strike Teams, which include officers from the variety of disciplines needed on the frontlines. This kind of ready-made unit allows the Corps to deploy a "cavalry" to support healthcare systems under stress in states across the country. COVID-19 Clinical Strike Teams have deployed to a long-term care facility in Kirkland, Washington, to the Javits Center in New York City, and to the TCF Center in Detroit. At the end of March, the Navajo Nation requested CDC assistance to provide care amidst a surge of COVID-19 cases. Since that time, the Corps has deployed teams to support the response. Most recently, the Corps deployed two teams, totaling more than 70 officers, to the Pennsylvania and the Florida State Health Departments to provide infection control, personal protective equipment (PPE) training, and consultation to long term care facilities.

The United States Public Health Service Commissioned Corps stands ready and willing to respond to the public health needs of our country and to provide essential healthcare services.

Conclusion

Thank you for the opportunity to provide an update on the activities of HHS related to procurement and distribution strategies in responding to the COVID-19 pandemic. I am happy to answer any questions.

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STATEMENT

OF

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DEPARTMENT OF DEFENSE

BEFORE
THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENT AFFAIRS
UNITED STATES SENATE
WASHINGTON, D.C.

"Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic."

Submitted
By
Federal Emergency Management Agency
500 C Street SW
Washington, D.C. 20472

June 9, 2020

Introduction

Good morning, Chairman Johnson, Ranking Member Peters, and distinguished Members of the Committee. My name is Pete Gaynor, and I am the Administrator of the Federal Emergency Management Agency (FEMA). I am joined today by my colleague and commander of the Supply Chain Task Stabilization Task Force, Rear Admiral John Polowczyk, as well as Admiral Brett Giroir, Assistant Secretary for Health, from US Department of Health and Human Services. Thank you for the opportunity to discuss FEMA's response and the actions underway to protect the American people during the coronavirus (COVID-19) pandemic, as well as the Agency's ongoing engagement with the emergency management community to enhance disaster preparedness within a COVID-19 environment.

For the first time in the United States' history, there are 57 concurrent Major Disaster Declarations—at least one in every single state, 5 territories, the Seminole Tribe of Florida, and the District of Columbia. From islands across two oceans to the major metropolitan cities of America, the scale of this historic event has required FEMA to adapt its response practices and workforce posture in order to both respond to COVID-19 and simultaneously maintain mission readiness for more common disasters such as hurricanes, earthquakes, floods, or wildfires.

Regardless of the challenges that FEMA continues to confront, the bedrock of our mission remains constant: helping people before, during, and after disasters. Although—and indeed *because*—COVID-19 has changed our daily lives and the scope of its impact is unprecedented, the Nation is counting on us to accomplish our mission and we will do so in accordance with our core values of compassion, fairness, integrity, and respect.

Since March 13th the start of FEMA's expanded involvement in this unprecedented event, the Agency has obligated $6.2 billion from the Disaster Relief Fund to provide personal protective equipment (PPE) to our responders nationwide; establish alternative medical facilities; and fund National Guard troops in every state to support response efforts. More than 3,100 FEMA employees are directly supporting these efforts joining over 4,200 U.S. Public Health Service Commissioned Corps officers, 5,600 Department of Defense (DoD) Title 10 forces, 44,000 National Guard men and women, and the thousands of others from over 40 federal departments and agencies who have brought the full resources of the Federal government to bear. I would like to thank the Members of this Committee for appropriating the resources FEMA needs to meet these complex and historic mission requirements. Today's testimony will offer an overview of FEMA response efforts and strategies for COVID-19, some of the lessons we have learned, and implementable planning considerations as we pivot to prepare for future disasters during a pandemic response.

Overview of FEMA Response

On March 13th, 2020, President Trump declared a nationwide emergency pursuant to section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act). As part of this unprecedented nationwide declaration, all state, local, tribal, and territorial (SLTT) partners became immediately eligible for FEMA Public Assistance (PA) Category B, emergency protective measures as authorized by section 403 of the Stafford Act and funded by the Disaster Relief Fund. Such assistance includes, but is not limited to, funding for Alternative Care Facilities, tribal medical centers, non-congregate sheltering, community-based testing sites, disaster medical assistant teams, mobile hospitals, emergency medical care, and the transportation and distribution of necessary supplies such as food, medicine, and personal protective equipment.

Subsequent to the President's emergency declaration, all states, territories, and some federally recognized tribes requested Major Disaster Declarations. To date, all 50 states, five territories, the District of Columbia, and the Seminole Tribe of Florida have been approved for major disaster declarations to assist with additional needs. FEMA is also working directly with 74 tribes under either the nationwide emergency declaration or a major disaster declaration.

On March 19th, FEMA's role in the pandemic response changed. Under the direction of the White House Coronavirus Task Force, FEMA moved from playing a supporting role in assisting the U.S Department of Health and Human Services (HHS), which was designated as the initial lead federal agency for the COVID-19 pandemic response, to directing the Whole-of-Government response to the COVID-19 pandemic.

In Washington, D.C., the National Response Coordination Center (NRCC) transformed into the fulcrum of federal interagency coordination efforts under the Unified Coordination Group (UCG), which is co-chaired by the FEMA Administrator and Robert Kadlec, M.D., HHS's Assistant Secretary for Preparedness and Response. Seven Task Forces were quickly assembled to address top priorities for the pandemic response, with focuses ranging from addressing community testing to supply chain disruptions.

FEMA's ten Regional Offices are on the front lines of the response, to include activation of their respective Regional Response Coordination Centers (RRCC). In support of this Whole-of-Government effort, there have been up to 46,603 personnel from over 40 agencies—such as the DoD, HHS, Centers for Disease Control and Prevention (CDC), Department of Veterans Affairs (VA), U.S. Army Corps of Engineers (USACE), Defense Logistics Agency (DLA), Customs and Border Protection (CBP) - imbedded within the NRCC and RRCCs to coordinate response and recovery efforts both nationally and at the local level. At its peak, over 40 federal agencies were involved in this coordinated process.

Managing Critical Shortages

From the outset, a key element of FEMA's response has been managing shortages of medical supplies needed to combat the pandemic, such as PPE, ventilators, swabs, and the chemical reagents required for testing. This effort alone has presented a historic challenge for FEMA and its federal partners. COVID-19 has been a global crisis—leaders across over 150 countries have simultaneously been competing for the same medical supplies. We have been further challenged as most of the manufacturing for PPE occurs in Asia, where the virus significantly slowed down private sector production capabilities.

Concurrently, American medical professionals on the front lines of the pandemic have required an exponentially increased volume of PPE and other medical supplies. On average, the United States began consuming a year's worth of PPE in a matter of weeks. FEMA worked closely with HHS to ensure that locations in danger of running out of supplies within 72 hours received life-saving equipment from the Federal government's reserve within the Strategic National Stockpile (SNS), as administered by HHS.

Phase 1: Distributions from HHS' Strategic National Stockpile

From the beginning, FEMA and HHS understood and acknowledged that the SNS alone could not fulfill all of our Nation's requirements. The SNS was never designed or intended to fully supply every state, territory, tribe and locality in the United States concurrently and cannot be relied upon as the single solution for pandemic preparedness. It was principally designed as a short-term stopgap buffer to supplement state and local supplies during an emergency.

During the SNS distribution process, the Federal government worked to balance each state's requests with the need to prioritize hotspots and locations in danger of depleting their own lifesaving medical supplies within 72 hours. Emergency supply shortage notifications were relayed from the local level to state emergency managers or public health departments, who then passed them on to the RRCC to be vetted by FEMA, HHS, and CDC. These requests were then prioritized and shared with the NRCC to adjudicate. The NRCC had the benefit of a national perspective to inform the decision-making process. This national perspective incorporated understandings of increasing or decreasing disease activity and its effects, a broad picture of where resources were needed most urgently, and the resources available in the SNS.

Given the finite number of medical devices such as ventilators in the SNS and the limited capacity of the private sector supply chains to meet the demand, the Federal government adopted a process to manage federal ventilator resources to ship them to the states only in the quantities needed to manage the immediate crisis. As such, ventilators were designated as strategic national assets to be distributed in accordance with immediate need. Ventilator donations from the private sector and federal partners such as the DoD made meaningful contributions to SNS distributions, and while ventilators were low, we were able to fulfill every state's validated request. Due to these efforts, and federally supported innovations within the American

healthcare community to modify or retool medical devices such as anesthesia machines, we are proud to say that no one who needed a ventilator went without a ventilator.

Decisions on where to allocate these limited medical resources were thoughtfully and deliberately informed by a series of intervening variables and a data-driven approach. Considerations such as the number of cases, deaths, available Intensive Care Unit (ICU) beds, available ventilators, prevalence of vulnerable populations, and knowledge of a location's medical infrastructure helped to inform FEMA decision making. A series of influenza models, such as the University of Washington's Institute for Health and Metrics (IHME) Model funded by the Gates Foundation specifically for COVID-19, also played a critical role in helping FEMA allocate medical resources.

Phase 2: The Supply Chain Stabilization Task Force and Project Airbridge

To address the imbalance between supply and demand for PPE and other medical supplies, the Supply Chain Stabilization Task Force, under the direction of Rear Admiral John Polowczyk, was swiftly assembled by FEMA, HHS, DOD, CBP and other federal partners to address widespread shortfalls amidst the global competition for life-saving equipment.

The task force sources PPE, swabs, ventilators and other critical resources requested by states, tribes and territories, with a special consideration given to supporting healthcare workers on the front line. Other priority groups included first responders and critical infrastructure workers in lifeline industries who are unable to practice social distancing due to the nature of their work. However, to reiterate my earlier testimony, FEMA and the Supply Chain Stabilization Task Force have never intended to be the single source of PPE or medical supplies for any entity.

To efficiently maintain the country's existing medical supply chain infrastructure, FEMA and the Supply Chain Stabilization Task Force have sought to supplement – not supplant – the supply chain through a variety of strategies, including Project Airbridge.

Project Airbridge has expedited the movement of critical supplies from the global market to medical distributors in various locations across the United States (U.S.). FEMA is supporting Project Airbridge by covering the cost to fly supplies into the U.S. from overseas factories. To be clear, the Federal government does not own the content of these flights, but simply facilitates the rapid transportation of these materials to the United States on behalf of the six largest American medical distributors who have partnered with the Supply Chain Task Force. This airbridge cuts the amount of time it takes to send via cargo ship supplies from manufacturers abroad to American cities from months to days. Each flight contains critical PPE (e.g., gloves, gowns, goggles, and masks) in varying quantities. Since March 29th, Project Airbridge has completed over 200 flights with additional shipments scheduled, or in transit, for a total of 222 flights.

Once flown in via the Air Bridge, 50 percent of the supplies on each plane were sent by the distributors to customers in areas of greatest need. These areas are determined by HHS and FEMA personnel within the National Resource Prioritization Cell (NRPC), based on information

provided by states and CDC epidemiological data. In addition, FEMA's distribution decisions are also informed by the immense amounts of data provided by the six distributors who are partnered with Project Airbridge. These companies are Cardinal Health, Concordance, Owens and Minor, McKesson, Medline, and Henry Schein.

These six distributors allow us to see what inventory is coming in and where it is going – down to the zip code. This data provides FEMA the ability to prioritize hospitals, nursing homes and other healthcare facilities with the most critical needs and highest COVID-19 rates. This information is updated frequently by the NRPC to provide an accurate view of evolving conditions, PPE accessibility, and shifting hotspots.

The remaining PPE from Project Airbridge is distributed through the companies' regular networks into the broader U.S. supply chain. Prioritization is given to hospitals, health care facilities, and nursing homes around the country. In some cases, the Federal government may purchase some of the supplies upon arrival to provide to states with identified and unmet needs.

This is truly a historic accomplishment by FEMA and its federal partners. The result is a data-informed process that helps FEMA better ensure the right supplies are getting to the right places at the right time to save lives.

Project Airbridge was integral to the federal strategy to manage critical shortages of PPE and other medical supplies by accelerating international deliveries until domestic and foreign manufacturers could increase production to well above pre-COVID-19 levels and standard supply chains could begin to stabilize.

Phase 3: Transition to Expedited Shipping and Increased Manufacturing managed by DLA

Although Project Airbridge was able to fill critical shortages of PPE and other medical supplies, it was never intended to be a permanent component of a stabilized supply chain. As global production levels continue to increase, FEMA and the Supply Chain Stabilization Task Force have begun transitioning towards traditional and expedited sea lane shipping with cargo ships able to carry considerable volume. Additionally, on May 10th, FEMA's first shipment of N-95 masks arrived by sealift in the Port of Long Beach, California, with a subsequent delivery of N-95s arriving on May 21st.

As of June 6th, FEMA, HHS, and the private sector combined have coordinated the delivery of approximately 93 million N-95 respirators, 148.9 million surgical masks, 13.9 million face shields, 37.6 million surgical gowns, and over 1 billion gloves.

Expansion of the industry is also simultaneously taking place. Manufacturers are enhancing domestic production capacity with additional machinery, and in some cases re-tooling assembly lines to produce new products. As an example of this work, the Food and Drug Administration (FDA) is providing salient information to manufacturers who have produced other products, such

as automobiles, on adding production lines or alternative sites for making more ventilators during the COVID-19 public health emergency.

In addition, the Supply Chain Stabilization Task Force is working through over 350 leads to match American businesses who have excess raw materials, workforce, or factory production capacities combined with an overwhelming desire to provide their support to the national response effort. Task Force members are actively working to facilitate the creation of private sector partnerships to pair companies that have offered their excess factory production capacity, the talents of their workforce and access to their raw material supply chains with critical supply manufacturers who have expertise in producing PPE, ventilators, and other needed equipment.

Over two months into the emergency declaration, FEMA's role within the federal response to the COVID-19 pandemic is evolving. FEMA and the DoD's Defense Logistics Agency (DLA) have coordinated the transition of PPE procurement from FEMA to the DLA, with FEMA transitioning its contracts and DLA procuring PPE requested by states and tribes. New procurements for COVID-19 will reside with the DLA, which has a robust procurement and distribution capacity and capability. This transition will help FEMA to better prepare and support the upcoming hurricane season and other potential disasters Americans may face. Regardless of FEMA's role in the management and distribution of critical resources, this COVID-19 response effort will continue to be federally supported, state managed, locally executed, and in this instance, private sector enabled.

Like all task forces assembled to confront specific challenges in crisis, the COVID-19 Supply Chain Stabilization Task Force's lines of effort require longer-term institutional solutions to ensure that America is ready for a sustained response to COVID-19 and other pandemics. The expansion of our domestic industry to increase the production of PPE and other supplies is key to our ability to conduct a sustained response, and this expansion continues – both inside and outside of the Supply Chain Stabilization Task Force. One of the most prominent examples of efforts to expand the domestic industry is demonstrated by interagency efforts to leverage the Defense Production Act.

The Defense Production Act (DPA)

The Defense Production Act (DPA) of 1950, as amended (50 U.S.C.§ 4501 et seq.) is an authority the President may use to expand the production of supplies and services from the private sector needed to promote national defense. This course of action includes emergency preparedness and response activities conducted pursuant to Title VI of the Stafford Act, and protection and restoration of critical infrastructure operations. FEMA specifically has relied on the DPA, as delegated, to focus on increasing the production and distribution of ventilators, N-95 masks, and medical countermeasures.

The authority to use the DPA for health and medical resources for COVID-19 was delegated to the Department of Homeland Security (DHS) and HHS in Executive Order 13911, "Delegating Additional Authority under the Defense Production Act with Respect to Health and Medical Resources to Respond to the Spread of COVID-19." This Secretary of Homeland Security delegated its authority to the FEMA Administrator.

In response to the COVID-19 pandemic, FEMA is utilizing DPA authorities to address disruptions in medical and healthcare lifelines necessary for the continuous operation of critical government and business functions which are essential to human health and economic security. The DPA enables FEMA to leverage domestic industry's ability to supply materials and services in support of the national defense. In addition to using the DPA to protect essential health resources and combat materials shortages, the Federal government is also using the DPA to increase domestic manufacturing capabilities. Increasing domestic manufacturing through the DPA will help to ensure the United States' future preparedness for pandemics is not overly reliant upon the foreign production of medical supplies which, as we have seen, may be vulnerable to supply chain disruptions.

FEMA is the Federal government's lead coordinating agency for DPA activities in response to COVID-19. FEMA has established the Unified Coordination Group (UCG), chaired by me, with leaders from FEMA, the Department of Health and Human Services, CBP, and other federal agencies to review all incoming requests for use of the DPA for COVID-19. Given the scope of COVID-19, the UCG considers and resolves (or elevates to the White House Coronavirus Taskforce, as appropriate) strategic operational and policy decisions.

FEMA's authorities within the DPA are described in Titles I, III, and VII of the Defense Production Act.

DPA Title I - Priorities and Allocations:
Title I of the DPA provides the Federal government with the authority to require contracts and orders to be accepted and to receive priority over non-rated contracts and orders not prioritized by the Federal Government for the national defense. Priority Rated orders take precedence over all unrated orders, when necessary to meet delivery dates specified in the rated orders. Between priority ratings, DX rated orders take precedence over DO rated orders. Most rated orders carry the DO priority rating. Priority ratings can be added to contracts and orders to procure health resources, including PPE, to ensure the federal government has the necessary resources to combat COVID-19.

DPA Title I also provides authority to allocate limited supplies of materials, services, and facilities in the domestic market, which allows the Federal government to control the distribution of scarce, over-taxed health resources.

Furthermore, in response to a Presidential Memorandum, "Memorandum on Order Under the Defense Production Act Regarding 3M Company," on April 3, 2020 FEMA issued a DPA order to 3M for 166.5 million respirator masks from its factories in China, South Korea and Singapore, to be delivered from April to July 2020. FEMA is using this rated order to fill state requests for support and to help fill normal supply chains for PPE.

FEMA has also exercised allocation authority under Title I to impose export limitations ensuring that critical medical supplies needed for the domestic response to COVID-19 are preserved for domestic use. In furtherance of President Trump's April 3rd "Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use", FEMA published an Interim Final Rule to allocate five categories of scarce medical items. These categories include N-95 respirators, surgical gloves, PPE surgical masks, and other air purifying respirators for domestic use. FEMA reviews planned exports of these items and may purchase them, return them for distribution in the domestic market, or, if they fall within one of several established exemptions, allow them to proceed to export. FEMA coordinates closely with our federal partners in implementing this order, including DHS's CBP, the U.S. Department of Commerce, HHS's FDA, and the U.S. Department of State.

Title III – Expansion of Productive Capacity and Supply

Title III of the DPA allows the Federal government to make loans, loan guarantees, and to take other actions to facilitate increased production capabilities needed to maintain, expand, or protect services and materials essential to the national defense. All DPA Title III actions as a result of the CARES Act have been to expand production capacity to support COVID-19 response. To date there have been no loans or loan guarantees made under the DPA.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136) allocated $1 billion for Title III projects related to COVID-19. Title III funds are held in the DPA Fund, managed by the DOD. These funds have been allocated to support increased production capacity and speed of production of critical healthcare resources including N-95 respirators, N-95 filter media, and testing swabs. .

DPA Title VII – Voluntary Agreements with Private Sector Partners:

Based on a finding that COVID-19 presents a direct threat to the national defense and its preparedness programs, FEMA has also initiated efforts under Title VII of the DPA to establish a Section 708 voluntary agreement for the response to COVID-19 and future pandemics. Under Title VII, FEMA plans to enter into the voluntary agreement with private sector manufacturers and distributors of critical healthcare resources necessary in a pandemic. Participants in a voluntary agreement are granted relief from antitrust laws for actions taken pursuant to a voluntary agreement at the direction of the federal government.

As part of the effort to develop a voluntary agreement, FEMA held an open meeting on May 21st to present the draft agreement and solicit stakeholder feedback. Consistent with positive feedback and interest expressed by industry partners, FEMA is in the process of finalizing the agreement. If this agreement is approved by the Attorney General and the Federal Trade Commission, this agreement would formalize the unity of effort between the private sector and the federal government for integrated coordination, planning, and information sharing for the manufacture and distribution of PPE, pharmaceuticals, and critical healthcare resources identified as necessary to respond to COVID-19 and future pandemics.

Lessons Learned

FEMA has responded to this pandemic while continuing to adapt its operations and procedures to support preparation for complex future crises. Among the first lessons learned was the need to preserve PPE and prioritize its distribution.

Preservation and Prioritization

Within the context of a disrupted supply chain, it quickly became apparent that healthcare workers, first responders, patients, and critical infrastructure workers needed prioritization for distributed PPE. While increased production capacity was coming online, FEMA, CDC, and other partners ensured that scarce PPE was allocated to those on the frontlines of the pandemic, and also maximized the utility and useful life of available PPE by releasing guidance to reduce, reuse, and repurpose this PPE. Due to global PPE shortages, the implementation of contingency and crisis capacity plans were sometimes necessary to ensure the continued availability of protective gear.

The BATTELLE Critical Care Decontamination System (CCDS) became another component of the plan to preserve PPE. These units can sterilize compatible N95 respirators using a mobile CONEX box-based Vapor Phase Hydrogen Peroxide (VPHP) generator. It is the subject of an emergency use authorization issued by FDA, with capacity to sterilize 80,000 such respirators daily. The Federal Government purchased sixty systems and distributed 45 for use

nationwide, with five new systems arriving every week. FEMA continues to work with HHS to support their distribution. We hope that Members of Congress will help to communicate the importance of utilizing preservation techniques such as the CCDS with your constituencies.

Rapid Testing for Vulnerable Populations

Given the wide selection of platforms to administer COVID-19 diagnostic testing and the supply chain limitations for the materials needed to support them, FEMA supported HHS efforts to prioritize rapid testing for vulnerable populations such as those found in nursing homes. Prioritizing the limited number of rapid tests for populations with underlying health considerations was key to facilitating a rapid response and the strategic distribution of scarce supplies. COVID-19 diagnostic platforms with longer turnaround times were found to be more appropriate in situations with lower risk of rapid spread and escalation.

In further support of vulnerable populations within nursing homes, FEMA has been coordinating shipments totaling a 14-day supply of personal protective equipment to all 15,400 Medicaid and Medicare-certified nursing homes.

Rapid testing was also proven to be an effective tool in places such as the Navajo Nation, in which limited medical infrastructure and high rates of chronic illnesses combined to create a vulnerable demographic. Rapid testing, as supported by HHS, Indian Health Services, and FEMA, has allowed for increased diagnostic screenings above the national average.

As part of our Agency's efforts to support HHS led community-based testing strategies, FEMA continues to support the White House Coronavirus Task Force and the Administration's Testing Blueprint. Beginning in early May, large quantities of testing swabs and transport media began shipping to help increase testing capacity in support of individualized state, territorial, and tribal plans. As of the end of May, FEMA has delivered over 14 million swabs and 10.2 million tubes of transport media. Each state, territory, and tribe will develop its own distribution strategy to align with its testing plan and unique needs. All states received their initial delivery by May 14, and all states and territories will continue to receive weekly distributions of swabs and media through the month of June. Nationally, partnerships with major retail companies and local independent pharmacies to increase testing access will provide Americans with faster, less invasive, and more convenient testing for under-tested and socially vulnerable communities.

Improving the Ease of Data Sharing with SLTT Partners

An important component of FEMA's data-based decision-making processes has relied upon state, local, tribal, and territorial (SLTT) partners to share critical data elements about the status of hospital capacity, ventilators, and PPE with both HHS and FEMA. This data enables short and long-term strategic decision support on resource allocation, mitigation strategies, health

system needs, and coordination of medical countermeasure development and production. The collection and interpretation of this data has largely fallen under the purview of the NRPC and Data Analytics Task Force.

Significant effort has gone into gathering and submitting this data. To address challenges in this process and streamline the reporting of information, FEMA encouraged all facilities to utilize the National Health and Safety Network (NHSN) tracking system, which most healthcare facilities already access and use. Although reporting this data through states and FEMA regions remains an option, using NHSN ensures this information gets to our data and analysis team in the most efficient way and that we can receive the facility level data that we need to support decisions. Improving the ease of collecting this data better enables FEMA to make informed decisions about where to send limited supplies and provides context to support the resource requests we receive from our SLTT partners. This data sharing will continue to be of critical importance in FEMA's continued COVID-19 response, as will corresponding cyber-security considerations.

Rumor Control and Myth Busting

Throughout all stages of FEMA's COVID-19 response, we have consistently worked to correct misconceptions about the Agency or Federal government's actions and established a Rumor Control Page on our website to assist in this effort. The Agency frequently gets questions regarding FEMA "seizing" or "commandeering" critical PPE. To be clear, FEMA does not seize PPE from its federal, state, local, tribal, or territorial partners, hospitals, or any entity engaged in lawful transactions to distribute these resources. FEMA does not divert any PPE orders to replenish the Strategic National Stockpile.

However, what is true is that certain individuals and businesses are trying to profit from the confusion and fear surrounding COVID-19, hoarding scarce resources with intent to resell them at prices in excess of prevailing market prices. This price gouging profoundly harms the Nation's ability to fight the COVID-19 pandemic and protect those men and women on the medical front lines of that fight. The U.S. Department of Justice (DOJ), under the direction of Attorney General William Barr, established the COVID-19 Hoarding and Price Gouging Task Force, focused on the detection, investigation, and prosecution of illegal hoarding and price gouging related to the pandemic. In some instances, FEMA has assisted the DOJ in its anti-price gouging efforts by issuing rated orders requested by the Hoarding and Price Gouging Task Force to purchase hoarded stockpiles that DOJ has identified as being involved in price gouging efforts.

In addition to concerns about price gouging, FEMA is aware of the threat posed by fraudulent PPE being manufactured, acquired, and shipped to customers desperate to obtain PPE for use in healthcare and other industries. The U.S. Government, academia, and the private sector are working collaboratively to minimize the risk to Americans posed by fraudulent PPE.

Disaster Preparedness in a COVID-19 Environment

COVID-19 is not the last pandemic the American people will face. It is, therefore, imperative that we continue to prepare at all levels of government, within our communities, and across the private sector by learning from our experience with this novel coronavirus. Furthermore, building a culture of preparedness through a Whole-of-America response could become an important component of our ability to most effectively respond to other disasters such as hurricanes or wildfires during a sustained pandemic response.

Operating in overlapping disaster environments will create new intricacies within already complex mission requirements. For example, there will be a new need to evacuate strategic national assets such as ventilators or key pharmaceuticals. Evacuating people within the current COVID-19 environment will present an even larger challenge, and it will likely require the widespread availability of non-congregate sheltering.

Furthermore, COVID-19 may slow down state, territorial, and tribal abilities to conduct damage assessments for disasters such as flooding, severe storms, and hurricanes. Response to other disasters, in turn, can slow down the ability of officials to collect crucial information about COVID-19 cases and stymie their ability to share the critical data needed to combat it. Consequently, there is a potential for a compounded effect that could result in a larger emergency than each disaster would be on its own.

These are just some of the considerations FEMA has accounted for as we pivot to prepare for what could become active hurricane and wildfire seasons.

2020 Hurricane Season Operational Guidance

With a watchful eye on hazards of any type, on May 20th, FEMA released COVID-19 Pandemic Operational Guidance for the 2020 Hurricane Season to help emergency managers and public health officials best prepare for disasters, while continuing to respond to and recover from COVID-19. The guide describes anticipated challenges to disaster operations posed by COVID-19, as well as actions emergency managers and public officials can take to prepare for those challenges. By creating a shared understanding of expectations among FEMA and our SLTT partners, the nation will be better positioned to achieve successful operational outcomes in disaster response and recovery efforts. While this document focuses on hurricane season preparedness, most planning considerations can also be applied to any disaster operation in the COVID-19 environment, including no-notice incidents, spring flooding and wildfires, and typhoon response.

FEMA expects to maintain COVID-19 activation into the 2020 hurricane season in order to best support SLTT operations. To ensure that operational decisions are made at the lowest level possible, consistent with the National Response Framework, FEMA is organizing to prioritize resources and adjudicate accordingly, if needed.

FEMA personnel who are currently deployed will be prepared to pivot to support emergent needs. FEMA regions continue to provide technical assistance and coordination for a range of program areas with their respective SLTT partners. FEMA is also well-positioned with thousands of personnel in the field supporting existing operations, thousands more available ready to support emergent disaster operations, and more personnel joining the Agency through virtual onboarding every two weeks. In order to better adapt plans in this environment and support our partners, FEMA programs will continue to provide assistance to survivors, but many programs may require online or phone registration processes (in lieu of in-person), remote assessments or inspections, and adapted program delivery within impacted areas experiencing localized outbreaks or periods of peak COVID-19 activity. However, when and if SLTT partners are overwhelmed, FEMA is prepared and postured to provide program support, regardless of delivery method.

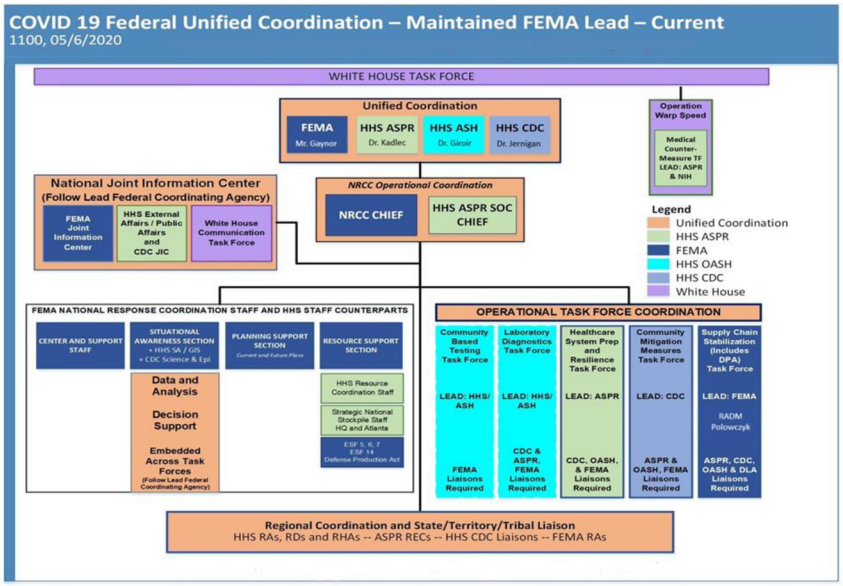
Conclusion

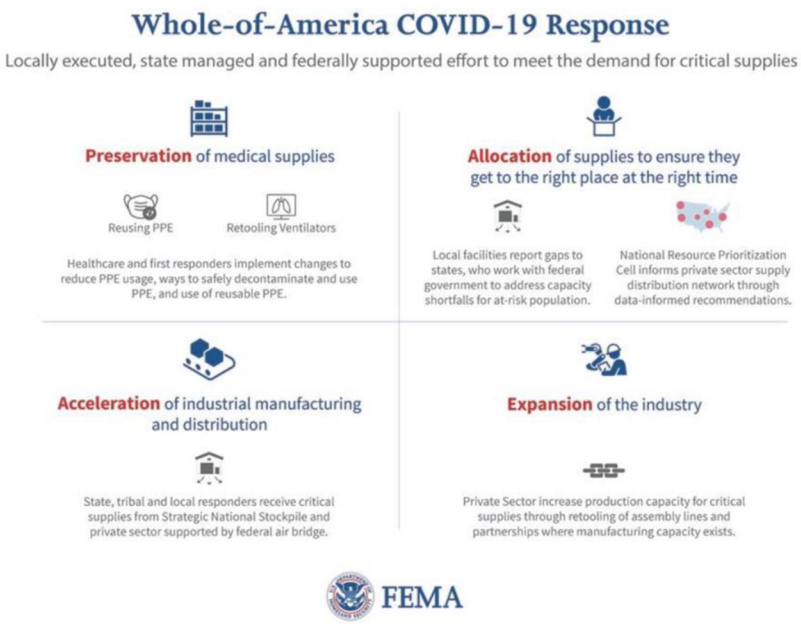
In closing, I would like to emphasize my pride and gratitude to the men and women of FEMA, as well as our partner departments and agencies for their adaptability, hard work, and endurance during this unprecedented response. Their safety and wellbeing remain at the very top of our Agency's priorities.

Furthermore, this Agency would like to thank all Americans. Through coordinated social distancing campaigns across the country, the sacrifices made by millions of Americans bought valuable time as part of this Whole-of-America response. These contributions by the public allowed FEMA and its partners to strategically allocate, and then continuously shift, globally scarce resources such as ventilators to hotspots where they could immediately save lives within a 72-hour window. This Whole-of-America response was personified by leaders in places such as Washington State who voluntarily donated their ventilators to new hotspots in locations like New York.

Finally, we again express our appreciation to Congress and the President for providing FEMA with the necessary resources to meet very complex mission requirements and conditions. This historic and unprecedented response will continue to require a Whole-of-America effort, and FEMA looks forward to closely coordinating with Congress as we work, together, to protect the health and safety of the American people during the COVID-19 pandemic.

Thank you for this opportunity to testify. We look forward to answering any questions that you may have.


COVID 19 Federal Unified Coordination – Maintained FEMA Lead – Current
1100, 05/6/2020
WHITE HOUSE TASK FORCE
Unified Coordination
FEMA
Mr. Gaynor
HHS ASPR
Dr. Kadlec
HHS ASH
Dr. Giroir
HHS CDC
Dr. Jernigan
Operation Warp Speed
Medical Counter-Measure TF LEAD: ASPR & NIH
National Joint Information Center
(Follow Lead Federal Coordinating Agency)
FEMA Joint Information Center
HHS External Affairs / Public Affairs and CDC JIC
White House Communication Task Force
NRCC Operational Coordination
NRCC CHIEF
HHS ASPR SOC CHIEF
Legend
Unified Coordination
HHS ASPR
FEMA
HHS OASH
HHS CDC
White House
FEMA NATIONAL RESPONSE COORDINATION STAFF AND HHS STAFF COUNTERPARTS
CENTER AND SUPPORT STAFF
SITUATIONAL AWARENESS SECTION
+ HHS SA / GIS
+ CDC Science & Epi
PLANNING SUPPORT SECTION
Current and Future Plans
RESOURCE SUPPORT SECTION
Data and Analysis
Decision Support
Embedded Across Task Forces
(Follow Lead Federal Coordinating Agency)
HHS Resource Coordination Staff
Strategic National Stockpile Staff HQ and Atlanta
ESF 5, 6, 7
ESF 14
Defense Production Act
OPERATIONAL TASK FORCE COORDINATION
Community Based Testing Task Force
LEAD: HHS/ ASH
FEMA Liaisons Required
Laboratory Diagnostics Task Force
LEAD: HHS/ ASH
CDC & ASPR, FEMA Liaisons Required
Healthcare System Prep and Resilience Task Force
LEAD: ASPR
CDC, OASH, & FEMA Liaisons Required
Community Mitigation Measures Task Force
LEAD: CDC
ASPR & OASH, FEMA Liaisons Required
Supply Chain Stabilization (Includes DPA) Task Force
LEAD: FEMA
RADM Polowczyk
ASPR, CDC, OASH & DLA Liaisons Required
Regional Coordination and State/Territory/Tribal Liaison
HHS RAs, RDs and RHAs -- ASPR RECs -- HHS CDC Liaisons -- FEMA RAs


Whole-of-America COVID-19 Response
Locally executed, state managed and federally supported effort to meet the demand for critical supplies
Preservation of medical supplies
Reusing PPE
Retooling Ventilators
Healthcare and first responders implement changes to reduce PPE usage, ways to safely decontaminate and use PPE, and use of reusable PPE.
Allocation of supplies to ensure they get to the right place at the right time
Local facilities report gaps to states, who work with federal government to address capacity shortfalls for at-risk population.
National Resource Prioritization Cell informs private sector supply distribution network through data-informed recommendations.
Acceleration of industrial manufacturing and distribution
State, tribal and local responders receive critical supplies from Strategic National Stockpile and private sector supported by federal air bridge.
Expansion of the industry
Private Sector increase production capacity for critical supplies through retooling of assembly lines and partnerships where manufacturing capacity exists.
FEMA

United States Senate

May 15, 2020

The Honorable Peter Gaynor
Administrator
Federal Emergency Management Agency
500 C Street SW
Washington, DC 20472

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Administrator Gaynor and Secretary Azar:

We are gravely concerned with recent reporting that President Trump and members of the Coronavirus Task Force are attempting to deflate the number of deaths attributed to COVID-19. As the Administrator of the Federal Emergency Management Agency (FEMA), the agency leading the All-of-America response to the pandemic, and the Secretary of the Department of Health and Human Services (HHS), the agency with expertise in tracking morbidity and mortality, it is incumbent on you to ensure an accurate and transparent death toll and consistent COVID-19 statistics.

On May 1, 2020, Senator Harris sent you a letter calling for an accurate COVID-19 death count during this pandemic. In that letter, she noted that a report by the National Academies of Sciences, Engineering, and Medicine on best practices for tracking significant morbidity and mortality during a disaster that was mandated by legislation enacted in the aftermath of Hurricane Maria, is expected to be released later this year. However, because this pandemic necessitates federal guidance immediately in order to ensure an accurate death toll, the letter called on FEMA and HHS to work with the experts from the study to establish temporary federal protocols for counting and tracking COVID-19 morbidity and mortality. To date, Senator Harris has not heard back from either of your agencies.

Unfortunately, over the last two weeks, we have seen a misinformation campaign coming from the White House surrounding the COVID-19 death numbers, claiming the death count has been inflated. President Trump has publicly suggested that there are far fewer deaths than currently reported and reports indicate that administration officials asked Centers for Disease Control and Prevention (CDC) officials to exclude individuals from the official death count who were presumed positive or who may not have died as a direct result of contracting the virus.

Public health experts know this is a mistake and reporting indicates that officials inside the CDC pushed back against that request, claiming it could falsely skew the mortality rate at a time when

state and local governments are already struggling to accurately ensure that every person who dies as a result of COVID-19 is counted.

Additionally, federal scientists and doctors, including Dr. Anthony Fauci, the head of the National Institute of Allergy and Infectious Diseases, have said the U.S. death toll is likely higher than is being reflected in government data sets. This is supported by examining the number of excess deaths this year compared to the same time period in previous years, which is remarkably higher than the current COVID-19 death count.

The misinformation surrounding the COVID-19 death count is not a new tactic from President Trump. This is the exact behavior that led to an extreme undercount in Puerto Rico after Hurricane Maria. Without clear, unambiguous guidelines led by science and data on how to correctly count COVID-19 mortalities, inconsistent numbers and misinformation will impact government accountability, how resources will be allocated, and how we recover from this crisis.

We must have accurate, reliable information in order to successfully fight COVID-19. It is imperative that FEMA and HHS work with experts, including those involved in the National Academies study, to establish interim guidelines specifically for this pandemic and put an end to inconsistent data and messaging surrounding the COVID-19 death count. We look forward to hearing back as soon as possible on this pressing issue.

Sincerely,



Kamala D. Harris
United States Senator

/s/ Richard Blumenthal

Richard Blumenthal
United States Senator

/s/ Mazie K. Hirono

Mazie K. Hirono
United States Senator

/s/ Edward J. Markey

Edward J. Markey
United States Senator

/s/ Sherrod Brown

Sherrod Brown
United States Senator

KAMALA D. HARRIS
CALIFORNIA
WWW.HARRIS.SENATE.GOV

United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
COMMITTEE ON THE JUDICIARY
SELECT COMMITTEE ON INTELLIGENCE
COMMITTEE ON THE BUDGET

May 7, 2020

The Honorable Peter Gaynor
Administrator
Federal Emergency Management Agency
500 C Street SW
Washington, DC 20472

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Administrator Gaynor and Secretary Azar:

I am writing to request more transparency around the federal government's distribution of remdesivir to hospitals and health systems. I urge the Federal Emergency Management Agency (FEMA) and the Department of Health and Human Services (HHS) to ensure equitable distribution of the drug across states and regions, including to communities with high levels of racial and ethnic disparities in COVID-19 cases and deaths.

As you know, the Food and Drug Administration (FDA) granted an emergency use authorization (EUA) for remdesivir, an investigational antiviral treatment, on May 1, 2020.[1] This was based on preliminary data from a National Institute of Allergy and Infectious Diseases study showing patients who received remdesivir recovered faster than similar patients who received a placebo.[2] Gilead Sciences has donated 1.5 million doses of remdesivir – their existing supply of the product – to the federal government.[3] Assuming a 10-day course of treatment, this donation is likely enough for 140,000 patients.[4]

It is crucial that distribution of this drug and any subsequent authorized treatments optimizes public health. Given the staggering racial and ethnic disparities that have emerged during this pandemic, an equitable distribution of remdesivir is necessary to address and reduce the adverse COVID-19 health outcomes in the African American, Latinx, American Indian, Alaska Native, and Pacific Islander communities.

The American people deserve transparency about the methodology and timeline of distribution of remdesivir. Public reporting suggests FEMA and HHS are in charge of distributing the existing doses of remdesivir.[5] As of May 6, HHS reportedly approved 25 hospitals to receive remdesivir under the EUA.[6] At this time, I am unaware of any California hospitals – including those in current hot spots – that have received a remdesivir allocation from the federal government despite some even participating in clinical

[1] https://www.fda.gov/media/137564/download
[2] https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19
[3] https://www.gilead.com/news-and-press/press-room/press-releases/2020/5/gileads-investigational-antiviral-remdesivir-receives-us-food-and-drug-administration-emergency-use-authorization-for-the-treatment-of-covid19
[4] Id.
[5] https://www.politico.com/news/2020/05/06/remdesivir-helps-coronavirus-patients-but-at-what-cost-240230
[6] https://www.statnews.com/2020/05/06/doctors-lambaste-federal-process-for-distributing-covid-19-drug-remdesivir/

trials on the drug. Additionally, the Howard University Hospital, the only Historically Black College and University (HBCU)-owned hospital, which plays a critical role in serving African Americans, one of the communities that has been hit the hardest by COVID-19, also did not receive any remdesivir in the initial distribution. In fact, no hospital in the District of Columbia received doses, a city where African Americans make up 46% of the population but 79% of the COVID-19-related deaths.[7] The fact that many of the hospitals and areas with high rates of COVID-19 cases and deaths were left out of the initial distribution raises significant questions about FEMA and HHS' decision making.

I have previously requested information on how FEMA and HHS are making critical decisions and addressing racial and ethnic disparities. On April 3, I sent a letter to FEMA and HHS requesting detailed information on how scarce resources were being distributed. On April 24, I sent a letter to FEMA requesting information on how the agency was addressing the racial and ethnic disparities in COVID-19 cases and deaths. I have not received an answer to either letter and the current reporting regarding the distribution of remdesivir is cause for continued concern.

I request answers to the following questions by next Friday, May 15, 2020.

1. To date, how many hospitals and/or health systems have received allocations of remdesivir from the federal government?

2. What criteria or methodology did FEMA and HHS use to select which hospitals and/or health systems received remdesivir?
    a. Did you consider hospitals and/or health systems serving COVID-19 hot spots?
    b. Did you consider hospitals and/or health systems serving disproportionately impacted communities of color, such as public hospitals and hospitals owned or affiliated with HBCUs?

3. What criteria or methodology does FEMA and HHS plan to use to allocate the remaining doses of remdesivir?

4. When do FEMA and HHS plan to announce further allocations of remdesivir?

5. Given the current number of available doses, how many additional hospitals and/or health systems do FEMA and HHS anticipate will receive remdesivir allocations?

6. How do FEMA and HHS plan to ensure an equitable distribution of remdesivir to hospitals and health systems across regions and states?

7. How do FEMA and HHS plan to ensure equitable distribution of remdesivir for racial and ethnic groups that have been disproportionately affected by COVID-19?

8. How are FEMA and HHS addressing the needs of public hospitals, hospitals owned or affiliated with HBCUs, and other hospitals and/or health systems serving disproportionately impacted communities of color?

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[7] https://www.census.gov/quickfacts/DC; https://coronavirus.dc.gov/page/coronavirus-data

9. As clinical trials continue across the nation and the world, how do FEMA and HHS plan to ensure equitable distribution of future COVID-19 treatments and vaccines?

Thank you for your attention to this urgent issue.

Sincerely,



KAMALA D. HARRIS
U.S. Senator

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United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
COMMITTEE ON THE JUDICIARY
SELECT COMMITTEE ON INTELLIGENCE
COMMITTEE ON THE BUDGET

May 1, 2020

The Honorable Peter Gaynor
Administrator
Federal Emergency Management Agency
500 C Street SW
Washington, DC 20472

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Administrator Gaynor and Secretary Azar:

As our nation continues to combat COVID-19, we know that the true death toll from the virus is likely far higher than the current count.[1] An accurate count of the lives lost to the pandemic is critical to understanding the impact of the crisis, ensuring the federal government is held accountable for an adequate response, and providing information on rates and distribution of mortality and morbidity to inform public guidance as communities being to open up. This data is especially crucial to tracking deaths in minority populations and informing decisions on how to effectively address observed disparities in the COVID-19 mortality rate. Already, we have seen a COVID-19 mortality rate for Black Americans that is about 2.5 times higher than the rest of the population.[2] Accurate and consistent data is also critical to understanding where to send scarce resources, such as ventilators and personal protective equipment (PPE), and it is one of the few ways to understand how and where the disease has the potential to establish a hotspot.[3]

Unfortunately, the United States does not currently have a standard protocol for counting mass casualties during a disaster, which can cause inaccurate disaster-related data. Recent reports have indicated that inconsistent protocols from state to state and limited testing resources have led to potentially high numbers of uncounted COVID-19 deaths.[4] Each state, coroner, and medical examiner are potentially operating under different policies when it comes to classifying and reporting deaths linked to the disease. Additionally, many coroners and medical examiners are unable to test the deceased due to a lack of testing capacity, which compounds the issue of incomplete death counts.

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[1] https://www.nytimes.com/interactive/2020/04/28/us/coronavirus-death-toll-total.html
[2] https://www.apmresearchlab.org/covid/deaths-by-race
[3] https://www.nbcnews.com/news/world/official-coronavirus-death-tolls-are-only-estimate-problem-n1183756
[4] https://www.cnn.com/2020/04/06/health/coronavirus-coroners-uncounted-deaths-invs/index.html

As uncertainties and inconsistencies have emerged, health departments have had to amend previously reported counts.[5] For example, New York City's death toll did not originally include those who died at home without getting tested, or who died in nursing homes or at hospitals, but did not have a confirmed positive test result. Then, earlier this month, the city decided to include presumed coronavirus cases in its data, suddenly increasing the death toll by thousands.[6] Additionally, Santa Clara County, California recently announced three previously unidentified deaths from the coronavirus, all predating the first reported death in the county, implying that the virus had been circulating in the community much earlier than originally documented.[7] Further, experts believe that many of the earliest cases of COVID-19 were likely overlooked and were incorrectly attributed to the flu as the nation was in the middle of the typical influenza season.[8]

The United States has recently experienced the ramifications of an inaccurate death toll from a disaster. In the immediate aftermath of Hurricane Maria, disturbing reports suggested the official death toll in Puerto Rico of 64 was a dramatic undercount and that the real number was in the thousands. This vast discrepancy had detrimental effects on Puerto Rico's recovery, especially because death toll numbers influence the urgency and scale of federal response efforts and the aid disaster victims and their families can receive from the Federal Emergency Management Agency (FEMA).

One year after Hurricane Maria hit, FEMA received 2,431 requests for funeral assistance from Puerto Ricans, and only 75 (3%) were approved.[9] To qualify, Puerto Ricans had to provide a death certificate or letter from a government official, "that clearly indicates the death was attributed to the emergency or disaster, either directly or indirectly," but getting that information was impossible for many families because officials were not counting hurricane-related deaths appropriately or consistently.[10]

As Puerto Ricans grappled with the true cost of the hurricane, President Trump downplayed the disaster, making false accusations that the toll was being inflated to "make me look as bad as possible."[11] President Trump has again attempted to spread false information surrounding death counts by retweeting statements claiming that the COVID-19 death toll has been inflated. We cannot allow the failed disaster response we saw in Puerto Rico to happen ever again.

That is why I introduced the Counting Our Unexpected Natural Tragedies' (COUNT) Victims Act,[12] which was passed into law with the FAA Reauthorization Act of 2018. The bill directed

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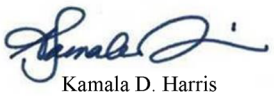
[5] https://www.nytimes.com/2020/04/05/us/coronavirus-deaths-undercount.html
[6] https://www.politico.com/states/new-york/albany/story/2020/04/14/new-york-city-coronavirus-death-toll-jumps-by-3-700-after-uncounted-fatalities-are-added-1275931
[7] https://www.sfchronicle.com/health/article/First-known-U-S-coronavirus-death-occurred-on-15217316.php
[8] https://www.sfchronicle.com/health/article/First-known-U-S-coronavirus-death-occurred-on-15217316.php
[9] https://www.buzzfeednews.com/article/nidhiprakash/puerto-rico-hurricane-funeral-assistance-fema
[10] https://www.buzzfeednews.com/article/nidhiprakash/puerto-rico-hurricane-funeral-assistance-fema
[11] https://www.wsj.com/articles/trump-says-democrats-inflated-puerto-rico-death-toll-from-hurricane-maria-1536846719
[12] https://www.harris.senate.gov/news/press-releases/harris-velzquez-call-for-probe-into-disaster-death-counts-

FEMA to contract with the National Academies of Sciences, Engineering, and Medicine (Academies) to conduct a study on how to best assess significant morbidity and mortality during and in the aftermath of a natural disaster and to provide best practices and policy recommendations that can be used to help establish federal procedures. Currently, this process is left up to individual states and territories and there is no agreed upon set of best practices.

The Academies have informed me that the committee is in the process of finalizing their findings, conclusions, and recommendations and they expect to release the report to the public later this year.[13] Unfortunately, we are in the middle of the COVID-19 crisis and we cannot afford to wait for the study's full report. That is why I am requesting that in the interim, FEMA work with the Department of Health and Human Services to utilize the experts from the study to set clear, temporary, federal guidelines specifically for this pandemic in order to obtain an accurate and consistent count of COVID-19 fatalities.

Thank you for your immediate attention to this matter.

Sincerely,



Kamala D. Harris
United States Senator

[13] https://www.nationalacademies.org/our-work/best-practices-in-assessing-mortality-and-significant-morbidity-following-large-scale-disasters

Congress of the United States
Washington, DC 20515

April 20, 2020

The Honorable Peter T. Gaynor
Administrator
Federal Emergency Management Agency
500 C Street, NW
Washington, DC 20472

Dear Administrator Gaynor:

We write to seek information about what specific steps the Federal Emergency Management Agency (FEMA) is taking to ensure that it is adequately prepared to respond to a natural disaster during the COVID-19 pandemic and beyond. While these are unprecedented times and your Agency is working diligently to lead the Federal government response to the pandemic, we know that a natural disaster could strike at any moment. As the lead Federal agency responsible for emergency preparedness, response and recovery, it is imperative that your disaster preparation and recovery plans reflect the unique challenges presented by this ongoing pandemic response, so that the Federal government can provide adequate and timely assistance to any impacted State, local, tribal, or territorial government.

As the number of confirmed COVID-19 cases across the country has steadily increased since the President invoked the Stafford Act, spring flooding season is now upon us, wildfire season is fast approaching, tornado outbreaks are starting to spread, a major earthquake could strike at any moment, and hurricane season—which is projected to be above average—is just around the corner. Addressing major disasters like these requires a highly coordinated response across all levels of government that will be greatly complicated by the COVID-19 national emergency, including the social distancing measures public health officials are recommending. Further, the COVID-19 response has overwhelmed FEMA's already thin resources, raising concerns about the Agency's ability to handle both a nationwide public health crisis and the upcoming seasonal hazards that await.

The hurricane and wildfire seasons of 2017 and 2018—which saw an unprecedented volume of catastrophic disasters—and the declared events in the years since have greatly tested FEMA's all-hazards approach to disaster response. In Puerto Rico, we saw the devastating effects of a smaller scale public health crisis that resulted from an inadequate response to a natural disaster. In the Agency's own after-action report, FEMA acknowledged that it was unprepared for Irma and Maria in both supplies and personnel. The report found that chronic understaffing in the

Agency had put it in a position where they "placed staff in positions beyond their experiences and, in some instances, beyond their capabilities."[1]

Unfortunately, such issues remain while we are now facing the prospect of a simultaneous major natural disaster compounding the current public health emergency arising from the COVID-19 pandemic. Concerns are not just limited to inadequate staffing levels, sheltering procedures in a time of social distancing, a global shortage of necessary protective gear. It is critical that FEMA share with Congress the steps it is taking to ensure that the Agency is fully prepared to carry out its mission in responding to natural disasters during this pandemic.

Therefore, we respectfully request answers to the following questions:

1. If a natural disaster were to hit today, how many of FEMA's specialized staff—those fully qualified to work in operations, safety, and planning—would be immediately available to deploy?
2. With the Agency's own Daily Operations Brief consistently reporting single digit availability of FEMA's field leadership contingent—Federal Coordinating Officers, who are trained and certified to manage disasters around the country—available to be deployed, what is the Agency's plan to grow the ranks of this cadre and how long will it take to train new field leaders?[2]
3. How soon does FEMA anticipate needing to utilize the Surge Capacity Force and/or increase the number of contractors, and what is the current strategy for doing so?
4. FEMA's two main training facilities – the Emergency Management Institute and the Center for Domestic Preparedness -- have been closed since March 14 and are not scheduled to open until at least May 10. What is the Agency's plan for training both Federal staff and its State, local, tribal, and territorial partners?
5. What are the specific strategies FEMA is using to coordinate with Federal, state, and local agencies in order to share information and prepare for the unique challenges these upcoming and overlapping disaster seasons will bring?
6. How have those strategies changed to account for the unique challenges facing stakeholders such as limited training, conferences, and briefings that normally provide opportunities for sharing information and best practices?
7. How is FEMA preparing for the possibility that a significant number of its own personnel may be ill or in self-isolation when faced with short- or no-notice natural disaster response and recovery?
8. With FEMA relying on federal firefighters from the USFS, BLM, and other agencies to provide qualified incident management expertise for the COVID-19 response, what coordination has been undertaken with their home agencies to ensure that such personnel are ready for their primary mission come wildfire season and to reduce their risk of COVID-19 infection during their service under the FEMA-led pandemic response?

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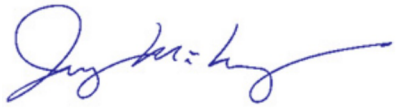
[1] https://www.fema.gov/media-library-data/1531743865541-d16794d43d3082544435e1471da07880/2017FEMAHurricaneAAR.pdf

[2]https://content.govdelivery.com/attachments/USDHSFEMA/2020/04/14/file_attachments/1426564/FEMA%20Daily%20Ops%20Briefing%2004-14-2020.pdf

9. How will FEMA ensure its Reservist cadre—which includes personnel who have underlying health conditions or may be older in age—are not penalized for opting out of a potentially hazardous deployment?
10. With supply shortages of basic personal protective equipment (PPE) well-known, what is FEMA's plan for providing PPE and other critical equipment to its staff and volunteers in order to ensure their health and safety during upcoming response operations?
11. What is FEMA's plan for coordinating with an already over-burdened health care system in the event that thousands of potential disaster survivors require medical assistance?
12. What is FEMA's alternate plan to address the need for mass sheltering and evacuation facilities when public health officials have advised for social distancing and against large gatherings?
13. Is FEMA considering using its authority to activate Transitional Sheltering Assistance to utilize hotels and other non-congregate sheltering options in the immediate wake of a disaster rather than long-planned congregate shelters?
14. What is FEMA's plan to address the potential need for first responder base camps, which can often be crowded and make it difficult to follow social distancing guidelines?
15. What efforts are being made by FEMA to coordinate directly with state and local entities to ensure that individuals in need of temporary housing as a result of a natural disaster have access to the food supplies they need, such as ensuring adequate numbers of volunteers to assist in food preparation and distribution or developing a program to reimburse states if they hire caterers and service industry workers should other voluntary organizations or aid not be available?
16. What is FEMA doing to coordinate with the National Voluntary Organizations Active in Disasters (NVOAD) to prepare for the real possibility of not being able to readily deploy the traditional volunteer force?
17. What is FEMA's plan for managing already stretched thin personnel across potentially multiple simultaneous natural disasters during the pandemic response, and what challenges does FEMA foresee in carrying out response efforts under these circumstances?
18. Is FEMA considering halting permanent work on still-open past disasters and other ongoing projects in order to allocate additional resources and personnel for its pandemic response? If so, please specify the projects that would be impacted.
19. Is FEMA considering proactively activating Public and Individual Assistance given the challenges states will face gathering Preliminary Damage Assessments?
20. Is FEMA planning to provide states, tribes, and territories with any additional resources for natural disaster response, given that their emergency response capacity is being consumed by the COVID-19 pandemic?
21. Does FEMA have a plan to expand the National Response Coordination Center at FEMA Headquarters or set up an expanded site in the event additional large-scale interagency activations are needed over the next few months?
22. In the case that FEMA has to respond to natural disasters during this pandemic, how will that affect the resources it is currently dedicating to the Coronavirus Task Force operations and other COVID-related efforts?

Thank you for your attention to these matters. Given the urgency of this situation, we ask that you respond within two weeks from the date of this letter to Mike Stoever in Representative McNerney's office (Mike.Stoever@mail.house.gov) and Isaac Irby in Senator Harris' office (Isaac_Irby@harris.senate.gov).

Sincerely,



JERRY MCNERNEY
Member of Congress



KAMALA D. HARRIS
United States Senator

Also signed by:

/s/
PETER DEFAZIO
Member of Congress

/s/
GARY C. PETERS
United States Senator

/s/
DINA TITUS
Member of Congress

/s/
EDWARD J. MARKEY
United States Senator

/s/
RICHARD BLUMENTHAL
United States Senator

/s/
CATHERINE CORTEZ MASTO
United States Senator

/s/
RON WYDEN
United States Senator

/s/
CHRIS VAN HOLLEN
United States Senator

/s/
JACK REED
United States Senator

/s/
JEFFREY A. MERKLEY
United States Senator

/s/
BOB CASEY
United States Senator

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TAMMY DUCKWORTH
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TINA SMITH
United States Senator

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JULIA BROWNLEY
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/s/
J. LUIS CORREA
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EMMANUEL CLEAVER, II
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Member of Congress

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CEDRIC L. RICHMOND
Member of Congress

/s/
MIKE DOYLE
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/s/
JUDY CHU
Member of Congress

/s/
DAVID CICILLINE
Member of Congress

/s/
DORIS MATSUI
Member of Congress

/s/
HENRY C. “HANK” JOHNSON, JR.
Member of Congress

/s/
ROBERT C. “BOBBY” SCOTT
Member of Congress



COVID-19 Pandemic Operational Guidance for the 2020 Hurricane Season

May 2020

FEMA

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Executive Summary

On March 13, 2020, President Donald J. Trump declared the ongoing novel coronavirus (COVID-19) pandemic to be of sufficient severity and magnitude to warrant a nationwide emergency declaration for all states, tribes, territories, and the District of Columbia pursuant to Section 501(b) of the Stafford Act. In response to COVID-19, the entire Nation, including every level of government—federal, state, tribal, territorial, and local—has been engaged in efforts to slow and stop the spread of COVID-19 through a multitude of initiatives including stay-at-home orders, travel restrictions, use of Personal Protective Equipment (PPE), and adherence to Centers for Disease Control and Prevention (CDC) guidelines.

As a result of the COVID-19 pandemic, the Nation is facing unprecedented challenges as we respond to additional disasters, anticipate emergent incidents, and prepare for the 2020 hurricane season. Although the operating environment has changed, the Federal Emergency Management Agency's (FEMA) mission of *helping people before, during, and after disasters* remains the same. Federal, state, local, tribal, and territorial (SLTT) officials, along with the private sector and non-governmental organizations (NGO), must partner together to fulfill their respective missions and help disaster survivors. As the Nation continues to respond to and recover from COVID-19 while posturing for the coming hurricane season, emergency managers must continue to operate under a framework of a **locally executed, state managed, and federally supported** approach to incident stabilization.

To help SLTT emergency managers and public health officials respond to incidents during the 2020 hurricane season amid the COVID-19 pandemic, FEMA is releasing the *COVID-19 Pandemic Operational Guidance for the 2020 Hurricane Season.* This document will:

- Describe anticipated challenges to disaster operations posed by COVID-19 and describe planning considerations for emergency managers in light of these challenges;
- Outline how FEMA plans to adapt response and recovery operations to the realities and risks of COVID-19 to:
  - Ensure prioritization for life safety, life sustainment, and workforce protection, and
  - Maintain the delivery of FEMA's programs and help to solve complex problems by using whole-of-community disaster assistance to the highest level possible;
- Allow SLTT emergency managers to prepare and plan accordingly based on FEMA's operational posture and create a shared understanding of expectations between FEMA and SLTTs prior to hurricane season; and
- Provide guidance, checklists, and resources to enable emergency managers to best adapt response and recovery plans.

This document is comprised of two main sections: response planning and recovery planning. Throughout each section, emergency managers will find detailed information on FEMA's operating posture and guidance for SLTT governments. In the appendixes, emergency managers will find checklists and resources on FEMA operations and additional COVID-19 related guidance. While SLTT emergency managers are the primary audience for this document, this guidance can also be used by Emergency Support Function (ESF) and Recovery Support Function (RSF) partners as these departments and agencies plan and posture for the 2020 hurricane season.

Purpose

In preparing for the 2020 hurricane season, this document provides actionable guidance to SLTT officials to prepare for response and recovery operations and encourages personal preparedness measures amidst the ongoing COVID-19 pandemic. While this document focuses on hurricane season preparedness, most planning considerations can also be applied to any disaster operation in the COVID-19 environment, including no-notice incidents, spring flooding and wildfire seasons, and typhoon response.

Information presented in this document regarding FEMA's operating posture should serve as a baseline for SLTT partners. For specific disaster response and recovery operations, FEMA will continue to work directly with federal and SLTT partners and may adjust this guidance based on the requirements of the incident, the operating environment and phased reopening as directed by SLTT officials, and any updates to existing guidance at the time of the incident.

While much of the SLTT considerations and planning guidance is specific to the public sector, NGOs and the private sector can utilize these factors for planning and preparedness. This document can be used to gain a better understanding of governmental posture, planning, and readiness efforts and how NGOs and the private sector play critical roles in response and recovery operations.

Questions, comments, and feedback from non-FEMA emergency management readers should be directed to the appropriate FEMA Regional Office. Questions, comments, and feedback from FEMA personnel and stakeholders regarding this document should be directed to the Office of Response and Recovery at FEMA Headquarters.

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Introduction

Emergency managers should anticipate the added complexities of conducting response and recovery operations while taking preventative measures to protect the health and safety of disaster survivors[1] and the disaster workforce. By creating a shared understanding of expectations among FEMA and SLTT partners in anticipation of emergent incidents, emergency managers at all levels will be better positioned to successfully deliver the mission and achieve operational outcomes in disaster response and recovery this season. FEMA will continue to coordinate closely with jurisdictions and align or adjust disaster operations based on SLTT guidance, the best available health information, and in alignment with the White House Guidelines for Opening Up America Again (Guidelines).[2]

As SLTT partners continue to prepare for hurricane season and other emergent incidents, emergency managers should review and adjust existing plans, including continuity of operations (COOP) plans, to account for the realities and risks of COVID-19 in their prioritization of life-saving and life-sustaining efforts. All reviews and adjustments to plans should factor-in FEMA's planned operational posture, social distancing measures, CDC guidance, and SLTT public health guidance. Additionally, SLTTs should begin preparing and distributing communication materials that address preparedness while under the threat of COVID-19 for use in local communities as soon as possible.

Adapting to the COVID-19 Operating Environment

FEMA is prepared to support SLTT entities in accordance with the National Incident Management System, *National Response Framework* (NRF), *National Disaster Recovery Framework* (NDRF), *Response Federal Interagency Operational Plan* (FIOP), *Recovery FIOP,* and *Comprehensive Preparedness Guide 101.* There will be adaptions at all levels of emergency management in the COVID-19 environment, but to the greatest extent possible, the foundational concepts will remain intact. Preparedness, response, recovery planning, and COOP at all levels of government must:

- Be built upon scalable, flexible, and adaptable coordination;
- Align key roles and responsibilities across the Nation;
- Ensure successful incident stabilization of community lifelines;
- Provide programs and services to disaster survivors; and
- Ensure successful restoration of the health, social, economic, natural, and environmental fabric of the community.

Response Planning for 2020 Hurricane Season

Emergency managers should anticipate evolving and emergent incidents throughout the 2020 hurricane season that may require response operations with life-saving and life-sustaining efforts. SLTTs should be prepared to lead scalable and flexible response operations and adapt to adjustments in how FEMA implements disaster assistance and delivers programs. Since many aspects of disaster response may be conducted remotely this year, SLTTs should be prepared to coordinate through virtual

[1] Disaster survivors include people with civil rights protections, such as persons with disabilities, older adults, individuals with limited English proficiency, and others with civil rights protections.
[2] All references in the document are included in Appendix A: Additional Resources.

communications and ensure the public is aware that the FEMA application process may be virtual and not in-person due to health and safety considerations.

FEMA's Current Posture

FEMA has ongoing disaster operations in all 10 regions, with personnel supporting at the National Response Coordination Center (NRCC), Regional Response Coordination Centers (RRCC), Joint Field Offices (JFO), and other field locations and fixed facilities. Personnel who are currently deployed will be prepared to pivot to support emergent needs. FEMA regions will continue to provide technical assistance and coordination for a range of program areas with their respective SLTT partners. FEMA is also well-positioned with thousands of personnel in the field supporting existing operations, thousands more available national assets ready to support emergent disaster operations, and more personnel joining the Agency through virtual onboarding every two weeks. In order to better adapt plans in this environment and support SLTT partners, FEMA programs will continue to provide assistance to survivors, but many programs may require online or phone registration processes (in lieu of in-person), remote assessments or inspections, and adapted program delivery within impacted areas experiencing localized outbreaks or periods of peak COVID-19 activity. However, when and if SLTT partners are overwhelmed, FEMA is prepared and postured to provide program support, regardless of delivery method.

Funding Sources to Support Preparedness and Operational Readiness

FEMA awarded $100 million in FY 2020 Emergency Management Performance Grant Supplemental (EMPG-S) funding to state and territorial government agencies to prevent, prepare for, and respond to the COVID-19 public health emergency. FEMA expects that recipients prioritize EMPG-S funds to 1) review, modify, and/or execute logistics and enabling contracts to increase capability to stockpile and provide necessary resources needed to stabilize lifelines; 2) modify evacuation plans to account for limited travel options and increased time needed for healthcare facilities in a COVID-19 environment; 3) identify mass care and shelter options that meet CDC guidance and mitigate risks to communities and vulnerable citizens; and 4) emphasize collection, analysis, and sharing of data to strengthen decision-support capabilities.

In addition, FEMA expects recipient emergency managers to work with their assigned FEMA Regional Administrator to develop FY 2020 EMPG Work Plans that ensure adequate funding and planning for hurricane preparedness and response efforts in a COVID-19 environment.

Operational Coordination

In response to the COVID-19 national emergency declarations, the NRCC, all 10 RRCCs, all state and territorial emergency operations centers (EOC), and several tribal EOCs were activated. FEMA field leaders and regions are developing response plans and reviewing stabilization considerations for the seven community lifelines with a focus on areas that may already be impacted by COVID-19 operations.

FEMA expects to maintain some level of activation into the 2020 hurricane season in order to best support SLTT operations. To ensure that operational decisions are made at the lowest level possible, consistent with the NRF, FEMA is organizing to prioritize resources and adjudicate accordingly, if needed:

Community Lifelines During the COVID-19 Pandemic

The NRF defines community lifelines as those services that enable the continuous operation of critical government and business functions that are essential to human health and safety or economic security. FEMA will use the community lifelines to prioritize response efforts and support resource adjudication decisions across the Nation. The seven community lifelines are:

- Safety and Security;
- Food, Water, Shelter;
- Health and Medical;
- Energy (Power and Fuel);
- Communications;
- Transportation; and
- Hazardous Materials.

- At the incident level, Federal Coordinating Officers (FCO), in consultation with Regional Administrators, will work to address incident requirements using available resources. FCOs will proactively manage and identify risks and communicate new requirements to the RRCCs as they arise.
- At the regional level, the RRCCs will coordinate with FEMA personnel deployed to SLTT EOCs and adjudicate resource requests until operational control is ready to be transitioned to the FCO at the incident level, when designated, and will adjudicate resources within their area of operation and coordinate with other RRCCs and the NRCC as required.
- At the national level, the NRCC will coordinate with the regions on requirements and adjudicate resources to address national priorities.

FEMA routinely responds to multiple incidents simultaneously and will continue to posture support for stabilization of community lifelines. The NRCC is structured, designed, and staffed to support concurrent operations; however, due to the nationwide response efforts supporting COVID-19, FEMA is preparing additional personnel and physical space to meet expanded NRCC incident support requirements. Training and mobilizing additional personnel will provide a more flexible and scalable workforce that can expand the capacity and capability of the existing structure in the event of additional concurrent incidents. Additionally, FEMA regions are also planning for contingencies to handle multiple operations concurrent with the ongoing COVID-19 response.

FEMA Personnel and Augmentation

FEMA's national personnel assets remain prioritized and ready for deployments for life-saving and life-sustaining response operations. In addition to FEMA personnel, FEMA will work with federal partners to provide capabilities for community lifeline stabilization through ESF support and mission assignments.

National Incident Management Assistance Teams

National Incident Management Assistance Teams (NIMAT) are on standby to support any disaster operation and are modifying equipment caches to ensure self-sufficiency. Planning factors for deploying a NIMAT in a COVID-19 environment include:

- The ability of the Regional Incident Management Assistance Teams (IMAT) to support the incident;
- Whether the disaster response has an inherently large-scale life-saving mission; and/or
- The disaster response appears to be extraordinarily complex.

In order to maintain posture for emergent incidents, NIMAT will plan for transition and team demobilization after lifelines are stabilized or stability is imminent, initial mitigation efforts are in place to protect property and the environment, and Regional IMAT or other personnel are in place and able to assume operational control. In addition to full team demobilization, specific team members may be demobilized early to minimize exposure if a suitable replacement is on site and able to properly support existing and future operations.

Urban Search and Rescue Teams

FEMA is actively monitoring the availability of all internal resources to support National Urban Search and Rescue (US&R) teams and is conducting contingency planning for both traditional and non-traditional models to meet potential operational needs. The National US&R Response System has established procedures, which will be temporarily expanded to enable greater operational capacity during the COVID-19 pandemic. FEMA is prepared to increase capacity by using all levels of potential additional resources (e.g., military, state/local search and rescue resources, first responders) to include the ability to deliver training and deployment of smaller Type III assets in lieu of Type I teams.

Disaster Emergency Communications

FEMA's Disaster Emergency Communications (DEC), being a primary contributor to support restoration of communication infrastructure, is postured to deploy Mobile Emergency Response Support detachments, Mobile Communications Office Vehicles (MCOV), and DEC personnel in a COVID-19 environment. Increased requirements for and use of Mobile Emergency Operations Vehicles, Emergency Operations Vehicles, Incident Response Vehicles, and MCOVs are anticipated to help FEMA personnel manage social distancing requirements, including to support personnel working from outside state EOC facilities. FEMA will also support requirements for cloth face coverings and increased hand hygiene for all employees operating within mobile vehicle platforms.

Personnel Augmentation

As always, FEMA intends to leverage local hire support for any emergent disaster operations. If the Department of Homeland Security (DHS) activates the Surge Capacity Force (SCF), deployment assignments will follow CDC guidance and maintain FEMA's posture to minimize travel and direct contact, and potentially increase telework flexibilities. FEMA is also developing virtual training and skill set assessments for existing SCF members in order to rapidly and efficiently align the thousands of available SCF members to meet operational needs.

Contract and Commodity Readiness

FEMA has prepared for hurricane season and other emergent incidents by aligning resources, awarding contracts, and readying Logistics personnel for rapid response operations. In addition to owning and purchasing resources, FEMA also has multiple partnerships with other federal agencies such as the U.S. Army Corps of Engineers, the Defense Logistics Agency, and NGOs such as the American Red Cross.



FEMA Logistics Staff coordinate the transportation of COVID-19 test kits arriving through Project Airbridge on April 14, 2020.

FEMA continues to ensure Distribution Centers maintain commodity levels at, or near, pre-COVID-19 status. FEMA is focusing on rapidly replenishing commodities used in support of COVID-19 pandemic operations. Based on refined requirements implemented following the 2017 hurricane season, FEMA has increased its storage space both inside and outside of the contiguous United States; trailer fleets have been increased and modernized; and staging and distribution plans have been enhanced to increase strategic stockpiling, prepositioning, and expedited transportation of commodities to the field.

Remote Disaster Operations

While COVID-19 morbidity and mortality persist, FEMA will generally minimize the number of personnel deploying to disaster-impacted areas and minimize the number of new field deployments by using personnel already deployed to the impacted region, including FEMA Integration Team (FIT) members or other FEMA personnel already working at EOCs, deploying locally-available personnel, and leveraging remote disaster support. FEMA Regional Administrators, in partnership with FEMA Headquarters (HQ), will evaluate risk in their regions and determine the most appropriate approach to deployments while considering the guidance and direction of public health officials and the factors established in the White House Guidelines.

To support virtual deployments and remote disaster operations, FEMA is planning to:

- Increase communications to the public through social media platforms, virtual townhalls, and coordinated messaging to survivors from FEMA officials and SLTT leadership, and ensure that all communications are provided in ways that are accessible to individuals with disabilities and limited English proficiency;
- Ensure remote disaster personnel have the most up-to-date policies and procedures, training needs are met, and supervisors have the tools needed to appropriately manage employees;
- Increase availability and deployment options for FEMA personnel to make informed decisions on how to support disaster operations while protecting the health and safety of the workforce;

- Continue use of virtual personnel mobilization center process to facilitate rapid deployment of personnel and ensure that deployed personnel receive information technology services as needed to prepare them to directly support impacted areas; and
- Increase information technology support for remote disaster operations, including, but not limited to, remote inspection processes, remote preliminary damage assessments, and working with partners to pre-identify accessible technology platforms that can support virtual meetings with interagency, private sector, NGOs, and SLTT partners.

Disaster Facilities

While FEMA will generally minimize deployments, some emergent incidents may still require disaster facilities and a limited field presence. Field leaders, in consultation with FEMA regional offices, will consider additional safety requirements in accordance with SLTT public health guidance and phased reopening when planning for new FEMA disaster facilities. When considering new facility floorplans and leases, field leaders, in coordination with the Unified Coordination Group (UCG), FEMA safety and security personnel, and CDC and SLTT public health officials, will develop localized mitigation strategies, including temperature and health screenings, increased cleaning and disinfection requirements, and reduced personnel footprints for social distancing, to ensure the safety and security of FEMA personnel and partners. When feasible, FEMA will employ engineering and administrative controls, such as the use of transparent barriers as appropriate and labeling interior floor areas in appropriate areas to encourage proper social distancing.

Guidelines for Opening up America Again

The White House's Guidelines provide critical considerations for FEMA and SLTTs planning for disaster operations. Depending on the Guideline phase of a disaster-affected jurisdiction (as determined by the Governor, tribal, or local leadership), FEMA will work with SLTT leadership to determine the most appropriate operational posture to protect impacted communities and deployed personnel. FEMA may adopt a more conservative posture than a jurisdiction, but will generally not adopt a more relaxed posture.

FEMA has developed a Reconstitution Exercise Starter Kit with sample documents that SLTT departments, agencies, or organizations can use to conduct planning workshops on returning to full operations. Suggested discussion questions build upon reconstitution planning principles and the White House's Guidelines.

Field leaders will use modified personnel plans to assess how many personnel will be deployed to field operations and ensure that facility layouts can accommodate CDC guidance and social distancing recommendations. FEMA, in coordination with SLTT officials, will provide PPE and/or cloth face coverings and other supplies (e.g., hand sanitizer, cleaning wipes) for personnel to use in disaster facilities and implement other protective measures, based on the Department of Health and Human Services, CDC, and Occupational Safety and Health Administration guidance and exposure risk levels.

Additionally, FEMA will adjust Incident Support Base operations to appropriately minimize large numbers of personnel and truck operators on site. FEMA will use smaller staging teams, additional workspace and facilities to accommodate needed personnel, PPE and/or cloth face coverings, social

distancing guidance, additional procedures to control entry into staging sites, and incorporate new documentation requirement processes as needed to minimize exposure.

To ensure workforce safety, FEMA will work with SLTT partners to address:

- Facility specifications, which shall include the requirement for a co-location of organizational elements across a sufficient space capable of allowing for social distancing of six feet (as appropriate);
- Instruction on the use of cloth face coverings to personnel delivering to or working in any operational disaster facilities;
- Policy modifications that may be needed to accommodate employees with disabilities in accordance with Equal Employment Opportunity Commission guidance;
- Guidance for individuals instructed not to enter FEMA facilities (e.g., persons tested positive for COVID-19 or symptomatic and not cleared to return to work);
- Temperature and health screening procedures prior to entry at all facilities or sites;
- Cleaning and disinfection procedures, including high touch areas such as computer equipment, telephones, clipboards, paperwork, door handles, and bathrooms; and
- Safe movement of personnel in potentially high physical transfer areas, such as distribution centers, fueling stations, high density office areas, enclosed spaces, congregate housing, hospitals, and public areas.

SLTT Response Planning

The Nation's emergency management system is most successful when it is locally executed, state managed, and federally supported. Jurisdictions across the country are responsible for leading efforts to stabilize community lifelines, distributing commodities and resources to meet the needs of an emergency, and supporting program delivery. FEMA continues to support these efforts. Emergency managers should begin reviewing existing response plans and guidance to align, link, and synchronize community response actions with federal planning efforts like those described in this document and prepare protective measures for their disaster workforce and survivors. SLTTs should consider adopting COOP strategies and prepare for a variety of potential conditions to account for localized outbreaks, periods of peak COVID-19



FEMA Leaders and Staff Coordinating with New York City and Department of Defense Personnel on May 7, 2020.

activity, or phased reopening. SLTTs should exercise updated plans via virtual tabletop exercises. FEMA programs can provide additional support for training, drills, or products for exercise plans.

Response Considerations Checklist

- Do you have a plan to respond if your emergency management agency/department has reduced staffing due to COVID-19?
- Have you reviewed and updated your COOP plans to continue essential functions and tasks with little to no interruption?
- Do you have a plan to prioritize resources to stabilize the communication lifeline?
- Do you have a plan to determine which personnel must be physically deployed to the field and how they will be protected?
- Does your emergency management agency/department have an established senior liaison with the senior public health officer for your jurisdiction to ensure current, timely public heath advice?
- Have you implemented CDC's Strategies to Optimize the Supply of PPE?
- Have you purchased and stockpiled medical-grade PPE for those who need it according to CDC guidelines?
- Have you purchased and stockpiled cloth face coverings?
- Do hospitals in evacuation zones have a plan to not only evacuate patients, but also ventilators, dialysis machines, and stockpiled PPE?
- Do you have a plan for a high-risk population (e.g., nursing home residents, people with disabilities, people requiring evaluation assistance, people experiencing homelessness) that has an ongoing outbreak and needs to be evacuated?
- Do you have a system that can collect and share data to support decision-making around community lifelines?
- Have you developed communication materials accessible to people with access and functional needs (e.g., deaf or hard of hearing, blind or have low vision, people with an intellectual disability, people with low literacy, limited English proficient persons, older adults) that address hurricane preparedness while under the threat of COVID-19 in your communities?
- Have you considered the extra time it may take to evacuate given the need for social distancing for increased mass transit modes (e.g., buses) may require?

See Appendix B and Appendix C for additional Preparedness and Response checklist considerations

Operational Coordination and Communications

SLTTs should review existing response operations plans and consider:

- Leveraging efforts underway for COVID-19 response, including maintaining current command and control roles and responsibilities.
- Expanding UCG membership beyond senior leaders to ensure appropriate coordination among private sector and public health or medical leadership for the scope and nature of the incident, and better enable jurisdictions to jointly manage and direct incident activities through establishment of common incident objectives, strategies, and a single incident action plan.

- Emphasizing stabilization of the communication lifeline as operational adaptations include or may rely heavily on virtual coordination, including the ability to work directly with FEMA's virtually deployed personnel.
- Preparing for COVID-19 impacts to community lifeline stabilization and the interdependencies between lifelines, especially those that may already be significantly impacted, like the health and medical lifeline.
- Utilizing EMPG-S funding to strengthen decision-support capabilities through the collection, analysis, and sharing of data.
- Preparing for an increased need for accessible and multi-lingual messaging and communications through available media, wireless emergency communications, and use of virtual townhalls for coordinated communications to survivors from SLTT leadership, FEMA officials, and others.
- Reviewing and updating existing Orders of Succession and Delegations of Authority for key leadership and personnel.
- Preparing state national guard forces and associated resources for potential deployment to support during disaster operations while in a COVID-19 environment.
- Engaging community-based partners that support and serve persons with disabilities, limited English proficient persons, low income communities, communities of color, and houses of worship to formalize partnerships to meet the needs among these populations and ensure the equitable and impartial delivery of disaster assistance.

Commodities and Points of Distribution

Point of Distribution (POD) operations will continue to be state, territory, and/or tribal-led and operated with federal support where required. SLTTs should review existing plans and consider:

- Utilizing EMPG-S funding to strengthen contracts, if needed, to provide medical-grade PPE, cloth face coverings, and necessary commodities during disaster operations, especially if available resources have been allocated to COVID-19 response.
- Determining alternate options for locating and procuring critical resources if traditional methods for procurement of needed response and recovery supplies may not be feasible.
- Reinforcing the supply chain through preservation, expansion of warehouse footprints, and stockpiling mission-critical materials.
- Adjusting planned POD sites to accommodate operational adaptations for the COVID-19 environment, including considerations for significantly increased demand, social distancing, and regulated traffic flow.
- Reviewing and evaluating current mutual aid agreements and Emergency Management Assistance Compact (EMAC) mission-ready packages to assess if available resources may be limited due to COVID-19 operations and consider virtual EMAC agreements when possible.
- Reviewing alternative commodity distribution sites that can be used to limit direct contact between personnel and survivors, and ensuring commodity distribution sites have plans in place to provide services to people with disabilities.

- Incorporating federal POD Monitor to assist with burn rate management and resupply efforts that may also be impacted.
- Altering plans to limit physical points where communities will congregate and preparing for restricted/diminished support from NGOs for commodity distribution.

Staffing and Workforce Protection Planning

SLTTs should review existing plans for workforce protective measures to support personnel who will be deployed to the field and associated disaster facilities and consider:

- Increasing membership of Community Emergency Response Teams (CERT) and Medical Reserve Corps (MRC), and conducting associated volunteer training virtually, as necessary, to ensure the health and safety of its members.
- Reviewing the readiness of typical disaster support personnel (e.g., first responders, logistical personnel, health and medical personnel) who may already be deployed to ongoing operations.
- Procuring and distributing PPE and workforce protective measures for personnel required to be in the field, including first responders, search and rescue teams, logistics support, and health and medical professionals.
- Implementing safety measures at disaster facilities to include temperature and health screenings, facility cleaning and disinfection measures, and social distancing requirements for on-site personnel.
- Ensuring personnel can continue to respond if the emergency management agency or department has reduced staffing due to COVID-19.
- Providing additional telework flexibilities and remote disaster support strategies that can be integrated with FEMA remote disaster operations, if needed, and plan to minimize disaster facility personnel.
- Planning for virtual coordination with federal partners, bolstering communications and information technology support for remote operations, and pre-identifying approved technology platforms that can be used for increased virtual meeting capabilities among SLTTs, FEMA officials, federal interagency partners, volunteer organizations, and the private sector.

Evacuation Planning

SLTTs should review evacuation plans and consider:

- Assessing community demographics and identifying areas facing high risk, including considerations for those under stay-at-home orders, at higher risk of serious complications from COVID-19, individuals with disabilities, and others with access and functional needs.
- Reviewing clearance times and decision timelines, with COVID-19 planning considerations, such as mass care and sheltering plans.
- Considering impacts of business closures/restrictions along evacuation routes; limited restaurant/lodging availability will place extra stress on state and local officials and may require unprecedented assistance to travelers.

- Maintaining availability of mass transit and paratransit services that provide a transportation option for those individuals who are unable to use the fixed-route bus or rail system for evacuation of people with disabilities in accordance with CDC guidance and social distancing requirements.
- Using EMPG-S funding to modify evacuation plans to account for limited travel options and increased time needed for evacuation of health care facilities.
- Targeting evacuation orders and communication messages to reduce the number of people voluntarily evacuating from areas outside a declared evacuation area.
- Developing communication plans for communities likely impacted by hurricane season or other emergent incidents for any updates or alterations to evacuation strategies, and ensuring communications are provided in a way that is accessible to people with disabilities and limited English proficiency.
- Reviewing available alternate care sites and federal medical stations as potential evacuation sites or longer-term solution for hospitals and medical facilities, if needed, and considering staffing needed to support facilities.
- Determining logistics and resource requirements to support government-assisted evacuations.
- Reviewing, expanding, and/or establishing agreements with NGOs, agencies, volunteers, and private sector vendors that will be needed for evacuee support and ensuring partners are prepared to deliver services in a COVID-19 environment.
- Engaging with neighboring states and jurisdictions to coordinate cross-border movement of evacuees in large-scale evacuations.
- Developing host jurisdiction sheltering agreements.

Recovery Planning for 2020 Hurricane Season

Given the complexity of operations in a COVID-19 environment, some aspects of recovery planning and posture will change to ensure the safety of disaster survivors and emergency managers. SLTTs should be prepared to lead flexible recovery operations based on FEMA's adapted posture and procedures for implementing disaster assistance and program delivery. Given the increased use of remote processes for recovery operations, SLTTs should also be prepared to coordinate through virtual communications, anticipate alternative methods to verify applicant eligibility, and ensure the public is aware of these modifications. Successful recovery will require that FEMA, SLTTs, NGOs, and private sector partners coordinate planning efforts to adapt standard processes and procedures for synchronized recovery.

FEMA's Current Recovery Posture

FEMA will continue to coordinate technical assistance and recovery operations through FEMA regions in partnership with SLTTs, NGOs, and the private sector, including Voluntary Agency Coordination support to non-governmental, faith-based, non-profit, humanitarian, philanthropic, and community-based organizations that provide the wrap-around and social services necessary for effective SLTT response and recovery. While the level of technical assistance will remain the same, SLTTs should be prepared to adapt to remote coordination. For operations in a COVID-19 environment, FEMA will adapt its traditional field operations and program delivery models to expedite services, support, and assistance to SLTT partners.

Mass Care/Emergency Assistance

The operational realities of the COVID-19 environment will require adaptations to many aspects of the Mass Care and Emergency Assistance service areas, particularly all stages of sheltering assistance. Due to the risks associated with COVID-19 and congregate sheltering, including standards for occupancy rates, equipment requirements, and assessment of at-risk or vulnerable populations, this approach will be adjusted. Recognizing some congregate sheltering will still be necessary in many hurricane scenarios, FEMA will support SLTT partners and NGOs to mitigate risks and support efforts consistent with public health guidance.

Given the changes to non-congregate shelter support this hurricane season, FEMA regions

Use of Non-Congregate Shelters in 2020 Hurricane Season

In an emergency or major disaster declaration that authorizes Public Assistance (PA), Category B, Emergency Protective Measures, FEMA will adjust polices to allow SLTTs to execute non-congregate sheltering in the initial days of an incident. Non-congregate shelters include, but are not limited to, hotels, motels, and dormitories. FEMA Regional Administrators will have delegated authority to approve requests for non-congregate sheltering for hurricane-specific disasters for the 2020 season.

While not a single solution, this funding will assist with sheltering operations in the short-term. SLTTs will need to work with FEMA and NGO partners to determine how non-congregate options can be incorporated into larger sheltering plans.

SLTTs should coordinate with FEMA regions to:

- Ensure adequate sheltering plans are in place and coordinated, including consideration of contractual agreements and federal funds (if required) in accordance with federal procurement standards.
- Plan for appropriate scope and duration for sheltering resources based on anticipated needs.
- Ensure that data, documentation, and tracking mechanisms are in place.
- Plan appropriate accessibility considerations for people with disabilities, and those with functions and access needs, and ensure adequate availability of such resources.

As part of the sheltering plan, SLTTs should outline a transition from non-congregate sheltering to alternate options, including Transitional Sheltering Assistance (TSA) for eligible applicants if a major disaster declaration is approved, or for a timely termination when non-congregate sheltering is no longer needed.

will assist in planning and providing additional technical assistance. Recognizing the timing and potentially greater need for non-congregate sheltering, FEMA will work with SLTT partners to provide greater flexibility for the eligibility of both congregate and non-congregate options for reimbursement under the PA program.

In addition, FEMA, along with federal partners and National Voluntary Organizations Active in Disaster partners will continue to provide mass care technical support to SLTTs for the following:

- Planning for protective measures for all mass care personnel and survivors;
- Planning for additional needs at shelters for supplies and material for cleaning, disinfection, and social distancing;
- Developing strategies for how shelf-stable meals and other feeding commodities can be used to supplement initial primary feeding requirements and/or serve as primary feeding options;
- Planning for resource requirements for individuals and households who arrive at shelters without medical equipment, medical prescriptions and/or supplies, personal assistance services (caregivers), and cloth face coverings;
- Developing strategies to address health screening criteria (e.g., positive, presumptive positive, symptomatic, known exposure) upon arrival at a congregate shelter and procedures if a case is identified;
- Planning for protective measures at sheltering locations, to include health screening, social distancing requirements, cleaning and disinfection, and quarantine or isolation areas, as needed;
- Considerations for shelter staffing options outside of volunteers, as resources may not be available;
- Planning for feeding strategies for survivors sheltering in place and those located in non-congregate shelters in accordance with CDC guidance and social distancing requirements;
- Planning for timely demobilization of sheltering resources when they are no longer needed based on the impact or forecasted impact of an incident;
- Planning for necessary information collection and tracking; and
- Planning for possible modifications to how federal mass care personnel support evacuees, including, but not limited to:
    - Transportation to evacuation points/congregate/non-congregate shelters;
    - Supporting health screenings of staff and clients entering facilities;
    - Supporting COVID-19 isolation/medical care shelters;
    - Triage of vulnerable populations processed into non-congregate options;
    - Coordination of workforce lodging across agencies and responder organizations to prioritize hotel access for non-congregate sheltering; and
    - Pet sheltering.

Virtual Preliminary Damage Assessments

To ensure workforce protection, FEMA regions may elect to utilize virtual or desktop Preliminary Damage Assessment (PDA) options. Virtual PDAs may include use of aerial imagery (as appropriate), Hazus,[3] resident or SLTT submitted data, documentation, photos, and local emergency manager detailed and verified statements to document damages as accurately as possible as opposed to conducting physical, in-person assessments to validate cost, work, facility, and applicant eligibility. Regions will work with SLTTs to determine the appropriate type of PDA process given the level of public health emergency, which may vary across counties based on localized hotspots. If personnel deploy to the field, FEMA will use as few personnel as possible to ensure social distancing and may rely on windshield assessments to complete the PDA process in a timely manner.

FEMA Disaster Registration Methods

In areas with a limited field presence, FEMA will continue to use its primary registration methods via an online website (www.DisasterAssistance.gov) and telephone services (800-621-FEMA). These methods account for most registrations and continue to be successful in limited or degraded communication environments. FEMA will work with local officials and the media to encourage people to leverage digital registration capabilities.

Disaster Survivor Assistance and Disaster Recovery Centers

FEMA, in coordination with SLTT partners, will determine the use of Disaster Recovery Centers (DRC) or Disaster Survivor Assistance (DSA) teams according to the phased reopening of an impacted area. In areas with limited field presence, FEMA will use online and phone registration and virtual assessments to ensure program delivery. If phone lines are down, FEMA will prioritize stabilizing the communication lifeline in order to restore networks and support registration processes. FEMA will also coordinate with federal and voluntary agency partners



FEMA personnel and disaster survivors at a DRC during Hurricane Michael depicts limited potential for social distancing measures using standard facility footprints.

[3] Hazus is a nationally applicable standardized methodology that contains models for estimating potential losses from earthquakes, floods, and hurricanes. Hazus uses Geographic Information Systems (GIS) technology to assist government planners and emergency managers in estimating physical, economic, and social impacts of disasters.

to promote digitally available disaster recovery resources, support, and referral services, as well as to ensure service delivery methods are accessible and widely promoted for individuals with disabilities.

If DRCs and DSA team support are requested by the state, territory, or tribal nation, and FEMA determines it is consistent with phased reopening guidelines, FEMA will consult with SLTT public health officials on local requirements. In DRCs, FEMA will implement additional health and safety measures based on current CDC guidance, such as requiring cloth face coverings (if appropriate), hand hygiene, and social distancing measures.

Individual and Households Programs and Direct Housing

FEMA does not anticipate major changes in program eligibility, timeliness of grant awards, or the level of assistance provided under the Individual and Households Program. However, the delivery mechanisms of certain aspects of the program will be modified.

FEMA will utilize remote inspections and field work to evaluate damage as much as possible, with the goal of expediting the delivery of recovery assistance. FEMA will only conduct remote inspections on homes where occupants have indicated a certain degree of damage upon registration. For applicants who self-report minor damage and can remain in the home, FEMA will determine whether an inspection is necessary, enabling FEMA to focus its limited resources on those with the greatest need.

These remote inspections and field work, consistent with eligibility, will support numerous programs including Rental Assistance, Home Repair Assistance, Replacement Assistance, Other Needs Assistance for Personal Property, and Assistance for Miscellaneous Items. Types of Other Needs Assistance that do not require an inspection, including childcare, transportation, medical and dental, funeral expenses, moving and storage, and procurement of Group Flood Insurance Policies, will be administered as normal. Clean and Removal Assistance will not be authorized in disasters that utilize remote inspections.

Remote Inspection Assistance

For remote inspections, FEMA inspectors will contact applicants and complete the standard onsite inspection process by phone. Reasonable accommodations, including translation and American Sign Language interpreters via Video Relay Service will be available to ensure effective communication with applicants with limited English proficiency, disabilities, and access and functional needs. FEMA will also work to provide flexibility to applicants who need to provide documentation within certain timeframes.

Direct Housing

FEMA does not anticipate changing the criteria necessary for approving a request for Direct Housing. However, given the challenges associated with implementing some forms of Direct Housing in a COVID-19 environment, FEMA may rely more on certain forms of temporary housing (i.e., rental assistance) and non-congregate sheltering. For new disasters that are approved for Direct Housing, FEMA will prioritize the placement of Transportable Temporary Housing Units on private sites and the use of Direct Lease.

Community Services Programs

Request processes and the criteria for Community Services Programs (Crisis Counseling, Disaster Unemployment, Disaster Case Management, and Disaster Legal Services) remain unchanged. The

delivery of these programs will be remote as much as possible. This includes the use of crisis counseling hotlines; socializing information through various forms of media; delivering leaflets, brochures, or other educational materials to disaster survivors; and providing all services and communications in an accessible manner for individuals with disabilities.

Public Assistance

The basic principles, application procedures, eligibility, and award mechanisms of the PA program will remain unchanged. However, most PA work will be conducted virtually. Recipients should be prepared to conduct virtual applicant briefings, with virtual participation by FEMA. The Recovery Scoping Meeting to develop the Program Delivery Plan and discuss damage inventory will also be conducted remotely. Recipients and subrecipients should be prepared for virtual applicant engagement to work through program delivery, formulate projects, and upload documentation.

PA Program Delivery in a COVID-19 Environment

Operational Planning

- *Applicant Briefings* – Encourage virtual briefings
- *Request for Public Assistance* – No change
- *Staff and Operational Planning* – Mix of virtual and, if required, minimized personnel requested
- *Exploratory Call* – No change
- *Recovery Scoping Meeting* – Encourage remote meetings and, if required, minimized personnel presence

Damage Intake and Eligibility Analysis

- *Applicant Engagement* – Encourage virtual engagement and, if required, minimized personnel presence
- *Damage identification, Essential Elements of Information, and Project Formulation* – No change
- *Conducting Site Inspections* – Likely encourage virtual/ tabletop inspections with minimized personnel presence

Scoping and Costing

- *Grant Development* – No change

Final Reviews

- *Field and Final Reviews* – No change

Obligation and Recovery Transition

- *Project Obligation* – No change
- *Recovery Transition Meeting* – Conducted remotely

FEMA will conduct inspections remotely whenever possible. While remote inspections may not be possible for all applicants, the dual use of remote and in-person inspections expedites the delivery of recovery assistance to grant recipients and reduces the number of personnel required in the field. For some incidents, FEMA may still deploy PA personnel to perform specific activities, such as critical infrastructure stabilization coordination or just-in-time site inspections, which cannot be completed virtually. FEMA will continue to provide technical assistance to grant recipients and applicant personnel through virtual training, job aids, online how-to videos, the Grants Portal Hotline, virtual mentorships, and remote customer assistance.

Hazard Mitigation

FEMA is taking proactive steps to address the COVID-19 pandemic to help serve its National Flood Insurance Program (NFIP) customers who may be experiencing financial hardships. One example of this is extending the grace period to renew flood insurance policies from 30 to 120 days. Additionally, the NFIP has issued guidance to the Write Your Own companies and NFIP Direct on remote claims handling. FEMA is currently developing new methods to improve program delivery, including extension of application deadlines and Periods of Performance, and also granting a 12-month extension to meet the hazard mitigation plan requirements for local and tribal governments that apply for FEMA hazard mitigation assistance grants, including the Hazard Mitigation Grant Program (HMGP). FEMA regions continue to provide technical assistance to SLTTs to meet the hazard mitigation plan requirements in order to be eligible for certain FEMA assistance programs, such as HMGP, Building Resilient Infrastructure and Communities, High Hazard Potential Dams Rehabilitation Grants, and Flood Mitigation Assistance.

Though aspects of the Hazard Mitigation (HM) Program delivery are typically highly dependent on personal interaction (e.g., Community Education and Outreach), FEMA can conduct mitigation interviews with Individual Assistance (IA)-registered survivors through a dedicated phone line or use a model similar to remote flood insurance claim adjustments to continue providing services to disaster survivors. HM's Flood Insurance personnel will also conduct virtual visits with insurance agents in disaster-impacted areas to promote the NFIP and its benefits, rather than in-person office visits. HM's Floodplain Management personnel will also conduct virtual visits with State Floodplain Coordinators and Local Floodplain Administrators in disaster-impacted communities to provide technical assistance and ensure ordinance compliance, as needed. FEMA may deploy HM personnel to carry out infrastructure inspections, among other critical assignments. FEMA may also deploy HM or contract personnel to support local, substantial damage inspections as well as produce and share data analytics in making as many remote determinations as possible to limit the number of physical inspections required.

Environmental Planning and Historic Preservation

Many elements of an Environmental Planning and Historic Preservation (EHP) review, which are required for all proposed FEMA grants, will be conducted through desktop analysis of environmental considerations (e.g., presence/absence of historic properties or critical habitat for endangered species, project requirements associated with special flood hazard areas). However, EHP's ability to conduct in-person site inspections will likely be limited due to COVID-19. Without the full capability to conduct site visits, EHP will rely more heavily on site-specific critical information to be provided by FEMA grant programs and applicants in order to understand the environmental and historic preservation resources present. Therefore, applicants should be prepared to provide adequate documentation to facilitate remote inspection and evaluation of proposed project sites when possible. FEMA may require in-person site visits for EHP activities, such as biological or archaeological monitoring, depending on specific conditions present at a given location, and will work with FEMA Grant Program personnel and applicants to ensure that these requirements are met safely.

Public participation requirements found in several EHP laws and regulations, sometimes in the form of public meetings, may also be modified to ensure effective public comment is facilitated safely. Additional actions may be delayed or deferred on a case-by-case basis at the discretion of the incident-

specific Regional Environmental Officer and the Director of the Office of Environmental Planning and Historic Preservation in conjunction with the State Coordinating Officer.

Interagency Recovery Coordination

Regional and national Interagency Recovery Coordination will continue to prioritize the coordination of assistance in support of SLTT recovery outcomes in the following ways:

- Ensuring clear communication and comprehensive, accessible information about available assistance leveraging existing information sharing platforms;
- Streamlining and/or simplifying the application and delivery processes;
- Aligning policies to streamline access to funding sources;
- Actively coordinating among federal partners to reduce duplication, waste, and fraud;
- Coordinating with federal partners to share information on promising practices for sequencing federal funds to maximize impacts on SLTT recovery goals and outcomes; and
- Developing and sharing SLTT recovery "self-help" tools.

FEMA will consolidate coordination and recovery management support at the regional level throughout hurricane season to better serve all disaster operations in achieving SLTT outcomes. This approach will allow partners to streamline and enhance consistent support across multiple operations. The Recovery Support Function Leadership Group is supporting the coordination of assistance among partner agencies at the national level to resolve operational and policy challenges as needed.

SLTT Recovery Planning

Based on FEMA's planned operating posture and impacts to a community from COVID-19 prior to a follow-on incident, SLTT partners may need to consider revising recovery operational plans, long-term recovery objectives, and pre-disaster recovery plans. SLTTs should coordinate with FEMA regions if there are questions on implementing any new policies or delivery methods for FEMA recovery programs and prepare for FEMA to rely more heavily on virtually deployed personnel.

Furthermore, FEMA recommends that state, tribal, and territorial leadership establish coordination and management mechanisms that could be used across multiple incidents and that focus support on achieving state, tribal, and territorial goals and outcomes. State governors as well as tribal and territorial leaders may consider appointing a State Disaster Recovery Coordinator (SDRC) or Tribal Disaster Recovery Coordinator (TDRC) to lead recovery coordination activities for a jurisdiction. SDRCs and/or TDRCs could lead the recovery organization, recovery priority setting, and serve as the jurisdiction's primary point of contact with the state and federal agencies to explore and resolve unmet recovery needs. If a SDRC or TDRC is currently leading the COVID-19 recovery effort, close coordination with FEMA regions will enable better assistance.

Recovery Considerations Checklist

- Do you have reopening and reconstitution criteria that support opening of businesses damaged by a hurricane and/or tropical storm that is also impacted by COVID-19 restrictions?
- Have you identified sufficient congregate shelter space to safely implement social distancing?
- Have you reviewed and incorporated CDC's Interim Guidance for General Population Disaster Shelters During the COVID-19 Pandemic into sheltering plans and strategies?
- Do you have a plan to conduct health screenings of evacuees that may enter sheltering locations?
- Do you have a medical care plan for those evacuees that meet screening criteria (e.g., positive, presumptive positive, symptomatic, known exposure) upon arrival at a congregate shelter?
- Do you have a plan to support virtual PDAs and inspections?
- How will you manage building and housing inspections and re-occupancy procedures given the constraints and impacts of COVID-19 (e.g., social distancing)?
- How will you maximize community input and buy-in for your recovery efforts to ensure they are delivered in an equitable and impartial manner (e.g., by receiving input from members of low-income communities, members of communities of color, persons with disabilities, older adults, persons with limited English proficiency)?
- Can you hold effective public meetings while maintaining social distance? Do you have mechanisms to reach isolated or underserved communities?
- Do you have a process to determine eligibility for all relevant funding opportunities? Do you have access to associations that can support disaster-related projects?
- Does your jurisdiction's financial practices and procedures for non-disaster projects follow the same practices and procedures for disaster-related projects?

See Appendix D for additional Recovery checklist considerations

Mass Care/Emergency Assistance Planning

The impacts of COVID-19 will require SLTTs to reassess their mass care plans and strategies. SLTTs should work with partners to reassess all aspects of their plans to ensure they can effectively execute sheltering and other mass care activities in a pandemic environment in coordination with public health officials and updated guidance. SLTT emergency managers should assess which functions they will continue to provide during sheltering operations, identify alternate options for maintaining capabilities, and determine the availability of voluntary and non-governmental organizations to support human services needs in shelters.

Important readiness measures that jurisdictions can take now include reviewing and re-validating emergency operations and sheltering plans; proactively preparing accessible and multi-lingual messaging regarding individual and family preparedness; and modifying resource acquisition and allocation plans. This should also include identifying COVID-19 high-risk populations that may require additional protective measures. SLTTs should also re-emphasize evacuation messaging to focus sheltering efforts on only those that have a need to leave their homes.

SLTTs should review mass care and sheltering plans and consider:

- Pre-identifying locations and altering sheltering strategies, to include:
  - Selecting appropriately sized shelter facilities to support CDC guidance and SLTT public health guidance, social distancing requirements, establishment of isolation areas, and cloth face covering distribution.
  - Leveraging non-congregate sheltering options and working with FEMA on solutions for providing sheltering, including considerations for survivors who need isolation but do not require hospitalization.
  - Using EMPG-S funding to identify mass care and shelter options that meet CDC guidance and mitigate risks to communities and the most vulnerable citizens, such as the elderly, those with underlying conditions, and people with disabilities.
  - Developing plans to account for the care of individuals requiring additional assistance, including vulnerable populations, older adults, individuals with disabilities, and others with access and functional needs.
  - Developing a plan to conduct health screenings of staff and evacuees for COVID-19 that may enter sheltering locations.
  - Assessing the need for PPE and planning for distribution as needed.
  - Planning for evacuees and staff that meet screening criteria (e.g., positive, presumptive positive, symptomatic, known exposure) upon arrival at a congregate shelter, including establishment of isolation areas for symptomatic survivors and others at congregate shelters
  - Planning for support to increase pet sheltering as co-habitation may not be a viable option due to increased shelter space requirements.
- Developing accessible, timely, and actionable communication plans for conveying alterations to sheltering strategies for communities likely impacted by hurricane season, including for limited English-proficient persons and people with disabilities.
- Supporting health and medical systems that are already stressed, with an expectation that those emergency services will continue to be taxed into hurricane season, including potential exposure of disaster survivors and emergency response personnel in facilities, testing requirements, and contact tracing support.
- Assessing capabilities and available resources within Voluntary Organizations Active in Disaster, NGOs, and faith-based organizations to determine any alternative sourcing requirements.
- Attempting to fulfill resource requests and resolving logistical issues using existing local capabilities, including requesting assistance from local NGOs, local vendors (e.g., restaurant/caterer, staffing agency), or options with national-level NGOs.

Individual Assistance, Public Assistance, and Hazard Mitigation Application Processes

SLTTs should review recovery operations plans and consider:

- Revising to account for FEMA's virtual work for IA, PA, and HM programs in a COVID-19 impacted environment.

- Ensuring familiarity with the PA process and access to the Grants Portal system.
- Ensuring familiarity with procurement and documentation requirements for PA grants and pre-positioning contracts.
- Working to provide support to applicants for new virtual application processes, particularly for communities with existing gaps in information technology resources.
- Reviewing the *State-Led Public Assistance Guide* and preparing to take on some or all customer service, site inspection, and scoping and costing functions.

SLTT Recovery Process

FEMA recommends that SLTT partners explore how to modify existing recovery plans and structures to not only support current COVID-19 recovery operations and outcomes, but to also accommodate potential future disasters. Modification of existing recovery plans and structures will enable SLTTs to focus coordination around clear outcomes and goals across disasters, as well as enhance SLTT leaders' ability to pool and target resources for maximum impact.

SLTT leaders should review recovery operations plans and consider:

- Strengthening remote work and virtual inspection processes.
- Managing PA operations, customer service, and site inspections in accordance with the *State-Led Public Assistance Guide*.
- Establishing communication best practices, including accessible and multi-lingual messaging, and information technology solutions to better facilitate coordination between state, tribal, and territory RSF partners and their relevant federal, non-governmental, and private sector counterparts.
- Identifying or developing internal systems to proactively address federal and state procurement regulations and processes.
- Developing or modifying existing plans that include defining essential operations, building staff redundancy, and outlining devolution procedures and authorities.
- Strengthening contracts for pre-positioned resources, such as debris removal.
- Working with FEMA regions to obtain guidance in the development of a State Disaster Recovery Plan for the jurisdiction to include housing annexes.
- Accounting for increased recovery efforts to address compounded impacts from COVID-19 and a follow-on incident, to include:
    - Economic impact, including impacts to non-essential businesses and loss of livelihood in the impacted area;
    - Long-term impacts to health and social services, increased use of telemedicine providers, reduced utilization of medical services for chronic conditions, and additional need for social services and mental/behavioral health resources; and
    - Infrastructure, communication systems, and healthcare restoration given the need to build certain core capabilities back better for the future.

    - Planning for increased demand for mental/behavioral health support as survivors may experience significant distress with the addition of disaster impacts on quarantined communities.
- Coordinating donation management and assistance (e.g., mapping additional funding, preventing duplication of benefits, project sequencing) and identifying overlapping recovery goals/outcomes.
- Evaluating and planning for support to local governments with reduced recovery management capacity due to budget shortfalls and reductions in personnel.

Conclusion

Given FEMA's planning and operating posture presented here, emergency managers should review existing COOP programs and begin increasing planning and posturing with a focus on key changes necessitated by the COVID-19 environment. The requirements for social distancing and the ability to follow CDC guidance to protect the health and safety of survivors, emergency managers, and other response and recovery personnel could impact operational concepts such as sheltering plans, commodity distribution, and establishment of disaster facilities. With many FEMA personnel working remotely, SLTTs should be prepared to conduct disaster work virtually, including using available media to ensure survivors are aware of and understand the changes to the application process, holding virtual townhalls throughout response and recovery, and conducting virtual coordination meetings with volunteer organizations and the private sector. If the communications lifeline is impacted by follow-on incidents, stabilization will be even more essential to support remote work. When additional resources—personnel, commodities, contract support, mutual aid—are needed to support changes within the COVID-19 environment, SLTTs should begin increasing planning and posturing for these eventualities.

FEMA expects our SLTT partners and fellow emergency managers to problem-solve, act, and do what emergency managers do best—coordinate, communicate, and collaborate. As the Nation moves into hurricane season, emergency managers will need to lead, innovate, and be resourceful to address challenges and adapt disaster operations to meet the needs of survivors in the current environment.

Appendix A: Additional Resources

All the links referenced in the sections above are collected below for ease of reference.

Preparedness Resources

- The Federal Government's official COVID-19 website provides information relevant to individuals, households, schools, businesses, health care professionals, health care departments, and emergency managers

  (https://www.coronavirus.gov/)

- FEMA's pandemic resource page for SLTT partners across the emergency management community includes:

  (https://www.fema.gov/coronavirus/governments)

  - Best practices and lessons learned from communities across the Nation (NOTE: this collection is not exhaustive and is updated regularly)

    (https://www.fema.gov/coronavirus/best-practices)

  - Economic Support and Recovery to address the economic needs of American families, workers, and small businesses

    (https://www.fema.gov/coronavirus/economic)

- Other FEMA Resources include:

  - The CERT website with videos, training materials, and access to the Citizen Responder Programs Registration portal

    (https://www.ready.gov/cert)

    (https://community.fema.gov/Register)

  - Emergency Management Performance Grant Program and FY2020 Emergency Management Performance Grant – COVID-19 Supplemental

    (https://www.fema.gov/emergency-management-performance-grant-program)

  - The Emergency Financial First Aid Kit (EFFAK) with guidance for individuals and families to strengthen financial preparedness for disasters and emergencies

    (https://www.fema.gov/media-library/assets/documents/96123)

  - Emergency Manager Best Practices

    (https://www.fema.gov/coronavirus/best-practices)

  - Healthcare Facilities and Power Outage

    (https://www.fema.gov/media-library-data/1566392446802-cb3f4603ff821158811d3f55f370238e/Healthcare_Facilities_and_Power_Outages.pdf)

  - Ready.gov/Pandemic personal preparedness site

    (https://www.ready.gov/pandemic)

  - FEMA Preparedness Grants Manual

(https://www.fema.gov/media-library/assets/documents/178291)

- Comprehensive Preparedness Guide 101

  (https://www.fema.gov/media-library-data/20130726-1828-25045-0014/cpg_101_comprehensive_preparedness_guide_developing_and_maintaining_emergency_operations_plans_2010.pdf)

- Continuity Guidance Circular

  (https://www.fema.gov/media-library/assets/documents/132130)

- Planning Considerations for Organizations in Reconstituting Operations During the COVID-19 Pandemic

  (https://www.fema.gov/news-release/2020/04/30/planning-considerations-organizations-reconstituting-operations-during-covid)

- Healthcare Capacity Building: Alternative Care Sites and Federal Medical Stations

  (https://files.asprtracie.hhs.gov/documents/understanding-acs-and-fms-final.pdf)

- Reconstituting Operations Starter Kit

  (https://www.fema.gov/media-library/assets/documents/188077)

- The CDC's COVID-19 website has guidance for keeping individuals, healthcare professionals and communities safe:

  (https://www.cdc.gov/coronavirus/2019-nCoV/index.html)

  - Preparing for Hurricanes During the COVID-19 Pandemic

    (https://www.cdc.gov/disasters/hurricanes/covid-19/prepare-for-hurricane.html)

  - Strategies to optimize the supply of PPE and other equipment

    (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html)

  - Interim guidance for businesses and employers to plan and respond to COVID-19

    (https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html)

  - Guidance for cleaning and disinfection for households

    (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cleaning-disinfection.html)

  - Considerations for employers on cleaning and disinfecting your facility

    (https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html)

  - What you should know about COVID-19 to protect yourself and others

    (https://www.cdc.gov/coronavirus/2019-ncov/downloads/2019-ncov-factsheet.pdf)

  - Communication resources and guidance documents

    (https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Adesc)

- White House Guidelines for Opening Up America Again

  (https://www.whitehouse.gov/openingamerica/#criteria)
- COVID-19 fact sheets and guidance provide SLTT partners with updated information, including:

  (https://www.fema.gov/coronavirus/fact-sheets)
  - COVID Best Practice Information for SLTT 9-1-1 Call Centers

    (https://www.fema.gov/media-library-data/1587583826898-7edfe29901f3025da758b9e29cb7fbb5/2020_04_21_COVID_BP_911Centers_F.pdf)
- The EMAC website provides information on the all-hazards national mutual aid system

  (https://www.emacweb.org/)

Response Resources

- The National Response Framework is a guide to respond to all types of disasters and emergencies

  (https://www.fema.gov/media-library-data/1582825590194-2f000855d442fc3c9f18547d1468990d/NRF_FINALApproved_508_2011028v1040.pdf)
  - Response FIOP

    (https://www.fema.gov/media-library-data/1471452095112-507e23ad4d85449ff131c2b025743101/Response_FIOP_2nd.pdf)
  - Community Lifelines Implementation Toolkit

    (https://www.fema.gov/media-library/assets/documents/177222)
- FEMA's Coronavirus Emergency Management Best Practices compiles best practices and lessons learned from communities fighting COVID-19

  (https://www.fema.gov/coronavirus/best-practices)
- COVID-19 fact sheets and guidance provide SLTT partners with updated information, including:

  (https://www.fema.gov/coronavirus/fact-sheets)
  - COVID-19 supply chain guidance

    (https://www.fema.gov/media-library-data/1586011228351-ee9dd63af03bc879168c827bf922cb90/COVID19SupplyChain.pdf)
  - COVID-19 SLTT public information guidance

    (https://www.fema.gov/media-library-data/1587250289402-3e2e773531d50b09890fe071e042e3e6/2020_04_18_COVID_BP_SLTTPublicInformation.pdf)
  - Ensuring Civil Rights During the COVID-19 Response

    (https://www.fema.gov/media-library-data/1586893628400-f21a380f3db223e6075eeb3be67d50a6/EnsuringCivilRightsDuringtheCOVID19Response.pdf)
  - COVID-19 SLTT 9-1-1 call center guidance

(https://www.fema.gov/media-library-data/1587583826898-7edfe29901f3025da758b9e29cb7fbb5/2020_04_21_COVID_BP_911Centers_F.pdf)

- COVID-19 floodplain considerations for temporary critical facilities

  (https://www.fema.gov/news-release/2020/04/13/coronavirus-covid-19-pandemic-floodplain-considerations-temporary-critical)

- COVID-19 Emergency Operations Center Guidance

  (https://www.fema.gov/media-library-data/1588336615101-0460905692bda72076abdc5943939a09/2020_04_30_COVID_BP_EOC.pdf)

- Other FEMA Resources include:
  - The Radiological Emergency Preparedness Program

    (https://www.fema.gov/radiological-emergency-preparedness-program)

  - FEMA's web-based storm tracking and decision support tool, HURREVAC assists SLTT partners with Hurricane Evacuation planning, training, and timely decision-making during response operations

    (http://hurrevac.com/)

- The CDC COVID-19 website has guidance for keeping individuals, healthcare professionals, and communities safe:

  (https://www.cdc.gov/coronavirus/2019-nCoV/index.html)

  - Correctional and detention facilities

    (https://www.cdc.gov/coronavirus/2019-ncov/community/correction-detention/guidance-correctional-detention.html)

  - Long-term care facilities and nursing homes

    (https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html)

  - People with disabilities

    (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-disabilities.html)

  - Public health communications

    (https://www.cdc.gov/healthcommunication/phcomm-get-your-community-ready.html)

  - Strategies to mitigate healthcare personnel staffing shortages

    (https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html)

  - Strategies to optimize the supply of PPE and other equipment

    (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html)

- The Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA) provides information on securing critical infrastructure during COVID-19

  (https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce)

- The Americans with Disabilities Act (ADA) has a list of resources useful to emergency managers regarding people with disabilities

  (https://www.ada.gov/emerg_prep.html)

- The Department of Labor (DOL) issued DOL COVID Workplace Guidance, in partnership with the Department of Health and Human Services, on safe work practices and appropriate PPE based on the risk level of exposure

  (https://www.dol.gov/newsroom/releases/osha/osha20200309)

- CISA released the CISA COVID Risk Management to help executives consider physical, supply chain, and cybersecurity issues that may arise from the spread of COVID-19

  (https://www.cisa.gov/sites/default/files/publications/20_0306_cisa_insights_risk_management_for_novel_coronavirus_0.pdf)

- The EMAC website provides information on the all-hazards national mutual aid system

  (https://www.emacweb.org/)

- The National Mass Care Strategy provides COVID-19-related feeding and sheltering guidance

  (https://nationalmasscarestrategy.org/category/covid-19/)

- The National Weather Service (NWS) statement addresses tornado shelters during a pandemic

  (https://www.wsfa.com/2020/03/22/nws-issues-statement-regarding-tornado-shelters-during-pandemic/)

Recovery Resources

- National Disaster Recovery Framework

  (https://www.fema.gov/national-disaster-recovery-framework)

  - Recovery FIOP

    (https://www.fema.gov/media-library-data/1471451918443-dbbb91fec8ffd1c59fd79f02be5afddd/Recovery_FIOP_2nd.pdf)

  - Mitigation FIOP

    (https://www.fema.gov/media-library-data/1471450195109-d68f4bb054782a379b341999317bd123/Mitigation_FIOP_2nd.pdf)

- Other FEMA Guidance includes:

  - Resilience Analysis and Planning Tool (RAPT)

    (https://fema.maps.arcgis.com/apps/webappviewer/index.html?id=90c0c996a5e242a79345cdbc5f758fc6)

  - Disaster Financial Management Guide

    (https://www.fema.gov/media-library/assets/documents/187126)

  - Community Recovery Management Toolkit

    (https://www.fema.gov/community-recovery-management-toolkit)

  - Continuity Resource Toolkit

    (https://www.fema.gov/continuity-resource-toolkit)
  - Individual Assistance Program and Policy Guidance

    (https://www.fema.gov/media-library/assets/documents/177489)
  - Mass Care/Emergency Assistance Pandemic Planning Considerations

    (https://nationalmasscarestrategy.org/covid-19-sheltering-guidelines/)
  - Guidance on Planning for Personal Assistance Services in General Population Shelters

    (https://www.fema.gov/pdf/emergency/disasterhousing/guidance_plan_ps_gpops.pdf)
  - Guidance on Planning for Integration of Functional Needs Support Services in General Population Shelters

    (https://www.fema.gov/pdf/about/odic/fnss_guidance.pdf)
- The CDC COVID-19 website has guidance for keeping individuals, healthcare professionals and communities safe:

  (https://www.cdc.gov/coronavirus/2019-nCoV/index.html)
  - Homeless service providers

    (https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/plan-prepare-respond.html)
  - People with disabilities

    (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-disabilities.html)
  - Public health communications

    (https://www.cdc.gov/healthcommunication/phcomm-get-your-community-ready.html)
  - Guidance for General Population Sheltering

    (https://www.cdc.gov/coronavirus/2019-ncov/downloads/Guidance-for-Gen-Pop-Disaster-Shelters-a-Pandemic_cleared_JIC_ADS_final.pdf)
- The EMAC website provides information on the all-hazards national mutual aid system.

  (https://www.emacweb.org/)
- The Hazus website for support on all-hazards risk assessments

  (https://www.fema.gov/hazus)
- The Grants Portal System for Public Assistance grantees

  (https://grantee.fema.gov/)
- Public Assistance Program and Policy Guide

  (https://www.fema.gov/media-library-data/1525468328389-4a038bbef9081cd7dfe7538e7751aa9c/PAPPG_3.1_508_FINAL_5-4-2018.pdf)
- State-Led Public Assistance Guide

(https://www.fema.gov/media-library-data/1558538652426-d4165531878c8c8795551d3a7665d03e/State-Led_PA_Guide_2-1-2019.pdf)

- The International City/County Management Association (ICMA) provides guidance, including:
  - ICMA guidance on public meetings and crisis communications

    (https://icma.org/coronavirus-crisis-response-resources-your-community?utm_source=CV19_landing_page&utm_medium=CV19_landing_page&utm_campaign=CV19_campaign)
  - Webinar on "Managing Crisis Communications during a Pandemic"

    (https://icma.org/events/free-webinar-managing-crisis-communications-during-covid-19-pandemic)
- The Procurement Disaster Assistance Team makes trainings available via webinar.

  (https://www.fema.gov/procurement-disaster-assistance-team)

Appendix B: Preparedness Considerations Checklist

The following considerations are presented here for SLTTs to utilize when modifying the preparedness phase of all hazards or hurricane specific plans in the COVID-19 environment.

Review and Modify

- ☐ Have you reviewed and modified your emergency operations plan to align with COVID-19 guidance, to include social distancing limitations, travel restrictions, fiscal impacts, reduction of government services, and potential impacts to your supply chain?
- ☐ Have you reviewed your jurisdiction's orders concerning any potential shelter-in-place or stay-at-home orders? Do any legal considerations require you to adjust your law enforcement, fire, Emergency Medical Services (EMS), or emergency operations?
- ☐ Are you coordinating updates to plans with the whole-community planning partners supporting your jurisdiction?
- ☐ Have you reviewed and modified your plans to include special considerations for those with access and functional needs in a COVID-19 environment?
- ☐ Have you reviewed and updated your COOP plans to continue essential functions and tasks with little to no interruption?
- ☐ Have you updated your resource management inventory to make response personnel available to support non-COVID-19 response?
- ☐ Have you identified essential personnel, based on organizational essential functions, by reviewing your existing or conducting new business process/business impact analyses to understand potential shortfalls and limitations?
- ☐ Have you identified orders of succession for key personnel and leadership? Do critical tasks and decision-making have approved delegations of authority?
- ☐ Have you identified alternate sites and capabilities to ensure COOP to include telework?
- ☐ Have you reviewed and evaluated current mutual aid agreements and EMAC agreements if available resources and/or personnel may be limited due to COVID-19 operations and considered virtual support where possible?

  (https://www.emacweb.org/)

Consider and Identify

- ☐ Do the constraints and impacts of COVID-19 within your, and neighboring, jurisdictions warrant the expansion of mutual agreements with new partners?
- ☐ Have COVID-19 response and recovery efforts identified new partners, resources, planning shortfalls, or solutions to include in emergency operations plans and annexes, including private sector partners in grocery, fuel, home mitigation supplies, and medical supplies?
- ☐ Have you considered resourcing secondary emergency management roles and responsibilities to support parallel disasters with extended timelines and limited resources?
- ☐ Have you assessed your increased personnel requirements and planned for contingency staffing?

- ☐ Have you determined if you can use alternate communications, information technology support, and remote operations to operate your EOC virtually?
- ☐ Have you explored virtual environment delivery platforms to exercise plans and overcome the challenges of limited face-to-face training, seminars, and workshops?
- ☐ Have you coordinated with public health officials to identify guidelines for workforce response? (NOTE: Local conditions will influence decisions that public health officials make regarding community-level strategies)
- ☐ Have you considered strategies to keep a disaster from overwhelming 9-1-1 centers, such as establishing alternative call lines for non-emergency queries from the public; increasing personnel capacity; and/or including the capacity to respond to calls from people who are deaf, hard of hearing, without speech, and/or have limited English proficiency?

  (https://www.fema.gov/media-library-data/1587583826898-7edfe29901f3025da758b9e29cb7fbb5/2020_04_21_COVID_BP_911Centers_F.pdf)

Message and Engage

- ☐ Have you developed and disseminated accessible, multilingual, and culturally appropriate messaging to inform the public of changes in expected services or procedures (e.g., changes to shelter locations, evacuation routes, available transportation methods) due to impacts from COVID-19 and ensured the messaging is accessible and available in alternative formats for people with disabilities?
- ☐ Have you updated pre-scripted messages to incorporate the current recommended PPE posture for disaster survivors (e.g., recommend wearing a cloth face covering) and provide deconflicting guidance regarding any stay-at-home orders or other guidance?
- ☐ Are you prepared to provide accessible multilingual and culturally appropriate messaging on increased personal preparedness measures and to encourage your community to evaluate personal emergency plans and familiarize themselves with guidance from their local jurisdictions related to COVID-19?

  (https://www.cdc.gov/coronavirus/2019-ncov/communication/print-resources.html?Sort=Date%3A%3Adesc

  (https://www.ready.gov/pandemic)
- ☐ Have you advised individuals and households to track their critical financial, medical, and household information by using the EFFAK tool as a guide?

  (https://www.fema.gov/media-library/assets/documents/96123)
- ☐ Have you translated relevant materials and messages in languages spoken in your community?
- ☐ Have you engaged with public health officials to identify guidelines for workforce response in a COVID-19 environment, and to plan for public health support for evacuations and sheltering?
- ☐ Have you identified the essential workforce necessary for continuing critical infrastructure viability by using the CISA advisory list as a guide?

  (https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce)

- ☐ Have you engaged non-profits and small businesses in your jurisdiction to discuss how you would respond and recover from a natural hazard event in a COVID-19 environment?
- ☐ How will you use accessible, multilingual, and culturally appropriate messaging to communicate to employees and stakeholders that normal operations are being resumed?

Appendix C: Response Considerations Checklist

The following considerations are presented here for SLTTs to utilize when modifying the response phase of all hazards or hurricane specific plans in the COVID-19 environment.

- ☐ Have you purchased and stockpiled appropriate PPE for personnel required to be in the field, including shelter management and shelter personnel?
- ☐ Have you considered updating your vendor contracts and agreements to procure and deliver supplies and equipment in case of a shortage?
- ☐ Have you confirmed your access to HURREVAC, FEMA's web-based storm tracking and decision support tool, to view data on National Hurricane Center and NWS forecasts, including forecast tracking and arrival of tropical storm winds; storm surge modeling; and evacuation clearance times under various storm scenarios; to support operational decisions?

  (http://hurrevac.com/)
- ☐ Have you modified your evacuation plan to account for limited travel options and hotel availability, increased need for health and medical evacuations, financial limitations of the general public, and additional impacts from COVID-19?
- ☐ Have you considered the extra time it may take to evacuate given the need for social distancing for increased mass transit modes (e.g., buses) may require?
- ☐ Have you considered using geographic information system platform planning tools, to include FEMA's RAPT, to identify population characteristics and infrastructure locations that may be impacted to help with your evacuation and shelter-in-place planning?

  (https://fema.maps.arcgis.com/apps/webappviewer/index.html?id=90c0c996a5e242a79345cdbc5f758fc6)
- ☐ Have you considered increasing the membership of CERT, MRC, and associated volunteer training? If so, do you have a mechanism to conduct remote recruiting and training?

  (https://www.ready.gov/cert)
- ☐ Have you reviewed and modified your logistics contracts to ensure you have adequate PPE and necessary commodities during response operations, especially if available resources have been allocated to COVID-19 response?

  (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html)
- ☐ Do your continuity plans adequately address how to respond if your agency/department or your partner agency has reduced staffing or other capabilities, such as facilities and commodities, due to COVID-19?
- ☐ Do you have a plan to integrate FEMA personnel and/or other federal partners into your response operations?
- ☐ Have you reached out to your critical infrastructure and private sector partners to assess their ability to respond to an emergency in a COVID-19 environment?
- ☐ Do you have a designated point of contact and information exchange platform to continue coordination with critical infrastructure and private sector partners?

- ☐ Have you considered expanded use of aerial imagery and other remote sensing capabilities to gain and maintain situational awareness and conduct damage assessments?
- ☐ Are any resources needed for a potential response currently unavailable or in short supply? Have you reached out to your EMAC or private sector partners for assistance and to discuss resource availability based on existing contracts and mutual aid agreements?

  (https://www.fema.gov/pdf/emergency/nrf/EMACoverviewForNRF.pdf)
- ☐ Does your EOC have enough information technology personnel to support increased numbers of remote emergency responders? Are they trained to work remotely and support remote work for extended periods on multiple disasters?
- ☐ Have you considered how your planning goals and objectives would be altered if resources are diverted for COVID-19?
- ☐ Have you established a Business Emergency Operations Center that can coordinate and collaborate with the private sector and the National Business Emergency Operations Center?

Safety and Security

- ☐ With the potential of decreased law enforcement availability, have you reviewed your contingency plans for on-site security?
- ☐ Have you considered COOP plans and ways to deliver essential government functions in a COVID-19 environment if conditions are further degraded by another disaster event?
- ☐ Have you reviewed your evacuation and sheltering plans for correctional facilities?

  (https://www.cdc.gov/coronavirus/2019-ncov/community/correction-detention/guidance-correctional-detention.html)
- ☐ How will you manage re-occupancy procedures given the constraints and impacts of COVID-19 (e.g., social distancing)? What agencies will need to be involved?
- ☐ Have you coordinated with neighboring jurisdictions to discuss impacts on access and re-occupancy procedures due to COVID-19?
- ☐ Have you coordinated with pass-through, host, and sending jurisdictions to verify that agreements to support and execute potential evacuations to accommodate COVID-19 considerations (or made any necessary updates) are in place?
- ☐ Are your special operations teams (e.g., Urban Search and Rescue, HazMat) still mission capable, and have they adopted CDC guidelines for PPE and training?
- ☐ Have you identified potential sites for disaster facilities that are consistent with CDC guidance and social distancing requirements and coordinated leasing requirements if needed?

  (https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html)

Food, Water, Shelter

- ☐ Have you considered how personnel shortfalls may impact your shelter operations?
- ☐ How do social distancing considerations affect current shelter capacity?

- ☐ Have you coordinated with public health officials in your jurisdiction regarding evacuation and shelter safety, infection control, and planning?
- ☐ Do sheltering and feeding plans incorporate social distancing guidelines and PPE requirements outlined by the National Mass Care Strategy?

  (https://nationalmasscarestrategy.org/category/covid-19/)
- ☐ Have you confirmed that public shelters you normally rely upon will be available in the aftermath of an incident (i.e., have schools been removed from use)?

  (https://www.ametsoc.org/ams/assets/File/aboutams/statements_pdf/StatementTornadoSheltEringPandemics.pdf)
- ☐ Have you considered identifying additional shelter locations, including in areas accessible to public transportation and/or in places accessible to low income communities, to reduce shelter density and promote social distancing?
- ☐ Have you explored options such as non-congregate sheltering (e.g., dormitories, hotels)? If so, have you developed a list of participating facilities, including in areas accessible to public transportation and/or in places accessible to low income communities?
- ☐ Considering current sheltering options, do individuals with access and functional needs, including individuals with disabilities, require additional sheltering resources and assistance in a COVID-19 environment?
- ☐ Have you evaluated the abilities and willingness of whole-community partners to operate or support mass care/sheltering in a COVID-19 environment?
- ☐ Have you coordinated with non-governmental and volunteer organizations to discuss changes in receipt, distribution, and delivery of commodities and services (e.g., food, donations, muck out) to incorporate any social distancing limitations?
- ☐ Have you assessed your eligibility to apply for assistance for the purchase and distribution of food in response to COVID-19?

  (https://www.fema.gov/news-release/2020/04/12/coronavirus-covid-19-pandemic-purchase-and-distribution-food-eligible-public)
- ☐ Are issues and status updates in supply chain and logistics of food and water identified and regularly communicated to appropriate partners for action?
- ☐ Have cleaning, disinfection, and sanitizing schedules increased, and are they actively monitored by designated sheltering facility personnel?
- ☐ Do your registration, health screening, and isolation care areas provide adequate physical separation (e.g., areas for potential temperature screening)?
- ☐ Have you included temperature and health screening in your screening protocol for upon arrival at mass care shelters? Do you have adequate temperature screening equipment and PPE to support your health screening protocols?

  (https://www.cdc.gov/coronavirus/2019-ncov/downloads/Guidance-for-Gen-Pop-Disaster-Shelters-a-Pandemic_cleared_JIC_ADS_final.pdf)

- ☐ Have you included COVID-19 testing in your screening protocol for mass care shelters if an evacuee meets criteria (e.g., symptoms, known exposure)? Do you have adequate PPE and testing kits to support your screening protocols?
- ☐ Do you need to increase your supply of hand hygiene products (soap, paper towels, hand sanitizer, etc.) and disinfection and sanitizing products in shelters in a COVID-19 environment?

Health and Medical

- ☐ Do you have an alternative staffing or recruitment strategy for healthcare professionals in the event of a reduction of personnel availability?

  (https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html)
- ☐ Do your healthcare, alternate care, and long-term care facilities have adequate, functional, and fueled emergency generators and a plan to keep emergency power systems operational during an emergency to reduce patient movement?

  (https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html)

  (https://www.fema.gov/media-library-data/1566392446802-cb3f4603ff821158811d3f55f370238e/Healthcare_Facilities_and_Power_Outages.pdf)
- ☐ Do your triage protocols and procedures facilitate efficient patient processing to reduce person-to-person contact, increase social distancing, and reduce the amount of time patients are in the triage area?
- ☐ Have you identified additional in-patient locations in the event of patient overflow to accommodate the need for physical separation in a COVID-19 environment?
- ☐ Have you reviewed or updated as necessary personal, family, or staff care plans for sustained emergency response operations?
- ☐ Have you coordinated with multi-disciplinary psychosocial support teams (e.g., social workers, mental health professionals, counselors, interpreters, patient service coordinators, clergy) to provide virtual support to patients, families, and medical personnel?
- ☐ Do you have sufficient information technology infrastructure and support to accommodate virtual coordination and support?
- ☐ Does your community have an established, streamlined process for information delivery and exchange between hospital administration, personnel, and, if required, governmental officials to facilitate situational awareness?
- ☐ Can your mass casualty management plans accommodate an increased number of fatalities? Have you identified additional contingencies for mortuary affairs management in a COVID-19 environment?
- ☐ Have you encouraged hospitals and other health care facilities to develop and maintain an updated inventory of PPE and other equipment? Do these facilities have a shortage-alert system with identified and well socialized triggers and associated actions to mitigate potential issues?

  (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html)

- ☐ To ensure equal access to information and resources, are key messages presented to patients, personnel, and the public in a variety of accessible formats (e.g., audio, visual, sign language, braille, multiple languages, culturally appropriate)?

  (https://www.cdc.gov/healthcommunication/phcomm-get-your-community-ready.html)

- ☐ Do you have coordinated plans in place to evacuate or shelter patients in place in Federal Medical Stations and Alternate Care Sites in your jurisdiction?

  (https://files.asprtracie.hhs.gov/documents/understanding-acs-and-fms-final.pdf)

  (https://files.asprtracie.hhs.gov/documents/acs-toolkit-ed1-20200330-1022.pdf)

Energy (Power and Fuel)

- ☐ Do energy sector partners have adequate staffing to generate, transmit, and distribute power and fuel to the community in the event of sick workers or family care needs? Have you identified surge support for emergency operations?
- ☐ How long would it take to restore power in a COVID-19 environment, considering the potential for reduced available staffing?
- ☐ Are damage assessments needed in this response? Can they be conducted virtually? How can your agency/jurisdiction limit personnel to allow for social distancing if damage assessments need to be done?
- ☐ Does your plan for potential emergency repairs for energy infrastructure account for COVID-19 social distancing or PPE needs?
- ☐ Has COVID-19 affected the supply of fuel in your jurisdiction (e.g., less people driving disrupting gas demand)?
- ☐ Does your jurisdiction have plans for priority power restoration for individuals with disabilities and health conditions that require power for life sustainment?
- ☐ Have changes in commercial trucking procedures affected your fuel distribution plan? Are you coordinating with representatives of the commercial trucking industry to ensure your needs are met?

Communications

- ☐ Have you and your response partners recently tested primary, alternate, contingency, and emergency communications capabilities?
- ☐ Have you evaluated your ability to send public announcements, and are the systems fully operational (e.g., mass notification systems, internet, radio, television, cable systems)?
- ☐ Have you verified the number of Integrated Public Alert & Warning System alerting authorities within your jurisdiction and worked to close any gaps in alerting authority coverage?
- ☐ Do you have a system to collect and share data to support decision-making and facilitate development of a common operating picture for multiple response operations?
- ☐ Have you considered converting town hall meetings and press conferences to accessible and multilingual virtual platforms, or requiring cloth face coverings (if appropriate) and social

distancing if they are conducted in person, and made provisions for accessibility for either virtual or in person meetings?

- ☐ Are 9-1-1 dispatch and public safety answering points available to citizens in need? Have you provided information on accessing 3-1-1, 2-1-1, mental/behavioral health hotlines, animal control, and other 24-hour community service help lines to control the flow of incoming calls?
- ☐ Can you implement text to 9-1-1 to improve services for people who have hearing or speech disabilities?
- ☐ Do you have plans to increase your 9-1-1 call center's capacity, including to respond to people who are deaf, hard of hearing, and/or without speech, or persons with limited English proficiency, in the event of increased incoming emergency calls? Have you considered establishing a coordinated call center system to divert non-emergency calls from the 9-1-1 system?

  (https://www.fema.gov/media-library-data/1587583826898-7edfe29901f3025da758b9e29cb7fbb5/2020_04_21_COVID_BP_911Centers_F.pdf)
- ☐ Is increased use of mobile or internet bandwidth disrupting emergency communications? Can responders receive prioritized access to dedicated bandwidth? Do responders have backup communications?
- ☐ Do you have accessible multilingual and culturally appropriate pre-scripted messages for communicating evacuation and shelter-in-place updates that include social distancing measures due to COVID-19 considerations?
- ☐ Do you have accessible, multilingual, and culturally appropriate communication materials that address hurricane, flood, tornado, or other hazards preparedness for your communities while under the threat of COVID-19?

  (https://www.cdc.gov/healthcommunication/phcomm-get-your-community-ready.html)

  (https://www.wsfa.com/2020/03/22/nws-issues-statement-regarding-tornado-shelters-during-pandemic/)
- ☐ Have you published guidance for non-essential businesses and unemployed workers on mitigating economic impacts due to COVID-19 (e.g., Small Business Administration support)?
- ☐ Are banking and financial services available? How long will it take to restore financial services? Is the disruption due to a lack of power/energy, overload of the system, or another factor? Is it possible to expand the bandwidth for financial service applications and technology temporarily?

Transportation

- ☐ Do you have capabilities to screen for COVID-19 on highways/roadways during an evacuation? Have you accounted for additional time needed for checkpoints during and evacuation?
- ☐ Do you have the resources necessary to re-establish critical mass transportation hubs (e.g., airports, train stations, local mass transit stations) under social distancing guidelines?
- ☐ How long after an incident can you begin maritime transportation while maintaining procedures to detect COVID-19 cases?

- ☐ Do you have access to the resources to repair pipelines that impact transportation services (understanding that PPE may be in short supply due to COVID-19)?
- ☐ Do you have accessible, multilingual, and culturally appropriate updated messaging to share with the public during an evacuation on social distancing to promote healthy behavior during COVID-19?
- ☐ Do you have a mechanism to increase public transportation, including accessible buses, vans, etc., if economic impacts preclude citizens from self-evacuating, to include paratransit for people with disabilities?
- ☐ Do your facilities and jurisdictions have adequate transportation agreements to accommodate medical evacuations within required timelines? Do they have patient tracking mechanisms to account for separations resulting from COVID-19 operations and evacuations?

Hazardous Materials

- ☐ Have you engaged critical infrastructure and private sector partners to coordinate accessible, multilingual, and culturally appropriate messaging, either through your local emergency planning committee or directly, to confirm their hazardous materials storage facilities are secure and their response plans are updated to reflect the current COVID-19 environment?
- ☐ Are your hazardous or toxic materials plans and messaging consistent with your COVID-19 procedures and messaging? Have you reviewed your messaging for a chemical, biological, radiological, or nuclear incident?
- ☐ How are you ensuring meaningful involvement of minority communities and low-income populations in the development and implementation of policy decisions impacting the environment during response and recovery?
- ☐ Have you reached out to the Radiological Emergency Preparedness Program or any hazardous and radiological materials groups to determine constraints and limitations from COVID-19 on facilities?

  (https://www.fema.gov/radiological-emergency-preparedness-program)
- ☐ Do you have the materials and resources needed for a hazardous or toxic materials incident? Have you identified any supply chain issues with procurement?
- ☐ Have you considered how to conduct site assessments, especially in areas with hazardous or radiological material, given COVID-19 considerations (e.g., potential personnel limitations, social distancing)?

Appendix D: Recovery Considerations Checklist

The following considerations are presented here for SLTTs to utilize when modifying the recovery phase of all hazards or hurricane specific plans in the COVID-19 environment.

Leadership and Authority

- ☐ Who are the lead agencies and individuals managing and coordinating disaster recovery efforts? Is this the same agency in charge of COVID-19 response actions?
- ☐ Have Delegations of Authority and Lines of Succession been reviewed for leadership and personnel positions critical to operations?
- ☐ How will COVID-19 response actions and leadership intersect with disaster recovery actions and leadership? What is the coordination mechanism for ensuring both efforts are coordinated?
- ☐ Will the recovery unified coordination group include relevant public health and medical officials?
- ☐ Who has the authority to make formal decisions in your jurisdiction related to disaster recovery?
- ☐ Does the health department need to certify that projects or locations comply with social distancing and other public health directives before their use?
- ☐ Can your jurisdiction pass ordinances, waivers, and policies in absentia given the constraints of the COVID-19 environment (e.g., social distancing)?

Staffing

- ☐ Do you have adequate staffing plans to assure continuity in staffing the management and implementation of recovery efforts throughout a COVID-19 environment with municipal/jurisdictional personnel, concurrent with the disaster?
- ☐ How will you manage building and housing inspections and re-occupancy procedures, given the constraints and impacts of COVID-19 (e.g., social distancing)?
- ☐ Are human resource policies and processes consistent with public health recommendations and state and federal statutes? Do you need to establish new policies (e.g., sick leave, scheduling, control measures) or continue them after COVID-19?
- ☐ Do you have a prioritized order of return for personnel after COVID-19?
- ☐ Do your mutual aid partners have adequate personnel to support your efforts in addition to their COVID-19 response efforts? Do you have enough personnel to share personnel with other impacted jurisdictions?
- ☐ Have you evaluated the staffing impacts of COVID-19 and the current disaster on your mutual aid partners?
- ☐ How will you manage inspections and re-occupancy procedures given the constraints and impacts of COVID-19 (e.g., social distancing)? What agencies should be involved?

Communications and Engagement

- ☐ Have you established a process to coordinate messaging related to COVID-19 disaster recovery efforts?

  (https://www.cdc.gov/healthcommunication/phcomm-get-your-community-ready.html)

- ☐ Do you have a process to synchronize messages between SLTT entities?
- ☐ Who is responsible for releasing information to the public within the jurisdiction? Is this the same individual(s) releasing information related to COVID-19?
- ☐ Which community organizations can help amplify important recovery information, helping to ensure whole of community recovery outcomes are realized?
- ☐ How will you determine critical vs. noncritical recovery functions?
- ☐ How will social distancing impact your recovery coordination structure? How will agencies and organizations coordinate efforts? Do you have a web platform that supports virtual coordination?
- ☐ Do you have any pre-positioned contracts for disaster housing-related services? Have you confirmed that these contracts are still valid and enforceable in the COVID-19 environment?
- ☐ What health and safety protocols can impact the return to, and occupancy of, homes and buildings? Who are the relevant agencies involved in making those determinations?
- ☐ How will you engage with potential PA Applicants virtually, including establishing virtual communications and information sharing platforms for Applicant Briefings and Requests for Public Assistance?

Recovery Planning

- ☐ Can you manage recovery functions as stipulated in your recovery plan following the constraints and impacts of COVID-19 (e.g., potential reduced staffing, budgetary shortfalls)?
- ☐ Do you have current and accurate information on COVID-19 cases and infection rates by census block or other scales that are most pertinent to your community?
- ☐ What analytic capabilities do you have to assess disaster impacts, vulnerable populations (i.e. protected populations, race, color, national origin, limited English proficiency, age, disability, sex, religion, and economic status), systemic risk, and other issues necessary for timely and data informed decision support? Have you considered using the RAPT for data-driven decision support?

  (https://fema.maps.arcgis.com/apps/webappviewer/index.html?id=90c0c996a5e242a79345cdbc5f758fc6)

- ☐ How will you maximize community input and buy-in for your recovery efforts? Can you hold effective public meetings while maintaining social distance? Do you have mechanisms to reach isolated or underserved communities?
- ☐ Do you have required software licenses to conduct large-scale public engagements remotely? What is your single meeting participant capacity? Do you have trained personnel to operate these systems?

- ☐ How will you provide individuals with access and functional needs, to include those with disabilities, with services in accordance with ADA and CDC guidance?
- ☐ How will you provide the homeless population with services in accordance with CDC guidance, while also ensuring the health and safety of emergency responders and recovery personnel?

  (https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/plan-prepare-respond.html)
- ☐ What portion of the community has received housing assistance from COVID-19-related funding? Are these populations at increased risk from housing displacement following a natural disaster?

Financial Management

- ☐ What are your jurisdiction's existing financial management practices for disaster and recovery? What adjustments, if any, are needed to comply with procurement requirements in a COVID-19 environment?

  (https://www.fema.gov/media-library-data/1586815358427-cc78a4a55abb9437c487ba72b1a57e02/COVID-19-and-Disaster-Financial-Management-Guide.pdf)
- ☐ Do you have access to a contingency planning fund? If not, how will you access critical recovery funding?
- ☐ How can your personnel and departments access virtual training to build and sustain skills, if necessary?
- ☐ What is your process to determine eligibility for all relevant funding opportunities? What access do you have to associations that can support disaster-related projects?
- ☐ Do your jurisdiction's financial practices and procedures for non-disaster projects follow the same practices and procedures for disaster-related projects?

Appendix E: Public Messaging Guidance on Hurricanes

The following contents, which have been approved by the CDC and the National Oceanic and Atmospheric Administration (NOAA), may be utilized by SLTTs to communicate hurricane preparedness actions to individual Americans and community organizations during a pandemic. All public messaging must be accessible to individuals with disabilities and individuals with limited English proficiency. This appendix also contains messaging designed specifically for youth audiences.

Be Prepared for a Hurricane

Highlight:

Threats from hurricanes include powerful winds, heavy rainfall, storm surges, coastal and inland flooding, rip currents, tornadoes, and landslides.

Definition:

A hurricane is a storm that forms over warm ocean waters and has sustained winds of 74 mph or higher. The Atlantic and Central Pacific hurricane season runs from June 1 through November 30. The East Pacific hurricane season runs from May 15 through November 30.

Quick Facts:

- Hurricanes can happen along any U.S. coast or territory in the Atlantic and Pacific Oceans or the Gulf of Mexico.
- Hurricanes can affect areas more than 100 miles inland.
- Hurricanes are most active in September.

Protect Yourself Key Messages:

- If you are under a hurricane warning, find safe shelter right away.
- Determine your best protection for high winds and flooding, as well as infectious diseases, including COVID-19. Keep in mind that your best protection from the effects of a hurricane may differ from your best protection from disease.
- Know your evacuation zone! Due to limited space as a result of COVID-19, public evacuation shelters may not be the safest choice for you and your family.
    - Unless you live in a mandatory evacuation zone, it is recommended that you make a plan to shelter-in-place in your home, if it is safe to do so.
    - If you live in a mandatory evacuation zone, make a plan with friends or family to shelter with them where you will be safer and more comfortable.
    - Only evacuate to shelters if you are unable to shelter at home or with family or friends. Note that your regular shelter may not be open this year. Check with local authorities for the latest information about public shelters.
    - If you must evacuate to a public shelter, try to bring items that can help protect you and others in the shelter from COVID-19, such as hand sanitizer, cleaning materials, and two cloth face coverings per person. Children under 2 years old, people who have trouble

breathing, and people who cannot take the cloth face covering off without help should not wear cloth face coverings.

(https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html?platform=hootsuite)

- Pay attention to emergency information and alerts.
- Only use outdoor generators outdoor that are at least 20 feet away from your home and away from windows, doors, and vents.
- Do not walk, swim, or drive through flood waters.

How to Stay Safe When a Hurricane Threatens

Prepare Now

- Know your area's risk of hurricanes.
- Have several ways to receive warnings and alerts from the National Weather Service and your local officials. Do not rely on a single source of weather alert information. Sign up for your community's warning system. The Emergency Alert System (EAS) and NOAA Weather Radios also provide emergency alerts. Turn on Wireless Emergency Alerts (WEA) in your smartphone settings.

  (https://www.ready.gov/alerts)
- If you are at risk for flash flooding, watch for signs such as heavy rain.
- Practice going to a safe shelter, such as a FEMA safe room or International Code Council (ICC) 500 storm shelter. The next best protection is a small, interior, windowless room in a sturdy building on the lowest level that is not subject to flooding. Practice going to these places while following the latest guidelines from the CDC and your state and local authorities to prevent the spread of COVID-19.

  (https://www.fema.gov/safe-rooms)

  (https://www.fema.gov/media-library/assets/documents/110209)

  (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html)
- Based on your location and community plans, make your own plans for evacuation or sheltering-in-place. Due to limited space as a result of COVID-19, unless you live in a mandatory evacuation zone, it is recommended that you shelter-in-place in your home. If you live in a mandatory evacuation zone, talk with your friends and family to see if you can shelter with them. Only evacuate to shelters if you are unable to shelter at home or with family or friends. Be sure to review your previous evacuation plan and consider alternative options to maintain social and physical distancing to prevent the spread of COVID-19, and update your plan accordingly.
- Become familiar with your evacuation zone, the evacuation route, and the shelter locations. Note that your regular shelter may not be open this year because of COVID-19. Check with local authorities for the latest information about shelters. Only evacuate to shelters if you are unable to shelter at home or with family and friends.

- Once you have identified your safe location, gather needed supplies, including cleaning supplies, non-perishable foods, and water. If you are able to, set aside items like soap, hand sanitizer, disinfecting wipes, and general household cleaning supplies that you can use to disinfect surfaces you touch regularly. After a hurricane, you may not have access to these supplies for days or even weeks. Keep in mind each person's specific needs, including medication. Do not forget the needs of pets.
- Keep important documents in a safe place or create password-protected digital copies.
- Protect your property. Declutter drains and gutters. Install check valves in plumbing to prevent backups. Consider hurricane shutters. Review insurance policies.

Survive During

- If you live in a mandatory evacuation zone and local authorities instruct you to evacuate, do so immediately. Do not drive around barricades or through floodwater.
- If you must evacuate, if possible, bring with you items that can help protect you and others in the shelter from COVID-19, such as hand sanitizer, cleaning materials, and two cloth face coverings per person. Children under 2 years old, people who have trouble breathing, and people who cannot take the cloth face covering off without help should not wear cloth face coverings.

  (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html?platform=hootsuite)
- If sheltering during high winds, go to a FEMA safe room, ICC 500 storm shelter, or a small, interior, windowless room or hallway on the lowest floor that is not subject to flooding.
- If staying at a shelter or public facility, take steps to keep yourself and others safe from COVID-19. Wash your hands often, maintain a physical distance of at least six feet between you and people who are not part of your household, and avoid crowds and gathering in groups. When possible, wear a cloth face covering. Children under 2 years old, people who have trouble breathing, and people who cannot take the cloth face covering off without help should not wear cloth face coverings. If possible, wash your cloth face covering on a regular basis.
- If you are sick and need medical attention, contact your healthcare provider for further care instructions and shelter-in-place, if possible. If you are experiencing a medical emergency, call 9-1-1 and let the operator know if you have, or think you might have, COVID-19. If possible, put on a cloth face covering before help arrives. If staying at a shelter or public facility, alert shelter staff immediately so they can call a local hospital or clinic.

  (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html)
- If trapped in a building by flooding, go to the highest level of the building. Do not climb into a closed attic. You may become trapped by rising flood water.
- Listen for current emergency information and instructions.
- Use a generator or other gasoline-powered machinery ONLY outdoors and at least 20 feet from your home and away from windows, doors, and vents. If you are using generators near your

home, install battery-operated or battery back-up carbon monoxide (CO) detectors and check to be sure they are working properly.

(https://www.cdc.gov/co/generatorsafetyfactsheet.html)

- Do not walk, swim, or drive through flood waters. Turn Around. Do not drown. Just six inches of fast-moving water can knock you down, and one foot of moving water can sweep your vehicle away.
- Stay off bridges over fast-moving water.

Be Safe After

- Pay attention to information and special instructions from authorities.
- Be careful during clean-up. Wear protective clothing, use appropriate face coverings or masks if cleaning mold or other debris, and maintain a physical distance of at least six feet while working with someone else. People with asthma and other lung conditions and/or immune suppression should not enter buildings with indoor water leaks or mold growth that can be seen or smelled, even if they do not have an allergy to mold. Children should not take part in disaster cleanup work.

  (https://www.cdc.gov/mold/cleanup-guide.html)

  (https://www.cdc.gov/disasters/clinicians_asthma.html)
- Continue taking steps to protect yourself from COVID-19 and other infectious diseases, such as washing your hands often and cleaning commonly touched surfaces.
- Do not touch electrical equipment if it is wet or if you are standing in water. If it is safe to do so, turn off electricity at the main breaker or fuse box to prevent electric shock.
- Avoid wading in flood water, which can contain dangerous debris. Underground or downed power lines can also electrically charge the water.
- Save phone calls for emergencies. Phone systems are often down or busy after a disaster. Use text messages or social media to communicate with family and friends.
- Document any property damage with photographs. Contact your insurance company for assistance.
- Be available for family, friends, and neighbors who may need someone to talk to about their feelings. Helping others cope with their anxiety and stress can make your community stronger. Many people may already feel fear and anxiety about COVID-19. The threat of a hurricane can add additional stress. Follow CDC guidance for managing stress during the COVID-19 pandemic.

  (https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/managing-stress-anxiety.html)

Take an Active Role in Your Safety

Go to ready.gov and search for “hurricane.” Download the FEMA app to get more information about preparing for a hurricane and for pandemics.

Helpful Links:

- https://www.ready.gov/hurricanes

Videos

- Storm Surge Public Service Announcements (FEMA) (Video) (https://www.youtube.com/playlist?list=PL720Kw_OojlLoTEBMTVHJ_bDUCBYM3V4_)
- Storm Surge (NOAA) (Video) (https://oceantoday.noaa.gov/hurricanestormsurge/)
- Six Things to Know Before a Disaster (FEMA) (Video) (https://www.fema.gov/media-library/assets/videos/159970)
- When the Waves Swell – Hurricane Animated (FEMA) (Video) (https://www.youtube.com/watch?v=STiMKEYZ3Q4)

Tip Sheets

- Hurricane Information Sheet (PDF) (https://www.ready.gov/sites/default/files/2020-03/hurricane_information-sheet.pdf)
- How to Prepare for a Hurricane (PDF)
- (https://www.ready.gov/sites/default/files/2020-03/fema_how-to-prepare-for-hurricane.pdf)
- Prepare Your Organization for a Hurricane Playbook (PDF) (http://www.fema.gov/media-library/assets/documents/98410)

More Information

- Coronavirus (Federal Government Response) (Link) (https://www.coronavirus.gov/)
- Flood Map Service Center (FEMA) (Link) (https://msc.fema.gov/portal/search)
- Floodsmart.gov (FEMA) (Link) (https://www.floodsmart.gov/)
- National Flood Insurance Program (FEMA) (Link) (https://www.fema.gov/national-flood-insurance-program)
- National Weather Service Hurricane Safety (NWS) (Link) (https://www.weather.gov/safety/hurricane)
- National Storm Surge Hazard Maps (NOAA) (Link) (https://www.nhc.noaa.gov/nationalsurge/)

Information for Youth

About

Hurricanes are severe tropical storms that form in the southern Atlantic Ocean, Caribbean Sea, Gulf of Mexico, and in the eastern Pacific Ocean. They collect heat and energy through contact with warm ocean waters and then move toward land. Evaporation from the ocean water increases their power. Hurricanes rotate in a counterclockwise direction around an "eye," which is the center of the hurricane.

Hurricanes have winds at least 74 miles per hour. When hurricanes come onto land, their heavy rain, strong winds, and large waves can damage buildings, trees, and cars. Storm surge is when rising water moves inland, or away from the coastline. It is very dangerous.

The COVID-19 pandemic will be ongoing as hurricane season and other natural disasters, such as flooding, earthquakes, and wildfires, continue to occur throughout the year. Remember to follow the latest guidelines from the CDC and your state and local authorities to protect yourself and your family from COVID-19.

Words to Know

Evacuation: Leaving an area that officials say is unsafe.

Eye: The center of the storm. Winds and rains die down, but they will start up again very quickly.

Inland: Away from the coastline.

Storm Surge: Heavy waves caused by high wind and a lot of rain.

Tropical: An area of the country that is closer to the equator.

Am I at Risk?

Hurricanes are most common from June through November. Any U.S. coast by the Atlantic or Pacific Oceans can get hit, and you can feel the effects more than 100 miles inland. People who live on the coast may experience extreme winds and flooding from rain and storm surge. People who live inland are at risk for wind, thunderstorms, and flooding.

Living through environmental disasters, like hurricanes, can be more complicated when we are also experiencing a pandemic like COVID-19. It is important to be prepared and to understand how COVID-19 might affect you and your family.

COVID-19 may affect different people in different ways. Most people who are diagnosed with COVID-19 have not been seriously sick. Those more likely to become seriously sick include adults over age 65 or those who already have other chronic conditions, like diabetes and heart disease. Based on available evidence, children do not appear to be at higher risk for COVID-19 than adults. By following the CDC's recommendations for protecting yourself from COVID-19, you can lower your chances of getting sick, both during a hurricane and in general.

(https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html)

(https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html)

What Can I Do?

Before

- Build an emergency kit.
- Make a family communications plan. Plan how you will keep in touch with family members if you lose power or are separated.
- Help your parents bring in outdoor items like potted plants, patio furniture, decorations, and garbage cans. They can fly away in strong winds!

During

- Do not open the refrigerator or freezer. In case you lose power, you want the cold air to stay in so food will last longer!
- Stay away from windows and glass doors. They could break and hurt you.
- If you do not evacuate, stay inside a closet, hallway, or a room without windows.
- If must evacuate, ask your parent or guardian to bring supplies that can help you protect yourself and your family from COVID-19, such as hand sanitizer, cleaning products, and two cloth face coverings for each member of the family who can wear one. Children under 2 years old, people who have trouble breathing, and people who cannot take the cloth face covering off without help should not wear cloth face coverings. (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html)
- Avoid touching your mouth, nose, and eyes, especially with unwashed hands.
- Pay attention to your parents or safety authorities for important instructions.

After

- If you and your family must stay at a shelter or public facility, take steps to protect yourself and others from COVID-19. Maintain a distance of at least six feet, or about two adult arm lengths, between you and people who are not part of your household. Do not get into crowds or groups. (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html)
- Wear a cloth face covering while at the shelter. Do not wear a cloth face covering if you have trouble breathing or cannot take off the cloth face covering without help. Babies and kids under the age of 2 should not wear them either. If you can, wash your face cloth covering regularly. (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html)
- **Do not go outside without a grown-up.**
- Do not go near any wires that are loose or dangling. They could electrocute you!
- Tell your parents if the air smells weird, it could mean that there are dangerous gasses in the air.
- Text, do not talk. Unless there is a life-threatening situation, send a text so that you do not tie up phone lines needed by emergency workers. Plus, texting may work even if cell service is down.
- Know that it is normal to feel anxious or stressed out. Everyone reacts differently to stressful situations. Take care of your body and talk with your parents or other trusted adults if you are feeling upset (https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/managing-stress-anxiety.html)

Getting Sick

- Cover your coughs and sneezes! Use a tissue or cough or sneeze into your elbow. If you do use a tissue, throw it in the trash right away.

- Wash your hands with soap and water for at least 20 seconds. Sing the “Happy Birthday” song twice while you wash your hands. Make sure to wash your hands after blowing your nose, coughing or sneezing, using the bathroom, and eating or making food.
- If you cannot find soap and water to wash your hands, use hand sanitizer.
- **Stay away from people who are coughing, sneezing, or sick.**
- Remind your parents to clean surfaces that people touch frequently, like desks, doorknobs, light switches, and remote controls.
- Tell your parents if you feel sick.

Learn More

Did you know?

Hurricanes can also affect areas greater than 100 miles away from the coastline. People who live inland are also at risk for wind, thunderstorms, tornadoes, and flooding.

Helpful Links:

- Ready.gov (https://www.ready.gov/hurricanes)
- Ready Wrigley Prepares for Hurricanes (CDC) (https://www.cdc.gov/cpr/readywrigley/documents/13_239066_ready_wrigley_hurricanes_508.pdf)
- Listo Calixto se Prepara para los Huracanes (CDC) (https://www.cdc.gov/cpr/readywrigley/documents/13_239066_ready_wrigley_hurricanes_spanish_508.pdf)
- Prepare with Pedro Disaster Activity Book (https://www.ready.gov/kids/prepare-with-pedro)
- Talking with Children about Coronavirus Disease 2019 (CDC) (https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/talking-with-children.html)

Appendix F: Acronyms

ADA	Americans with Disabilities Act
CDC	Centers for Disease Control and Prevention
CERT	Community Emergency Response Team
CISA	Cybersecurity and Infrastructure Security Agency
CO	Carbon Monoxide
COOP	Continuity of Operations
COVID-19	Novel Coronavirus Disease 2019
DEC	Disaster Emergency Communications
DHS	Department of Homeland Security
DOL	Department of Labor
DRC	Disaster Recovery Center
DSA	Disaster Survivor Assistance
EAS	Emergency Alert System
EFFAK	Emergency Financial First Aid Kit
EHP	Environmental Planning and Historic Preservation
EMAC	Emergency Management Assistance Compact
EMPG-S	Emergency Management Performance Grant Supplemental
EMS	Emergency Medical Services
EOC	Emergency Operations Center
ESF	Emergency Support Function
FCO	Federal Coordinating Officer
FEMA	Federal Emergency Management Agency
FIOP	Federal Interagency Operational Plan
FIT	FEMA Integration Team
FY	Fiscal Year
HM	Hazard Mitigation
HMGP	Hazard Mitigation Grant Program
IA	Individual Assistance
ICC	International Code Council
ICMA	International City/County Management Association
IMAT	Incident Management Assistance Team
JFO	Joint Field Office

MCOV	Mobile Communications Office Vehicle
MRC	Medical Reserve Corps
NDRF	National Disaster Recovery Framework
NFIP	National Flood Insurance Program
NGO	Non-Governmental Organization
NIMAT	National Incident Management Assistance Team
NOAA	National Oceanic and Atmospheric Administration
NRCC	National Response Coordination Center
NRF	National Response Framework
NWS	National Weather Service
PA	Public Assistance
PDA	Preliminary Damage Assessment
POD	Point of Distribution
PPE	Personal Protective Equipment
RAPT	Resilience Analysis and Planning Tool
RRCC	Regional Response Coordination Center
RSF	Recovery Support Function
SCF	Surge Capacity Force
SDRC	State Disaster Recovery Coordinator
SLTT	State, Local, Tribal, and Territorial
TDRC	Tribal Disaster Recovery Coordinator
TSA	Transitional Sheltering Assistance
UCG	Unified Coordination Group
US&R	Urban Search and Rescue
WEA	Wireless Emergency Alert

"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"

June 9, 2020

Post-Hearing Questions for the Record

Submitted to The Honorable Brett P. Giroir, M.D.

From Senator Thomas R. Carper

1) Racial Disparities in COVID Response

   a) Communities of color nationwide are clearly disproportionately impacted by COVID. African Americans make up 13% of the US population but 24% of US deaths. And, in almost every state, Hispanics and Latinos test positive for COVID-19 at disproportionately higher rates. What are your agencies doing to address racial disparities in COVID cases and outcomes?

   The Department of Health and Human Services (HHS) is engaged in multiple efforts to address racial disparities in COVID-19 cases and outcomes. This includes public-private partnerships with pharmacy and retail companies to expand testing capacity for more Americans. 70 percent of these public-private partnership sites are located in communities with moderate to high social vulnerability. The social vulnerability index takes into consideration race, ethnicity, housing and economics, language barriers, and similar factors. Another mechanism by which HHS is addressing the testing needs of those most vulnerable is through Health Centers. Health Centers provide care to 1 in 5 of those uninsured, 1 in 5 rural Americans, 1 in 3 individuals below the poverty line, more than 1.3 million homeless, and nearly 1 million migrant agricultural workers. 94 percent of the Health Centers provide COVID-19 testing. To fight COVID-19 among racial and ethnic minorities, as well as rural and other socially vulnerable communities, the Office of the Assistant Secretary for Health and the Office of Minority Health announced Morehouse School of Medicine as the awardee for a new three-year, $40 million initiative. Through this initiative – the National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities (NIMIC) – the Morehouse School of Medicine will develop and implement a strategic network of national, state, territorial, tribal, and local organizations to deliver COVID-19-related information to communities hardest hit by the pandemic.

The Federal Government has leveraged public-private partnerships with pharmacy and retail companies (CVS, Health Mart, Kroger, Rite Aid, Walgreens, and Walmart), also known as CBTS 2.0, to accelerate testing for more Americans in more communities across the country. CBTS 2.0 is composed of retail and pharmacy partnerships in more than 800 locations in all 50 states and the District of Columbia, which collectively have conducted over 2 million tests to date. The Federal Government focused on communities with high social vulnerability using the CDC's Social Vulnerability Index (SVI) as one of the main factors to select site locations. Approximately 65 percent are located in communities with moderate to high social vulnerability. The SVI measures the resilience of communities when confronted by external stressors along four main themes: socioeconomic status, household composition and disability, minority status, and housing type.

On July 24, the Centers for Disease Control (CDC) published a COVID-19 Response Health Equity Strategy to accelerate progress towards reducing COVID-19 disparities and achieving health equity. CDC is supporting activities in African American, Hispanic/Latino, American Indian and Alaska Native, Asian American, Pacific Islander, and Native Hawaiian communities. Through the engagement of trusted community-based organizations and institutions, CDC is developing tailored communications and forging partnerships nationwide to deliver COVID-19 prevention messages and community mitigation strategies.

b) FEMA has played a role with getting personal protective equipment (PPE) to essential health care workers, particularly in hospitals, during this public health emergency. However, there are many other essential workers working for grocery stores, meat-packing plants, and delivery services. These are often low-wage workers and are disproportionately people of color, and we have seen the disparities of low-income populations and communities of color.

c) Given these racial disparities, what do you think FEMA is doing to ensure that essential workers, particularly those not in a health care-related field, have access to PPE? What other efforts is FEMA making to ensure that communities of color are receiving targeted support?

HHS is engaged in many efforts to ensure that racial and ethnic minorities as well as those who are most vulnerable are receiving support. This question would be best addressed by FEMA.

2) Guidelines on Reopening

a) What is the Administration's plan to provide clear and uniform guidelines to businesses as states continue to reopen their economies?

The Administration has produced numerous documents that establish the strategy and specific tactics for testing in America. These documents include the Opening Up America

Again Guidelines, Testing Blueprint Opening Up America Again, Addendum to the Testing Blueprint, Report to Congress COVID-19 Strategic Testing Plan, and many other guidance documents released by the Centers for Disease Control and Prevention. Additional documents are being released that apply the strategic principles to specific situations. The table below displays some of the guidance documents released to support safe reopening.

Date	Title
7/23/2020	Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing
7/17/2020	Testing Guidelines for Nursing Homes
7/17/2020	Overview of Testing for SARS-CoV-2
7/17/2020	Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2
7/14/2020	Guidance for Healthcare Workers about COVID-19 (SARS-CoV-2) Testing
7/10/2020	Guidance for Health Departments about COVID-19 Testing in the Community
7/8/2020	Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19
7/3/2020	SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces
6/30/2020	Interim Considerations for Institutions of Higher Education Administrators for SARS-CoV-2 Testing
6/29/2020	Evaluation for SARS-CoV-2 Testing in Animals
6/27/2020	Completing the Person Under Investigation (PIU and Case Report Form
6/17/2020	Contact Tracing for COVID-19
6/13/2020	Testing Strategy for Coronavirus (COVID-19) in High-Density Crucial Infrastructure Workplaces after a COVID-19 Cases is Identified
6/11/2020	Interim Guidance for SARS-CoV-2 Testing in North American Wildlife
5/28/2020	Using Antibody Tests for COVID-19
5/26/2020	Data Management for Assigning and Managing Investigations
5/26/2020	Interim Guidance on Developing a COVID-19 Case Investigation and Contact Tracing Plan: Overview
5/23/2020	Interim Guidelines for COVID-19 Antibody Testing
5/19/2020	Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes
Guidance Documents List: https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Adesc&Search=test	

b) How will agencies assist in ensuring problems we saw in the first wave, including bidding wars between states and acute testing and PPE shortages, are addressed as the majority of states begin to reopen and a potential second wave in the fall?

Since the beginning of the pandemic, the Federal Government has focused on supporting and expanding domestic manufacturing capacity to strengthen related supply chains. Through the SNS 2.0 initiative and public-private partnerships, the Federal Government has greatly increased the availability of laboratory and testing supplies by engaging directly with distributors and manufacturers to increase production capacity through direct procurement, application of the Defense Production Act, formation of various public-private partnerships, and improved allocation criteria that ultimately help ensure

that supplies meet states' and territories' needs and reach the locations where the supplies are needed most.

Specific to the current COVID-19 response, as of August 18, 2020, and in coordination with interagency partners including the Department of Defense and the Department of Homeland Security, the SNS has provided more than 18.5 thousand tons of personal protective equipment (PPE) and other medical material to support States to aid in medical response as well as the federal repatriation effort to bring American citizens back from abroad. This deployment of PPE encompassed approximately 90 percent of the total SNS PPE inventory available at the beginning of the COVID-19 pandemic. In addition to PPE, the SNS deployed ventilators and Federal Medical Stations (FMS) to support the response. To respond and prepare for COVID-19, as well as prepare for any new and emerging public health threat, ASPR/SNS is working to implement SNS 2.0. This initiative has three main objectives:

- Ensure the SNS has the breadth and depth to meet any future pandemic or public health emergency;
- Bolster the U.S. industrial base for critical pharmaceuticals and medical supplies; and,
- Reduce America's vulnerabilities and reliance on foreign suppliers and manufacturers.

Under the first initiative, current planning is underway to achieve a capacity to meet 90 days of need by this fall, which will require a combination of actions to increase the supply of PPE and other critical items in the SNS, in the commercial supply chain, and at the point of use (such as hospitals).

The Federal Government has leveraged public-private partnerships with pharmacy and retail companies (CVS, Health Mart, Kroger, Rite Aid, Walgreens, and Walmart), also known as CBTS 2.0, to accelerate testing for more Americans in more communities across the country. CBTS 2.0 is composed of retail and pharmacy partnerships in more than 800 locations in all 50 states and the District of Columbia, which collectively have conducted over 2 million tests to date. The Federal Government has also set up surge testing to increase baseline testing 2X-5X for short periods of time. Surge testing sites have been implemented in 19 jurisdictions and have conducted over 290,000 tests.

3) Testing

a) It's been reported that you will soon step down from your role as "testing czar" in June without a successor in place. While public health experts have set different goals for the amount of tests that are needed, we remain short in what is needed for tests, PPE, and contact tracing capacity to safely reopen the country. Why are you stepping down from that role now?

I am not stepping down from my role of leading the coordination of COVID-19 diagnostic testing efforts within HHS. Although I am assuming my traditional duties as

the Assistant Secretary for Health, I am maintaining my role coordinating COVID-19 testing, including overseeing the NIH RADx Diagnostics program to ensure that innovations are immediately translated into practice. Specific to the current COVID-19 response, as of August 18, 2020, and in coordination with interagency partners including the Department of Defense and the Department of Homeland Security, the SNS has provided more than 18.5 thousand tons of personal protective equipment (PPE) and other medical material to support States to aid in medical response as well as the federal repatriation effort to bring American citizens back from abroad. This deployment of PPE encompassed approximately 90 percent of the total SNS PPE inventory available at the beginning of the COVID-19 pandemic. In addition to PPE, the SNS deployed ventilators and Federal Medical Stations (FMS) to support the response. To respond and prepare for COVID-19, as well as prepare for any new and emerging public health threat, ASPR/SNS is working to implement SNS 2.0. Under the first initiative, current planning is underway to achieve a capacity to meet 90 days of need by this fall, which will require a combination of actions to increase the supply of PPE and other critical items in the SNS, in the commercial supply chain, and at the point of use (such as hospitals).

Guidance has been issued for contact tracing for COVID-19 and can be found here: https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/contact-tracing.html

b) Who, or what entities, will take over your responsibilities coordinating and carrying out a nationwide testing strategy?

I am not stepping down from my role of leading the coordination of COVID-19 diagnostic testing efforts within HHS.

c) Testing supplies and capacity remain inefficiently distributed across the country. How is HHS and the Task Force addressing this set of challenges?

HHS and the Task Force are supplying all of the states and territories with the materials they need to reach their testing goals each month. This is achieved by shipping swabs and media throughout each month to all of the states and territories to help them test, at minimum, 2 percent of their population each month. Another product developed by the Administration to assist states and territories in leveraging the full testing capacity at their disposal is a database of nationwide lab locations and testing capacity, including the specific testing platforms at each laboratory.

The Federal government has worked with manufacturers to gain insight into diagnostic instrument install bases; procured and shipped collection supplies; and determined reagent inventory. The Federal Government then provided all information to states so they could better determine how to optimize their testing strategy. The Federal Government also purchased and allocated point-of-care devices and over 2.3 million tests; developed, implemented, and facilitated community-based testing sites across the country; and provided significant guidance and technical assistance for state plans. To

ensure states meet their testing goals, the federal government procured FDA authorized swabs and transport media, and is distributing these supplies to a single location in each state determined by the Governor's office. Starting in May and through September 11, the federal government has distributed over 95 million swabs and more than 77 million tubes of transport media.

The Federal Government has leveraged public-private partnerships with pharmacy and retail companies (CVS, Health Mart, Kroger, Rite Aid, Walgreens, and Walmart), also known as CBTS 2.0, to accelerate testing for more Americans in more communities across the country. CBTS 2.0 is composed of retail and pharmacy partnerships in more than 800 locations in all 50 states and the District of Columbia, which collectively have conducted over 2 million tests to date. The Federal Government has also set up surge testing to increase baseline testing 2X-5X for short periods of time. Surge testing sites have been implemented in 19 jurisdictions and have conducted over 290,000 tests.

On August 27th, the Administration announced that a $760 million contract was awarded to Abbott for the delivery of 150 million rapid BinaxNOW COVID-19 point of care tests. This initiative will expand strategic testing in the United States. The Abbott BinaxNOW COVID-19 Ag Card, which recently received an EUA from the FDA, does not require instrumentation and will deliver COVID-19 test results in 15 minutes or less. This test uses nasal swabs and can be easily deployed in many settings across the country.

d) Why haven't you asked testing companies such as Labcorp, Quest, and BioReference to share testing capacity to improve the turnaround time on test results?

The large reference laboratories play an important part of the testing ecosystem of the United States. These labs are being utilized across the country. Throughout the response we have leveraged all aspects of the testing infrastructure in the United States and are actively engaged in expanding testing capacity across the nation to meet the needs of all states, territories, and localities.

On July 14, 2020, the Administration announced that HHS would embark on a one-time procurement of rapid point-of-care testing instruments and tests to be distributed to nursing homes using the Defense Production Act. Through this aggressive action, nursing homes will be able to augment their current capacity for coronavirus testing, bolstering their response and helping to prevent the spread of SARS-CoV-2. This will facilitate baseline testing among nursing home residents and staff, and enable a pathway to conduct ongoing testing according to public health guidelines.

HHS is pleased to announce that all 13,850 initially eligible nursing homes have received one or more point of care instruments, and nearly 5 million tests. Following this initial distribution, we will facilitate nursing homes being able to reorder supplies via their normal commercial distribution channels.

On August 27th, the Administration announced that a $760 million contract was awarded to Abbott for the delivery of 150 million rapid BinaxNOW COVID-19 point of care tests. This initiative will expand strategic testing in the United States. The Abbott BinaxNOW COVID-19 Ag Card, which recently received an EUA from the FDA, does not require instrumentation and will deliver COVID-19 test results in 15 minutes or less. This test uses nasal swabs and can be easily deployed in many settings across the country.

From Senator Mike Enzi

1) I am glad to see the momentum behind Operation Warp Speed, which is supporting multiple projects with goals of accelerating safe and effective vaccine development as well as supporting manufacturing and distribution efforts to ensure an adequate vaccine supply. In addition to the vaccine itself, a national vaccination campaign would require supplies for administration – which may involve specialized materials like syringes and glass vials – as well as plans and infrastructure for distribution and storage. I am interested in learning more about the Department of Health and Human Services' (HHS) efforts. Specifically:
    a. What challenges does HHS face securing sufficient supplies for vaccine administration – like glass vials, syringes, needles, and alcohol swabs – without disrupting the sterile injectable market or delivery of influenza vaccine or other vaccinations recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP)? How does the Department plan to overcome those challenges?

        Operation Warp Speed (OWS) is taking a holistic view of vaccine administration supplies (vaccine, vials, syringes, etc.) to ensure we have ample quantities to meet demand. We are working closely with needle and syringe manufacturers to ensure sufficient supply remains available throughout the duration of the vaccine administration campaign. We are collaborating closely with CDC in the distribution and administration of vaccines without disrupting existing vaccine programs.

    b. When procuring supplies for vaccine administration, how does the Department account for the potential that global demand for such products will impede domestic access? Does the Administration intend to procure such supplies from domestic sources? Are there plans to set up sole source or guaranteed contracts?

        The Department has awarded contracts with negotiated delivery dates and quantities sufficient to meet our needs for administering the vaccine as it becomes available. HHS has awarded contracts to both domestic and off-shore suppliers.

As part of the SNS 2.0 initiative, current planning is underway to achieve a capacity to meet 90 days of need by this fall, which will require a combination of actions to increase the supply of PPE and other critical items in the SNS, in the commercial supply chain, and at the point of use (such as hospitals). SNS 2.0 has three main objectives:

- Ensure the SNS has the breadth and depth to meet any future pandemic or public health emergency;
- Bolster the U.S. industrial base for critical pharmaceuticals and medical supplies; and,
- Reduce America's vulnerabilities and reliance on foreign suppliers and manufacturers.

HHS is also working with DOD's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) office to expand domestic capacity for needles, syringes and vials that will be required for sterile injectable products.

Operation Warp Speed (OWS) is engaged in ensuring all required materials and supplies related to vaccine manufacturing and distribution will be available and deployed. For example, on May 12 the Department of Defense announced a $138 million contract with ApiJect for more than 100 million prefilled syringes for distribution across the United States by year-end 2020, as well as the development of manufacturing capacity for the ultimate production goal of over 500 million in 2021. On June 11, HHS announced $204 million in funds to Corning to expand the domestic manufacturing capacity to produce approximately 164 million Valor Glass vials per year if needed. Valor Glass provides chemical durability to minimize particulate contamination. The specialized glass allows for rapid filling and capping methods that can increase manufacturing throughput by as much as 50 percent compared with conventional filling lines, which in turn can reduce the overall manufacturing time for vaccines and therapies. Other information about OWS activities can be found here: https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

c. Does the United States need to expand capacity to support a domestic supply chain of vaccines and/or supplies related to vaccine administration? If so, how are the Centers for Innovation in Advanced Development and Manufacturing (CIADM) being leveraged to correct this? What specific work does the Department expect to do to support a domestic manufacturing supply chain under the $628 million task order with Emergent BioSolutions?

The Biomedical Advanced Research and Delivery Administration (BARDA) and OWS have started domestic manufacturing expansion projects for vials (SiO2 and Corning), needles and syringes, manufacturing supplies, and vaccine (Emergent) production capacity to support vaccine manufacturing and administrative efforts. Under the Emergent Biosolutions task order, Emergent Biosolutions will commit contract development and manufacturing organization (CDMO) drug substance and drug product manufacturing capacity for production of COVID-19 vaccine

candidates through 2021, in addition to rapid expansion of Emergent's viral and non-viral CDMO fill / finish capacity for vaccine and therapeutic manufacturing.

d. Do Biomedical Advanced Research and Delivery Administration (BARDA) contracts give the United States priority in vaccine manufacturing or production?

The Biomedical Advanced Research and Development Authority (BARDA) has, beginning well before COVID-19, worked to secure domestic manufacturing, where possible, for the development and manufacturing of its supported products. For COVID-19, BARDA is working to enhance existing domestic platforms to secure fast, efficient, and reliable manufacturing for needed vaccines, therapeutics, diagnostics, and ancillary supplies like vials, syringes and needles.

e. In capacity planning, how is the Department taking into account the possibility that a vaccine could require multiple doses? Could adjuvants be used to further the vaccine supply? If so, would certain populations like seniors or children require different adjuvants?

Vaccine candidates with studies that demonstrate initial safety and early clinical trials that look promising for effectiveness are included for Operation Warp Speed consideration; this includes adjuvanted vaccines. An adjuvant is used in a vaccine to help enhance the immune response of vaccinated individuals. Adjuvants may also allow for less of the vaccine's antigen to be used in the vaccine and thus, may further the vaccine supply. There are many adjuvanted vaccines that have been licensed by the Food and Drug Administration (FDA) to prevent various diseases for use in children, adolescents and the elderly. Based on this experience, it is not anticipated that different adjuvants as a vaccine component would be needed for different populations.

f. Can the Defense Department help support vaccine storage and distribution efforts?

Yes, the Department of Defense can provide support if needed. To date, OWS analysis indicates there is currently sufficient capacity within DoD and HHS as well as the commercial sectors to meet all storage and distribution efforts on the timelines projected.

2) Can you describe the role that ACIP will play in making recommendations regarding who should receive the vaccine? Would the Department encourage ACIP to review any approved vaccine on an expedited basis?

In the U.S., the Advisory Committee on Immunization Practices (ACIP) advises the CDC Director on national vaccine policy for preventing infectious diseases in the civilian

population. The immunization systems and expertise supported by CDC's immunization program make substantial contributions to the evidence base that informs immunization recommendations made by ACIP. The ACIP makes recommendations based upon data about the burden of disease, safety and efficacy of vaccines, economic analyses, including cost-effectiveness data, and information about other factors such as how recommendations can be implemented by the health care system in conjunction with other recommended vaccines.

To prepare for potentially FDA-licensed or authorized COVID-19 vaccines, ACIP has established a workgroup that is evaluating safety and immunogenicity data of vaccine candidates, as well as the epidemiology of COVID-19, to target populations and priorities for vaccination. ACIP workgroups are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. While the ACIP workgroup does not have the authority to act on behalf of the advisory committee and they cannot vote on ACIP vaccine recommendations, workgroups review specific topics in detail and clarify issues in a way that helps ACIP voting members make informed and efficient decisions, with the best and most current information available. ACIP meets routinely approximately three times per year (February, June, October), but may meet more frequently as needed. An additional meeting to discuss COVID-19 vaccines was held in July 2020 and another meeting was held in August 2020. In addition, under exceptional circumstances, an emergency ACIP meeting may be called without prior notice. If COVID-19 vaccines became available, it is expected that an emergency meeting will be called for the vaccine to receive consideration.

Also, in response to a request from the National Institutes of Health (NIH) and CDC, the National Academies of Sciences, Engineering, and Medicine have formed a committee that will develop an overarching framework to assist policymakers in the U.S. and global health communities in planning for equitable allocation of vaccines against COVID-19. The findings from the National Academies committee will be shared with ACIP and may help inform the committee's deliberations related to recommendations on vaccine priority groups and ensuring equity in vaccination in the United States. Information regarding the committee, including its membership can be found at: https://protect2.fireeye.com/url?k=a83cf865-f468d14e-a83cc95a-0cc47a6d17cc-a4c8dc534b4fbc19&u=https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus#sectionCommittee.

3) Given the value of social distancing and seeking medical care via telemedicine when appropriate, what preventive measures should seniors and other identified high-risk populations still do in person – like obtaining a yearly flu vaccine or other Medicare-covered preventive services – to mitigate the effects of a potential "second wave" that could coincide with flu season?

Personal responsibility and hygiene are paramount. The efforts that everyone should be engaged in are as follows: maintaining physical distancing; wearing a face covering, especially whenever physical distance is not possible; washing yhands; staying home if feeling sick; getting tested for COVID-19 if they have come into contact with someone who is infected or has been in a gathering without appropriate precautions, getting tested, and shielding the elderly and vulnerable of any age; and following the guidelines for Opening Up America Again. Getting the yearly influenza vaccination is also essential.

From Senator Maggie Hassan

1. The nation has made some progress on publicly providing clear numerical goals for COVID-19 testing, and you have shared some numbers in the past about certain high-level projections and demands. But when I talk to people at nursing homes, schools, colleges and businesses, it's not clear to me that the administration's projections adequately take into account the surge capacity needed to safely re-open these places and return to functionality. A robust testing strategy will be needed to give students and customers the confidence to return and enable a re-opening – and without it, we are going to continue to struggle. So when are we going to see a widespread public plan for testing that takes those factors into account and provides clear, numerical goals that will help Congress and the public conduct oversight and allow accountability?

   The Administration has produced numerous documents that establish the strategy and specific tactics for testing in America. These documents include the Opening Up America Again Guidelines, Testing Blueprint Opening Up America Again, Addendum to the Testing Blueprint, Report to Congress COVID-19 Strategic Testing Plan, and many other guidance documents released by the Centers for Disease Control and Prevention. CDC released testing guidance to assist healthcare providers testing in specific situations and facilities [e.g., correctional and detention facilities, homeless shelters, schools (https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing.html)] and to identify the types of tests that are available (https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html). CDC has also provided guidance to help laboratory professionals understand the different methods of testing (e.g., rapid antigen testing, pooling specimens) and correctly interpret results (https://www.cdc.gov/coronavirus/2019-ncov/lab/resources.html). HHS continues to work closely with state and territory leadership across the country to determine their testing goals and to provide technical assistance to each state and territory to help ensure that they can meet these goals.

From Senator Gary C. Peters

- **Vaccine Distribution**

1. When a vaccine is developed and is widely produced, will HHS be responsible for the distribution?

   As part of OWS, HHS is engaged in developing a vaccine distribution plan. Information about the vaccine distribution strategy can be found here: https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html

2. Please describe the distribution plan for when a vaccine is made available. Does such a plan include strategies for delivering a sufficient number of delivery devices, such as needles and syringes, so that Americans can effectively receive a vaccine once it is developed

   As part of OWS, HHS is engaged in developing a vaccine distribution plan and will be including all possible factors in that plan. HHS plans for a tiered approach to vaccine distribution, which will build on allocation methodology developed as part of the pandemic flu planning and be adjusted on experience during the first wave of the COVID-19 response, data on the coronavirus and its impact on populations, performance of each vaccine, and the needs of the essential workforce. Information about the vaccine distribution strategy can be found here: https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html

- **National Testing Plan**

3. The Administration's recently released National Testing Plan lacks specifics on how the federal government will ramp up testing production, ensure access to adequate testing supplies for states, or address testing disparities in communities, as mandated by Congress. Why does the testing plan not include these details as required by statute?

   The Administration has produced numerous documents that establish the strategy and specific tactics for testing in America. These documents include the Opening Up America Again Guidelines, Testing Blueprint Opening Up America Again, Addendum to the Testing Blueprint, Report to Congress COVID-19 Strategic Testing Plan, and many other guidance documents released by the Centers for Disease Control and Prevention. These documents lay out the COVID-19 strategic testing plan. The testing plan provides a framework by which the states and territories submit their own testing goals and plans to be reviewed by HHS and technical assistance is provided to ensure the states and territories have what they need to meet these testing goals. The first update to the Strategic Testing Plan, recently transmitted to Congress, further details the strategic plan and provides updated data. CDC released testing guidance to assist healthcare providers testing in specific situations and facilities [e.g., correctional and detention facilities, homeless shelters, schools (https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing.html)] and to identify the

types of tests that are available (https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html). CDC has also provided guidance to help laboratory professionals understand the different methods of testing (e.g., rapid antigen testing, pooling specimens) and correctly interpret results (https://www.cdc.gov/coronavirus/2019-ncov/lab/resources.html).

As part of the effort to address disparities in COVID-19 testing, laboratories are now required to report data elements such as the patient's race, ethnicity, zip code and county of residence, age, and sex. This requirement went into effect on August 1, 2020,per HHS guidance released on June 04, 2020 (https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf). These data will provide more thorough information about communities that may be underrepresented in testing as well as those communities that have a high positivity rate.

4. Does HHS intend to release a supplemental plan to address the gaps in the current one?

   HHS intends to update the report to Congress every 90 days as required by the same statutory provisions.

5. HHS's COVID-19 Strategic Testing Plan that it submitted to Congress on May 24 set a national target of 12.9 million tests for the month of May. This target was not met – the U.S. performed approximately 10.7 million tests in May – 2 million short. Why was this not met and what is being done to meet future testing targets?

   Throughout the response we have leveraged all aspects of the testing infrastructure in the United States and are actively engaged in expanding testing capacity across the nation to meet the needs of all states, territories, and localities. HHS worked very closely and is continuing to work with leaders of states and territories to establish testing goals that fit their needs and circumstances. We are equipping every state and territory with the materials they need to achieve these testing goals.

- **Preparations for Second Wave**

6. It is widely expected we will experience a resurgence of the virus in the late fall, potentially merging with the normal flu season. What are the major changes and/or preparations that the federal government is making to be ready for a second wave?

   HHS is working very closely with state, territory, and local leaders to ensure the states and territories have sound testing plans and are equipped with the resources necessary to meet those testing goals. The work early on to galvanize the testing infrastructure in the United States has ensured that the testing capacity and the testing innovations from the NIH RADx diagnostics program can be fully leveraged and utilized to help meet all of the testing needs in the months to come. HHS is also working to ensure more Americans than ever will be

vaccinated for influenza this year. HHS issued a third amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.

- **Serological/Antibody Tests**

7. The CDC recently issued guidance on the use of antibody tests in clinical and public health settings. The guidance noted that many of those testing positive may not actually have Coronavirus antibodies and the guidance further noted that these tests should not be used to make decisions about returning to schools or workplaces. What steps is HHS taking to educate the public, employers, and local governments about the accuracy and appropriate uses of serological tests?

   HHS, through CDC and FDA, is engaged in making sure the serological tests on the market are accurate and used in the proper circumstances. This includes recommending that clinical laboratories and health care providers stop using COVID-19 antibody tests that are listed on FDA's "removed" test list, and it includes working with the diagnostics industry on removing inaccurate tests from the marketplace. Guidance provided by CDC for the proper usage of tests and interpretation of results is available at https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-professional.html

   Sample pooling is an important public health tool because it allows for more people to be tested at once, using fewer testing resources. Because the samples are pooled, it is expected that more patients can be tested with existing test capacity, meaning testing supplies can be used more efficiently and more samples can be tested at the same time. This testing strategy is most efficient in areas with low prevalence, meaning most results are expected to be negative without a need to perform additional testing. CDC is working to help laboratories understand the different categories of pooled testing (diagnostic, screening, and surveillance), laboratory certification requirements, and reporting of results.

Post-Hearing Questions for the Record
Submitted to The Honorable Peter Gaynor & Rear Admiral John Polowczyk
From Senator Thomas R. Carper

"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"

June 9, 2020

Question#:	1
Topic:	DPA and Procurement Strategy
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Thomas Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: I have called for a transparent and clear Defense Production Act (DPA) strategy to obtain needed PPE and medical equipment to respond to the pandemic. What is the role of this White House, if any, in steering Defense Production Act policy in response to COVID? Specifically, what is the role of the President's Trade Advisor, Peter Navarro, in approving DPA requests, or shaping DPA policy?

Response: Executive Order (EO) 13909, signed on March 18, 2020 contained the Presidential finding necessary under Defense Production Act (DPA) Section 101(b) to enable the use of the priorities and allocations authorities. On March 27, 2020 the President signed Executive Order 13911, "Delegating Additional Authority Under the [DPA] with Respect to Health and Medical Resources to Respond to the Spread of COVID-19," which delegates DPA authorities to the Secretaries of the U.S. Departments of Health and Human Services (HHS) and Homeland Security (DHS) in response to COVID-19. Acting Secretary Wolf delegated DPA authority to the Federal Emergency Management Agency (FEMA) on April 1, 2020. In addition to authorities granted by 13909 and 13911, several agencies have existing DPA authorities delegated by the President in EO 13603, "National Defense Resources Preparedness" which was issued on March 16, 2012. DHS determines which programs are necessary or appropriate to promote the national defense for all national defense programs outside of energy and military matters. DHS has delegated its DPA responsibilities to FEMA.

The White House Coronavirus Task Force (WHTF) is composed of subject matter experts from across the Federal government. As DPA is a tool in the overall response efforts, DPA decisions are elevated to the WHTF for consideration.

Question#:	1
Topic:	DPA and Procurement Strategy
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Thomas Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: Is there a cohesive DPA strategy in place to produce needed supplies as we begin to prepare for a second wave?

Response: The DPA has been an effective tool in fighting the pandemic and remains a tool in the overall response efforts.

Question: Several media reports have indicated problems in the Administration's procurement efforts, including failure to appropriately vet suppliers before awarding contracts, and the existence of a "shadow task force" that directed contracts to friends of the President. Are you aware of these reports? How will these issues be addressed going forward?

Response: FEMA is aware that the media has extensively reported on the COVID-19 response including the federal contracts that have been issued to support the response. These reports regarding an alleged "shadow task force" that inappropriately participated in the procurement process are completely incorrect. FEMA conducts its procurements as it has for every disaster, in adherence to law, regulation, policy with a high level of integrity and transparency.

FEMA received more than 3,600 responses to the FEMA open Request for Proposals, and 1,600 plus injects, of which 228 distinct Offers received contract awards. All leads for possible personal protective equipment (PPE) were submitted to the proper procurement officials, and no one at the White House, including the President, directed, suggested, or implied that we favor any specific contractors over another. FEMA will continue to submit leads to the proper procurement officials for review.

Question: In one recent example reported by ProPublica on June 18, 2020, Texas company Fillakit LLC signed a deal with FEMA on May 7, 2020, to supply vials needed for testing to the Federal Emergency Management Agency (FEMA). Instead, FEMA received plastic tubes made for bottling soda, which health officials from multiple states have said are unusable for testing purposes. According to ProPublica reporting, despite these tubes being unusable, FEMA has reportedly paid Fillakit $7.3 million of a $10.16 million contract, and has approved and sent these tubes to states. Can you describe FEMA's inspection process for the supplies it purchases and recommend solutions for ensuring that states don't receive unusable supplies?

Response: The Fillakit contract is an aberration, FEMA is looking into every possible recourse in accordance with federal regulations, including debarment. FEMA is coordinating with federal partners in HHS including the Center for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), to perform a technical assessment of the media and vials. FEMA is supporting the HHS efforts to find other short-term fills using other companies to make up any shortfalls in capability. FEMA will seek remedies in accordance with federal regulations

Question#:	1
Topic:	DPA and Procurement Strategy
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Thomas Carper
Committee:	HOMELAND SECURITY (SENATE)

with any of our contractors who don't deliver products and services within the terms and conditions of contractual agreements.

Question#:	2
Topic:	Racial Disparities in COVID Response
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Thomas Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: Communities of color nationwide are clearly disproportionately impacted by COVID. African Americans make up 13% of the US population but 24% of US deaths. And, in almost every state, Hispanics and Latinos test positive for COVID-19 at disproportionately higher rates. What are your agencies doing to address racial disparities in COVID cases and outcomes?

FEMA has played a role with getting personal protective equipment (PPE) to essential health care workers, particularly in hospitals, during this public health emergency. However, there are many other essential workers working for grocery stores, meat-packing plants, and delivery services. These are often low-wage workers and are disproportionately people of color, and we have seen the disparities of low-income populations and communities of color.

Given these racial disparities, what is FEMA doing to ensure that essential workers, particularly those not in a health care-related field, have access to PPE? What other efforts is FEMA making to ensure that communities of color are receiving targeted support?

Response: FEMA's Office of Equal Rights (OER) has taken steps to ensure FEMA's COVID-19 response does not discriminate based on race and other protected bases so as not to exacerbate these existing inequities.

On April 14, 2020, FEMA issued a Civil Rights Bulletin reminding FEMA recipients (state, tribal, and territorial governments and others) of their civil rights obligations to provide equitable and impartial program delivery with respect to the COVID-19 recovery. *See* Ensuring Civil Rights During the COVID-19 Response (English) (Spanish). The Civil Rights Bulletin makes clear to members of the public that they may bring civil rights complaints to FEMA's OER in connection with FEMA activities or FEMA-funded programs and activities.

FEMA's OER also deployed 29 Civil Rights Advisors to support FEMA's ten Regional Response Coordination Centers and advise FEMA regional leadership, program offices, and recipients of FEMA financial assistance about their civil rights obligations. Civil Rights Advisors provide technical assistance and information about civil rights enforcement and compliance procedures in the event of alleged violations. In addition, Civil Rights Advisors engage community-based organizations advocating on behalf of or supporting the needs of communities of color and low-income populations, among others, and facilitate relevant information sharing about response and recovery activities to foster inclusion of these populations in decision making and equitable and impartial program delivery.

Question#:	2
Topic:	Racial Disparities in COVID Response
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Thomas Carper
Committee:	HOMELAND SECURITY (SENATE)

FEMA's OER has also held three public stakeholder calls with approximately 2,000 total participants to answer questions regarding civil rights during the COVID-19 response. The calls included participants from other FEMA offices, HHS Office for Civil Rights,CDC, DHS Office for Civil Rights and Civil Liberties, and the U.S. Department of Justice's Civil Rights Division.

FEMA's OER reviews all policies, directives, and guidance documents that are being developed or revised to ensure inclusion of explicit language related to FEMA's and recipients' civil rights obligations.

Question: FEMA has played a role with getting personal protective equipment (PPE) to essential health care workers, particularly in hospitals, during this public health emergency. However, there are many other essential workers working for grocery stores, meat-packing plants, and delivery services. These are often low-wage workers and are disproportionately people of color, and we have seen the disparities of low-income populations and communities of color.

Given these racial disparities, what is FEMA doing to ensure that essential workers, particularly those not in a health care-related field, have access to PPE? What other efforts is FEMA making to ensure that communities of color are receiving targeted support?

Response: FEMA and HHS distribute cloth facial coverings as part of a multi-prong approach to reopen American economic activity while continuing to limit the spread of COVID-19.

The federal government's delivery of facial coverings is in a phased-approach for infrastructure workers, first responders, and food producers who do not need medical-grade PPE for their daily work.

Many of our infrastructure sectors must have access to facial coverings in order to reduce possible spread of the virus and to ensure critical services continue throughout our communities. Distribution is based on DHS's Cybersecurity and Infrastructure Security Agency analysis of priority infrastructure sectors.

Priority infrastructure sectors included in the analysis are food production and distribution, energy, water and wastewater treatment, essential transportation and logistics, first responders, communications, hazardous materials management, manufacturing of medical supplies, and sanitation and disinfection supplies.

Question#:	3
Topic:	Guidelines on Reopening
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Thomas Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: What is the Administration's plan to provide clear and uniform guidelines to businesses as states continue to reopen their economies?

Response: FEMA defers to the WHTF on any questions relating to guidelines that may be provided to businesses as states continue to reopen their economies.

Question: How will your agency assist in ensuring problems we saw in the first wave, including bidding wars between states and acute testing and PPE shortages, are addressed as the majority of states begin to reopen and a potential second wave in the fall?

Response: To address shortages of PPE, the Supply Chain Task Force connected companies with suppliers of high demand materials required to produce PPE. FEMA also instituted Project Airbridge to expedite supplies to the U.S. markets for areas with the most critical needs for those supplies based on HHS and CDC data. To address shortages of critical medications for hospitals, the Advisory Group established a pharmaceuticals team comprising of federal agencies and industry partners to address pharmaceutical shortages.

The perception that FEMA is “out-bidding” states and others for supplies is incorrect. Due to the use of priority ratings in the DPA to reallocate critical resources, federal government requirements are put ahead of other orders so we can best assist areas most in need of supplies. As FEMA processes all orders through the supply chain, we maintain close coordination with states and tribes to identify potential bidding conflicts. If a bidding conflict occurs between states or tribes, we work closely with the state or tribe to resolve it in a way that best serves their needs.

Question#:	4
Topic:	Assistance to Firefighter Grants
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Thomas Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: As you know, firefighters and other first responders are among the front lines when it comes to COVID response, and due to the nature of their jobs are required to be out in the community without much ability to socially distance. Accordingly, it is incredibly important that they are able to access PPE. At the same time, the pandemic has slowed fire companies' ability to raise revenues.

Firefighters facing attrition and high call volumes in my state have had to choose between tracking down data needed for the grant application and prioritizing rest and essential activities.

How can we streamline the program's requirements to ensure accountability and clarity? Are more FEMA staff needed in order to address this issue?

Response: FEMA understands the importance of streamlining the application process to allow applicants to continue to focus on their first responder responsibilities and activities. At the same time, the funding for the Fiscal Year 2020 Assistance to Firefighters COVID-19 Supplemental Program (AFG-S) provided under the CARES Act is competitive, and there are statutory requirements that must be assessed and addressed prior to award. These statutory requirements, contained in the Federal Fire Prevention and Control Act of 1974 (Pub. L. 93-498), as amended at 15 U.S.C. § 2229, govern the Assistance to Firefighters Grant Program. Recognizing both the need to expedite distribution of CARES Act funds and to adhere to the legal requirements created by the Congress, FEMA took the following steps to streamline the process and expedite the distribution of funding:

- Worked with the fire service to develop application criteria and issue grant guidance, as required by law, in under one month—a five-month reduction in the time it normally takes to do so for the regular AFG program.
- Listed eligible PPE items in the Notice of Funding Opportunity.
- Reduced application requirements to ease the burden on applicants while responding to the demands of the COVID-19 public health emergency.
- Shortened the application period to three weeks. This helped reduce the time from application to award, while still allowing enough time for the fire community to apply.
- Began competitive peer review panels, as required by law, immediately after the application period closed on May 15.
- Prepared FEMA's Grants Manager system to begin making awards on a rolling basis once all required federal reviews were completed. FEMA began making AFG-S awards on Friday, June 19th and grants will continue to be awarded until all funds are exhausted.

Question#:	4
Topic:	Assistance to Firefighter Grants
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Thomas Carper
Committee:	HOMELAND SECURITY (SENATE)

- For post-award accountability, FEMA program staff will soon begin webinars for new recipients to help them understand how to manage their grants.
- FEMA has developed a monitoring process to ensure that selected grants are reviewed on both a financial and programmatic basis.

Post-Hearing Questions for the Record
Submitted to The Honorable Peter Gaynor
From Senator Maggie Hassan

"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"

June 9, 2020

Question#:	5
Topic:	Federal Cost Share
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Margaret Wood Hassan
Committee:	HOMELAND SECURITY (SENATE)

Question: In May, you said that more than 30 states had requested that the federal cost share for emergency protective measures for COVID-19 be increased to 100 percent, and that the White House was weighing whether to approve those requests. A month later, many states and localities are still desperately waiting for the administration's decision. While states have received CARES Act funding to cover some emergency costs, they lack clarity about whether these funds can be used to meet the current federal cost share requirement - and guidance from the administration has been inadequate. Why has the administration failed to approve the federal cost share to 100 percent? And in the interim, why has the administration failed to put out adequate guidance?

Response: FEMA does not have authority to adjust the federal cost share. It recommends an increase in the federal cost share from 75 percent to not more than 90 percent of the eligible cost of permanent work (section 406) and of emergency work (section 403 and 407) whenever a disaster is so extraordinary that actual federal obligations under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), excluding FEMA administrative costs, meet or exceed the qualifying threshold established in 44 CFR 206.47. For disasters declared in Calendar Year (CY) 2020, the qualifying threshold for a cost share adjustment is $149 per capita of state or tribal population; adjusted annually for inflation using the Consumer Price Index published annually by the U.S. Department of Labor. As of this date, all cost share adjustment requests remain in process. FEMA will continue to closely monitor the actual federal obligations for the COVID-19 declarations and will recommend cost share adjustments when the qualifying thresholds are met or exceeded.

The President has clarified to states that they may use Treasury's Coronavirus Relief Fund, provided under the CARES Act, to pay for FEMA's cost share requirements under the Stafford Act.

Question#:	6
Topic:	PPE Distribution
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Margaret Wood Hassan
Committee:	HOMELAND SECURITY (SENATE)

Question: The media continues to publish reports of unfair distribution of personal protective equipment by FEMA and other federal agencies. As you are well aware, accusations of PPE distribution based on political considerations have been in the public discourse since the start of the pandemic. However, Admiral Giroir, and Rear Admiral Polowczyk, and you each stated under oath on June 9th that the no member of the Trump Administration had pressured you into diverting PPE or other critical supplies to specific communities. Please explain the specific steps Coronavirus Task Force leadership takes to ensure the decisions of the Task Force, and specifically decisions about PPE disbursement, remain insulated from political bias.

Response: We reiterate that no member of the Trump Administration pressured anyone to distribute PPE or critical supplies to specific communities. Decisions on prioritization are based on National Resource Prioritization Cell (NRPC) data. The NRPC was established to support distribution decisions and consists of interagency subject matter experts who use a data-informed process to develop recommendations to ensure distribution of resources. The Prioritization Cell calculations provided leadership with a data-informed list of at-risk areas and the current and near-future critical medical supply needs. The team provided proposals on resource distribution to the Unified Coordination Group (UCG) – comprised of the HHS, CDC, and FEMA.

We then informed the private sector medical and surgical distributors of the latest priority jurisdictions in greatest need of specific medical supplies and equipment, so they were aware of the areas that may have the highest demand. Public information on the NRPC can be found at https://www.fema.gov/fact-sheet/coronavirus-covid-19-pandemic-national-resource-prioritization-cell%20.

In instances where an official contacted the White House or Members of Congress with resource needs (such as a request from a Governor, Tribe or local official), that information was assessed by the UCG if needed, and addressed accordingly based on resources.

Post-Hearing Questions for the Record
Submitted to The Honorable Peter Gaynor
From Senator Gary C. Peters

"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"

June 9, 2020

Question#:	7
Topic:	Contracting for PPE and Medical Supplies
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: Please describe the extent to which representatives of the Administration's Coronavirus Task Force (outside of FEMA and HHS) or the White House were involved in the contracting, procurement, allocation, or distribution of personal protective equipment or medical supplies for Coronavirus response efforts.

Response: FEMA received more than 3,600 responses to the FEMA Request for Proposal, and 1,600 plus injects, of which 228 distinct Offers received contract awards. All credible leads for possible PPE or medical supplies were submitted to the proper procurement officials, and no one at Congress or at the White House, including the President, directed, suggested, or implied that we favor any specific contractor over another.

FEMA's Office of the Chief Procurement Officer was responsible for the contracting and administration of contracts for personal protective equipment and medical supplies. The allocation of supplies was led by FEMA's Logistics Management Directorate.

Question: Did anyone from the Administration's Coronavirus Task Force (outside of FEMA and HHS) influence the contracting process for personal protective equipment or medical supplies for Coronavirus response efforts? If so, please explain.

Response: No.

Question: Did anyone from the Administration's Coronavirus Task Force or the White House refer vendors or companies for the procurement of personal protective equipment or medical supplies for Coronavirus response efforts? If so, please identify the vendor or company, what item(s) the referral was for, and whether or not a contract was issued to that vendor or company.

Question#:	7
Topic:	Contracting for PPE and Medical Supplies
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Response: As part of the federal efforts to scour the globe for PPE and consider all opportunities, FEMA and its federal partners explored thousands of leads both overseas and across the country. Whether a lead came from WHTF, members of Congress representing businesses in their state, or through an enterprise's unaffiliated inquiry, FEMA processed all leads through vetting procedures and the federal procurement process. Due to the massive volume of leads received, FEMA did not track which vendors were referred from which source. However, all leads were referred to FEMA's open solicitation for PPE and medical supplies in SAM.Gov under Notice # 70FA2020R00000011.

Question#:	8
Topic:	Vaccine Distribution
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: When a vaccine is developed and is widely produced, will FEMA be responsible for the distribution?

If so, please describe the distribution plan for when a vaccine is made available.

Does such a plan include strategies for delivering a sufficient number of delivery devices, such as needles and syringes, so that Americans can effectively receive a vaccine once it is developed?

Response: The development, production, and distribution of a vaccine in response to COVID-19 is under the purview of HHS and Department of Defense (DoD), therefore FEMA defers to HHS and DoD on a response to the questions above.

Question#:	9
Topic:	Coordination with Private Sector (DPA)
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: On March 24, you stated that FEMA was planning to use the Defense Production Act (DPA) for the first time in relation to coronavirus to acquire 60,000 test kits, however, that never occurred. Did anyone from the White House, the Department of Homeland Security, or the Administration's Coronavirus Task Force instruct you not to use the DPA?

Response: No. The company indicated that the DPA application to the contract was unnecessary and it would honor the 60,000 test kits order.

Question: Were you or your staff required to receive approval from the White House, the Department of Homeland Security, or the Administration's Coronavirus Task Force require prior to utilizing the DPA for Coronavirus response efforts?

Response: If an agency identified a potential need for a DPA action, it submits to the Joint DPA office relevant information about the request. The Joint DPA office would then review and send requests as appropriate to the Unified Coordination Group. If the Unified Coordination Group approved the action, it would be sent to the White House Coronavirus Task Force.

Question#:	10
Topic:	Preparations for Second Wave
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: It is widely expected we will experience a resurgence of the virus in the late fall, potentially merging with the normal flu season. What are the major changes and/or preparations that the federal government is making to be ready for a second wave?

Response: As we actively support ongoing operations, FEMA and our interagency partners continue to refine operational plans and source PPE and medical supplies. Key advancements include refining PPE burn rate calculators and automated mechanisms to monitor distribution, increasing integrated supply chain situational awareness, and the continued utilization of analytical information for impact modeling.

Question#:	11
Topic:	Distribution of Cloth Masks
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: What studies has FEMA or any other federal agency completed on the efficacy of cloth masks and which contexts they should be used in, versus medical-grade PPE like face shields and surgical masks?

Response: FEMA defers to the CDC on questions on the efficacy and use of cloth face coverings. CDC provided guidance and information on studies related to the use of cloth face coverings in response to COVID-19.

Please see the following from CDC for more information:

1. Online Report: "Effectiveness of Cloth Masks for Projection Against Severe Acute Respiratory Syndrome Coronavirus 2"
2. CDC Guidance on Cloth Face Coverings

Question#:	12
Topic:	Coordination with States
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: Several states have expressed concerns that federal supply acquisition and distribution efforts lacked coordination. For example, Governor Whitmer testified in a recent hearing held by the House Committee on Energy and Commerce that uncertainty in supplies, and the federal government's role in directing allocation of them, has undermined her state's ability to coordinate a testing strategy. How are you communicating with states so that they know what supplies the federal government will provide?

Response: The federal government communicates with states, tribes and territories through multiple modes. The CDC sends states and territories monthly letters, explaining the points of contact for various concerns. States and territories are referred to the CDC for technical questions on product use and the testing process and to HHS, Office of the Assistant Secretary for Health for questions on allocation numbers. Tribal requests are sent to the Indian Health Service and may be referred to other Federal Agencies, as needed.

FEMA Regions send states, territories and tribes notices on their inbound shipments of testing supplies weekly, including information on shipment arrival times. FEMA Headquarters distributes the inbound shipment notices nightly to the FEMA Regions and key stakeholders in the states, tribes and territories.

Question: What steps are you taking to improve communication with states?

Response: As outlined above, FEMA has been in consistent communication with states throughout the response to the pandemic. FEMA served as the primary source of supply through July 12, 2020. On July 13, 2020, HHS took over the distribution of testing supplies. States, and territories will continue to receive monthly communications from the CDC with an HHS contact for logistics and allocations concerns and a CDC contact for technical matters. This change streamlines the process by giving states, tribes and territories a single point of contact to those holding subject matter expertise in the field of testing.

Question#:	13
Topic:	FEMA Cost Share Increase
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: Since the onset of the pandemic, I have worked in a bipartisan way to encourage the Administration to increase the FEMA cost share to 100 percent to help state and local governments cover the costs of emergency assistance. Has FEMA recommended to the President to increase the cost share for the emergency declaration to 100 percent?

States have been asking for months now and many are in dire budgetary situations. When do you expect the President will make a decision on this issue?

Response: As of June 9, 2020, all cost share adjustment requests remain in process.

Per 44 CFR 206.47, FEMA recommends an increase in the federal cost share from 75 percent to not more than 90 percent of the eligible cost of permanent work (section 406) and of emergency work (section 403 and 407) whenever a disaster is so extraordinary that actual federal obligations under the Stafford Act, excluding FEMA administrative costs, meet or exceed the qualifying threshold. For disasters declared in Calendar Year 2020, the qualifying threshold for a cost share adjustment is $149 per capita of state or tribal population. FEMA will closely monitor the actual federal obligations for the COVID-19 declarations and will recommend cost share adjustments when the qualifying thresholds are met or exceeded.

Question#:	14
Topic:	Testing Supplies Swabs and Reagents
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: States report that shipments of testing supplies from FEMA have frequently been delayed, contain different types of swabs or transport media than were promised, and, at times, had quality issues. What is the cause of these problems and what is FEMA doing to address them?

Response: To support the Administration's Testing Blueprint, FEMA, at the direction of WHTF, worked to source and procure testing material – specifically, testing swabs and transport media. The FEMA-sourced material is being provided to states, territories, and tribes for a limited duration to help increase testing capacity in support of their individualized reopening and testing plans. As a result of joint FEMA and HHS efforts, procurement increased from approximately 230,000 tests in March 2020, to 13.9 million tests in May 2020. As of July 11, 2020, together HHS and FEMA procured 37 million tests. At the end of July 2020, FEMA no longer participated in procuring test media to support states, territories or tribes. FEMA provided technical assistance to HHS in establishing capability to procure and distribute supplies nationwide through the end of CY 20.

In order to accomplish this, FEMA contracted with vendors to provide testing materials, some of which had to expand their capacity and production. In most cases, testing materials were distributed immediately after production.

Additionally, U.S. companies have innovated and adapted to meet the Nation's needs. Items not previously used for testing, such as bulk spun polyester swabs, were brought into the marketplace. Along with the new products, new medical guidance and procedures for use were implemented and disseminated to providers by OASH and supported by FDA Emergency Use Authorizations (EUAs). To date, concerns about sterility were only raised about one product, which used a CDC recipe to produce Phosphate Buffered Saline. The product is not for internal use and poses no danger to patients. The product is a transport medium that serves as a storage mechanism for collected samples. It is currently under review by the FDA and only represents 12 percent of the total products distributed. The remaining product is being held until it is cleared by the FDA.

Question: What steps has FEMA taken to provide states more transparency about when shipments are coming and what they contain?

Response: The states, tribes and territories receive monthly communications on their monthly testing supply allocations will be. Points of contact at the CDC and HHS are also provided for state, tribes and territories to ask questions about products and their technical application.

Question#:	14
Topic:	Testing Supplies Swabs and Reagents
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: Does FEMA have plans to continue delivering these supplies past June? How will you ensure that the states will continue to have the supplies to meet testing needs through the summer and into the fall?

Response: FEMA served as the primary source of supply through July 12, 2020. On July 13, 2020, HHS took over the distribution of testing supplies and FEMA supports HHS in the testing supply mission. FEMA will only provide supplemental supplies to augment any shortfalls on the HHS contracts. HHS has established contracts to supply nationwide testing supplies through the end of CY 20. This change streamlines the process by giving states, tribes and territories a single point of contact to those holding subject matter expertise in the field of testing.

Question#:	15
Topic:	Lessons Learned
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: Goal 1 of FEMA's Strategic Plan focuses on building a culture of preparedness. What insights does FEMA have from the experience with COVID-19 that could help inform actions the nation should take to be better prepared for and resilient to large-scale biological events?

Response: FEMA is working closely with the federal interagency as well as our partners in state, local, tribal, and territorial (SLTT) jurisdictions to learn and improve upon our ability to respond to this pandemic. Learning is ongoing as communities continue to grapple with the long-term nature of this event. We remain in an active response phase and are focused on identifying best practices and innovations that can help improve our ability to mitigate the effects of this virus. To date, FEMA has published 14 community innovation stories, highlighting how the creative actions of individual organizations, communities, and other institutions have helped manage the outbreak. FEMA has also posted to its website 43 best practices, which emergency managers can reference when addressing specific challenges such as casualty management, continuity of operations, and business reopening. Finally, FEMA has developed updated operational planning guidance to support its partners in preparing for the compounding challenge this pandemic poses to hurricane-prone communities.

While FEMA remains focused on its response requirements, the Agency is also looking to learn from this event. FEMA can use case studies from its response to support the development of COVID-19 best practices, impactful investments, and innovations made during the response.

Question#:	16
Topic:	Contracting for PPE
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: Often times, when it comes to disaster response, contractors who may not have been suitable for providing the required goods and services emerge. For example, I understand there was a $55 million FEMA contract with Panthera for N95 masks that was awarded to a company with no history of being in the mask business that has since been terminated. Why was such a large contract issued to a company with no history of doing business in the healthcare medical supply field?

Response: The review of the company and its proposal by professional contracting officials led FEMA to conclude the offeror would be able to fulfill the contract. In addition, the Contracting Officer performed a contractor responsibility determination in accordance with Federal Acquisition Regulations (FAR) Part 9 and found the contractor responsible. On the day of award of contract 70FB702C00000006 to Panthera Worldwide, the Contracting Officer reviewed records from Federal Awardee Performance and Integrity Information System (FAPIIS), the Excluded Parties List System, and System for Award Management (SAM.gov). These databases assist Government Contracting Offices with determining if the contractors have, within the last five years, been the subject of a criminal, civil, and/or administrative proceeding at the federal or state level in connection with a federal award that resulted in a conviction or finding of fault or liability. They also provide information on suspensions, debarments, and active exclusions. When vendors register in sam.gov, they have to provide their Taxpayer Identification Number, and the Federal Government reviews all tax documents before they are approved and become active in sam.gov to accept a government contract. Vendors are required to re-apply with SAM.gov every 12 months.

Question: How is FEMA managing efforts to vet contractors and perform responsibility determinations?

Response: In accordance with FAR Subpart 9.103, the Contracting Officer must make an affirmative determination of responsibility before award, and that responsibility must reflect the requirements of the proposal. The award process includes reviewing the contractor's proposal in concert with review of FAPIIS, Contractor Performance Assessment Reporting System, and beta.SAM.gov to assess the contractor's technical, financial, and performance capability. In addition, FEMA contracting officers will refer any questionable vendors to the FEMA Fraud Prevention and Investigations Branch and the DHS Office of Intelligence and Analysis for further vetting.

Question: What challenges has FEMA experienced with the emergence of unsuitable contractors?

Question#:	16
Topic:	Contracting for PPE
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Response: As part of the federal effort to scour the globe for PPE and consider all opportunities, FEMA and its federal partners explored thousands of leads both overseas and across the country. Whether a lead came from WHTF, members of Congress representing businesses in their state, or through an enterprise's unaffiliated inquiry, we processed all leads through vetting procedures and the federal procurement process. Other than the time associated with vetting, unsuitable contractors did not present a cumbersome challenge to FEMA.

Question: How many contracts has FEMA been required to terminate for PPE or medical supplies? To what extent have FEMA and HHS needed to terminate contracts due the unsuitability of contractors?

Response: Of the thousands of contracts executed in response to the pandemic, to date, FEMA has terminated 16 contracts for PPE or medical supplies: 3 for cause and 13 for the convenience of the Government. The terminations for convenience were due to the product no longer being required by the Government or for inability to deliver due to justifiable circumstances. Those terminated for cause were due to inability to deliver without any justifiable circumstances due to performance issues. Having found nothing precluding award during the responsibility determination, all vendors were found suitable before award. FEMA has no insight into HHS terminations.

Question#:	17
Topic:	PPE Distribution to Nursing Homes
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: Why was it not until April 30, two months after the first outbreak of COVID-19 in a U.S. a nursing home, that FEMA first dedicated specific shipments of PPE directly to nursing homes?

Response: At the onset of the COVID-19 pandemic, prioritization was given to hospitals and long-term care facilities in CDC identified hotspots. As we progressed, additional PPE was sent to nursing homes in coordination with private sector sourcing solutions. These shipments were meant to supplement, not supplant, existing efforts to provide PPE to nursing homes. In addition to this initiative, nursing homes have been receiving PPE through their regular procurements and state efforts.

Question: Although FEMA has announced they would be delivering a two-week supply of PPE to nursing homes across the country. I am concerned that those supplies are not being directed according to greatest need. What metrics did FEMA use to determine how much PPE a nursing home would receive? How will you ensure that the hardest-hit nursing homes have enough PPE to keep workers and residents safe?

Response: The NRPC was established to support these distribution decisions and consists of interagency subject matter experts who use a data-informed process to develop recommendations. Prioritization is based on a review and analysis of data sets including demographic information for population factors, supply chain data, and disease activity across the Nation. The first shipments focused on facilities within prioritized hotspots and then expanded to facilities across all 50 states, the District of Columbia, Puerto Rico, and Guam.

Initial shipments started in May and focused on metropolitan-area priority sites, such as New York City, Northern New Jersey, Boston, Chicago and Washington D.C. Subsequent shipments began in June and focused on new hotspots in the southeast and southwest United States, including Houston, Dallas, Orlando, Miami, Phoenix, and Los Angeles.

Question#:	18
Topic:	Remdesivir Distribution
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Gary C. Peters
Committee:	HOMELAND SECURITY (SENATE)

Question: There is currently only one approved medication for Coronavirus treatment, Remdesivir, and reports indicate that this drug was distributed to some hospitals that had no eligible patients or no refrigeration units necessary to store the drug, resulting in returns to the federal government. What was the initial distribution plan and strategy for Remdesivir and how were hospitals assigned to receive the drug?

Did the federal government communicate with state officials as part of its distribution strategy to determine the hospitals most in need of the drug?

Why was the drug delivered to the wrong hospitals? What happened?

Response: In May 2020, the first Remdesivir shipment arrived to be delivered to hospitals by the HHS. As of May 22, 2020, deliveries were made to all states and U.S territories. The below HHS ASPR website provides further detail on the distribution of Remdesivir, including the allocation plan by jurisdiction.

https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/remdesivir.aspx

For more specific details on Remdesivir, FEMA defers to HHS/ASPR.

Post-Hearing Questions for the Record
Submitted to Rear Admiral John Polowczyk
From Senator Maggie Hassan

"Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic"

June 9, 2020

Question#:	19
Topic:	Longer-Term Projections
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Margaret Wood Hassan
Committee:	HOMELAND SECURITY (SENATE)

Question: The N95 projections that you provided to this Committee run through October, and the projections for gowns, surgical masks, gloves and shields only run through July. This pandemic is anticipated to last considerably longer than that. Do you have longer-term projections, and will you also commit to sharing those publicly?

Response: We are currently working with HHS on the SNS replenishment strategy and gaining better insight from state and local governments and points of care on their stockpile development. Those projections have not been updated to include the Fall/Winter months, as we are still evaluating factors. Demand is anticipated to continue at those levels, while estimated domestic production and imports increase.

Question#:	20
Topic:	Supply Chain Stabilization Task Force Tracking
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Margaret Wood Hassan
Committee:	HOMELAND SECURITY (SENATE)

Question: This document does not include projections for other vital supplies such as medications. What other supplies is the Supply Chain Stabilization Task Force Tracking? Does the Task Force have demand projections for those supplies?

Response: The Supply Chain Task Force projections focused specifically on the five main PPE items: N95 respirators, gowns, surgical masks, nitrile gloves, and face shields. The Task Force is tracking fill rates across the country for certain pharmaceuticals; however, we do not have specific demand figures for these medications.

Question#:	21
Topic:	Testing Supply and Demand
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Margaret Wood Hassan
Committee:	HOMELAND SECURITY (SENATE)

Question: This document provides projections for personal protective equipment, but I have not seen a similar document for tests and testing supplies such as swabs and reagents - do similar projections for testing supply and demand exist, and will you commit to sharing those publicly? If they do not exist, why not?

Response: FEMA is working to source and procure testing material, specifically testing swabs and transport media, in support of HHS. As of July 3, 2020, FEMA has procured and delivered 32.7 million swabs and 24.4 million units of media. The FEMA-sourced material will be provided to states, territories, and tribes for a limited duration to help increase testing capacity in support of their individualized plans.

For specific projections on testing demand, FEMA defers to HHS ASPR.

Question#:	22
Topic:	Analyses and Estimates
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Margaret Wood Hassan
Committee:	HOMELAND SECURITY (SENATE)

Question: This document indicates that these projections were created using "interagency analyses" and "industry estimates." Specifically, which analyses and estimates did you use when creating these projections? Do these projections account for the needs of non-traditional health care settings such as schools and businesses?

Response: The Supply Chain Task Force projections include estimated monthly production from 3M, Owens & Minor, Honeywell, Moldex, and Prestige Ameritech; historical data and best available distribution data from the six major U.S. medical-surgical distributors; and data from our interagency partners, such as Resource Prioritization Bulletins, which incorporate interagency data from HHS on disease activity to include, but not limited to: confirmed cases, increases in confirmed cases, total mortality, and increases in mortality.

Question#:	23
Topic:	Tracking State Procurements
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Margaret Wood Hassan
Committee:	HOMELAND SECURITY (SENATE)

Question: This document states that it does not consider procurement by states in its projections. Is the Supply Chain Stabilization Task Force tracking state procurements? If so, why was this information excluded from these projections?

Response: At the time of this document's development, state PPE supplies were not reported. Since then, FEMA and the Supply Chain Task Force have conducted preliminary conversations with state officials as we assess stockpiling by state and local governments for the development of the SNS to meet current and future needs. Approximately 70 percent of states report they are building to a 30-day or more stockpile. Many states are still addressing current COVID-19 PPE demands and others are still in the acquisition process.

Question#:	24
Topic:	Projections for PPE Demand
Hearing:	Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic
Primary:	The Honorable Margaret Wood Hassan
Committee:	HOMELAND SECURITY (SENATE)

Question: How have past projections for PPE demand compared to actual demand? Please provide specific examples.

Response: Current PPE needs far outpace pre-COVID-19 PPE needs in the United States. As an example, demand for N95 respirators and nitrile gloves are approximately three times greater in a post-COVID-19 environment, demand for surgical masks and face shields is approximately four-to-five times greater (though some of this demand could be attributed to general face coverings in non-medical settings), and demand for gowns is approximately double pre-COVID-19 numbers. Also, the private sector is now shipping approximately three times more PPE to nursing homes and long-term care facilities than it did in the months prior to COVID-19.

THE ROLE OF THE STRATEGIC NATIONAL STOCKPILE IN PANDEMIC RESPONSE

WEDNESDAY, JUNE 24, 2020

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met by videoconference, pursuant to notice, at 10:01 a.m., Hon. Ron Johnson, Chairman of the Committee, presiding.

Present: Senators Johnson, Portman, Lankford, Romney, Scott, Hawley, Peters, Carper, Hassan, Sinema, and Rosen.

OPENING STATEMENT OF CHAIRMAN JOHNSON

Chairman JOHNSON. Good morning. This hearing will come to order.

I want to welcome and thank all the witnesses for their participation and for their thoughtful testimony. I will ask unanimous consent (UC) to enter their full testimony into the record as well as Dr. Gerberding has requested that "Ending the Cycle of Crisis and Complacency," their report,[2] be added into the Congressional Record, as well as my opening statement.[1]

Again, I want to thank everybody for participating.

Coronavirus disease 2019 (COVID–19) continues to inflict a terrible human and economic toll on the United States. In just over 5 months, the United States has experienced over 120,000 deaths and over 2 million total infections, and tens of millions have lost their jobs. As Congress reviews our response to COVID–19, it is important to take the lessons we have learned during this crisis to better prepare for a pandemic or other biological event of this scale in the future.

The focus of today's hearing is the Strategic National Stockpile (SNS). First established with a $51 million appropriation in 1998 as the National Pharmaceutical Stockpile, the SNS was codified in 2002 and obtained its current name with an expanded mission in 2003. Over the years, management responsibility for the SNS has changed between different agencies within the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS).

[1] The prepared statement of Senator Johnson appears in the Appendix on page 817.
[2] The report appears in the Appendix on page 58.

In developing a plan for this Committee's oversight of the Federal Government's response to the Coronavirus, the role of the Strategic National Stockpile was an obvious area of interest, as is the vulnerability of our supply chain, and they are very interrelated. I had assumed that staff would be able to quickly obtain the list of items that should be held, together with the required and actual inventory levels of each item. Once again, I learned that it is dangerous to assume. We quickly found out that those lists do not exist or certainly are not made available to Congress or the public.

As we will hear in testimony, it is not from a lack of dedicated individuals working within the agencies or with the Strategic National Stockpile. Instead, it seems to be a more pervasive problem of a lack of clarity and understanding of exactly what the SNS' role is and what it should be. As indicated above, to the extent there has been a congressional or executive branch articulated mission statement, it has evolved over time, and outside the managing department or agency, it has not been generally understood.

We are paying the price for this lack of articulation and clarity during the current pandemic. The frustration expressed by State, local, tribal, and territorial (SLTT) governments and their elected representatives is largely caused by the reality that demand for so many of the needed products and supplies has dramatically exceeded supply—both in the form of available inventory and production capacity.

As a manufacturer in the private sector, whenever I was faced with a problem, I always asked what opportunity presented itself in finding a solution. The same dynamic can apply here. As the men and women who are working tirelessly to address the current demand develop data and models, that information needs to be captured and put immediately to use updating and redesigning the structure and management of the Strategic National Stockpile.

Again, I would like to thank our witnesses today for their testimony, their past efforts, and any future help they can provide to improve our Nation's response to future pandemics.

With that, I will turn it over to Senator Peters.

OPENING STATEMENT OF SENATOR PETERS[1]

Senator PETERS. Thank you, Mr. Chairman, and thank you to our witnesses for being here today.

Over the past several months, the United States has faced an almost unprecedented challenge, fighting a deadly virus that has infected millions and taken the lives of more than 120,000 Americans.

A pandemic can overwhelm even the most prepared communities, and that is why we have the Strategic National Stockpile, the Nation's largest store of lifesaving pharmaceuticals and medical supplies, to ensure the Federal Government has the resources to help States protect the health and safety of Americans during a public health emergency.

But the scale of the Coronavirus pandemic depleted our national stockpile in just a matter of weeks, leaving State and local govern-

[1] The prepared statement of Senator Peters appear in the Appendix on page 818.

ments scrambling to acquire the masks, the gloves, and other supplies that were so desperately needed in order to keep people safe.

Many communities facing the highest rates of infection struggled to obtain the supplies that they needed, including my home State of Michigan.

Instead of providing a coordinated, national approach to effectively using the Strategic National Stockpile and other tools to acquire and distribute supplies nationwide, the President told States that they were on their own. That move forced States to compete against each other and the Federal Government for lifesaving medical supplies that were already in shortage all across the world.

Since this crisis began, Congress has passed several supplemental emergency appropriations bills to rebuild the stockpile. While this funding will help provide some stability, there is no question that our Nation would have been better positioned to tackle the pandemic if Congress and both the current and prior administrations had invested more in the stockpile before this crisis struck.

It is abundantly clear that the Federal Government was not fully prepared to address a crisis on the scale of the Coronavirus pandemic. And the result is the tragic loss of 120,000 of our fellow Americans and millions of families who have suffered the consequences.

Ensuring the preparedness of the Strategic National Stockpile is an issue of national security and should be treated as such. We cannot allow a disaster of this magnitude to catch our government off guard again. We must provide steady funding to all our pandemic response efforts and also ensure that the Strategic National Stockpile is well maintained and prepared to address a broad range of possible threats.

We must improve the communication between States and the Federal Government regarding available resources and strengthen the Federal Government's role in managing supplies during this and future crises.

Finally, we must also take steps to address our overreliance on foreign manufacturers of critical drugs and medical supplies.

This is a serious national security vulnerability, and the pandemic has only further highlighted just how significant this risk is to the health and safety of the American people.

So today's discussion will help us identify and prioritize critical decisions and investments to ensure we can continue to combat the Coronavirus as well as emergencies in the future. I look forward to hearing from all of our witnesses and look forward to working alongside each and every one of you to deal with this very daunting challenge.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator Peters.

It is the tradition of this Committee to swear in witnesses. You do not need to stand, but if you will raise your right hand. Do you solemnly swear that the testimony you will give before this Committee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. GERBERDING. I do.

Mr. GERSTEIN. I do.

Mr. PHELPS. I do.

Mr. BUREL. I do.

Chairman JOHNSON. Thank you.

Our first witness is Dr. Julie Gerberding. Dr. Gerberding is the former Director of the Centers for Disease Control and Prevention (CDC) and the former Administrator of the Agency for Toxic Substances and Disease Registry. Dr. Gerberding is now the executive vice president for strategic communications, global public policy, and population health and the chief patient officer at Merck. She also co-chairs the Center for Strategic and International Studies (CSIS) Commission on Strengthening America's Health Security. Dr. Gerberding.

TESTIMONY OF JULIE GERBERDING, M.D.,[1] FORMER DIRECTOR (2002–09), CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GERBERDING. Chairman Johnson, Ranking Member Peters, as well as the distinguished Members of the Committee, I am really honored to have a chance to talk with you today about the Strategic National Stockpile because I know what an incredibly important asset it is and I know how disappointed some people have been in certain aspects of its deployment and performance this year.

I am going to testify in front of you from four perspectives: first and foremost is my background as an infectious doctor who was hospital epidemiologist at San Francisco General and responsible for occupational safety of health workers in the early acquired immunodeficiency syndrome (AIDS) era and an expert in personal protective equipment (PPE) and how to really keep health workers safe.

As you mentioned, I also co-chair, with former Senator Kelly Ayotte, the CSIS Commission on Strengthening America's Health Security, and thank you for accepting that into the record.[2]

I also am the chief patient officer and an Executive Vice President (EVP) at Merck, where we have engaged from a manufacturing perspective with various interactions with the U.S. Government in our efforts to bring an Ebola vaccine through the licensure process for the emergencies in the Democratic Republic of the Congo (DRC) and West Africa, but also other products that are germane to our overall health security.

And then, finally, I will say that I was the CDC Director during not the very beginning of the stockpile but in its infancy, and I watched it evolve over time. I visited several of the sites where the stockpile is hidden in plain sight and participated in observing some of the exercises of deployment and so forth. I have a pretty deep knowledge of what is in there and how it has evolved over time and what we may need to be doing going forward.

I do believe this is a strategic national asset. We are somewhat unique in the world in having such an asset at our disposal, and

[1] The prepared statement of Ms. Gerberding appears in the Appendix on page 820.
[2] The CSIS Report appears in the Appendix on page 58.

obviously it is an enormous investment and one that we need to make the best of.

It is incredibly innovative, and I would say overall through its entire history it has been reasonably well managed from a budgetary and fiscal responsibility perspective, and it has been innovative in its approaches to preparing for many challenges.

But in spite of that overarching point of view, I recognize that there are important areas where the stockpile needs clarification and improvement, and I will just mention a few.

I think the most important thing is the clarification and consistency of the strategic intent of the stockpile. It has gone from being something that was oriented toward bioterrorism, then to all hazards, chemical, biological, radiological, and nuclear (CBRN) preparation, then influenza pandemic. There have been debates and inconsistencies in whether or not it was conceived as something that would be deployed locally, not preparing for a national crisis of a pan-American scale, if you will, to where we are now today where we needed it to be able to meet the needs of our health system across the entire country.

It is also not clear whether it is an asset that should operate as a stand-alone entity and be prepared to provide for all the needs or whether or not it is there to augment what States and health care settings are already doing and have hardened into their own planning. So that inconsistency has led to somewhat of a ping-pong approach to what should be in it and how to make decisions about procurement.

I think there is another opportunity for improvement in terms of the accountable leadership of the stockpile. As you know, it has moved back and forth from the CDC to DHS to CDC to HHS, and Federal Emergency Management Agency (FEMA) has been involved in the logistics of the current deployment. So there has not been consistent and accountable leadership for really making sure that, No. 1, there is clarity of strategic intent; but, No. 2, that the stockpile consistently delivers in support of that intent and that there is accountability and measurement of the success.

I think a third area for improvement is the budget process. It is impossible for Congress or anyone else to be able to budget to the stockpile if there is not clarity about what it is supposed to accomplish at what scale. What has happened all too often is that the tail wags the dog, so we may have ideas about what the stockpile should be capable of supporting, but the budget is the thing that determines what actually gets procured. The current budget going into this event was not adequate to provide for the kind of PPE that we needed for a pan-American infectious disease pandemic. In part, that is because there was not consistency in exactly what the requirements were for the stockpile and whether it was supplemental to the States or whether it was intended to be able to supply the full force.

I think last there is a real opportunity to improve the engagement with the private sector. As you have said, our supply chains are very problematic, and the people who know the most about that and have the most to contribute are people in the private sector who I believe would be only too willing to engage to think through

how can we improve resilience, agility, and surge capacity in support of this strategic national defense.

The last point I would make is one that has not come up through the CSIS process, but I think as the commission moves forward, we would be very willing to take it on, and that is that the stockpile is not a warehouse full of stuff. The stockpile is a capability, and it needs to be thought of not just in terms of what do we buy but how do we learn how to deploy and utilize those resources at the State, local, territorial, and tribal level, in collaboration with the health system and the public health end users. And that means a strong exercise curriculum, continued deployment and utilization capability enhancement, and a cycle of planning and improvement that is inclusive of the front-line personnel.

I will stop there and, again, just thank you for the opportunity to testify. I am looking forward to the comments of my esteemed colleagues. Thank you.

Chairman JOHNSON. Thank you, Dr. Gerberding.

Our next witness is Dr. Daniel M. Gerstein. Dr. Gerstein is a senior policy researcher at the research and development (RAND) Corporation. Prior to his work with RAND, Dr. Gerstein served as the Acting Under Secretary and Deputy Under Secretary at the Department of Homeland Security's Science and Technology Directorate. Before his time with DHS, Dr. Gerstein served in the U.S. Army, both in active duty and as the Principal Director for Countering Weapons of Mass Destruction (CWMD) in the Office of the Secretary of Defense. Dr. Gerstein.

TESTIMONY OF DANIEL M. GERSTEIN, PH.D.,[1] SENIOR POLICY RESEARCHER, RAND CORPORATION

Mr. GERSTEIN. Good morning, Chairman Johnson, Ranking Member Peters, and distinguished Members of the Committee. I thank you for the opportunity to appear today and discuss the future of the pandemic preparedness and response and the Strategic National Stockpile.

While I will focus a majority of my remarks on looking forward, I do want to briefly assess the U.S. response to date. In short, COVID–19 has exposed serious weaknesses in our national preparedness and response systems. The United States relies on a just-in-time medical delivery system that lacks resilience in terms of crisis. We are also witnessing an inability to scale at that national level to meet the demands of a public health emergency.

Overall, the Federal response has been slow and inconsistent, confusing at times, and has deservedly become a target of criticism. We have seen shortfalls in areas from the basic science to our emergency management governance and doctrine through strategic communications with the American people.

One particular concern is the Strategic National Stockpile. Several key SNS issues have been evident, including unrealistic expectations for the SNS, the historical underfunding of the stockpile, lack of timely decisions regarding energizing supply chains, and the Federal Government's altering of the mission of the SNS during this national emergency.

[1] The prepared statement of Mr. Gerstein appears in the Appendix on page 824.

Looking to the future, a bipartisan commission should be established to review the Nation's performance during this pandemic. Basic assumptions regarding emergency management and disaster preparedness and response, including the role of government at all levels, should be on the table. One outcome should be agreement that public health must be elevated to and receive prioritization and funding as a national security issue, just as the Department of Defense (DOD) and intelligence community (IC).

Specifically, I offer five recommendations for improving our Nation's preparedness and response capabilities.

First, reexamine the SNS concept. Congress should ask for a complete accounting of the SNS performance during this pandemic. The mission of the SNS should also be reconsidered. A new mission statement, codified in law and not subject to the whims of any administration, should be developed to signal the capacities and limits of the stockpile. The Federal Government owes this to the State and local authorities. The agreed stockpile concept must be stress tested and optimized through training and exercises to ensure it meets the preparedness and response goals that have been set.

Second, develop a strategic national supply chain approach. Rather than consider the SNS as a discrete element, it needs to be thought of as part of a broader national supply chain that combines stockpiling and direct contracting with manufacturers, warm production lines for some key commodities, procuring large quantities at the national level to take advantage of economies of scale, and shortening supply chains. The goal should be to determine the most effective and efficient methods for ensuring critical needs will be met for the envisioned SNS scenarios. This would require mapping out critical equipment and supplies to allow for a determination of their anticipated availability over time.

Third, increase public health funding. Years of underfunding of State, local, tribal, and territorial public health programs should be reversed. These shortages affect preparedness and response for a wide variety of naturally occurring public health events, accidents and natural disasters, and deliberate attacks. During the COVID response these shortfalls have negatively affected staff support to government leaders at all levels, biosurveillance activities, contact tracing, stockpile shortages at the beginning of the pandemic, and broader supply chain issues. Public health shortages have also adversely affected the CDC and National Institutes of Health (NIH).

Fourth, develop the vaccine distribution system now. An important part of the supply chain for this current pandemic will entail the distribution of a vaccine when it becomes available. While a vaccine may be ready by early 2021, much remains to be done to ensure timely distribution. Planning should be ongoing now for administering a vaccine here in the United States and globally. Only after a large portion of the world's population is immunized will COVID–19 be controlled.

Fifth, reestablish U.S. leadership in global public health. U.S. leadership is needed now more than ever. International collaboration will be vital for understanding the spread of the disease and developing medical countermeasures. We should also seek to repair our relationship with the World Health Organization (WHO) while working to make the organization more accountable. We need the

WHO to serve as a conduit for information and to coordinate with other nations as the COVID–19 disease spreads to other parts of the world and for future health crises.

In conclusion, some have called the novel Coronavirus a "black swan event," an event that is unforeseen. I reject this characterization. We have had ample evidence of the potential for a global pandemic. However, competing priorities, inadequate funding, and a lack of national focus led us to ignore this potentially existential threat until it was too late. Unfortunately, we will see more pandemic events in the future given human activities that disrupt environmental habitats, promote the mixing of species, and allow humans and pathogens to crisscross the world along global supply chains. Efforts should be made now to ready ourselves for such a future event.

Thank you for inviting me to speak today, and I look forward to your questions.

Chairman JOHNSON. Thank you, Dr. Gerstein.

Our next witness is Andrew Phelps. Mr. Phelps is the director of Oregon's Office of Emergency Management. Previously Mr. Phelps managed the New Mexico Department of Homeland Security and Emergency Management's Local Preparedness Program. He also served as the planning section chief for New Mexico's Emergency Operations Center. He appears before our Committee today on behalf of the National Emergency Management Association (NEMA). Mr. Phelps.

TESTIMONY OF ANDREW PHELPS,[1] DIRECTOR, OREGON OFFICE OF EMERGENCY MANAGEMENT, ON BEHALF OF THE NATIONAL EMERGENCY MANAGEMENT ASSOCIATION

Mr. PHELPS. Thank you, Chairman Johnson, Ranking Member Peters, and distinguished Members of the Committee for inviting me today.

I am proud to present testimony representing the National Emergency Management Association. On behalf of my colleagues, we thank you for holding this discussion on the Strategic National Stockpile during the ongoing response to the COVID–19 pandemic.

The 122,000 COVID–19-related deaths in the United States, 190 of them Oregonians, each life lost has a profound impact on responders, State and national leaders, and me personally. Preventing loss of life is why we do what we do. Our heartfelt condolences go out to those currently diagnosed, recovering from, or bereaving the loss of a loved one during this pandemic.

Governor Brown took bold action early, likely saving hundreds if not thousands of lives. Comparatively speaking, Oregon has fared well to this point in the fight against COVID–19. We have utilized our entire emergency management system, including [inaudible] logistics, to support the important work of our public health partners and the Oregon health authority.

We continue to adapt our structure to compensate for insufficient Federal resources and continuing guidance. For instance, there was initial confusion as to whether Coronavirus Aid, Relief, and Economic Security (CARES) Act funding would enhance or replace pro-

[1] The prepared statement of Mr. Phelps appear in the Appendix on page 842.

grams typically available through Federal disaster assistance. We expect bold action from the Federal Government. When it became apparent that the SNS PPE allocation would be a fraction of what was planned for and what was [inaudible], we began preparing PPE on our own. To date, Oregon has received only 15 percent of the surgical masks and 5 percent of the gowns we were expecting.

While the major disaster declaration was certainly appreciated, Oregon has yet to receive a response for a requested investment of 75 percent Federal cost share submitted nearly 3 months ago. At least 44 other States are also awaiting a response. This lack of commitment added to an already uncertain financial [inaudible] as we manage this national crisis. We also await confirmation and guidance regarding reduced Coronavirus Relief Fund (CRF) dollars [inaudible] public assistance grants [inaudible] some of the critical response possible. This lack of guidance and unwillingness to commit to a cost-share adjustment leaves States in limbo, nervous about improper spending of CRF dollars, and slows our recovery efforts. Our experience in Oregon is shared by many of my colleagues across the country. It has led to six initial recommendations for improving the capacity of the SNS to support State and local pandemic response.

We need to understand inventory and demand. As keepers of the SNS, the Federal Government [inaudible] programs. States can integrate these shortfalls into planning assumptions and preparedness action. State and local pandemic emergency plans rely on SNS support in times of crisis. States need to know what they can or cannot expect from the SNS. We have to strengthen this [inaudible]. Rather than only maintaining a large stockpile [inaudible] our Federal partners [inaudible] to support States' critical needs of supply chain metrics [inaudible] manufacturers [inaudible]. Throughout the response, nearly every State [inaudible] external reliance on critical supply national security put States in an unfamiliar role [inaudible] some States [inaudible]. The average delivery time for gowns to one State was 46 days. Supplies are [inaudible] sometimes faulty supplies like [inaudible] masks, counterfeit respirators, [inaudible] or boxes that were fractions of what we paid them.

We must empower States and resource [inaudible]. To relieve some demand on the SNS, States should be encouraged to establish stockpiles. At a minimum, this should be done regionally, and when possible, shared between State Emergency Management Assistance Compact (EMAC). Some States receive [inaudible] some equivalent, more equivalent [inaudible] than they receive from the SNS.

Other recommendations included in my written testimony focus on [inaudible] and enhanced tracking [inaudible].

As a Nation, we remain in active response mode to COVID–19, [inaudible] uncertainty. Overall, any failure in the system does not rest solely with the SNS. Challenges with authorities, communication, and a lack of investment in the emergency management system at all levels have left us unprepared. The supply chain for PPE lacks transparency and relies too heavily on foreign entities. We have seen a lack of expectation management for what the SNS can and cannot do for officials managing a complex, statewide, national

event. Addressing these interrelated issues allows for a more sustainable and flexible response system through which States can utilize the SNS to respond to any disaster with greater efficiency, confidence, and most importantly, public trust.

Thank you for the opportunity to testify today, and I look forward to any questions you may have.

Chairman JOHNSON. Thank you, Mr. Phelps. I was able to hear you, but your audio is not coming in real strong. Your video looks good, so maybe you want to see if maybe you have a different microphone when you start answering some questions.

Our next witness is Greg Burel. Mr. Burel is the former Director of the Strategic National Stockpile, a position he held for 12 years. Prior to that, Mr. Burel served as FEMA's Director of Administration and Resource Planning and Senior Disaster Logistics Official. Mr. Burel is the president and principal consultant for Hamilton Grace LLC. Mr. Burel.

TESTIMONY OF GREGORY BUREL,[1] FORMER DIRECTOR (2007–20), STRATEGIC NATIONAL STOCKPILE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. BUREL. Chairman Johnson, Ranking Member Peters and Members of the Committee, thank you for the opportunity to testify on the Role of the Strategic National Stockpile in Pandemic Response. I am honored to continue to support the mission of this critical organization by testifying today. I had the privilege of serving as Director for almost 13 years. I am a Fellow of the National Academy of Public Administration and, as Chairman Johnson noted, president of Hamilton Grace LLC.

For more than 20 years, the SNS has protected national health security as the Nation's repository of medical countermeasures, both drugs and devices. SNS is a highly specialized and capable organization, but its utility for certain responses, such as those for a nationwide pandemic event, are constrained primarily by a lack of funding.

When SNS was established as the National Pharmaceutical Stockpile, the design was to develop inventory to respond to chemical, biological, radiological, and nuclear threats. By December 2019, the inventory was valued at around $8 billion.

Over time, SNS' highly specialized exceptional medical logistics capabilities became apparent across government. As a result, SNS expanded to an all-hazards mission. But instead of "mission creep," SNS actually experienced "mission gallop." Such a leap in expectation cannot occur, however, without commensurate increases in funding. Appropriations simply have not kept pace with the growing burden to expand inventory and capability to meet all-hazards mission expectations.

The statutes require a threat-based annual review that drives decisions to define the desired available content of the SNS. The review is conducted under the auspices of the Public Health Emergency Management Countermeasures Enterprise (PHEMCE). PHEMCE is comprised of those best experts across government in disease threats and other specialized medical and scientific areas.

[1] The prepared statement of Mr. Burel appears in the Appendix on page 849.

They recommend the content to be held in the SNS. The top level PHEMCE committee is actually led by the HHS Assistant Secretary for Preparedness and Response (ASPR), and it includes the Director of CDC, the Director of National Institute of Allergy and Infectious Disease (NIAID), and other highly senior officials across government. This group makes the final decisions for the SNS contents based on the recommendations of the other experts.

But because appropriations are limited, it is necessary to balance a risk-based need across threats to purchase the best mix of products when we try to buy down that risk. It is also notable that statute requires SNS prioritize products that are simply unavailable in the commercial market. Many things procured by the SNS are purchased and held nowhere else. These, for example, include the only Food and Drug Administration (FDA)-licensed botulinum antitoxin, which saved lives and reduced illness during the 2015 outbreak in Ohio. Simply put, without SNS procurements, these products would not be developed or manufactured, and there is insufficient demand for these product outside the Federal Government for them to allow continued development and manufacture.

Any lack of national public health preparedness does not sit solely or predominantly with SNS or any other individual entity, but is instead the result of insufficient investment in public health at all levels of government. Limitations on manufacturing compound these problems, and the Nation also must rely on a very lean medical supply chain, which, while optimized for the best value, is less than optimal for crisis response.

In the early 2000s, Congress authorized supplemental funds to prepare for pandemic influenza. Much of the products developed in that process were used to respond to the 2009 H1N1 pandemic flu, and additional funds were never reauthorized to replace that material.

State, local, tribal, and territorial public health are another key piece of the public health preparedness puzzle, and they have a vital role to play. These levels of government are responsible for planning and response in their unique jurisdictions so that Federal assets can be called upon and used correctly when other options have run out. Prior to the 2009 H1N1 response, many States had their own stocks, and these were ultimately disposed of later due to declining funds. State and local public health must be funded.

Public health overall must be consistently and robustly funded. We have a long history of heavily investing in public health when it is clear there is a problem. The further we move from those significant adverse events, the public memory fades and funds often decrease along with that. Our way forward must include more consistent mandatory funding for public health and include a greater emphasis on public-private partnerships. The Nation is better prepared with government and private sector working together for preparedness.

I would welcome the opportunity to work with my fellow panelists, the Congress, and all other stakeholders to improve the SNS and our public health preparedness.

Thank you again for the opportunity and the invitation to participate today.

Chairman JOHNSON. Thank you, Mr. Burel.

I do not think there is any doubt that we are going to have to provide more funding for the Strategic National Stockpile. But I think the first step—and I think it is an incredibly important first step—is it needs a mission statement designed and codified and articulated clearly.

The only one we can find right now is on the HHS website. It is not a codified statement, but let me read the current mission statement for the SNS:

"The Strategic National Stockpile's role is to supplement State and local supplies during public health emergencies. Many States have products stockpiled as well." I am not sure that is really true. "The supplies, medicines, and devices for lifesaving here contained in the stockpile can be used as a short-term stop-gap buffer when the immediate supply of adequate amounts of these materials may not be immediately available."

I think we just described what the problems have been. The Strategic National Stockpile implies we have this massive amount of well-thought-out supplies and we have them adequately stocked to handle a pandemic. There is nothing in the mission statement that even talks about the level of supplies we would need for a massive pandemic like we are going through right now.

So if that is the role we expect the Strategic National Stockpile to play, we need to articulate that. We need to codify that. So from my standpoint, the first step is, as Congress, we have to codify and articulate the mission statement that we intend. We need to assign the proper roles between local, State, and the Federal Government. And then the next step is going to be, really lay out that list.

I want to start with Mr. Burel. Was there a different mission statement when you were head of the national stockpile? Has this been modified? Has this been reduced?

Mr. BUREL. Senator Johnson, thank you for the question. I think that you have described the situation we find ourselves in extremely well. Originally, we were working toward building stocks, as Dr. Gerberding even noted, to respond to biological terrorism, chemical, radiological, nuclear events. What we have seen over the years is more and more emphasis has been placed in the Strategic National Stockpile to be prepared for all hazards.

Unfortunately, funding has not followed to be prepared for every hazard, particularly a nationwide pandemic. What we have been able to do is concentrate on that primary mission that we have held from the beginning, and that is establishing stocks of CBRN materials that really do not exist anywhere else. We have developed capabilities to be able to respond to those types of events. They have been used well also to respond to natural events. We have responded, I think successfully, to the H1N1 pandemic, and it really comes back to an issue of: What is the emphasis that the Congress chooses to give the SNS? How can it be funded to meet all of the many requirements that it is called upon to meet?

Chairman JOHNSON. Again, I want to talk about at what level. I mean, to be the sole supplier? To stockpile or having manufacturing capability to provide every N95 mask? I mean, is there no responsibility for the State and local governments to stockpile? Again, I think there is such a lack of clarity of what that mission

statement is. You can say, we were going to stockpile these kind of supplies. OK. At what level?

I know in my briefing I saw that with Ebola we have stockpiled 50 Ebola kits. Fifty. Now, fortunately, we did not need all those 50, but we might have needed thousands of tens of thousands. Or, in the case of this pandemic, we literally need hundreds of millions if not billions of some of these supplies.

So I will ask you, Dr. Gerberding, do you agree that just first it has to be to define the mission of what the SNS is going to be about? We can talk about what inventory items, but unless we really know what its mission is, what its role is, and what State and local government roles are, we are still completely blind and will come up short.

I cannot hear you, Dr. Gerberding.

Dr. GERBERDING. Thank you. That is exactly what I hoped to try to emphasize in my written testimony and my oral comments. If we do not have a consistent and clear strategic intent that the whole-of-government agrees with—and when I say "whole-of-government," I mean State and local, territorial and tribal, not just Federal—we are just bouncing around from the last crisis to the next crisis and not really consistently building that level of preparedness.

That is why one of the main recommendations from the CSIS report is that we establish permanent leadership of our health security at the level of the National Security Council who has accountability for articulating, among other things, the strategic intent of the Strategic National Stockpile to support the level of health security our Nation intends to achieve.

Chairman JOHNSON. In a number of different situations, whether it is cyber, whether it is biodefense, and now here, it seems like the recommendations of these commissions have been consistently somebody has to be in charge. While I do not disagree with that, I do not necessarily think it is going to be that person that should lay out this mission statement. I really do believe this falls to Congress working with the administration, possibly working with that individual to codify what this statement is so that everybody knows what the role is, what the level of the role is.

Dr. GERBERDING. I agree with you, Senator. I believe that the national strategy for health security is a responsibility of the National Security Council, but Congress is the bill payer, and obviously, in order to build the stockpile that we need, Congress needs to direct the strategic intent, in support of the national security agenda but, nevertheless, it would be a great help to have that clarity and consistency from Congress.

Chairman JOHNSON. Mr. Gerstein, real quick, again, I really appreciated your testimony. You laid things out quite nicely. Once we have established that mission statement, we are going to have to then identify the items; we are going to have to figure out certainly what the inventory levels and the manufacturing capability needs to be. I think you hit it in your testimony. I do not think this should be filling a bunch of distinct warehouses. This needs to be looking at the entire supply chain and figuring out exactly how this flows through that. At what level do we have excess inventories? And how do you keep rotating stock? I mean, this is actually a pretty complex logistics problem here. Would you agree with that?

Mr. GERSTEIN. Absolutely, Senator. I think you have hit it right on the head. We look at the SNS, and we are having a discussion about the SNS, and we are very focused on this particular program and set of facilities. But I think it goes broader than that. It is actually understanding where supplies come from and making strategic decisions about how to satisfy the requirements we anticipate.

There is not enough money, unless we completely redid lots of different programs, in order to outfit for every envisioned scenario. But what we can do is understand where supplies and equipment, reagents and such, will come from and be able to map those in and determine what are those choke points that we need to resource or have manufacturing here in the United States, what are those that we can outsource. We need to understand the timelines in which we can satisfy those.

So I would like to see it as part of a broader discussion. The SNS definition is absolutely essential starting out, but then we also need to on all sides of that talk about things like stockpiling and direct contracting and warm production lines and procuring large quantities. We need to have an agreement with the States and the locals in terms of what are they going to do and what are the Federal responsibilities. It is very important so that the expectations on all sides by all stakeholders, including industry, who is an absolutely essential stakeholder, needs to be able to come to the table and talk about how they would assist in this process.

Chairman JOHNSON. I am out of time, but let me make my final point. I think we absolutely have to change the name of the Strategic National Stockpile. I think it is misleading. That will be one of the components of what we need to do here. We will have to stockpile some things. This is more a coordinating role, very similar to FEMA, where we really rely on local governments to do what they can do first; when they cannot handle it, the States step in; when they cannot handle it, the national government steps in. So there are certain things that only the Federal Government can do, but it is a far more coordinating role.

So I guess for my colleagues, as we look at potentially legislative fixes for this, I would first suggest we need that mission statement, and we need a new name; because, otherwise, we will continue to mislead people and have them believe that literally there is all this PPE just sitting in a stockpile and why don't we have our fair share. Why can you not supply us everything we need? Again, the frustration—and it is a legitimate frustration, but it is because we simply do not have the supplies to meet the enormous demand in this type of situation.

With that, I will turn it over to Senator Peters.

Senator PETERS. Thank you, Mr. Chairman, and thank you to each of our witnesses for your very comprehensive opening statements, and I appreciate your testimony here today.

I want to spend a little time focusing on the supply chain, which has come up repeatedly in testimony as well as in some of the answers to the questions from the Chairman. So my first question is to Mr. Burel. Certainly this pandemic has exposed our country's reliance on foreign countries to provide critical medical supplies to us, particularly China, which manufactures critical drugs and medical supplies. In fact, last year I released a report from this Com-

mittee identifying vulnerabilities and called for action to address what is fundamentally in my mind a national security threat given our reliance on these foreign entities.

So my question to you, Mr. Burel, is: As the former Director of the SNS for 13 years, what is your opinion on our reliance on foreign suppliers for critical drugs and medical supplies? And what steps specifically would you believe that we should be taking in order to address this threat?

Mr. BUREL. Senator, I am as concerned as anyone else about our overreliance on foreign-produced products. I think that this is a significant issue that we face in this particular event, but in all events as well. If something disrupts that supply chain outside the United States and we cannot do anything about it domestically, we have a significantly worse issue than we would otherwise.

Some of the things that I think we can do is encourage manufacturing to come back into the United States. I think that we also have a responsibility to expand those public-private partnerships so that we can understand what it is going to take to get the private sector to come back and do more manufacturing and how they can create more robust capabilities themselves, whether it be more manufacturing, additional security stocks of finished products, additional security stocks, for example, in the drug world of active pharmaceutical ingredients.

So I believe that we must encourage continued relations with the private sector in a strong, comprehensive, cooperative way so that we can together find the best way forward not just for these events but for all health care needs in the United States. We see drug shortages routinely, and many are impacted by the situation you describe.

Senator PETERS. Thank you.

Dr. Gerstein, the same question to you. Do you have any recommendations on how the Federal Government can work more effectively with the private sector to address this national security threat?

Mr. GERSTEIN. I do. I think that we have to make known what the requirements are going to be that the Federal Government in coordination with the State, local, tribal, and territorial governments sees as what will be required for a pandemic or for any sort of event that we intend to have the SNS or whatever follows it, because whatever we intend to have is the set of scenarios. But I guess, it all comes down to really mapping this out very methodically and understanding the types of scenarios that we intend to be prepared for and building resilience and flexibility into the system.

This virus has been very different than, say, what we faced in the H1N1 in 2009 or during Ebola, and if history is any indication, we need to design it with a great deal of flexibility. So I would say that we should rely on U.S. innovation. We should get with stakeholder communities, including the private sector, and we need to figure out what their capacities are. In some cases we do need to have warm lines available that can be turned on very rapidly.

We know if it is going to be a global pandemic, we are going to face the exact same set of circumstances with a global competition which is unhelpful, but it is a matter of what is going to go on for

other nations to try to get supplies that they might need. So we need to be prepared and build in resilience.

And make no mistake, though, Senator. It will cost money to prepare for this, but we have done this in other areas where we have prioritization, and we should do it for global public health or for U.S. public health as well.

Senator PETERS. Very good. The point about how we have to have more information I think is significant, and my understanding is that ASPR does not have the information that it needs to inform planning for the Strategic National Stockpile or to sufficiently protect critical infrastructure such as essential manufacturing plants that we may have here in this country. For example, ASPR should know the location of where those manufacturing plants are for some of the active ingredients, the Active Pharmaceutical Ingredients (APIs), and other critical drugs.

I have actually introduced legislation called the Pharmaceutical Accountability, Responsibility, and Transparency (PART) Act which would address this by—it actually requires the FDA to share certain manufacturing data with ASPR and the DOD to help serve the drug supplies. So maybe your comments on what would be additional information required by this PART Act, how would that help us prepare for future pandemics, natural disasters as well, national security threats?

Mr. Burel, I am going to ask you to comment as well, but, first, your comments. You have been certainly focused on the lack of information. I would love to have your thoughts, Dr. Gerstein.

Mr. GERSTEIN. Yes, I think you have hit it right on the head, Senator. We need to understand in the same way that other corporations who are providing supply chain support—I will not name them, but I think we all know who many of them are. They know who their suppliers are. They know what happens and, what their lead times are and what happens if their supply chain is disrupted. So they have developed a business model that makes sure that they do not ever run out of those items within the supply chain. And we need to do the same thing. We need information.

One of the problems that occurred, interestingly, when you had the transition from CDC to ASPR and then during this immediate pandemic to FEMA providing some sort of support, an interesting outcome was that it was not clear that FEMA knew where all the stockages were. So they did not have the initial understanding of what was remaining in the stockpile. FEMA is good with management and logistics, but they do it for the sorts of supplies they typically rely on for natural disasters and such. This is a very specialized set of requirements that is inherent in the SNS, and so not having that information is a little bit like trying to make allocations with blinders on.

Senator PETERS. Thank you. I am out of time now. Mr. Burel, we will get back to you to get some information from you. I would like to get your viewpoints as well. But thank you for your testimony.

Thank you, Mr. Chairman.

Chairman JOHNSON. Senator Portman.

OPENING STATEMENT OF SENATOR PORTMAN

Senator PORTMAN. Thank you, Mr. Chairman.

First, I want to thank you all for having the hearing and to our witnesses, and this is a critical issue not just with regard to the pandemic but going forward. We need to change our approach. I agree with the Chairman that there needs to be a mission that is clearly defined. I also agree and was struck by Dr. Gerberding's comments about the lack of consistent accountable leadership. I have experienced some of that in dealing with the issues of PPE. But when you go from CDC to ASPR to DHS to FEMA to Defense Logistics Agency (DLA), there is a lack of consistent leadership and certain accountability. I know there are some interagency groups. As an example, Mr. Burel talked about the deal with the contents of the Strategic National Stockpile. But the problem is there does not seem to be consistent and accountable and performance measures are not in place to be able to keep people accountable. So a mission is a good idea, but leadership to me is critical.

I wondered, Dr. Gerberding, since you raised that issue, if you could comment on what that leadership ought to be, and perhaps, Mr. Burel, you could comment on that as well.

Dr. Gerberding, are you there?

Dr. GERBERDING. Yes, I am on. Can you unmute me, please? Can you hear me now?

Senator PORTMAN. We can hear you.

Dr. GERBERDING. OK.

Senator PORTMAN. Tell us what your solution is in terms of leadership and accountability.

Dr. GERBERDING. I wish it was that easy, sir. As I tried to express, people think of the stockpile as a warehouse of stuff we buy and store, but it really is a capability. And there are different aspects of capability, and they may not all need to be under the same roof.

For example, ASPR probably is the right place to do the contracting and procurement for novel countermeasures that need that NIH–Biomedical Advanced Research and Development Authority (BARDA) close interface for decisionmaking, prioritization, procurement, and management of those contracts and processes. But the stockpile utilization and planning is a very operationally driven effort, and to me that is why you have operating agencies like the CDC that is intimately connected with the users of the stockpile and is in a great position to be able to understand what are we aiming for, where are the gaps, and how do we plan, exercise, deploy, and improve our ability to be sure that the stockpile does meet the local requirements?

So in my world, I think the accountability for the operation of development, management, exercise, and deployment of the stockpile is best suited for an operating agency like the CDC, but the aspects of the contracting and procurement of these new and novel countermeasures and other things that may be on the innovation forefront, that is the kind of thing that ASPR and BARDA are really designed to do well. It is not a one-size-fits-all solution, but I think you can hold the accountability to the leaders who are responsible for their specific performance measures and requirements. And that has never really happened.

Senator PORTMAN. I am going to ask you to think about that a little bit because it seems to me you said leaders, plural. If no one

is in charge, then it is very difficult to hold one entity accountable. So I would challenge you on that, and I think CDC, if you say that is the operational entity, it certainly did not work this time. So I would challenge you to just give us some more clear guidance as to how do you get exactly what you identified, because it is absolutely right that you need consistent, accountable leadership——

Dr. GERBERDING. Senator, could I just very quickly come back to that is why we need the national strategy, and I do agree one person needs to have the accountability. My own view is that person should be the Director of the CDC because that has been my experience and my framework for that. But that does not mean that other agencies do not have specific responsibilities, and I think it is that sort of having an accountable leader, plan horizontally, and make sure you execute vertically with the appropriate measures of success.

Senator PORTMAN. That is helpful. I will say I am also intrigued by what I have heard today about our lack of understanding of the needs for a pandemic like this, but also the reality with regard to CBRN, everything else out there that the stockpile was supposed to be for initially, including a nuclear attack, let us say, CDC may not be the right entity for that. It is the Center for Disease Control, not for a biological or nuclear attack, which would be more of a war footing.

So, anyway, I think we need to do some thinking about that, and we need to figure out what is the right leadership model to go along with the appropriate strategy.

With regard to this issue of PPE and the stockpile, my great frustration is that we do not seem to be doing the obvious things to be able to reshore our PPE, and I would ask the question, I guess, of the entire panel here and see who would like to answer it. But do you agree, one, that we need a reliable source of PPE in the stockpile? Therefore, do you agree with me that we ought to be reshoring PPE—not all of it, depending on, again, what we find is the real mission of the Strategic National Stockpile, but some of it, enough of it to be able to be reliable. By the way, with something like a global pandemic, you cannot rely on global sources that you might otherwise, because they need the PPE also. We certainly learned that in the last few months.

I have a real frustration with the Executive Branch not providing long-term contracts, because for domestic reshoring you have to have the market signal that you are going to have a customer, and that customer is going to be the U.S. Government in terms of the stockpile at the national level. It may be the States; it may be even some private sector entities that are given responsibility here. But we do not have that now. DLA is only issuing contracts for 90 days right now.

So my question is: Do you agree that we need to give industry this clear signal to build up our capacity? And do you think that it is necessary to have a reliable surge capacity? You are on the video, so what do you think?

Dr. GERBERDING. I will start just by saying that we have to understand from the standpoint of PPE that we are supply constrained. It does not really matter whether it is in the stockpile or whether it is in the health care system or the State. We have a

supply constraint there, and that is the first and foremost thing we need to concentrate on remediating. And, yes, I agree that the more we can build out our national capacity in that regard, the more secure we will be in the context of a global pandemic.

The other point about long-term contracting I could not agree with more. As the company that just got an Ebola vaccine licensed and are under contract to fulfill a certain number of doses for our stockpile, what happens when that ends? We have built a factory to make this vaccine, and we are going to be sitting with idle capacity because there really is no future there.

Senator PORTMAN. You will not have the investment, and I hope to hear from the other panelists as well, but I know my time is up. Let me just say that today I am sending a letter to DLA along with three other Republicans and three Democrats asking for them to change their policy with regard to the 90-day versus a long-term contract so that U.S. companies can make that investment with certainty to be able to bring PPE back to our shores.

Thank you, Mr. Chairman.

Chairman JOHNSON. Is Senator Carper ready?

Senator PORTMAN. Mr. Chairman, by the way, could I ask unanimous consent to have that letter be made part of the record?[1]

Chairman JOHNSON. Absolutely. Without objection.

Senator PORTMAN. Thank you.

Chairman JOHNSON. Senator Carper, are you available?

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. I am here.

Chairman JOHNSON. OK. Go ahead.

Senator CARPER. Good morning, everyone. Our thanks to our witnesses. I do not know who lined up these witnesses, but this reminds me of the New York Yankees back in the 1930s. This is like the Killers' Row. What talent. Nice work.

In reading through the testimony, rereading it during this hearing, I have been looking at, Mr. Gerstein, what you said about recommendations. You made five recommendations, and I am just going to repeat them. What I am going to do is ask the other three witnesses if they agree with you on any of these five recommendations. All right? That is going to be my question.

The first recommendation that you make is to reexamine the Strategic National Stockpile concept, and let me just say for those of you who agree with that, raise your hand. If you agree with that recommendation, reexamine the SNS concept, raise your hand. OK. Some of you are raising two hands.

All right. The second recommendation you make is develop a strategic national supply chain approach. Develop a strategic national supply chain approach. If any of you agree with that, would you also raise your hand, please? OK. Thank you.

The third is to increase public health funding. Increase public health funding. If you agree, please raise your hand. All right.

Mr. Gerstein, you are not agreeing with your own recommendation. [Laughter.]

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[1] The letter referenced by Senator Portman appears in the Appendix on page 856.

All right. The fourth one is to develop the vaccine distribution system now. Develop the vaccine distribution system now. We got some two hands on those. All right. Good.

And, finally, to reestablish U.S. leadership in global public health. If you agreed with that? Yes, oh, good. All right. Mr. Gerstein, you have a lot of support there from your colleagues.

Mr. GERSTEIN. That is always good to hear, Senator.

Senator CARPER. I wish I did that well among my colleagues. You enjoy that position.

I have a couple other questions. This next question is for all of our witnesses, and let me just take a moment to discuss the importance of oversight. Our Committee is an oversight Committee. That is what we do. That is what they pay us the big bucks for. I often like to point to the Government Accountability Office (GAO's) High-Risk List as our to-do list for our Committee here in this Congress. GAO provides this Committee every 2 years specifically with routine information on government programs that help us do a better job in conducting oversight. Actually, they give us the High-Risk List every 2 years.

The Strategic National Stockpile has been managed and overseen by several different agencies over the years, and it appears that effective management would require agencies partnering with each other and with Congress to ensure that the stockpile has the resources and management needed to respond to a national emergency.

A question again for all the witnesses. What additional actions should Congress and the administration consider taking to ensure that effective oversight of the stockpile is being conducted on a regular basis? Anybody want to take a shot at that? Let us start with Dr. Gerberding.

Dr. GERBERDING. Thank you, and I do not have a short answer today, but as I do co-chair the CSIS commission, I would say that I, with former Senator Ayotte, oversee a panel of some incredible experts but also some bipartisan Members of Congress on both the Senate and the House side—Senators Young and Murray and Representatives Eshoo, Cole, Bera—and I forgot my fourth member. I apologize. But the point is that we are well positioned to be able to perhaps provide some advice on that issue and would be interested in doing that.

Senator CARPER. Tell Kelly her old colleagues send their best, OK?

Dr. GERBERDING. Thank you.

Senator CARPER. Same question. What additional action should Congress and the administration consider taking to ensure that effective oversight of the stockpile is being conducted on a regular basis? Mr. Burel, would you like to take that?

Mr. BUREL. There are several different things that can be done. I am a Fellow of the National Academy of Public Administration (NAPA) has done a good job in the past making recommendations to Congress about how to manage government programs, how to think about government programs. NAPA might be an excellent source to try to get involved in thinking in these things.

I think one of the things that I would suggest is the good thing about the oversight particularly would make people more aware of

what the SNS does, what the SNS needs, and how to move forward. So I think to help suggest a comprehensive oversight structure beyond what exists today, I, as Dr. Gerberding suggested, would love to come back to you with additional thoughts on that.

Senator CARPER. That would be great. I am going to ask our other two witnesses to answer that question for the record.

I have a different question relating to GAO that I would like to ask of Mr. Gerstein and Mr. Phelps. That question is: Should an independent organization such as GAO be tasked with regularly reviewing the stockpile and reporting on its ability to respond to a national emergency? Do you think that is a good idea?

Mr. GERSTEIN. Senator, this is Dan Gerstein. If I understood—you broke up a little bit there, but I think you were asking about should an organization such as GAO do periodic reviews. And in answer to that, I would say, having been subjected to many reviews during my fairly lengthy service in government, I would say absolutely. The reviews will be important, especially given that we are talking now about redefining what the SNS is, thinking about turning it into an element within a national supply chain for public health equipment and supplies, and all of that is really something that is going to require somebody to take a look at it.

An issue that you also brought up had to do with—and I will use the military term, and that is "command and control." I think it is going to be very important to understand—and the GAO is well suited to look at this and to determine, if things are moving in the right direction with respect to who is going to be in charge, who is going to have oversight and the authorities to be able to manage this process.

Senator CARPER. Thank you.

Same question, then I am done. Mr. Phelps, should an independent organization such as GAO be tasked with regularly reviewing the stockpile and reporting on its ability to respond to a national emergency? Just very briefly, please.

Mr. PHELPS. Thank you, Senator. Absolutely. I think it would help with identifying performance metrics, evaluating the efficacy of the existing performance metrics and hopefully help with expectation management. If we at the State level and the local level have a better idea of what we can expect [inaudible] our procurement, our ability to stockpile much more effectively.

Senator CARPER. Mr. Chairman, I do not come up with many good ideas, but I think that might be a good idea and something we could do every couple of years, a request to make, and I am sure they would be interested in doing that. Thank you, everybody.

Chairman JOHNSON. OK. I appreciate that, Senator Carper.

Just so everybody is aware, it will next be Senator Scott, then Rosen, Lankford, Hawley, Romney, and Hassan. So, Senator Scott?

OPENING STATEMENT OF SENATOR SCOTT

Senator SCOTT. Sure. First of all, thank you, Chairman, for organizing this, and I agree with you. I think it starts with coming up with exactly what our mission is, and if you have the right mission and you have the right funding, then you can probably get a good result.

I finished 8 years as Governor of Florida, we went through quite a few hurricanes, and we did not just sit down and wait for the Federal Government to show up. We created our own stockpiles for food and water, tarps, and things like that just to make sure that we were prepared, because we did not—you cannot expect that somebody else is going to always be able to take care of you.

I think we have a lot of people all across the country who are trying to figure out how to put ourselves in a better position for the next pandemic while they are also trying to figure out how to make sure we have all the right protective gear just with this pandemic. I know as I talk to some of my friends in the health care community, they are still struggling with getting the right protective gear, and part of it, it is all being controlled by FEMA, which might make a lot of sense, but we have to change how we do this.

I think all of us have learned that we cannot trust China. It is Communist China. We know now that they are our adversary, and I am very concerned that we do anything in the future that continues to rely on Communist China for any part of our protective gear or pharmaceuticals or anything, because we know they are not a reliable partner.

I think we have to figure out how to produce American goods and also have American companies ready to ramp up at the time that we have the next pandemic.

So I propose today—I have a bill called the "American-Made Protection for Healthcare Workers and First Responders Act," and basically what it requires is, whether it is through stockpile or whether it is through companies getting ready in America, but we build-up American capacity to take care of our first responders and deal with the next pandemic.

I just want to get your feedback on how important do you think it is to reduce our reliance on Communist China and how important it is to help make sure, whether it is through stockpile or whether it is through having American companies ready to ramp up, that we have American-made products ready for the next pandemic.

Mr. BUREL. Senator Scott, I appreciate your question. I think it is vitally important to our preparedness overall that we ensure as many of the products we need for essential health care be made in the United States so that we can control the supply chain better, so that we understand how to protect it better. We have done some work with the Health Industry Distributors Association to map locations of manufacturers, but we cannot reach back to active pharmaceutical ingredient manufacturers, for example, or some constituent components of devices because they are outside the United States.

I think that we need to have as much capability in the United States to do that as we possibly can. But we have to work with the private sector to understand what it is going to take to really bring that back to the United States, what they need, whether it is the longer-term contracts that have been mentioned before, which I also support, or anything else that we need to do to help encourage them to do that work with the Federal Government and for the public. I know they want to do that.

I would say to your comment about FEMA doing buying, I think FEMA can be a great partner for the SNS and anyone else, but as has been said previously, some of these are very unique items, and to try to buy the right things that are licensed and appropriate for use, I think HHS and SNS are best qualified to help direct that, and particularly to direct how we work with bringing manufacturing of those critical items back to the United States.

Thank you, sir.

Senator SCOTT. Thanks.

Mr. Gerstein and Ms. Gerberding, what do you think about stopping our reliance on Communist China and our inability to rely on them in the future and the importance of making sure it is American-made products?

Mr. GERSTEIN. Senator, I will start off. I certainly agree that we need to take a look at the supply chain and understand those critical elements, if you will, that are on the critical path to be able to have the capability that we need for a future pandemic. I would try to inject a dose of reality on a couple things. The way our supply chains have stood up with respect to things like active pharmaceutical ingredients, some of the PPE, these have been made through economic decisions that essentially have been turned over to industry, that is, those that are providing the health care. And so if those kinds of commitments are to be made, it is going to be more than just, putting out a pronouncement. It also has to do with looking at subsidizing the medical delivery industry to be able to incentivize them to want to be a provider, to bring the manufacturing back.

We should also recognize there are probably some elements that we are not all that keen to bring back if it can be done more cheaply and they are not on the critical path. So we need to figure out the critical path issues.

The other thing I would say is that, we do need to think about the international role in global public health, or in our national public health, said another way. So while there are frustrations with some of the ways in which China has gone about with transparency and such, we definitely need to continue to rely on a global system, and that was why I recommended in the fifth recommendation about trying to repair our relationships on the global public health stage.

Senator SCOTT. Ms. Gerberding.

Dr. GERBERDING. From the CSIS Commission perspective, I think we are trying to frame our health security in the same mental model that we use for other elements of our national security. And in that sense, I think we might want to have this same outlook on how we manage our critical pathway supply chain that we would if we were thinking about how we outfit our Department of Defense and our foot soldiers. If in that domain we would not want to be dependent on an international supply chain, I do not think we should be dependent on an international supply chain when it comes to protecting the health of Americans.

Senator SCOTT. That is a good way of thinking about it because, you are right, it is no different than buying supplies for our military and trying to keep our public safe. It is the same issue, and we should be thinking about it the exact same way.

Mr. Phelps, did you want to add anything?

Mr. PHELPS. Yes, let me add that I think that our reliance on the foreign supply chain caused a couple of different problems for us at the State and local level. We saw FEMA do something pretty innovative, bringing [inaudible] much less visibility on where PPE was going. In many cases [inaudible] hospitals or to counties, and that caused problems for us.

The other big problem, I think, is the quality of the actual equipment. It was very frustrating for us here in Oregon [inaudible] based on emergency use authorization, thousands of KN95 masks that we were told we could go ahead and purchase, only to be told at a later date those were no longer suitable for [inaudible]. The quality control is as big of an issue if not bigger than [inaudible] relying on [inaudible].

Senator SCOTT. Thank you.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator Scott. Senator Rosen.

OPENING STATEMENT OF SENATOR ROSEN

Senator ROSEN. Thank you, Mr. Chairman and Ranking Member, for bringing this important hearing here today. I want to thank all of our witnesses for their lifetime of hard work in this area, preparing and planning for emergencies, pandemics, disasters. It is hard work, it is good work, and we appreciate you there.

First, we were talking about the supply chain and Federal response. According to Johns Hopkins, the United States has now over 121,000 deaths from COVID–19. A recent data analysis shows that 70 to 99 percent of the deaths from the virus so far could have been prevented. However, there is still time to make a difference based on how we proceed.

As Dr. Fauci has recently said, we are still in the first wave, so with this in mind, we must continue to respond to this pandemic with urgency. Our response must be timely, targeted, and thoughtful because different parts of the country are experiencing the pandemic at different rates with varied timing. We can and we must protect lives and livelihoods, and we have to do better than we have done before.

It does require a strong national strategy and a process for delivering key supplies to all of our communities, and we should be constantly correcting our actions to be sure that we improve our response.

So I know we need to improve transparency in the supply chain. Of course, we are all going to recommend that. I believe we should have used greater use of the Defense Production Act (DPA) in our national response. But to Mr. Burel and Mr. Phelps, I want to talk about our rural areas. They have seen fewer cases of COVID–19 compared to urban areas, but they have felt a real impact of this pandemic. They have a huge scarcity of supplies. Access to care has been a challenge, especially for the more remote areas in my State of Nevada.

So what specific recommendations do you have on how we might improve responses for our rural areas' critical testing supplies, PPE? What changes might you recommend in the future? I guess, Mr. Burel, you can go first, then Mr. Phelps.

Mr. BUREL. Thank you, Senator. We have long recognized that there is a vast difference among the States and the localities in what their capabilities are to respond, how they are positioned in terms of whether it be material assets or personnel assets to respond, both from a regular emergency management perspective or from a health care need. So I think that we need to continue to create better relationships, stronger ties with State and local government so that we understand better what some of those unique needs of those rural localities, for example, are.

So just as we might consider a dense urban populated area and how we need to respond to that differently, we need to think about the same thing for a rural area. I think that for the States to be able to establish stockpiles that are independent of the Federal Government, as many of them had some years ago to try to help supply those rural areas directly as we bring in more product, they have a better understanding. We recognize the States and the locals have a better understanding of what they need for support than the Federal Government does. If we position them to be better able to support themselves, I think that the response would be stronger in the rural areas.

Senator ROSEN. Thank you. I actually am going to—Senator Hassan has another call that she needs to be on, so I am going to yield the balance of my time to Senator Hassan, if everyone does not mind. Thank you.

OPENING STATEMENT OF SENATOR HASSAN

Senator HASSAN. Thank you so much. Thank you, Senator Rosen, so much for your graciousness and the Chair for accommodating my schedule, and to all of the panelists, thank you so much for your work in this area.

I wanted to ask a question first of Dr. Gerstein. Obviously, we have to improve the procurement and distribution of Strategic National Stockpile supplies during a pandemic. My State of New Hampshire, like so many others, struggled to get the basics. And when they did get supplies from the national stockpile, many items were unusable or they were expired. It is not enough to say that we have a stockpile. Our stockpile has to be sufficient, and it has to be up to date.

What best practices do you recommend that the Assistant Secretary for Preparedness and Response implement to ensure that the Strategic National Stockpile supplies are adequate but also that they are rotated and distributed before they expire?

Mr. GERSTEIN. Thanks for that question. Obviously, the rotation of stocks is a big deal. It is a very expensive process. The Federal Government is spending about $570 million a year to maintain the stockpile, which includes the rotation; it includes, moving things through and restocking where necessary.

I would also say that improving the stockpile is also going to come down to things like Dr. Gerberding talked about, and that is that last mile. It is about training the State and local. It is not that they just have a different focus at the State, local, tribal, territorial level. And, one of the things the Federal Government can do is to assist with the training on some of these very complex medical countermeasures, things like nerve agent antidotes and you heard

about the serum for botulinum neurotoxin. These kinds of training capacities need to be pushed from the Federal level down into the State, local, tribal, territorial.

One of the calls we had is we need—once we get it in position, once we get the stockpile the way we want, we need to exercise and stress test it hard to make sure it is doing what we think, and that all partners, all stakeholders can actually be confident with what has been developed. That is where I would be interested in seeing it go.

Senator HASSAN. Thank you for that answer.

One other question to Mr. Burel. The Strategic National Stockpile consists of a variety of items, some shelf-stable, some needing refrigeration, and most requiring regular rotation before they expire, as we just discussed. Does the SNS maintain a national database of every item in the stockpile, including condition, date of purchase, and expiration date?

Mr. BUREL. Senator, we do maintain that information in a national database that we rely on for the kind of product rotation we do. We also invest in assuring that we can extend life spans where it is chemically and scientifically proven that we can do that for particular drugs as long as possible to protect the Nation's investment.

The other thing that would help us is if we had the ability to, let us use the term, "sell off" stock as it nears its expiry and realize the income from selling off that stock so that we could invest it in new stock. Right now we do not have that option.

Senator HASSAN. Thank you for that answer. It kind of begs the question about why the administration has failed to provide a clear picture of disbursement and replenishment rates over the past 3 months. But I will take that up with them. I thank you for your service.

Thank you, Mr. Chair.

Chairman JOHNSON. Senator Lankford. Then it will be Hawley and Romney.

OPENING STATEMENT OF SENATOR LANKFORD

Senator LANKFORD. Thank you, Chairman.

Let me pick up on what Senator Hassan was just talking about on expiration, because that is an issue that needs to be resolved long term.

Mr. Burel, you just mentioned before about the authority to be able to sell off. There are really two philosophies here. As you have talked about frequently, this is not a big warehouse that would just store things. At this point it is not that kind of structure. Selling off things is one way to do this. Managing the stockpile in another location, that is, with the producers, that they actually manage it at spots, and they do a regular rotation to be able to move out is another way to do it. Are you trying to determine what is the right way to be able to do this, have it, own it, and then be able to ship it out once it gets close to expiration so they can sell it before it is lost, be replenished, or to be able to maintain it in other locations and there is a normal turn there?

Mr. BUREL. Senator, we already engage in what you describe. We call it "vendor-managed inventory." The problem is much of the

material that we hold we hold in so great a quantity that the market cannot absorb the rotation of that material on a regular basis. We have to hold those large quantities to protect the United States, and as we discuss a pandemic, it seems like we need even larger quantities of some things.

I think that there is a lot of logic in using vendor-managed inventory where it makes economic sense, and we have actually done a lot of work in the Strategic National Stockpile when I was there to do economic analysis of where that vendor-managed inventory works well and saves the government money versus the government owning it itself and then trying to dispose of it in some other way.

Senator LANKFORD. So you are saying you need legislation for those resources that we own that we could sell before expiration?

Mr. BUREL. We need legislation that would allow us to sell off product before it expires, but also to realize the income and have it not go back to the general fund so that we can use that to buy replacement for that product or to buy the next generation of product in that line or to buy whatever else the stockpile needs that day.

Senator LANKFORD. All right. I think it is a reasonable request, and I think it is something our Committee should be able to work on as a result of this hearing. Do you have text that you are proposing on that, or it is just an idea that you propose?

Mr. BUREL. Thank you, sir. I have proposed text previously, and I will send that to you under separate cover.

Senator LANKFORD. Great. Thank you. We appreciate that very much.

How do we avoid the pendulum swing that is always inevitable, that the Strategic National Stockpile is not just about a virus pandemic naturally occurring? Obviously, there are a lot of other issues, chemical attacks and other things that we focus in on. The natural pendulum swing here is, hey, we were not ready for this, and so let us do whatever we can and take our eye off the ball in other areas. What are we doing to be able to turn and say let us be strategic in all areas, not just overcompensate for one?

Mr. BUREL. Sir, I think that again is an excellent question. We get concerned about that, and we have always been concerned about not having enough money to cover the entire waterfront of known threats, including pandemics.

I would suggest that we consider making the Strategic National Stockpile or the successor organization whatever we think we need to do here, mandatorily funded at a minimum level to be able to manage and rotate current requirements at the time that that mandatory appropriation is set. I think that we can continue to grow the stockpile beyond that. I think there are a number of things that could contribute to that, whether it is additional supplemental appropriations as new requirements are identified that cannot be covered in a mandatory appropriation, whether it may be, for example, setting up a capability for the stockpile to receive donations from philanthropic organizations, to reinvest the sales authority I spoke to before, and so on.

Senator LANKFORD. We talked before about supply chain, and that is a very significant issue for all of us in this. I have seen

some for our military, for instance, where it is not just the manufacturer of the parts of the plane, whatever it may be, the product. It is the products that go into that product obviously getting in the supply chain. And you asked the question, who actually manufactures, the manufacturers, and start working your way back to be able to identify it. I would hope that there is a process in place already like that that you all are working through. It is not just who is the contractor, who is the subcontractor, and who is the subcontractor to the sub.

We talked before about precursor chemicals for pharmaceuticals. That is the most obvious issue at this point, because obviously we are very dependent on Communist China for a lot of the precursor chemicals. It may be the pharmaceuticals from there, but the chemicals that go into the pharmaceuticals are from there. It may not be the product, but the rare earth mineral that goes into that product is 60 to 90 percent from Communist China, so all of those areas.

How in-depth are you going as you are actually pursuing the supply chain?

Mr. BUREL. Senator, this is something that we have struggled with over years, but we are trying to make inroads in this area in just the last several years, in fact. Much of that supply chain beyond that precedes that finished product is extremely opaque to the Federal Government and to the Strategic National Stockpile in particular. We understand that many private firms want to closely hold the information about their ultimate supply chain all the way back to the earliest item in that constituent product, but we have to understand better what that comes from, because only then would we be able to say to you we are particularly concerned about this product because the only active pharmaceutical ingredient availability comes from China or some other location, and we are concerned that we may not be able to get it.

We would need your help to allow the Strategic National Stockpile to reach into FDA for data that they hold and to possibly even ask for additional data around things like what is the API source of all these critical products, but with the authority to insist that we get that data. I know that that is concerning to the private sector.

Senator LANKFORD. So do you believe you or the organization should house them should track that? Or should there be someone else that actually manages that supply chain and delivers it to you?

Mr. BUREL. I think the SNS could do that work, but it is going to have to be expanded to do that kind of work. One of the reasons I think it is well placed under the Assistant Secretary for Preparedness and Response is it can work across that organization with BARDA who knows about the products they are buying, maybe in more depth than we do commercially available products, and with the critical infrastructure protection group that already exists in the ASPR, maybe combining that in some way with the SNS to figure out how best to understand that supply chain, all the way back to the earliest precursor product or finished good.

Senator LANKFORD. I would hope that we could do that, and let us start to work on authorities to be able to break down barriers,

trying to get access to that information. I appreciate how many times you have all talked about local entities have to be prepared. We found for the PPE that a lot of hospitals and clinics and such had only days' supplies there. They also were not prepared for this, and there was a wide assumption that they would be able to get PPE when they needed it. That proved not to be true. So we are grateful for what you are doing and also helping local entities be better prepared for the next time as well.

Thank you.

Chairman JOHNSON. Senator Hawley.

OPENING STATEMENT OF SENATOR HAWLEY

Senator HAWLEY. Thank you, Mr. Chairman. And thanks to all of the witnesses for being here.

Mr. Burel, can I start with you? I want to ask, if I could, a couple of questions about stockpile levels and replenishment after the H1N1 pandemic in the late 2000s. You wrote about this in your testimony about some of the factors that affected replenishment following the 2009 outbreak.

I have seen reports that the H1N1 pandemic drew down 100 million masks, including N95 respirators, from the stockpile. Is that right? Do I have those figures right?

Mr. BUREL. Senator, I no longer have access to that exact data, but I believe that your numbers are approximately correct.

Senator HAWLEY. It is also my understanding that a federally sponsored H1N1 task force recommended replenishing those masks in that supply. Is that your understanding?

Mr. BUREL. Yes, sir.

Senator HAWLEY. Do you have any idea why those task force recommendations were not acted upon?

Mr. BUREL. It is a matter of available appropriations to make those purchases. All of the purchases made for H1N1 were made with supplemental funding authority that we were provided to prepare for a pandemic. That funding, after we used those products, was never reauthorized. We never received funding to do that again, so we closely guarded what we had available in the event that it needed to be used again. We need more funds to be able to address the CBRN threats as well as emerging infectious disease threats.

Senator HAWLEY. Let me ask you more about the funding. Back in 2012, I believe it was, the HHS Secretary at the time, Kathleen Sebelius, was asked to explain the rationale for why the administration, President Obama's administration, was proposing cutting $48 million out of the stockpile funding. This was at a House Appropriations Committee hearing, and she responded that resources ought to be focused on replacing expiring countermeasures such as anthrax treatments, which I think we would probably all agree are very vital. I am just wondering if you think enough attention was being paid to restocking PPE at that time. And did you ever get the sense that when it came to the stockpile, in the balance of things PPE was really being prioritized?

Mr. BUREL. Sir, what we tried to do is prioritize the best that we can do across threat levels based on available funds. We looked to the PHEMCE that I mentioned earlier to help us make those

priorities. A reality is many of the drugs we need for those CBRN events would never be produced and would stop being available if we did not invest in those. Unfortunately, when we do that, that leaves limited funds available for many of these expected to be commercially available items like PPE.

So to your question, I think that we have to prioritize both in some way, but the problem is the funds do not support being able to do that. If we give up buying CBRN drugs, they will not be made. But we also see we need more of the commercially available products.

Senator HAWLEY. In your view, what should have been done differently following the H1N1 pandemic to adequately restock the stockpile, particularly when it comes to these vital PPE that we have been in such short supply of?

Mr. BUREL. Sir, I believe that we should have had available funding so that we could buy what we used and replace that, and maybe that is something we need to think about legislatively such that every time product is deployed from the SNS, there would be an automatic fund for replenishing that.

I also think that we never achieve the full amount of product to be prepared for a complex pandemic such as we face with COVID to build the stock to the place it should have been for pandemic influenza even. So there were additional funds needed then.

Senator HAWLEY. Very good. Thank you for that. I think clearly as we look back, I mean, there is a lot we can learn from this recent experience. But as we look back about choices that were made in the past, we arrived at the present crisis clearly at a deficit. I think we have got to take steps to make sure that that does not happen again, particularly with something as basic as PPE, which was not adequately provided for in the stockpile, and that is a big problem.

Dr. Gerberding, let me switch to you, if I could. I would like to discuss a little bit more the dual role that SNS currently plays in our crisis response. I know the Chairman and some of my colleagues have raised issues about the stockpile's mission, and you have been discussing that. But let us talk about it just a little bit more. You write in your testimony that we need an effective balance in the stockpile's dual mission, and you have discussed that that covers both public health threats and biological, chemical, radiological, and nuclear threats. Can you just elaborate a little bit more on what you think that effective balance is and given the resource constraints that Mr. Burel and I were just discussing?

Dr. GERBERDING. Thank you, Senator. I used the expression "the tail wagging the dog," and I just think when you listen to Greg's testimony, he is basically saying the same thing. We have a finite budget, and so we build the stockpile to utilize the budget, but we do not necessarily build the stockpile to address the threats that, implicit or explicit, are on the table in part of the planning scenario. So, the history of the stockpile has flexed between one point of view and another, but I think always in the background the intent was to be assured that the stockpile was able to handle the all-hazards or CBRN threats. As Greg said, that is an area where, if we did not invest Federal dollars in those countermeasures, we would not have those countermeasures. And we are not done yet.

Ideally, in my point of view, the thinking about those bioterrorism—or, excuse me, terrorism threats, the all-hazard threats, we need to be thinking not what is the countermeasure for this but, really, what can we do to take this threat off the table. And that mentality is not afforded by the current budget approach that we have to the Strategic National Stockpile.

But we have revealed how vulnerable we are to those kinds of threats. I do not think the terror threat is any less today than it was in 2001 when we were dealing with anthrax.

Senator HAWLEY. In your experience, Doctor, when you think about the role that SNS plays, public health, bioterrorism, has one of those typically been given priority over the other in your observation?

Dr. GERBERDING. Independent of the Strategic National Stockpile alone, I think broadly speaking we fight the last war. So we have an anthrax attack, so we make sure that will not happen again. Then we have a severe acute respiratory syndrome (SARS), so then we go to SARS. And we are constantly responding appropriately to what we needed to learn from the last problem we had, but we do not consistently forge ahead in the prospective sense to assure that we are broadening our preparedness, not just adjusting to what we missed last time.

Senator HAWLEY. What do you think of the idea of creating a separate stockpile just for the procuring and deployment of PPE in a disease outbreak?

Dr. GERBERDING. I do not think that would really help things because what PPE and disease outbreak materials are necessary would largely depend on the nature of the specifics of the biological threat, so it is really hard to draw a dividing line. And the capabilities and the planning and exercising for that are going to apply to a much broader set of issues. So I think by segmenting that out, you would create a redundancy, and to some extent there is an overlap between the PPE you need for COVID and the PPE you need for an anthrax attack. So it is hard to separate them.

Senator HAWLEY. But given the fact that PPE was not prioritized after the last major pandemic and we entered this crisis at a very significant deficit, which it took us quite some time to recover from, and given your testimony and Mr. Burel's about the often lack of available funds to do everything that you would like to do, wouldn't creating a separate authorization and funding stream be something that is useful?

Dr. GERBERDING. It is always worth looking into. I do want to emphasize, however, that the PPE bottleneck is a supply constraint, and in order to improve the availability of those materials, we really have to create the capacity in the market for us to tolerate an inventory. And right now those products are commoditized, and they are purchased really just in time in most health care settings. They do not keep a large inventory because they count on the availability of the turnover. So when suddenly there is a surge in demand, there is no pipeline of product to flow into it. So the stockpile really has to create the bubble in the system.

That will not be efficient, as Greg has pointed out, because those materials will be at risk for expiry. But if we are trying to build a stockpile for efficiency, we have already lost the battle.

Senator HAWLEY. Very good. I see my time has expired. We will follow up with some additional questions for you in written form.

Thank you very much, Mr. Chairman.

Chairman JOHNSON. Senator Sinema.

OPENING STATEMENT OF SENATOR SINEMA

Senator SINEMA. Thank you, Chairman Johnson, and thank you, Ranking Member Peters, for this important discussion. I want to thank our witnesses for joining us today to discuss the Strategic National Stockpile and its role as part of the Coronavirus response.

As you all are aware, Arizona is a growing hot spot. The number of confirmed cases, positive test rates, and hospitalizations have increased dramatically since the end of the State's stay-at-home orders in the middle of May. We have lacked sufficient supplies of personal protective equipment, which has stunted our testing capacity since the pandemic first started and, of course, significantly contributed to our State's current dangerous situation.

Arizona still ranks in the bottom quartile of States for testing numbers, according to data from Johns Hopkins University. That leads me to my first question for Dr. Burel and Mr. Phelps. When we realized that State and local supplies of personal protective equipment and allocations from the stockpile would be grossly inadequate for Arizona's coronavirus response, I moved to help our local manufacturers switch their production lines to making PPE. I was inspired by the dozens of local businesses and manufacturers in Arizona that shifted or retooled their production and manufacturing capabilities and began producing face shields, masks, gowns, hand sanitizer, and other needed PPE. These are companies like AmSafe in Phoenix, WL Gore in Flagstaff, TYR Tactical in Peoria, ClickTech in Scottsdale.

Our breweries and distilleries began producing hand sanitizer and donating them to food banks, first responders, and local businesses. Arizona State University and entrepreneurs like the Van Hook Dental Studio in Tempe have used their 3D printers to help produce the nasal swabs and the face shields needed to stand up community testing sites.

So my question is: How do we make it easier for the stockpile as well as State, local, and tribal governments to partner with these types of domestic suppliers who step up during a crisis but do not normally produce these items in the regular course of business?

Mr. BUREL. Thank you for your question. I was the recipient of several questions from small business that wanted to try to help, and many of those wanted to try to do it in more of a philanthropic way than anything else. They knew that they had capabilities to make something else, and they wanted to be able to donate those for us where they were best needed.

So one of the things that we need to do is we need to continue the ongoing outreach from the Strategic National Stockpile to private sector partners. Maybe we need to think about how to widen

that audience from that health care marketplace that we normally talk to, that we have talked to very frequently, to other businesses.

Another thing that would be helpful is I have been able to watch over the years the CDC Foundation support the CDC in its mission. So to provide for the Strategic National Stockpile to have an outlet, a capability to work with a foundation dedicated to the Strategic National Stockpile, to help look for those philanthropic new capabilities and so on, and bring those to bear through the stockpile or directly to States and locals when they need them I think would be useful as well.

Mr. PHELPS. Senator, from my perspective here in Oregon, we were overwhelmed in a positive way with the outpouring of support and innovation from our private sector partners. We saw, as you saw in Arizona, a lot of distilleries producing hand sanitizer. We saw our athletic manufacturing companies producing face masks. A lot of this equipment was not meant necessarily for medical use but for individual citizens to use as face coverings and some of those individual protective measures.

I think we can empower and make it a little bit easier for these private sector partners to integrate into the system. We stood up a website very early on that allowed manufacturers to indicate to us what they could offer, and we would do outreach to those manufacturers to plug them into our system and incorporate them into our distribution effort.

Ultimately, though, in a State like Oregon with over 4 million people, it was a drop in the bucket, quite frankly, and we really rely on those mass producers of quality medical grade equipment to protect our first responders. But I will say that the private sector and the resources they brought to bear certainly had an impact on limiting the spread, the community spread here in the State of Oregon.

The other issue with a lot of these requests to assist, it forced a lot of time in tracking down whether or not it was a viable resource. Everyone seemed to have a cousin who knew someone who could produce or procure N95 masks, and that was an inordinate amount of time to track those down, vet those requests, and make sure that we were getting the resources that would ultimately help protect our medical front-line workers.

Senator SINEMA. Thank you.

I am going to move on to my next question for Dr. Gerberding and Dr. Burel. The initial allocation from the Strategic National Stockpile was based on population size, and there were additional supplies of personal protective equipment and ventilators going to States with the highest level of need. That hurt us in Arizona because our lack of testing made our caseload appear artificially low at the beginning of the coronavirus.

What recommendations do you have on how the stockpile and other Federal resources can establish a better allocation process that is more fair and equitable and takes into account testing and consistencies, which, of course, are likely to be present in any pandemic-type situation?

Dr. GERBERDING. Thank you. I will just start. I think there is a situational dependence here because, obviously, in this case the pandemic did not roll out simultaneously around the United States

and was initially at least concentrated in certain places that had higher needs and whose health systems were very overwhelmed. But I do think that is an opportunity where advance planning and exercising could be extremely informative.

I looked at Arizona. I know something about the population demographics in your State, and you and I have talked about that. So, it would not surprise me at all that there would be a fairly high need for personal protective equipment in Arizona, and I think that is something that in the process of planning ahead for this kind of situation, that need could have been better recognized and would have been a factor that could have been better considered in the allocation process.

Mr. BUREL. I agree with Dr. Gerberding. It is very situationally dependent. One of the things that we had at the Strategic National Stockpile when I initially became Director was a strong tie to public health emergency preparedness at the State level and, to a certain extent, even at the local level.

Unfortunately, the decision was made that that would better reside in another part of CDC's organization. At that time the SNS lost its direct tie to the States and to the localities. I think that we need to reestablish those. At the time that we did that work, we used a tool called the "Technical Assistance Review" to really understand what the demographics were, what they would really need, and how we could better do allocation in the event of this type of a concern.

Senator SINEMA. Thank you.

Mr. Chairman, I see my time has expired. Thank you.

Chairman JOHNSON. Thank you, Senator Sinema.

Again, I just want to thank all of our witnesses. I think this has been, first of all, an incredibly important hearing, but also a very informative one. I cannot thank you enough. I really want to work with a number of you moving forward on this incredibly complex issue. I think we need to emphasize how complex this problem truly is, which is why I emphasized from the very beginning we need to articulate exactly what the national stockpile needs to accomplish, what those capabilities are, what the responsibilities are between local, State, and the Federal Government. So it starts there, and then you start—once we have that established, then you start really dealing with the complexity.

So, again, thank you for your participation, and I look forward to working with you in the future on this, as well as my colleagues not only on this Committee but also within the Senate.

The record will remain open for 15 days until July 9 at 5 p.m. for the submission of statements and questions for the record. This hearing is adjourned.

[Whereupon, at 11:49 a.m., the Committee was adjourned.]

APPENDIX

Opening Statement for Chairman Ron Johnson
The Role of the Strategic National Stockpile in Pandemic Response
Wednesday, June 24, 2020

As prepared for delivery:

COVID-19 continues to inflict a terrible human and economic toll on the United States. In just over five months, the U.S. has experienced over 120,000 deaths and over 2 million total infections, and tens of millions have lost their jobs. As Congress reviews our response to COVID-19, it is important to take the lessons we have learned during this crisis to better prepare for a pandemic or other biological event of this scale in the future.

The focus of today's hearing is the Strategic National Stockpile (SNS). First established with a $51 million appropriation in 1998 as the National Pharmaceutical Stockpile, the SNS was codified in 2002 and obtained its current name with an expanded mission in 2003. Over the years, management responsibility for the SNS has changed between different agencies within HHS and DHS.

In developing a plan for the committee's oversight of the federal government's response to the Coronavirus, the role of SNS was an obvious area of interest. I had assumed that staff would be able to quickly obtain the list of items that should be held, together with the required and actual inventory levels of each item. Once again, I learned that it is dangerous to assume. We quickly found out that those lists do not exist, or certainly are not made available to Congress or the public.

As we will hear in testimony, it's not from a lack of dedicated individuals working within the agencies or with the SNS. Instead, it seems to be a more pervasive problem of a lack of clarity and understanding of exactly what the SNS's role is and what it should be. As indicated above, to the extent there has been a congressional or executive branch articulated mission statement, it has evolved over time, and outside the managing department or agency, it has not been generally understood.

We are paying the price for this lack of articulation and clarity during the current pandemic. The frustration expressed by state, local, tribal and territorial governments and their elected representatives is largely caused by the reality that demand for so many of the needed products and supplies has dramatically exceeded the supply - both in the form of available inventory and production capacity.

As a manufacturer in the private sector, whenever I was faced with a new problem, I always asked what opportunity presented itself in finding a solution. The same dynamic can apply here. As the men and women working tirelessly to address the current demand develop data and models, that information needs to be captured and put to immediate use updating and redesigning the structure and management of the SNS.

I'd like to thank our witnesses today for their testimony, their past efforts, and any future help they can provide to improve our nation's response to future pandemics.

U.S. Senate Committee on Homeland Security and Governmental Affairs
"The Role of the Strategic National Stockpile in Pandemic Response"

OPENING STATEMENT OF RANKING MEMBER GARY C. PETERS
June 24, 2020
AS PREPARED FOR DELIVERY

Thank you, Mr. Chairman, and thank you to our witnesses for being here today.

Over the past several months, the United States has faced an almost unprecedented challenge, fighting a deadly virus that has infected millions and taken the lives of more than 120,000 Americans.

A pandemic can overwhelm even the most prepared communities.

That is why we have the Strategic National Stockpile, the nation's largest store of lifesaving pharmaceuticals and medical supplies, to ensure the federal government has the resources to help states protect the health and safety of Americans during public health emergencies.

But the scale of the Coronavirus pandemic depleted our national stockpile in just a matter of weeks, leaving state and local governments scrambling to acquire the masks, gloves, and other supplies they so desperately needed to keep people safe.

Many communities facing the highest rates of infection struggled to obtain the supplies they needed, including in my home state of Michigan.

Instead of providing a coordinated, national approach that effectively used the Strategic National Stockpile and other tools to acquire and distribute supplies nationwide, the President told states that they were on their own. That move forced states to compete against each other and the federal government for lifesaving medical supplies that were already in shortage around the world.

Since this crisis began, Congress has passed several supplemental emergency appropriations bills to rebuild the stockpile. While this funding will help provide some stability, there is no question that our nation would have been better positioned to tackle the pandemic if Congress and both the current and prior Administrations had invested more in the stockpile before crisis struck.

It is abundantly clear that the federal government was not fully prepared to address a crisis on the scale of the Coronavirus pandemic. And the result is the tragic loss of 120,000 of our fellow Americans, and millions of families who have suffered the consequences.

Ensuring the preparedness of the Strategic National Stockpile is an issue of national security and should be treated as such. We cannot allow a disaster of this magnitude to catch our government off guard again. We must provide steady funding to all pandemic response efforts and also ensure the Strategic National Stockpile is well maintained and prepared to address a broad range of possible threats.

We must improve the communication between states and the federal government regarding available resources and strengthen the federal government's role in managing supplies during this and future crises.

Finally, we must also take steps to address our overreliance on foreign manufacturers of critical drugs and medical supplies.

This is a serious national security vulnerability. And the pandemic has only further highlighted just how significant this risk is to the health and safety of the American people.

Today's discussion will help us identity and prioritize critical decisions and investments to ensure we can continue to combat the Coronavirus as well as emergencies of the future. I look forward to hearing from all of you and to working alongside you to address these daunting challenges. Thank you.

CSIS | CENTER FOR STRATEGIC & INTERNATIONAL STUDIES

Statement before the

Senate Committee on Homeland Security and Governmental Affairs

"The Role of the Strategic National Stockpile in Pandemic Response."

A Testimony by:

Julie Gerberding

Co-Chair, CSIS Commission on Strengthening America's Health Security

June 24, 2020

Remote Hearing

Chairman Johnson, Ranking Member Peters, and distinguished members of the Committee, thank you for the opportunity to appear today. The topic of the Strategic National Stockpile (SNS) could not be more timely: its mission, the maintenance of its inventory, and the effective management of its relationships with industry and state, local, tribal and territorial authorities. Thank you for your leadership in this critical area.

The SNS is a critical asset in our nation's readiness against health security threats from both infectious outbreaks and deliberate bioterror attacks. I saw that first hand in my seven years as Director of the Centers for Disease Control and Prevention. In that period, I also had the pleasure of working closely with Greg Burel, who directed the stockpile for twelve years. I am delighted that he is joining us here today.

In the face of an unprecedented public health crisis like the coronavirus, we have seen the SNS deliver some promising innovations but at the same time discovered areas where there is room for improvement. I believe the time is now to systematically examine how to best strengthen the SNS performance to be the most effective, efficient, and responsive during a pandemic. The COVID-19 pandemic provides us an opportunity to make pragmatic changes; we must act now to avoid becoming complacent and finding ourselves in the same position when the next pandemic occurs.

For the past two years, I have co-chaired with former Senator Kelly Ayotte the Center for Strategic International Studies (CSIS) Commission on Strengthening America's Health Security. Members of Congress on the Commission include: Senators Murray and Young, and Representatives Bera, Brooks, Cole, and Eshoo, in addition to several security experts. In November 2019, the Commission released a report entitled, *Ending the Cycle of Crisis and Complacency*. The report lays out several key steps that the Administration and Congress should take to create a sustainable foundation for strengthening the health security of Americans.

These recommendations include:

- Establishing permanent leadership at the National Security Council to guarantee effective oversight of global health security and biodefense policy and spending;
- Long-term financing of capacity-building among low income partner countries;
- Enhanced commitments to accelerate new vaccines, therapies, and diagnostics;
- Greater operational capability to execute in disordered settings around the world; and
- More aggressive efforts to combat disinformation and promote better communications that are science and evidence-based.

I would like to request your consent to submit the full *Ending the Cycle of Crisis and Complacency* report into the Congressional Record.

Recognizing the unforeseen challenges to America's health security that the coronavirus pandemic has revealed, we have committed to extend the work of the Commission through 2022. We have begun discussions to determine the priorities for this next phase. The Commission's work thus far has acknowledged the importance of the SNS but has not made it a major focus of

our analytic work. However, as the Commission's work advances, we would welcome the opportunity to collaborate further with the Committee on examining additional actions needed to strengthen the stockpile.

For today's discussion, I would like to highlight a few select points.

First, it is important to reaffirm a clear vision of what constitutes success for the stockpile and the essential factors needed to achieve that success. I believe the essential elements should include:

- A truly strategic approach that is forward looking, tied explicitly to evolving U.S. national interests, preemptive, and agile in its ongoing adaptation. We should not build a stockpile based on previous pandemics but rather build a stockpile that anticipates what a future pandemic will likely require. This will require science and some imagination.
- An effective balance in the stockpile's dual mission of addressing public health and biodefense threats.
- A deep commitment to serve its partners at the state, local, tribal, and territorial levels.
- Robust, long-term financing that meets true needs and adequately plans for regular replenishment.
- Special attention to the needs of vulnerable and marginalized populations. The pandemic and the resulting economic crisis have reinforced that racial and ethnic minority groups, individuals living in poverty, the elderly, and those with underlying health conditions bear a disproportionate burden of risk and suffering. These considerations need to be built into our policy approaches to address future pandemics, including ensuring that changes to the SNS help solve the critical needs of these special populations.
- Collaborative relationships with private industry that are based on transparency and accountability, so that the innovation within the private sector can be leveraged to its fullest potential in the development of medical countermeasures that often lack strong commercial market incentives.
- Continuous assessment and review of strategy, performance, and priorities.

Second, it is essential to clarify the core mission of the SNS. In April, the Administration defined the SNS's mission as a supplement to the action taken by states and local governments – a stop-gap measure only in case of need beyond those immediate actions. I believe the original mission – which envisioned the SNS as a lead national mechanism charged with strategically anticipating and answering the needs of states and localities across the full range of public health emergencies – must be restored.

One stark lesson from our experience with the coronavirus crisis thus far is the acute fragility of U.S. supply chains. This was seen in the availability of diagnostic tests, reagents, personal protective equipment, ventilators, and oxygen. I believe that when states and local governments are left to fend for themselves when supplies are scarce, in an uncoordinated way, it can lead to a chaotic free-for-all in the marketplace that is not efficient when time is of the essence. Having

the SNS strategically coordinating the fast-breaking needs of its partners can stabilize markets, ensure accountability, and effectively address hot spots and other urgent priority areas.

Third, as we learned in the CSIS Commission's work on the oversight of international health security programs, it is essential to have clear lines of responsibility and authority. This is one area where, I believe, more work can and should be done with respect to the SNS. It is unclear who exactly controls the stockpile, as well as the precise chain of command for its use. Resolving these issues are fundamental to executing a clear vision. Congress can contribute to achieving this clarity by conducting an open and thorough examination of these questions.

Fourth, we need to take full account of the many innovations happening in the face of the coronavirus pandemic, and better understand how the SNS can make optimal use of them. I was impressed by the recent report of the Ad hoc Pandemic Response Group, which highlighted the need to focus on the accelerated speed of manufacturing, the conversions underway of private and public spaces, the reuse of medical items, and the repurposing of manufacturing. Americans have risen to the challenges of acute scarcities in highly creative ways that have revealed options we have not imagined.

Finally, the government must prepare the SNS capacity aggressively and rapidly for the challenges that lie just over the horizon – namely, the threat of a second coronavirus wave later this year, and the arrival (we hope) of safe and effective vaccines and medicines.

Chairman Johnson, Ranking Member Peters, and distinguished members of the Committee, the health security needs of the U.S. are formidable and complicated, but the SNS is a critical part of fulfilling those needs. We must rely on the lessons from this historical moment to design an approach to improving the SNS that takes advantage of the opportunities for positive change that lie in front of us. We need to remain pragmatic and focused on what are truly important issues for the future safety and health of Americans. Again, thank you for the opportunity to testify here today, and it is my sincere hope that we can work closely together to advance the U.S. health security agenda.

Testimony

The Strategic National Stockpile and COVID-19

Rethinking the Stockpile

Daniel M. Gerstein

CT-A530-1
Testimony presented before the Senate Committee on Homeland Security and Governmental Affairs on June 24, 2020.



For more information on this publication, visit www.rand.org/pubs/testimonies/CTA530-1.html

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The Strategic National Stockpile and COVID-19

Testimony of Daniel M. Gerstein[1]
The RAND Corporation[2]

Before the Committee on Homeland Security and Governmental Affairs
United States Senate

June 24, 2020

Good afternoon, Chairman Johnson, Ranking Member Peters, and distinguished members of the committee. I thank you for the opportunity to testify today regarding the Strategic National Stockpile (SNS). I will focus my remarks on the role of the stockpile during pandemics, concentrating on the parts that the federal government and state, local, tribal, and territorial (SLTT) governments play in responding to pandemics and how the SNS supports their efforts. I will also provide recommendations for rethinking our national stockpiling capabilities for future biological events, including pandemics.

Introduction

COVID-19 has exposed serious weaknesses in our national preparedness for and response to a global pandemic. The global tally of confirmed cases and deaths from the novel coronavirus—the severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2—continues to grow, and the disease continues to spread to previously uninfected parts of the globe. COVID-19 has spread to over 210 countries and territories, causing over eight million confirmed cases and almost a half-million deaths worldwide, yet the progression of the disease shows little sign that the worst is over.

In the United States, we have had over two million confirmed cases and over 120,000 deaths to date,[3] which is considerably less than was projected had nonpharmaceutical interventions (including social distancing; home quarantine; closures of schools, universities, and businesses;

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[1] The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

[2] The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

[3] Worldometer, "COVID-19 Coronavirus Pandemic," webpage, updated June 18, 2020, https://www.worldometers.info/coronavirus/.

and case isolation) not been put in place. These measures, although slow to be implemented, flattened the curve of viral spread.

Early estimates from studies done by the Imperial College of London estimated the United States could suffer 2.2 million deaths,[4] while the U.S. Centers for Disease Control and Prevention (CDC) estimated 200,000 to 1.7 million deaths, assuming no interventions.[5] Still, the most recent estimates have U.S. coronavirus deaths rising to nearly 150,000 by early August.[6] These totals do not include "excess deaths" during this pandemic that are likely to further increase associated COVID-19 mortality.[7]

Despite these assessments, the federal response has been slow and inconsistent and has deservedly become a target of criticism, especially regarding critical equipment and supplies. One former senior emergency management coordinator for the City of Chicago summed up the federal response, stating, "Let's be clear: The federal government has failed. If we maintain the status quo, the cavalry is not coming. Pandemic prevention efforts were ineffective. Pandemic preparedness efforts were ineffective. Pandemic coordination efforts were ineffective."[8]

Although the old adage claims "all disasters are local," preparedness and response consist of a series of nested systems designed to support local authorities when their capabilities become overwhelmed. The SNS is a critical part of that support. To this end, the Public Health Service Act has authorized the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to maintain a stockpile of drugs, vaccines, and other medical products and supplies (known as the SNS) to provide for the emergency health security of the United States and its territories.[9]

With respect to the COVID-19 response, understanding the SNS's history provides an important point of departure. In addition, SNS support has been negatively affected by several key issues that occurred pre-COVID-19 and during the response. They include unrealistic

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[4] Sabine L. van Elsland and Ryan O'Hare, "COVID-19: Imperial Researchers Model Likely Impact of Public Health Measures," Imperial College London, March 17, 2020, https://www.imperial.ac.uk/news/196234/Covid19-imperial-researchers-model-likely-impact.

[5] Sheri Fink, "Worst-Case Estimates for U.S. Coronavirus Deaths," *New York Times*, March 13, 2020, https://www.nytimes.com/2020/03/13/us/coronavirus-deaths-estimate.html.

Josh Katz, Margot Sanger-Katz, and Kevin Quealy, "Could Coronavirus Cause as Many Deaths as Cancer in the U.S.? Putting Estimates in Context," *New York Times*, March 16, 2020, https://www.nytimes.com/interactive/2020/03/16/upshot/coronavirus-best-worst-death-toll-scenario.html

[6] Joseph Guzman, "US Coronavirus Deaths Could Rise to Nearly 150,000 by Early August, According to Leading Computer Model," *The Hill*, June 9, 2020, https://thehill.com/changing-america/resilience/natural-disasters/501804-us-covid-19-deaths-could-surpass-145000-by.

[7] *Excess deaths* are typically defined as the difference between the observed numbers of deaths during specific periods and expected numbers of deaths during the same periods. From CDC, "Excess Deaths Associated with COVID-19," webpage, updated June 17, 2020, https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm.

[8] Thomas Henkey, "Perspective: It Is Not Too Late to Get the Coronavirus Response Right," *Homeland Security Today*, April 1, 2020, https://www.hstoday.us/subject-matter-areas/emergency-preparedness/perspective-it-is-not-too-late-to-get-the-coronavirus-response-right/.

[9] Association of State and Territorial Health Officials, "Emergency Use Authorization Toolkit: Strategic National Stockpile," webpage, accessed June 11, 2020, https://astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-Authorization-Toolkit/Strategic-National-Stockpile-Fact-Sheet/.

expectations for the SNS, historical underfunding of the stockpile, lack of timely decisions regarding energizing supply chains, and the federal government's altering of the mission of the SNS during this national emergency.

The History of the Strategic National Stockpile

The history of the SNS dates to 1998, when President William J. Clinton signed into law authorization for a national pharmaceutical stockpile (NPS). The U.S. Congress appropriated $51 million for pharmaceutical and vaccine stockpiles that were to be established under the CDC and within the Department of Health and Human Services (HHS).[10] Understanding the roots of the SNS is very important to understanding the response to the COVID-19 pandemic.

In fact, the rapid establishment of the NPS was in response to President Clinton's growing interest in bioterror preparedness and response. As former HHS Secretary Donna Shalala, now Congresswoman Shalala, said at the first National Symposium on Medical and Public Health Response to Bioterrorism in February 1999, "We are creating, and will be maintaining, an unprecedented national stockpile of drugs and vaccines for civilian use in case of a bioterrorist attack."[11] This early history is critical because it established the mission for the SNS as being related to bioterrorism.

The 2001 anthrax attacks, allegedly perpetrated by a scientist working at an Army disease research lab, reinforced concerns about bioterrorism and resulted in a series of Homeland Security Presidential Directives related to bioterrorism. The so-called Amerithrax attacks sickened 17 and killed five, reinforcing the case that a stockpile to be used in the event of a bioterrorism event was necessary to bolster our national biodefenses. In fact, the NPS was used in response to the Amerithrax attacks.

One of the measures undertaken during the George W. Bush administration in March 2003 was renaming the NPS to the SNS. The SNS is stored in climate-controlled facilities and has been geographically dispersed to allow for rapid deployment in the event of an emergency. Over time, the contents of the SNS have been expanded, as have the stockpile's uses. Specifically, the new SNS was expanded from "drugs and vaccines" to a stockpile of antibiotics, vaccines, antitoxins, chemical antidotes, and other medical supplies.

The original bioterror mission has been expanded and now includes preparedness and response for chemical, biological, radiological, and nuclear (CBRN) threats; pandemic influenza; and natural disasters, such as hurricanes and earthquakes. The SNS has antiflu drugs, generic medical supplies (such as ventilators, personal protective equipment [PPE] and needles), and

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[10] Public Law 105–277, Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, October 21, 1998, https://www.govinfo.gov/content/pkg/PLAW-105publ277/pdf/PLAW-105publ277.pdf.

[11] Olivia B. Waxman, "Coronavirus Is Putting the U.S. Strategic National Stockpile to the Test. Here's the Surprising Story Behind the Stash," *Time*, March 11, 2020, https://time.com/5800393/coronavirus-national-stockpile-history/.

even rapidly deployable medical centers complete with beds.[12] Portions of the SNS deployed to Hurricanes Katrina and Rita in 2005, were used for the 2009 H1N1 influenza outbreak, and were available for use during the 2014 Ebola response in the United States.

Decisions about which medicines and material should be included in the SNS are made by the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). This governing body coordinates federal efforts to enhance CBRN and emerging infectious diseases preparedness from a medical countermeasure (MCM) perspective.[13]

The PHEMCE is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes the following HHS internal agency partners: the CDC, the Food and Drug Administration, and the National Institutes of Health (NIH). It also includes several interagency partners: the Department of Defense, the Department of Veterans Affairs, the Department of Homeland Security (DHS), and the Department of Agriculture.[14] DHS uses the integrated CBRN risk assessment models, formerly run by the Science and Technology Directorate and now under the Countering Weapons of Mass Destruction Office, to develop material threat determinations (MTDs) for CBRN-related risks. These determinations signal the need for MCMs for these threats. The DHS Secretary issues the MTD, and the requirement is forwarded to the HHS and PHEMCE for action.

In the case of an emergency, state governors can request deployment of the SNS, but the federal government ultimately makes the determination to release the stockpile. During exercises, scenarios are developed that cause the SLTT capacity to become overwhelmed and therefore lead to a request for SNS support. These exercises train the SLTT participants in the procedures for requesting SNS support and require federal authorities to determine whether and how to support the requested deployments.

This process played out in the initial phases of the COVID-19 response as SLTT health systems became overwhelmed and states began requesting supplies. However, COVID-19 presented an unusual set of circumstances involving nearly simultaneous requests from all 56 SLTT authorities. The quantities of material in the stockpile were not nearly enough to fill all of the requests, resulting in a heated competition. More on this will be discussed later because it is important to considering the future of the SNS.

The overwhelming number of requests highlighted four shortfalls regarding the stockpile: (1) unrealistic expectations for the SNS, (2) the historical underfunding of the stockpile and SLTT public health preparedness, (3) a lack of timely decisions regarding energizing supply chains, and (4) the federal government's altering of the mission of the SNS during the national emergency.

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[12] Nell Greenfieldboyce, "Why Even a Huge Medical Stockpile Will Be of Limited Use Against COVID-19," *National Public Radio*, March 14, 2020, https://www.npr.org/sections/health-shots/2020/03/14/814121891/why-even-a-huge-medical-stockpile-will-be-of-limited-use-against-covid-19.

[13] HHS, ASPR, "Public Health Emergency Medical Countermeasures Enterprise," webpage, accessed June 12, 2020, https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx.

[14] HHS, ASPR, 2020.

Unrealistic Expectations for the Strategic National Stockpile

The original rationale for the SNS stemmed from bioterrorism preparedness and response. Over time, the mission expanded to include CBRN threats, emerging infectious diseases, and natural disasters. As the mission changed, the types of materials the SNS was charged with stockpiling also changed to include a variety of countermeasures against CBRN threats, as well as general MCMs, such as antivirals and antibiotics, that would have use against naturally occurring biological pathogens (such as the COVID-19 virus), nuclear accidents, natural disasters, and CBRN terrorist events.

Stockpiling supplies is only part of the process. Procedures must be developed and exercised for dispensing the material. Distributing portions of the SNS throughout the United States cuts down on transportation times. However, moving the supplies from these regional sites to the "last mile" (i.e., to where they are needed) and then knowing how to employ the materials has been a longstanding challenge. For example, in 2016, some users of the SNS material at the SLTT levels did not have adequate training in the use of the countermeasures and equipment.[15] To address this concern, one assessment offered the following recommendation: "The SNS should not only deliver MCMs to local public health authorities, but also support local-level dispensation efforts, provide clinical guidance about the use of MCMs, and implement the appropriate systems to monitor treatment compliance during adverse events."[16]

Another challenge inherent to the growth in missions has been stockpiling of materials with little thought on the practicalities of how that countermeasure would be used. For example, the SNS had 300 million doses of smallpox vaccines, which would be enough for almost the entire country. However, that is not the likely way that response to a smallpox attack would be handled. The vaccine often causes side effects, is not recommended for either children under two or their parents and cannot be given to immunocompromised individuals. Therefore, it is more likely that a ring vaccination technique that relies on contact tracing and vaccinating only those who have been exposed would be the more likely option for use of the vaccine. In fact, this was how humankind eliminated smallpox as a naturally occurring disease in the late 1970s.[17]

Although large-scale events were often considered in discussions about the SNS, these discussions did not account for the realities of such events. The scenarios were often geographically limited in exercises. For example, in addressing response to an improvised nuclear device, the exercise would look at a single device being exploded in a major city. Exercises that saw all 56 states, territories, and the District of Columbia affected simultaneously (or nearly simultaneously) were not played out to conclusion, meaning that the effects of the rapid depletion of SNS supplies were not fully played out. Most exercises dealing with pandemic influenza were tabletop exercises that did not exercise the last mile.

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[15] National Academies of Sciences, Engineering, and Medicine, *The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary*, Washington, D.C.: National Academies Press, 2016, p. 6.

[16] National Academies of Sciences, Engineering, and Medicine, 2016, p.6.

[17] World Health Organization, "Smallpox," webpage, undated, https://www.who.int/csr/disease/smallpox/en/.

This is not to say that those who developed and maintained the SNS were unaware of the shortcomings, but these same understandings and expectations were not necessarily held by the SLTT governments, which were depending on federal support from the SNS. In reference to the stockpile capacity, the 2016 National Academies of Sciences, Engineering, and Medicine chairperson of a study of the SNS concluded, "It's never going to be as big as you want, because it's just too expensive to do that."[18] In fact, the SNS provides a nearly immediate capacity for rapid response to emergencies but should be considered a bridge that allows private sector manufacturers to ramp up their production.[19] Unfortunately, during the COVID-19 response, this ramping up was slow in coming. Even today, supplies for testing and PPE remain in short supply and certainly constitute less than is required.

Historical Underfunding of the Stockpile and SLTT Public Health Preparedness

The stockpile contains approximately $8 billion worth of supplies and requires rotation of stocks to ensure they remain current. The annual budget is approximately $575 million.[20] However, neither the stockage levels nor funding were ever considered to be adequate for large-scale biological events, certainly not ones that affected all 56 states, territories, and the District of Columbia simultaneously. One former director of the stockpile cited several challenges to maintaining the stockpile, including limited funds, costly treatments that are not mass-manufactured because the afflictions are so rare, and treatments with short shelf lives. The director of the stockpile for more than a decade (before retiring in January 2020) said, "The stockpile was never intended to meet every need.[21] Of note, the 2020 SNS budget has been raised to $705 million.

Congressional underfunding of the SNS has also resulted in shortages in the stockpile. Congressionally ordered budget cuts resulted in some of the stocks that were used during the 2009 H1N1 response not being replenished (most notably, 85 million N-95 masks).[22]

Shortfalls in resources for state and local public health departments have also resulted in underperformance during the COVID-19 response. State and local public health departments have been under-resourced for decades, with one analysis indicating that 52 health agencies (48 states, three territories, and the District of Columbia) had reported budget cuts from 2008 to

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[18] Greenfieldboyce, 2020.

[19] Greenfieldboyce, 2020.

[20] Donovan Slack and Dinah Voyles Pulver, "US Never Spent Enough on Emergency Stockpile, Former Managers Say," *USA Today*, March 27, 2020, https://www.usatoday.com/story/news/investigations/2020/03/27/u-s-never-spent-enough-emergency-stockpile-former-managers-say/2915567001/.

[21] Slack and Voyles Pulver, 2020.

[22] Jane C. Timm, "Fact Check: Trump Falsely Claims Obama Left Him 'Nothing' in the National Stockpile," *NBC News*, May 6, 2020, https://www.nbcnews.com/politics/donald-trump/fact-check-trump-falsely-claims-obama-left-him-nothing-national-n1201406.

2014.[23] The Trump administration's fiscal year 2020 budget proposal would have further exacerbated the issue, calling for significant reductions to the CDC and NIH, which would have received 12 percent and 10 percent reductions, respectively.[24] Of note, these same state and local public health professionals are charged with conducting contact tracing, which is vital to biosurveillance and, ultimately, to halting the spread of the disease and getting people back to work and the economy restarted.

Expecting individual SLTT authorities to resource and maintain large stockpiles of specialized CBRN supplies or the quantities of material that would be required for large-scale events (such as the COVID-19 pandemic) would be unrealistic. In many cases, they lack understanding of the threats, and they lack technical capacity and resources to develop and maintain such a stockpile capability. The requirements would be exacerbated, given the large number of scenarios they would need to prepare for.

The response to COVID-19 at the SLTT level—in particular, the competition for supplies—was also affected by decisions made at the federal level. The HHS is designated as the sector-specific lead agency for the health care and public health sector for all emergencies, including a pandemic. Initially, Secretary of Health and Human Services Alex Azar was in charge of the response. However, the president putting Vice President Mike Pence in charge of the response represented a change in doctrine.

In standing up the White House Coronavirus Task Force on January 29, the president essentially disconnected some of the relationships that were needed to handle routine issues associated with disaster response and recovery. Many of these relationships ran down into state public health offices, which were in charge of the COVID-19 response in their respective states. Not relying on doctrine at the federal level has caused confusion at the state and local level as well. The effect was to reduce emergency management professionals' roles in the decisionmaking and to hinder the ability of the normal information and supply chains to function.

As a result, almost 220 years of U.S. emergency management experience going back to 1803 got a makeover during the COVID-19 response.[25] The notion that preparedness and response consist of a series of nested systems designed to support state and local authorities when their capabilities become overwhelmed was no longer the central organizing construct for this response. Furthermore, it was no longer the process that had been planned and exercised for decades: "The locals execute, the states coordinate, and the feds support." The federal government had created a "parallel response apparatus."[26]

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[23] Association of State and Territorial Health Officials, "Budget Cuts Continue to Affect the Health of Americans," September 2014, https://www.astho.org/budget-cuts-Sept-2014.

[24] Kim Krisberg, "President's Budget Would Hinder US Public Health Progress: Huge Cuts Proposed," *The Nation's Health*, Vol. 49, No. 3, May 2019.

[25] FEMA P-592, Stafford Act, as Amended, and Related Authorities, May 2019, https://www.fema.gov/media-library-data/1582133514823-be4368438bd042e3b60f5cec6b377d17/Stafford_June_2019_508.pdf.

[26] Joel Rose, "A 'War' for Medical Supplies: States Say FEMA Wins by Poaching Orders," *National Public Radio*, April 15, 2020, https://www.npr.org/2020/04/15/835308133/governors-say-fema-is-outbidding-redirecting-or-poaching-their-medical-supply-or.

Lack of Timely Decisions Regarding Energizing Supply Chains

Response to a large-scale event requires making timely decisions according to the emerging situation. It implies having situational awareness, effective communications across the federal government and SLTT governments, coordination and partnership with the private sector for providing key supplies and services, and regular, clear, and accurate strategic communications with citizens who must follow the guidance and direction. Shortfalls in these areas created confusion that prevented the timely emerging of critical supply chains.

Despite China's lack of initial transparency, initial reports of the virus were provided to the CDC by Chinese counterparts on January 3, 2020. U.S. intelligence agencies—which had been following events in China since late November—began regularly reporting on the coronavirus spread throughout January and into early February.[27] By mid-February, global examples of the virus transmissibility and virulence were evident, and a global competition was underway for masks, gowns, ventilators, and reagents and nasal swabs for test kits.

Despite this information, miscues—particularly at the federal level in the early stages—hindered mounting a coherent national response and rapidly energizing the capabilities that would be essential to understanding the progression of COVID-19. These shortfalls undoubtedly resulted in greater mortality and morbidity because they led to decisions that were some two to four weeks later than would have been useful to contain the spread of the disease in the United States in the early stages of the pandemic.[28]

During this early period, a failed CDC test that had to be recalled and mixed messaging contributed to inaction regarding activating our supply chains and manufacturing capacity. Without adequate testing, biosurveillance and contact tracing were not possible, requiring nonpharmaceutical interventions to prevent the further spread of the disease and attempt to flatten the curve. The federal response also failed to learn the lessons of nations such as South Korea that had been successful in containing the disease.[29]

Delays in declaring a national emergency (and waiting for the World Health Organization to declare the coronavirus outbreak a pandemic) meant that the Federal Emergency Management Agency (FEMA) was limited in its ability to begin preparations. FEMA efforts—largely triggered by the emergency declaration under the Stafford Act—began on March 13, 2020. By mid-April, a "war for medical supplies" was being waged, with one account stating that "FEMA wins by poaching orders."[30] In effect, there was a confused national response, and the different

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[27] Shane Harris, Greg Miller, Josh Dawsey, and Ellen Nakashima, "U.S. Intelligence Reports from January and February Warned About a Likely Pandemic," *Washington Post*, March 20, 2020, https://www.washingtonpost.com/national-security/us-intelligence-reports-from-january-and-february-warned-about-a-likely-pandemic/2020/03/20/299d8cda-6ad5-11ea-b5f1-a5a804158597_story.html.

[28] Daniel M. Gerstein, "The Federal Research Enterprise and COVID-19: A Lesson in Unpreparedness," testimony presented to the House Science, Space, and Technology Committee on May 5, 2020, Homeland Security Operational Analysis Center operated by the RAND Corporation, CT-A360-1, 2020, https://www.rand.org/pubs/testimonies/CTA360-1.html.

[29] Gerstein, 2020.

[30] Rose, 2020.

levels of the government (federal and SLTT) were competing against each other rather than collaborating.

The delay in understanding the urgency of the situation resulted in early failures to take advantage of opportunities to acquire critical supplies. Reports have surfaced that some manufacturers of PPE offered the federal government opportunities to ramp up production of key equipment but their overtures were rebuffed—with one vendor indicating that a senior member of the administration expressed "little immediate interest in the offer."[31]

Debates played out publicly about whether to invoke the Defense Production Act (DPA), which also delayed the decisionmaking at the federal level and resulted in lost time. One account summarizes the president's decision regarding the DPA as "Mr. Trump has elected to rely on the volunteerism of the private sector to obtain additional personal protective equipment, virus test kits and hospital equipment." This is curious because the DPA has been used hundreds of thousands of times by the Department of Defense and over a thousand times by DHS in 2018.[32]

The result of the supply chain mismanagement was critical shortages. One survey taken in April 2020 of 978 institutions, from 47 states and Washington, D.C., found that there were growing shortages of N-95 masks, surgical masks, face shields, booties, gloves, gowns, hand sanitizer, disinfecting wipes ,and thermometers. More than one-third of the institutions responded that they had no face shields, booties, or thermometers. Twenty percent had no N-95 masks or gowns remaining. Nearly all had no supplies remaining of at least one form of PPE.[33] Interestingly, a shipment was made to China in early February of 17 tons of donated U.S. masks and medical supplies that, only a few weeks later, would be in short supply for mounting the U.S. initial response.[34]

Federal Government's Altering of the Mission of the Strategic National Stockpile During the National Emergency

Emergency management in the United States is based on the understanding that all initial response is local. When local authorities no longer have the capacity to mount an effective response, states provide necessary support. When the state capacity is exhausted, federal support is requested by the states and invoked by the president through a Stafford Act declaration. The

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[31] Aaron C. Davis, "In the Early Days of the Pandemic, the U.S. Government Turned Down an Offer to Manufacture Millions of N95 Masks in America," *Washington Post*, May 9, 2020, https://www.washingtonpost.com/investigations/in-the-early-days-of-the-pandemic-the-us-government-turned-down-an-offer-to-manufacture-millions-of-n95-masks-in-america/2020/05/09/f76a821e-908a-11ea-a9c0-73b93422d691_story.html.

[32] Zolan Kanno-Youngs and Ana Swanson, "Wartime Production Law Has Been Used Routinely, but Not with Coronavirus," *New York Times*, March 31, 2020, https://www.nytimes.com/2020/03/31/us/politics/coronavirus-defense-production-act.html.

[33] Zoë Schlanger "Begging for Thermometers, Body Bags, and Gowns: U.S. Health Care Workers Are Dangerously Ill-Equipped to Fight COVID-19," *Time*, April 20, 2020, https://time.com/5823983/coronavirus-ppe-shortage/.

[34] Glenn Kessler, "Did Trump Ship 17 Tons of 'American' Masks and Medical Supplies to China?" *Washington Post*, April 22, 2020, https://www.washingtonpost.com/politics/2020/04/22/did-trump-ship-17-tons-american-masks-china/.

Stafford Act allows the president to declare a major disaster or emergency and provides access to the Disaster Relief Fund. The national emergency management system also has established doctrine for reporting information and making requests for support. The structure includes frameworks, critical functions, and training and exercises designed to test systems and ensure proficiency. An important part of the emergency management doctrine involves managing the logistics and supply chains that support the response. COVID-19 has exposed both the interconnectedness and the shortfalls of these global supply chains.

The state requests for access to the SNS proved to be overwhelming and resulted in a change to the mission statement of the SNS. This change created tensions regarding the 1988 Stafford Act, which describes the process for federal natural disaster assistance for state and local governments. Equally important is that this change upended established national emergency management doctrine that has been repeatedly exercised. This doctrine is embedded in the expectations for and management of the SNS.[35]

Since December 2018, the SNS mission on the HHS website was for the SNS to be available "when state, local, tribal, and territorial responders request federal assistance to support their response efforts" and to ensure the "right medicines and supplies get to those who need them most during an emergency."

Shortly after a statement made by Jared Kushner on April 2, 2020, the mission on the website was changed to indicate the SNS was intended to "supplement state and local supplies during public health emergencies" and noted that "many states have products stockpiled as well." The revised mission also stated that the SNS is intended to be "a short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available."[36]

The changes to the SNS mission had important implications for states that were depending on the SNS. The reformulation of the purpose of the SNS was not in keeping with the national emergency management doctrine—which focuses on the federal government supporting the states when their capacity is overrun—nor with the planning exercises that were conducted prior to the pandemic. Nor is such an approach practicable given the specialized countermeasures that are stocked in the SNS and the cost of maintaining the stockpile. Furthermore, given the significant underfunding of SLTT public health programs, building and maintaining their own stockpiles would also likely not be a high priority in competition with other public health priorities.

Rethinking the Strategic National Stockpile

The COVID-19 pandemic is highlighting the need to rethink the SNS. The combination of unrealistic expectations for the SNS, historical underfunding of the stockpile, lack of timely decisions regarding energizing supply chains, and the federal government's altering of the mission of the SNS during this national emergency signal that such an examination is in order. It

[35] FEMA P-592, 2019.

[36] Andrew Feinberg, "Strategic National Stockpile Website Changes After Jared Kushner's Controversial Claim It Was Not for States' Use," *Newsweek*, April 3, 2020, https://www.newsweek.com/strategic-national-stockpile-website-changes-after-jared-kushners-controversial-claim-it-was-not-1496051.

should include a consideration of how the stockpile is managed, provisioned, resourced, and accessed to ensure expectations are understood and realistic.

With the COVID-19 response, we are witnessing an inability to scale at the national level to meet the demands of a public health emergency. The United States relies on a "just in time" medical delivery system, which cannot provide the necessary PPE and specialized equipment (such as ventilators) required for a widespread naturally occurring pandemic such as COVID-19. The pandemic is also demonstrating the interconnectedness of the global supply chains, which source PPE and supplies, such as reagents for testing. In previous exercises dealing with public health emergencies, the answer has consistently been to request support from the SNS; yet, as COVID-19 demonstrates, this strategy might not be prudent. In 2018, the stockpile was transferred from the CDC to the ASPR within the HHS. Although the stockpile has a stated purpose that includes providing support during a pandemic response, the stockage levels and types of vaccines and therapeutics indicate a predisposition toward response to a bioterrorism event or a much smaller outbreak event, such as the 2014 Ebola response. Furthermore, some have expressed concern that this transfer from the CDC to ASPR could have played a role in the SNS issues experienced during COVID-19, as ASPR's Assistant Secretary Robert Kadlec shifted focus to "biologic attacks, intentional attacks, terrorist attacks, and definitely away from natural disease outbreaks."[37]

General equipment in the stockpile, such as PPE and ventilators, would be useful regardless of whether the incident is a pandemic or bioterrorism event, but the stockpile was not intended to have enough for supplying a national crisis of this magnitude.[38] The failure to replenish the SNS after previous biological incidents exacerbated the situation and left the stockpile with less than authorized stocks at the beginning of this pandemic.[39] The result of these shortages is that governors have to search on the open market to find needed supplies and the federal government has changed its definition of the stockpile's purpose midway through this pandemic.[40]

The National Security Council under President Obama, in coordination with other government organizations involved with pandemic response, developed a playbook in 2016 that provided a set of priorities and insights for managing a pandemic of this magnitude. It was developed because of the Obama administration's concerns about response to the 2014–2015 Ebola outbreak. Although the Trump administration was briefed about the playbook, it was not used for the COVID-19 response. The playbook covered many of the issues encountered during

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[37] Peter Weber, "Trump Official in Charge of National Stockpile Bet Big on Smallpox and Anthrax, Cut Infectious Disease Funds," *The Week*, May 5, 2020, https://theweek.com/speedreads/912735/trump-official-charge-national-stockpile-bet-big-smallpox-anthrax-cut-infectious-disease-funds.

[38] Lev Facher, "The Coronavirus Outbreak Has Left Medical Supplies in Short Supply. Is the Nation's Emergency Stockpile Ready to Help?" *STAT*, March 10, 2020, https://www.statnews.com/2020/03/10/coronavirus-strategic-national-stockpile.

[39] Doug Palmer, "U.S. Medical Stockpile Wasn't Built to Handle Current Crisis, Former Director Says," *Politico*, April 8, 2020, https://www.politico.com/news/2020/04/08/national-stockpile-coronavirus-crisis-175619.

[40] Nathaniel Weixel, "Trump Administration Changes Definition of National Stockpile After Kushner Remarks," *The Hill*, April 3, 2020.

the COVID-19 response, such as early actions in response to credible threats, use of emergency funds and the SNS, and the DPA.[41]

The complexity regarding developing, maintaining, and employing a stockpile means that SLTT governments will continue to depend on the federal government for much of their stockpiling. In addition, many of the MCMs and supplies cannot necessarily be developed in advance. Each biological pathogen is different, and specific diagnostics, therapeutics, and vaccines must be developed for each. For example, point-of-care diagnostics for use in a clinical setting to identify who is infected and serological tests to determine who has antibodies to COVID-19 must be developed using the genomic sequence of the pathogen to ensure specificity and sensitivity. We also need to be able to mass produce these diagnostics, therapeutics and vaccines at the speed of the disease.

Many lessons have been learned about the shortages in supplies, equipment, and services, including regarding the SNS. On June 9, 2020, this committee heard from a government panel in a hearing titled "Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic." Witnesses included Admiral Brett Giroir, Assistant Secretary for Health at HHS; Peter Gaynor, the FEMA Administrator; and Rear Admiral John Polowczyk, Vice Director for Logistics for the Joint Chiefs of Staff. The testimony included discussions of the challenges presented by this pandemic, with particular focus on obtaining supplies such as PPE and material for testing kits. The witnesses highlighted the global competition for these supplies and the inadequacy of the SNS for meeting these challenges.[42]

Concerning the supply chain challenges, Administrator Gaynor said, "FEMA typically manages abundant resources for disasters that are limited in geographic scope and impact. In responding to COVID-19, FEMA has had a much different and difficult task of managing the lack of critical medical supplies and equipment. Rather than managing resources, we are managing shortages."

The testimony also highlighted the innovations developed for responding to the pandemic. FEMA created a Supply Chain Stabilization Task Force and established an airbridge to "expedite critical supplies already purchased and owned by some of the nation's largest medical distributors with the goal of providing temporary relief through stabilizing supply chains."[43] FEMA also developed a data lake of information and used a health care supply chain tool from the Department of Defense to manage distribution of critical supplies. This was done in real time during the crisis. However, the amount of equipment obtained represented only a fraction of the critical needs. In addition, mixed messaging at the federal level regarding responsibility for

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[41] Dan Diamond and Nahal Toosi, "Trump Team Failed to Follow NSC's Pandemic Playbook," *Politico*, March 25, 2020, https://www.politico.com/news/2020/03/25/trump-coronavirus-national-security-council-149285.

[42] Senate Homeland Security and Governmental Affairs Committee, "Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic," June 9, 2020, https://www.hsgac.senate.gov/evaluating-the-federal-governments-procurement-and-distribution-strategies-in-response-to-the-covid-19-pandemic.

[43] On March 20, 2020, the Supply Chain Stabilization Task Force was established to address the widespread shortfalls amid the global competition for life-saving equipment. The task force consisted of over a dozen departments and agencies across the U.S. government and liaisons from the private sector.

acquiring test kits and conducting testing, the SNS purpose, and obtaining critical equipment shortages created unnecessary confusion, leaving SLTT authorities to fend for themselves. The new system, particularly the airbridge, has received considerable criticism: Although timelines for delivery appear to have been positively affected, it added to the supply chain confusion and has triggered allegations about FEMA poaching state procured supplies, a lack of oversight, and using taxpayer dollars while allowing private companies to benefit financially.

The global competition turned into a national competition among federal, state, local, tribal, and territorial authorities. As the inadequacy of the SNS became clearer, lower levels were left to fend for themselves, as in the case of Maryland's governor procuring a half-million test kits from South Korea.[44] This affected the Emergency Management Assistance Compact, which is the mutual aid agreement among states and territories of the United States.[45] Given the supply shortages, what should have been collaboration between states turned into a fierce competition for resources.

COVID-19 has also proved illuminating regarding global supply chains for essential pandemic supplies. Much of the material for the medical community comes from overseas markets. In early March, one account highlighted that the United States required 300 million respirators and face masks to protect health workers but that the SNS had less than 15 percent of this requirement. Additionally, the United States is the world's largest importer of pharmaceuticals and medical supplies from China, which manufactures some 50 percent of global totals.[46] Notably, Rear Admiral Polowczyk in his testimony spoke of needing to change this dynamic and said, "Using the Defense Production Act, we are creating investment across manufacturers in the U.S. to make domestic production equal to the surging COVID demand."

In short, the national supply system had failed, including the SNS, which failed to deliver as expected, even if those expectations were overhyped and perhaps even unrealistic. Even months into the response, shortages in PPE continue to be an issue.

Recommendations

The response to COVID-19 has exposed key shortfalls in our nation's preparedness and response capabilities. Going forward, the United States should undertake a comprehensive accounting of the COVID-19 pandemic by a bipartisan commission. Basic assumptions—including regarding the role of government at all levels in emergency management and disaster preparedness and response—should be on the table. Several DHS organizations, in addition to departments and agencies that have responsibilities as part of the PHEMCE, should be part of this discussion. The SNS should also feature prominently in these discussions.

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[44] Brakkton Booker, "Maryland Buys 500,000 Test Kits from South Korea, Drawing Criticism From Trump," *National Public Radio*, April 21, 2020, https://www.npr.org/sections/coronavirus-live-updates/2020/04/21/839919655/maryland-gets-500-000-test-kits-from-south-korea-drawing-criticism-from-trump.

[45] Emergency Management Assistance Compact, homepage, undated, https://emacweb.org/.

[46] Nsikan Akpan, "U.S. Has Only a Fraction of the Medical Supplies It Needs to Combat Coronavirus," *National Geographic*, March 3, 2020, https://www.nationalgeographic.com/science/2020/03/us-america-has-fraction-medical-supplies-it-needs-to-combat-coronavirus/.

To this end, I offer five recommendations that focus on the stockpiling, the supply chains, and the decisionmaking process and that should be considered for improving our nation's preparedness and response capabilities.

1. **Reexamine the SNS concept.** The COVID-19 response has exposed critical weaknesses in the SNS; has represented a significant departure from planning, doctrine, and exercises; has left the states, in particular, to fend for themselves; and has caused a loss of confidence in the federal government. The root causes of this underperformance should be evaluated, and actions should be taken to ensure such a deficit does not occur during future events. Specific actions should frame this reexamination. First, Congress could ask for a report evaluating the SNS's performance during COVID-19. Second, the mission of the SNS must be reconsidered. A new mission statement, codified in law and not subject to the whims of any administration, should be developed to signal the capacities and limits of the SNS. Third, the new stockpile concept must be stress-tested and optimized through training and exercises to ensure it meets the preparedness and response goals that have been set.
2. **Develop a strategic national supply chain approach.** Many have called for the United States to decouple manufacturing and supply chains and to develop an indigenous capacity for production of critical supplies and equipment, with some even calling for complete independence from the global market for such items. Although this might not be economically prudent, developing an approach for all critical items that combines stockpiling, direct contracting with manufacturers, warm production lines for some key commodities, procuring large quantities at the national level to take advantage of economies of scale, and shortening supply chains should be looked at to determine the most effective and most efficient methods for ensuring 100 percent of critical needs will be met for envisioned scenarios.[47] Using such an approach would require all critical equipment and supplies to be independently mapped out to allow for a determination of their anticipated availability over time. This approach would require inputs from key stakeholders, including government (federal and SLTT), industry, and the Emergency Support Function (ESF) #8 – Public Health and Medical Services sector.
3. **Increase public health funding.** Years of underfunding of SLTT public health programs should be reversed. Public health should be considered a national security issue and should receive similar priority in funding as the Department of Defense and Intelligence Community. These public health shortages affect preparedness and response for a wide variety of naturally occurring public health events, accidents and natural disasters, and deliberate attacks. For COVID-19, inadequate public health funding affected staff support to government leaders at all levels, biosurveillance activities (including contact tracing), stockpile shortages at the beginning of the pandemic, and broader supply chain issues. Public health shortages have also adversely affected the CDC and NIH. The lack of an operational capability that supports public health emergencies directly relates to shortfalls in public health funding as well. FEMA provides the management structure for all hazard response. ESF #8 represents a loose collection of public and private departments, agencies, and organizations for coordination but does not create a unity of effort in addressing public health emergencies. When considering the lessons learned, perhaps an

[47] Smartsheet, "Supply Chain Management 101: Principles, Examples, and Templates," webpage, undated, https://www.smartsheet.com/supply-chain-management.

important issue to be addressed is the utility of having the national capacity for a more operationally focused national public health enterprise.

4. **Develop the vaccine distribution system now.** An important part of the supply chain for this current pandemic will entail the distribution of a vaccine when it becomes available. Just as with the SNS, the last mile should be considered for vaccine distribution. Some have public health officials have claimed that a vaccine will be available by early 2021, but much remains to be done before a safe and effective vaccine is ready for widespread use: getting the science right, vaccine trials, production and distribution of the vaccines, and administering the vaccine at scale to populations. Given the time, expense, and regulatory requirements of vaccine development, global collaboration would speed up vaccine development, lead to more-rapid approvals, and help determine priorities for vaccine administration.[48] The U.S. government has committed to spending $1.2 billion to obtain 300 million doses of the Oxford vaccine that is in development.[49] This is encouraging, but planning should be ongoing now for administering a COVID-19 vaccine here in the United States and globally. Only after a large portion of the world is immunized will COVID-19 be controlled. Key questions remain: What will be the priority for vaccination? Who will pay for vaccination of the population in the United States (e.g., the government or individual) and globally (e.g., funded by individual nations or similar to PEPFAR[50])? Can a policy that requires individuals to pay the costs be successful? What happens to people who refuse vaccination?
5. **Reestablish U.S. leadership in global public health.** U.S. global leadership is needed now more than ever. International collaboration will continue to be important to understanding the spread of COVID-19 and developing key MCMs. This collaboration will also be important to preventing and managing new instances of the virus in developing countries and for vaccine trials. We should also seek to repair our relationship with the World Health Organization while working to make the organization more accountable. We need the World Health Organization to serve as a conduit for information and to coordinate with other nations as the COVID-19 disease spreads to other parts of the world and for future international health crises.

Conclusion

We should expect to see more pandemic events like COVID-19, given human activities that disrupt environmental habitats, promote the mixing of species, and allow humans and pathogens to crisscross the world along global supply chains. Efforts should be made now to address these events more effectively in the future.

Some have called the novel coronavirus a *black swan event*: an event that is unforeseen. I reject that characterization: We have had ample evidence of the potential for a global pandemic

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[48] Kari Oakes, "COVID-19 Vaccine Race a Balance of Safety and Speed," *Medscape*, April 20, 2020, https://www.medscape.com/viewarticle/929072#vp_2.

[49] Julie Steenhuysen, "Exclusive: U.S. Plans Massive Coronavirus Vaccine Testing Effort to Meet Year-End Deadline," Reuters, May 22, 2020, https://www.reuters.com/article/us-health-coronavirus-usa-vaccine-exclus/exclusive-us-plans-massive-coronavirus-vaccine-testing-effort-to-meet-year-end-deadline-idUSKBN22Y2L3.

[50] The U.S. President's Emergency Plan for AIDS Relief.

and, indeed, more than one national commission to advise on how to plan for one. However, competing priorities, inadequate funding, and a lack of national focus led us to ignore this potentially existential threat until it was too late. Underperformance has contributed to a lackluster national response, including failures in supply chains (and the SNS) that could not respond to the growing demands for critical equipment, supplies, and services.

Thank you again for the opportunity to appear today, and I look forward to your questions.

Mr. Andrew Phelps

Region X Vice President, National Emergency Management Association
Director, Oregon Office of Emergency Management

STATEMENT FOR THE RECORD
On behalf of the
National Emergency Management Association

Submitted to the Senate Committee on Homeland Security and Governmental Affairs

"The Role of the Strategic National Stockpile in Pandemic Response"

June 24, 2020

National Emergency Management Association
444 N Capitol Street, NW, Suite 401
Washington, D.C. 20001
202-624-5459

Thank you, Chairman Johnson, Ranking Member Peters, and distinguished members of the Committee for allowing me to testify before you today.

I am proud to testify today representing the National Emergency Management Association (NEMA). NEMA represents the state emergency management directors of all 50 states, territories, and the District of Columbia. As Director of the Oregon Office of Emergency Management and on behalf of my colleagues in state emergency management, we thank you for holding this discussion on the use of the Strategic National Stockpile (SNS) during the response to the COVID-19 pandemic.

Oregon represents 190 of the 122,000 COVID-19 deaths nationally, but each one has a profound effect on responders, state and national leadership, and me personally. Our heartfelt condolences go out to those currently diagnosed, recovering from, or bereaving the loss of a loved one during this pandemic.

THE NATION'S RESPONSE

To understand the challenges of the SNS during the response to COVID, we must first examine the evolution of the overall response. During the earliest days of the COVID response, the federal government designated the Department of Health and Human Services (HHS) in the lead role. Many states, on the other hand, opted for more diverse leadership by also giving prominent roles to emergency management, the National Guard, and other state agencies depending on their experience with prior emergency incidents. This led to confusing, conflicting, and incomplete information when state officials attempted to communicate with their federal counterparts.

The process took a dramatic turn on March 13, 2020, when the President utilized Section 501(b) of the Stafford Act to grant Emergency Declarations for all states and territories. Even in early statements by the administration, the intent behind this action was to increase "federal support to the Department of Health and Human Services (HHS) in its role as the lead federal agency for the ongoing COVID-19 pandemic response." The Stafford Act is intentionally flexible to give the President and states the maximum level of discretion in choosing the best combination of federal assets to help respond to a disaster. This action, however, unintentionally deepened the divide between state and federal governments. For a while, HHS remained in the lead federal role while states were now tapping into FEMA's far superior program flexibility and funding opportunities, but as questions arose from state emergency managers, the response from FEMA was often insufficient with referrals to HHS.

Less than a week later, the White House realized the impacts of this discordance and designated FEMA as the lead federal agency. This action helped coalesce the overall response and state/federal coordination. Regardless of how states managed the event to-date, there was now a clear line between the governor's office, state emergency management, and the host of potential FEMA programs.

On March 27, the President signed into law the CARES Act which made available trillions of dollars to aid state and local governments, stimulate the economy, and address the ongoing pandemic. While critical for injecting funds for state and local government response, there were challenges inherent in bringing online additional federal programs that may not normally operate in a disaster environment, including overlapping with the capabilities of existing FEMA programs or exacerbating a morass of

federal requirements and cost-share agreements. These changes to normal disaster funding processes caused accounting nightmares for state and local governments.

Significantly, the determination of cost-share adjustments remains an issue of indecision within the administration. In accepting the Emergency Declarations and subsequent Major Disaster Declarations, nearly every state requested an adjustment to the federal cost share required of FEMA programs from 75 percent to 90 or 100 percent. No state has yet received a response. Meanwhile, the Administration verbally agreed on a non-public conference call to allow the Coronavirus Relief Fund as a source to meet the 25 percent match. One month later, no agency has of yet produced guidance or official communication. This lack of confirmation is one of the primary reasons why the rate of spending against federal programs is not significantly higher. Few states are willing to take the risk of a negative audit against billions of dollars without specific guidance.

The decision on adjusting cost-share should be an easy one. Section 501(b) of the Stafford Act, which the President utilized in the initial declarations, is clear under which circumstances the President may unilaterally declare disasters, saving that authority for only when:

> *"…he determines that an emergency exists for which the primary responsibility for response rests with the United States because the emergency involves a subject area for which, under the Constitution or laws of the United States, the United States exercises exclusive or preeminent responsibility and authority." (Robert T. Stafford Disaster Relief and Emergency Assistance Act, Public Law 93—288, SEC. 501(b))*

Given this clear legislative language, the mere action of utilizing Section 501(b) placed responsibility with the federal government, and a decision on the cost-share adjustment should not be in question.

THE OREGON EXPERIENCE

Oregon's emergency management system, like most other states, is structured around the use of Emergency Support Functions (ESF). These functions leverage subject matter expertise, day-to-day operational capacity and the external relationships of our state agencies. We use the established organizational infrastructure to better position ourselves for emergency response. This allows for continuity across our all-hazards response and helps define roles and responsibilities as we prepare for disasters.

At the federal level, there are fifteen ESFs, each representing a specific functional area and with an assigned lead agency or agencies. Most states, including Oregon, utilized the expertise of ESF 8 which addresses Health and Medical requirements and is led by the Oregon Health Authority. As part of their assigned emergency support function within this structure, we rely on the Oregon Health Authority to maintain responsibility for SNS coordination via direct interface with the federal officials managing the SNS. In turn, Oregon's Public Health staff provide direct connections with local county and tribal health officials as well as their federal counterparts in their day to day work.

Additionally, we consolidated logistics functions to support all ESFs with resource management and distribution across the state. This ensures that subject matter experts remain focused on their core capabilities within the Oregon's emergency management system. In the case of COVID-19, our utilization of ESF-8 personnel helped Oregon's essential medical professionals received the crucial PPE they needed in a timely manner.

INTEGRATING THE SNS

The response to COVID-19 revealed that while the SNS originates in the Public Health field, utilizing the system must involve a broader stakeholder group. In working with my fellow state directors in developing this testimony, many states faced issues accessing the SNS. Successes and challenges, however, varied and seemed to be tied to the level of impact of the pandemic on each state.

Practice Did Not Meet Process. Based on federal guidance and requirements, states and municipalities have traditionally trained to rely on the SNS as the major supplier of resources in a public health emergency. Unfortunately, as the response to COVID-19 continued to escalate, we quickly learned the SNS resources were vastly insufficient. Originally designed to manage pharmaceutical distribution, the movement of masks, gloves, gowns, face shields, vents, and other supplies and equipment proved a daunting task. Furthermore, states had very little visibility into available caches.

As state and municipality pandemic emergency plans are predicated on SNS support in times of crisis, it is critical that there be more transparent support and engagement at the federal level with states on what they can (or cannot) expect and when in the event of incidents of varied escalation - local, state, regional, and national - to allow for improved expectations management and therefore partnership at all levels of government, as well as greater trust from the communities we serve that we can effectively support their public health needs.

Aggregation of Demand. Put simply, states generally did not receive items from the SNS that they needed, or if they did, it was in increments so small that it became insignificant or what was provided was past a functional expiration date. With limited information about the size of equipment caches or their expiration date, states faced further challenges regarding knowing how many PPE items they would need to procure on their own during the early stages of the response.

Some states even indicated they received more equipment through donations or the state-led Emergency Management Assistance Compact (EMAC) than from the SNS. Furthermore, while state officials may appreciate Emergency Use Authorizations (EUA), mid-stream changes to the EUAs and inconsistent guidance proved to be difficult to navigate during a crisis. This led to confusion for both PPE procurement and use of PPE by frontline healthcare professionals.

The Supply Chain. While some states indicated a successful flow of equipment to help bridge the gap of more supply being available, others noted a severe situation whereby the reliance on foreign manufacturing for critical supplies amounts to a national security issue. Large orders of PPE required a few states to charter aircraft to collect materials directly from China. Average delivery time on gowns for one state was 46 days.

Additionally, despite promises of inbound equipment and GPS tracking capabilities, states were often advised of delivery timelines that were not met. In some cases, state staff were called upon to wait at a warehouse for hours for shipments that did not arrive until the next day or even days later. On numerous occasions, supplies were shipped to the wrong locations. Other instances saw states expecting a specific number of "pallets" of equipment only to find one or two boxes on each pallet. Unfortunately, there were also circumstances where the wrong supplies were shipped to states or they were unusable.

Federal Engagement. As states were advised of depleted SNS quantities and that they should begin relying on FEMA to obtain further resources, confusion arose at the state level as they attempted to decipher FEMA versus SNS resources. Here again, the issue and confusion over cost-share became a significant factor as different funding sources had different cost share requirements. The SNS has no cost-share while FEMA funds requires a 25 percent cost share. Requests for 100 percent cost-share on FEMA programs remains unapproved.

As FEMA instituted "Project Airbridge," PPE and other resources started moving by air from the manufacturer to the six major suppliers with FEMA prioritizing the receipt of some of the PPE delivered to the COVID-19 hotspots leaving many states with orders not being filled. This eliminated the ability of state governments to prioritize based on actual need in their jurisdictions. Federal intervention into the procurement process forced states to vie with one another and other entities for limited resources. In essence, a costly and time-consuming bidding war emerged while the virus was at its peak in many states. Later in the process, the federal government did develop a plan to ship PPE directly to some facilities such as nursing homes, but in some cases, this occurred with little or no input from the state.

LIMITATIONS ON TRADITIONAL ASSISTANCE

To meet many of these challenges independently, states would typically utilize EMAC, which is implemented by the state emergency management agencies and allows for an efficient, effective, and coordinated response between states. Since Congress ratified Public Law 104—321 in 1996, EMAC grew to include all 50 states, the District of Columbia, the U.S. Virgin Islands, Puerto Rico, Guam, and the Commonwealth of the Northern Mariana Islands. Never before in the history of EMAC, however, has a single event occurred that affected every member state simultaneously.

During the response, some states were able to share ventilators, PPE, MREs and other resources with states suffering the greatest impacts from COVID-19. EMAC could also be leveraged by states to expand their health care capacity virtually across states lines through telehealth. Mutual aid response to COVID-19 has been somewhat limited as states have needed every resource in their inventory to take care of their own residents.

Early in the response, Oregon sent an incident management team to Washington State which returned with valuable lessons learned we implemented in our own fight against COVID-19. But in later missions, this type of assistance became impractical because states needed the resources themselves, there was a fear of exposing personnel to the virus, and those who deployed to assist other states would need to quarantine for fourteen days upon return.

Since 2016, nearly 30,000 personnel deployed through EMAC. States rely upon one another to fill resource shortfalls during disasters and emergencies. States are now turning their attention to planning for what is predicted to be a busy fire and hurricane season and developing specific guidance for how mutual aid will be safely implemented in a COVID-19 world.

RECOMMENDATIONS

The nation is still in a state of response, and a comprehensive after-action review process will need to integrate all participants of this event. But we do have enough experience and hindsight to begin shaping how the future of the SNS can better serve all customers:

1. **Understand Inventory and Demand.** Before worrying about what states have or maintain, the federal government should assess what they have and where shortfalls exist. States can then integrate these shortfalls into planning assumptions and preparedness actions.

2. **Sort Out the Supply Chain.** Manufacturing of PPE occurs almost exclusively outside the United States which means the supply chain can be compromised, be made of questionable quality, or be delayed to the point of uselessness. Instead of maintaining large stockpiles or an inventory of PPE which must be regularly rotated for efficacy, federal agencies should focus on issues such as supply chain metrics and standing agreements with manufacturers to help meet demand on short notice.

3. **Provide Visibility into the Process.** A secure online portal or other method could take the burden off federal staff and allow states to track their own shipments. Information could also be exchanged with traffic management centers across the country to help route deliveries when transportation infrastructure may be compromised. For example, SNS personnel at the regional level maintained strong lines of communication through a liaison on-site with state and local personnel. As the process dragged on, however, more communication went directly to local hospitals which prevented the state from adequately communicating additional statewide needs to federal partners.

4. **Defense Production Act.** In March of this year, the President signed an Executive Order invoking aspects of the Defense Production Act (DPA) which made available a broad set of authorities to influence domestic industry in the interest of national defense. While the DPA has previously been used with broad success, this invocation appeared to suffer some additional challenges with federal agencies unsure as to how best to coordinate the functions and utilize the Act to its fullest advantage.

5. **Restructure Allocations.** States should be encouraged to establish stockpiles to relieve some demand on the SNS. At a minimum, this should be done regionally, and when possible shared between states through EMAC. Additional discussion will need to occur to determine at what level of demand is reasonable or sustainable for the SNS. It may be useful to consider requiring that states have individual capacity to meet initial surge expectations, with the SNS providing

backup or sustainable capacity in the event of another protracted event like COVID-19. Furthermore, part of the SNS could be apportioned to each state, while leaving the balance to dynamically deploy to meet the most urgent needs nationally.

6. **Find Creative Funding Solutions.** The primary challenge to overcome in recommendations related to states assuming more responsibility for managing SNS caches will be the costs associated with obtaining and rotating equipment and the ability to maintain warehousing capabilities. Congress should resist the urge to require existing grant programs to lurch toward this latest issue and work with states in finding solutions that integrate federal assistance with state expertise and private sector capabilities.

CONCLUSION

Like most of the nation, Oregon remains in active response mode to COVID-19, but we have already begun applying valuable lessons learned in our processes. Cross-discipline and inter-jurisdictional agency partnerships remain crucial in completing our mission to ensure we have the PPE necessary to protect the public. These partnerships across public and private sector proved invaluable as we utilized federal, state, and private industry to strengthen and maintain our supply chain.

Overall, any failure in this system does not rest solely with the SNS. Conflicting information on procurement between the states and federal government on availability and prioritization led to utilization of the Defense Production Act and ultimately an unhelpful bidding war between the federal government and states with FEMA given priority by vendors. Challenges of "who's in charge?" of the response created broken communication chains and processes. The supply chain for PPE relies too heavily on foreign entities and lacks transparency to state emergency managers. Finally, there was a lack of expectations management for what the SNS could or could not do for officials trying to manage a complicated event within their state or community. Moving forward, addressing these interrelated issues will allow for a more sustainable and flexible response system through which states utilize the SNS efficiently in times of critical need.

Testimony of Gregory Burel
Committee on Homeland Security and Governmental Affairs
June 24, 2020

Chairman Johnson, Ranking Member Peters and members of the Committee, thank you for the opportunity to testify on the Role of the Strategic National Stockpile in Pandemic Response. I am honored to continue to support the mission of this critical organization by testifying today before your committee. I had the privilege of serving as Director of the Strategic National Stockpile or SNS, for almost 13 years. My long-planned retirement from Federal Service was effective on January 3rd of this year. I remain a Fellow of the National Academy of Public Administration and am President of Hamilton Grace LLC.

For more than 20 years, the SNS has been the nation's repository of medical countermeasures, both drugs and devices, to protect our health security. SNS is a highly capable organization but its utility for certain responses, such as those for a nationwide pandemic event, are constrained by a lack of funding. I hope my testimony can provide better context for understanding the SNS response to COVID-19 in full view of its limitations.

In 1999, when SNS was established as the National Pharmaceutical Stockpile the design was to develop inventory to respond to Chemical Biological Radiological and Nuclear or CBRN threats. By December of 2019, the inventory was valued at around $8 billion. SNS is more than its inventory and encompasses the skill and capability that support the unique needs of a civilian health and medical response. These unique and specialized capabilities of the SNS cannot be rapidly developed by some other organization in an event. While others can assist SNS, SNS must always manage the work of those providing assistance.

Over time, its highly specialized material and medical logistics capabilities became apparent, and it expanded to an all-hazards mission. All-hazards includes, among others, pandemic disease and natural events. Instead of 'mission creep', SNS experienced 'mission gallop'. Such a leap in expectation cannot occur, however, without commensurate increases in funding. Appropriations have not kept pace with the growing burden to expand inventory and capability to meet all hazards mission expectations.

SNS' inventory is its most visible component but as important are its capabilities to acquire, manage and distribute medical countermeasures to protect our nation's health security. There is no other federal department or agency more prepared and experienced in this field than the SNS. The dedicated federal and contract professionals are some of the best in the field of medical logistics.

SNS has vast experience in purchasing the correct, properly licensed, and effective drugs and devices to support any civilian health response. This ensures that funds are not unwisely invested in material that does not actually meet requirements. SNS material quality control is outstanding and always results in the most appropriate material being acquired and delivered for health and medical needs. In times of crisis, It is vital that the SNS is always the organization responsible for the purchase, either directly or through other agencies acting on its behalf. SNS uses many acquisition methods and procures products under several inventory management scenarios. We can be confident that the SNS experts will steer the federal family to buy the right things and get them to the right place at the right time all while assuring those products are managed in the most appropriate and cost effective manner. SNS can deploy inventory tailored to meet specific needs in many cases beginning within 4 to 6 hours of decision and completing deployment within 8 to 15 hours of decision.

SNS is uniquely qualified to address the large, usually regional threats, from the devastating impact of CBRN events. These same capabilities allow the SNS to be the best source of a response to other smaller regional outbreaks and national disasters that might require medical material intended for these threats but useful in other scenarios. The bottom line is that the capabilities of SNS to deploy its inventory are unmatched by any other organization.

The inventory of the SNS can save lives and greatly reduce illness caused by a variety of naturally occurring hazards, but again, preparing for and responding to CBRN threats has been its primary purpose. The specific threats are determined by the Department of Homeland Security and products to respond to these threats are determined by a robust, science-based governance process that brings together experts from across the executive branch.

SNS annually responds to a variety of illnesses that do not rise to the level of a national emergency, but that only its inventory can manage. Some of these involve a single patient and others involve a larger scale outbreak. As an example, a 2015 botulism outbreak in Ohio was far less deadly because the SNS mobilized to distribute a large quantity of antitoxin for those affected, many gravely ill. This antitoxin is available from no other source than the SNS.

Recent proposals questioning whether SNS should be moved to or its material and logistics be controlled by another department reflect a fundamentally flawed understanding of these issues and trouble me greatly. As part of ASPR, SNS is well integrated in the health and medical response framework and is ideally positioned to be supported by the science of all the operating divisions of HHS directly.

Statute requires a threat based annual review to drive decisions around funding which ultimately yields the available content of the SNS. This review is conducted under the auspices of the Public Health Emergency Management Countermeasures Enterprise (PHEMCE) governance process. PHEMCE is composed of experts in disease threats and other specialized medical and scientific areas and recommends the content to be held in SNS. Specialist groups make recommendations to an Executive Committee which provides final recommendations to a committee, including the highest ranks of the departments engaged in health and medical response. Led by the ASPR and including the Directors of CDC, NIH NIAID, and others, this body makes final decisions for the SNS formulary. PHEMCE experts use data from the required annual review in its regular work to determine the content requirements to meet contemporary needs.

Because available appropriations have been limited for the SNS, it is necessary to balance risk-based needs across threats to purchase the best mix of product. It is also notable that statute requires SNS prioritize products unavailable in the commercial market. Simply put, many things procured by the SNS, including the like the life-saving botulinum antitoxin deployed in the 2015 outbreak in Ohio, wouldn't be developed or manufactured otherwise because there is no or insufficient demand for the product outside of the Federal Government. Thus, it is important to remember that the SNS is the only source of a number of products that are often needed in healthcare, absent a declared disaster or emergency. SNS

has routinely deployed those products extremely rapidly, saving lives and reducing illness as a result.

In deciding what to hold in the SNS, the PHEMCE must consider matters such as:

1. If the government has invested in development of needed new MCM the SNS must continue to purchase them or we will lose access to the product and the investment of government funds for development will have been wasted;

2. Many products that have not been developed solely under government contracts are needed for CBRN defense but have no viable commercial market - meaning if the SNS does not invest in the continued manufacturing and delivery of those products, we will lose access to them;

3. General commercial availability of certain products and the capability of a normal supply chain to supply those products. That is to say, if the products needed for a specific event are normally available in the market, we would buy less of those products to assure that the material not available in the normal market yet vital for preparedness is not lost to the US.

Keeping the history and inventory requirements process in mind for context, We've all heard the disturbing accounts of brave doctors and nurses short on critical supplies treating COVID-19 patients at overcrowded hospitals. These initial shortages led to the logical question of why the United States was seemingly so unprepared for a pandemic. For many, there was an assumption that SNS should have been poised to immediately deliver everything needed, for all facets of a pandemic response. The truth is that, our lack of preparedness as a nation does not sit solely or predominantly with the SNS, but is instead the result of insufficient investment in public health at all levels of government. Our lack of capability to mount a swift, whole community response to such events also can be attributed to, among other things, limitations on manufacturing of important healthcare products in the United States. Finally, the SNS must rely on the very lean medical supply chain, optimized for the best value, but less than optimal for any crisis response.

As I have addressed already, the SNS was never envisioned to be the first stop in response to emerging infectious disease, particularly pandemics. The appropriations for SNS are far below a level that would enable it to be even close to a comprehensive source of every necessary supply in a pandemic.

SNS only began to invest in inventory to respond to pandemic influenza in response to special supplemental appropriations for that purpose in about 2006. In the early 2000s, Congress authorized funds for a minimal level of pandemic influenza supplies including PPE. Those items were largely depleted following a highly successful response to the 2009 H1N1 pandemic flu, and specific funds for replacement were never reauthorized. With no further appropriations to specifically restock and expand things such as PPE for a pandemic, SNS had little option but to carefully guard the remaining material and try to extend its usable life as best as possible. To that end, the SNS even commissioned a study by NIOSH to determine if this older, marked expired PPE was safe and effective for use. Ultimately, without increases in appropriations to rebuild, expand and maintain the old stock of pandemic influenza material the PHEMCE, was left with little recourse except to plan reliance on the commercial market for these commercial products, and focus on those that cannot be drawn from the market in an instant response to a CBRN event.

The SNS was designed to be just one piece of the public health preparedness puzzle. State, local, tribal and territorial or SLTT public health have a vital role to play. These levels of government are responsible for planning in their unique jurisdiction so that federal assets can be called upon when the options have run out, ideally enabling them to be more effective and efficient. However,t he capabilities of the SLTT can only respond effectively when they are built and maintained through proper funding.

Public health generally and preparedness specifically must be consistently and robustly funded at all levels of government. We have a long history of heavily investing in public health when it is clear there is a problem, but as we move away from those significant adverse events, and the public's memory fades, funds for public health often decrease as well.

Just after 9/11 there was a large federal investment through various grants and cooperative agreements to fund and support states, locals, tribes and territories to be prepared for the next public health crisis. At the same time, federal investment in grants and cooperative agreements to assure state and local preparedness were declining. Funds for every aspect of public health preparedness have declined and negatively impact planning, exercising, stockpiling and daily operations.

Prior to H1N1, many states were invested in their own stockpiles that the SNS could supplement and replenish. As available funds from both the federal and state government for public health investment began to decline, these state stockpiles were some of the first programs to be slashed. Thus, when it was time to respond to a pandemic disease, states did not have material on hand themselves to support their requirements until either the federal government or the operating market could provide more material.

Commercially, as medical supply chains have become more just in time oriented, uncommitted material stocks have become more and more lean or non-existent. It is difficult for the operating market to shift and provide massive quantities of material exceeding the normal operating requirements of healthcare for these types of events.

There is a need for more robust investment at the federal level, at the SLTT level and in the commercial sector to be prepared for the next pandemic. Among considerations to be evaluated, are whether there should be mandatory federal funding for public health annually, whether there should be federal support to increase on-shore manufacturing and stock of material for the next pandemic, and whether we really expect the SNS to be solely responsible for all health and medical response material. The way forward must incorporate elements of all these considerations, and include a stronger partnership between federal, SLTT and the commercial healthcare manufacturing and distribution sector.

It is for good reason that the SNS has been the envy of the preparedness experts all over the world. Its record of achievement in accomplishing its intended mission is nothing short of exemplary. If we now want this critical strategic asset to

surpass prior expectations, we must invest in it and expand its authorities accordingly.

Our national health security suffered a blow from COVID-19 and the threat is far from over. At the same time, additional deadly threats against our nation, many which can only be addressed by the SNS, have not diminished. Unfortunately, this pandemic has illustrated the high cost of not making the necessary investments in public health. We wouldn't expect the US military to go into battle with half of its firepower. And we cannot expect the SNS to arm our nation for success against an invisible, yet ruthless enemy without the necessary resources to do so.

United States Senate
WASHINGTON, DC 20510

June 24, 2020

The Honorable Ellen Lord
Under Secretary of Defense for Acquisition and Sustainment
United States Department of Defense
3010 Defense Pentagon Room 3E1010
Washington, DC 20301

Dear Under Secretary Lord:

Thank you for your efforts thus far to increase domestic manufacturing of personal protective equipment (PPE). As head of the new Joint Acquisition Task Force (JATF), we ask you to continue to prioritize the procurement of American-made PPE and pursue more comprehensive measures to incentivize the reshoring of additional PPE production back to the United States. We believe this can be done in three ways.

First, strong domestic content rules – such as the Berry Amendment – are a proven model for ensuring essential long-term investment in the PPE supply chain in the United States. Applying this domestic sourcing requirement to PPE purchases is critical to helping build a strong domestic supply chain now and into the foreseeable future.

While we were concerned to see the Defense Logistics Agency (DLA) issue a Domestic Non-Availability Determination (DNAD) — which provides the option to waive Berry Amendment requirements — for procurements over the next 90 days, we understand that DLA's immediate demand for hospital gowns and PPE may exceed the capacity of Berry Amendment-compliant U.S. producers. Yet, there are still U.S. companies who are able to produce PPE using varying amounts of American content. We believe DLA and the JATF must give priority consideration to all domestic offers to supply PPE product to the United States government.

Despite the DNAD, we believe that PPE, with value added in the United States should receive preference over entirely foreign-made PPE and urge in the contract review process that you reward those companies and workers in the United States to every extent possible. We were pleased that DLA recently amended the solicitation to take into consideration concerns raised by domestic producers by prioritizing Berry Amendment-compliant offers. We want to underscore the importance of ensuring that all DLA procurements encourage, rather than undercut, initiatives to develop a U.S.-based PPE supply chain.

To that end, we urge DLA to maximize all procurement of Berry Amendment-compliant hospital gowns and masks going forward. When Berry-compliant items are exhausted, we ask that you

maximize procurement of products that have the next-highest U.S. content level. We strongly urge you to give full preference to items made at least in part in the U.S. over those that are wholly made abroad. These orders are even more critical to the manufacturing sector at this time. Many domestic producers have submitted proposals with both full, or substantially, domestic production chains, and we urge the Department in this contract review process to give all these offers the fullest consideration possible.

Second, we must think long term. Unfortunately, the pandemic will not have ended after 90 days, and we know that our country must be prepared for similar crises in the future. In order to achieve that, the Task Force must send a strong, and consistent, demand signal to American industry so as to incentivize the re-shoring of PPE production to the United States. Supply chains that were created in a matter of days will disappear if we do not put the long-term structures in place that will help realize significant investment in the United States. Therefore, we urge the JATF to ensure any future PPE procurement includes long-term contracts and minimizes the use of DNADs. Applying such a strategic approach will provide U.S. producers sufficient time and certainty to expand existing production or bring new production online.

Third, the administration should use the full range of powerful authorities provided in the Defense Production Act (DPA) which it has already triggered to bolster American manufacturers' ability to produce urgently needed medical equipment and supplies. If the DPA loan and purchase authorities recently delegated to the International Development Finance Corporation prove effective for PPE re-shoring efforts, they should also be used to bolster such domestic capacity.

Made-in-America PPE is absolutely vital to the success of our pandemic response. We thank you for your leadership during this time of crisis and look forward to working with you to ensure the expansion of PPE manufacturing capacity in the United States of America.

Sincerely,

/s/Rob Portman
Rob Portman
United States Senator

/s/Sherrod Brown
Sherrod Brown
United States Senator

/s/Mike Braun
Mike Braun
United States Senator

/s/Michael F. Bennet
Michael F. Bennet
United States Senator

/s/Josh Hawley

Josh Hawley
United States Senator

/s/Christopher A. Coons

Christopher A. Coons
United States Senator

/s/Todd Young

Todd Young
United States Senator

/s/Lindsey O. Graham

Lindsey O. Graham
United States Senator

/s/John Cornyn

John Cornyn
United States Senator

/s/Debbie Stabenow

Debbie Stabenow
United States Senator

Post-Hearing Questions for the Record
Submitted to Dr. Julie Gerberding

U.S. Senate Homeland Security and Governmental Affairs Committee Hearing
"The Role of the Strategic National Stockpile in Pandemic Response"
June 24, 2020

From Senator Jacky Rosen

1. **Antibiotic resistance is a growing public health threat, as infections that were once treatable become more dangerous due to resistance to older antibiotics. As we lose viable treatment options, we must ensure new treatments are available, especially in times of public health crisis—like what we are currently facing today. We have seen some COVID-19 patients developing secondary bacterial infections, which can be deadly when resistant to standard antibiotics. Can you please summarize how the Strategic National Stockpile medication inventory, including antibiotics, is updated to ensure the most effective treatments are included in the stockpile? Are novel antibiotics included? What recommendations do you have to ensure that the supplies and medications our nation is stockpiling meets the current public health needs?**

I agree that the threat of AMR is more relevant than ever as we face unprecedented challenges with the SARS-CoV-2 pandemic. A study published in the Lancet found that 1 in 7 patients hospitalized with COVID-19 has acquired a dangerous secondary bacterial infection, and 50% of patients who have died had such infections. This study also found that 95% of patients with COVID-19 were treated with antibiotics.[1] Health experts have warned that "it is reasonable to anticipate that an appreciable minority of patients with severe COVID-19 will develop superinfections".[2]

An increase in infections and subsequent use of antibiotics will only accelerate the rate of drug resistance, further exacerbating the current situation and increasing the stress on an already fragile health care system. As antimicrobial resistance grows, the products used to treat these infections do not work as well or at all. The loss of effective antimicrobial treatments will not only cripple the ability to fight infections caused by SARS-CoV-2, but will also undermine the treatment of infectious complications in patients with other diseases. Many of the advances in medical treatment – joint replacements, organ transplants, cancer therapy, and treatment of chronic diseases such as diabetes, asthma, and rheumatoid arthritis – are dependent on the ability to fight infections with effective antimicrobials.

[1] Zhou, MD, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *The Lancet*, March 2020.Page 4. Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext#.
[2] Clancy CJ, Nguyen MH. Coronavirus Disease 2019, Superinfections, and Antimicrobial Development: What Can We Expect? *Clinical Infectious Diseases*. May 2020. Available at: https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa524/5828436.

Given the significant impact of antimicrobial resistance, I can understand your interest in ensuring the Strategic National Stockpile has access to the most innovative antimicrobials available. However, for stockpiling to be successful, we must address the lack of industry investment as a first step. Novel antimicrobials are difficult and expensive to develop and typically provide little to no return on investment because they are generally used sparingly to preserve effectiveness. As a result of this unique market dynamic, overall pharmaceutical industry investment into antimicrobial research and development is declining. Today, the U.S. sales of all branded antibiotics combined can be outpaced by a single cancer therapy. This is why so many emerging biotechnology companies in this field have filed for bankruptcy and why so few large pharmaceutical companies are investing in early antimicrobial development. In fact, in the past three years, five companies that brought new agents to market (Allergan, The Medicines Company, Achaogen, Melinta, and Tetraphase) have declared bankruptcy or abandoned the pursuit of innovative antimicrobials altogether.[3]

In an effort to provide immediate support to the failing antibiotic industry, in 2019, the Biomedical Advanced Research and Development Authority (BARDA) initiated a contract with Paratek Pharmaceuticals for $169 million over five years to "complete the studies and manufacturing activities necessary for FDA to consider Emergency Use Authorization (EUA) of NUZYRA® (omadacycline) to treat people exposed to anthrax".[4] If the product is authorized by the FDA for this EUA, BARDA has indicated that they will seek to move forward with procurement for the Strategic National Stockpile. This agreement would be the first of its kind and, depending on the size of the procurement, this model could provide some much-needed relief to support existing novel antimicrobials.

However, to comprehensively address the market failure of novel antimicrobials, additional policy solutions will be necessary to encourage and sustain investment in new products moving forward. Specifically, comprehensive reimbursement reform and a novel pull incentive will be two critical pieces to not only maintaining patient access to existing novel antimicrobials, but also encouraging long-term investments to ensure a sustainable pipeline of products.

As one of the few remaining large pharmaceutical companies developing and commercializing novel antimicrobials, we would welcome the opportunity to work with you further to improve innovation and access to novel antimicrobials.

2. **The Strategic National Stockpile is a critical resource for our entire country, for which we should continue to support and expand the capacity, especially for critical PPE, testing materials, and supplies needed for large-scale vaccine distribution. In thinking through the challenges we have seen with testing supply shortages, and the strain on the Strategic National Stockpile, are there other testing methods that could increase testing capacity while also conserving supplies? For example, I recently heard about a testing model where groups of people that are in close proximity to each other – for instance, students in the same classroom, nursing home residents, or workers on the same shift –**

[3] Clancy, Craven. Coronavirus Disease 2019, Superinfections, and Antimicrobial Development. Page 1.
[4] HHS, "HHS Supports Advanced Development for Treatment of Anthrax Lung Infections", December 18, 2019. Available at: https://www.hhs.gov/about/news/2019/12/18/hhs-supports-advanced-development-treatment-anthrax-lung-infections.html.

provide saliva samples and one test is run on the group as a whole. If negative, you know the whole group is cleared. If positive, the whole group is monitored, quarantined, or tested individually. Do you think this should be explored further to save resources and improve efficiency for testing certain groups?

Addressing the SARS-CoV-2 pandemic requires adequate personal protection equipment, ample testing capacity, and a coordinated testing strategy that ensures people who need testing the most – those with symptoms of infection or recent contact with an infected person – have priority access, timely results, and appropriate follow-up. Recently, the FDA issued the first emergency use authorization for sample pooled testing, which would allow samples collected from multiple individuals to be tested at once. If the samples are pooled, fewer tests are needed, the testing backlog is reduced, and people may be able to receive their results more quickly. The caveat to this testing framework is that it is most effective and most efficient in areas where there is low prevalence of infection. The reason for this is that if any one sample in the pool is positive, then all the samples in that pool must be separately retested, and that takes time. I applaud the development of new testing strategies and the efforts that NIH, academia, health systems, and industry are making through the Rapid Acceleration of Diagnostics initiative. Planning for future pandemics and other infectious disease threats must include rapid development and deployment of scalable diagnostic tests as critical objectives.

From Senator Gary Peters

- **Vaccine Distribution**
  1. **What is being done in the private sector to ensure swift distribution of a vaccine, once available, and what role should the federal government play?**

The SARS-CoV-2 pandemic is a significant reminder of the critical importance of vaccines in helping to protect our health and our economies. The return to a "new normal" hinges in part upon the development and widespread access and distribution of safe and effective vaccines against SARS-CoV-2, while simultaneously maintaining continuity in access and delivery of routine vaccines.

Merck has a long track record of making our vaccines and medicines accessible wherever they are needed. The recent deployment of ERVEBO, our licensed vaccine for Zaire Ebola virus infection, is a case study in how we worked with the federal government – including BARDA, HHS, DARPA, with the support of other DOD assets – to accelerate development and availability of this emergency vaccine. We are committed to the same urgency for any vaccines or therapeutics we develop for SARS-CoV-2. We are already working to scale up manufacturing capacity at-risk to produce as many doses of our two candidate vaccines as fast as possible, targeting hundreds of millions of vaccine doses. We are also engaged with stakeholders – alongside industry peers and the federal government – to anticipate and inform national supply chain needs. Similar steps are being taken across industry. We believe the world will need multiple vaccines to meet the urgent need, recognizing that different vaccines candidates will have different profiles and will need to address the unique efficacy and safety requirements of diverse target populations.

To ensure that these vaccines reach people and communities across the United States, an unprecedented, robust, efficient distribution and immunization system will be required, and the federal government – in close collaboration across multiple sectors – has an important role to play in meeting this need. One of the most important aspects of distribution will be maintaining cold chain throughout storage and transportation, including at the state and local levels, all the way to the point of vaccination.

There may be multiple SARS-CoV-2 vaccines available in the United States, each with a different profile and different cold chain requirements. It is important to highlight that some vaccines, at least in the near term, might require freezer storage at low temperatures (e.g., -70^{o}C). We need to address this challenge and start working together now to ensure solutions are in place on time.

Another critical element of distribution is tracking and monitoring. This includes tracking the distribution and utilization of vaccines and corresponding supplies (e.g., syringes), as well as monitoring their safety and physical security. Collecting this information can help the federal government, as well as state, local, tribal, and territorial (SLTT) governments manage inventory deployment, respond quickly to potential safety signals, and tailor communication strategies and other interventions to address gaps in vaccination coverage rates. The federal government played an important role in

allocating and distributing H1N1 influenza vaccines during the 2009 influenza pandemic and that experience can be applied to the current situation. Innovations such as electronic tracking would improve the ability to monitor vaccines throughout the distribution system and allow states to plan accordingly. A sound monitoring and tracking system complemented by a robust communication strategy will be critical in promoting confidence in SARS-CoV-2 vaccines and the infrastructure that will deliver and administer them.

The federal government can also help SLTT governments prepare for the distribution of SARS-CoV-2 vaccines by ensuring necessary infrastructure is in place (e.g., relevant freezers) and providing clear guidance on how the vaccine should be ordered, allocated, distributed, and administered at the local level. Early guidance and communication can help SLTT governments develop plans for mass vaccination efforts and deploy vaccines without delay. Such guidance can also help SLTT governments plan for the last mile of distribution and ensure that vaccines are available in hard to reach areas. This may include, for example, using non-traditional delivery settings and ensuring that adequate cold chain capacity exists in such settings.

Timely and coordinated distribution of a vaccine is only part of the solution. The federal government has an important role to play in harmonizing the execution of the vaccination program across multiple jurisdiction and increasing the confidence that the public has in SARS-CoV-2 vaccines. The CDC, as our most trustworthy public health agency, should play a lead role in this effort. Recent polls indicate that only half of Americans would be confident to receive a SARS-CoV-2 vaccine if available today. Building trust in the SARS-CoV-2 vaccine and trust in the delivery systems are necessary for an effective distribution and administration strategy. We recommend the federal government have a clear and coordinated national strategy to mitigate vaccine hesitancy. Working alongside partners, the federal government could increase vaccine confidence through public awareness campaigns, empowering health care providers, and engaging the media to ensure timely, clear, and accurate information is reaching all Americans.

- **SNS Composition**
  2. **How can the federal government best prepare the SNS for what many experts anticipate will be a second wave of COVID-19 in the fall or winter?**

Ensuring the preparedness of the Strategic National Stockpile (SNS) is an issue of national security and we have learned a great deal through the current wave of the SARS-CoV-2 pandemic that can help us anticipate and prepare for a potential second wave.

First and foremost, ensuring adequate supply of essential commodities, including masks and other personal protection equipment (PPE), will be important to manage another potential wave of this pandemic. Recognizing that development, manufacturing, and distribution of vaccines in sufficient supply to meet the full needs across the United States will take time, ensuring the SNS is adequately stocked will be critical. Further, the

SNS should have an agile logistics plan that can ensure timely, data-driven, equitable access to commodities and be responsive to the needs across the country. In addition, the SNS must have sufficient flexibility to meet the emerging needs of the SARS-CoV-2 virus, which requires active monitoring, a flexible budget, and fit for purpose private-public partnerships. One of the many lessons learned from the current pandemic is that our planning cannot solely be based on previous health emergencies; we must use science and ingenuity to anticipate what may be necessary to respond to a novel crisis.

In this context, it is imperative that our nation mount an assertive campaign to encourage people to get their flu shot this year. Though we can't predict the timing or severity of seasonal influenza, its appearance will complicate management of SARS-CoV-2, create additional demand for health care services and PPE, and potentially increase the severity of other respiratory illnesses including COVD-19.

- **Pandemic Preparedness**

3. **Since January, the Trump Administration has cut funding, ignored critical warnings, and disbanded the pandemic planning office. It also seems that supply chain responsibility has shifted away from the SNS and toward FEMA. What are your thoughts on this and our federal government's preparedness and response to this pandemic?**

The SARS-CoV-2 pandemic is an unrivaled scientific and global health challenge and our actions today will determine the magnitude of the short- and long-term negative implications for individual Americans, for our nation, and for people around the world. We can already see some of the vulnerabilities in our system that need to be addressed now and for the future. Pandemic preparedness requires a new health security doctrine. The SNS is a critical asset in our nation's readiness against health security threats from both infectious outbreaks and deliberate bioterror attacks. I would recommend the federal government focus on the following areas to advance preparedness and response efforts for this pandemic and for what I believe are the inevitable future pandemics we will face:

1) Establishing permanent leadership at the National Security Council to guarantee effective oversight of global health security and biodefense policy and spending;
2) Establishing a clear and sustained national preparedness health security doctrine and strategy;
3) Creating an immediate and long-term financing mechanism to properly execute the health security strategy and assure ongoing preparedness capacity-building in the United States, including front-line public health and health care facility preparedness and a fit-for-purpose SNS;
4) Ensuring that the SNS mission and budget are in full alignment with the national health security strategy and that lines of responsibility and authority regarding control of the stockpile, and the precise chain of command for its use – from the federal level to the state and local public health and health care entities that will utilize its assets – is clearly articulated;
5) Augmenting CDC's capability to combat disinformation and promote better communications that are science-based, including providing clear and coordinated

communication with the American public about the emerging evidence and evolving guidelines for this virus;
6) Fully engaging the private sector in planning and executing the national health security strategy; and
7) Investing to accelerate development of countermeasures to address known threats and new platforms and manufacturing innovations to prepare for new and emerging threats.

- **SNS Expectations/Communications**

4. During your tenure as Director of the CDC, which controlled the SNS at the time, how did CDC communicate with states regarding the supplies and capabilities of the SNS, as well as its limitations?

When the SNS was the responsibility of the CDC, the CDC Office of Public Health Preparedness and Response (OPHPR) was accountable for the SNS and executed two main responsibilities in close collaboration with public health officials in the 62 jurisdictions (50 states, Chicago, Los Angeles County, New York City, and Washington, D.C, and eight U.S. territories and freely associated states) that were funded through CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement program.

First, working with state, local, and territorial public health leaders, the CDC provided technical assistance and targeted resources through the grant program to determine what SNS assets and capabilities were required to support jurisdictional preparedness plans and priorities, assisted in planning for their deployment, and then monitored and reported progress in achieving stated preparedness objectives.

Second, a tailored pool of specialized SNS responders were available to assist jurisdictions during a public health emergency. These experts were trained to deploy and offload SNS materials up to the scale of "push pack" – which filled a 747 cargo plane – and support their full deployment at the point of use. In addition, these professionals periodically exercised SNS deployment in various jurisdictions to augment local capabilities and to identify gaps in response capability.

5. How would you recommend HHS/ASPR ensure states' understanding of the capabilities of the SNS moving forward, and help them to prepare for the next event?

The SNS must be designed and appropriately funded to support the stated intent and requirements of the national health security strategy and its priority objectives. This "fit-for-stated-purpose" approach requires close communication between the federal government and SLTT planners, health officers, health care delivery system leaders, and other critical stakeholders.

It is essential that all jurisdictional plans be formed in alignment with the national health security strategy. Without this doctrine, planning, prioritization, and asset allocation will be inefficient and uncoordinated. Second, once the strategy is developed,

specific assets and capabilities including the SNS need to be funded, evolved, and exercised, and progress toward strategic objectives must be measured and reported at each jurisdictional level.

6. Do you believe it was in the best interest of the SNS to be transferred from CDC to ASPR?

CDC and ASPR are essential agencies in supporting the nation's emergency preparedness and response. CDC is the most effective interface between the federal government and state, local, and territorial public health entities, and plays a pivotal role in ensuring that public health systems plan and prepare for public health emergencies. The CDC's strong science base, combined with its technical experts across a broad domain of capabilities including infectious, occupational, and environmental threats that affect the public's health, make it critical to these efforts. CDC continues to provide guidance to help health departments develop, test, operationalize, and improve preparedness and medical countermeasure plans; technical assistance to provide information and resources to ensure health departments are ready to respond to threats that might require medical countermeasures; and evaluation to standardize approaches and tools to measure the readiness of health departments to get life-saving medicines and supplies to the public.

Reflecting on CDC's oversight of the SNS, there are many positive examples of successful responses to health emergencies such as during the Ebola response, where in part, CDC monitored local supplies of personal protective equipment (PPE) and encouraged hospitals, public health, and health care coalitions to develop sharing plans during a time when supply was not meeting demand. Similarly, in the wake of the Zika virus outbreak, the SNS provided immediate vector-control services and preventive supplies for pregnant women to protect themselves from mosquito bites. Success was also demonstrated in relief and support provided to Puerto Rico in 2017, after Hurricane Maria devastated the island. The hard work and expertise of the CDC in managing the SNS through responses like the one in Puerto Rico helped build the capabilities to support partners and provide the right materials, at the right time, to secure our nation's health.

At the same time, one of the primary responsibilities of ASPR is to lead and coordinate the public health and medical response for the federal government under the National Response Framework, Emergency Support Function #8. As such, ASPR is on the front lines, with CDC, in supporting communities in preparedness for, response to, and recovery from disasters and public health emergencies. ASPR is charged with collaborating with hospitals, health care coalitions, biotech firms, community members, state, local, tribal, and territorial governments, and other partners across the country to improve readiness and response capabilities.

From Senator Kyrsten Sinema

1. **What recommendations do you have on how the Strategic National Stockpile and other federal resources can establish a better allocation process that is more fair and more equitable for Tribal governments? How can future distribution strategies ensure Tribal governments and tribal health facilities that order their supplies from the Indian Health Services receive what they need from the federal stockpile?**

Merck shares your commitment to an allocation process that is fair and equitable to all, including American Indian/Alaska Native (AI/AN) Tribal governments, as we have seen that AI/AN communities have been one of the populations hardest hit by the SARS-CoV-2 pandemic. Presently, there is no streamlined pathway for AI/AN governments, including Indian Health Service (IHS), AI/AN health authorities, and urban Indian organizations, to directly request SNS assets. Furthermore, access is not only limited but it is not expressly guaranteed in the SNS statute. Federal law makes no provision or requirement for ASPR to deploy SNS supplies or medications to IHS facilities, AI/AN health organizations, or urban Indian organizations. The unintended consequences of the SNS statutory framework and current approach are inadequate AI/AN community engagement and SNS access limitations.

The current requirement that AI/AN governments must exhaust all resources prior to submitting a request through a governing body (i.e., relevant state government or IHS headquarters) may result in additional delays before they receive needed SNS assets. This multi-step approach is not only time intensive but also creates a risk that not all assets are incorporated or appropriately reflected in the larger governing body's asset request.

As we have learned during this pandemic and those before it, time is a critical factor and it is essential that efforts are made to streamline timely and equitable access for our AI/AN communities. After H1N1, AI/AN governments expressed that the federal government should deal directly with and closely involve them in the planning process from the beginning. One solution may be an interagency coordination platform, implemented through the executive branch, that would support developing infrastructure to work directly with AI/AN governments.

Short-term, state and local planners should continue to work with AI/AN governments, as well as the IHS, to plan how to request, receive, distribute, and dispense SNS assets during a public health emergency. For example, during the 2009 H1N1 pandemic, Arizona guaranteed that the first 5% of every vaccine order went to Native Americans.

Moving forward, the federal government should include AI/AN governments early in the planning process, establish meaningful and transparent communication pathways, and establish a more direct and streamlined approach to SNS asset request and deployment.

Through the aforementioned processes, we can improve the allocation process such that it is fair and equitable for AI/AN communities and ensure that AI/AN Tribal governments and health facilities have streamlined and timely access to SNS assets.

2. Your written testimony mentioned a need for the Strategic National Stockpile to consider the needs of vulnerable and marginalized populations. Based on your former experience at the CDC, how can the Stockpile, and those making acquisition and distribution decisions, do a better job taking these populations and their needs into account for this and future pandemics?

We share your commitment to protecting our most vulnerable and marginalized populations. As we saw during the 2009 H1N1 pandemic, hospitalization rates among minority groups were consistently more than double those of White, non-Hispanics. Similarly, there is increasing evidence of racial and ethnic disparities in those affected by COVID-19. The most pervasive disparities are observed among African American and Latinx individuals, and where data exist, American Indian, Alaska Native, and Pacific Islander populations.

A robust, and resilient public health infrastructure is critical for meeting the needs of vulnerable and marginalized populations. We applaud the SNS for taking action and believe there are additional steps to support these high-risk populations. In determining and reviewing the composition and allocation of SNS assets, ASPR, in coordination with CDC, takes into consideration multiple factors, including the medical vulnerability of the U.S. population (and of at-risk populations such as children and other vulnerable populations), current biological/chemical threats, the availability of medicines and medical supplies, and the ease of disseminating specific medicines. ASPR defines "at risk" individuals as people with access and functional needs that may interfere with their ability to access or receive medical care before, during, or after a disaster or emergency.

While taking "at risk" populations into consideration when determining and reviewing the composition of SNS assets is essential, this also must be translated into dissemination planning as well. The 2009 H1N1 pandemic demonstrated that despite efforts to include "at risk" populations in preparations, access barriers still existed for deployment and delivery of services for certain vulnerable populations, resulting in disparities in health outcomes. After the 2009 H1N1 pandemic, HHS completed a retrospective analysis that, in part, identified opportunities for improvement that could be implemented now to address these disparities, ensure equitable and timely access, and improve overall pandemic preparedness and response efforts. Some examples of these opportunities include:

- Develop a centralized system to track medical countermeasure activities and effects at the more granular state and local levels. The CDC/Division of Strategic National Stockpile Dashboard was designed to maintain situational awareness of medical countermeasures at a national level. Among other benefits, this detailed, centralized system would help to identify opportunities for performance improvement (e.g., population disparities in antiviral medication use), facilitate redistribution, and support local decision making regarding medical countermeasure distribution.
- Complete systemic evaluation to understand the underlying causes of health disparities identified during the pandemic. Information collected during and after the pandemic response indicated that racial and ethnic minorities were vaccinated

at comparatively lower rates than other groups. This research can be used to inform targeted communications and outreach strategy development for vulnerable and high-risk populations and help to overcome community-level or system-wide barriers.

In addition to the opportunities highlighted from the H1N1 retrospective analysis, there are other initiatives the federal government can lead and support. During the pandemic, it is critical that SLTT SNS planners assess ongoing community needs and develop a predefined, comprehensive logistics plan. The jurisdiction's plans must reflect unique community considerations and needs identified with input from members of the community. Plan implementation must be adequately resourced and supported to ensure equitable and timely access across the country. We recognize that it is critical to ensure equitable and timely access to essential SNS assets for all Americans and support efforts from federal, state, local, tribal, and territorial governments to achieve this goal.

Testimony

The Strategic National Stockpile and COVID-19

Rethinking the Stockpile

Addendum

Daniel M. Gerstein

CT-A530-2

Document submitted August 21, 2020, as an addendum to testimony before the Senate Committee on Homeland Security and Governmental Affairs on June 24, 2020



For more information on this publication, visit www.rand.org/pubs/testimonies/CTA530-2.html

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The Strategic National Stockpile and COVID-19: Rethinking the Stockpile

Testimony of Daniel M. Gerstein[1]
The RAND Corporation[2]

Addendum to testimony before the Committee on Homeland Security and Governmental Affairs
United States Senate

Submitted August 21, 2020

Following the hearing on June 24, 2020, the congressional committee sought additional information and requested answers to the questions in this document. The answers were submitted for the record.

Questions from Senator Gary Peters

Question 1: State Acquisition Efforts

What are the obligations of the federal government to support states during public health emergencies?

Answer

The National Response Framework guides the national response to all types of disasters and emergencies, including pandemics. It is designed to be scalable, flexible, and adaptable with concepts identified in the National Incident Management System to align key roles and responsibilities.[3] The framework has been designed to create responsibilities for response at all levels of the government and with stakeholders, down to and including individuals. When one part of the response does not function effectively—as in the case of the federal response to

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[1] The opinions and conclusions expressed in this addendum are the author's alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

[2] The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

[3] Federal Emergency Management Agency (FEMA), "National Response Framework," webpage, July 31, 2020, https://www.fema.gov/media-library/assets/documents/117791.

coronavirus disease 2019 (COVID-19), which, as I characterized in my testimony, "has been slow and inconsistent and has deservedly become a target of criticism"[4]—the overall response suffers.

U.S. emergency management traces its roots to the Congressional Act of 1803, which is considered the nation's first piece of disaster legislation and aided a New Hampshire town following an extensive fire. FEMA—established in 1979—also traces its root back to this original legislation.[5] Emergency management in the United States is based on the understanding that all initial response is local. When local authorities no longer have the capacity to mount an effective response, states provide necessary support. When the state capacity is exhausted, federal support is invoked through a Stafford Act declaration.

The 1988 Stafford Act describes the process for federal disaster assistance for state and local governments to request assistance. The Stafford Act allows the President to declare a major disaster or emergency and provides access to the Disaster Relief Fund.[6] The national emergency management system also has established doctrine for reporting information and making requests for support. The structure includes frameworks, critical functions, and training and exercises designed to test systems and ensure proficiency. An important part of the emergency management doctrine involves managing the logistics and supply chains that support the response.

The Department of Health and Human Services (HHS) is designated as the sector-specific lead agency for the health care and public health sectors for all emergencies, including a pandemic. The requirements for HHS are spelled out in Emergency Support Function 8 (ESF 8).[7] ESF 8 leads the public health and medical response, and the secretary of HHS is responsible for coordinating these assets; this coordination is principally through the Assistant Secretary for Preparedness and Response. ESF 8 resources can be activated through the Stafford Act or the Public Health Service Act.

Additionally, the Strategic National Stockpile (SNS)—which was established in 1999 for response to a bioterrorism event but has been broadened to encompass all hazards—contains

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[4] Daniel M. Gerstein, "The Strategic National Stockpile and COVID-19: Rethinking the Stockpile," testimony presented before the U.S. Senate Committee on Homeland Security and Government Affairs on June 24, 2020, Santa Monica, Calif.: RAND Corporation, CT-A530-1, 2020b, https://www.rand.org/pubs/testimonies/CTA530-1.html.

[5] FEMA, "Emergency Management Institute (EMI) Overview," webpage, undated, https://training.fema.gov/history.aspx#:~:text=FEMA%20can%20trace%20its%20beginnings,town%20following%20an%20extensive%20fire.&text=This%20piecemeal%20approach%20to%20disaster%20assistance%20was%20problematic.

[6] Public Law 93-288, Robert T. Stafford Disaster Relief and Emergency Assistance Act, FEMA P-592, May 2019, https://www.fema.gov/media-library-data/1582133514823-be4368438bd042e3b60f5cec6b377d17/Stafford_June_2019_508.pdf.

[7] According to the HHS Office of the Assistant Secretary for Preparedness and Response, "Emergency Support Functions (ESFs) is the grouping of governmental and certain private sector capabilities into an organizational structure to provide support, resources, program implementation, and services that are most likely needed to save lives, protect property and the environment, restore essential services and critical infrastructure, and help victims and communities return to normal following domestic incidents" (Public Health Emergency, "Emergency Support Functions," webpage, undated, https://www.phe.gov/Preparedness/support/esf8/Pages/default.aspx).

equipment and medical countermeasures for pandemic response. The SNS was formerly under the Centers for Disease Control and Prevention (CDC) but was moved under the Assistant Secretary for Preparedness and Response in 2018. In the case of an emergency, state governors can request deployment of the SNS, but the federal government ultimately makes the determination to release the stockpile. This process played out in the initial phases of the COVID-19 response as state, local, tribal, and territorial (SLTT) health systems became overwhelmed and states began requesting supplies. However, COVID-19 presented an unusual set of circumstances involving nearly simultaneous requests from all 56 SLTT authorities. The quantities of material in the stockpile were not nearly enough to fill all of the requests, resulting in a heated competition.

The SNS was not intended to satisfy all requirements for the entirety of a pandemic but rather to allow for activating critical supply chains. This would require being prepared to combine direct contracting with manufacturers, having warm production lines for some key commodities, and procuring large quantities at the national level to take advantage of economies of scale.

The federal government also has the role of coordinating a national response. All emergencies are local and should be managed at the lowest level possible, but in the case of a national emergency (and COVID-19 is arguably the first in some time), the only way to have a coordinated national response is for the federal government to play that role. The SLTT authorities also depend on the federal government for information and intelligence, scientific and technical guidance, and leadership, to name a few. For example, the SLTT authorities need the federal government to develop a national strategy for testing, which has yet to be accomplished even five months into the pandemic. In addition, the SLTT authorities need guidance on the use of face masks to reduce virus transmission rates.

Question 2: Pandemic Preparedness

Since January, the Trump Administration has cut funding, ignored critical warnings, and disbanded the pandemic planning office. It also seems that supply chain responsibility has shifted away from the SNS and toward FEMA. What are your thoughts on this and our federal government's preparedness and response to this pandemic?

Answer

In a virtual congressional roundtable with the House of Representatives' Science, Space, and Technology Committee on May 5, 2020, I provided a written statement regarding the federal response to the pandemic.[8] My assessment remains that the response has been slow and inconsistent and "has deservedly become a target of criticism." Overall, the federal government,

[8] Daniel M. Gerstein, "The Federal Research Enterprise and COVID-19: A Lesson in Unpreparedness," testimony presented before the House of Representatives Science, Space, and Technology Committee at a virtual roundtable on May 5, 2020, Santa Monica, Calif.: RAND Corporation, CT-A360-1, 2020a. https://www.rand.org/pubs/testimonies/CTA360-1.html.

in particular, was between two and four weeks behind on all decisions in the first four months of the pandemic (i.e., from January through April 2020).

Initial reports of the virus were provided to the CDC by Chinese counterparts on January 3, 2020. U.S. intelligence agencies—which had been following events in China since late November—began regularly reporting on the coronavirus spread throughout January and into early February.[9] By mid-February, global examples of the virus transmissibility and virulence were evident, and a global competition was underway for masks, gowns, ventilators, and reagents and nasal swabs for test kits.

Despite this information, miscues—particularly at the federal level in the early stages—hindered mounting a coherent national response and rapidly energizing the capabilities that would be essential to understanding the progression of COVID-19. These shortfalls undoubtedly resulted in greater mortality and morbidity because they led to decisions that were some two to four weeks later than would have been useful to contain the spread of the disease in the United States in the early stages of the pandemic.[10]

To the nation's peril, decisions and guidance at the federal level were not based on the best science. The result was a response that was largely led by the state governors and that lacked federal support. This absence of federal support cascaded across the response. The 2018 dissolution of the National Security Council staff element responsible for pandemics meant that relationships that had been developed across the government were no longer functioning. The issue was further exacerbated by the failure to employ the pandemic response playbook developed by the Obama administration following the 2014 Ebola pandemic.

The Trump administration was briefed about the playbook, but it was not used for the COVID-19 response. The playbook covered many of the issues encountered during the COVID-19 response, such as early actions in response to credible threats, use of emergency funds and the SNS, and the Defense Production Act.[11]

The turbulence surrounding the SNS also proved costly. As noted earlier, in 2018, oversight for the SNS was transferred within HHS, from the CDC to the Assistant Secretary for Preparedness and Response. At the beginning of the COVID-19 pandemic, oversight for the SNS transferred again, this time to FEMA in the Department of Homeland Security. All of this turbulence caused confusion and disconnected relationships that had been practiced during numerous trainings and exercises.

The SNS also was found to be ineffective when managing a national emergency of this magnitude. In congressional testimony, FEMA Administrator Peter Gaynor offered the following assessment of the SNS: "FEMA typically manages abundant resources for disasters that are limited in geographic scope and impact. In responding to COVID-19, FEMA has had a much different and difficult task of managing the lack of critical medical supplies and equipment.

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[9] Shane Harris, Greg Miller, Josh Dawsey, and Ellen Nakashima, "U.S. Intelligence Reports from January and February Warned About a Likely Pandemic," *Washington Post*, March 20, 2020.

[10] Gerstein, 2020a.

[11] Dan Diamond and Nahal Toosi, "Trump Team Failed to Follow NSC's Pandemic Playbook," *Politico*, March 25, 2020.

Rather than managing resources, we are managing shortages."[12] In previous exercises dealing with public health emergencies, the answer has consistently been to request support from the SNS; yet, as COVID-19 demonstrates, this strategy might not be prudent. Additionally, the pandemic is also demonstrating the interconnectedness of the global supply chains, which source personal protective equipment and other supplies, such as reagents for testing.

As noted earlier, activating critical supply chains that support the national response requires being prepared to combine direct contracting with manufacturers, having warm production lines for some key commodities, and procuring large quantities at the national level to take advantage of economies of scale.

Historic underfunding of public health—specifically, not treating public health as a national security priority—has also contributed to the shortfalls in the U.S. response. Funding cuts to the CDC, the National Institutes of Health, and state and local public health programs have left inadequate staff capacity in these organizations and a lack of supplies for use in a pandemic.

The lack of a national strategy for combating the pandemic, mixed messages that confused political leaders and U.S. citizens, and federal failure to lead have resulted in the United States having the most COVID-19 deaths of any country, economic devastation, and an enormous human toll.

My overall assessment is that the response to COVID-19 has exposed key shortfalls in the United States' preparedness and response capabilities. Going forward, a bipartisan commission should undertake a comprehensive accounting of the COVID-19 pandemic. Basic assumptions—including regarding the role of government at all levels in emergency management and disaster preparedness and response—should be on the table.

[12] "FEMA: Supplies, a Test During COVID and Disasters," Yahoo News, July 24, 2020, https://news.yahoo.com/fema-supplies-test-during-covid-173337653.html.

Post-Hearing Questions for the Record
Submitted to Mr. Andrew Phelps
Director, Oregon Emergency Management

on behalf of the
National Emergence Management Association

From Senator Gary Peters

"The Role of the Strategic National Stockpile in Pandemic Response"

June 24, 2020

- **SNS Allocations**
  1. Reports from Michigan identified multiple concerns with the SNS, and subsequent FEMA distributions, including delays, miscommunication or a lack of communication at all, mislabeled or unlabeled items, and expired medical supplies. Did you have a similar experience in Oregon?

     Response: We experienced many of the same challenges in Oregon throughout the response including boxes with incorrect quantities or expired masks with elastic bands so brittle they snapped when medical providers tried to use them. The Oregon Department of Veteran Affairs reported receiving procedural gowns without arm holes and when staff at their facility tried to modify the gowns so they could be used, the gowns simply fell apart.

     While each state's experience is unique, other states also experienced issues with delays, including waits of 46 days for gown deliveries and instances where state staff were informed of an impending delivery of PPE that did not materialize for hours or even days later than expected. On numerous occasions, supplies were shipped to the wrong locations. Other instances saw states expecting a specific number of "pallets" of equipment only to find one or two boxes on each pallet. In some cases, states received KN95 masks, but FEMA records indicated that they were N95s. These miscommunications added layers of complexity to an already challenging PPE procurement process.

  2. From your perspective, what parts of the federal supply allocation process worked well and what could the government improve upon?

     Response: Early in the pandemic's response, it was critical to provide necessary PPE to hotspots around the country. This process, however, limited visibility for states and localities on where PPE was going to be sent and it did not always ultimately match state-identified need. Allowing for stronger visibility of the composition of SNS inventory would strengthen future responses and allow states to more appropriately plan for gaps in supplies.

Federal intervention into the procurement process forced states to vie with one another and other entities for limited resources. This could be improved by a more coordinated usage of the Defense Production Act (DPA). Federal agencies should focus in the future on issues such as supply chain metrics and standing agreements with manufacturers to help meet demand on short notice.

The federal supply allocation process did improve over time with more communication and longer advance notice for deliveries, but this was a trial-and-error process. The CDC's guidance on how to extend the life of these limited items was also helpful to states dealing with shortages.

Additional challenges were posed when the initial authorization of KN 95 mask use in medical settings from some manufacturers was rescinded after many states, including Oregon, had already made purchases.

3. Are you aware of any exercises that FEMA or HHS conducted with states or localities that involved the SNS during an emergency? Would more exercise and preparation in this area be beneficial?

Response: States regularly conduct exercises of all varieties with FEMA, HHS, and other federal agencies as part of our nation's all-hazards approach to preparedness. Primarily, states' previous experiences with the SNS were based on training and exercise, including regularly scheduled operational exercises to test state and federal SNS plan integration. These often took the form of a bioterrorism attack or incident with a short timeline (e.g. 48 hours for antibiotics to then be delivered to a jurisdiction's population) for a response. While I want to be clear that additional training and exercise measures are always welcome, a significant challenge with this response in particular was that these previously exercised plans were not consistently utilized at various levels of government. Plans did not adequately prepare for an incident that would impact all states and continue for so long. As such, the SNS request process evolved from its usual procedures to a "push" model whereby we were advised of known quantities of PPE being shipped to us based on the remaining availability of assets within the SNS itself. This divergence from longstanding process, while necessary to mitigate losses in hotspots, was more impactful to state response than a lack of previous exercise experience.

- **State Acquisition Efforts**

4. When the President indicated that, following the depletion of the SNS, states were "on their own to obtain PPE," what impact did that have on your state's efforts to obtain those vital medical supplies?

Response: In order to close the gap between available SNS inventory and state needs, most states moved to procure their own supplies through a mix of donations and sales from in-state companies and international supply chain sourcing. In Oregon, private industry stepped up to retool their factories to make PPE but even these significant efforts were not enough to fill the demand. This pushed states to procure PPE on the international markets which developed into a costly and time-consuming bidding war that emerged while the virus was at its peak in many states.

Oregon, like most states, implemented PPE conservation measures, forced the cancelation of non-emergency, or elective, medical procedures, and used the Battelle N 95 respirator decontamination system to further extend limited supplies of N 95 respirators in particular. Oregon also has at least one manufacturing facility awaiting NIOSH approval for a sustainably-produced N 95 respirator, which would alleviate some of our supply chain challenges.

5. How do we avoid this situation in the event of a second wave or another pandemic?

Response: In the event of a second wave or another pandemic, states should be encouraged to establish stockpiles to relieve some demand on the SNS. At a minimum, this should be done regionally, and when possible shared between states through the Emergency Management Assistance Compact (EMAC). Additional discussion will need to occur to determine at what level of demand is reasonable or sustainable for the SNS.

As part of this effort, federal agencies should develop an average national "burn rate" for PPE that can then inform both regional and national stockpiles. This will also be critical to states as they invest in their own stockpiles.

Additionally, as we plan for a potential new wave or new pandemic, we must consider ways to expand the manufacturing of critical medical supplies within our borders. The reliance on foreign manufacturing for these items is tantamount to a national security issue as supplies manufactured offshore can be significantly delayed and therefore be inaccessible when America needs them most.

- **Pandemic Preparedness**

6. Since January, the Trump Administration has cut funding, ignored critical warnings, and disbanded the pandemic planning office. It also seems that supply chain responsibility has shifted away from the SNS and toward FEMA. What are your thoughts on this and our federal government's preparedness and response to this pandemic?

Response: The SNS' supply and capabilities were far outstripped by demand within weeks of the outbreak's spread in the United States. FEMA then instituted

Project Airbridge, which shipped PPE and other resources from the maker to major vendors directly to their major customers. This bypassed state governments, reduced the visibility state emergency managers had on what was arriving in their states, and increased the likelihood of duplicated efforts and an inefficient allocation of resources at the state level.

It is challenging to keep a large enough quantity of supplies available and ensure that the products are rotated out so that new, unexpired products are ready for immediate shipment. Moving forward, federal agencies should ensure that the U.S. has capabilities to manufacture PPE quickly and assess what items they have and where shortfalls exist. States can then integrate these shortfalls into planning assumptions and preparedness actions.

- **SNS Expectations/Communications**

7. As a state emergency manager, what information do you currently receive from HHS and ASPR regarding the SNS – during crises and outside of them – and what information would be useful for you to receive in the future?

Response: It is our understanding the SNS has been largely depleted with the majority of future requests for PPE to be filled (if they are filled at all) through FEMA procurement and therefore subject to federal cost share requirements. This bifurcated process strengthens the case for an adjustment of the federal Public Assistance grant program cost share to 100%, a request made by nearly all 50 states with no response received to date.

My office maintains daily connectivity with our FEMA Region X (Ten) partners and they serve as our conduit to the rest of the federal agencies supporting our response, including HHS. Our state partners at the Oregon Health Authority also have direct relationships with and lines of communication to their federal counterparts at HHS and ASPR.

Additional information on quantities that each state would be allotted ahead of an incident could allow for additional planning and preparation. This would help us determine how to best utilize supplies and procure items to fill gaps. Understandably, the items needed will vary by incident, but planning in this manner will help us make important decisions about prioritizing critical resources.

8. How can federal communication with the states be improved?

Response: Communication is an area of response that can always be improved. At the federal level early in the pandemic, the Department of Health and Human Services (HHS) was designated the lead for response, while states chose a wide array of leadership including emergency management, National Guard, and others depending on prior disaster experiences. This served as a challenge for

information sharing and was quickly changed to FEMA in the lead at the federal level to provide for better communication. In the future, when incidents like this occur, it is critical to immediately utilize previously exercised plans at all levels of government and to fully engage FEMA for stronger information flow.

As states were informed that the SNS was depleted, states turned to FEMA programs to help fill the gap. However, there was confusion for an extended period of time about the federal cost-share for FEMA programs, which is 25 percent, although most states had requested a waiver for this to be reduced. The federal government did not provide a clarification of if states could utilize CARES Act funding for this cost-share for over a month, stymieing state spending at the risk of a negative audit against billions of dollars. This has now been resolved, but in the event of any future coronavirus legislation, it is key for the federal government to provide rapid guidance on how these monies can be spent.

Post-Hearing Questions for the Record
Submitted to Mr. Andrew Phelps
Director, Oregon Emergency Management

On behalf of the
National Emergency Management Association

From Senator Kyrsten Sinema

"The Role of the Strategic National Stockpile in Pandemic Response"

June 24, 2020

1. Together with Senator Lankford, I help lead a subcommittee tasked with improving the effectiveness and efficiency of the federal government. We have asked GAO for a broad-based study on the coronavirus response and recovery, with the purpose of providing recommendations on how the county can be better prepared for future pandemics. Your testimony suggested that the Strategic National Stockpile and the federal government should have been more transparent with states on what they could or could not expect from the Stockpile and when.

   How can Congress and the Administration go about meaningfully adopting this approach for the second wave of the virus and in future pandemics and what do you anticipate to be the major impediments to doing so?

   Response: In the early weeks of the response to the pandemic, states encountered challenges when trying to communicate with their federal counterparts due to conflicting information on which agencies were leading what lines of effort. This was compounded by a rapid depletion of SNS inventory and confusion about utilizing FEMA resources as opposed to the SNS.

   This had significant implications for response because FEMA programs require a 25 percent cost-share that the SNS does not. When the CARES Act was passed, the Administration indicated that CARES Act funding could be used towards that FEMA cost-share, but it took over a month to receive official guidance from Treasury on allowable expenditures. States were understandably concerned about integrating these funding streams without official guidance in the event of a negative audit against billions of dollars. In the event of a second wave of the virus and any future pandemics, it is imperative that Congress and the Administration provide rapid guidance for any new or adapted funding streams.

   Additionally, early in the pandemic's response the federal government understandably prioritized sending limited numbers of PPE to hotspots around the country. While necessary, there was little to no visibility for states on what PPE was available in the stockpile and when any of it would be received by the state in

question. This caused additional challenges for states when they were estimating the number of PPE they would need to compete for in the open marketplace, not only against one another, but against countries around the world.

Moving forward, states should be encouraged to establish stockpiles to relieve some demand on the SNS. At a minimum, this should be done regionally, and when possible shared between states through EMAC. It may be useful to consider requiring that states have individual capacity to meet initial surge expectations, with the SNS providing backup or sustainable capacity in the event of another protracted event like COVID-19. Furthermore, part of the SNS could be apportioned to each state, while leaving the balance to dynamically deploy to meet the most urgent needs nationally. As part of this effort, federal agencies should develop an average national "burn rate" for PPE that can then inform both state, regional, and national stockpiles.

Of course, a major obstacle is the impending budget shortfall for states in the aftermath of COVID-19's impacts. States will have ever more constrained budgets with which to provide their services while also seeking to invest in their own stockpiles. Congress and the Administration should resist the urge to require existing grant programs to lurch toward this latest issue and work with states in finding solutions that integrate federal assistance with state expertise and private sector capabilities.

Finally, when states were informed that a shipment of PPE was on its way, there was effectively no way for the states to track the shipment independently, leading to state staff waiting hours and in some cases days for a promised delivery to arrive. A secure online portal or other method could take the burden off federal staff and allow states to track their own shipments. Information could also be exchanged with traffic management centers across the country to help route deliveries when transportation infrastructure may be compromised. The foremost challenge here lies in developing a new or effectively adapting a preexisting system that appropriate members of state staff can access and use to understand what is currently available in the stockpile, what is included in a given shipment, and tracking the shipment as it moves through the shipping process. Congress and the Administration can work to kickstart this process through engaging with HHS, the federal interagency, and states to develop a system that is efficient and effective in the event of a second wave or future public health emergencies.

Post-Hearing Questions for the Record
Submitted to Mr. Gregory Burel
From Senator Gary Peters

"The Role of the Strategic National Stockpile in Pandemic Response"

June 24, 2020

- **Supply Chain Transparency**
  1. ASPR does not have the information it needs to inform planning for the SNS or to sufficiently protect critical infrastructure, such as essential manufacturing plants. Sen. Peters' bill, the PART Act, would address this by requiring the FDA to share certain manufacturing data with ASPR and DOD to help better secure our nation's drug supply. How would additional information, required in the PART Act, help the federal government prepare for future pandemics, natural disasters, and other national security threats?

ANSWER: The Information that would be shared under the PART Act would allow the government to perform regular analysis of medical supply chain strengths and weaknesses. Knowing any weakness or vulnerability would allow the government to take action to address those in some way. For example, if it is clear that production of a certain product is limited due to availability of specific raw material, the government might contract for acquisition of that material such that new supply is created or to simply allow for stockpiling of the raw material over time to turn over to manufacturing concerns at need. This would effectively create a strategic reserve of this raw material that might be released as needed to shore up production.

- **Vaccine Distribution**
  2. What role should the SNS have in preparing for the distribution and administration of a vaccine?

ANSWER: A whole of government plan for distribution and dispensing (administration) of a potential pandemic vaccine should be created and implemented immediately. Prior work in this area was undertaken by past administrations and should form the basis if not the entirety of these plans. In such planning the SNS can support vaccine distribution by acquiring and moving the vaccine in large lots to support max vaccination clinics. This planning is already in place in SNS and the states to respond to a Smallpox Response.

Daily, regular distribution to healthcare providers can occur as H1N1 vaccine distribution occurred through the CDC's Vaccine for Children's Program (VFC). The VFC will likely need to expand support for its objectives beyond the usual, I believe sole, contractor that supports the program. It should be, at least for distribution of this magnitude, expanded to include all the major national and some regional pharmaceutical distributors to assure the

vaccine reaches points of dispensing rapidly.

SNS further can support states and localities by quickly assessing current plans for vaccine administration and providing technical assistance in that area. SNS performed this mission well until CDC removed it from SNS portfolio. With the move to ASPR it was not returned to SNS portfolio even though moved to ASPR. SNS is best position to support this medical logistics management consulting and technical assistance requirement.

- **SNS Management**

3. What should the stockpile's priorities be moving forward to help prepare for a potential second wave and future pandemics?

ANSWER: The priority of the SNS should be to rapidly acquire additional stock of anticipated PPE, any therapeutic developed and all ancillaries required for vaccine administration. This effort must be undertaken in such a way that existing markets not be damaged further. That is to say, SNS must carefully time purchases so that supply can continue to enter the private marketplace as stocks are built. SNS should be authorized and funded to invest in additional manufacturing capacity and immediate purchase of new and novel PPE and other materials that can support long term response. The Congress must not act to in any way limit the sources upon which SNS can draw to meet this requirement.

4. If you had the ability to restock the SNS after COVID-19, what are key changes that you would make?

ANSWER: This discussion must assume that the Congress will or has appropriated adequate funding and will continue to do so for the SNS to property invest in pandemic preparedness. A one time capital infusion will simply purchase material but, as was the case after H1N1, will not allow for continuing to repurchase material as it is used or expires. Given the funding requirement SNS should:

1. Determine the necessary stock level of each product to serve as a buffer to ramp up production in a guaranteed fashion such that expiry is limited and storage requirements can be managed. This level could be determined assuming SNS must provide a percentage of the full requirement of use for each necessary item to sustain a response until new manufactured product is available and output of manufacturing achieves a higher surge rate.

2. Determine the necessary production requirements to support the first step above and invest in manufacturing capacity to assure surge operations can occur. This might include outright ownership of plants or lines as well as joint ventures or other options to increase on shore manufacturing and assure the government of that outputs availability rapidly.

5. Is the SNS appropriately housed under ASPR, or should Congress consider moving it to another government agency?

ANSWER: The SNS is appropriately housed under ASPR and Congress should not consider moving it.

1. ASPR is and should be the lead agency for health and medical response. SNS is a primary element of such a response.

2. The ASPR has delegated authority from the Secretary for SNS asset release and there should be no intervening layer, for example CDC, for the execution of that release.

3. ASPR is solely focused on response and planning for such response for health and medical and as such will not have a need to subordinate SNS requirements vital to that response to other priorities that are important to another agency such as CDC.

4. The health and medical response to such events should remain under civilian and not military authority. Much as FEMA is not placed under DoD neither should any part of health and medical response be placed under DoD. Under the National Response Framework, HHS can call on DoD for support. DoD needs to remain focused on our national defense from a military perspective and HHS should remain focused on National Health Security in conjunction with the other related civil authorities.

5. The medical and public health scientific community that must advise and support the requirements planning for the SNS and the response operations of the same are appropriately housed in HHS and its several OPDIVs. Cutting SNS off from this community would be problematic at best. This is especially true in the case of BARDA that develops and delivers new, cutting edge products to SNS; the FDA with whom SNS must closely work for regulatory needs and the CDC to provide public health and medical advice as required.

- **Pandemic Preparedness**

6. Since January, the Trump Administration has cut funding, ignored critical warnings, and disbanded the pandemic planning office. It also seems that supply chain responsibility has shifted away from the SNS and toward FEMA. What are your thoughts on this and our federal government's preparedness and response to this pandemic?

ANSWER: We will not successfully combat the current COVID crisis or any future pandemic event without a coordinated "all of nation" response. It is vital that an office such as the Pandemic Planning Office exist at the top level of the Executive Branch to coordinate an overall federal response in a logical and predictable way. It is vital that the federal government work to assure all states have what they need to respond to a pandemic. Leaving that up to each individual state creates chaos in an already complex response. For example, competing actors attempting to secure scare products creates supply chain inability to respond to any need in a logical fashion.

Shifting of supply chain responsibility to FEMA for medical supplies and medical logistics is detrimental to a good health and medical response. FEMA does not have the experience or resources available within HHS, particularly SNS, to rationally make purchases and assure their delivery to needed points. There are several published stories that clearly show FEMA does not have significant mastery of this unique medical supply chain or product requirements to meet this need. It may be useful in future response to place FEMA contracting personnel under the direction of HHS, particularly SNS, to make correct purchases.

- **PPE Supplies and SNS Coordination with Private Sector**
    7. Experts are calling on every hospital and/or state to have a 90-day supply of PPE on hand to prepare for a second wave or future pandemic, which seems untenable both because of the cost to update expiring supplies and the space it would take to store such large volumes of PPE. How can the SNS maximize its partnerships with private sector companies and associations to improve its ability to ramp up PPE supply to respond to future pandemics to avoid costly storage of PPE?

ANSWER: Respectfully, I do not believe asking hospital, hospital systems or potentially states with sufficient government funding to hold such a stock of PPE. Part of the initial problem in this response was the lack of preparedness in the private sector to support any surge in patient needs combined with a lack of material preparedness at the state level. A 90 day stock held between the private healthcare market and state stocks is the right start. The reach back to SNS can occur as that product is exhausted while at the same time the SNS can be working with manufacturers and distributors to increase the availability of products required.

To rapidly increase PPE or other medical material requirements, SNS should be provided funds and authorities to enter in to contracts designed to jointly own or create government owned manufacturing capability. Another option would be to fund and authorize SNS to create other incentives that would bring this manufacturing back on shore. SNS could also hold stock of raw material required for certain product manufacturing.

Post-Hearing Questions for the Record
Submitted to Mr. Gregory Burel
From Senator Kyrsten Sinema

"The Role of the Strategic National Stockpile in Pandemic Response"

June 24, 2020

1. What recommendations do you have on how the Strategic National Stockpile and other federal resources can establish a better allocation process that is more fair and equitable for Tribal governments? How can future distribution strategies ensure Tribal governments and tribal health facilities that order their supplies from the Indian Health Services receive what they need from the federal stockpile?

ANSWER: Support for tribal governments is currently planned and executed by the state(s) where the various tribes are located. In this way, we can be assured tribes are integrated with the overall federal response without effectively attempting to establish and manage two separate operations within the same geographic area. All health facilities in a state, regardless of where they normally order supplies, are included in these plans. States and localities should always assure that tribal needs are represented in planning.

SNS at one time was responsible for assisting the states and localities in creating response plans and assured that tribal needs were considered and incorporated. Unfortunately, CDC removed that responsibility from the SNS some years ago and SNS understanding of and ability to influence these plans was much diminished. These types of plans must mesh with SNS plans and are primarily medical logistics oriented. This responsibility was not returned to SNS when it moved to ASPR. This responsibility should be returned to SNS direct management to assure seamless planning and a seamless response with SNS material. This would directly benefit tribes by assuring they are correctly accounted and planned for response.

2. Based on your experience working with the Public Health Emergency Management Countermeasures Enterprise that is responsible for making recommendations on what gets added to the Strategic National Stockpile, what will happen once a vaccine is approved regarding its future inclusion in the Stockpile?
   a. For example, what happens in the event that several different vaccines get approved and prove effective?
   b. Does the advisory body make recommendations on the acquisition of the different consumables and medical supplies that will be needed to deploy the vaccine and other approved therapeutics, such as syringes?

ANSWER: Immediate plans for distribution of approved vaccines seems to be planned as was the distribution of H1N1 vaccine. That is, distribution will be through the CDC Vaccines for Children Program (VFC).

Inclusion of COVID vaccine in the SNS long term, other than a small stock to bridge production gaps, may not be advisable. After the initial vaccine push, it is probably better that the private healthcare delivery market simply operate as normal to provide this vaccine as long as and where needed. Vaccines are administered everyday for routine needs across the US with no involvement of the SNS. If the vaccine becomes an annual needs in one or more doses, then the market should adjust and provide that product through normal operations.

PHEMCE makes some recommendations on the necessary ancillaries to administer all drugs in the SNS. Ultimately, the SNS is responsible with its own science team collaborating with PHEMCE to identify the appropriate ancillaries for administration of all drugs in the SNS. There is no problem in the identification of these requirements. The problem is as for the rest of the SNS. Namely, inadequate funds have been provided to meet the mission requirements. This leave the SNS in a position often of having to choose between purchasing such ancillaries that are generally available in the market or purchasing a drug without which response is impossible. If it is necessary to choose between a product that, if SNS doesn't purchase it, will not be available and a product that is generally available commercially and produced for normal use SNS must choose the former.

Post-Hearing Questions for the Record
Submitted to Mr. Gregory Burel
From Senator Jacky Rosen

"The Role of the Strategic National Stockpile in Pandemic Response"

June 24, 2020

1. Antibiotic resistance is a growing public health threat, as infections that were once treatable become more dangerous due to resistance to older antibiotics. As we lose viable treatment options, we must ensure new treatments are available, especially in times of public health crisis—like what we are currently facing today. We have seen some COVID-19 patients developing secondary bacterial infections, which can be deadly when resistant to standard antibiotics. Can you please summarize how the Strategic National Stockpile medication inventory, including antibiotics, is updated to ensure the most effective treatments are included in the stockpile? Are novel antibiotics included? What recommendations do you have to ensure that the supplies and medications our nation is stockpiling meets the current public health needs?

ANSWER: Formulary decisions are made by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). BARDA, at the direction of the ASPR and PHEMCE is engaged in supporting the development and delivery of new antibiotics to the SNS. I would defer to the ASPR for a more fulsome discussion of BARDA work and priorities and how the PHEMCE engages in planning for SNS formulary.

2. The Strategic National Stockpile is a critical resource for our entire country, for which we should continue to support and expand the capacity, especially for critical PPE, testing materials, and supplies needed for large-scale vaccine distribution. Thinking beyond the standard methods of supply acquisition, what other creative approaches should be considered for how we can improve our response to a crisis, such as the current pandemic, that impacts the entire country at once? Should the stockpile also be acquiring 3D printers and raw materials to *produce* additional supplies, or other small scale and nimble manufacturing equipment? How else can the stockpile adapt in situations where usual supply chains are disrupted?

ANSWER: There are many new technologies and potential capabilities that can support SNS requirements to be nimble and flexible. It is unlikely any of these will ultimately lead to significant diminution of many of the stocks held by SNS. Rather than simply buy 3D printers or other items, SNS could be funded to work to identify new technologies for investment that will allow the SNS to become more nimble and address emerging threats in novel ways. This is some departure for BARDA from its primary mission of developing new products and must include SNS as an equal partner and investor in developing new technology to enable response. ASPR currently operates an innovation group that has been able to create new capability through items such as: portable hemodialysis units, prototype machines to fill sterile water and other hydration fluid requirements "on the fly", and new drug delivery technologies that cost less to produce and store than traditional needle/ syringe combinations. The key to accomplishing any of this type of work is to create a continual, stable funding stream to engage in this innovation effort while not diminishing the funding for traditional stockpiling responsibilities unless they can be rationally replaced through such new technology. At present, the SNS is not adequately funded to accomplish its regular mission much less engage in these endeavors as other than a minor effort.

3. In thinking through the challenges we have seen with testing supply shortages, and the strain on the Strategic National Stockpile, are there other testing methods that could increase testing capacity while also conserving supplies? For example, I recently heard about a testing model where groups of people that are in close proximity to each other – for instance, students in the same classroom, nursing home residents, or workers on the same shift – provide saliva samples and one test is run on the group as a whole. If negative, you know the whole group is cleared. If positive, the whole group is monitored, quarantined, or tested individually. Do you think this should be explored further to save resources and improve efficiency for testing certain groups?

ANSWER: I appreciate the question but I am not expert in diagnostic testing and must defer to those with appropriate expertise in this field to answer.

CBP OVERSIGHT: EXAMINING THE EVOLVING CHALLENGES FACING THE AGENCY

THURSDAY, JUNE 25, 2020

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 9:31 a.m., in room SD–562, Dirksen Senate Office Building, Hon. Ron Johnson, Chairman of the Committee, presiding.

Present: Senators Johnson, Portman, Lankford, Romney, Scott, Hawley, Peters, Carper, Hassan, Harris, and Rosen.

OPENING STATEMENT OF CHAIRMAN JOHNSON

Chairman JOHNSON. Good morning. The hearing will come to order.

I am looking at the title of this hearing: U.S. Customs and Border Protection "(CBP) Oversight: Examining the Evolving Challenges Facing the Agency." I was talking to Mr. Morgan earlier. I am wondering, if he could have foretold the future before he took this position, whether he would have done so. I mean, it has just been—challenges, yes; crisis after crisis after crisis. So I first want to thank the witness, thank you, Mr. Morgan, for your perseverance, for your service to this Nation, both past, present, and in the future, too. Things are not getting a whole lot better anytime soon, I fear.

I would ask consent that my written opening statement be entered into the record.[1]

It is a hearing on the border. We have not had one for quite a few months, so I obviously need to use a chart, and that is really what I want to talk about in my opening comments.

We have held I think close to 40 hearings on some aspect of the issues on the border, and with our horribly broken immigration system, we began keeping this chart[2] particularly on unaccompanied children, but then as the whole issue with people coming across and exploiting our asylum laws, coming in as families, the problem just exploded in late 2018 and into 2019. And the main reason I want to show this chart, you can see the gold-colored bars

[1] The prepared statement of Senator Johnson appear in the Appendix on page 925.
[2] The chart referenced by Senator Johnson appears in the Appendix on page 940.

are single adults, down slightly, but that has been pretty persistent, pretty stable for the 8 years that this chart represents.

What you do see, though, in red is unaccompanied children, blue are the family units, and, again, you can see the explosion of the family units drawn by the incentives of our broken immigration system where they really crescendoed in May 2019.

I am not going to put the chart[1] up, but you all have a little spread sheet here where we have been keeping track of monthly averages. In May 2019, we were averaging 4,651 individuals either crossing illegally between the ports of entry (POE) or showing up at the ports claiming asylum. That is 4,651 people per day. The most recent month where we have consolidated figures, that number is down to about 745 people per day, and when it comes to an approximate number of children, it is down to about 50 a day, 49 a day.

So we have made a huge level of progress, and I did want to point out particularly with this chart, it is not just because of coronavirus disease 2019 (COVID–19). I think that has definitely reduced the numbers, but we had made dramatic reductions prior to that because of some of the programs that Customs and Border Protection has implemented. I know some of them not everybody agrees with, but from my standpoint, it is extremely important that we enforce our laws. And I know that is certainly what Mr. Morgan agrees with as well.

Again, I think this has been some tremendous progress. In my own mind, I am thinking, What would it have been like if COVID hit when we were at May 2019 numbers, close to 4,651 people per day showing up at the border, with CBP personnel having to deal with that? It would have been completely overwhelming. It was overwhelming back then, but, throw COVID on top of that, so, again, congratulations, very good work at bringing the numbers down before this crisis hit. We obviously extend our condolences to the family members of the Customs and Border Protection Officers (CBPO) who lost their life because they contracted COVID and others that have contracted it as well.

So you are still dealing with enormous challenges. I am certainly looking forward to hear your testimony in terms of how you have handled it, how you are trying to deal with it today, and, again, thank you for your service.

With that, I will turn it over to Senator Peters.

OPENING STATEMENT OF SENATOR PETERS

Senator PETERS. Thank you, Mr. Chairman, and thank you, Acting Commissioner Morgan. Thank you for being here today. It is always good to see you.

Mr. Chairman, before I make my statement, I have three statements—one from Human Rights First, one from Kids in Need of Defense (KIND), and a testimony from the U.S. Conference of Catholic Bishops (USCCB)—that I would like to enter into the record by unanimous consent.[2]

Chairman JOHNSON. Without objection.

[1] The chart referenced by Senator Johnson appears in the Appendix on page 941.
[2] The statements referenced by Senator Peters appear in the Appendix on page 953.

Senator PETERS. Thank you, Mr. Chairman.

Customs and Border Protection certainly has played a vital role on the frontlines of our Nation's efforts to limit the spread of COVID–19 and, as always, to keep Americans safe.

Even in the face of this deadly virus that has infected millions around the globe and killed more than 120,000 Americans, the men and women of the CBP continue to do their essential jobs and protect our national security in very difficult situations.

However, CBP's service has not been without sacrifice, and I want to acknowledge the losses that your agency has suffered during this pandemic.

The lives of officers is a terrible price to pay, and I think I speak for all Members of this Committee when I express my grief and condolences to the families and to everyone at CBP.

In order to prevent more tragedy at the agency, we must ensure that frontline agents and Customs and Border Protection Officers have access to the personal protective equipment (PPE) necessary to defend themselves against COVID–19. We count on these officers to keep us safe. But they cannot do so effectively if they themselves are left unprotected.

Even in normal times, the agency plays an important role in border States like my home State of Michigan. And as we are all aware, these are far from normal times.

In the face of the Coronavirus, CBP has been tasked with limiting unnecessary travel between Canada and the United States, while continuing to support trade and essential services, including the vital medical professionals who cross the border to support Detroit's efforts to combat COVID–19.

As the Nation looks to reopen, cross-border communities in States like Michigan will rely on clear and well-communicated information about plans for loosening restrictions at the border. We must avoid confusion and uncertainties that occurred as these restrictions were announced and were implemented.

As we continue reopening, more trade and travelers will be returning to our Nation's ports of entry, especially at airports and land crossings. We must be diligent in applying the lessons learned over the past few months to ensure that CBP is ready to safely meet these very changing circumstances.

As we continue to move forward, we must strive to both implement strong safety and security measures and uphold our Nation's long-held values for the families and children who continue to seek asylum at our Southern Border.

CBP's priorities are often difficult to balance but the agency cannot simply abandon one part of their mission because things get tough. Congress and the Administration must work together to support effective trade, travel, migration, and security operations, particularly in this time of a pandemic.

So, again, Mr. Morgan, thank you for taking the time to be here with us here today. I look forward to your testimony and hearing what we can do to assist you in facing these extensive challenges.

Thank you.

Chairman JOHNSON. Thank you, Senator Peters.

It is the tradition of this Committee to swear in witnesses, so if you will please stand and raise your right hand. Do you swear that

the testimony you will give before this Committee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. MORGAN. I do.

Chairman JOHNSON. Please be seated.

Mark Morgan is the Chief Operating Officer (COO) and Senior Official Performing the Duties of the Commissioner at U.S. Customs and Border Protection. He began serving his country as a U.S. Marine and his community in local law enforcement. After completing a 20-year career in the Federal Bureau of Investigation (FBI), Mr. Morgan started at the Department of Homeland Security (DHS) as the Acting Assistant Commissioner for Internal Affairs before being appointed by President Obama as Chief of the U.S. Border Patrol. He served as Chief until January 2017. He later returned to DHS as the Acting Director of Immigration and Customs and Enforcement (ICE) in May 2019 and has been leading U.S. Customs and Border Protection since July 2019. Mr. Morgan.

TESTIMONY OF MARK A. MORGAN,[1] CHIEF OPERATING OFFICER AND SENIOR OFFICIAL PERFORMING THE DUTIES OF THE COMMISSIONER, U.S. CUSTOMS AND BORDER PROTECTION, U.S. DEPARTMENT OF HOMELAND SECURITY

Mr. MORGAN. Chairman Johnson, Ranking Member Peters, and Members of the Committee, thank you for giving me the opportunity to appear before you today to discuss the many challenges facing the United States Customs and Border Protection. Of course, topping the list of those challenges is the global COVID–19 pandemic. Infectious diseases, as we know, they do not know borders, and it serves as another example of why border security is so important.

Today and every day, individuals arriving at our border, with or without COVID symptoms, pose potential public health risks to the American people, our frontline personnel, our health care workers, and our community.

As we have discussed before, CBP encounters travelers and illegal aliens from more than 130 countries in a given year, most of which are also currently facing significant COVID–19 outbreaks. Thankfully, several early Presidential proclamations temporarily suspended the entry of travelers from certain countries. And as was mentioned, CBP, along with other United States Government (USG) personnel, were on the front lines enforcing those critical and essential containment and mitigation strategies. These actions no doubt saved American lives early on, and I am proud of the CBP workforce for their efforts.

Moreover, CDC issued a public health order on March 20 of this year, finding that the introduction of persons who would likely be held in congregate settings in ports of entry and Border Patrol stations increases the risk to public health. The Centers for Disease Control and Prevention (CDC) order has been a critically important tool in the fight against this public health crisis. It allows CBP to prevent the introduction and further spread of this virus in an effort to protect the American people, our workforce, and the immigrants themselves.

[1] The prepared statement of Mr. Morgan appears in the Appendix on page 928.

Let us be clear. This order is not about immigration enforcement. It is about taking immediate and decisive actions to address the public health threat that still continues today. Early on after that order, we saw those trying to illegally enter our country drop by more than 50 percent from our pre-COVID numbers. And rather than introducing the illegal aliens into our facilities, increasing the exposure risk to our workforce and our country, CBP, because of this order, is returning approximately 95 percent of those we encounter expeditiously to their country of last transit.

And as the Chairman said, can you imagine what we would be going through right now if we were going through this pandemic this same time last year when our Southwest Border facilities were overwhelmed and overcrowded with families and children? At one point we had more than 20,000 individuals in our custody. Introducing a single COVID migrant into these conditions would have been catastrophic, and I hope we are united that we must work together to prevent those conditions from ever happening again.

Now we are averaging about 150 to 200 people in our custody at any given time, and we have seen a 70-percent reduction in unaccompanied minors. As the Chairman said, it is important to note that CBP and DHS as a whole were already better positioned to deal with this global pandemic because of the success of the administration's network of immigration policies and initiatives that had been in place 10 months prior to COVID. These initiatives, as well as our partnership with the Government of Mexico and Central American countries had already reduced the flow of illegal migration by 76 percent from the height in May 2019. Our custody numbers went from 20,000 to just over 3,400, and the driving force behind the crisis—families from the Northern Triangle countries—have been reduced by 94 percent. And we had all but ended catch-and-release.

Even as CBP shifted our resources to mitigate the spread of this deadly virus, we maintained and continued our efforts against a vast, complex, and challenging array of threats. This year, fiscal year (FY) to date, we have seized over 500,000 pounds of drugs, an increase from this same time last year. Although the cartels had to adjust their tactics because of COVID, they are alive and well, and they adjusted quickly.

In fact, just after the first few months of this year, we saw a little bit of a downward departure at the beginning, but then soon after that, last May, they began to skyrocket back up. We saw a significant increase this past May. Methamphetamine seizures alone jumped 66 percent. This is why border security is national security. This is why border matters and, importantly, why the wall matters as well.

Last, while many in our country are self-quarantining or working from home, the majority of the CBP workforce does not have that option. They get up every day, they say good-bye to their loved ones, and they go to work protecting this Nation. They are our frontline defenders, as we have just said already. They are good, decent, honorable people who heroically carry out CBP's broad mission day after day, despite the risk to their own health and safety. I personally want to thank you, Chairman, Ranking Member Peters, for your acknowledgment of the seven CBP personnel that

we have lost this year. That is personal, and I sincerely appreciate you knowing that, understanding that, and acknowledging that. That means a lot that we can be united in acknowledging their sacrifices and the dedication to this country and the citizens they protect. I personally thank you for that, and I am looking forward today to answering your questions.

Chairman JOHNSON. Thank you, Mr. Morgan.

Without a doubt, the men and women of CBP, from my standpoint they are heroes. We are witnessing now an assault against law enforcement. I do not know how that could even possibly be a solution. And the same thing is true in terms of enforcing and securing our borders as well. Again, think of the situation we would have been in.

My first question really has to do with moving forward, anticipating what we are going to be dealing with, let us say, August, September, or October of this year. This is far different from the position we were in in May 2019 when America's unemployment rate was at record lows across all demographic lines. And, of course, those opportunities that only America is really known for was a huge draw combined with our broken system that could be exploited. Now we are going to have, I would anticipate, unemployment levels in excess of 10 percent. We are going to have Americans out of work. But we are also going to have economic hardship in countries south of our border as well.

How are you going to cope with that? Just talk a little bit about what your plans are and what you think the challenge is going to be.

Mr. MORGAN. Yes, sir. So, first of all, I think you are spot-on. And so right now, what we are going through right now with the CDC order, as I mentioned, really is from a public health perspective. But at some point, we are going to get on the other side of COVID, and my concern—I share your concern—is that what we are seeing right now is that while our economy has started going, it is by far worse in Mexico, Northern Triangle countries, really in the Western Hemisphere. So what I am concerned about is we are going to see the same pull factors that we have historically, but it is going to be magnified, because what we like to say with the accelerant of COVID it is that we are going to see these countries—their economic conditions are going to be far worse than ours. And we anticipate that we are going to see an increase, another surge of migration due to the economic conditions and the economic pull factor coming forward. It is a significant concern for us.

Chairman JOHNSON. For years, I have been saying, as we faced this crisis at our border, that the first goal is to reduce the flow of people coming in, exploiting our system, breaking our laws. Describe some of those programs. And, again, I realize not everybody agrees with them, but I think it is hard to disagree with the results. We have reduced the flow. Talk about those programs, what was most effective, and will they remain effective?

Mr. MORGAN. Yes, sir.

Chairman JOHNSON. And are they going to be challenged?

Mr. MORGAN. Yes, sir. I will take the latter first. So, yes, they are challenged. They have always been challenged, and I am assuming they are going to continue to be challenged. But as you

said, although we may philosophically disagree, as the Acting Commissioner of CBP, from our perspective, they have been effective with the goal of reducing the flow of illegal immigration. So you are spot-on. We have a multitude of programs that we are working with the Northern Triangle countries. I think most people are familiar with the Asylum Cooperative Agreement (ACA), and that is where those that transit through a country and come to our border, for example, we send them to Guatemala where they can go through the asylum process there in Guatemala. It has been effective.

Another program I know everyone here is familiar with is the Migrant Protection Protocol (MPP). That has been an unbelievably effective program, probably the most successful program that we have. Within a few months of its application, we started seeing a significant decrease in those that were trying to illegally enter the country because of that.

There are a couple other programs, Prompt Asylum Claim Review (PACR) and Humanitarian Asylum Review Process (HARP), and, sir, I think you know them well because they really mirrored what you started, Operation Safe Return, I believe last year, and I know there are other Members of this Committee that kind of joined you, how we can still give them the due process according to our laws that they deserve with respect to the law, how can we do that more effectively, more efficiently. Basically in a nutshell, that means we are just bringing the whole-of-government approach to the border, and we are doing it more efficiently. And we have done that. Again, conceptually, the same as Operation Safe Return, that has been effective as well.

So as we are seeing, as we are anticipating the increase of the flow coming because the economic conditions driving the pull factors that they always have, these programs are going to be absolutely essential to continue to stem the flow.

Chairman JOHNSON. Do you have any doubt, had you not initiated those programs, implemented them, carried them out, that we would not be at those excess of 4,000 people per day?

Mr. MORGAN. There is no doubt in my mind, without those programs we would still be in the middle of a crisis, seeing thousands of folks illegally entering every day.

Chairman JOHNSON. I know something else that is not 100 percent agreed on or appreciated is the border fencing. I know you were just down with the President earlier this week talking about how many miles we have implemented. Can you talk a little bit about what we have done in terms of new fencing, what you anticipate will be completed by the end of the year, and your evaluation of the effectiveness of that fencing now that it is in place?

Mr. MORGAN. Yes, sir. So, first of all—and I think this is something that I try to get every time. This is not the President's wall. This is the wall system for the United States Customs and Border Protection, for the American people. This is something that, when this Administration came into being, they asked: What do you need? They actually asked the men and women on the front lines. They asked the leadership of Border Patrol, What do you need? And they said: We need a border wall system.

And I say "system" on purpose, sir, because that is very important. So far, 220 miles of wall system has been built, and people ask me, well, how many new miles have been built? I say 220 miles of new wall system, because it is not just a bunch of metal going into the ground. It has integrated lighting, technology, access roads. This new wall system, every mile that is built is a new mile of capability that did not exist before. So it is a new mile of wall when it goes in the ground. So far, 220 miles, and as we have anticipated, we planned, we believe that in this year we are going to have completed 450 miles of the wall system.

And here is the fact: Again, this is not a political statement. This is a factually based statement that I can open the checkbook and show everybody, everywhere that a wall system has been built as part of a multi-layer strategy, infrastructure technology and personnel, all the stats you can imagine go in the right direction. Less people enter in that area. Less drugs come across that area. Less criminals come across that area. Less gang members come across that area. That is just a fact, and we can prove it, and it is effective. It is an effective impedance and denial tool, and everybody Border Patrol agent on the lines will tell you that.

Chairman JOHNSON. Thank you, Mr. Morgan. Senator Peters.

Senator PETERS. Thank you, Mr. Chairman, Commissioner Morgan.

The border restrictions at land ports of entry have been, as you know, extended three times and are going to remain in place until at least July 21. These restrictions, while very important—and I understand the importance of them—also have real-world impacts on States like Michigan. For example, hospitals in the Detroit area rely on Canadian doctors and especially nurses; a very large number of nurses cross the border daily to work in those hospitals in Detroit.

So my question to you, sir, is: What factors is CBP considering when determining the need for additional extensions? Are there any particular metrics or criteria that need to be met before reopening?

Mr. MORGAN. So, first of all, I completely agree with what you just said, and we are seeing the same thing on the northern border and the southwest border as well. And it even goes beyond, you know, those heroes in the medical profession that actually come to the United States to provide some vital service. But it is also economies on both sides. Obviously, I do not need to tell you, you are very well aware that there are economies on the Mexican side as well as the United States side that thrive and are dependent on each other, especially in the border cities. That is important.

And so we have been involved in those discussions. They have sought our input with respect to each time that they have made the decision to first implement the travel restrictions and to implement them, additionally to renew them. We are an integral part of that. I can tell you personally I have had conversations, for example, on the Southwest Border from Baja to Brownsville of leaders all across the board, not just law enforcement but local leadership as well, to really listen to them and understand, get a better understanding of exactly what they are experiencing. And so I think when we look at this, it cannot be done just from a public health

perspective. It has to be a balance of the public health risks and the economy.

I feel very confident, at least the elements that I have been involved with in CBP, that we are trying to do just that.

Senator PETERS. So when can we expect details from CBP about what the reopening of the border is going to look like and specifically get a better sense of how you engage in with our partners like the Canada Border Services Agency? There was some confusion between the United States and Canada, as you are well aware. I want to make sure that we have proper guidance so we do not have that kind of confusion as you are starting to reopen. Tell me a little bit about your work with the Canadian Government.

Mr. MORGAN. So, again, I completely agree. Early on there were some fits and starts, but we had and did and continue to work with our counterparts there to make sure that we are addressing those issues, to make sure that we are implementing these restrictions better. But equally as important, as we start to open back up—now, obviously, as CBP we do not make that decision when the travel restrictions will be lifted or modified. But we are already working both on the Northern Border and Southern Border with our partners what that will look like, how that will look like.

We anticipate, for example, on the land border that when the travel restrictions are lifted, we are going to see—we anticipate it is going to get back to normal pretty quick. Right now, if you look at the pedestrian vehicle traffic, those are down 50 and 60 percent, respectively. We think when we lift those restrictions in the land environment, those numbers are going to get back to normal pretty quick, unlike the air environment. So it is definitely an issue. We are working with them, I would say almost on a daily basis with our partners.

Senator PETERS. Good. We certainly saw some confusion at the beginning stages of the crisis at airports, including Detroit, with travel restrictions, lack of screening protocols, and some of those shortfalls created some dangerous situations with folks waiting in very long lines to get through the process and often not having any kind of protection that they were wearing. And now, months later, if we are looking at infection totals around the globe, they are actually very high and continue to be high. Yet we are also seeing travel now starting to pick up at the same time.

So my question to you is: What lessons did CBP learn from securing our border in the early days of COVID–19? And what practices would you plan to resume in the event of a continued resurgence abroad, particularly folks coming from China?

Mr. MORGAN. I will give you an example: contact tracing. I think that is one of those areas where we had some challenges when we implemented that at the start and we learned. There is another example in Chicago, same thing, where lines were lengthy. We are trying to look at our system. We have Advance Passenger Information System (APIS) and a couple other systems that we use, that we were able to collect the data that CDC needs, but it is cumbersome, it is manually, and it is not efficient.

And so early on that is where you saw we were trying to collect this information that CDC needs for the very important contact tracing. So what we are doing is we are working with CDC, we are

working with the Department of Health and Human Services (HHS), we are working with industry stakeholders, for example, in the air environment, I personally have been on a couple of calls. We have had those discussions of what can we do to get better to collect that information. And so that is what we are trying to work toward in the future, and when I saw pretty quickly, probably by September, we need to have an interim solution. But what we have done since then, though, immediately, kind of the 3-meter target, if you will, is we changed how we have done that now, so now that contact information, we kind of do what we call "pre-primary," really right after they get off the plane, they de-board from the plane, and we have our DHS contract personnel there collecting that information, doing the medical screening, and asking the questions that they should while CBP personnel are there. That has absolutely helped tremendously. But we still need to get better on that, and that is why we are still working for a better solution.

Senator PETERS. Good. Reports indicate that, like the U.S. Citizenship and Immigration Services (USCIS), CBP is going to face some funding shortfalls as a result of COVID–19-related decrease in the user fees that folks pay. I have worked on a number of provisions to support the hiring and adequate staffing within CBP and worked with you to make that happen, which I appreciate. But I am concerned about the impact that the shortfall will have on the workforce as well as security at the ports of entry.

My first question: Will you have to furlough officers based on some of the reports that we are seeing?

Mr. MORGAN. Right now, seeing what I see, no. I am not anticipating that right now. But, sir, you are absolutely right. It is an issue. Right now, I think you probably know better than most, about 40 percent of the workforce are funded through user fees, and most of those are through international travel. We are seeing a significant reduction. We are looking at a $600 to $700 million shortfall in user fees. So it is definitely a challenge. We are working with DHS, we will work with the Office of Management and Budget (OMB), we will work with the appropriators to try to find a solution.

Senator PETERS. Do you expect that you are going to be requesting some supplemental funding to get through this?

Mr. MORGAN. I do not want to get too far ahead of that, but I think we are going to need some help from Congress. What that help is going to look like I think we are still trying to work through, but we will definitely need some assistance.

Senator PETERS. Thank you.

Mr. MORGAN. Thank you, sir.

Chairman JOHNSON. Senator Lankford.

OPENING STATEMENT OF SENATOR LANKFORD

Senator LANKFORD. Mr. Chairman, thank you. Mark, thanks so much for——

Chairman JOHNSON. We cannot hear you.

Senator LANKFORD. I am not on mute, so——

Chairman JOHNSON. Still cannot hear you, James.

Senator CARPER. You look great.

Chairman JOHNSON. Yes, we can see you just fine.

Senator LANKFORD. I am not on mute, so it is on your end.

Chairman JOHNSON. If you do not mind, let us go to Senator Carper, and then we will come back to you once we get your audio fixed. Sorry about that. Senator Carper.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Mr. Morgan, welcome. Thank you for joining us today. And I want to join my colleagues in expressing our appreciation and our affection for the men and women that you serve with and lead.

It is true that travel bans, when used effectively and imposed in a timely manner, can help delay the arrival of a highly contagious virus to our shores. But we were reminded just earlier this week by Dr. Julie Gerberding, former CDC Director who appeared before our Committee yesterday, she said back in February at a roundtable, a Homeland Security and Governmental Affairs Committee (HSGAC) roundtable, and I will quote her: "Once you see sustained community transmission, the horse is out of the barn." And Ron Klain, who was the Ebola czar back a couple of years ago, and quite a successful effort, as you will recall, he said in February about the President's order blocking travel from China, he said, "We do not have a travel ban." He said, "We have a travel Band-Aid right now."

First, before it was imposed, 300,000 people came here from China in the previous month, so the horse is out of the barn.

This week, seven States reported their highest-ever hospitalizations from COVID. Three months and 121,000 deaths later, unfortunately, we are still not prepared.

I have a friend, and if you ask him how he is doing, he always says, "Compared to what?" I just want to review with you and share with you some numbers that I shared with my colleagues a couple of weeks ago. "Compared to what?" Let us compare population and deaths in Taiwan to what we face. Taiwan has about 25 million people. So far they have suffered seven deaths. Twenty-five million people, seven deaths. South Korea has over 50 million people. They have suffered 274 deaths. Singapore, about 6 million people, 25 deaths. New Zealand, 22 deaths; Australia, 102 deaths; Japan with 126 million people, 916 deaths; China, with 1.4 billion people, they are reporting about 4,600 deaths. Let us say they are not telling the truth. Let us say it is twice that much. That is still under 10,000. Germany, 83 million people, 9,000 deaths; Canada, our neighbor to the north, 38 million people, 7,800 deaths. Mexico, our neighbors to the south, 128 million people, 14,000 deaths; and the United States with 328 million people, now we are up to 121,000 deaths.

Back in February, February 28, the President said of the virus, he said, "It is going to disappear. One day it is like a miracle. It will just disappear."

March 6, he said, "Anybody that wants a test can get a test. That is what the bottom line is.

March 10, 2020, he said, "This was unexpected, and we are prepared and we are doing a great job with it. And it will go away. Just stay calm. It will go away."

March 24, he said, "We have never closed down the country for the flu, so you say to yourself, 'What is this flu all about?'"

May 20, 2020, on the United States having the most cases in the world at 1.5 million to that date, despite testing shortages, he said, "When you say that we lead in cases, that is because we have more testing than anybody else. We do not look at that as a bad thing. That is a badge of honor."

"A badge of honor" to have 121,000 people die from this pandemic.

I want to ask you a couple questions, if I may, Commissioner, and one of those—let me just ask you to just react to what I just shared. Just react to what I just shared.

Mr. MORGAN. Sir, I think I guess my initial thought is I am not a medical professional, and as Acting Commissioner of CBP, when we were called upon to implement and provide our guidance and our knowledge with respect to what would be the most appropriate way to implement travel restrictions, both in the air environment, sea environment, and land environment, that is what we did. And I think that the men and women of the CBP have done an incredible job doing that.

There are areas where individual agencies like the CDC are needing a certain type of information, and CBP has done just yeoman's work to try to improve those processes to get the work they need to be able to safeguard this country. And what I can say is from a public health perspective, in our role as CBP, I think we have done an incredible job. I think the efforts that we have taken both in the air, sea, and land environment have saved countless. I could not even guess how many thousands of American lives have been saved because——

Senator CARPER. I am going to reclaim my time. Can you imagine, had you not done a great job, how much worse it would be? The numbers that I just shared with you, we have less than 5 percent of the world's population; we have over 25 percent of the world's deaths. Can you imagine how much worse it would have been if CBP had not been doing a sterling job?

Let me ask another question, if I can. Last summer, as you will recall, in response to the growing humanitarian crisis at the Southern Border, Congress passed and the President signed into law a supplemental appropriations bill of about $4.5 billion. Of that funding, $1.1 billion went to CBP. The funds were to be used to ease severe overcrowding at CBP stations and at ICE detention facilities, lack of adequate health care facilities and personnel, and a lack of administrative capacity to support CBP agents and officers. Congress provided the funding with strict instructions on how it should be used and how it should not be used. This month, the Government Accountability Office (GAO) reported that CBP has misspent a portion of these funds, violating the statutory provisions that governed their use. Among the items purchased with taxpayer funding to ensure the safety of migrants in CBP custody were such items as dirt bikes, motorcycle, all-terrain vehicles (ATVs), and surveillance equipment.

GAO has recommended that CBP either adjust its expenditures to account for these deficiencies or that it report a violation of the Anti-Deficiency Act as required by law. I would just ask for—I do

not have any more time left, but just a yes or no answer: Do you commit to following GAO's recommendations?

Mr. MORGAN. Absolutely. Yes, sir.

Senator CARPER. Thank you very much.

Chairman JOHNSON. That is one way to——

Senator CARPER. Live and in person.

Chairman JOHNSON. That is one way to solve technological problems. Senator Lankford.

Senator LANKFORD. Yes, physical presence does make a difference. Apparently they could hear me online, but it does make it harder for you to answer the questions, Mark, so you could not actually hear. Mark, thanks for your work and for your service. Please pass on our condolences to the families of the seven that we have lost from CBP and a lot of folks that live every day with the threats that are coming at them, as every person coming across the border they do not get the privilege of being socially distanced from and they are not wearing masks when they come across. It is a very different environment for them. So for those folks, please tell them thank you for the work that they continue to do.

I want to back up on a series of questions dealing with seizures. I know CBP has been very engaged in seizing fake testing kits and fake medications, fake masks, N95 masks. What is the status on that and what are you seeing?

Mr. MORGAN. Absolutely, sir. Unfortunately, every time that there is a crisis, from a law enforcement perspective the first thing we get together collectively is we set up a task force because we know that criminals are going to take advantage of it, and COVID–19 has been no exception, and that is right. So we have really gotten together as USG, we have gotten together with a host of investigative agencies to really focus on this, and hundreds of thousands of fake masks have been recovered, countless COVID tests have been recovered that really could have done serious harm to the American consumer had it gotten into their hands, and this is something that as we are trying to implement the travel restrictions and stop COVID from coming into our country, we have still been equally as committed to this.

Senator LANKFORD. I appreciate that very much. You also made a comment earlier that the number of individuals illegally crossing the border has decreased and the apprehensions, obviously, have been along those same lines as well. The amount of drugs coming into the country has increased per pound. Are you seeing changes in amounts? Are you seeing more methamphetamine, more fentanyl, more cocaine? Are there trends that you are seeing in that as well, not only total amounts but are you seeing—what I am looking for is types of drugs as well.

Mr. MORGAN. Absolutely. So the four hard narcotics that I call—they are increasing, especially from this time last year. I think I said in my opening that methamphetamine, for example, just last month increased 66 percent. I will get the numbers if I am off a little bit—but from this time last year, it is up 20, 30 percent from this time last year. What we are seeing, the cartels do what they do best. They change their tactics and techniques quicker than anything that I have ever seen in the history of law enforcement. And so when COVID hit, it impacted them.

I will give you a quick example. The number of vehicles coming across have dropped by 65 percent, and so their normal mode was smaller loads and vehicles and just try to get them through the masses, and it was fairly effective. And now since the number of vehicles coming through has drastically reduced, that is not working anymore. So now they are going to the cargo environment because cargo has continued to flow the entire time, and so now they are taking a little bit of risk, and they are actually putting larger loads in the cargo to get it through. So they are shifty.

But now we are seeing them take greater risk. They are using pedestrians more, body carries, and we have seen them continue to shift, and they are effective.

Senator LANKFORD. We know the cartels make a significant amount of money in transporting families and children across the border. That has been a significant amount as well as single adults, as the cartels' major income source, along with drugs, is to be able to move people. Obviously, with the significant drop of people, is it your assumption that we are seeing the increase in drugs because they want to be able to keep their same income source? Or why do you think we are seeing the increase in drugs at this point?

Mr. MORGAN. Absolutely, sir. I think you are spot-on. I think that is part of it. I mean, that is what they do, right? They will go to anything to them for a profit, and if something is being hit and taking profit away, they are just going to shift to another entity to make profit. As I said, from this time last year, overall pre-COVID, 76-percent reduction. Since COVID, we have had an overall 84-percent reduction in the total flow from this time last May. So you can imagine that has taken billions of dollars out of their pocket. So they are absolutely shifting. That is why I think we are going to continue to see an increase of drugs coming into this country. I think that is why we have seen an increase of the hard narcotics increase across the board. They are changing their tactics. They are going by sea more. They are doing what we call "mixed loads" now, both drugs and smuggling humans as well. And so they are really branching out. We are seeing them use air more, tunnels more. They are expanding as much as they can.

Senator LANKFORD. OK. Title 42 authorities dealing with a health emergency and communicable disease overseas an from people transiting into the country at this point, there is a significant amount of authorities that are there. Walk me through how those are actually applied, those Title 42 authorities, and what you think the difference is in the enforcement and the number of people trying to cross, because, obviously, there are still a lot of people that want to be able to come to the United States. What difference do you think those Title 42 authorities make and what are they?

Mr. MORGAN. So it has been significant. I think, if I can, if I back up fairly quickly to put it in context, prior to COVID and prior to Title 42, because of administration admission policies, we had already made a significant decrease in the flow—again, 76 percent. We went from 20,000 in custody to 3,400 in custody prior to COVID.

OK, now COVID, Title 42. What we saw initially, March 21, within the first probably 2, 3 weeks, we saw a 50-percent decline in those trying to attempt to illegally enter. That was significant.

I mean, it really shows that the individuals listened to the medical experts, they are self-quarantining, they are not taking a risk from a public health perspective, and it was working.

What we have seen now, though, is we are seeing the numbers start to increase a little bit, especially Mexican nationals. So now we have seen that shift in demographics 100 percent. About 75, 80 percent now are Mexican nationals, and that is a shift from what it was last year.

Senator LANKFORD. Do you think the count of Mexican nationals is increasing or the percentage is increasing?

Mr. MORGAN. The percentage is increasing.

Senator LANKFORD. But you think the count is close, folks that are other than Mexican has declined that much?

Mr. MORGAN. That is correct. If you look at this time last year, I think it was around 17,500. This past month it was almost that, but the percentage increased. But what we are concerned about, though, is that, again, as we get on the other side of COVID, Mexico's economy, really the Western Hemisphere's economy is really bad, we think that that is going to create an additional pull factor because of the economic conditions.

Senator LANKFORD. The last number that I saw was this fiscal year, which would be October 1 of last year until the end of May this year, about 276,000 people that had been apprehended that were inadmissible. Those were either at ports of entry or between ports of entry along the Southwest Border. Does that number seem about right?

Mr. MORGAN. Yes, it does.

Senator LANKFORD. So around a quarter million at this point that we have picked up during that time period. That is a significant decrease from what we have seen in the past, but that is a very large number.

I also thought it was interesting as well, I went back to look at the number of people that were given naturalization last year, to be able to just look at the last year that we have a full year of naturalization: 833,000 people legally went through the process and were naturalized. That is an 11-year high.

So one of the things I just want to be able to mention to you is this administration has continued to be able to accelerate into legal immigration and naturalization with an 11-year high for the number of people that legally went through the process to be naturalized, but have also been very focused on declining illegal admissions into the country. So just, again, tell your folks thank you for the work that you continue to be able to do to enforce the law and continue to be able to protect your people.

Thank you.

Mr. MORGAN. Yes, sir, and if I can, thank you for that. I thanked the Chairman and Ranking Member earlier, too. I will take that back, and I can tell you the men and women out there, when they hear that from their elected leaders, it means something. So I will take that back, sir. Thank you.

Chairman JOHNSON. Thank you, Senator Lankford.

We will try Senator Scott. Try to talk and see if we can hear you.

OPENING STATEMENT OF SENATOR SCOTT

Senator SCOTT. Hi, can you hear me?

Chairman JOHNSON. Yes, I think we can. Turn it up.

Senator SCOTT. So we would like to thank you, Chairman Johnson, for the hearing. I want to thank Mr. Morgan and everybody at Customs and Border Protection for what you are doing.

Earlier this year, I had the opportunity to visit——

Chairman JOHNSON. We can barely hear you. We are trying to boost the volume. Do you have volume control on yours?

Mr. MORGAN. I cannot hear at all.

Senator SCOTT. Is this better? Can you hear me now?

Chairman JOHNSON. A little bit better, yes.

Senator SCOTT. OK. So do you want me to go ahead and go? Or do you want to go to somebody else first?

Chairman JOHNSON. Actually, we can hear you pretty good. Just get as close to your—there you go?

Mr. MORGAN. Where is the speakers at, sir? I am still having a hard time hearing.

Senator SCOTT. All right. So, Mr. Morgan, can you hear me?

Chairman JOHNSON. Mark, can you hear?

Mr. MORGAN. It is tough, sir.

Chairman JOHNSON. OK. It is not going to be good if the witness cannot hear you, so I think we are just going to have to say if you want to come in and ask questions, you are going to have to come down to the hearing room—or come up to the hearing room.

Senator SCOTT. OK. All right. Let me try it one more time. Can you hear me now?

Chairman JOHNSON. Mark, you have to answer that.

Mr. MORGAN. I can but it is not great. We can try it.

Chairman JOHNSON. OK. Give it a shot.

Senator SCOTT. OK. First off, I just want to thank you for what everybody does at the international mail facilities around the country. I had the opportunity to visit the one down in Miami, and one of the concerns I have, which I think a lot of us have, is the amount of counterfeit goods that are coming in from Communist China, and I want to compliment you for what you are doing all the time. If you could talk about what Customs and Border Protection is trying to do to stop the amount of counterfeit goods that are coming in from Communist China, I would appreciate it.

Mr. MORGAN. Yes, sir. So I did hear that, and this is something that you are absolutely spot-on. This is a significant issue. The counterfeit goods that are coming in, a considerable amount from China, absolutely cross the spectrum. If it is made, it is being counterfeited. And many of these items go directly to impact the public health of the consumers here in this country. So we are continuing to work with all of the appropriate partners in USG to come up with not only new policies to address to better position us, but also new techniques and new processes which will increase our ability to actually identify, detect, seize, and stop those counterfeit goods from coming into this country.

Senator SCOTT. Do you have the resources to be able to do it?

Mr. MORGAN. So that is always the question, and it depends on what the scale is. If you look at the amount of volume, especially on the ecommerce, especially on the *de minimis*, which I know you

are familiar with, the numbers are astronomical that come in. And so that is a challenge. So we are doing some operations, Operation Mega Flex, for example, where we are surging resources. We are working with the United States Postal Service (USPS) as well where we are surging resources to increase our capacity to seize, interdict, and stop those counterfeit goods. But to say that we have both the technology and the boots on the ground, if you will, to be able to adequately look at everything coming across right now, the answer is no.

Senator SCOTT. The trade deal that we signed with Communist China, did it do anything to require them to try to crack down on either the counterfeit or the substandard products that they ship over to the United States?

Mr. MORGAN. Yes. In fact, I have had several conversations with Peter Navarro, and we are working together, and that is exactly something that they are trying to drive. That is really a driving factor outside of CBP, but we are fully supportive of that because that is important. If there is not some sort of accountability, then we are not going to see a significant shift. And the last strategic plan that we put out last year had provisions in there where we will as the USG be able to hold China more accountable with respect to counterfeit goods.

Senator SCOTT. Are they complying? Are they actually trying to be helpful at all? I mean, my concern is that China never complies with anything. They will say they will do something, and then, of course, they never do it. They have never complied with any agreement they have ever signed that I have found.

Mr. MORGAN. I think what I am probably comfortable saying is those dialogues and negotiations are continuing, and we will continue to look at the data and make an assessment.

Senator SCOTT. OK. Are there things that Customs and Border Protection is doing now to deal with our airports and how we can make them safer as a result of the COVID or the risk of things coming—I guess it is primarily goods, but coming from outside this country, including Communist China?

Mr. MORGAN. Yes, sir, and that may be when it comes to a global pandemic, we are mainly going to implement what the medical experts decide. In this case, CDC, our medical professionals within DHS, as well as the medical professionals we have with the CBP, they are engaged. They have been early on, often, all day, every day, it seems like. They are talking to each other, and they are trying to come up with new solutions on how we can make that environment safer for passengers that are coming in.

I think a key important element to that is also the stakeholders, the airlines. So we are working with the airlines. In fact, last week, I participated personally in a couple of trade conversations when we talked to the airlines and we specifically had conversations about this. How can we do that? Because part of this is, balancing that public health risk, but also increasing consumer awareness and their comfortableness with flying again. That is critical. So we have to balance that, both of those needs.

Senator SCOTT. It is pretty important to the Florida economy to be able to get individuals comfortable flying again. There are

things that, of course, government can do, but a lot of it has to be done at the airline level to get people comfortable.

I just want to finish by thanking you for what you do. I want to thank everybody at Customs and Border Protection for what they do every day to try to keep Americans safe and try to make sure American products that come in here are not, counterfeit, they are not things that are bad for us. So if you will thank everybody on behalf of me from the State of Florida, I am very appreciable of what you all do.

Mr. MORGAN. Yes, sir, I absolutely will. Thank you.

Chairman JOHNSON. Senator Rosen.

OPENING STATEMENT OF SENATOR ROSEN

Senator ROSEN. Thank you, Senator Johnson, Ranking Member Peters, for having this important oversight hearing today. And, of course, Acting Commissioner Morgan, I appreciate you being here in person with us today as well.

I want to talk a little bit about the entry restrictions for children. On March 21, 2020, CDC and DHS suspended admission of certain immigrants regardless of their country of origin, purportedly due to the health concerns of COVID–19. Reports indicate that under new policy DHS has deported nearly 3,000 unaccompanied children arriving at the U.S. border instead of transferring them to the Office of Refugee Resettlement (ORR) custody, as required by Federal anti-trafficking law. The Trafficking Victims Protection Reauthorization Act (TVPRA), as it is a lot easier to say that, the removal really places these children at risk of human trafficking, persecution, and other grave harm.

So is CBP transferring unaccompanied children arriving at the U.S. Southern Border to ORR custody and screening them as required by law?

Mr. MORGAN. So the answer is yes and no. So Title 42—and I think this is important. Again, I am being obvious here, but as we are in the midst of this public health pandemic, this global pandemic, the priority must be to contain and mitigate the spread of this virus and to keep it from further being introduced into the United States.

But, ma'am, I can assure you that CBP, through implementing the CDC order, it is consistent with law, policy, including our nonrefoulement obligations.

Senator ROSEN. Can you tell me how many, do you know how many unaccompanied children you have removed since March 21?

Mr. MORGAN. Yes, I have those numbers——

Senator ROSEN. And then while you are looking for those, do you have the number of how many were not screened for trafficking or protection concerns? Because that is what we are concerned about.

Mr. MORGAN. Yes, ma'am. So I have this down. I will make sure I follow up with my staff to make sure the numbers are right, but approximately under Title 42, the CDC order, about 2,000 were processed under Title 42, and just shy of 300 were processed under Title 8, and they would go to the normal procedure through——

Senator ROSEN. So only 300 were screened out of the 2,000?

Mr. MORGAN. No, ma'am. No, ma'am. So they are all screened, and——

Senator ROSEN. A hundred percent of these kinds were screened for trafficking and protection concerns?

Mr. MORGAN. Yes, ma'am. So that does not change. So we are still—if we see anybody, any signs that someone is trafficked, then they are going to fall out of Title 42, and they are going to be then treated under——

Senator ROSEN. Regardless of seeing signs, the regulation is that all unaccompanied minors are screened. You are screening all unaccompanied minors. Is that what I am understanding?

Mr. MORGAN. Yes, ma'am. We are complying with our nonrefoulement requirements under the law. Yes, ma'am.

Senator ROSEN. OK. Thank you. I want to move on a little bit now to a little bit of transparency and oversight, this is a Committee hearing on oversight, and so Nevada, of course, we are home to thousands of immigrant families. They make up part of the diverse fabric of our State and of our country. And too often, unfortunately, I hear concerns from our State's immigrant community and advocates about DHS oversight when it comes to investigating abuse by ICE and CBP personnel, including sometimes racist remarks made by Border Patrol agents at the Southern Border.

So can you please give us a little insight into what accountability measures are in place for CBP agents and their officers who engage in verbal abuse or other forms of misconduct directed at immigrants?

Mr. MORGAN. It is handled like any allegation of misconduct, ma'am. So we have a robust Internal Affairs Office of Professional Responsibility. It used to be called "Internal Affairs."

Senator ROSEN. Could you describe the grievance process then? The immigrant has to make the claim? Another officer makes the claim? Can you speak to that a little bit, please?

Mr. MORGAN. It depends on the circumstances, but if an individual, if an immigrant feels that they have been mistreated in any form or fashion, yes, it——

Senator ROSEN. So what is their process? If I am an immigrant, I am in custody at the border. I have been a victim of some form of abuse or comment. How do I go about talking about that?

Mr. MORGAN. There is a variety of options for them, ma'am.

Senator ROSEN. Just give me one example.

Mr. MORGAN. I can give you one. They can report it to a supervisory CBPO or a Border Patrol agent.

Senator ROSEN. And then where does it—like where is the oversight in there that they have some way to get their claim heard?

Mr. MORGAN. Right. So then the process is that claim—like for this example, if it is reported to a supervisory Border Patrol agent or CBPO, then that allegation will immediately go to our joint intake center and our Office of Professional Responsibility.

Senator ROSEN. And have you conducted an independent review of this process?

Mr. MORGAN. Yes. Yes, we actually have a cadre of hundreds of special agents that this is what they do. Their full-time job is to investigate allegations of misconduct.

Senator ROSEN. And so have you produced reports of this independent review? Is there something that we can look at and see?

Mr. MORGAN. Yes, ma'am. Every year—in fact, the 2018 report just recently came out.

Senator ROSEN. It is 2020, so can we see that? Can you please direct that to us so we can see how the grievance process——

Mr. MORGAN. Yes, ma'am. We can work with your staff to get you whatever current information we have. Absolutely.

Senator ROSEN. Thank you. I appreciate that.

I guess I have about a minute left, and so how about if we talk a little bit about the remain in Mexico program, the Migrant Protection Protocols (MPP). Two months ago, DHS and Office of Immigration Review announced they are going to be rescheduling all those MPP hearings due to COVID–19, so people in Mexico awaiting their court dates are forced to travel to their destination port only to find that their date—they have traveled unnecessarily, only to find that their date has been changed to receive notice that they have a new hearing date. And so I think this is a shortsighted policy, and how do we be sure that people are not traveling just to find out that they cannot get there?

So can you tell me how many immigrants waiting in Mexico for their scheduled court date were required to make the journey back just to receive notice of the postponed court dates?

Mr. MORGAN. So I am not aware of that, ma'am. My understanding was we communicated that out for those circumstances where they had to come. We can take a look at that and we can get——

Senator ROSEN. I would like to see some numbers on that, if I could.

Mr. MORGAN. We can get better at that, but I can assure you the decision behind continuing to postpone this I fully support. As Mexico cases continue to rise, deaths continue to rise really in the Western Hemisphere—Brazil now has become the epicenter, Latin America really has become higher than the European countries as far as the number of cases. So it is still a real threat——

Senator ROSEN. So if you are going to change the court date and you are going to require someone to come in person to receive that tear notice or however that notice is, can you modify that policy to let them know so they do not have to make this trip unnecessarily just to find out that they cannot be——

Mr. MORGAN. My understanding is that was not happening, but if that was, yes, ma'am, we can get better at that.

Senator ROSEN. I appreciate that. I look forward to hearing those numbers. Thank you.

Mr. MORGAN. Yes, ma'am.

Chairman JOHNSON. So I do not see Senator Hawley. I do not think he is coming in. So we will go next to Senator Romney. Then it would be Senator Hassan, then Senator Portman. Senator Romney.

OPENING STATEMENT OF SENATOR ROMNEY

Senator ROMNEY. Yes, can you hear me?

Chairman JOHNSON. We actually can, yes.

Senator ROMNEY. Good. Thank you.

Chairman JOHNSON. Talk as loud as you can, though.

Senator ROMNEY. OK. I have a big voice. I will do my very best.

First, I want to express appreciation to your entire team for the work that you do helping keep our country safe from products that are coming in that are adulterated that could cause harm to our citizens, products that are also coming in that are not adulterated but are themselves going to cause harm to our citizens, and I am talking about, of course, drugs and other illegal substances, and also protecting our workforce from those who would come in and take jobs that they are not qualified or authorized to take.

One of the things I learned on my trip to the border in San Diego, as I met with Border Patrol agents and, in fact, with the head of the Border Patrol agent union, he said to me something interesting. He said, "One of the problems we have is that the magnet is so strong, people are going to find a way to get here, whether we like it or not." And I said, "What magnet are you talking about?" And he said, "The magnet I am talking about is the job magnet," which is if people can earn $10 an hour on one side of the border and $1 an hour on the other side of the border, they are going to try and move from one to the other. They are going to come to America for the opportunity for a better-paying job and also for a better future for their kids. And his point was that, yes, it is important to have a wall built, to make it more difficult for people to cross into our country illegally, but that if we really want to stop the amount of illegal immigration that comes in and takes American jobs, we are going to have to have an effective way to prevent people from getting American jobs if they are here illegally.

And that is why, of course, the Nation has our E–Verify system, and yet this is not mandatory. Businesses of all kinds are not required and not using the system to determine if someone is here legally or illegally.

I guess the question is: What is your perspective and the perspective of the people you work with on what we need to do not just to build a wall, which is important and I support, but also to change the conditions in our country so that we reduce the incentive for people to come here illegally?

Mr. MORGAN. Yes, sir. So you are spot-on. The job magnet statement I completely agree with. That is what we see. That is absolutely without a doubt. The overwhelming majority of the pull factor is that they are coming here for economic reasons. That is a fact. That is not hyperbole. It is a fact. So you are absolutely right. So we have to do things collectively as USG, as a Congress, to pass meaningful legislation to address those incentives, job factors. We need to continue to make sure and hold employers accountable that continue to hire people that are in this country illegally. If we do not do that, they are going to continue to come. No matter how bad our economy is in this country, it is worse elsewhere, and that is what we are seeing right now with COVID. If not, they would not keep coming. It is just, a little bit of common sense.

So you are absolutely right on that, and there are more incentives, though, than just the jobs. I mean incentives that once they get here, they know that they are going to be able to stay here and remain. We have so many loopholes in our system, and that is why, with all due respect, I have been saying for a long time we still need Congress to step up to pass meaningful legislation to address this crisis, to actually address the incentives. So I agree with you.

I will say, though, that the wall is still a very important thing because it helps us with drugs and criminals and a lot of other bad stuff coming in as well. We need to do it all, including the wall.

Senator ROMNEY. Thank you. I do agree. I am one of those that is pushing for mandatory E–Verify and penalizing companies, penalizing employers that do not use E–Verify, penalizing them just like we do if they do not pay their taxes, they get in trouble. I would have the same kind of penalties associated with not using E–Verify and hiring people that are here illegally. I welcome, as Senator Lankford indicated, legal immigration, and the fact that that has been enhanced is good news. But illegal immigration is not fair to the millions of people who would like to come here ultimately and want to do so legally.

Of course, the other issue relates to drugs coming into our country, and I do not know that you have any recommendations in that regard. Of course, as long as there is demand, as long as there are people here willing to spend a lot of money to buy drugs, the drugs are going to find a way to get into this country, either through the mail system or through tunnels that people dig, or in the ocean or in aircraft. I mean, they will find a way.

Do you or do your colleagues have any thoughts about what we could do to reduce the demand pull, the magnet, if you will, that has been a scourge for so long in our country, a health scourge, but also a real challenge, I am sure, for you and your agents as you seek to try and close off as many avenues as possible?

Mr. MORGAN. Sir, again, I think you are spot-on. I say often we are not going to seize our way out of this drug problem. That is not going to happen. This really does take a whole-of-government approach to this as well, and so as we are looking at the criminal element, as we are targeting the Transnational Criminal Organizations (TCOs), we also have to address that very real demand side in this country. If we are going to solve the problem, it has to be simultaneously attacking that.

But you are right. We are seeing drugs coming in the mail environment. We are seeing them come in through the air environment, through the sea environment, the land environment. You name it, they are using every technique that they can. But Attorney General (AG) Barr is spearheading a USG collective approach of how we can get better to target the cartels, target the smuggling organizations. CBP is an integral part of that. And we are making some headway. We are continuing to improve our strategies so that positions ourselves to more effectively go after these cartels and hopefully try to disrupt them as much as we can.

Senator ROMNEY. Thank you, Director. I appreciate your responses to these questions and very much appreciate the work that you and your team are carrying out on behalf of our country.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator Romney. Senator Hassan.

OPENING STATEMENT OF SENATOR HASSAN

Senator HASSAN. Thank you, Mr. Chairman and Ranking Member, for holding this hearing, and thank you, Mr. Morgan, for coming before the Committee. I just want to add my thanks to those

you have already heard for the men and women of CBP for all the hard work they do, and I join my colleagues in mourning the loss of the officers that we have lost.

I want to follow up a little bit on questions that Senator Lankford and now Senator Romney had asked you about the drugs that are trafficking across our border, but I want to focus on fentanyl. As you know, my State and many States continue to grapple with the effects of opioid abuse stemming from the trafficking of drugs like fentanyl. Our latest numbers in New Hampshire, unfortunately, indicate that overdose deaths are keeping pace with recent years in the midst of this pandemic, if not being slightly higher.

Can you please provide me with an update on fentanyl and other drug seizures at the Southern Border and all other points of entry during the pandemic?

Mr. MORGAN. So for the most part, it has not slowed down. We saw, early on this year, at the height of COVID, we saw drugs across dip down a little bit, but I would say in the last 30 days, in May, they went back up to include meth and fentanyl both. In fact, Border Patrol seizures in between the ports of entry of meth have gone up. So it is still there, and it is still coming, and it is still a problem.

Senator HASSAN. And are they still using the same essential strategies on fentanyl?

Mr. MORGAN. Yes.

Senator HASSAN. OK. Can you also please update us on efforts to combat illegal trafficking of fentanyl through the U.S. mail system from countries like China? Have we seen any changes in patterns since the start of the pandemic?

Mr. MORGAN. We have. Actually, I would go forward before the pandemic.

Senator HASSAN. OK.

Mr. MORGAN. So that is really where we made our strides. So we worked with China. We got them to schedule certain drugs so they are made illegal in China.

Senator HASSAN. Right.

Mr. MORGAN. So China was working with us, but that was dramatic. In the mail environment, we saw drugs coming in from China specifically go down dramatically, and this has really been, pre-COVID.

Senator HASSAN. OK.

Mr. MORGAN. We are working with the United States Postal Inspection Service. We are doing operations; I mentioned Mega Flex. We are specifically targeting the mail environment, and we have seen that go down. But the cartels, what do they do? They just have the precursor chemicals sent right to Mexico. They have their own chemists.

Senator HASSAN. Right.

Mr. MORGAN. They are developing them themselves now.

Senator HASSAN. That is right. OK. Thank you for that update.

I also want to follow up a little bit on something that Senator Carper mentioned. A Government Accountability Office review of emergency border security aid expenditures appropriated by Congress revealed that CBP spent funds reserved for migrant care and

aid on CBP border equipment, like motorcycles, all-terrain vehicles, and boats. After the release of this audit, your agency has conceded that the GAO report is accurate and that CBP was at fault for spending these funds incorrectly. I really appreciate that forthrightness and admission, but I would like to know specifically how much was misspent on equipment. Can you give us those numbers, please?

Mr. MORGAN. So what it came to is that 95 percent of the $1 billion emergency supplement, there were no errors, and what they found was there was a chunk of $112 million that there were some issues. Sixty million of that is what is really in question. And so some of that, about half of that we believe were due to some technical errors. I am not an accountant, but basically we put it in the wrong line, and so it was a technical error. Thirty million is really what is left that we think is in question. It still requires some further analysis and kind of a legal opinion with respect to that, and we will work with the GAO on that. Again, glad they did the audit.

The last thing I would say is we believe that there was no violation of the Anti-Deficiency Act, meaning we believe all the charges appear to be valid CBP operating expenses. We just may have put them in the wrong bucket.

Senator HASSAN. So what you are telling me is it may have been as much as $30 million of aid that Congress appropriated for emergency purposes which was intended to address an overwhelming crisis from last summer. I know that—I appreciate, again, that you guys are being forthright, but it is important that you are fixing this after the GAO audit. But why isn't CBP doing a real-time audit of these numbers in order to ensure that misspent emergency aid can be refocused in an equally timely manner?

Mr. MORGAN. So two things, ma'am. If I misspoke, I apologize. I am not saying that we actually agree that the money was misspent. Again, that $30 million is what we believe is what requires further analysis. And so what we think, it was technical errors, which we need to correct, and we need to get better and make sure that does not happen. But we do not believe that there was any violation, again, of the Anti-Deficiency Act going forward.

Senator HASSAN. As I read the summary of the GAO report, I might differ with that because I think expenditures on certain kinds of vehicles are not connected to the kind of emergency care that Congress intended that funding to be spent on, and I would look forward to following up with you all on that.

Mr. MORGAN. Yes, ma'am, absolutely.

Senator HASSAN. One last question. Last fall, I traveled to Afghanistan in part to assess U.S. efforts to battle opium production by Afghan poppy farmers and the Taliban. Unfortunately, it appears that opium farming remains widespread, and we have made far less progress than I would have liked and I am sure all of us would have liked on this effort.

We also learned that the opium farmed in Afghanistan generally supplies Europe and Canada and rarely makes its way to the United States. However, my State shares a border with Canada, as do many of my fellow Committee Members' States. If U.S. forces withdraw completely from Afghanistan without addressing opium

production, how do you think this will affect our ability to stop opioid trafficking efforts into the United States?

Mr. MORGAN. Ma'am, I am really not positioned to be able to definitively address that, but obviously, as you stated, that is a problem. That is a problem that has to be addressed, and that is why we need to and I know we are attacking this as a USG problem. And we are not just attacking this and waiting for this stuff to come to our borders. We are trying to get out there and stop it from coming to our borders.

Senator HASSAN. I thank you for that. One of my concerns is that as we continue to attempt to slow drug trafficking from our Southern Border, if our Northern Border is considerably more porous and we know that opium from Afghanistan goes to Canada, that gives traffickers a whole other strategy to pursue.

Mr. MORGAN. Yes, ma'am.

Senator HASSAN. So, again, I would look forward to continuing this conversation with a whole-of-government approach. Thank you.

Mr. MORGAN. And you well know most of the drugs coming in come from outside our borders.

Senator HASSAN. Thank you very much.

Thank you, Mr. Chair.

Chairman JOHNSON. Senator Portman, we will see if we can hear you.

OPENING STATEMENT OF SENATOR PORTMAN

Senator PORTMAN. How is that, Mr. Chairman?

Chairman JOHNSON. Actually, very good. Great. Thank you.

Senator PORTMAN. Thank you for holding the hearing. And, Mark, thank you for being here.

I, first of all, want to say that I think during the COVID–19 period, your people have not gotten the credit they deserve to be able to keep our transportation system working well. Having traveled a lot on airplanes in the last couple months, I can say that people are back. The airports are not entirely full again, but planes, instead of being 10 percent and instead of being 25 percent, are now 80 percent full that I have been on, and the people you have who are putting their own health at risk every day are to be commended, and I thank you for that. Please, pass along our gratitude for all of those individuals for helping to protect all Americans as we try to get this economy back going again in the midst of continued concerns about COVID.

One question I have for you, I have talked to your people; I have talked to them about the importance of the masks and the hand sanitizer and the gloves and so on. What has the incidence of COVID been among your people that you can attribute to infections that are resulting from interaction with passengers? Have you had an issue there?

Mr. MORGAN. So that is a hard one to quantify, but overall I would say, yes, clearly. And if you look at, as well, the epicenter for us as CBP, it has kind of mirrored what has happened in the United States. So our first largest degree of COVID-related outbreak for our personnel happened in New York a few weeks ago. And now as expected, as we are starting to get additional out-

breaks in Texas and Arizona and California, the trend of CBP personnel is following that.

What is hard to determine sometimes is whether they have that from community spread outside of work or they got that while at work. But, again, I know I am saying the obvious here, as you said, they are out there every day, especially right now on the Southwest Border. They happen to—not everybody has given up down there. A lot of these folks are running from them, and they are having to go down and get up close and have close contact, "high-risk contact," we could call it, so definitely exposed. We have had several hundred that have tested positive.

Senator PORTMAN. Thanks for helping to keep Americans safe and also to keep your people safe.

On the kids, I think about 22,000 UACs, kids, have come in. And as you know, we have done a lot of work on this issue in the Permanent Subcommittee on Investigations (PSI) and some of the four interagency communication between HHS, DHS—my sense is some of that is better. I want to hear from you on that. But my general point would be I am pleased to hear that you continue to do the screenings on trafficking. None of us want to see these kids trafficked. And it is in the COVID era a different situation. I know you have to return some people because of the fear of COVID being spread. But I want you to know I appreciate your personal commitment to continuing this screening for trafficking.

Mr. MORGAN. Sir, if I could real quick, if we go back to May of—this time last year, we were averaging about 370 children a day. Now it is 31. That is just tremendous. And so those children that under Title 42 we do return, we are intensely working with the government that we are returning them to, to make sure that they are returned in a safe, humane, compassionate manner, and then make sure that those countries that we are returning them to are working to return them with their families.

I mean, this process actually is—that is what we are trying to do. We are actually trying to reunite the children with their families back in their home country.

Senator PORTMAN. And that is exactly what we should be doing. As you know, I got involved with this egg farm issue in Marion, Ohio, my home State, where you had kids actually returned to the traffickers by HHS. And my sense is that the reforms have been put in place to help on that.

With regard to Customs and Border Protection and the fentanyl issue, you did not mention the Synthetics Trafficking and Overdose Prevention Act of 2018 (STOP Act) earlier, and this Committee, as you know, passed the STOP Act and got it through Congress, and what it did was it required the Postal Service for the first time to require this advance electronic data so that your people can identify the packages coming from China and elsewhere that might have fentanyl in them. And we required 100 percent from China, by the way, for good reason.

Can you give us a report on that? My sense is we are not quite at 100 percent. We were at 86 percent as of last year. And my sense is that this has been very successful. Already the Federal Express (FedEx) and the DHSs, the other private carriers, had to provide this data. You all were in their distribution centers. You were

finding the contraband. Now you are doing it with the post office. As a result, the traffickers have shifted their means of entry into the United States, and more of it is coming across the border now instead of through the mail.

But could you give us a sense of how you have been working with the Postal Service in particular and whether you think that is working well, whether the STOP Act needs to be improved, or whether you think it is actually effective at stopping this fentanyl that was coming almost entirely through the mail at one point and then primarily through the mail?

Mr. MORGAN. So I do not know—I will have to get back to you, sir, on the exact stats, the percentage we are at right now, but we can get back to you on that.

But the work of CBP and the Postal Service, it is a great relationship. It is a great partnership. We have been working together for a very long time. I think I mentioned a couple times the Operation Mega Flex that we have done, and because of that work, we actually went out to the corporate world, and we put a statement out there saying, hey, we need some folks to come up with innovative ideas on how we can get better at detecting drugs in the mail environment. And that is being worked on right now.

So we are continuing to do things to improve our ability to do that, but you are spot-on. Like I said earlier, we attack that together kind of a USG perspective, and we saw a dramatic increase, especially coming from China. But as you said, unfortunately, they are just shipping it now directly to Mexico, and it is coming across the land border.

Senator PORTMAN. Yes. By the way, the best thing we can do to help you is stuff like the STOP Act, which required the post office to do what they refused to do. The International Narcotics Trafficking Emergency Response by Detecting Incoming Contraband with Technology Act (INTERDICT) Act also provided funding for some of this technology to be able to help you do your job. So let us know where we can be helpful. I think the place we can be most helpful right now, frankly, is on the prevention, treatment, and recovery side, to try to reduce that demand that drives so much of this with these huge profits that you talked about earlier. And we were making great progress there with regard to opioids. As you know, in the 3 years before COVID hit, we finally had reductions for the first time ever in any way you measure it, including the number of overdoses and overdose deaths. Now I think we are back up again, unfortunately. At least in my home State of Ohio, we are seeing more overdose deaths in some cities than we had last year or the year before, getting back to our high level of 2017. So we have to do a better job to help you to reduce that demand because, otherwise, you have an impossible job, very much the same as we were talking about the importance of the E–Verify system and immigration, that magnet of jobs, whether it is the magnet of the demand for drugs here or the magnet for jobs.

On E–Verify, quickly, our big issue has been the identifier. So the E–Verify system, in my view, ought to be mandatory. I think Senator Romney spoke well about that previously, but the issue is these employers who say, yes, I accepted the ID, which was the Social Security card and driver's license that were issued in my State,

and it seemed valid. But they are fraudulent, and it has been difficult for us to figure out a way without a national identifier to be able to assure that the person is, in fact, someone who should be in this country and is here legally.

What are your thoughts about fraudulent documents and identifiers and how we can address that issue which is really the bottleneck in having an effective E–Verify system?

Mr. MORGAN. What I would say, as you know, it is a little—E–Verify is outside of CBP. It really is in ICE's purview, so I want to be cautious and not speak on behalf of Director Albence for ICE. But it is a challenge.

Senator PORTMAN. I understand that, but it affects your guys and women as they are trying to do their job, unless we can deal with the demand, again, and this magnet. So, if you could weigh in a little bit this morning—and my time has expired, but also just stay engaged in this issue because your telling them, "This helps us to be able to do our job," I think may be effective in getting us to a better system.

Mr. MORGAN. Yes, sir, and we have those discussions all the time. So even though it is outside my purview, trust me, I am on board. Again, we have to get better at holding those companies that are intentionally hiring illegal workers, we have to hold them accountable. But it is a complicated, tough matter to investigate.

Senator PORTMAN. Yes. I will say there is some new technology, facial recognition technology that people are talking about, because, again, you cannot rely on these documents, many of which are fraudulent. You can buy a Social Security card apparently for $25 on the street that is fraudulent but effective sometimes for those purposes.

So thank you again. Thank your people. Tell them that we appreciate what they are doing every day.

Mr. MORGAN. Thank you. I will.

Chairman JOHNSON. Senator Harris.

OPENING STATEMENT OF SENATOR HARRIS

Senator HARRIS. Thank you, Mr. Chairman.

Commissioner Morgan, for the past several weeks, as you know, people from all walks of life have been demonstrating in all the 50 States, and they are protesting the unlawful killing of, in particular, black men and women by police.

According to a government document obtained by Yahoo News, at least 400 CBP personnel have been deployed to some of these marches. I sent you a letter on June 5, and it was joined by my colleagues, asking you a number of questions that included what identification and equipment your personnel are carrying, what forms of force are they authorized to use, and what surveillance are you conducting during these deployments. I have not received a response. Can you give me today a date that I can expect to get that response?

Mr. MORGAN. I will get with the staff, ma'am, and we will get that to you as fast as we can.

Senator HARRIS. By the end of next week, please.

Mr. MORGAN. We will do our best to do that, yes, ma'am.

Senator HARRIS. OK. Thank you. And given your mission to focus on our borders, why are you deploying your folks to these protests?

Mr. MORGAN. Because we were asked.

Senator HARRIS. By whom?

Mr. MORGAN. By a few different individuals, and it is not just that we deployed resources to the National Capital Region. We also deployed resources all over this country.

Senator HARRIS. I am glad you brought that up. Which States did you deploy them to?

Mr. MORGAN. I have that information. I can provide it to you. I think it was 11 or 12 States that we deployed, and we got those requests from a variety of individuals. We got some of those requests from other Federal agencies, but we also received those requests directly from State and local police departments that specifically requested a certain type of assistance.

Senator HARRIS. Great, so I look forward to the follow-up, and if you could include, just as you have mentioned, not only where you have deployed but also the requester.

Mr. MORGAN. Yes, ma'am. We have all that information.

Senator HARRIS. Thank you. I appreciate that.

As you know, U.S. Customs and Border Protection is the largest Federal law enforcement agency in the country and has, unfortunately, a documented history of abuse and misconduct allegations. And there is a 2014 analysis that I am familiar with by the American Immigration Council of 809 complaints of abuses by Border Patrol agencies from 2009 through 2012, which found that in 97 percent of the cases in which an outcome was reported, no action was taken against the officer. The complaints included hitting someone's head against a rock, stomping on someone's back, touching women inappropriately, and kicking a pregnant woman, causing her to miscarry.

In a 2017 report, on 2,178 complaints from 2012 to 2015, the percentage of cases with reported outcomes where no action was taken against the officer was 96 percent. So, obviously, the people in the streets are marching because of their concern about those cases where law enforcement has abused its power and exercised excessive force.

How are you dealing with these cases in your agency? Because, obviously, these numbers are troubling when in the high 90-percent-range there is no action taken on these complaints. Do you believe that that number reflects the actual behaviors that have been reported? And are you confident that you have conducted the investigations accurately and adequately?

Mr. MORGAN. So I am not sure what you are implying by that totally, but to answer that question, yes, I have confidence in the system. I think we have a robust process, and when there is——

Senator HARRIS. So let me just, so I can clarify——

Mr. MORGAN [continuing]. An allegation of misconduct, that it is fully investigated.

Senator HARRIS. So I will clarify. So where there were 809 complaints, there was no action taken in 97 percent of the cases. So you are confident that only 3 percent of those cases were actionable?

Mr. MORGAN. I am confident, ma'am, that we—like you said, we are the largest law enforcement organization, 61,000. Now, a single allegation of misconduct is important, but if you look at that number and put it in perspective, that number is actually very low for a workforce of 61,000. And what I will say is that I am confident in the system. Is it a perfect system? I would never say that. But I am confident in the system that we have a cadre of individuals within our own agency as well as outside agencies. These allegations of misconduct are routinely reviewed from the local district attorney's office, as you well know, to the Department of Justice Civil Rights Division as well as our own internal mechanism as well.

Senator HARRIS. What is your internal——

Mr. MORGAN. So I am confident in that system.

Senator HARRIS. What is your internal mechanism? Is there a division within your agency?

Mr. MORGAN. Yes, ma'am.

Senator HARRIS. What is the name of that division?

Mr. MORGAN. Office of Professional Responsibility. Back then it would have been called "Internal Affairs." So we have hundreds and hundreds of special agents that are dedicated, their whole job 24/7 is to do nothing but investigate allegations of misconduct.

Senator HARRIS. And do you report these investigations and outcomes in a public report?

Mr. MORGAN. We put out a report every year, yes, ma'am.

Senator HARRIS. And that report, what is the name of that report?

Mr. MORGAN. I do not know the title of the report off the top of my head.

Senator HARRIS. So you produced one last year as well?

Mr. MORGAN. The last one that I have seen is 2018, and they are working on 2019s.

Senator HARRIS. OK. When do you expect that to be complete?

Mr. MORGAN. I do not have that information, but I could get that to you.

Senator HARRIS. OK.

How are you ensuring then that your personnel who are now being deployed to these demonstrations are complying with your rules and your ethical rules as well?

Mr. MORGAN. So, one, they are trained, so they fully understand what their use-of-force guidelines are. We have an appropriate leadership and supervision that is there also. And then like we always do when there is a special deployment, we have briefings, and the totality of the circumstances are explained to them, what their mission is, and what the expectations are.

Senator HARRIS. And so do you have in written documents an outline of what are your stages of discipline for specific types of behavior of your agents when they break the rules or break the law?

Mr. MORGAN. Absolutely. It is well documented and pretty extensive.

Senator HARRIS. Can you provide our Committee with that, please.

Mr. MORGAN. Of course. Yes, ma'am.

Senator HARRIS. Thank you.

Since March 20 of this year, there was a policy that your agency has implemented that turns away people who come to our border without fully letting them make their case for why they are in danger in their home countries and deserve refuge in the United States. By many accounts, this policy denies these folks due process and access to our asylum protections.

Since implementation of this policy, I understand you have turned away 43,000 people, and reportedly at least 2,175 of them are unaccompanied children.

Mr. MORGAN. Ma'am, what policy are you referring to?

Senator HARRIS. The policy that you initiated on March 20, 2020.

Mr. MORGAN. CDC order.

Senator HARRIS. Yes?

Mr. MORGAN. Right, so that was actually not a DHS or CBP policy. That was actually a CDC directive and order under Title 42——

Senator HARRIS. Which you implemented.

Mr. MORGAN. Yes, directed us to implement——

Senator HARRIS. Right, that is what I said.

Mr. MORGAN [continuing]. For the public health of the country, yes, ma'am.

Senator HARRIS. Right, you implemented it.

Mr. MORGAN. Yes, ma'am.

Senator HARRIS. OK. So public health experts have said that this policy "fails to protect public health" and "disregards alternative measures that can protect public health while preserving access to asylum and other protection."

Mr. Chairman, I am going to ask unanimous consent (UC) to submit a package of letters from these organizations into the record.[1]

Chairman JOHNSON. Without objection.

Senator HARRIS. Thank you.

So, Commissioner Morgan, I understand today you testified that you have expelled about 2,000 unaccompanied children. Is that right?

Mr. MORGAN. We have removed approximately 2,000 children under the CDC Title 42 order to ensure the public health and reduce the introduction of COVID–19 into this country, yes.

Senator HARRIS. And have any of those children suffered violence, trafficking, assault, or any other harm after you turned them away?

Mr. MORGAN. We work extensively with the government of the countries that they are being returned to, to make sure that they are returned in a safe, humane, compassionate way, and that they are actually reunited with their parents in their home country.

Senator HARRIS. Have you received any reports of any of those children that you have turned away having been——

Mr. MORGAN. No, I have not seen——

Senator HARRIS [continuing]. Exposed to any type of abuse or harm?

Mr. MORGAN. I have not seen any report.

Senator HARRIS. Have you been told of any reports of that?

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[1] The letters referenced by Senator Harris appear in the Appendix on page 943.

Mr. MORGAN. I have not been told of any specific child that under the CDC order that we returned to their country of origin, that was a victim of abuse.

Senator HARRIS. And my last question on this point: How many of those children have been reunified with their family?

Mr. MORGAN. We would have to work with the government that we returned them to to get that information. The governments would have that information. We do not track that information.

Senator HARRIS. Is there a reason you do not track that information if you are concerned about their safety after you turn them away?

Mr. MORGAN. Because we rely on the country of origin for them to reunite them with their family.

Senator HARRIS. I would ask that you consider putting in place a policy where you do track whether those children are actually reunified with their families once you turn them away.

Mr. MORGAN. We can look at that, ma'am. Yes, ma'am.

Senator HARRIS. Thank you. I appreciate it.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator Harris.

Mr. Morgan, again, thank you. Thank the men and women that work in your agency. They are putting their lives on the line. Again, tragically we lost seven due to COVID, but we have also had over the years, tragically, other CBP officers that have lost their lives in the line of duty. So law enforcement is hard. I think you saw pretty unanimously of this Committee, we truly appreciate the level of service and sacrifice, so please pass that along to them as well. So thank you for your testimony. Thank you for your time.

The hearing record will remain open for 15 days until July 10 at 5 p.m. for the submission of statements and questions for the record.

This hearing is adjourned.

[Whereupon, at 11:04 a.m., the Committee was adjourned.]

APPENDIX

Opening Statement of Chairman Ron Johnson
"CBP Oversight: Examining the Evolving Challenges Facing the Agency"
June 25, 2020

As prepared for delivery:

Last year the men and women of Customs and Border Patrol faced a humanitarian and national security crisis along the southern border with an unprecedented surge of migrants. More than 144,000 migrants were apprehended or deemed inadmissible in May 2019 alone. This year, CBP faces the challenge of having to perform its duties during the COVID-19 pandemic. Today's hearing will focus on how CBP is confronting these new and evolving challenges.

CBP's mission is to secure America's borders while enabling lawful trade and travel. These responsibilities do not stop during a pandemic; they only become more difficult. CBP must continue to protect against the flow of illegal drugs, terrorism, and human trafficking, among other threats. They must remain vigilant as bad actors adapt and seek out new ways to circumvent our laws. Now during this pandemic, CBP officers and agents must also enforce other legal restrictions to protect the health and safety of migrants, CBP personnel, and our nation's border communities, while at the same time helping to safely process migrants with legitimate claims for asylum.

Unfortunately, even when this pandemic subsides, our broken immigration system all but ensures that there will be future crises at the border. The administration has taken necessary steps to curb the flow of illegal migration. Programs like the Migrant Protection Protocols, Prompt Asylum Claim Review, Humanitarian Asylum Review Process, and the execution of Asylum Cooperative Agreements with the northern triangle countries have all helped to reduce the flow of illegal migration. I appreciated the opportunity to work with CBP and some of my colleagues on our Operation Safe Return proposal that formed the basis for some of these programs.

Although these programs help ensure the processing of asylum claims is more efficient and effective, they are only temporary solutions to a long-standing problem. Our immigration system is outdated and ill-equipped to deal with the reality we face today, and the blame falls squarely on Congress. Regardless of your opinion of the Supreme Court's recent decision on DACA, it is a stark reminder of how much authority Congress has ceded to the Executive Branch on immigration issues. It is well past time for Congress to pass legislation to fix this horribly broken system.

I would like to conclude by thanking the men and women of CBP. They continue to work tirelessly on the frontlines to keep America safe and secure. In addition to CBP's work securing our border and responding to COVID-19, CBP has also provided assistance to local, state, and federal law enforcement agencies to protect the right to peacefully protest. We ask CBP to do a lot, and time after time, they respond with admirable dedication and professionalism. I would also like to thank Mr. Morgan for testifying before our Committee today and for his leadership during this critical time. I look forward to your testimony and discussion.

U.S. Senate Committee on Homeland Security and Governmental Affairs
"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

OPENING STATEMENT OF RANKING MEMBER GARY C. PETERS
June 25, 2020
AS PREPARED FOR DELIVERY

Thank you Mr. Chairman, and thank you Acting Commissioner Morgan for being here with us today.

Customs and Border Protection has played a vital role on the frontlines of our nation's efforts to limit the spread of COVID-19 and keep Americans safe.

Even in the face of a deadly virus that has infected millions around the globe and killed more than 120,000 Americans, the men and women of CBP continue to do their essential jobs and protect our national security in very difficult situations.

However, CBP's service has not been without sacrifice. And I want to acknowledge the losses your agency has suffered during this pandemic.

The lives of officers is a terrible price to pay, and I think I speak for all members of this committee when I express my grief and condolences to their families and to everyone at CBP.

In order to prevent more tragedy at the agency, we must ensure that frontline agents and Customs and Border Protection Officers have access to the personal protective equipment necessary to defend against COVID-19. We count on these officers to keep us safe. But they cannot do so effectively if they themselves are left unprotected.

Even in normal times, the agency plays an important role in border states like my home state of Michigan. And, as we are all aware, these are far from normal times.

In the face of the Coronavirus, CBP has been tasked with limiting unnecessary travel between Canada and the United States, while continuing to support trade and essential services, including the vital medical professionals who cross the border to support Detroit's efforts to combat COVID-19.

As the nation looks to reopen, cross-border communities in states like Michigan will rely on clear and well-communicated information about plans for loosening restrictions at the border. We must avoid confusion and uncertainties that occurred as these restrictions were announced and implemented.

As we continue reopening, more trade and travelers will be returning to our nation's ports of entry, especially at airports and land crossings. We must be diligent in applying the lessons learned over the past few months to ensure that CBP is ready to safely meet changing circumstances.

And as we continue to move forward, we must strive to both implement strong safety and security measures and uphold our nation's long-held values for the families and children who continue to seek asylum at our Southern Border.

CBP's priorities are often difficult to balance but the agency cannot simply abandon one part of their mission because things get tough. Congress and the Administration must work together to support effective trade, travel, migration, and security operations, especially in the midst of a pandemic.

Thank you for taking the time to be here with us today. I look forward to your testimony and hearing what we can do to assist you in facing those challenges head on.

TESTIMONY OF

Mark A. Morgan
Chief Operating Officer and
Senior Official Performing the Duties of the Commissioner
U.S. Customs and Border Protection

BEFORE

U.S. Senate
Committee on Homeland Security and Governmental Affairs

ON

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

June 25, 2020
Washington, DC

Chairman Johnson, Ranking Member Peters, and Members of the Committee, it is my honor to appear before you today to discuss the major challenges that U.S. Customs and Border Protection (CBP) will face in the coming year, and to discuss how we responded to prior challenges, such as the migration surge, from last year.

At the top of the list of ongoing challenges is responding to the COVID-19 pandemic. The global scale of this pandemic is unprecedented in the 21st Century, and underscores that one of the most important missions we undertake at the border is protecting the American people from global health threats. The heightened attention around this disease shows how intertwined border enforcement is with public health and safety. COVID-19 is a highly infectious disease. Make no mistake: any individual arriving at our borders—with or without symptoms—is a potential risk to our frontline personnel, healthcare workers, the American people, our communities, and even the U.S. healthcare system itself.

As of June 23, there were 9.1 million COVID-19 cases worldwide, with more than 472,000 deaths.[1] On June 23, the United States was approaching 2.3 million confirmed cases and nearly 120,000 deaths.[2] Among those fatalities are, tragically, five CBP employees.

From the outset of the global pandemic, President Trump has taken bold actions to protect the health and safety of the American people. This has undoubtedly saved lives and slowed the spread here at home. In the past, CBP dealt with outbreaks of tuberculosis, SARS, Ebola, and other communicable diseases; dealing with outbreaks is nothing new for CBP. The infectious disease procedures we already had in place enabled us to implement the President's vision quickly and effectively.

Looking back at 2019, CBP saw a massive surge in migration. During the humanitarian crisis of fiscal year (FY) 2019, CBP took more than 1.1 million enforcement actions against individuals who entered illegally into the United States or were determined to be inadmissible. Border Patrol agents encountered the largest group of migrants ever—more than 1,000 migrants—and 128 groups of more than 100 migrants. If the COVID-19 pandemic had occurred during the 2019 humanitarian crisis, when CBP's Southwest border (SWB) facilities were overwhelmed and crowded, or when the U.S. immigration system was still using the "catch and release" policy of releasing aliens into surrounding U.S. communities, the pandemic in this country could have been catastrophically worse.

Fortunately, in part as a result of implementing the Migrant Protection Protocols (MPP), the number of migrants in CBP custody had already dropped dramatically when the COVID-19 pandemic emerged. For the first eight months of FY 2020, CBP took enforcement action against more than 403,000 migrants who illegally entered or were determined to be inadmissible, compared to the same timeframe in FY 2019, when we had taken more than 676,000 actions. By the time the pandemic emerged, we had in place a number of other mass migration mitigation

[1] Johns Hopkins University, Coronavirus Resources Center, COVID-19 Case Tracker (June 19, 2020) https://coronavirus.jhu.edu/map.html.
[2] Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19) (June 19, 2020) https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.

strategies that we developed in cooperation with U.S. Immigration and Customs Enforcement (ICE) Enforcement Removal Operations (ERO), U.S. Citizenship and Immigration Services (USCIS), and the Department of Justice (DOJ) Executive Office for Immigration Review (EOIR). Prompt Asylum Claim Review (PACR) and Humanitarian Asylum Review Process (HARP) are programs to promptly assess credible fear claims. Asylum Cooperative Agreements (ACAs) facilitate cooperation with partner countries to expand humanitarian protections, and the Electronic Nationality Verification (ENV) and Interior Repatriation Initiative (IRI) programs are designed to quickly return migrants with final removal orders to their home countries. CBP deems MPP and these other strategies a success, and will seek to continue implementing them in full once the pandemic subsides.

Protecting Americans from COVID-19

CBP regularly encounters travelers from more than 130 countries, most of which are also facing significant outbreaks of COVID-19. While the number of CBP apprehensions has dropped dramatically in FY 2020, there are still migrants trying to enter this country illegally every single day. They continue to ignore the travel restrictions despite the risk they present to the health of the American people.

CBP assesses all arriving travelers to determine whether or not they have been in a country with travel restrictions within 14 days of arriving at a U.S. border. This assessment is occurring at all air, land, and maritime ports of entry (POEs), and CBP officers routinely observe all travelers—regardless of their country of origin—for overt signs of illness. Border Patrol agents apprehending aliens between the POEs are also observing everyone they encounter for symptoms of COVID-19 so they can refer them to further medical screening by the appropriate health authorities if necessary.

Centers for Disease Control and Prevention Order Suspending Introduction of Certain Persons from Countries Where a Communicable Disease Exists

An important authority for protecting the health of the American people is the one Congress granted to the U.S. Department of Health and Human Services (HHS) under the *Public Health Service Act*.[3] Pursuant to this authority, the Centers for Disease Control and Prevention (CDC), as a component of HHS, issued an order temporarily suspending the introduction of certain people based on the director's determination that the introduction of aliens, regardless of their country of origin, migrating through Canada and Mexico into the United States creates a serious danger of introducing COVID–19, and that the danger is such that a temporary suspension is necessary to protect the public health.[4] The CDC determined that placing people into congregate settings in POEs and Border Patrol stations increases the already serious danger to public health. The CDC requested U.S. Department of Homeland Security (DHS) assistance with enforcement of the order, and that responsibility falls primarily to CBP.[5] The original order has been amended and extended until the CDC determines it is no longer necessary to protect public health.

[3] Pub. L. No. 78-410 § 362, 58 Stat. 682, as amended, 42 U.S.C. § 265.
[4] Order Suspending Introduction of Persons from a Country Where a Communicable Disease Exists, 85 FR 17060. May 26, 2020.
[5] 42 U.S.C. § 268(b).

Currently, CBP has an average of 150 to 200 migrants in custody at any given time, compared to the 20,000 migrants we sometimes had in custody during the peak of the 2019 humanitarian crisis. Since the pandemic emerged, CBP's enforcement of the CDC order under the Title 42 authority to protect public health has kept our in-custody numbers down. However, it is important to understand that before the COVID-19 pandemic emerged, MPP was a driving force behind the reduced migration numbers. Before this pandemic, CBP had already been collaborating with our partners in Mexico to implement MPP and in Canada to establish a North American approach to migration.

In compliance with the CDC order to temporarily suspends entry, CBP is denying entry, or, if already in the United States, returning migrants covered by the order to their country of last transit—Canada or Mexico. When that is not possible, the U.S. Government makes every attempt to return these individuals to their country of origin. After considering significant factors such as public health, law enforcement, public safety, and humanitarian concerns, an officer or agent may determine that the CDC order should not apply to a particular person. For instance, the order does not apply to individuals USCIS determines meet the reasonable fear of torture standard, in which they are more likely than not to be tortured in the country to which they would otherwise be sent.

All aliens CBP encounters, including minors, may be subject to the CDC order. CBP also may, on a case-by-case basis, such as when it is not possible to return a minor to his or her home country or when an agent or officer suspects trafficking or sees signs of illness, exempt any alien from the CDC order on a humanitarian basis. Minors exempted from the CDC order who are encountered without a parent or legal guardian will be processed as unaccompanied alien children under our Title 8 authorities and will be transferred to the custody of HHS' Office of Refugee Resettlement (ORR).[6] During any time spent in CBP facilities, minors processed under either Title 42 or Title 8 receive amenities and services consistent with applicable law and policy.

The CDC has determined that without the order, CBP would have to hold large numbers of migrants in close proximity to each other in congregate, often enclosed areas for the duration of immigration processing. That situation would dramatically increase the risk of an outbreak inside CBP facilities that could spread into local communities via the healthcare system or from CBP personnel, who live and work in border communities. To avoid this potentially catastrophic situation, the CDC has requested that CBP assist with the enforcement of the order issued on March 20, as amended and extended.[7] This strategy builds on the cooperation we have already established with foreign governments under such initiatives as MPP and other coordinated migration mitigation efforts that involve returning migrants to their countries of origin.

[6] Pub. L No. 110-457, § 235, 122 Stat. 5044, as amended, 8 U.S.C. § 1232.
[7] Centers for Disease Control and Prevention, "Order Suspending Introduction of Persons from a Country Where a Communicable Disease Exists," 85 FR 170603. May 26, 2020.

Air Travelers

President Trump signed proclamations on January 31, February 29, March 11, March 14, and May 24 to suspend entry for individuals who pose a risk of transmitting COVID-19. This includes most foreign nationals who have been physically present in mainland China, Iran, Ireland, the United Kingdom, Europe's 26-country Schengen Area, and Brazil within 14 days of attempting to enter the United States. The proclamations do not apply to U.S. citizens. In addition, lawful permanent residents and certain foreign nationals are exempt from the proclamations and may continue to travel into the United States from restricted areas. However, all travelers that arrive from a restricted country are subject to enhanced health screening by CDC staff, supported by DHS Countering Weapons of Mass Destruction Office (CWMD) contract personnel.[8]

CBP's National Targeting Center identifies travelers with recent travel to restricted countries and, unless they meet an exception, works with relevant air carriers to prevent those individuals from boarding flights to the United States. All flights from the restricted areas, or otherwise carrying passengers with recent travel in a restricted country, are funneled to 15 U.S. airports, where CBP follows CDC guidelines and supports CDC's enhanced health screening of returning travelers. CBP refers travelers who meet the CDC criteria to CWMD contract personnel, who conduct enhanced entry screenings under CDC guidance and complete the CDC's *Traveler Health Declaration Form*, which collects U.S. contact information and details to assess potential exposure to COVID-19. Travelers answer questions about their health and symptoms such as fever, cough, or difficulty breathing. Contract personnel randomly take and record traveler temperatures and alert CDC as appropriate. If there is a line of people to be processed, CWMD contract personnel take the temperature of every tenth traveler being screened. If there are fewer people waiting, screeners have the latitude to take the temperature of more people.

As of June 6, CBP had referred more than 328,000 people arriving from impacted areas for this enhanced entry screening by CWMD contract personnel. CWMD then refers to CDC those visibly ill, symptomatic passengers or anyone answering yes to either an exposure determination question or a health status question on the CDC's *Traveler Health Declaration Form*. Travelers who are not visibly ill, do not present with an elevated body temperature and answer no to the health status questions are allowed to proceed. Travelers are instructed to stay home and self-monitor their health for 14 days from the date they left the area of concern. They are given a health card that also advises them to limit social interactions, stay in contact with their state or local health department, and visit the CDC website for more information.

Land Travelers

Since January, when the COVID-19 pandemic began to emerge, pedestrian traffic at land POEs has dropped more than 62 percent while vehicle traffic has decreased nearly 50 percent. However, U.S. borders are not closed. On March 20, at 11:59 p.m. EDT, temporary restrictions were introduced, in coordination with Canada and Mexico, at the U.S. northern and southern land borders that limit entry to only those people engaged in essential travel, as defined in the

[8] U.S. Department of Homeland Security, "Protecting Air Travelers and the American Public" (June 19, 2020) https://www.dhs.gov/coronavirus/protecting-air-travelers-and-american-public.

relevant Federal Register notices. Essential travel includes U.S. citizens and lawful permanent residents returning to the United States and people traveling for the purpose of lawful trade, emergency response, military service, travel for military spouses and children, public health, to attend an educational institution, official government or diplomatic travel, and people traveling for medical care or work in the United States.

CBP reduced the hours of operation at 45 land border POEs along the northern and southern borders—in some cases significantly—based on travel restrictions and the resulting decrease in traffic. These reduced hours have helped limit potential exposure for our frontline officers assigned to these POEs, and will remain in place as long as they are deemed appropriate in the COVID-19 crisis. Meanwhile, CBP respects the unique mobility needs of Native Americans. We continue to facilitate border crossing into the United States for members of federally recognized tribes whose reservations are located in proximity to or on both sides of the U.S. border.

Legitimate Trade and Protecting Scarce Medical Resources

Every day, more than $3 billion in trade crosses the land border between the United States, Mexico, and Canada. As a crucial component of our overarching efforts to fight COVID-19, CBP continues to prioritize our role in promoting economic security and securing global supply chains. The governments of the United States, Canada, and Mexico all recognize how important it is to preserve the critical supply chains that link our countries and ensure adequate supplies of necessary materials, food, fuel, and life-saving medicines reach people on all sides of the borders.

CBP continues to facilitate legitimate commercial cargo at POEs nationwide. Some supply chains, including trucking, are not subject to the current travel restrictions in North America, such as the non-essential travel restrictions at the northern and southern borders. CBP is working closely with the trade community to assess additional operational flexibilities and business support, particularly with regard to imports of critical medical supplies needed to combat the virus. CBP is leveraging existing emergency authorities, and working with government partners such as the U.S. Food and Drug Administration (FDA) and the Federal Emergency Management Agency (FEMA) to expedite the clearance of critical supplies. CBP's Pharmaceuticals, Health and Chemical Center of Excellence and Expertise established the COVID-19 Cargo Resolution Team to coordinate inquiries regarding the importation of medical supplies and personal protective equipment (PPE). This multidisciplinary team triages incoming inquires, coordinates with affected ports, and responds directly to inquiries, as appropriate.

President Trump also recently initiated several trade-specific policies. In an executive order signed April 18, he provided authority to allow a 90-day deferment period on certain payments for importers who have faced a significant financial hardship due to the pandemic. This important step provided American companies with financial flexibility while ensuring that revenue owed to the U.S. Government will be paid. In a memorandum signed April 3, he directed the secretary of Homeland Security, through the FEMA administrator, to use authority under section 101 of the *Defense Production Act (DPA)*. Under this authority, FEMA, in consultation with HHS, may keep the following scarce and threatened PPE materials within the United States for domestic use: N-95 filtering face-piece respirators; other filtering face-piece

respirators; elastomeric, air-purifying respirators and appropriate particulate filters and cartridges; surgical masks; and gloves or surgical gloves. CBP is supporting FEMA in executing President Trump's memorandum by temporarily detaining shipments of the specified PPE until FEMA determines whether to issue a rated order under the DPA to purchase the PPE, return it to the sender for use within the United States, or allow part or all of the shipment to be exported. As of June 5, CBP had identified at least 82 export supply shipments that were referred to FEMA. Of those, 64 were cleared for export, 8 were cancelled, and 10 were returned to the U.S. supply chain. Under this authority, FEMA and CBP have returned 4.2 million protective masks and nearly 30,000 sets of gloves to U.S. markets.

CBP has seen a staggering number of incidents in which nefarious actors attempt to profit from this tragic global situation by importing counterfeit, unapproved, or otherwise substandard medical supplies and COVID-19 products that threaten the health and safety of American consumers. Among these items are fraudulent test kits and products falsely touted as treatments for COVID-19. As of June 12, CBP had seized more than 110,000 illegitimate COVID-19 test kits in 307 incidents; more than 1 million counterfeit face masks in 79 incidents; 2,500 EPA-prohibited anti-virus lanyards in 91 incidents; and 20,000 illicit chloroquine tablets in 128 incidents.

Pandemic Planning and Preparedness

CBP's baseline for responding to pandemic circumstances is the National Response Framework and Federal Interagency Operational Plans. The references and operational plans are publicly available on the FEMA website.[9] CBP maintains lines of communication with our federal, state, and local partners. We also adhere to *Federal Continuity Directive 1*, which requires federal agencies to develop continuity plans and exercise them annually in preparation for hazardous situations, including pandemics.[10]

CBP continues to monitor and plan for potential mass migration events at the SWB, which could occur as a result of the COVID-19 pandemic, especially if the economies of South and Central America are impacted over the longer term. CBP offices at all levels provide information to CBP Headquarters on current, potential, and future political, economic, security and health trends as well as COVID-19 pandemic preparedness and response. In addition, CBP's Office of Intelligence works with CBP's operational offices to periodically reassess the situation along our borders. CBP uses all available information to reassess and adjust its operational posture and resources.

In addition to these coronavirus-related measures, CBP has continued implementing important trade initiatives as well as important trade enforcement and facilitation functions. For example, the dedicated trade professionals within CBP have worked diligently to provide the trade community with necessary guidance on the *U.S.-Mexico-Canada (USMCA) Trade Agreement*,

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[9] Federal Emergency Management Agency, "Federal Interagency Operational Plans" (June 19, 2020) https://www.fema.gov/federal-interagency-operational-plans.

[10] Federal Emergency Management Agency, "Federal Continuity Directive 1 (FCD 1)" January 17, 2017. (June 19, 2020) https://www.fema.gov/media-library/assets/documents/86284.

which will go into force on July 1.[11] Our offices have maintained regular communication to ensure that we are providing transparency and predictability for the trade community and our government partners, even in these trying times.

Protecting CBP's Workforce

CBP's frontline personnel are among America's bravest law enforcement professionals. Our agents and officers are essential workers who heroically carry out CBP's broad mission day after day despite the risk to their own health and safety. Throughout their careers, they are exposed to dangerous people, cargo, and even infectious diseases; however, none of the previous epidemics were of the same magnitude as COVID-19. From the onset of this pandemic, CBP has placed the highest priority on workforce health and safety. We have aggressively addressed these issues with comprehensive risk assessments, PPE guidance such as the *CBP Job Hazard Analysis* and our electronic COVID-19 toolkit, and by ensuring appropriate PPE is available for our workforce. As a result of CBP's action to enforce the CDC order, we have been able to minimize the number of migrants in custody, which reduces the person-to-person contact in our facilities, and has minimized the number of both frontline staff and migrants in custody who have or become infected with COVID-19. CBP has implemented guidelines for sanitizing all our facilities as well. Unfortunately, however, we have now passed the 600 mark on CBP federal employees who tested positive for COVID-19. As stated earlier, five have died.

CBP will continue to take robust measures to protect our dedicated agents, officers, and mission-support personnel as they work tirelessly to defend our national borders and facilitate trade, travel, and the cross-border flow of food, medicine, and other essential commerce. The CBP workforce is using social distancing as much as possible. Those who can telework are doing so. We are ensuring those who cannot telework have access to PPE and comprehensive guidance for the use of PPE. Generally speaking, CBP provides a 30-day supply of PPE, including gloves, masks, disposable coveralls, and hand sanitizer for all employees. These are located locally across all field offices, sectors, and air and marine branches, and CBP has also set aside funding to procure additional PPE as needed. CBP continues to work with DHS and the CDC to monitor global supply chain impacts and project critical PPE needs for the CBP workforce.

With limited exceptions, CBP agents and officers are required to wear agency-approved masks when performing job functions that have an elevated risk of COVID-19 exposure or are public-facing. These jobs include passenger processing, inspection duties at immigration checkpoints, and interactions at POEs. CBP's senior medical advisor and our occupational safety and health team have established robust procedures as well as a decision matrix to ensure that any CBP employee exposed to COVID-19 receives appropriate, timely medical evaluation, diagnosis, and treatment. When an exposure occurs, CBP notifies all employees at that facility as soon as possible. If an employee has been in direct contact with a colleague who tested positive for COVID-19, he or she receives guidance based on the risks associated with the specific exposure.

[11] Congressional Research Service, "U.S.-Mexico-Canada (USMCA) Trade Agreement" Updated January 20, 2020. (June 19, 2020) https://crsreports.congress.gov/product/pdf/IF/IF10997.

All CBP training academies, which were closed to prevent the possible spread COVID-19, have reopened. The Trusted Traveler Program enrollment centers were likewise temporarily closed and will remain closed until further notice. The Enrollment on Arrival portion of the program, however, remains operational at POEs.

Mass Migration Mitigation Strategies

Migrant Protection Protocols

Before the COVID-19 pandemic emerged, CBP made much progress utilizing MPP to address the primary 'pull factor' that drove the humanitarian and security crisis of 2019. In late 2018 and 2019, the number of Central American families and unaccompanied alien children (UACs) arriving at our SWB increased exponentially. Adults believed—correctly—that if they brought their child, they would be released into the United States pending disposition of removal hearings. That pull factor provided an incentive for more families to make the long and arduous journey to the SWB. MPP removed that incentive for families.

MPP operates under the express statutory authority granted to DHS under the *Immigration and Nationality Act (INA)*.[12] Under this authority, CBP returns to Mexico certain applicants for admission, including those who enter illegally between the POEs, pending removal proceedings under INA Section 240. Under MPP, most aliens attempting to enter the United States illegally or without documentation are no longer released into the United States. On January 28, 2019, CBP issued guidance for implementing MPP. At the end of May, nearly 63,000 migrants had been enrolled in the MPP. However, MPP hearings were rescheduled in light of the pandemic, but are expected to resume on July 20.[13]

From a public health standpoint, we cannot afford to overlook the fact that the vast majority of the nearly 1.1 million people CBP apprehended or found inadmissible during FY 2019 entered the United States from Mexico. The *New York Times* and the *Wall Street Journal* have both reported recently that Mexico is likely underreporting the number of COVID-19 cases and deaths.[14] The same may well be true for other Latin American countries, but it will likely be some time before we know the true extent of the healthcare situation in those countries. Of the 363,000 people CBP has encountered this fiscal year, most of them—more than 210,000—were encountered by Border Patrol agents along the southwest border, which indicates they crossed the border illegally from Mexico between the POEs. During the humanitarian crisis of 2019,

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[12] Pub. L. No. 82-414, § 235(b)(2)(C), 66 Stat. 163, as amended, 8 U.S.C. § 1225(b)(2)(C).

[13] The U.S. Department of Homeland Security and the U.S. Department of Justice (DOJ) temporarily suspended MPP hearings and in-person document service to alleviate the need for migrants to travel within Mexico to a U.S. POE. DHS and DOJ will periodically reassess the situation throughout the duration of the crisis. U.S. Department of Homeland Security, "Joint DHS DHS/EOIR Statement on MPP Rescheduling" (press release, June 16, 2020), https://www.dhs.gov/news/2020/06/16/joint-dhseoir-statement-mpp-rescheduling.

[14] Azam Ahmed, "Hidden Toll: Mexico Ignores Wave of Coronavirus Deaths in Capital," *New York Times* May 8, 2020. (June 19, 2020) https://www.nytimes.com/2020/05/08/world/americas/mexico-coronavirus-count.html; Juan Motes, "Death Certificates Point to Much Higher Coronavirus Toll in Mexico," *The Wall Street Journal* May 8, 2020 (June 19, 2020) https://www.wsj.com/articles/death-certificates-point-to-much-higher-coronavirus-toll-in-mexico-11588957041

most of the migrants CBP encountered were families from Central America. Now, however, they are primarily single men from Mexico.

To reduce the number of people in custody—prior to MPP—migrants were often issued an order to appear and released into the United States. More often than not, those migrants did not appear for their court hearings. Under MPP, those migrants entering from Mexico must wait in Mexico for their hearings. CBP implemented several other programs to address specific situations, such as asylum and credible fear, or to quickly remove migrants with final removal orders.

Prompt Asylum Claim Review (PACR) and Humanitarian Asylum Review Process (HARP)

CBP, ICE, USCIS, and EOIR developed these programs prior to the COVID-19 pandemic to promptly assess credible fear claims of amenable individuals. Both programs are initial processing pathways for single adults and members of family units in expedited removal proceedings, as well as those who have expressed a fear of persecution, torture, or return to their country of origin or nationality or an intent to apply for asylum. PACR is for individuals who have passed through a third country before arriving in the United States (with an exception for Guatemalans, who pass through Mexico only), while HARP is applied to Mexican citizens, unless there is an applicable exception. UACs are excluded from both of these programs.

Asylum Cooperative Agreement (ACA)

DHS signed ACAs with El Salvador, Guatemala, and Honduras in 2019. Of these three agreements, we have only implemented the agreement signed with Guatemala. ACAs facilitate cooperation between the United States and our partner nation governments to deter illegal immigration to the United States and promote access to humanitarian protections. Under these agreements, certain aliens requesting protection in the United States may be transferred to a country other than the country of their nationality to allow them to pursue their protection claim there.

USCIS conducts a threshold screening to determine whether or not the alien 1) may be subject to transfer under the ACA; 2) meets an exception to the ACA; and 3) can establish that it is more likely than not that he or she would be persecuted on account of a protected ground or tortured in a country that is a signatory to the agreement. Transfers under the U.S.-Guatemala ACA began in November 2019, but have been temporarily suspended due to the COVID-19 pandemic. Likewise, transfers to Honduras under the U.S.-Honduras ACA have not yet begun due to the pandemic. The U.S.-El Salvador ACA has not yet entered into force.

Electronic Nationality Verification (ENV) Program and Interior Repatriation Initiative (IRI)

These programs are designed to quickly return individuals to their countries of citizenship. Under the ENV program, ICE can remove individuals with final removal orders without first acquiring travel documents from the government of the national because the nationalities are verified electronically. IRI is for Mexican nationals, who are returned to the interior of Mexico under a joint agreement with the Mexican Ministry of the Interior.

Drug Smuggling

While legitimate businesses have had to shutter their doors to the public and make significant changes to continue operating under the impact of the pandemic, criminal organizations that conduct business across national borders, or transnational criminal organizations (TCOs), have not. TCOs put a lot of effort into moving drugs across land borders by blending in with vehicular traffic at the POEs. We do not yet know the long-term impact the COVID-19-related changes in traffic patterns at the POEs will have on narcotics smuggling. What we do know for certain about TCOs is that they will not stop trying to find better, more successful ways to get their illicit goods across our borders. However, reduced vehicular traffic at the POEs and reduced migration between the POEs is certainly making it more difficult for the Mexico-based TCOs to successfully get drugs across the SWB land border.

Since MPP has removed the main incentive for Central American families to come to the United States, TCOs have lost much of their human-smuggling revenue. MPP also freed up our Border Patrol agents. Now, instead of processing and caring for large number of migrant families, these agents can focus on our border security mission—such as drug interdiction—between the POEs.

Nationwide, drug seizures rose sharply in May from the previous month of April. Cocaine seizures more than doubled while seizures of methamphetamine and crystal meth rose by 66 percent. Marijuana seizures increased by nearly 35 percent and fentanyl seizures increased 11 percent.[15] We are watching carefully to see how the changes in vehicle and pedestrian travel at the POEs will affect the narcotics smuggling that occurs between those POEs. We may begin to see an increase between the POEs.

Border Wall System

The border wall system remains a crucial element of CBP's strategy to achieve operational control of the border. In the event that reduced vehicle traffic forces drug smugglers to shift more smuggling activities between the POEs, the border wall system will become increasingly important. The wall system uses technology and lighting in addition to physical barriers to stop or slow illegal cross-border traffic between the POEs. So far, CBP has completed construction on 216 miles along the SWB, with 339 miles currently under construction. In addition, 183 miles are in the pre-construction phase. CBP prioritized these construction projects and locations based on extensive threat assessments to determine where the wall system is needed most. In the last 12 months we've constructed more than 165 miles and funded an additional $9 billion of new border wall system, an expeditious undertaking given traditional large-scale federal construction timelines. With every day that passes, the Department continues to make significant progress. We now have more than 500 miles of border wall system in progress. We are completing, on average, about seven miles per week compared to roughly two miles per week this time last year.

DHS and CBP are closely monitoring the evolving pandemic, in coordination with the U.S. Army Corps of Engineers (USACE), while simultaneously working on long-term border security

[15] U.S. Customs and Border Protection, "CBP Enforcement Statistics, Fiscal Year 2020" (June 19, 2020) https://www.cbp.gov/newsroom/stats/cbp-enforcement-statistics

plans and investments. CBP is working with USACE to ensure all state, local, and CDC-issued guidelines are followed to the greatest extent possible in accordance with our mission.

Conclusion

CBP's highest priority is to ensure the health, safety, and security of not only the American people, but also our workforce and the migrants in our custody. CBP officers and agents have worked tirelessly throughout this pandemic—despite the risk to themselves—to hold the line at our national borders. The border, now more than ever, is vital to protecting public health, and CBP is answering that call.

The CDC order is a critical policy tool that protects the health and wellbeing of the American people. You need not be a doctor or a public health expert to imagine what could happen with just one infected person among the migrants in a filled congregate processing area. CBP cannot enforce 'social distancing' in our facilities, and we lack the space to quarantine or isolate. We do not have the medical facilities or the manpower to handle such a situation. This is especially true for the U.S. Border Patrol. Over the last few years, the Border Patrol has been responsible for an increasingly larger percentage of CBP's enforcement actions.[16] It was true when the Border Patrol was established in 1924 and it is especially true now: border enforcement should not involve holding migrants any longer than absolutely necessary. We are, after all, a law enforcement agency, not a health-care provider.

If this pandemic has taught us anything, it has certainly taught us this: infectious diseases do not recognize borders. People who appear perfectly healthy can spread the virus. As such, CBP must treat every person we encounter as a health and safety risk. Processing in the field and quickly returning these individuals enables CBP to protect migrants, our agents and officers, and the American public from potential exposure. If that cannot be done, we risk finding ourselves with as many migrants in CBP holding facilities as we did last year during the height of the humanitarian crisis, but this time, with a pandemic in our midst.

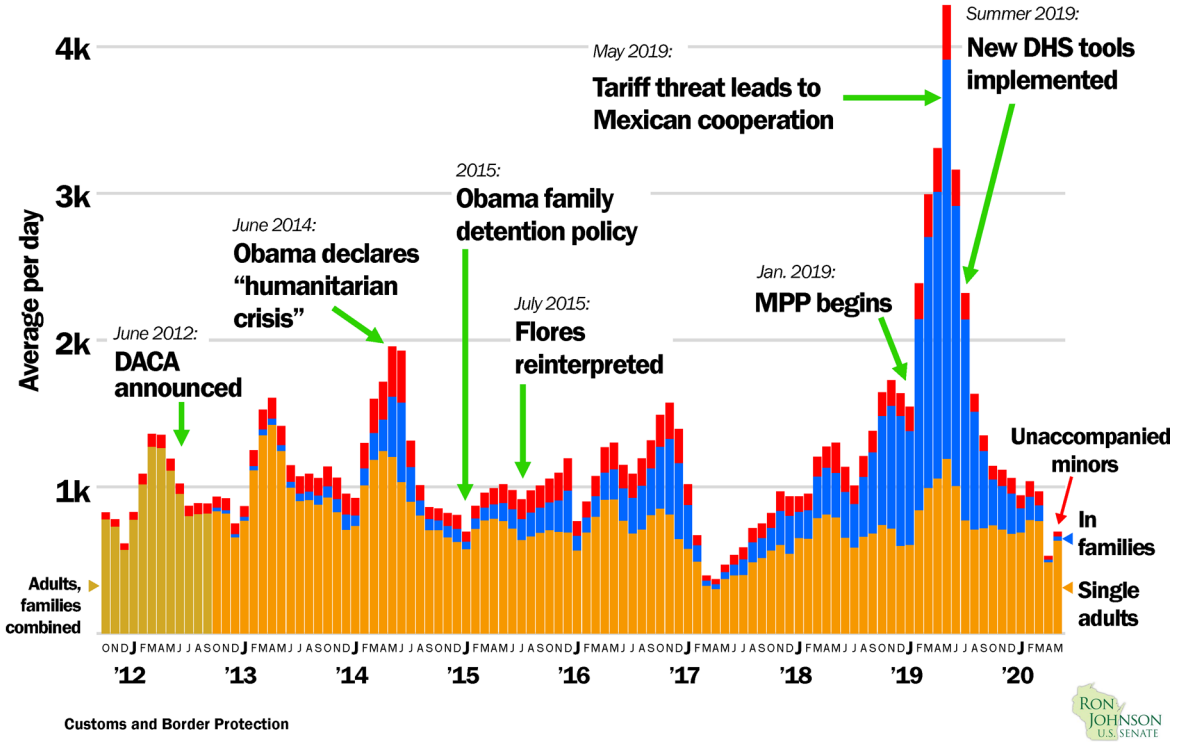
Rest assured that, no matter what, CBP will continue to support the whole-of-America response to fighting the COVID-19 pandemic. We are, and will continue to be, determined to protect Americans by securing our borders while enabling legitimate trade and travel.

Thank you for the opportunity to testify today. I look forward to your questions.

[16] Ibid.

SW BORDER APPREHENSIONS

DAILY AVERAGE BY MONTH



Customs and Border Protection

RON JOHNSON U.S. SENATE

Southwest border apprehensions /asylum claims

Apprehensions between ports of entry and claims of asylum at ports of entry. Southwest border only; individuals from any country.

Year to date

	as of 5/31/20	244 day daily avg:		Approx # of children:	244 day daily avg:
Minors	22,015	**90**		22,015	**90**
Families	60,650	**249**	@ 50% =	30,325	**124**
subtotal	82,665	**339**		52,340	**215**
Single adults	258,962	**1,061**			
total	341,627	**1,400**			
fy2019 total:	976,558	**2,676**	*365 day average*		
fy2018 total:	521,090	**1,428**	*365 day average*		

Most recent month:

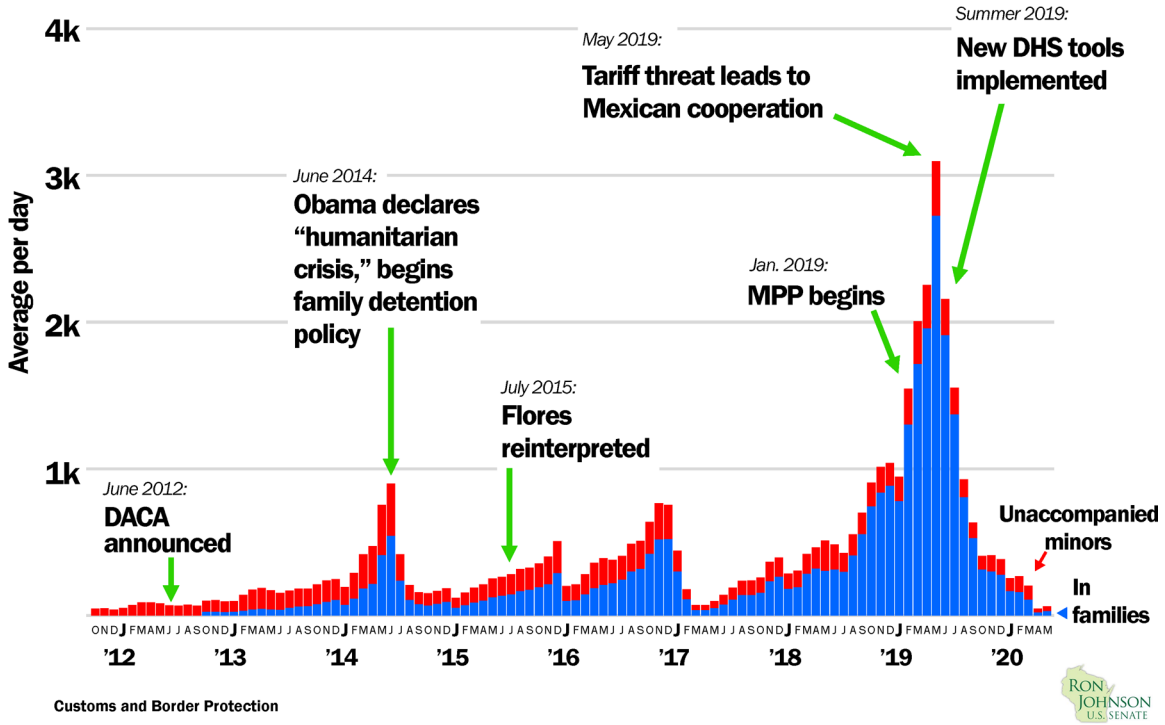
	May	31 day daily avg:	May '19 daily avg:	Approx # of children:	31 day daily avg:	May '19 daily avg:
Minors	1,001	**32**	**383**	1,001	**32**	**383**
Families	1,045	**34**	**2,859**	@ 50% = 523	**17**	**1,430**
subtotal	2,046	**66**	**3,242**	1,524	**49**	**1,812**
Single adults	21,043	**679**	**1,410**			
total	23,089	**745**	**4,651**			

Source: Customs and Border Protection



SW BORDER APPREHENSIONS

DAILY AVERAGE BY MONTH: *UNACCOMPANIED MINORS AND FAMILIES ONLY*



May 18, 2020

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 3032

Dear Secretary Azar and Director Redfield:

We are public health experts at leading public health schools, medical schools, hospitals, and other institutions across the United States who are working at the forefront of the response to the novel coronavirus. We recognize that extraordinary circumstances require extraordinary measures to keep us all safe and healthy. However, we are gravely concerned that the current administration is using the imprimatur of the Centers for Disease Control and Prevention (CDC) to circumvent laws and treaty protections designed to save lives and enable the mass expulsion of asylum seekers and unaccompanied children through an order first issued on March 20, 2020.[1] The CDC order is based on specious justifications and fails to protect public health.

We urge the CDC and Department of Health and Human Services (HHS) to withdraw – not extend or expand indefinitely – this policy and instead direct U.S. officials to use rational, evidence-based public health measures to safeguard both the health of the public and the lives of adults, families, and unaccompanied children seeking asylum and other protection. The nation's public health laws should not be used as a pretext for overriding humanitarian laws and treaties that provide life-saving protections to refugees seeking asylum and unaccompanied children.

The Order's Specious Public Health Rationale

Despite its public health pretext, the CDC order fails to further public health and disregards alternative measures that can protect public health while preserving access to asylum and other protection.[2]

The order focuses on non-citizens who lack documentation and arrive by land. It exempts permanent residents and U.S. citizens, and does not apply to tourists arriving by plane or ship – even though these modes of transportation are explicitly listed by HHS as congregate settings with *higher* risk of disease transmission than land travel.[3] A travel restriction issued the same day as the CDC order similarly provides broad exceptions for travel related to education, trade, and commerce.[4] The rule is thus being used to target certain classes of noncitizens rather than to protect public health.

There is no public health rationale for denying admission to individuals based on legal status. The order's stated justification is that the migrants and asylum seekers who are subject to it would normally be held by Customs and Border Protection (CBP) in "congregate settings" for prolonged periods of time.[5] However, instead of holding individuals in facilities widely recognized as dangerous and unsanitary,[6] CBP has the discretion and legal authority to parole adults and families seeking asylum or other legal protection, and the government could facilitate the expeditious release of unaccompanied children from custody.[7] A recent study found that of several hundred asylum seekers currently at the Mexico-U.S. border, 92 percent have family or friends they could live with in the United States.[8] Allowing individuals to shelter in place with family or friends would reduce the need for quarantine facilities, resolving another concern stated in the CDC order.

While availability of testing is rapidly evolving, the current lack of accurate testing capability is not a justification to shut the border to people seeking safety, despite the assertion in the CDC order, particularly when other safeguards – like use of masks, hand sanitizer, and other screening measures – are available.[9]

Finally, the order points to the spread of COVID-19 in open-air "asylum camps" and shelters along the border as "inevitable" and yet another reason to close the border to asylum seekers.[10] These camps, and the high occupancy of migrant shelters, are a direct result of U.S. policy decisions to restrict access to asylum. Under the "Migrant Protection Protocols" (MPP), tens of thousands of asylum seekers have been forced to wait in dangerous and precarious conditions in Mexico, and to risk their lives and health to travel repeatedly across the border to attend hearings and receive notices of new hearing dates due to COVID-related adjournments.[11] As noted above, the vast majority of these individuals could instead be safely sheltering in place – one of the few measures proven to stop the spread of the virus – at the homes of family or friends in the United States. The CDC order, which countenances mass expulsions of asylum seekers to Mexico, will only increase the risk to the health and safety of people seeking protection and endanger public health on both sides of the border.

Over 20 European countries have explicitly exempted asylum seekers from entry bans and border closures, and the European Union included an exemption for persons seeking international protection in its travel restrictions.[12] The United States should follow suit, relying on the measures outlined below.

Our Recommendations for an Alternative Approach

Protecting public health is of paramount importance during the COVID-19 pandemic. However, a pandemic does not absolve the federal government of its legal and treaty obligations to asylum seekers and unaccompanied children.[13] The CDC remains the source of information Americans most widely trust as they navigate this crisis. [14] Trust is the cornerstone of an effective pandemic response; yet it is undermined when public health authorities such as the CDC issue orders that endanger public health or when their public health guidance is subject to political interference.

Rather than imposing a ban or suspension on people seeking protection from harm, U.S. authorities should use evidence-based public health measures to process asylum seekers and other persons crossing the U.S. border. Asylum seekers and migrants should not be discriminated against due to their immigration status or displacement and should not be subjected to more stringent health restrictions at the border than other persons. We urge you to rescind this order and instead advise U.S. government counterparts to implement the following measures, which are grounded in the best available public health guidance:

- During border processing, facilitate social distancing through demarcations and the use of outdoor and other areas for processing; require wearing of masks or similar cloth coverings over the face and nose for both officers and persons crossing into the United States; use plexiglass barriers and/or face shields for officers during interviews and identity-checks; provide hand-sanitizer and other handwashing for both officers and other persons; and provide requisite distance, as well as masks and other measures, in transport;
- Rather than detaining asylum seekers in congregate settings, allow asylum seekers to wait for their court hearings with their families or other contacts in the United States through parole, case management and other alternatives to detention;
- Promptly transfer unaccompanied children to the legal authority of the Office of Refugee Resettlement for swift reunification with family members and caregivers in the United States; and
- Facilitate self-quarantine at destination locations, should all individuals crossing the southern border be required to do so. Under no circumstances should CBP operate mass quarantine facilities.

As the World Health Organization, the U.N. Refugee Agency, and other U.N. agencies have explained, "there are ways to manage border restrictions in a manner which respects international human rights and refugee protection standards, including the principle of non-refoulement, through quarantine and health checks" and that "our primary focus should be on the preservation of life, regardless of status."[15] We can

– and we must – both safeguard public health and uphold laws requiring the protection of asylum seekers and unaccompanied children.

Sincerely,

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[1] Affiliation for identification purposes only.

[2] Joanna Naples-Mitchell, "There is No Public Health Rationale for a Ban on Asylum Seekers," Just Security, Apr. 20, 2020, https://www.justsecurity.org/69747/there-is-no-public-health-rationale-for-a-categorical-ban-on-asylum-seekers; Lucas Guttentag & Stefano Bertozzi, "Trump Is Using the Pandemic to Flout Immigration Laws," NY Times, May 11, 2020, https://www.nytimes.com/2020/05/11/opinion/trump-coronavirus-immigration.html; Dr. Chris Beyrer & Yael Schacher, Expelling Asylum Seekers is not the Answer, April 27, 2020, https://www.refugeesinternational.org/reports/2020/4/26/expelling-asylum-seekers-is-not-the-answer-us-border-policy-in-the-time-of-covid-19.
[3] U.S. Dep't of Health and Human Services & Centers for Disease Control and Prevention, "Control of Communicable Diseases; Foreign Quarantine; Suspension of Introduction of Persons into the United States from Designated Foreign Countries or Places for Public Health Purposes," 85 Fed. Reg. 16559, 16561.
[4] *Id*. at 16547.
[5] U.S. Dep't of Health and Human Services & Centers for Disease Control and Prevention, *supra* note 1, at 2.
[6] American Immigration Council, "Challenging Unconstitutional Conditions in CBP Detention Facilities," https://www.americanimmigrationcouncil.org/litigation/challenging-unconstitutional-conditions-cbp-detention-facilities; *see also* DHS Office of Inspector General, "Management Alert – DHS Needs to Address Dangerous Overcrowding and Prolonged Detention of Children and Adults in the Rio Grande Valley," Jul. 2, 2019, https://www.oig.dhs.gov/sites/default/files/assets/2019-07/OIG-19-51-Jul19_.pdf.
[7] *See, e.g.*, 8 C.F.R. § 212.5 (describing circumstances under which CBP could parole an individual into the United States); 8 U.S.C. § 1182(d)(5)(A) (describing DHS's authority to parole individuals into the United States). *See* Human Rights First, "Parole vs. Bond in the Asylum System," Sept. 2018, https://www.humanrightsfirst.org/sites/default/files/PAROLE_BOND.pdf (Asylum seekers who are paroled into the United States overwhelmingly appear for their court hearings).
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[10] *See* U.S. Dep't of Health and Human Services & Centers for Disease Control and Prevention, *supra* note 1, at 9.
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MAY 2020

Public Health Measures to Safely Manage Asylum Seekers and Children at the Border

The United States has the ability to both safeguard public health in the midst of the COVID-19 crisis and safeguard the lives of families, adults, and children seeking asylum and other humanitarian protection at the U.S. southern border. Public health experts recommend the use of the measures outlined below to protect U.S. border officers, those exercising their legal right to request protection in the United States, and the public health of our nation. These measures include social distancing, wearing masks or similar coverings, using hand sanitizer, demarcations and barriers, health screenings, sheltering in place at homes of family members through proven case management strategies, and more. Such measures, rather than banning people seeking humanitarian protection, protect both public health and the lives of those seeking safety and freedom.

The Humanitarian Protection Ban's Specious Public Health Rationale

Using a highly flawed order issued by the Centers for Disease Control and Prevention (CDC) on March 20, 2020 and an April 20 extension, the Department of Homeland Security (DHS) is expelling people seeking asylum and unaccompanied children – without screening them for international protection needs, despite U.S. refugee and anti-trafficking laws and treaties designed to protect them.

The rule has been described as an immigration policy masquerading as a public health policy by public health experts, and as "medical gerrymandering" by a leading legal scholar:

> Unquestionably, the United States faces a pandemic of unknown scope and duration that has led to the greatest social and economic disruption and restrictions on personal movement in our lifetime.… But the COVID-19 ban is an act of medical gerrymandering. It is crafted to override critical legal rights and safeguards in singling out only those arriving at the border without authorization and deeming that class of people a unique and unmitigable public health threat. It tries to justify an end-run around congressionally mandated procedural rights and protections essential for refugees and unaccompanied minors and it does so to achieve an impermissible goal. What's additionally shocking here: the statutory provision does not actually give the executive branch expulsion authority.

While the CDC order was presented as an urgent response to the pandemic, a recent report revealed that it "was in large part repurposed from old draft executive orders and policy discussions that have taken place repeatedly" since the administration came into office, with the idea of invoking public health powers "on a 'wish list' of about 50 ideas to curtail immigration" crafted early on by White House Senior Advisor Stephen Miller.

In concluding that alternatives to suspending entry were not viable, the CDC order relied on incorrect and insufficient DHS assertions that the (now barred) individuals likely lack homes or places in the United States to self-isolate and that these individuals must necessarily be held in congregate areas in the custody of Customs and Border Protection (CBP) for hours or days. In essence, the CDC order pointed to CBP's own processing and detention practices at the border as the justification for expelling asylum seekers and unaccompanied children.

Using the CDC order, DHS has expelled more than 21,000 people – including asylum seekers and unaccompanied children – as of early May 2020. These families, adults, and unaccompanied children have been sent to dangerous areas of Mexico as well as to other countries of origin from which they have fled. In the first two weeks of

expulsions, nearly 400 children were expelled, including 120 unaccompanied children who were sent to Central America. In April, more than 700 additional unaccompanied children were expelled, in violation of U.S. anti-trafficking laws. As of early May, DHS has allowed only 59 people subject to the CDC order to be screened for a fear of returning to their country of origin; only two have passed.

Distinguishing the order from reasonable health measures such as careful screening, a Washington Post editorial on April 12, 2020 explained that "[i]t's a different thing to impose a systematic, draconian, extralegal regime, one never contemplated by Congress, whose effect is to ignore and override 40 years of asylum and immigration law." Noting that "it is precisely in times of emergency that any country faces its most severe tests – ones that call into question the nation's essential character and values," the editorial board warned that the administration was "betraying this country's long tradition as a beacon to those fleeing oppression."

This document outlines key points and recommendations developed with input from public health,[1] humanitarian, legal, and human rights experts and provides background on public health measures at the border.

Key Points and Recommendations

- **The United States has the ability to both safeguard public health in the midst of the COVID-19 crisis and safeguard the lives of families, adults, and children seeking asylum and other protection at the U.S. southern border**. With political will and necessary action, both can be protected; there is no need to sacrifice the safety of asylum seekers and unaccompanied children to protect Americans. The World Health Organization (WHO), the UN Refugee Agency (UNHCR), the International Organization for Migration, and the Office of the High Commissioner for Human Rights explained in a statement on March 31, 2020 that "there are ways to manage border restrictions in a manner which respects international human rights and refugee protection standards, including the principle of non-refoulement, through quarantine and health checks" and that "our primary focus should be on the preservation of life, regardless of status."
- **A ban or suspension directed at asylum seekers and unaccompanied children is not justified from a public health perspective**. The public health consensus is clear: there is "no public health rationale" to bar people based on their immigration status. UNHCR explained in March 2020 legal guidance that states may not impose measures that preclude refugees from admission or deny them an effective opportunity to seek asylum, and that "(d)enial of access to territory without safeguards to protect against refoulement cannot be justified on the grounds of any health risk."
- Rather than imposing a ban or suspension on people seeking protection from harm, **U.S. authorities should use measures recommended by public health experts** to process asylum seekers and all other travelers crossing the U.S. border. Asylum seekers and migrants should not be discriminated against due to their immigration status or displacement and should not be subjected to more stringent health restrictions at the border than other people allowed into the country.
- **These public health measures should include measures such as social distancing, appropriate masks, disinfectants, and sanitation supplies,** as well as the use of parole to family and friends rather than detention in congregate settings; and – when and if required of people crossing the southern border – self-quarantine at destination locations instead of mass quarantine by CBP in congregate settings.
- **Men, women, and children seeking asylum or other protection should not be held in congregate settings** by CBP but should instead be released to join their families or other contacts in the United States

[1] Numerous epidemiologists and other public health experts, including those with prior CDC experience, weighed into the development of these recommendations including experts with or contacted through: the Forced Migration and Health Program at Columbia University's Mailman School of Public Health; the Center for Humanitarian Health at John's Hopkins Bloomberg School of Public Health; Physicians for Human Rights; Médecins Sans Frontiéres; and Doctors of the World; as well as Dr. Ronald Waldman, Milken Institute School of Public Health, George Washington University; Dr. Michele Heisler, School of Public Health, University of Michigan; Dr. Rohini J. Haar, School of Public Health, U.C., Berkeley; and Dr. Monik C. Jiménez, Harvard T.H. Chan, School of Public Health.

through parole, case management, and other alternatives to detention. The parole of asylum seekers in the Trump administration's so-called "Migrant Protection Protocols" should be swift, as they have already undergone CBP processing on prior occasions and are already in U.S. immigration court proceedings. Requiring them to travel back and forth again and again through dangerous parts of Mexico to attend hearings, and now to receive notices of new hearing dates as hearings adjourn due to COVID-19, puts their health and the health of others at risk.

Background on Various Public Health Measures at the Border

- **Social distancing in lines and at processing.** People permitted to cross into the United States at southern border posts are asked to practice social distancing. CBP and CDC should instruct CBP officers to facilitate social distancing to the extent possible in lines at ports of entry, during processing, and as officers conduct outdoor processing. Officers can use lines or other demarcations to set six-feet distances where people should stand in lines or sit during interviews. Some ports of entry have outdoor parking or other areas that could be used to conduct interviews if additional space is needed. CBP can use facilities like those operated by the Health and Human Services (HHS) Office of Refugee Resettlement to conduct swift processing, rather than holding families, children, and others in CBP custody. CBP should work with Mexican counterparts to encourage distancing in lines as people approach U.S. border posts, without leaving people waiting in danger.
- **Masks or cloth coverings.** Asylum seekers and all others approaching U.S. ports of entry should be recommended to wear masks, bandanas, scarves, or similar cloth coverings over the mouth and nose, as the CDC currently recommends in the United States for public settings where social distancing is difficult to maintain. Border officers should be required to wear masks while on duty. CBP could also add clear plastic or plexiglass barriers at interview locations, and interviewing officers could wear face shields, if necessary from a public health perspective. While officers should provide masks to any people who do not have such face coverings, young children should be excused per CDC guidance and, as breathing can be restricted by such coverings, a child should not be forced to wear a mask or similar covering without instructions and assistance from a trusted adult. Children under two years old, and other vulnerable people as specified in CDC guidance, should not be expected to wear masks because of the risk of suffocation.
- **Disinfectants and Sanitizers.** Border officers, asylum seekers, and all people crossing at ports of entry or apprehended between ports should be provided with and asked to use hand sanitizer before and after exchanging documents, using any fingerprint machinery, or touching other surfaces. As hand-washing facilities at the border are limited and often lack soap, CBP and Mexican counterparts should take steps to expand their availability, including by using portable washing stations such as those in the Laredo and Brownsville, Texas tent courts.
- **Parole and other alternatives to holding people for days in congregate settings.** Men, women, and children seeking asylum or other protection should not be held in congregate settings but should instead be released to join their families or other contacts in the United States. CBP has the legal authority to parole asylum seekers from the border or defer their inspection; it also has the ability to use case management and other alternatives to detention for cases that require appearance support. Medical evidence has proven that alternatives to immigration detention result in improved physical and behavioral health outcomes. To save – rather than endanger – more lives, these other options should be pursued. CBP must provide people with documentation that includes name and photograph, so they will be able to travel to their destinations.
- **Unaccompanied children.** U.S. anti-trafficking law requires that children be screened to determine if they meet the criteria to be designated as an unaccompanied child, a designation that is critical for them to access protections from return to trafficking or other harms. Screenings should occur using the public health safeguards outlined and, as necessary, accommodations should be made based on the age and

developmental stage of the child. Officials should use age-appropriate language to communicate the risks of COVID-19 and advise on any specific safety measures. Unaccompanied children should be immediately transferred to the legal authority of HHS, using safe and appropriate transportation that meets the minimum protections referenced in this document.

- **Transport.** CBP should clean vehicles frequently, wiping down door handles and internal surfaces between trips, and use larger vehicles and buses to enable social distancing by leaving empty seats and providing six feet of space between people. It is recommended that windows be opened, if possible, to increase ventilation. Officers and migrants should wear or be provided masks or similar face coverings.
- **Quarantine at homes.** The CDC recommends that people returning to the United States from Mexico stay at home for 14 days and practice social distancing. CDC advises those who cross the southern border to refrain from crossing if ill and follow health requirements on both sides of the border, without recommending self-quarantining. Should public health authorities direct all people crossing the southern border to quarantine for 14 days, asylum seekers – the vast majority of whom have family or other close contacts they are planning to join – should do so at the homes of family, friends, or other community contacts, using distancing, face-covering, hand-washing, and other safeguards in transit. Mass quarantining conducted by CBP or ICE, which use congregate settings, should not be employed. For the few asylum seekers who do not have destination locations, the CDC should work with local health authorities to identify quarantine locations. Some refugee assistance shelters and organizations may also be able to assist.
- **Health screening.** Under existing operating procedures for ports of entry, any person with a fever over 100 degrees Fahrenheit who exhibits symptoms consistent with an infectious disease like COVID-19 should be referred for further medical screening. Enhanced health screening – where all arrivals are required to be "asked about their medical history, current condition, and asked for contact information for local health authorities" – is currently directed at airport arrivals from China, Iran, and certain European countries – and *not* currently required for other travelers at airports or the northern and southern land borders. If enhanced screening of people crossing ports of entry or encountered by CBP should be recommended for public health reasons, a quick three-question screen of symptoms can be administered to ask about any fever, cough, or difficulty breathing, along with temperature testing. The WHO has issued detailed guidelines for interviews and other steps to detect and manage COVID-19 at international ports of entry. A CBP physician adviser informed Physicians for Human Rights that, with respect to people in the agency's custody, it conducts a phased approach to the identification of medical issues such as potential COVID-19; there have, however, been many reports of deficiencies in CBP medical care.
- **Testing.** While prompt, accurate testing may one day become widely available, the lack of such testing is *not* a public health justification for refusing to allow men, women, and children seeking asylum or other protection into the United States. The other measures outlined here can be employed to safeguard public health. Any testing of individuals who may have the virus should be conducted free of charge.
- **Treatment and isolation for any ill people.** For any arrival who is determined to be ill with COVID-19 but does not require hospitalization, U.S. agencies should send them to the home of their families or other planned destination to isolate, as the CDC recommends for people within the United States. However, as the use of public transportation is discouraged for people who are ill, for those who would otherwise use public transportation, the CDC should work with local health authorities to provide access to facilities like unused dorm rooms or motel rooms that allow those who are ill to actually isolate away from other people rather than in congregate settings – a measure being used for homeless populations in many U.S. localities. Neither CBP nor ICE should be the agency charged with conducting either quarantine or isolation.

CWS Statement to the U.S. Senate Committee on Homeland Security and Governmental Affairs, pertaining to its hearing "CBP Oversight: Examining the Evolving Challenges Facing the Agency" June 25, 2020

As a 74-year old humanitarian organization representing 37 Protestant, Anglican, and Orthodox communions and 24 refugee resettlement offices across 17 states, **Church World Service (CWS) urges Congress to condemn the administration's anti-asylum policies, including family separation and inhumane treatment at the border, and put an end to the dehumanizing practices occurring in Department of Homeland Security's (DHS) Customs and Border Protection (CBP) facilities.** The United States has moral and legal obligations under international and U.S. law to see that individuals seeking protection are not returned back to the persecution they fled.

CWS is strongly opposed to immigrant and family detention and any proposal that would undermine *Flores* protections. Detention in CBP custody and family detention are plagued with systemic abuse and inadequate access to medical care. In 2019, 17 deaths were reported by CBP, two of those who died being children. Numerous reports have revealed the systemic human rights abuses, sexual assaults, and dehumanizing conditions that exist in such detention facilities. These exceedingly overcrowded detention centers are unsanitary, unhealthy, unsafe and are leading to otherwise preventable, sometimes fatal, mental and physical health outcomes for children. It is equally concerning that the administration has revived family separation, as no child should be in detention centers or separated from their parents. These conditions and abuses are the result of intentionally cruel policies put in place to deter children and families from seeking protection.

CWS urges Congress to defund the administration's deadly Migrant Protection Protocol (MPP) policy, which violates U.S. and international legal and moral obligations. In September 2019, the Trump administration's policy of returning asylum seekers to Mexico was expanded, sending men, women and children from Cuba, El Salvador, Guatemala, Honduras, Nicaragua, Venezuela, and other countries to wait in the notoriously dangerous state of Tamaulipas. CBP officers have sent late-term pregnant women back to Mexico under the MPP policy, despite the fact that individuals with known health issues are supposed to be exempted from the program. In one case, doctors gave a woman who was already experiencing contractions medication to stop the contractions so that she could be sent back across the border to Mexico. This policy has sentenced nearly 65,000 children, their families, and other asylum seekers to areas so plagued by violence that the State Department has designated the state of Tamaulipas a Level 4 threat risk—the same warning as Afghanistan, Iraq, Syria, Somalia, North Korea, and Yemen. In fact, the number of reported attacks on returned asylum seekers continues to rise—now to 1,114—despite reduced in-person research due to the pandemic.

CWS condemns DHS for using a Centers for Disease Control and Prevention (CDC) order to expel asylum seekers and unaccompanied children, ignoring legally required processes. Public health experts have indicated the CDC order lacks a public health rationale. In addition, DHS had also stranded over 14,000 asylum seekers on "metering" lists along the southern border under its illegal practice of reducing the number of asylum seekers processed at ports of entry, causing back-ups of asylum seekers waiting in Mexico. The brutal conditions have been made worse by the COVID-19 pandemic; many are without safe and secure housing, adequate medical care, or sufficient food. Shelters are cutting capacity, not accepting new residents, and in some cases closing all together. The administration can and should employ sensible measures recommended by public health experts, such as safe distancing, masks, and hand sanitizer, to expeditiously process asylum seekers who should be paroled and able to shelter with family members. Unaccompanied children should be swiftly transferred to Office of Refugee Resettlement (ORR) custody, again with the use of health safeguards. Asylum seekers should not be subjected to detention given the related health risks and human rights violations, but case management and other alternatives to detention can and should be employed.

CWS is outraged by CBP's mismanagement of emergency appropriations intended to address the humanitarian crisis at the border. On June 11th, the U.S. Government Accountability Office released its decision that CBP broke the law when spending congressionally appropriated funds under H.R. 3401. Rather than utilize these funds to improve conditions for immigrants and asylum seekers at the border and in detention, CBP used the designated funds on unauthorized items such as ATVs, dirt bikes, and dog food. CWS urges Congress to cut funding for detention, deportations, and border militarization - and to exert robust oversight over DHS detention centers to end harmful abuses.

CWS condemns the deployment of Immigration and Customs Enforcement (ICE) and CBP to civil protests across the country. During a time of mass movements across the nation demanding racial justice and accountability, ICE and CBP's presence in our communities is alarming, especially given their record of human rights abuses. With a proven history of abusing, profiling, and targeting immigrants and people of color as a militarized force, ICE and CBP should not be allowed to police protests.

human rights *first*

American ideals. Universal values.

Statement for the Record of Human Rights First
U.S. Senate, Committee on Homeland Security and Governmental Affairs
Hearing on Customs and Border Protection Oversight

June 25, 2020

Thank you for the opportunity to submit a statement for the record for the Hearing on Oversight of Customs and Border Protection (CBP). This hearing comes as CBP is blocking and expelling thousands of asylum seekers and unaccompanied children at the southern U.S. border in violation of U.S. law and treaty obligations and was recently inappropriately deployed in the interior of the United States in response to public protests in support of the Black Lives Matter movement.

Human Rights First is an independent advocacy and action organization that presses the U.S. government to respect human rights and the rule of law, both around the world and here at home. We advocate for fair asylum and refugee resettlement systems to protect and provide safe haven to refugees who have fled human rights abuses, and we partner with the nation's leading law firms to provide pro bono legal representation to refugees seeking asylum in the United States.

CBP Expelling Asylum Seekers and Unaccompanied Children

The administration is exploiting the coronavirus crisis to pursue its long-held goal of preventing refugees from seeking and receiving humanitarian protection in the United States. Under the guise of a much-criticized Centers for Disease Control and Prevention (CDC) order, CBP is blocking and expelling asylum seekers and unaccompanied children without the legally required processes to countries where they face persecution, trafficking, and other serious violence.

Between March 20, 2020, when the CDC order was issued, and the end of May 2020, CBP expelled more than 42,000 people at the southern border, including many asylum seekers and at least 2,175 unaccompanied children to countries where they fear persecution and other violence.

In a report from May 2020, Pandemic as Pretext, Human Rights First documented examples of those denied protection by CBP due to the CDC order including, a Honduran rape survivor and her two children, a mother with her five-day old daughter and three-year-old son, a Salvadoran family who faced threats from a gang that wanted to "rent" their 9-year-old daughter, and a Honduran asylum seeker and her daughter who were detained by Mexican migration after being expelled and forced to cross the border into Guatemala by Mexican migration agents who also denied them a chance to apply for asylum. CBP has also expelled some Central American unaccompanied children to Mexico in plain violation of the Trafficking Victims Protection Reauthorization Act, including 12- and 15-year-old Central American children sent alone by CBP to dangerous Ciudad Juárez, Mexico, where they were left homeless and on their own, according to a KIND policy brief from April 2020.

Government data received by CBS News, but not publicly released by the administration, indicates that by the end of May 2020 border officials referred only 85 people for additional fear screening who were subject to the CDC order and only four were permitted to stay in the United States and request asylum.

Of the more than 42,000 expelled under the order in March and April 2020, 99.99 percent were denied even an opportunity to apply for refugee protection.

Using the CDC order, CBP is likely expelling or blocking from seeking protection at least 4,000 men, women, and children a month. This estimate by Human Rights First is a conservative one based on an 86 percent drop in credible fear referrals and steep declines in processing of inadmissible individuals, often asylum seekers, at southern ports of entry. Indeed, CBP has entirely stopped processing of requests for protection at ports of entry under the guise of the CDC order, including for the 14,000 asylum seekers who have been waiting in some instances for more than nine months on metering lists.

Expulsions of asylum seekers and other migrants by CBP violate U.S. treaty obligations to refugees and are an attempt to circumvent the laws passed by Congress that require the agency to process individuals seeking protection in the United States. As Senator Patrick Leahy and other senators wrote in expressing their grave concern about these expulsions, the administration "blatantly misinterpret[s] its limited authorities" under the CDC order in an attempt "to override existing federal statutes."

Moreover, the CDC order CBP is citing as authority to carry out expulsions, lacks a public health rationale. In a letter to the director of the CDC, more than 40 public health experts from leading U.S. public health schools, medical schools, hospitals, and other public health institutions concluded that:

- "there is no public health rationale for denying admission to individuals based on legal status**.** The order's stated justification is that the migrants and asylum seekers who are subject to it would normally be held by Customs and Border Protection (CBP) in 'congregate settings' for prolonged periods of time. However, instead of holding individuals in facilities widely recognized as dangerous and unsanitary, CBP has the discretion and legal authority to parole adults and families seeking asylum or other legal protection, and the government could facilitate the expeditious release of unaccompanied children from custody. A recent study found that of several hundred asylum seekers currently at the Mexico-U.S. border, 92 percent have family or friends they could live with in the United States. Allowing individuals to shelter in place with family or friends would reduce the need for quarantine facilities, resolving another concern stated in the CDC order."

These eminent public health experts wrote that "other safeguards – like use of masks, hand sanitizer, and other screening measures – are available" and urged CDC to rescind the order and to work with U.S. government agencies, including CDC, to implement measures grounded in the best available public health guidance, including:

- During border processing, facilitate social distancing through demarcations and the use of outdoor and other areas for processing; require wearing of masks or similar cloth coverings over the face and nose for both officers and persons crossing into the United States; use plexiglass barriers and/or face shields for officers during interviews and identity-checks; provide hand-sanitizer and other handwashing for both officers and other persons; and provide requisite distance, as well as masks and other measures, in transport;
- Rather than detaining asylum seekers in congregate settings, allow asylum seekers to wait for their court hearings with their families or other contacts in the United States through parole, case management and other alternatives to detention;
- Promptly transfer unaccompanied children to the legal authority of the Office of Refugee Resettlement for swift reunification with family members and caregivers in the United States; and

- Facilitate self-quarantine at destination locations, should all individuals crossing the southern border be required to do so. Under no circumstances should CBP operate mass quarantine facilities.

Indeed, the CDC also relies on false assertions by DHS about CBP's capacity to process asylum seekers, unaccompanied children and other migrants at the southern border. Contrary to the agency's claims that individuals subject to the CDC order must be held in congregate settings for many hours or days, Human Rights First recently detailed in a June 2020 analysis of government documents revealed in litigation and through FOIA as well as federal court findings that CBP is capable of completing border processing in a matter of hours, that CBP ports of entry have numerous detention cells and holding rooms where social distancing could be observed and that these ports have 11 percent more staffing compared to 2016 when CBP processed far more individuals. Even if people arriving at the border were placed in separate holding cells for 12 hours—far longer than generally needed to complete border processing—CBP could still process hundreds of families, unaccompanied children, and individuals requesting humanitarian protections at the southern border each day.

While administration officials use debunked public health claims made in the CDC order as a fresh opportunity to turn away asylum seekers and unaccompanied children, many CBP officers and Border Patrol agents fail to consistently observe even the most basic health precautions at border posts and on patrol, like wearing masks and maintaining safe distancing, as Human Rights First documented in our recent report. For instance, we received reports from attorneys, humanitarian volunteers, and members of the public who have crossed the border on foot or vehicle at San Ysidro, California, Nogales, Arizona, Columbus, New Mexico, and El Paso and Brownsville, Texas ports of entry in April and May that some CBP officers in vehicle lanes and inside ports of entry who were not wearing masks and that none had been offered or observed hand-sanitizing gel available for use by the public. Recent photographs posted by Border Patrol officials on Twitter show uniformed, on-duty agents in California, Arizona, New Mexico, and Texas not consistently using masks and not maintaining social distancing, even among agents not wearing protective gear.

CBP Continues to Strand Asylum Seekers and Other Migrants in Danger in Mexico

At the same time, despite escalating violence in Mexico, the administration continues to implement the Remain in Mexico policy threatening the lives of asylum seekers. Since the so-called Migrant Protection Protocols (MPP) went into effect in January 2019, DHS has returned thousands of asylum seekers primarily from Cuba, El Salvador, Guatemala, Honduras, Nicaragua, and Venezuela to Mexico. During the pandemic, CBP continues to place additional asylum seekers in MPP, including those from Cuba and Nicaragua, although all MPP hearings have been cancelled since March 23.

CBP has also halted all processing of asylum seekers requesting protection at U.S. ports of entry on the southern border leaving an estimated 14,000 asylum seekers from Angola, Cameroon, Cuba, the Democratic Republic of Congo, Eritrea, Nicaragua, and Venezuela, among other countries, in limbo – some waiting since August 2019.

Asylum seekers turned back to Mexico by CBP face life-threatening dangers. As of early May, Human Rights First had tracked 1,114 incidents of murder, rape, kidnapping, torture, and assault against individuals returned to Mexico under the MPP policy alone. But this count is only the tip of the iceberg, as the overwhelming majority of returned people have not spoken with human rights investigators or journalists. COVID-19-related restrictions have further limited reporting. Of the reported attacks, 265 were kidnappings or attempted kidnappings of children. Other victims documented in Human Right First's

recent report include a Venezuelan asylum seeker kidnapped in Reynosa while traveling to her hearing, a Cuban LGBTQ asylum seeker twice attacked in Reynosa and nearly raped, a pregnant Cuban doctor who miscarried after being beaten and nearly kidnapped in Ciudad Juárez, and a Guatemalan man assaulted and robbed in Tijuana, where police refused to allow him to file a complaint.

Following the cancellation of MPP hearings, for weeks the Department of Homeland Security (DHS) needlessly forced asylum seekers to travel through dangerous border regions of Mexico to U.S. ports of entry, exposing them to the risk of COVID-19 infection, merely to pick up notices of MPP hearings cancelled due to COVID-19 court closures. CBP officers threatened that asylum seekers who failed to pick up updated notices would be deported, falsely informed individuals unable to reach the port of entry on the date of a cancelled hearing that they had already been ordered removed *in absentia*, at times failed to provide new hearing notices to asylum seekers who had traveled to the port of entry on the date of their hearing, and distributed hearing notices at some ports of entry in the middle of international bridges putting asylum seekers at additional risk of kidnapping. Indeed, a Venezuelan asylum seeker was kidnapped in April immediately after receiving a hearing notice on an international bridge while walking away from the Laredo port of entry. In mid-April 2020, Human Rights First and 26 other organizations providing services to those in MPP wrote to CBP and DHS warning of these and other dangers. Despite changes in rescheduling policy, many asylum seekers in MPP must and will still continue to undertake long and dangerous journeys through the border region to reach ports of entry, as the administration has no means to contact individuals in MPP to inform them of these changes.

Despite claims by some administration officials, including Acting CBP Commissioner Mark Morgan, that asylum and MPP fear screening interviews are available on a "case-by-case" basis, CBP is rejecting requests for asylum and fear interviews without consideration. Those refused fear interviews by CBP include a Venezuelan asylum seeker forced back without a screening to highly dangerous Nuevo Laredo, a Brazilian lesbian couple and their child denied a fear screening in El Paso, and a Honduran asylum seeker denied a fear screening after his finger was chopped off by his kidnappers in Ciudad Juárez. On June 20, 2020, non-profit organizations serving asylum seekers in MPP wrote to DHS and CBP documenting recent instances in which asylum seekers from Cuba, El Salvador, Guatemala, Honduras, Nicaragua, Venezuela and other countries were blocked from fear screenings by CBP.

While the MPP screening process is deeply flawed and lacks basic safeguards that Congress created to prevent the deportation of asylum seekers to persecution through the credible fear screening process, these interviews are the only means for people whose safety and lives are at risk in MPP to be removed from the program and permitted to continue their asylum process in safety from within the United States. Conditioning access to refugee protection on the discretion of an individual border officer violates U.S. refugee and immigration laws and treaty-based obligations. It also contradicts the administration's assertion to the U.S. Supreme Court, in arguing for the legality of MPP, that fear screenings are available "at any time."

On June 16, DHS and the Department of Justice (DOJ) extended the cancellation of MPP hearings through July 17, meaning that by the time hearings resume those in MPP will have been prevented from even requesting protection for at least four months.

CBP Fear Screening Farce

Trump Administration officials have repeatedly complained about the rate at which professional U.S. Citizenship and Immigration Services (USCIS) asylum officers determine that asylum seekers meet the

credible fear of persecution legal standard. Indeed, White House senior advisor Stephen Miller reportedly demanded that USCIS tighten, *i.e.* lower, the pass rate.

Indeed, the administration has proceeded to rig the asylum process through a barrage of illegal policy changes, agency regulations, and unilateral Attorney General rulings that render many refugees ineligible for asylum or effectively block them from this life-saving protection. Through asylum cooperative agreements with Central American countries that are unsafe for refugees, the third-country transit asylum ban, fast-track "asylum review" programs that hold asylum seekers in substandard CBP border cells that effectively block them from legal representation, and by deploying CBP border enforcement officers to conduct some fear interviews, the administration is achieving its goal to block asylum seekers at the credible fear stage and deport them to the countries they have fled without letting them apply for asylum or have an asylum hearing. In fiscal year 2020, positive credible fear determinations dropped sharply by 50 percent from the preceding year to just 37 percent, according to USCIS data – a significant departure from credible fear rates during the Barack Obama and George W. Bush administrations, when they averaged 78 percent.

Another element of the administration's efforts to rig the credible fear process is the use of CBP enforcement officers to conduct some screenings. These border enforcement officers are determining that asylum seekers meet the fear standard at a rate 20 percent lower than compared to interviews conducted by trained asylum officers. Allowing CBP officers, who are not suited to carrying out sensitive, legally complex, non-adversarial screenings of often traumatized asylum seekers, undermines the safeguards Congress intended to protect refugees.

CBP Inappropriately Deployed in the Interior of the United States

The deployment of CBP air and ground resources and personnel in response to largely peaceful protesters also raises concerns given that CBP does not have a track record of prioritizing the protection of the rights of those it encounters or who have been placed in its care, as is made clear by the widespread abuse of children in its custody. Considering the routine lack of oversight, including shoddy recordkeeping, lack of accountability, low hiring standards, destruction of life-saving water left for migrants in the desert, frequent excessive use of force and escalation of force, antiquated policies, as well as the high prevalence of corruption and misconduct, CBP should not be deployed to "keep the peace." For CBP officers to be deployed well beyond their general responsibilities over immigration and customs enforcement at the border, raises legitimate concerns, particularly for immigrant populations, attempting to exercise rights to peaceful assembly and protest. Further, these deployments may, in some instances, be illegal, such as the use of a CBP drone over the Minneapolis/St. Paul area well outside of the border zone in which CBP is authorized to operate.

Continued Congressional Oversight and Action Needed

To restore the asylum system that Congress established through the historic Refugee Act of 1980 and subsequent legislation and respect for the rule of law at our borders and in the interior of the United States, Human Rights First calls on Congress to:

- ☑ Withhold appropriations to DHS and DOJ used to carry out the Migrant Protection Protocols, expulsions under the CDC order, transfers under asylum cooperative agreements, the third-country transit asylum ban, fast-track asylum deportation programs, including the Prompt Asylum Claim Review (PACR) and Humanitarian Asylum Review Process (HARP) programs, and the use of CBP officers to conduct preliminary fear screenings.

- ☑ Pass the Refugee Protection Act of 2019.
- ☑ Hold continued oversight hearings on the administration's policies designed to block or deter people seeking humanitarian protections in the United States, which violate the Immigration and Nationality Act, Refugee Act of 1980, Foreign Affairs Reform and Restructuring Act 1998, Trafficking Victims Protection Reauthorization Act of 2008, among other laws, as well as U.S. treaty obligations to refugees.
- ☑ Request investigations of the claimed justifications and legality of the CDC order by the Offices of Inspector General for DHS and the Department of Health and Human Services.
- ☑ Conduct official visits, when safe given the COVID-19 pandemic, to Mexican border towns, CBP facilities and Border Patrol stations on the southern border, and immigration courts to ensure compliance with U.S. laws and treaty obligations.
- ☑ Prohibit the future deployment of CBP and Immigration and Customs Enforcement officers and resources outside of DHS's border enforcement mandate in order to conduct general law enforcement activities, including policing of individuals exercising protected First Amendment rights to freedom of assembly and speech.



Statement for the Record by Kids in Need of Defense (KIND)

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

Senate Committee on Homeland Security and Governmental Affairs

June 25, 2020

Kids in Need of Defense (KIND) is the leading national organization working to ensure that no child faces immigration court alone. KIND was founded by the Microsoft Corporation and the United Nations Refugee Agency (UNHCR) Special Envoy Angelina Jolie. We have served more than 20,000 unaccompanied children in removal proceedings, trained over 50,000 attendees on the pro bono representation of these children, and formed pro bono partnerships with more than 650 corporations, law firms, law schools, and bar associations. KIND also helps children who are returning to their home countries to do so safely and to reintegrate into their home communities. In addition, we seek to change law and policy to improve the protection of unaccompanied children in the United States and to build a stronger regional protection framework throughout Central America and Mexico.

KIND strongly opposes the Department of Homeland Security (DHS)'s illegal expulsions of unaccompanied children and Customs and Border Protection (CBP)'s role in implementing them. Under indefinite Centers for Disease Control and Prevention (CDC) and DHS entry restrictions, DHS has summarily returned to Mexico and Central America over 2,000 unaccompanied children who arrived at the U.S. southern border.[1] These expulsions violate the bipartisan Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA)[2] by stripping children of vital legal protections and any meaningful opportunity to seek humanitarian relief before being returned. As a consequence, expelled children face a heightened risk of human trafficking and persecution—precisely the outcomes that the TVPRA was intended to prevent. Though DHS has used the COVID-19 pandemic as a pretext for its actions, medical experts have made clear that this policy lacks a valid public health rationale and that the U.S. government is fully capable of upholding our laws and humanitarian values while also protecting public health and safety.[3]

By helping carry out these expulsions, CBP bears direct responsibility for contravening the TVPRA. Under the Act, the U.S. government must screen unaccompanied children to determine whether they are at risk of trafficking or fear return to their home countries. The TVPRA further requires that DHS transfer unaccompanied children from noncontiguous countries, as well as unaccompanied children from contiguous countries who are at risk of trafficking, fear return, or are unable to make an independent decision about withdrawing their application for admission, into ORR care and custody and place them into full immigration court proceedings. Yet CBP is flouting these requirements by summarily returning children to their country of origin or pushing

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[1] *See, e.g.*, Lauren Villagran, "Despite coronavirus, children are still arriving at the border. They're being turned away" El Paso Times (Jun. 10, 2020); https://www.elpasotimes.com/story/news/2020/06/10/border-patrol-rejects-migrant-children-cdc-authority-covid-19/5274691002/.

[2] P.L. 110-457.

[3] Priscilla Alvarez, "Health experts slam Trump administration's use of public health law to close border" CNN (May 18, 2020); https://www.cnn.com/2020/05/18/politics/border-closure-public-health/index.html.

them back into Mexico without any consideration of their safety. In fact, of the more than 1,000 unaccompanied children encountered by DHS at the U.S. southern border in May, only 39 were referred to ORR.[4]

CBP's disregard for these statutory protections is squarely linked to the enhanced danger—not least of human trafficking—to which arriving unaccompanied are now exposed. By omitting screenings of these children for trafficking concerns, for instance, CBP fails to observe and respond to any evidence that they were trafficked into the United States for commercial sex or forced labor or would be returned into trafficking situations if expelled. Moreover, because CBP has refused to apply the legal definition of "unaccompanied alien child" provided for in the Homeland Security Act—as addressed in more detail below—it has incentivized the rapid return of children to Mexico together with unscreened adults who could pose a danger to them. Additionally, expelled children are not benefitting from the skilled and protective screenings performed by attorneys and social workers specially trained to identify protection needs among this vulnerable population. CBP's website states that it is "uniquely situated to deter and disrupt human trafficking,"[5] but the bureau's contributions to the expulsions of unaccompanied children makes clear that it has abdicated any such 'unique' position. Ultimately, CBP's defiance of Congress's anti-trafficking requirements does not deter or disrupt human traffickers at all—it emboldens them.

No less troubling, CBP has elected not to adopt a readily available measure that would shield unaccompanied children from these harmful expulsions. The CDC and DHS orders underlying expulsions limit entry at the U.S. southern border to "essential travel." Notably, however, the orders allow for exceptions when appropriate. DHS has already designated a host of traveler populations, including students and truck drivers, "essential" and thereby exempt from the entry restrictions, while also expressly authorizing CBP to designate additional populations in this manner.[6] Yet CBP has failed to deem unaccompanied children "essential." CBP's refusal to follow the TVPRA and exercise its authority to exempt unaccompanied children from expulsions is wrong and dangerous for children. The TVPRA, after all, reflects a bipartisan determination that unaccompanied children's often life-and-death pursuit of protection is so imperative as to warrant a unique array of due process safeguards. In the strongest terms, then, KIND rejects CBP's position that the safety of unaccompanied children is "non-essential."

Alarmingly, a leaked CBP memorandum guiding agents and officers' implementation of expulsions reveals that CBP has gone so far as to fashion the term "unaccompanied juvenile"—one that appears nowhere in relevant statute—in order to bypass the existing definition of an "unaccompanied alien child" in the Homeland Security Act of 2002 (HSA)[7] and the corresponding legal obligations in the HSA and the TVPRA. On an immediate level, this invented term facilitates DHS's expulsion of unaccompanied children under the pretext of returning family units. More

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[4] Camilo Montoya-Galvez, "Just 39 unaccompanied migrant children avoided Trump's border expulsions in May" CBS News (Jul. 18, 2020); https://www.cbsnews.com/news/unaccompanied-migrant-children-trump-expulsion-border-policy/.

[5] Customs and Border Protection, "Human Trafficking" (Jan. 9, 2020); https://www.cbp.gov/border-security/human-trafficking.

[6] DHS Order, "Notification of Temporary Travel Restrictions Applicable to Land Ports of Entry and Ferries Service Between the United States and Mexico" (May 19, 2020); https://www.dhs.gov/sites/default/files/publications/20_0519_as1_frn_us-mexico-border.pdf.

[7] 6 U.S.C. 279(g)(2).

fundamentally, by seeking to administratively limit application of the "unaccompanied alien child" definition codified by the legislative branch, CBP is aiming to effectively extinguish bipartisan statutes core to the protection of unaccompanied children.

In view of these grave concerns, KIND calls upon CBP to: (1) exempt unaccompanied children from the CDC and DHS entry restrictions by declaring them "essential" and cease summary removals of children under the CDC order; and (2) fully conform to all TVPRA and HSA requirements by, among other actions, performing full protection screenings and making referrals to ORR as mandated under the TVPRA, and by adhering to the HSA's definition of "unaccompanied alien child." CBP, and DHS as a whole, can and should process children's protection claims in accordance with the law while still safeguarding the health of these children and of the public at large.

Written Testimony of

Most Reverend Mario E. Dorsonville
Auxiliary Bishop of Washington

Chairman of the Committee on Migration of the
United States Conference of Catholic Bishops

for
Senate Homeland Security & Governmental Affairs Committee

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

562 Dirksen Senate Office Building
9:30am Thursday, June 25, 2020

"Particular concern must be shown for migrant children and their families, those who are victims of human trafficking rings, and those displaced due to conflicts, natural disasters and persecution. All of them hope that we will have the courage to tear down the wall of "comfortable and silent complicity" that worsens their helplessness; they are waiting for us to show them concern, compassion and devotion."

--Pope Francis, Message for 2nd Conference on International Migration between Mexico & Holy See,"[1]

Thank you to Senator Ron Johnson(R- WI) Chairman and Senator Gary Peters(D-MI) Ranking Member and members of the Senate Homeland Security & Governmental Affairs Committee for the opportunity to submit this written testimony regarding the recent developments regarding Customs and Border Protection and their engagement with unaccompanied children and asylum-seeking families.

As chairman of the Committee on Migration for the United States Conference of Catholic Bishops (USCCB), I wish to address the importance of America's acceptance of and care for unaccompanied children and asylum-seeking families, of which the Customs and Border Protection (CBP) plays an important role, frequently as the first U.S. government entity these individuals encounter. The United States is a global leader and over the years has developed many noteworthy humanitarian and child-friendly responses to caring for these vulnerable populations. I speak on behalf of the Catholic Church when I say that the Church teaches that every human being is created in God's image and deserves dignity and respect. We view assisting those in need as a fundamental Christian duty that is derived directly from the words and the life of Christ, who himself was a migrant and part of a refugee family. As Christians, we are called to welcome our new neighbors and those fleeing persecution with the same love and compassion that we would want ourselves to be shown.

Pope Francis himself has spoken with great compassion and detail as to the importance of caring for unaccompanied children and families seeking refuge. Accordingly, recent changes to the way CBP and the Border Patrol are encountering unaccompanied children and asylum-seeking families in light of COVID-19 and the U.S. government's abrogation of the requirements under the Trafficking Victims Protection Reauthorization Act (TVPRA)[2] are of great concern to us. We are sincerely worried about the well-being of the children and families and for the CBP and Border Patrol officers who are working on the frontlines to ensure our safety. Many Catholic dioceses along the U.S. border work every day with CBP and Border Patrol officers and value the work that these brave men and women undertake in order to keep our country safe. We recognize that CBP is working to deal with COVID-19 and appreciate those efforts; however, USCCB strongly urges the U.S. government to ensure the safety of unaccompanied children and other vulnerable groups searching for protection at the U.S./Mexico border as well as the safety of the CBP and Border Patrol officers. We believe that this can be achieved without sacrificing our moral and legal duty to help unaccompanied children and asylum seekers in need. We regularly work with CBP and pledge to continue doing so in an effort to find a more humane and legally compliant way to protect all people from COVID-19 to the extent possible, while simultaneously honoring our laws and offering refuge to those fleeing violence. As Pope Francis notes, we must not look away and ignore the suffering of those on the margins.

In this testimony, I will describe the Catholic Church's work and mission assisting unaccompanied children and asylum-seeking families and our concerns related to the lack of protections for these two vulnerable populations due to recent COVID-19-related regulations promulgated by the Administration. I will also offer

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[1] Pope Francis, Message of His Holiness Pope Francis for the "Second Holy See- Mexico Conference on International Migration," Vatican City, 14 June 2018. http://w2.vatican.va/content/francesco/en/messages/pont-messages/2018/documents/papa-francesco_20180614_messaggio-migrazione.html

[2] 8 U.S.C. § 1232.

recommendations to help ensure that immigrant children and families are protected and treated with dignity and ensure such children and families are in compliance with their immigration proceedings, while honoring the existing legal and legislative protections found in the TVPRA.

I. Catholic Social Teaching and Concern, Care and Support for Unaccompanied Children and Asylum-Seeking Families

The principle point of faith for assisting unaccompanied children is rooted in the belief that they, like all God's children, were created in His image and have a unique and sacred human dignity. Consequently, the Catholic Church in the United States has played a critical role in the care of unaccompanied children and asylum-seeking families, and USCCB's Migration and Refugee Services (MRS) has been a leader in the protection of and advocacy for these populations. While the Catholic Church recognizes governments' right to control their borders and enforce immigration laws, we also hold a strong pastoral interest in the welfare and humane treatment of unaccompanied immigrant children. In the Old Testament, God calls upon his people to care for the alien because of their own experience as aliens: "So, you, too, must befriend the alien, for you were once aliens yourselves in the land of Egypt" (Deut. 10:19). In the New Testament, the image of the migrant is seen in the life and teachings of Jesus Christ. In his own life and work, Jesus identified himself with newcomers and other marginalized persons in a special way: "I was a stranger and you welcomed me" (Mt. 25:35). Jesus himself was an itinerant preacher without a home of his own, and as noted, a refugee fleeing to Egypt to avoid persecution and death (Mt. 2:15).

In modern times, popes over the last 120 years have developed the Church's teaching on migration. Pope Leo XIII pioneered the Catholic Church's commitment to care for pilgrims, aliens, refugees, and migrants of every kind, affirming in *Rerum Novarum*, that all peoples have the right to conditions worthy of human life and, if these conditions are not present, the right to migrate.[3] Meanwhile, we advocate to address the root causes for such poor conditions while also protecting those forced to migrate. In our joint pastoral letter with the Mexican bishops in 2003, *Strangers No Longer: Together on the Journey of Hope*, *A Pastoral Letter Concerning Migration*,"[4] January 23, 2003, we call for nations to work toward a "globalization of solidarity." In that document, we affirm that "Refugees and asylum seekers should be afforded protection. Those who flee wars and persecution should be protected by the global community." (No. 99). We likewise state that refugees should "have access to appropriate due process protections consistent with international law." (No. 99). We believe that once an unaccompanied child arrives at our border, our nation has a moral obligation to ensure his or her safety and wellbeing. As Pope Francis has said: "Among migrants, children constitute the most vulnerable group, because as they face the life ahead of them, they are invisible and voiceless."[5]

Since 1994, USCCB/MRS has operated the "Safe Passages" program. This program serves unaccompanied immigrant children apprehended by the Department of Homeland Security (DHS) and placed in the custody and care of the Office of Refugee Resettlement (ORR), within the Department of Health and Human

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[3] Pope Leo XIII *Rerum Novarum*, ENCYCLICAL OF POPE LEO XIII ON CAPITAL AND LABOR, *1891*. http://www.vatican.va/content/leo-xiii/en/encyclicals/documents/hf_l-xiii_enc_15051891_rerum-novarum.html

[4] Strangers No Longer: Together on the Journey of Hope, A Pastoral Letter Concerning Migration from the Catholic Bishops of Mexico and the United States, *United States Conference of Catholic Bishops, Inc. and Conferencia del Episcopado Mexicano, January 22, 2003* http://www.usccb.org/issues-and-action/human-life-and-dignity/immigration/strangers-no-longer-together-on-the-journey-of-hope.cfm .

[5] Pope Francis, *2017 World Day of Migrants and Refugees Message* (September 8, 2016). https://w2.vatican.va/content/francesco/en/messages/migration/documents/papa-francesco_20160908_world- migrants-day-2017.html .

Services (HHS). Through cooperative agreements with ORR, and in collaboration with community-based social service agencies, the Safe Passages Program provides community-based residential care (foster care and specialized groups homes) and small-scale shelter placements to unaccompanied children in ORR custody, as well as family reunification services (pre-release placement screenings (home studies)[6] and post-release social services for families). In fiscal year 2019, the USCCB/MRS Safe Passages Program served 1,294 youth who arrived as unaccompanied children—1,365 through the family reunification program and 203 through the residential care programs.

In addition to our work serving unaccompanied children through the Safe Passages Program, we have extensive experience throughout our Catholic network in serving asylum-seeking families. Traditionally, and especially in recent years (as family units have been arriving with increased frequency to the U.S./Mexico Border since 2014[7]), Catholic entities and Border Patrol officers have formed valuable partnerships and relationships working in coordination to assist asylum-seeking families. This collaborative working relationship has grown particularly since 2018-2019, when CBP began releasing family units directly to humanitarian service providers. Specifically, the areas that received the largest number of families released were led by Catholic service providers in: (1) El Paso, Texas – coordinated by Annunciation House with support from the Diocese of El Paso and other religious organizations; (2) McAllen, Texas –coordinated by Catholic Charities Rio Grande Valley with support from the Diocese of Brownsville; and (3) Tucson and Yuma, Arizona – coordinated by Catholic Community Services of Southern Arizona with support from the Diocese of Tucson and other religious organizations.

Additionally, in the summer of 2018 USCCB/MRS worked in partnership with Lutheran Immigration and Refugee Service to assist the Trump Administration to reunify separated families as was required by law. In addition to providing initial humanitarian and reunification assistance, USCCB/MRS worked with families into late 2018 and early 2019 to provide access to social and legal service and case management.[8] USCCB/MRS provided these charitable services because of our belief that such services would help support the separated children and families, reduce their ongoing trauma, and help ensure positive compliance outcomes. Throughout all of this work, we have learned of the trauma and violence that many unaccompanied children and asylum-seeking families suffer and regularly face, and they have noted the life-saving protection that American laws have afforded these vulnerable people.

II. Recent Regulations Undermine Protections for Vulnerable Children and Families and Ignore Systemic Root Causes of Violence and Forced Migration

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[6] During a home study, a community-based case worker assesses the safety and suitability of the proposed caregiver and placement, including the caregiver's capacity to meet the child's unique needs, any potential risks of the placement, and the caregiver's motivation and commitment to care for the child. Home studies result in a recommendation on whether placement with the proposed caregiver is in the child's best interest.

[7] During Fiscal Year 2018, the number of arriving family units increased to roughly 107,000 members arriving at the U.S./Mexico border, up from 76,000 in Fiscal Year 2017. As March 2019, the number of arriving family units was already estimated at over 189,000 for Fiscal Year 2019. *U.S. Border Patrol Southwest Border Apprehensions by Sector FY 2017*, U.S. CUSTOMS AND BORDER PROTECTION (Feb. 11, 2019), https://www.cbp.gov/newsroom/stats/usbp-sw-border-apprehensions-fy2017; *U.S. Border Patrol Southwest Border Apprehensions by Sector FY 2018*, U.S. CUSTOMS AND BORDER PROTECTION (Oct. 23, 2018), https://www.cbp.gov/newsroom/stats/usbp-sw-border-apprehensions*; Southwest Border Migration*, U.S. CUSTOMS AND BORDER PROTECTION (April 29, 2019), https://www.cbp.gov/newsroom/stats/sw-border-migration.

[8] U.S. CONFERENCE OF CATHOLIC BISHOPS AND LUTHERAN IMMIGRATION AND REFUGEE SERVICE, SERVING SEPARATED AND REUNITED FAMILIES: LESSONS LEARNED AND THE WAY FORWARD TO PROMOTE FAMILY UNITY (2018). https://justiceforimmigrants.org/2016site/wp-content/uploads/2018/10/Serving-Separated-and-Reunited-Families_Final-Report-10.16.18-updated-2.pdf.

During the global COVID-19 pandemic, there have been several new regulations promulgated by the Trump Administration regarding the ability of immigrants to enter the country. The ability of the federal government to create these regulations exists under Title 42 of the United States Code. Title 42 of the United States Code, otherwise known as the "Public Health and Safety Act," which is made up of hundreds of individual laws governing the health, safety, and civil rights of those within the United States. Under section 265 of this act[9], the Surgeon General may halt any immigration or entrance of persons from countries they find to be a source of communicable disease.

Citing the rise of COVID-19 in our country, on March 20, 2020, the Centers for Disease Control and Prevention (CDC) issued an interim final rule that restricted any persons traveling over either the northern or southern border, regardless of their country of origin, into the United States[10]. Although issued by the CDC, the order stated that it would be implemented by the U.S. Department of Homeland Security.[11] In addition, on April 22, 2020, President Trump issued a presidential proclamation stating that, in order to preserve the United States economy, most immigration into the United States would be suspended.[12] Since the Proclamation and the rule published by the CDC in March, the U.S. Border Patrol has reported a total of 41,557 migrants expulsed from the United States under Title 42.[13] On May 20th, the CDC announced the amendment and extension of the rule issued on March 20th, 2020 which will remain in effect until the CDC director determines that it is no longer necessary.[14]

While we note the importance of public health measures to protect the well-being of our country, the recent immigration-related changes have left many unaccompanied children in extremely dangerous and vulnerable situations and has violated existing U.S. requirements under the TVPRA. [15] The March 20th order has had true human consequences: it is estimated that approximately 2,175 unaccompanied children have been "expelled" since March 2020.[16] Noting the extreme violence[17] that unaccompanied children encounter both in their home countries (primarily the Northern Triangle[18]) and on their journey, especially during this time when

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[9] 42 U.S.C. §265 (1944). ("Whenever the Surgeon General determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health, the Surgeon General, in accordance with regulations approved by the President, shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose.")

[10] 85 Fed. Reg. 16567 (March 23, 2020).

[11] *Id.*

[12] Presidential Proclamation 10013 (April 22, 2020). For more information, see JFI's resource available at https://justiceforimmigrants.org/wp-content/uploads/2020/05/April-Presidential-Proclamation.pdf

[13] *Nationwide Enforcement Encounters: Title 8 Enforcement Actions and Title 42 Expulsions*, U.S. DEP'T OF HOMELAND SECURITY, CUSTOMS AND BORDER PROTECTION, https://www.cbp.gov/newsroom/stats/cbp-enforcement-statistics/title-8-and-title-42-statistics (last accessed June 17, 2020).

[14] Order Suspending Introduction of Certain Persons from Countries Where a Communicable Disease Exists, Center for Disease Control, May 19, 2020. https://www.cdc.gov/quarantine/order-suspending-introduction-certain-persons.html

[15] *See* 8 U.S.C. § 1232.

[16] Lauren Villagran, The Trump administration is turning away unaccompanied children at the border because of coronavirus, *USA Today*, June 10, 2020. https://www.usatoday.com/story/news/nation/2020/06/10/border-patrol-rejects-migrant-children-cdc-rule-amid-covid-19/5333392002/

[17] *See e.g.* Mission to Central America: The Flight of Unaccompanied Children to the United States, Report of the Committee on Migration of the United States Conference of Catholic Bishops, November 2013. http://www.usccb.org/about/migration-policy/fact-finding-mission-reports/upload/Mission-To-Central-America-FINAL-2.pdf

[18] *See* Southwest Border Migration Statistics FY15- FY 20, Customs and Border Protection. https://www.cbp.gov/newsroom/stats/sw-border-migration

the criminal networks and others may utilize this moment to prey on the children, it is extremely distressing to know that our government is turning such vulnerable youth away from accessing protection in the United States. Traveling alone, underage and often exposed to extreme violence and poverty, these children are among the most vulnerable and prone to abuse, trafficking, or exploitation.

Additionally, of the 2,175 unaccompanied children who have been denied protection by the U.S. government since March, it is unclear to service providers: how many of them are "tender age"; the safety of their home environments that they are being returned to; what has happened to the children generally; and whether they have been exposed to coronavirus themselves. This information is vital to help ensure that unaccompanied children are safe and not subject to exploitation from traffickers, family abuse or gangs and also that they do not become locked into a circular forced re-migration pattern due to a lack of protection and a life-threatening need to flee. This information would be collected if the U.S. government, through CBP, were processing unaccompanied children as required under the TVPRA. Most importantly, this information would help to ensure the children were safe and would also help to ensure children are protected from criminal networks.

Such a breakdown in protection for unaccompanied children as a result of the particular implementation of the CDC order ignores the reality of the persistent and systemic violence that has fueled forced migration of vulnerable families and children in recent years. Through the work of the Catholic Church around the world, and especially in the Northern Triangle, we see the consistently high levels of violence in Central America, political instability in parts of South America (namely Venezuela), and the lack of many countries' capacity to offer adequate protection.[19] The Church in Guatemala, Honduras and El Salvador is experiencing, publicly reflecting on, and responding to the escalation of violence in urban communities, in rural communities, and to family units. In his pastoral letter, *I See Violence and Strife in the City*, Archbishop José Luis Escobar Alas, Archbishop of San Salvador, stated: "[t]he faithful know that they are being monitored [by gangs] in their comings and goings in the communities. The same applies to pastoral agents who are constantly watched . . . The exodus of families is heartbreaking . . . It is truly unfortunate and painful that the Church cannot work because of this atmosphere of insecurity and anxiety that shakes our beloved country."[20] The archbishop describes that over the course of one year, one parish alone was "exposed to murder, persecution, exodus, and extortion," including the murder of six active parishioners by stabbing, dismemberment, or firearms.[21]

Catholic social teaching recognizes the right to migrate but also recognizes the right not to migrate—people can and do have the right to remain in their homeland and be able to provide a decent life for themselves and their families. Many programs that have been implemented in Central America by the Church, our federal government and other partners are working to help ensure people can actually have a decent life and have access to a steady job and a safe community. We as a global Church are always reminding people that they have the right to remain in their home country. Unfortunately, due to increased violence and lack of opportunity that is not always something that families who are facing persecution feel is an option; sometimes migration is seen as the only option to protect one's life. In these times of a global pandemic with the coronavirus, this is an even more pressing reality. This is precisely why the United States must continue to offer protection—especially during this global pandemic—to

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[19] For example, the Mexican asylum system has seen large increases in requests for protection: from just over 1,000 in 2013 to nearly 30,000 in 2018. In the first two months of 2019, there was a further 185-percent increase in the number of people seeking asylum in Mexico compared to the same period in 2018 and efforts to meet the demand are not able to ensure adequate access to protection. COMISIÓN MEXICANA DE AYUDA A REFUGIADOS, BOLETÍN ESTADÍSTICO DE SOLICITANTES DE REFUGIO EN MÉXICO (2013), *available at* https://www.gob.mx/cms/uploads/attachment/file/413013/COMAR_2013.pdf.; Rachel Schmidtke, *2018 Migration To and Through Mexico Fact Sheet*, WILSON CENTER (March 15, 2019), https://www.wilsoncenter.org/article/2018-migration-to-and-through-mexico-fact-sheet.

[20] Most Reverend Jose Luis Escobar Alas, *I See Violence and Strife in the City: A Pastoral Letter on the Occasion of the Feast of the Beloved Blessed Oscar Romero*, 18 (March 24, 2016).

[21] *Id.* at 15.

those vulnerable families and children fleeing persecution as it is an issue of life and death now more so than ever. Looking at solutions that are focused solely on overriding protections found in domestic laws will erode existing due process for such asylum-seeking children and families and will not necessarily stem the spread of coronavirus domestically or internationally.

III. CBP Can Ensure Public Health Precautions for Officers, Unaccompanied Children, and Asylum-Seeking Families

The Trump Administration has stated that the CDC order is being implemented with regards to unaccompanied children and asylum-seeking children to ensure minimal exposure to coronavirus in congregate care and border processing facilities.[22] However, there are measures that the Administration can take to ensure that unaccompanied children and asylum-seeking families are processed and able to access protection, while still adhering to CDC guidelines to mitigate the spread of coronavirus. Many of these items begin with the work of CBP and the Border Patrol. We offer the following recommendations for your consideration:

Asylum-Seeking Families:

- During border processing, CBP and Border Patrol officers can facilitate social distancing through demarcations and the use of outdoor and other areas for processing; require wearing of masks or similar cloth coverings over the face and nose for both officers and persons crossing into the United States; erect plexiglass barriers and/or face shields for officers during interviews and identity-checks; provide hand-sanitizer and other handwashing for both officers and other persons; and provide requisite distance, as well as personal protection equipment and distancing measures in transport.

- Invest in robust training of CBP and Border Patrol officers on safety and wellness guidelines. Facilitate extensive public information dissemination at all processing areas in English, Spanish, and in infographics and widely distribute such information to arriving asylum-seekers.

- Rather than detaining asylum-seekers in congregate settings, allow them to wait for their court hearings with their families or other contacts in the United States through parole, case management and other alternatives to detention, including ankle monitors. Ensure that asylum seekers have education on immigration compliance requirements and proper health measures such as mask-wearing and social distancing. Provide PPE to all members of the family unit and reduce any potential barriers to securing PPE at this time. Require that family or friend sponsors are informed of released asylum-seekers transportation needs, and health needs and exhort asylum-seekers to check in with public health officials in the final destination location.

- For asylum seekers who are released with sponsors in the United States, facilitate and educate on self-quarantine at destination locations, and provide education and guidance on best health practices in linguistically appropriate materials.

- For asylum-seeking families that are not released with sponsors in the United States and are required to wait in Mexico, work with the Mexican government and public health and civil society health entities to improve shelter conditions, including access to testing and healthcare.

- Continue to work with local faith-based and civil society agencies on the ground to assist in humanitarian aid for individuals who need extra and immediate medical care or temporary lodging or assistance.

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[22] 85 Fed. Reg. 16567 (March 23, 2020)

Unaccompanied Children:

- Process all unaccompanied children as required under the TVPRA.
- Utilize social distancing, masks, gloves and plexiglass dividers for the health and wellbeing of unaccompanied children as well as CBP and Border Patrol officer health and wellbeing during interviews of unaccompanied children that are required by the TVPRA and inputting of Form 93 by CBP and Border Patrol officers.
- Ensure accurate and timely data collection on all repatriations and expulsions of unaccompanied children that have occurred since March and are on-going. DHS should provide information regarding the child's age, reunification and health outcomes and disseminate to Congress and ORR.
- Promptly transfer all unaccompanied children to the legal authority of the ORR for swift reunification with family members and caregivers in the United States;
- Encourage ORR to expedite reunifications of unaccompanied children when safe release is possible and in consideration of public health guidelines and travel restrictions put in place by state and local governments. Expediting reunification will ensure children's length of stay in ORR care is not unnecessarily prolonged when another caregiver is available. A child placed in a host family setting with access to medical resources (including pediatric care) in a local community and where they can maintain distance from others, is more likely to stay safe during COVID-19. Proper vetting of sponsors and assessment of the sponsor's ability to provide a safe and stable home for the child must continue to ensure that children are not released into unsafe situations. Additionally, connecting with existing ORR post-release services following reunification is an additional measure to ensure unaccompanied children and families are informed of public health guidelines related to this COVID-19 pandemic and linked with health care providers in their respective communities.

IV. Conclusion

We welcome and appreciate the work of CBP to keep our country safe and thank you for the opportunity to share our insights and our long-standing commitment to protecting unaccompanied children and asylum seekers. Upholding protections for the vulnerable and keeping Americans safe are not mutually exclusive. We know that our country can do both. We respectfully urge the Committee to pursue these recommendations and we pledge our continued cooperation with CBP and our continued service for the care of unaccompanied children and asylum-seeking families.

Post-Hearing Questions for the Record
Submitted to Mark A. Morgan
From Senator Rand Paul

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

June 25, 2020

*****Due to the change-over in Administration, responses were not received to these questions for the record.*****

1. On January 5, 2018, U.S. Customs and Border Protection (CBP) released updated guidance[1] on their standard operating procedures for searching electronic devices under the so-called border search exception to the Fourth Amendment. However, CBP's most recent interpretation of the border search exception still requires every American who wishes to travel abroad to surrender any and all expectation of privacy in their digital devices.
   Question: Do you think that this updated device search policy is appropriate? Why or why not?
   Question: Do you think this policy violates the Fourth Amendment?
   Question: Do you agree with the premise that a smartphone is a physical container indistinguishable from a suitcase?
   Question: Do you think most Americans would accept the premise that a device containing every photo, email, contact, calendar item, appointment, text message, and direct message they have, as well as every Google search, browser visit, navigation search, and note they ever made, along with a detailed history of everywhere they've been—is no different from the contents of their toiletry bag and suitcase?
   Question: Do you think that most Americans are aware that forensic searches of their cell phones could yield some 900 pages of information (as was the case in *United States v. Kolsuz*[2])? And that to produce this report, their phone may be confiscated by government agents for an entire month, based on nothing more than reasonable suspicion (vs. probable cause)?

2. Travelers rely on cell phones to navigate foreign cities, communicate in foreign languages, pay for goods and services, and to keep their families safe while abroad.

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[1] https://www.cbp.gov/newsroom/national-media-release/cbp-releases-updated-border-search-electronic-device-directive-and
[2] https://www.ca4.uscourts.gov/opinions/164687.P.pdf

Federal courts have acknowledged as much—In *U.S. v. Cotterman*, the Ninth Circuit wrote[3] that it is "impractical, if not impossible, for individuals to make meaningful decisions regarding what digital content to expose to the scrutiny that accompanies international travel". In *U.S. v. Kolsuz*, the Fourth Circuit wrote[4] that "it is neither realistic nor reasonable to expect the average traveler to leave his digital devices at home when traveling."

Question: Given the impracticality of traveling without a cell phone, is abandoning Fourth Amendment protection a *de facto* requirement for international travel under existing DHS border device search policies?

Due to the change-over in Administration, responses were not received to these questions for the record.

[3] http://cdn.ca9.uscourts.gov/datastore/opinions/2013/03/08/09-10139.pdf
[4] https://www.ca4.uscourts.gov/opinions/164687.P.pdf

Post-Hearing Questions for the Record
Submitted to Mark A. Morgan
From Ranking Member Gary C. Peters

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

June 25, 2020

*****Due to the change-over in Administration, responses were not received to these questions for the record.*****

1. The National Treasury Employees Union recently testified that "one of the most critical pandemic related issues facing CBP is the reduction of user fee funding that is threatening nation's economic recovery as international trade and travel struggles to return to normal."[1] We all want to re-open our economy as fast as possible, but we want to make sure it is done safely, so we need to look at innovative ways to minimize exposure to our CBP Officers while maximizing our trade and travel operations and returning to "pre-COVID" flows of commerce as soon as possible. I am aware of a proposed pilot project in my home state of Michigan where the Detroit DFO is exploring integrated Non-Intrusive Inspection (NII) systems at regional Air, Land, and Rail Ports of Entry (POEs) and consolidated operations at a centralized command center, which will expedite the flow of commerce, optimize security, and reduce potential COVID-19 exposures to CBP Officers. I understand CBP is partnering with Delta Airlines to invest in a pilot at DTW.

    a. When do you anticipate finalizing the partnership with Delta, and when will you be integrating the other land, rail & mail vectors?

    b. What is the status of current NII pilot projects?

    c. Has CBP's NII rollout plan allowed for the implementation of lessons learned through pilot projects? If so, how does CBP apply these at ports of entry?

    d. Has COVID-19 delayed or otherwise impacted any NII programs?

    e. The Port of Detroit presents a convergence of air, sea, land, and rail ports of entry and includes some of the nation's busiest ports of entry by trade volume. Is CBP considering any pilot projects at these ports of entry? If so, what are the details of the project(s)?

    f. The Gordie Howe Bridge is also expected to become operational in 2024. How is CBP preparing for this additional port of entry?

[1] https://homeland.house.gov/imo/media/doc/Testimony-%20Reardon.pdf

2. CBP has been working hard to make progress towards 100% scanning at U.S. Land POEs, and Congress has supported CBP's efforts with increased NII funding in FY2018 and FY2019, and full funding in FY2020. The President's FY2021 budget request, however, "zeroed-out" CBP's NII procurement budget - presumably because CBP may have some excess FY19 NII funds available for expenditure in FY21. According to CBP's FY19 NII spend plan, the FY19 funds are designated for specific equipment purchases, including the new $379 million IDIQ you recently awarded to upgrade Rail POEs, and two other large projects that will likely expend all or most of your FY19 & FY20 NII funding.

    a. Will you need FY21 NII Procurement funding to avoid gaps in this critical multi-year program, and to fully fund the equipment and integration requirements revealed in recent pilots, and to ensure you have a "bridge" to continue making progress towards achieving 100% scanning in FY21?

    b. What, if anything, is CBP doing to implement guidance from OMB's March letter to all Federal Agencies encouraging you to leverage special emergency procurement authorities authorized in connection with the President's COVID-19 emergency declaration under section 501(b) of the "Stafford Act" to support the federal contractors that support CBP's missions?[2]

    c. Can you share any examples of what CBP is doing, or planning to leverage special procurement authorities such as "Other Transaction Authority" (OTA), and other contract vehicles that allow for interagency procurements such as DLA's Tailored Logistics Support, or NASA's Solutions for Enterprise Wide Procurement – specifically for NII integration efforts?

3. CBP has many officers that also serve as national guardsmen. The National Guard has been called to serve on multiple fronts over the past several months. Guardsmen are entitled to 22 days of military leave in the event they are called to serve.

    a. How does CBP process requests for military leave?

    b. What policies does CBP have in place for granting military leave requests?

    c. Has CBP identified issues with these policies during the last few months, in particular delays in granting military leave requests and/or pay issues for CBP personnel under military leave status?

    d. Since CBP officers do not work traditional Monday-Friday work schedules, how does CBP accommodate weekend Drill requirements? What kind of pay or leave status are CBP officers under when the attended National Guard drill training? Are there any accommodations for days spent traveling to their Drill and Annual Training?

[2] https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-18.pdf

4. At our borders, CBP has seized hundreds of thousands of illegitimate COVID-19 test kits, pharmaceuticals, and counterfeit supplies, such as masks. The widespread presence of these fraudulent supplies is a severe threat to public health.

    a. What resources or tools does CBP need to ensure that you are maximizing the detection of these faulty supplies?

5. CBP personnel were among the federal assets deployed to demonstrations across the country following the killing of George Floyd.

    a. How many CBP agents, disaggregated by component and duty station, have been deployed in response to First Amendment-protected activities over the past few weeks?

    b. What specific training have CBP agents deployed to the demonstrations received in crowd control and in ensuring protesters' rights are protected?

    c. How are CBP personnel trained in de-escalation techniques and protection of first Amendment rights?

    d. What was the amount of taxpayer funds used to support the recent deployments and collaboration between CBP and ICE in response to protests and for interior enforcement operations?

    e. Are CBP Personnel deployed for law enforcement or security purposes required to identify themselves as CBP officials or agents when asked or wear identifying markers?

    f. What is CBP's approval process in response to requests from federal, state or local law enforcement to provide CBP personnel, equipment or other resources? How are these requests and approvals tracked?

6. Facial recognition can be prone to misidentification based on a host of factors, and is more likely to misidentify people of color. If an individual is misidentified during a biometric check overseen by CBP at an airport (specifically a "false negative," in which the CBP facial recognition system may incorrectly state that the individual does not match any photos in the flight manifest), officials should simply proceed with a traditional ID check. But without training, such officials may assume a facial recognition system non-match indicates suspicion, and improperly subject a passenger to additional questioning or screening.

    a. Does CBP provide any training so that officials will know not to assume suspicion based on a facial recognition failing to match at airports?

    b. If officials conducted additional questions or screening because they assume a non-match in itself indicates suspicion, isn't this more likely to impact people of color given disparate error rates in facial recognition systems?

7. In March, the Centers for Disease Control (CDC) and Prevention issued the so-called Title 42 order that allows U.S. Customs and Border Protection to remove individuals from the U.S. border based on public health grounds. CBP has expelled 41,491 individuals through the order at the U.S.-Mexico border between March and May 2020. USA Today reports that through early June, CBP expelled 2,175 unaccompanied children.[3] Reports indicate that children have been moved from CBP facilities and instead may be held in hotels, sometimes with other migrants, before being expelled.

    a. Please describe the step-by-step process through which adults, family units, and single minors are expelled.

    b. Please describe how this process may differ for nationals from Mexico and Central America and for nationals from other countries.

    c. Are single minors, family units and adults held in hotels or other private facilities before being expelled? If so, how are these facilities contracted and how much funding has been expended for these facilities?

    d. Under what agency's jurisdiction are they being held while in these private facilities and what are the applicable detention standards?

    e. How are you ensuring the safety and wellbeing of these minors in these locations?

    f. Has your agency reclassified children as "single minors" to bypass protections under the Trafficking Victims Protection Reauthorization Act (TVPRA)?

    g. With the Title 42 CDC order in place is CBP bound to abide by any provisions of the TVPRA while processing individuals under that order?

    h. On what legal basis does CBP justify processing unaccompanied children via Title 42 instead of the legal requirements of the TVPRA?

    i. Please list the number of single minors expelled under the Title 42 CDC order by month, nationality, age, gender, and Border Patrol Sector or Office of Field Operations Field Office where encountered.

    j. Is CBP tracking whether these children have experienced violence, persecution, or kidnapping after being expelled? What measures are you taking to ensure their safety?

    k. Does CBP document the length of time that single minors processed under Title 42 spend in CBP custody prior to expulsion?

[3] https://www.usatoday.com/story/news/nation/2020/06/10/border-patrol-rejects-migrant-children-cdc-rule-amid-covid-19/5333392002/

l. What is it the average time a minor spends in U.S. government custody before being expelled? If CBP does not document this, why not?

m. What screening questions are administered for unaccompanied children before they are expelled? Are the responses to these questions recorded in any document and if so, which one?

n. Please list the number of family units expelled under the Title 42 CDC order by month, nationality, number of individuals within the unit, and Border Patrol Sector or Office of Field Operations Field Office where encountered.

o. Please list the number of adults expelled under the Title 42 CDC order by month, nationality, age, gender, and Border Patrol Sector or Office of Field Operations Field Office where encountered.

p. Are women with infants born in the United States while under CBP custody being expelled to Mexico?

q. Have pregnant women been expelled to Mexico?

r. Are there any limitations on which migrants can be processed via Title 42?

s. On what legal basis does CBP justify processing migrants via Title 42 instead of the legal requirements of Title 8 of the Immigration and Nationality Act?

t. How many individuals have been referred for torture screenings who were being processed for expulsion and what are their nationalities? How many of those individuals have been minors?

u. How many have passed these torture screenings?

v. How many of those referrals were made by CBP officers, by Border Patrol agents, or by other officials (ICE, etc.)?

w. What training have CBP officers and Border Patrol agents received to assess whether an individual should be referred for a torture screening? What questions are being asked during this screening?

8. CBP has managed several communicable disease outbreaks in the past among people in their custody, but it seems that the Title 42 authorities were enacted as a result of CBP's and the CDC's belief that facilities and medical resources are inadequate.

    a. What upgrades and increased capacities does CBP need to confront potential COVID-19 cases among its detainees?

b. Will CBP seek or request funding or additional authorities from Congress in the coming months to enact these upgrade or increased capacities and move beyond these emergency authorities?

c. What specific metrics will CBP report to the CDC Director, or vice-versa, that will determine that these authorities are no longer needed?

9. The U.S. government made representations to the Ninth Circuit and Supreme Court that non-refoulement interviews for individuals in the Migrant Protection Protocols (MPP) are available at any time.

a. Is CBP currently referring individuals returned to Mexico under MPP who request protection at a port of entry for non-refoulement interviews? If not, why not?

b. Are CBP and Border Patrol referring individuals newly being placed in MPP for fear screenings when they express a fear of return to Mexico? If not, why not?

c. How many individuals in MPP have received non-refoulement interviews by nationality? What percentage have passed? Please disaggregate these number by initial MPP enrollees and those subsequently returning to a port of entry.

10. On June 16, the administration cited "severe pandemic conditions" in Mexico as justification to continue postponing MPP court hearings. But the only reason asylum-seekers are in dangerous conditions Mexico is because of US policy forcibly sending them there.

a. Do you thus acknowledge that asylum-seekers are being sent to dangerous conditions in Mexico?

b. When will the MPP court hearings resume? What specific conditions will determine that?

c. How many people in the MPP program have been forced to travel to the U.S.-Mexico border to get their "tear sheets" for their postponed court date?

d. Is CBP tracking how many individuals are missing their court hearings because they cannot travel to the border to obtain their tear sheets, or because of threats of violence, kidnappings, or extortion?

e. How has CBP ensured that individuals in MPP are directly notified of changes to their hearing dates? Are you monitoring what is happening to them in Mexico while they're forced to wait for increasingly long periods of time?

f. Have (or will) CBP officers be instructed to permit individuals in MPP to appear for their hearings even if they do not have a copy of their updated hearing notice?

g. What steps, if any, has CBP taken to make access to counsel available in Immigration Hearing Facilities for individuals in MPP who are unrepresented when MPP restarts?

h. What instructions have been provided to CBP officers regarding information to be provided to individuals with cancelled MPP hearings who appear at the port of entry?

i. How many individuals have been placed into MPP proceedings since the implementation of the Title 42 expulsions? What are their nationalities?

j. Since the issuance of the Title 42 order, what percentage of migrants encountered have been processed into MPP program and through Title 42?

k. How do CBP agents determine which individuals enter the MPP program and which ones are expelled through the Title 42 order?

11. The Guatemalan government suspended the Asylum Cooperative Agreement (ACA) with the United States in mid-March due to concerns about the spread of COVID-19 as a result of these removals. In A February 27 House Appropriations hearing, Acting Commissioner Morgan noted that DHS had removed 1,000 individuals subject to the agreement. Close to 75% of people who've been sent to Guatemala are women and children.[4]

a. How many people have been transferred to Guatemala under the ACA by nationality, month, gender, age, and demographic group?

b. Do you have any idea what's happened to the CBP has transferred to Guatemala under the ACA?

c. When, if at all, do you plan to resume the Guatemala ACA?

d. Have you assessed the capacity of Guatemala, El Salvador, or Honduras' asylum system to receive and duly process hundreds of asylum seekers?

e. What is asylum capacity of each these countries?

f. What is the status of the implementation of the ACAs in Honduras and El Salvador? When does DHS expect to implement these ACAs, and what conditions will need to be met before this occurs?

[4]https://static1.squarespace.com/static/506c8ea1e4b01d9450dd53f5/t/5ec3f0b370656c62ed7daa24/1589899466780/Guatemala+ACA+Report+-+May+2020+-+FINAL.pdf

g. Are you aware of a report by Human Rights Watch that over one hundred individuals deported from the United States to El Salvador since 2013 were murdered there after their deportation?[5]

h. How has CBP determined which migrants to process under the ACA or Title 42?

12. The administration maintains two programs – the Humanitarian Asylum Review Process (HARP) and Prompt Asylum Claim Review (PACR) – that allow Customs and Border Protection to remove asylum-seekers who do not succeed in their asylum claims through the expedited removal process. In a February 27 House Appropriations hearing, you noted that CBP removed 2,500 migrants through PACR and 1,200 through HARP.

a. How many individuals, disaggregated by month and nationality, were subject to removal through these programs since their implementation?

b. Has CBP issued guidance to process migrants through Title 42 instead of PACR and HARP since mid-March? If so, what percentage go through these programs versus Title 42 expulsions?

c. How do CBP agents determine which individuals go through these programs and which ones are expelled through the Title 42 order?

d. How many individuals, and from which countries and demographic groups, have been placed into the Prompt Asylum Claim Review (PACR)?

e. How many Mexican nationals, and from which demographic groups, have been placed into the Humanitarian Asylum Review Process (HARP)?

f. Has anyone been placed into PACR or HARP since the implementation of Title 42 expulsions? If so, how many individuals by program, nationality and demographic group?

g. How much time and how often are individuals in PACR/HARP permitted to speak with an attorney on the telephone?

h. What accommodations do you provide for interpretation during attorney calls?

i. How many individuals have been represented by counsel through these programs and associated screenings?

Due to the change-over in Administration, responses were not received to these questions for the record.

[5] https://www.hrw.org/report/2020/02/05/deported-danger/united-states-deportation-policies-expose-salvadorans-death-and

Post-Hearing Questions for the Record
Submitted to Mark A. Morgan
From Senator Thomas R. Carper

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

June 25, 2020

*****Due to the change-over in Administration, responses were not received to these questions for the record.*****

1. Coronavirus Outbreak in Latin America

Mexico and South and Central America, after evading the initial wave of COVID-19 spikes worldwide, are now becoming hotspots for the virus. For years now, most asylum seekers and migrants to the U.S. come from the Northern Triangle countries of Guatemala, Honduras, and El Salvador. Under agreements concluded by the Trump administration last fall, the United States has begun returning asylum seekers to these countries.

a. What efforts has CBP made to work with authorities in Mexico and Central America to halt activities that may contribute to the international spread of COVID?

b. Who in your organization is in charge of working with the governments of neighboring countries to assist in combating the coronavirus?

c. Please provide detailed information regarding CBP's plans to resume asylum processing as quickly as possible in order to come back into compliance with U.S. obligations under international law.

2. Preparedness for a Second Wave

a. As states begin to open up and commercial travel ramps up, do CBP officers and agents have sufficient PPE and access to testing to ensure their safety? What metrics and guidelines is CBP using to forecast and meet need for PPE?

b. How is CBP working with other agencies, the White House, and the private sector, including airports and airlines, to ensure that commercial travel and trade are kept safe as they continue to reopen?

3. CBP involvement in peaceful protests

During peaceful demonstrations protesting the death of George Floyd in police custody, CBP deployed large detachments of agents, officers, and resources to U.S. cities, including

Washington, D.C., as a "show of force." The agency reportedly also deployed surveillance assets, including drones designed for use in combat.

a. For the record, please provide a detailed description of the training these CBP employees received and a full accounting of the resources deployed to the U.S. interior during the protests.

b. Please also provide a copy of any and all guidelines relating to the wearing of PPE by CBP personnel during these protests.

4. Operational Changes During COVID

Mr. Morgan, a second wave of COVID may come in the fall, and in many states, the first wave has never ended. Despite these circumstances, CBP continues to undertake nonessential or non-time sensitive activities that put the safety and well-being of personnel and surrounding communities at risk. Wall construction has continued in Arizona despite the pandemic, contributing to fears about local outbreaks as workers test positive. And in recent weeks, CBP deployed agents, many without masks, to surveil peaceful protests against police brutality.

a. Does CBP have a comprehensive plan to limit nonessential operations, such as wall construction, to protect officers, agents, and communities against a second wave of coronavirus? If so, please provide a copy of that plan for the record.

b. How, if at all, are nonessential operations defined?

5. Response to Oversight Letter

On January 14th of this year, I sent a letter with 19 of my colleagues with questions and concerns regarding recent reports that, earlier that month, CBP officers detained travelers, including American citizens, at U.S. ports of entry or airports based solely or predominately on their Iranian national origin. CBP must follow our laws and not discriminate against individuals based upon any protected characteristics and that U.S. citizens and other travelers posing no risk to the homeland should not be subjected to unnecessary delay or unjustified intrusions as they transit across our border.

a. Please provide a fulsome response to that letter immediately.

Due to the change-over in Administration, responses were not received to these questions for the record.

Post-Hearing Questions for the Record
Submitted to Mark Morgan
From Senator Kamala Harris

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

June 25, 2020

Due to the change-over in Administration, responses were not received to these questions for the record.

CBP's Involvement in Demonstrations and Protests

On June 5, 2020, I sent a letter to you with 99 of my Senate and House colleagues asking a series of questions about deployment of U.S. Customs and Border Protection (CBP) personnel to demonstrations nationwide. The questions regarding these deployments included what identification CBP personnel are wearing, what equipment they are carrying, what forms of force they are authorized to use, and what surveillance is being conducted at these demonstrations. On June 25, 2020, when you appeared before the Senate Homeland Security and Governmental Affairs Committee 20 days later, I asked you to respond to my letter by the end of the following week, July 3, 2020. To date, my office has yet to receive a response to that letter.

1. **When will my office receive a response to my June 5, 2020 letter?**

    a. **In your response, as we discussed during the June 25 hearing, please include a list of all states to which CBP personnel have been deployed.**

    b. **Additionally, as we also discussed during the June 25 hearing, please provide a list of all individuals and entities, including but not limited to individuals at DHS, the Justice Department, the White House, or any other entity or individual, including federal, state, or local entities or individuals, that requested those deployments.**

The *New York Times* reports that, according to CBP data, DHS collected over 270 hours of surveillance footage in at least 15 different cities in which there were demonstrations and protests. The footage was reportedly stored on a digital network that can be accessed by law enforcement agencies and police departments across the country.

2. **What is DHS doing with this footage?**

3. **Which federal, state, and local agencies have access to the footage?**

4. **Is facial recognition technology or other biometric surveillance technology being used in connection with this footage?**

On July 1, 2020, Acting Homeland Security Secretary Wolf announced the establishment of the DHS Protecting American Communities Task Force (PACT). According to the announcement, this special taskforce will coordinate DHS law enforcement agency assets, including CBP assets, to protect monuments, memorials, statues, and federal facilities. According to Acting Secretary Wolf's statement, Rapid Deployment Teams were expected to be deployed and pre-positioned prior to the July 4, 2020 weekend to "respond to potential threats to facilities and property."

5. **How many CBP personnel have been deployed to monuments, memorials, statues and federal facilities?**

    a. **How many CBP personnel were part of the Rapid Deployment Teams that were deployed prior to the July 4, 2020 weekend?**

6. **Which specific monuments, memorials, statues, and federal facilities have CBP personnel been deployed to?**

7. **Please provide responses to all of the questions my colleagues and I asked you in our June 5 letter on CBP's deployments to the demonstrations and protests regarding the newly announced rapid deployment teams to monuments, memorials, statues, and federal facilities.**

Alleged Misconduct by CBP Personnel

The American people are marching in the streets because law enforcement responsible for keeping us safe have too often disregarded the value of Black lives.

During the June 25 hearing, we discussed troubling data illustrating a culture of impunity for misconduct at CBP. Specifically, we discussed a 2014 analysis conducted by the American Immigration Council of 809 complaints of abuse by Border Patrol agents that occurred between 2009 and 2012, including complaints of hitting someone's head against a rock, stomping on someone's back, touching women inappropriately, and kicking a pregnant woman, causing her to miscarry. According to the analysis, in 97% of cases in which an outcome was reported, no action was taken against the officer. In a 2017 follow-up report by the American Immigration Council on 2,178 complaints from 2012 to 2015, the percentage of cases with reported outcomes where no action was taken against the officer was 96%.

On July 7, 2020, ACLU Foundation of San Diego and Imperial Counties and the ACLU Border Rights Center filed an administrative complaint documenting reports of abuse and mistreatment of individuals in CBP custody based on 100 interviews between March and July 2019. The ACLU's complaint documents verbal abuse, bullying, harassment, and threats of violence.

8. **How is CBP responding to this complaint?**

9. **Do you have plans to reform CBP's complaint and discipline system in light of mounting evidence that your current system is failing to hold CBP personnel responsible for misconduct? If so, how? If not, why not?**

10. **Where should complaints regarding the conduct of CBP personnel deployed in connection with demonstrations, monuments, memorials, statues, or federal facilities be directed?**

11. **As of the date of your response, have you received any complaints in connection with these deployments? If so, please provide the total number of complaints received and descriptions of how they are being resolved.**

12. **Who at CBP is responsible for resolving any such complaint, including the first point of contact through the CBP official ultimately responsible for determining whether CBP personnel are disciplined?**

13. **Please detail the precise process by which any such complaint will be adjudicated.**

    a. **Please provide all Office of Professional Responsibility reports investigating allegations of misconduct at CBP that you referenced during the June 25 hearing.**

    b. **Please provide the stages of discipline for specific types of behavior for CBP personnel that you referenced during the June 25 hearing.**

Expulsion of Children and Families at the Southern Border

On March 20, 2020, the Centers for Disease Control and Prevention (CDC) issued an order exercising its authority under Title 42 of the U.S. Code to provide CBP with the ability to expel individuals without proper documentation coming in from Mexico and Canada. Title 42 grants limited authorities to temporarily suspend the entry of certain categories of persons into the United States "when doing so is required in the interest of the public health." However, this policy denies asylumseekers and unaccompanied children due process and access to our asylum and humanitarian protections.

Since implementation of this policy, CBP has turned away nearly 70,000 people under the CDC's order, including at least 2,175 unaccompanied children according to public reports. In the June 25 hearing, you testified that approximately 2,000 unaccompanied children had been removed under the CDC Title 42 Order.

14. **As of the date of your response, how many unaccompanied children has CBP expelled at the border under the CDC Title 42 Order?**

    a. **How many total children have been expelled with their families?**

    b. **Please provide the number of unaccompanied children that have been reunified with their families. If this information is not available, does CBP plan to implement a policy of tracking unaccompanied children that have been expelled?**

c. **What number and percent of children expelled at the border were tested for COVID-19? What number and percent tested positive for COVID-19?**

d. **What medical care is CBP providing to any individuals who test positive for COVID-19?**

e. **How many children have been sent to Mexico as opposed to their countries of origin? For each child, please provide the basis for the decision to send them to Mexico as opposed to their country of origin.**

f. **What specific measures is CBP undertaking to ensure the safety of children in the countries they are being sent to?**

During the June 25 hearing, you confirmed that "100 percent of [unaccompanied children that were expelled under the CDC Title 42 Order] were screened for trafficking and protection concerns." You further testified that "if [CBP] sees any signs that someone's trafficked, then [that individual would] fall out of [the CDC's] Title 42 [order] and they're going to be then treated under Title 8."

15. **Are unaccompanied children being screened for torture?**
    a. **Please provide the number of unaccompanied children screened for torture since March 2020.**

16. **Are unaccompanied children being screened for trafficking?**
    a. **Please provide the number of unaccompanied children screened for trafficking since March 2020.**

17. **Are unaccompanied children being screened for risk of persecution on the basis of race, religion, nationality, political opinion, or membership in a particular social group?**
    a. **Please provide the number of unaccompanied children screened for persecution since March 2020.**

18. **Please describe the procedures for conducting the screening, including provisions for the protection of privacy, language access, and attorney access. Please include copies of any relevant documents, including forms, relating to the screening.**

19. **Is CBP using Form 93 to screen unaccompanied children subject to Title 42? If not, please provide your rationale for failing to do so.**
    a. **Please provide the number of unaccompanied children for whom CBP has utilized Form 93 since March 2020.**

20. **Who is conducting the screenings?**

21. **Please detail the training received by individuals conducting the screenings, including any training regarding torture, trafficking, and persecution, interviewing survivors of trauma, and forensic and child-friendly interviewing methods.**

22. **What steps, if any, is CBP taking to ensure that children expelled to Mexico who are nationals of Northern Triangle countries are placed in safe and secure conditions with adequate shelter, food, and access to health care?**

23. **Please provide copies of any agreements with Mexico, Guatemala, Honduras, and El Salvador relating to the return to those countries of unaccompanied children who arrived to the United States.**

24. **Since March 20, 2020, how many unaccompanied children that presented at the border have been referred to the Office of Refugee Resettlement (ORR)? Please provide the basis for their referral to ORR.**

25. **In any sectors, has CBP adopted a policy or practice precluding referral of unaccompanied children to ORR? If so, please describe that policy or practice, list the sectors to which they apply, and provide copies of associated guidance or other documentation.**

From March 20 to May 27, about 85 people were interviewed about fear of return to their home countries and only four people passed their interviews, allowing them to pursue their claims for refuge in the U.S. On May 21, the CDC order was extended and will remain in effect indefinitely "until the CDC Director determines that the danger of further introductions of COVID-19 into the United States from covered aliens has ceased to be a serious danger to the public health, and the Order is no longer necessary to protect the public health."

26. **As of the date of your response, how many individuals has CBP expelled at the border under the CDC Title 42 Order?**

    a. **How many presented themselves as a family unit?**

    b. **Please provide a demographic breakdown of those expelled, including (1) single adults; (2) family units; (3) unaccompanied children; and (4) countries of origin.**

    c. **Of those expelled, how many people have been expelled to Mexico?**

    d. **How many have been returned to their home countries?**

27. **As of the date of your response, how many individuals were processed under Title 8?**

28. **As of the date of your response, how many individuals have expressed fear of return to their home countries?**
    a. **As of the date of your response, what number and percent of those individuals were processed under Title 8 and were therefore permitted to seek relief from deportation?**

e. What number and percent of those individuals were expelled under Title 42?

CBP's Use of Humanitarian Funding

On June 11, the Government Accountability Office (GAO) released a legal decision regarding their audit of CBP's use of funding that was provided through the 2019 Emergency Supplemental Appropriations for Humanitarian Assistance and Security at the Southern Border Act. The 2019 Emergency Supplemental appropriated $802 million to CBP specifically for items such as hygiene products, food, diapers, medical supplies, and migrant care. GAO's legal decision found that CBP used some of that money to fund all-terrain vehicles, dirt bikes, and canine programs instead.

29. **When did CBP leadership first become aware that a subset of the funds appropriated in the 2019 Emergency Supplemental for humanitarian purposes had been used for other purposes?**

30. **What steps did CBP take to investigate the issue? Please provide any relevant documentation with your response.**

31. **When did GAO first contact CBP in connection with this issue?**

32. **What mechanisms are in place at CBP to ensure that funds appropriated by Congress are used for their authorized purposes? Has CBP conducted any analysis to determine why those mechanisms failed in this instance? Please provide any relevant documentation with your response.**

33. **What steps is CBP taking to address GAO's findings? Please provide any relevant documentation with your response.**

34. **Based on CBP's analysis, has the agency violated the Anti-Deficiency Act in connection with the 2019 Emergency Supplemental? If so, in what amount?**

35. **In light of GAO's findings, what steps have you taken personally to ensure that funds appropriated by Congress are used for their authorized purposes?**

Migrant Protection Protocols (Remain in Mexico Program)

According to human rights organizations, there have been at least 1,114 reported cases of murder, rape, torture, and kidnapping against people that have been sent to Mexico under the Trump administration's "Remain in Mexico" policy. On February 27, 2020, you testified before members of Congress that individuals enrolled in the Remain in Mexico program are able to inform CBP they are in danger in Mexico and ask to be removed from the program at any time.

36. **What is the process for individuals who are living in fear in Mexico to be removed from the Remain in Mexico program since the CDC order was issued?**

37. **Since March 2020, how many people have reported they were living in fear in Mexico, making them eligible for a screening?**

a. **What type of screening are individuals given? Please provide any relevant documents, including the criteria for being removed from the "Remain in Mexico" program and training that CBP personnel receive.**
b. **What number and percent of these people received a screening?**
c. **Who determines if individuals are eligible for removal from the Remain in Mexico program?**
d. **What number and percent of individuals who expressed fear of living in Mexico were then removed from the "Remain in Mexico" program?**

38. **Has CBP consulted with any public health experts about how to conduct the screenings safely? Please provide the dates of any such consultation, the names of the experts with whom CBP consulted, and any relevant documents setting forth their recommendations.**

Military Deployments to the Border

According to a Pentagon statement, Secretary Mark Esper approved the deployment of 4,000 Department of Defense (DoD) personnel, with approval from DHS, to the Southern border starting October 2020 through September 2021. These DOD personnel will purportedly support CBP in carrying out detention and monitoring, logistics, and transportation.

39. **How many DoD personnel are currently present at the Southern border?**
    a. **How many of those individuals are in California?**
    b. **Please provide the cities and states along the Southern border where DoD personnel are present and the number of DoD personnel.**

40. **How many DoD personnel are currently present at the Northern border?**
    a. **Please provide the cities and states along the Northern border where DoD personnel are present and the number of DoD personnel.**

41. **How many DoD personnel does CBP expect to be deployed between the date of your response and September 2021?**
    a. **How many of those individuals will be deployed to California?**
    b. **Please provide the number of individuals and the cities to which they will be deployed along the Southern border.**

42. **What specific activities will DoD personnel at the Southern border be conducting?**

43. **What type of military equipment and resources does CBP expect to be deployed (e.g., tanks, helicopters, surveillance drones)? Please provide a list of each type of equipment expected to be deployed, the number expected to be deployed, and the locations to which they are expected to be deployed (including the city and state).**

44. **Have DoD personnel received any training on the conduct of civilian law enforcement activities? Please detail what training they received.**

DNA Collection

On January 6, 2020, CBP initiated the implementation of the Department of Justice's directive to collect DNA samples from certain migrants, including individuals in CBP custody. The implementation began through a 90-day pilot program in the Border Sector in Detroit, Michigan and the Eagle Pass Port of Entry in Texas requiring the collection of DNA samples from individuals apprehended and processed by CBP. Reportedly, the biometric data collected from migrants under the new policy will be added to a DNA database maintained by the Federal Bureau of Investigation (FBI) and used by federal and state law enforcement nationwide. On June 29, 2020, CBP announced that U.S. Border Patrol planned to expand DNA collection at the Rio Grande Valley, Laredo, and Del Rio Sectors starting July 1, 2020.

45. **Since January 6, 2020, how many DNA samples has CBP processed and turned over to the FBI?**

46. **Are the DNA samples collected by CBP available to U.S. Immigration and Customs Enforcement or any other law enforcement agency for immigration enforcement purposes?**
    a. **If so, please provide the number of samples that are available to ICE.**

International Students/Scholars

On July 6, 2020, the administration proposed a new policy for immigrant students in the Student and Exchange Visitor Program (SEVP) seeking to continue their education this coming fall 2020 semester. According to guidance published by U.S. Immigration and Customs Enforcement (ICE), CBP has been directed to not allow students enrolled in schools and/or programs that are fully online for the fall semester to enter the United States.

47. **Was CBP involved in discussions regarding the policy on the Student and Exchange Visitor Program (SEVP)? Please provide the names of CBP officials who participated in any such discussions, the names and agencies of other participants in each discussion, and the dates of the discussions.**

48. **Please provide the guidance and training being provided to CBP personnel to enforce this policy.**

49. **Please provide the date on which CBP plans to implement this policy.**

50. **Does CBP plan to hold students in custody for any reason in connection with this policy? If so, please provide the basis for any such detention and any relevant guidance provided to CBP personnel, including provisions for access to counsel.**

51. **What, if any, assessment will CBP conduct regarding whether arriving students are permitted to return home after having arrived in the United States?**

In border communities, it is common for students—including U.S. citizen students—to cross the border to attend both K-12 schools and universities in the U.S. for the day and then return home in the evening.

52. How will CBP be treating students in this situation?

53. Since March 2020, what number and percent of U.S. citizens stated that they crossed the border for "educational" reasons?

Border Crossing for Medical Care
According to the California Hospital Association, the state has seen an increase in U.S. citizens crossing the border to receive medical care for COVID-19 in the United States.

54. How many U.S. citizens have entered the United States at the Southern border since the March 21st border closure to non-essential travel?

55. What number and percent of U.S. citizens stated that they crossed the border for "medical" reasons?

CBP User Fee Changes
On July 1, 2020, CBP implemented changes to the User Fee Facility (UFF) program for airports that rely on CBP's customs services. The new policy would change the current flat rate fees to a full cost recovery approach. The amount to be collected would then be based on the salary with benefits of the CBP Officer assigned at the facility. An additional charge for administrative overhead costs will be collected to reimburse CBP for compensation and/or expenses of CBP Officers performing reimbursable services. This policy change in the UFF program would place a significant financial burden on at least 58 airports around the country relying on CBP's customs services, including seven in my state of California. Some airports have reported seeing an increase of 100.3% in these user fees, whose operations and revenue stream continue to be impacted by the COVID-19 pandemic and will likely be for the foreseeable future.

56. Did CBP conduct any analysis on the impact this policy change would have on airports' ability to continue to operate and serve travelers? If so, please share this analysis.

57. Please provide the rationale for the immediate need for implementing this policy change.

58. Given the heightened concerns expressed by airports, does CBP have any plans to transition airports back to a fee structure that enables them to serve international destinations once flight enplanements increase?
   a. Please explain the impact of administering this program on CBP's resources.
   b. What other methods of maintaining services at airports did CBP explore before implementing this program?

Agricultural Quarantine Inspections
CBP and the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service jointly administer the Agricultural Quarantine Inspection (AQI). The AQI is largely

funded by fees on international passengers and commercial vessels, trucks, aircraft, and railcars at U.S. Ports of Entry.

59. What effect has the global pandemic and consequent economic downturn had on AQI fees collected by CBP?

60. How are CBP and USDA ensuring AQI inspections continue uninterrupted during this pandemic?

Due to the change-over in Administration, responses were not received to these questions for the record.

Post-Hearing Questions for the Record
Submitted to Mark A. Morgan
From Senator Kyrsten Sinema

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

June 25, 2020

Question#:	1
Topic:	Title 42, TVPRA, and CAT
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: I understand the need to adapt policies and procedures to protect the public health while also supporting strong border security. However, the sheer volume of overlapping restrictions and policies regarding asylum at the border, including Title 42 authority regarding the ongoing coronavirus pandemic, seems to have effectively closed our southwest border to those who have a legal right to seek asylum. Using this expansive Title 42 authority, CBP is quickly expelling almost every person who crosses the border, and there are reports that CBP is doing so with very little consideration of safeguards such as the Trafficking Victims Protection Reauthorization Act (TVPRA) and the Convention Against Torture (CAT).

Does policy guidance provided by CBP to agents in the field address the interaction of Title 42 authority with the Trafficking Victims Protection Reauthorization Act (TVPRA), Convention Against Torture (CAT), and other potential asylum claims made by migrants CBP?

Response: The Centers for Disease Control and Prevention's (CDC) March 20, 2020 Order Suspending Introduction Of Persons From A Country Where A Communicable Disease Exists under Section 362 applies to "covered aliens," defined as aliens traveling from Canada or Mexico (regardless of their country of origin) who would otherwise be introduced into a congregate setting in a land or coastal port of entry (POE) or a Border Patrol (BP) station operated by the U.S. Department of Homeland Security (DHS) at or near the United States border with Canada or Mexico, subject to exceptions. The CDC Order does not apply to: U.S. citizens, lawful permanent residents, and their spouses and children; members of the armed forces, and associated personnel, and their spouses and children; persons from foreign countries who hold valid travel documents and are not otherwise subject to travel restrictions and arrive at a POE or otherwise authorized location; or persons from foreign countries in the visa waiver program who are not otherwise subject to travel restrictions and arrive at a POE or other authorized location. Additionally, the CDC Order does not apply to persons whom customs officers determine, with approval from a supervisor, should be excepted based on the totality of circumstances, including significant law enforcement, officer and public safety, humanitarian, or

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public health interests. In addition, persons will not be sent to countries where they are more likely than not to be tortured.

The Order does not suspend our commitment or legal obligation to identify victims of trafficking. Agents who suspect that an individual is trafficked will conduct further investigation and will refer the case to U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI), as appropriate.

Question: Can you provide the committee any and all policy and implementation documents issued by DHS that outline the use of Title 42 authority to expel migrants and how Title 42 procedures interact with traditional asylum claims and the withholding of removal, including claims made under the Trafficking Victims Protection Reauthorization Act (TVPRA) or Convention Against Torture (CAT).

Response: DHS does not have additional information, including any law enforcement sensitive operational information, at this time due to law enforcement sensitivities and ongoing litigation.

Question#:	2
Topic:	Public Health Data
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: You recently said in the press that the immigration restrictions in use today, including Title 42 authority, are directly related to public health and not to enforcement. How will CBP examine public health data and trends to determine when it is safe to make changes and recommend an easing of restrictions currently in place at the border?

Response: The CDC determined that the introduction and spread of COVID-19 in U.S. Customs and Border Protection (CBP) stations and temporary holding facilities presents a danger to aliens subject to the Order, our frontline agents and officers, doctors and nurses, and the American public. CBP will defer to the CDC on their continuance of the order under Title 42.

Question#:	3
Topic:	Title 42 Penalties
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: Will expulsion orders made under Title 42 authority have the same consequence as a traditional removal order would have? Does expulsion under Title 42 trigger any of the same penalties?

Response: No, DHS is not operating under Title 8 in the exercise of the CDC Order.

Question#:	4
Topic:	Closest Port of Entry
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: The extended closure of MPP courts since March and the most recent joint DHS/DOJ announcement to suspend all hearings and in-person document services through July 17th has caused massive confusion among migrants awaiting their court hearings in Mexico. While I understand and agree with the need to limit in-person court proceedings during this public health crisis, it is critical to lay out a clear plan to resume operations safely and keep lines of communication open to those impacted by these changes.

I remain concerned about the inconsistent and confusing communication from CBP about these extended suspensions and new protocols for migrants. For several months, migrants returned to Nogales under MPP were forced to travel to El Paso to get a new tear sheet with a new court date. This practice seriously increased the risk of infection and virus spread for migrants and DHS officials across Mexico, Arizona, and Texas. Furthermore, all members of a family had to make this dangerous trip to El Paso together when one family member representing the family unit should have been enough to receive new court information.

Have DHS and DOJ/EOIR discussed the possibility of individuals receiving updated MPP hearing information at the Port of Entry closest to where they are sheltered in Mexico?

Response: As you mentioned, DHS and U.S. Department of Justice (DOJ) suspended in-person document service on June 16, 2020 due to concern about individuals subject to the Migrant Protection Protocols (MPP) traveling through areas with high incidence rates of COVID-19 in Mexico in order to reach the designated POE and receive their updated court documents. DHS and DOJ remain committed to resuming removal hearings for aliens subject to MPP as expeditiously as possible.

Since hearings were paused for individuals in MPP in March 2020, DHS and DOJ have communicated in press releases and with international organizations that individuals in MPP should check their case statuses by calling the Executive Office for Immigration Review's (EOIR) Automated Case Information Hotline or visiting its Automated Case Information Portal.

To lend greater certainty in a fluid COVID-19 environment, DHS and DOJ publicly announced on July 17 the criteria that will be used to determine when it safe to resume MPP hearings. Once the criteria are met, DHS and DOJ will provide public notification at least 15 calendar days prior to resumption of the hearings with location-specific details. When the hearings begin, DHS will adhere to CDC social-distancing and sanitization standards.

At least fifteen days prior to the resumption of immigration court hearings for aliens subject to MPP, DHS and DOJ expect to provide public notification offering location-specific directions

Question#:	4
Topic:	Closest Port of Entry
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

for the resumption. Such instructions will address issues such as how individuals will learn of their new court dates.

Question: What is needed by CBP and/or the Executive Office for Immigration Review (EOIR) to allow migrants currently sheltered in Nogales, Sonora, to appear at the Nogales Port of Entry to receive updated information for future MPP court dates should hearings be further delayed beyond July 17th?

Response: DHS encourages individuals in MPP to check their case statuses by calling EOIR's Automated Case Information Hotline or visiting its Automated Case Information Portal.

Question: Will you raise the issue of allowing migrants, who were returned to Mexico under MPP, to get updated court information at the closest port of entry to where they are sheltered during any ongoing discussions with EOIR regarding the reopening of MPP courts and report back to me on any challenges?

Response: Immigration court hearings for aliens in MPP will resume once conditions in the United States and Mexico are such that all criteria for resuming removal hearings for individuals in MPP are met. When removal hearings for aliens in MPP resume, public notification expected to be issued at least 15 days in advance of the resumption will offer location-specific directions for the resumption. Such instructions will address issues such as how individuals will learn of their new court dates and matters involving family units. Individuals can always check case status by calling EOIR's Automated Case Information Hotline or visiting its Automated Case Information Portal.

Question#:	5
Topic:	One Family Member
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: Can CBP and EOIR agree to allow one family member representing a family unit to appear at a POE to receive new court information to limit travel and risk of infection if additional delays occur in MPP hearings? If not, what are the challenges which prevent this from occurring?

Response: Immigration court hearings for aliens subject to MPP will resume once conditions in the United States and Mexico are such that all criteria for resuming removal hearings for individuals in MPP are met. When removal hearings for aliens subject to MPP resume, public notification issued at least 15 days in advance of the resumption will offer location-specific directions for the resumption. Such instructions will address issues such as how individuals will learn of their new court dates. Individuals can always check case status by calling EOIR's Automated Case Information Hotline or visiting its Automated Case Information Portal.

Question#:	6
Topic:	Alleviate Confusion
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: There are several different groups of migrants currently sheltering in Mexico, waiting for their chance to appear at a POE and make a legal asylum claim. These individuals include those whose MPP dates were suspended, those who were expelled under Title 42, and those who are still on a metering list, waiting for their first opportunity to present themselves. How does CBP plan to alleviate confusion and make clear communication to these groups once operations begin to normalize to ensure maximum public health guidance is followed?

Response: For aliens subject to MPP, public notice likely issued at least 15 days prior to the resumption of immigration court hearings will provide location-specific guidance on how removal hearings will be resumed in a safe and coordinated manner consistent with CDC social-distancing guidelines.

DHS and DOJ remain committed to resuming removal hearings for aliens subject to MPP as expeditiously as possible. To be fully transparent, DHS and DOJ publicly announced on July 17 the criteria that will be used to determine when it safe to resume MPP hearings. Once the criteria are met, DHS and DOJ will provide public notification at least 15 calendar days prior to resumption of the hearings with location-specific details. When the hearings begin, DHS will adhere to CDC social-distancing and sanitization standards.

CBP will defer to the CDC on their continuance of operation under Title 42. Once CDC determines the use of title 42 procedures are no longer necessary, CBP will begin to resume normal processing procedures. CBP anticipates the cross-border volumes will increase and are prepared. When necessary, CBP may implement queue-management procedures to ensure the health, welfare, and safety of all applicants for admission and CBP Officers.

Question#:	7
Topic:	Supporting Programs
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: In June 2019, I signed onto a bipartisan letter calling for the implementation of Operation Safe Return, a first step in trying to address the crisis at our southwest border and create a pilot program using existing law and authorities to rapidly, accurately, and fairly determine and process credible fear claims. A lot has changed since that letter was sent including, but not limited to, new authorities used by the administration to curb asylum claims and the global pandemic we are still facing.

The rollout of expedited asylum processes such as MPP, Prompt Asylum Claim Review (PACR), and Humanitarian Asylum Review Process (HARP) at Arizona Ports of Entry in Nogales and San Luis was chaotic and inconsistent even before we faced a public health crisis on both sides of the U.S.-Mexico border. My staff visited both El Paso, Nogales and Yuma/San Luis earlier this year to observe operations on the ground, better understand the interplay between the various expedited programs, and determine what best practices were carried over from programs started in El Paso and what operational changes were needed in Arizona.

What factors were reviewed to determine if a Port of Entry (POE) or Border Patrol Sector could support one or more of these programs in operation?

Response: Practical, physical, and legal limitations such as extended transport times, physical space limitations, proximity to DOJ EOIR facilities, proximity to soft-sided BP facilities, and restrictions on the movement of certain aliens based on nationality, heavily influenced the ability to expand these programs to all amenable populations in all locations.

Question: What specific factors made Arizona POEs more or less likely to be able to full implement these programs?

Response: There were practical, physical, and legal limitations that impacted the ability to implement these programs in Arizona. These factors included extended transport times, physical space limitations, proximity to DOJ EOIR facilities, proximity to soft-sided BP facilities, and restrictions on the movement of certain aliens based on nationality.

Question: Do you believe facilities in Arizona - both at Ports of Entry and Border Patrol stations - are equipped to ensure public health best practices and follow CDC guidance in order to operate expedited asylum programs such as PACR and HARP?

Response: Prior to case disposition, CBP conducts a health intake interview and medical assessments on people in custody, with referral to appropriate medical service when necessary, as directed by the Enhanced Medical Directive (CBP Directive 2210-004). Additionally, CBP

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protects aliens, employees, and the traveling public in CBP facilities by adhering to CDC guidelines and applicable provisions of CBP's National Standard on Transportation, Escort, Detention, and Search (October 2015) (TEDS).

Question: What factors does CBP consider critical in making this determination and has a full review been done? If so, can you share the results of this review with my office?

Response: In addition to the above-referenced guidance documents, CBP follows the latest guidance from CBP's Senior Medical Advisor, in conjunction with the CDC. CBP's Senior Medical Advisor and Occupational Safety and Health Division directly support management officials in making determinations on the correct procedures and protocols for CBP's ports and stations.

The availability of wraparound services, such as food and medical contracts and shower and laundry services are also factors that are considered. Finally, the operational capabilities of partner agencies are also taken into account.

Question#:	8
Topic:	Access to Counsel
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: How was the ability of CBP to offer legal orientation to migrants taken into account when making these decisions?

Response: The decision to implement additional programs to expedite asylum or credible fear processing, while also providing the procedural protections required by the Immigration and Nationality Act and implementing regulations, for aliens arriving at the Southwest Border took into account the facilities' capabilities to provide an orientation to aliens who would be subject to these programs. Aliens processed for Expedited Removal with Credible Fear are provided with a Form M-444, Information About Credible Fear Interview.

Additionally, all aliens (whether or not they are asylum-seekers) who are placed in a removal proceeding before an immigration judge under 8 U.S.C. § 1229a based on the issuance of a Notice to Appear are provided with a list of free legal service providers, which is maintained by the EOIR. Aliens processed under MPP and appearing at an immigration hearing facility (IHF) are able to view "Know Your Rights" videos in the waiting rooms, and DHS permits in-person "Know Your Rights" presentations to be provided by outside parties at the IHFs, consistent with those parties' resources.

Question: How will the new factor of following CDC guidance and promoting social distancing impact the operation of these programs and access to legal counsel?

Response: CBP will continue to facilitate aliens' access to counsel while adhering to CDC guidelines regarding social-distancing standards.

Question: Specifically, what considerations were given to physical space in POE facilities and Border Patrol stations to allow for migrants to make calls to legal aid groups, receive calls in return, meet with legal representation within CBP facilities, and have legal representation present while doing credible fear interviews, whether in person or telephonically?

Response: Aliens in CBP custody are afforded reasonable telephone access. Considerations took into account the existing capabilities to provide legal orientation to aliens who would be subject to the PACR/HARP programs. In the locations where the PACR/HARP programs have been implemented, CBP has constructed rooms with private telephones, which afford aliens private telephonic access to legal counsel. There are no policy restrictions on how long individuals can use the phones for consultation.

Question#:	9
Topic:	Challenges Identified
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: Moving forward, what are the major challenges identified during the pilots of these programs that will need to be addressed before fully implemented any of these programs across the southwest border?

Response: CBP BP stations and ports of entry were constructed as short-term holding facilities. The COVID-19 pandemic has disrupted operations for all agencies within the immigration continuum. As stated previously, the health and safety of CBP personnel, aliens in custody, and the public remain at the forefront of all operational decisions. Although CBP is responsible for the initial apprehension, intake, and processing of aliens that enter illegally, the operational capabilities of partner agencies due to the pandemic will have a direct impact on CBP operations.

Question#:	10
Topic:	Nogales Construction
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: Will the new proposed renovation, operation, and maintenance of a new central processing center at the Nogales Border Patrol Station be used to further expand programs such as MPP, PACR and HARP to the Nogales area with this increased detention capacity?

Response: U.S. Border Patrol constantly analyzes the operational capabilities of our facilities. As is the case with other centralized processing centers, the day-to-day operations in Nogales will be dictated by the scale of illegal activity that occurs in the geographic area.

Question: What is the timeline for construction of this new facility in Nogales, and will court facilities be part of this expansion, even if it is just space for court operations to take place by phone?

Response: The Design/Build contract duration is estimated at 14 - 16 months after award, which is anticipated in the third quarter of Fiscal Year (FY) 2021. The current Statement of Work provides space for phone booths, which would be available for use by aliens in CBP custody to engage with their legal representation.

Question#:	11
Topic:	Improve Wait Times
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: As of June 16th, DHS extended the restrictions on nonessential travel at land border crossings with Mexico till at least July 21. My team has received extensive complaints about long wait times at the San Luis and Nogales POEs, and I asked Acting Secretary Wolf for a direct review of these issues. We have also heard from local CBP leaders about concerns over too many U.S. citizens and residents taking nonessential cross-border trips. I understand and support the need to protect our communities and port officers, but long lines also present some health risks and many individuals must cross the border each day for economic purposes.

What additional support can CBP provide Arizona ports to improve wait times while also protecting the health of our communities?

Response: CBP will continue to take every necessary precaution in order to keep our employees, their families, and the American people safe from the spread of COVID-19. Southwest border communities have been disparately affected by COVID-19, and CBP's workforce has also been affected. CBP has implemented a proactive, multi-layered approach to minimize exposure to COVID-19 as we fulfill CBP's critical national security mission. Through continuous surveys of the traveling public, CBP leadership in Arizona has assessed peak hours of legitimate traffic flow and continues to adapt measures that increase effective passenger processing. CBP will continue to allocate resources in a manner that ensures an appropriate balance of facilitation and enforcement is maintained to meet all mission requirements for which CBP is responsible. CBP continues to operate with protocols in place to prevent the spread of COVID-19, to include social distancing and proper use of Personal Protective Equipment.

Question: Is it possible, for example, to open up additional lanes or areas for pedestrians to cross or allow more individuals, such as cross-border workers, to access Sentri lanes?

Response: CBP continues to see an increase in daily traffic that is expected to grow as businesses begin to reopen on both sides of the border. CBP continues to facilitate lawful trade and essential travel and enhance enforcement in other important mission areas. CBP continues to monitor traffic and open up additional lanes, as needed, during peak traffic hours. In order to reduce the spread of COVID-19, however, travelers must know and understand the risks of cross-border travel. As this adjustment unfolds, CBP will continue coordinating efforts with the CDC and local public health officials to ensure consistent messaging is provided to travelers about the importance of adhering to the health guidelines. Our Tucson Field Office has conducted continuous surveys of the traveling public and found that the vast majority of cross-border travel by U.S. citizens and Lawful Permanent Residents during non-peak hours is for purposes that are not deemed essential. The vast majority of travel during peak traffic hours has been identified as essential as most of those travelers have been identified as cross-border

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workers and school children. The Tucson Field Office continues to monitor hourly wait times, and we will increase both vehicle and pedestrian lanes as needed at all Arizona border crossings during peak essential-travel times of legitimate traffic flow.

Question#:	12
Topic:	Resumptions of International Travel
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: While we are most focused on the U.S.-Mexico border restrictions in Arizona, many other travel restrictions were imposed by the administration in response to the public health crisis. In March, when the administration announced travel restrictions for the Schengen area, United Kingdom and Ireland, there was a lot of confusion about how this would impact Americans. We all saw the images of thousands of individuals pouring into airports with no testing, no social distancing and no contact tracing. I hope we can agree that we don't want to see similar circumstances when restrictions begin to lift and international air travel resumes.

What are CBP's plans to prepare for their role in the resumption of international travel to ensure staff and travelers are safe?

What work is being done in cooperation with TSA or the airlines to put appropriate safeguards in place?

Response: On July 2, 2020, a whole of government action plan, *Runway to Recovery,* was published, which can be found here:
https://www.transportation.gov/sites/dot.gov/files/202007/Runway_to_Recovery_07022020.pdf

Within that action plan, there are recommendations for how airlines and airports can work locally with CBP to support and promote the safety of the traveling public and CBP employees. Additionally, CBP is implementing appropriate risk-mitigation measures, including segregation of flight crews and passengers. These measures should be implemented to the maximum extent practicable within the Federal Inspection Station (FIS) in order to minimize risk to arriving passengers, as well as to CBP officers. Streamlining passenger flows in and outside the FIS allows for greater use of social distancing, greater public-health protections for passengers and CBP officers, and greater travel satisfaction for passengers.

Additional recommendations within the action plan include the following measures:

- Separating passengers within the queuing space to adhere to social distancing practices and limiting the number of passengers allowed into the FIS at any one time to the extent practicable.
- Considering the expansion of existing facial biometrics capabilities for primary processing to limit the need to handle documents and thereby maintain separation between the traveling public and officers.
- Considering the expansion of ways to verify traveler documentation while maintaining maximum social distancing.

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- Streamlining local processes and passenger flows for the rescreening of passengers with connecting flights.
- Developing any necessary infrastructure changes to implement modified egress, enable installation of Plexiglas barriers at locations not currently available, and eliminate any potential choke points upon exiting the FIS.
- Encouraging participation in Global Entry for crew and passengers, which will allow people to leverage this expedited inspection and clearance program, reducing lines and congregation in the FIS.
- Defaulting to verbal Customs declarations where appropriate.

Question#:	13
Topic:	Technology Improvement
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Kyrsten Sinema
Committee:	HOMELAND SECURITY (SENATE)

Question: Monthly reports from CBP indicate international criminal organizations, such as drug cartels, are exploiting gaps in our ports of entry to move large amounts of illegal narcotics, Opioids, and their precursors across our southern border. CBP does an extraordinary job locating and seizing the contraband but these efforts only yield a percentage of the total amounts that are smuggled across annually.

What technology improvements does CBP need to implement to improve its effectiveness at combatting the large amount of narcotics and opioids that pour through our ports of entry?

Response: Technology investments are a critical component of our comprehensive approach to border security. CBP is modernizing its Non-Intrusive Inspection (NII) scanning operations by moving towards scanning vehicles pre- or post-primary inspection. At land ports of entry where this operational concept can be employed, CBP stands to decrease the average NII Imaging processing time by greater than 50 percent (from 8 minutes to 4 minutes or less), which will allow for increased scanning of vehicles, thereby increasing the probability of interdiction of narcotics.

Since 2018, CBP has significantly increased the deployment of chemical handheld analyzer capabilities and presumptive testing equipment across all environments.

Question: Is CBP working to Implement 100 percent Non-Intrusive Inspection for all ports on the southern border? If yes, what is the timeline for this effort?

Response: CBP is working to significantly increase NII Scanning Capacity at land ports of entry on the Southwest border. To the extent possible, CBP is looking to increase vehicle scanning to 100% at locations where drive-through operations are deemed feasible. The feasibility for each location is taking into account the footprint of the operation, existing and planned port infrastructure, and interoperability with other CBP processing tools. In addition to personnel, these elements are collectively important in order for CBP to modernize POEs and transform how we do business. Congress's investment in NII, specifically the FY 2019 Procurement Construction and Improvement (PCI) appropriations, is projected to greatly increase these scanning rates post full deployment of the technology.

CBP also plans to expand its Drive-Through NII systems, which will address integration requirements based on the results of ongoing Drive-Through NII technology demonstrations and acquisition approvals for the NII Integration Program.

Post-Hearing Questions for the Record
Submitted to Mark A. Morgan
From Senator Jacky Rosen

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

June 25, 2020

Question#:	14
Topic:	UAC Screening
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

Question: During the Committee hearing on June 25, 2020, you testified that ALL unaccompanied children crossing the U.S. southern border were being screened for trafficking and other protection concerns, consistent with the statutory safeguards established for unaccompanied children under the Trafficking Victims Protection Reauthorization Act (TVPRA), even under the Title 42 public health restrictions issued by the Centers for Disease Control and Prevention (CDC).

Please clarify CBP's position on the screening requirements for unaccompanied children that cross U.S. borders under Title 42.

Response: The Administration's COVID-19 policies comport with both domestic-law obligations under federal statutes and international obligations under the 1951 Refugee Convention (as incorporated in the 1967 Protocol Relating to the Status of Refugees) and the Convention Against Torture. The policies ensure the protection of the public's health and the national security of the United States as well as the protection of aliens illegally seeking to enter the United States during the present health emergency.

All aliens whom CBP encounters, including minors, may be subject to the CDC March 20, 2020 Order Suspending Introduction Of Persons From A Country Where A Communicable Disease Exists, 85 Fed. Reg. 16567 (Mar. 24, 2020) and its amendments.

When minors who are subject to the CDC Order are encountered without adult family members, CBP works closely with all appropriate federal and foreign partners to ensure the minors, regardless of nationality, are safely and expeditiously returned to their country of last transit or their country of citizenship to reunite them with their families as quickly and safely as possible.

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If an alien in CBP custody claims that he or she has a fear of returning to the country to which the U.S. Government intends to expel them, that alien is sent to U.S. Citizenship and Immigration Services for a Convention Against Torture screening interview.

In other cases the CDC Order does not apply to persons whom, during an initial encounter, CBP officers determine, with approval from a supervisor, should be excepted based on the totality of the circumstances, including consideration of law enforcement, officer and public safety, humanitarian factors, and public health interests.

Minors excepted from the order who are encountered without a parent or legal guardian will be transferred to U.S. Department of Health and Human Services' (HHS) Office of Refugee Resettlement (ORR) custody and will receive amenities and services consistent with applicable law and policy.

Question: Under Title 42 and the TVPRA, are CBP and/or other federal agencies responsible for screening unaccompanied children to determine whether they are victims of trafficking?

Response: The application of Title 42 does not suspend CBP's commitment or legal obligation to identify victims of human trafficking. Agents and officers who suspect that an individual is trafficked will conduct further investigation and will refer the case to ICE HSI, as appropriate.

Question: Does the law require that these screenings take place? If so, is CBP conducting these screenings?

Response: Yes, CBP is conducting the screenings. The CDC Order does not suspend CBP's commitment to identify victims of human trafficking. Agents who suspect that an individual is trafficked will conduct further investigation and will refer the case to HSI, as appropriate.

Question: Has CBP taken any actions inconsistent with TVPRA since CDC implemented Title 42 public health restrictions due to the COVID-19 pandemic?

Response: The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA) provides specific processes governing the custody and removal of unaccompanied alien children (UACs), a legal status defined in terms of an alien minor's immigration status under Title 8. The CDC has prohibited the introduction of aliens under section 362 of the Public Health Service (PHS) Act for public health reasons without regard to the age of the alien (or the persons accompanying him), and actions to enforce the CDC prohibition necessarily involve the prohibition on entering or return of an alien outside of Title 8's procedures. Section 362 of the PHS Act operates independently from Title 8 and the TVPRA UAC processing provisions with respect to minors and other aliens is not applicable. For clarification, CBP officer and agents

Question#:	14
Topic:	UAC Screening
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

will ensure that subjects encountered during the PHS Act that are amendable to Title 8, are processed accordingly.

Question#:	15
Topic:	Screening Training
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

Question: If CBP officers are screening unaccompanied children at the U.S. southern border, what training does CBP provide to its officers on identifying and interviewing potential victims of trafficking?

Response: CBP provides annual training on the inspection of UAC, to include screening for victims of trafficking. The basic-training academies provide training in accordance with the TEDS policy. The training curriculum on processing subjects identifies the rights and protocols in place for identification. Adults and children claiming fear or suspected of victimization are referred for further interview or investigation by the relevant agency/authority.

The Border Patrol Academy provides all trainees with an introduction to processing UAC during the e3 processing section of the curriculum. Part of this training covers credible-fear questions and trafficking questions in compliance with the CBP-93.

Question#:	16
Topic:	Where Screened
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

Question: Where are unaccompanied children screened to determine whether they are victims of trafficking?

Response: All UACs processed under Title 8 are screened in CBP facilities as part of the inspection process.

Question: What arrangements do CBP and/or other federal agencies make for privacy, language access, and the timing on screenings after the point of apprehension?

Response: Under the DHS Language Access Plan, CBP is required to inspect applicants for admission in the preferred language the alien understands, when feasible. CBP agents are trained in the Spanish language to ensure communication with aliens during processing. Further, CBP contracts translation services for other languages.

The screening of a UAC under the TVPRA is conducted as part of the processing of the case. As per CBP policy, unaccompanied alien children are prioritized for processing where TVPRA screening occurs. The processing of the case for the inadmissible applicant for admission, including an UAC, is conducted in a private area, when operationally feasible. As per the TEDS policy, unaccompanied alien children are held and transported apart from unrelated adults.

Question#:	17
Topic:	Screening Times
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

Question: Please provide the times and dates, including the duration from start to completion, of the screenings of unaccompanied children apprehended at the U.S. southern border conducted since the CDC implemented Title 42 public health restrictions due to the COVID-19 pandemic.

Response: Between 3/20/20 (USBP start date) and 3/27/20 (OFO start date) through June 25th, 2020, there were 431 UAC who were processed under Title 8 authorities and 2,662 single minors processed under Title 42 authorities.

Question#:	18
Topic:	Screening Forms
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

Question: Please provide a copy of any forms and/or interview questions used to screen unaccompanied children apprehended at the U.S. southern border since CDC implemented Title 42 public health restrictions due to the COVID-19 pandemic.

Response: CBP may, on a case-by-case basis, such as when return to the home country is not possible or an agent suspects trafficking or sees signs of illness, except any alien from the CDC order and process the alien pursuant to Title 8. For those cases, processing of UACs under Title 8 is conducted consistent with existing policies and procedures. Several named federal defendants, including the Acting Secretary, have been sued before the United States District Court for the District of Columbia. Due to ongoing litigation, DHS cannot comment further at this time on this issue.

Question#:	19
Topic:	Guidelines Provided
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

Question: Please provide any guidelines provided to CBP personnel concerning screening of unaccompanied children apprehended at the U.S. southern border since CDC implemented Title 42 public health restrictions due to the COVID-19 pandemic.

Response: CBP may, on a case-by-case basis, such as when return to the home country is not possible or an agent suspects trafficking or sees signs of illness, except any alien from the CDC order and process the alien under Title 8. In those cases, processing of UACs under Title 8 is conducted consistent with existing policies and procedures. Several named federal defendants, including the Acting Secretary, have been sued before the United States District Court for the District of Columbia. Due to ongoing litigation, DHS cannot comment further at this time on this issue.

Question#:	20
Topic:	UACs Apprehended
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

Question: What is the exact number of unaccompanied children apprehended at the U.S. southern border that CBP screened under Title 42 and TVPRA since the CDC implemented Title 42 public health restrictions due to the COVID-19 pandemic?

Response: From March 21, 2020 – June 25, 2020, CBP encountered 3,093 UACs and Single Minors. There were 431 UAC who were processed under Title 8 authorities and 2,662 single minors processed under Title 42 authorities.

Question: How many were identified as victims of trafficking?

Response: Please reference all publicly available Title 42 data on our website located here: https://www.cbp.gov/newsroom/stats/cbp-enforcement-statistics/title-8-and-title-42-statistics

Question: How many were referred to the Office of Refugee Resettlement, as required by the TVPRA?

Response: According to CBP systems of records, there were 263 UAC who were from a country other than Mexico. There were 168 UAC who were from Mexico. The majority of those from Mexico may have been repatriated as they are not required to be transferred to HHS/ORR.

Question#:	21
Topic:	Title 42 Exception
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Jacky Rosen
Committee:	HOMELAND SECURITY (SENATE)

Question: Since CDC implemented Title 42 public health restrictions, under what circumstances has CBP made an exception to Title 42 and conducted formal screenings of unaccompanied children required by TVPRA and other applicable law? In how many instances since DCD implemented its restructions has CBP made an exception to Title 42 in order to comply with TVPRA and other applicable law?

Response: These instances are handled on a case-by-case basis. CBP may, on a case-by-case basis, such as when return to the home country is not possible or an agent suspects trafficking or sees signs of illness, except any alien from the CDC order. Minors excepted from the CDC order who are encountered without a parent or legal guardian will be processed as unaccompanied alien children under Title 8 and may be transferred to HHS ORR. During any time spent in CBP facilities, minors processed under either Title 42 or Title 8 will receive amenities and services consistent with applicable law and policy.

From March 21, 2020 – June 25, 2020, CBP processed 431 UAC under Title 8 authorities.

Post-Hearing Questions for the Record
Submitted to Mark A. Morgan
From Senator Josh Hawley

"CBP Oversight: Examining the Evolving Challenges Facing the Agency"

June 25, 2020

Question#:	22
Topic:	Section 307 Enforcement
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

Question: As you know, Section 307 of the Tariff Act of 1930 prohibits the importation of goods into the United States that are produced by means of forced labor. Under the law, CBP has the power to seize and require forfeiture of such property that is deemed tainted by forced labor. It is my view that the Tariff Act has significant potential as a tool reduce the available market for tainted goods and the corresponding economic incentive to traffic human labor if enforced to the fullest extent.

In your view, is Section 307 of the Tariff Act currently being enforced to the fullest extent as it relates to halting the importation of goods tainted with forced labor? Why or not?

Response: CBP is committed to enforcing 19 U.S.C. 1307 to the fullest extent possible. CBP and DHS have prioritized working to prohibit the importation of goods made with forced labor in several agency strategies. On July 15, 2020, CBP issued its largest withhold release order (WRO) to date, in terms of the value of potential detentions against Malaysia Top Glove Sdn Bhd and TG Medical Sdn Bdh for disposable gloves. This follows the detention of 13 tons of hair products from the Xinjiang region in China on July 1, 2020. CBP followed up on this enforcement action by issuing five more WROs on September 14, 2020 on products originating from the Xinjiang region in China.

However, CBP faces several challenges in its enforcement of 19 USC 1307:

- Information about forced-labor conditions and supply chains in foreign countries is difficult to obtain given CBP's limited presence abroad. Information gathered by the U.S. Departments of State and Labor has been invaluable, but it does not always include sufficiently specific information regarding the indicators of forced labor or how goods make their way to the United States.
- The logistics of implementing a WRO require extensive coordination with CBP ports and Centers of Excellence and Expertise, a time-consuming process that has diverted

Question#:	22
Topic:	Section 307 Enforcement
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

resources from investigating allegations of forced labor. The need to review lengthy submissions from importers to modify or revoke WROs, as well as proof of admissibility petitions for particular shipments, has also placed additional strains on the same limited resources.

CBP remains committed to focusing the available resources on tackling this very important area of work. It does bear mentioning that the investigative work is only a part of the enforcement work. When an investigation is underway, CBP uses resources from a number of offices within CBP, including the Office of Chief Counsel, and the Office of Trade's Regulatory Audit Directorate, and National Threat Analysis Division, and once a WRO has been issued, CBP further relies on the Office of Field Operations to detain all of the suspect shipments and handle any subsequent seizure, forfeiture, or penalty actions. These are complex and involved actions, and we are rigorously reviewing all of our processes in this regard to make sure that we stay agile and effective in executing our responsibilities, as articulated in the statute.

Question: Does CBP have all the tools it needs to fully enforce section 307 of the Tariff Act as it relates to the importation of banned goods into the U.S.?

Response: To fully enforce 19 USC 1307, CBP needs actionable, on-the-ground information about forced labor conditions and U.S.-bound supply chains. Acquiring that type of information requires utilizing existing resources to hire qualified staff with language expertise, engaging with organizations that have a presence overseas, and leveraging the intelligence available to the interagency. It also requires experimenting with new ways of collecting data, including through lab testing at the ports to allow CBP to determine the origin of merchandise.

Question#:	23
Topic:	WRO's
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

Question: A 2016 amendment to the Tariff Act had the intent to increase the scope of Section 307 to enable broader enforcement by CBP with respect to goods produced by means of forced labor. When the consumptive demand loophole was closed in 2016, there was an initial spike in Withhold Release Orders (WROs) issued by CBP but soon after the number of WROs fell again. Can you explain this trend?

Response: After a brief decline in the number of WROs issued, CBP issued country-wide WROs to detain cotton from Turkmenistan and tobacco from Malawi. Additionally, some resources were spent on pursuing a civil penalty, which required a higher level of proof than a WRO. In FY 2019, the CBP Office of Trade's Forced Labor Division issued 6 WROs and, as of June 25 2020, had issued 4 WROs for FY 2020.

Question#:	24
Topic:	Annual Reports
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

Question: The 2016 amendment also requires CBP to file annual reports with Congress describing the agency's Section 307 enforcement efforts. How many of these update reports have been filed to date?

Response: To date, CBP has submitted 3 annual reports per Section 307, and will continue to do so annually.

Question#:	25
Topic:	Public Awareness
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

Question: CBP regulations state that any person who has reason to believe that merchandise produced by forced labor "is being, or is likely to be," imported into the U.S. in violation of Section 307 may communicate his or her belief to any Port Director or the Commissioner of CBP through a prescribed form provided by CBP or by other means, as long as the submission follows relevant regulations.

Have there been any efforts within CBP to bring public awareness to this particular provision in the Tariff Act to further engage the public on this vital issue?

Response: CBP maintains a website replete with information about 19 U.S.C. section 1307, has worked with the DHS Blue Campaign on creating outreach information on the prohibition on importing goods made with forced labor, and actively responds to press inquiries about its work, which involves publicizing the statute and regulations. Earlier in 2020, CBP created tear sheets in multiple languages to be distributed at airports around the country to raise awareness, although the distribution was delayed by the spread of COVID-19. DHS and CBP regularly conduct outreach with trade associations, companies, NGO's, and Congress to explain 19 USC 1307 authorities.

Question#:	26
Topic:	Section 307 Petitions
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

Question: About how many Section 307 petitions does CBP receive from a general member of the public in a given year?

About how many Section 307 petitions does CBP receive from anti-trafficking/forced labor organizations in a given year?

Response: In FY 2018 CBP received 4 petitions, in FY 2019 CBP received 8 petitions, and in FY 2020 to date, CBP has received 31petitions. Some were received through CBP's e-Allegation portal. Given that allegations can be submitted anonymously, CBP is not always able to tell who submitted them.

Question#:	27
Topic:	New Evidentiary Standard
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

Question: Generally, enforcement of Section 307 is limited to the enterprise level, meaning petitioners must prove that forced labor is taking place in a particular factory or farm and trace the tainted product to a particular shipment entering a U.S. port. In many cases it can be incredibly difficult to trace a particular shipment in this fashion. Has there been any consideration regarding a new evidentiary standard as applied to a petitioner's filing under Section 307 of the Tariff Act?

Response: CBP will gladly receive any and all information regarding allegations of forced labor. Certainly, the more fulsome and detailed the allegation is, the easier it will be for CBP to understand the allegation and to conduct the research and investigation necessary to take action on those petitions and allegations.

CBP may issue a WRO under its regulations when the information available reasonably but not conclusively indicates that merchandise within the purview of Section 307 is being, or is likely to be, imported to the United States. CBP continually considers updating its regulations, as appropriate.

Question#:	28
Topic:	Prosecutions
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

Question: To your knowledge, how many prosecutions have there been, if any, for false statements made in connection with the importation of goods at a port of entry?

Response: CBP has civil trade enforcement authority under Section 307 to detain and seize goods produced with forced labor at the ports of entry. CBP refers potential criminal violations to HSI for investigation.

Question#:	29
Topic:	Recommendations
Hearing:	CBP Oversight: Examining the Evolving Challenges Facing the Agency
Primary:	The Honorable Josh Hawley
Committee:	HOMELAND SECURITY (SENATE)

Question: Do you have any recommendations for how we in Congress can crack down further on these terrible practices?

Response: CBP appreciates the continued support that it has received from Congress. CBP does foresee that as CBP's trade-enforcement enterprise adjudicates the many more allegations of forced labor around the world, the results will likely impact supply chains of important industries in the United States. It will be vital for Congress to continue to message that importing goods produced wholly or in part with forced labor is a violation of U.S. law. Modern-day slavery is abhorrent and will not be tolerated in U.S. supply chains, regardless of the industry. If someone brings information on forced labor in the U.S. supply chains to the attention of Congress, please report this information to CBP and HSI.