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THE FISCAL YEAR 2021 HEALTH AND HUMAN SERVICES BUDGET AND OVERSIGHT OF THE CORONAVIRUS OUTBREAK

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

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[1] Mr. Azar did not answer submitted questions for the record by the time of publication.

[2] The witnesses did not answer the submitted questions for the record by the time of publication.

[3] The information has been retained in committee files and also is available at https://docs.house.gov/meetings/IF/IF14/20200226/110589/HHRG-116-IF14-20200226-SD003.pdf.

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THE FISCAL YEAR 2021 HEALTH AND HUMAN SERVICES BUDGET AND OVERSIGHT OF THE CORONAVIRUS OUTBREAK

WEDNESDAY, FEBRUARY 26, 2020

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 1:00 p.m., in the John D. Dingell Room 2123, Rayburn House Office Building, Hon. Anna G. Eshoo (chairwoman of the subcommittee) presiding.

Present: Representatives Eshoo, Engel, Matsui, Sarbanes, Luján, Schrader, Kennedy, Cárdenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Pallone (ex officio), Burgess, Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Hudson, Carter, Gianforte, and Walden (ex officio).

Also present: Representatives DeGette and Schakowsky.

Staff present: Joe Banez, Professional Staff Member; Kevin Barstow, Chief Oversight Counsel; Jacquelyn Bolen, Counsel; Jeffrey C. Carroll, Staff Director; Kimberly Espinosa, Professional Staff Member; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Stephen Holland, Health Counsel; Zach Kahan, Outreach and Member Service Coordinator; Saha Khaterzai, Professional Staff Member; Chris Knauer, Oversight Staff Director; Una Lee, Chief Health Counsel; Kevin McAloon, Professional Staff Member; Aisling McDonough, Policy Coordinator; Meghan Mullon, Policy Analyst; Alivia Roberts, Press Assistant; Tim Robinson, Chief Counsel; Kimberlee Trzeciak, Chief Health Advisor; Rick Van Buren, Health Counsel; C. J. Young, Press Secretary; Nolan Ahern, Minority Professional Staff, Health; Jennifer Barblan, Minority Chief Counsel, Oversight and Investigations; S. K. Bowen, Minority Press Secretary; William Clutterbuck, Minority Staff Assistant; Jordan Davis, Minority Senior Advisor; Caleb Graff, Minority Professional Staff Member, Health; Tyler Greenberg, Minority Staff Assistant; Brittany Havens, Minority Professional Staff, Oversight and Investigations; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; Kate O'Connor, Minority Chief Counsel, Communication and Technology; James Paluskiewicz, Minority Chief Counsel, Health; Kristin Seum, Minority Counsel, Health; Kristen Shatynsky, Minority Professional Staff Member, Health; and Alan Slobodin, Minority Chief Investigative Counsel, Oversight and Investigations.

Ms. ESHOO. The Subcommittee on Health will now come to order.

I just want all members to know that our witnesses today have to leave at 5:00 p.m. So the questions for the first panel on the HHS budget with the Secretary and welcome, Mr. Secretary—are going to be limited to four minutes. In the second panel, on the coronavirus response, those questions will be limited to 5 minutes, which is the usual case, but only ten members are going to be able to ask questions during that round. So I will have to be strict with the gavel since the witnesses have a tight timeframe, and I know that you will all cooperate with that.

And so let us begin.

Welcome, Mr. Secretary. We are glad that you are here. We have a lot to take up, and every bit of it is, obviously, serious.

The Chair now recognizes herself for 5 minutes for her opening statement.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

And let me begin with this, Mr. Secretary: I think that confusion is the enemy of preparedness. Confusion is the enemy of preparedness. I believe that the administration's lack of coordination for the coronavirus response is on full display. We all know that. Markets are reacting, I think, at least in some part, to the lack of trusted information, amongst many other factors.

Our government, across the government, has to speak with credibility and authority. Instead, it is like a Greek chorus chanting on the side of the stage. We have one saying one thing, the President saying something else, and that adds to the confusion.

I think that there are key questions that need to be addressed for the American people: What is the plan, the overall plan; should this virus infect Americans in high numbers?

What is the plan for increasing diagnostic capacity, and what is the target number for that? Dysfunctional tests, we all know, have limited our ability to diagnose the virus, and the small number, it could be said, of U.S. cases may reflect limited testing and not the virus's spread. But it is up to our professionals to put out with clarity that kind of information.

What is the plan for protecting our healthcare workers that are on the front lines of this? What is the plan to increase hospital capacity?

Now, in my view, the United States of America has the premier professional public health professionals in the world—in the world—our scientists, our doctors, and those that are heading up the agencies, those that are part of the agencies. I think the problem rests more with administration people, one saying one thing, others saying something else.

I think that the briefings that are done for the Congress, if I might suggest, should be open to the public. There is no reason to have secrets about this. And I say that because it raises the element of fear with people. "There is something going on behind closed doors that they are not telling us."

And it is a time for us, if I might use the expression, to give them an inoculation of confidence. And certainly the virus triggers fear, and I think the antidote for this is truth and transparency,

including informing the American people of a coordinated, fully-funded government plan to keep us safe.

These are not things they can do for themselves. We are the ones. You are certainly in the driver's seat on this. And I think that the funding request—and later in my questions, I will ask you about that—is wholly inadequate.

Now, before requesting the emergency funding, the President's budget contained dangerous cuts that weaken our public health frontline response, gut the healthcare safety net, and end programs focusing on increasing our healthcare workforce.

So we are driving in the wrong direction. It is as if there is a fire and the fire engine is going down the wrong end of the road instead of to the fire. We need these resources in order to care for the American people.

As the author of the Pandemic and All-Hazards Preparedness Act, I know that the best way to fight outbreaks is by preparing and investing in advance, not by rushing after a pandemic hits.

And while the virus is spreading, the President's budget cuts almost $700 million from the CDC, $430 million from the national institute focused on infectious diseases, $3 billion from the government's global health program. This is a jaw-dropping $1.6 trillion cut from the very Federal programs that cover one in three Americans. This doesn't make any sense.

And the President's budget virtually ends the workforce development programs that trained more than a half a million clinicians each year. I see them every week in my congressional district at Stanford Medical Center and Lucile Packard Children's Hospital.

So the budget weakens our public health safety net and it hurts our country's resiliency. The CDC, NIH—all of these agencies cannot run on fumes—cannot run on fumes. And it is not even a Tesla if it doesn't have a battery that is going to last.

And if Americans are uninsured or underinsured, they are not going to seek care, and that will contribute to the spread of the disease.

So I don't know what is—the President often has promised "beautiful" healthcare. I don't find beauty in what I just said, and I am sorry that this is a part of it.

So, with that, I will have questions, and thank you again for being here.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Confusion is the enemy of preparedness.

The Administration's lack of coordination for the coronavirus response is on full display and the markets are reacting to the lack of trusted information, amongst many factors.

Our government must speak with credibility and authority.

•That means answering key questions for the American public:

•What is the plan should this virus infect Americans in high numbers?

What is the plan for increasing diagnostic capacity and what is the target number? Dysfunctional tests have limited our ability to diagnosis the virus. The small number of U.S. cases may reflect limited testing, not the virus's spread.

•What is the plan for protecting our healthcare workers?

•What is the plan to increase hospital capacity?

The virus triggers fear and I think the antidote for this is truth and transparency, including informing the American people of a coordinated, fully-funded government plan to keep us safe.

Instead of taking this situation seriously, the President has sent Congress a coronavirus funding request that is inadequate for this emergency.

And before requesting the emergency funding, the President's budget contain dangerous cuts that weakens our public health frontline response, guts the healthcare safety net, and ends programs focused on increasing our healthcare workforce.

As the author of the Pandemic and All Hazards Preparedness Act, I know that the best way to fight outbreaks is by preparing and investing in advance, not by rushing after a pandemic hits.

While the virus is spreading, the President's budget cuts almost $700 million from the CDC, $430 million from the National Institute focused on infectious diseases, $3 billion from the government's global health program . . . and a jawdropping $1.6 trillion from the federal programs that cover one in three Americans.

And the President's budget virtually ends the workforce development programs that train more than half a million clinicians each year.

The President's budget weakens our public health safety net, hurting our country's resiliency. If Americans are uninsured or underinsured, then they won't seek care and will contribute to the spread of the disease.

The President has often promised "beautiful" healthcare, but his HHS budget shows an ugly truth.

The people of our country need a swift advancement of a strong, strategic funding package that addresses the scale and seriousness of this public health crisis.

The Chair now recognizes Mr. Burgess, the ranking member of our subcommittee, for his 5 minutes for his opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. And I thank the Chair.

Thank you, Secretary, for being here. Always great to see you in our committee. I hope the feeling is mutual; you always are grateful to be here at our committee.

I just have to say, Madam Chair, that two weeks ago I was criticized rather severely for even suggesting that we needed a coronavirus hearing. The work we were doing that day, which was a bill that was never going to become law, was so important that we didn't need to do that hearing. We did need to do that hearing. I am grateful we are having it today. I am grateful we have the Secretary.

Now, this hearing is also being coincidently run with the President's budget proposal for fiscal year 2021. And that is a lot of stuff to cover in one hearing, but I guess we will do our best, Mr. Secretary.

So let me just say, I do appreciate the administration's commitment to healthcare. I appreciate the commitment to lowering healthcare costs and reducing the complexity of the system so that patients can more easily access their care.

One thing the administration and, Mr. Secretary, particularly you led on was advancing kidney health for Americans. That trend continues in the Health and Human Services budget proposal and the support for H.R. 5534, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act.

As you know, Mr. Secretary, this bill would extend Medicare coverage of immunosuppressive drugs past the current 36-month limit. A patient with a kidney transplant needs to take immunosuppressives or their body will ultimately reject the graft, causing the patient to return for dialysis treatment.

A kidney transplant is indeed an investment in the future of that recipient patient, and this bill will help protect that investment. I have worked on this policy for a decade, and I am thankful it has been highlighted as a priority by the administration. It is time for Congress to finally pass this commonsense legislation.

The budget also continues the work of the SUPPORT Act, one of the major pieces of legislation passed in the last Congress, by making clear that the opiate epidemic and programs in the oversight investigation—and making sure that the opiate epidemic and response programs are indeed a priority.

In our Oversight and Investigations Subcommittee, we have heard from various States about the efforts they are making to help those with substance use disorder. Funding for these State opiate response grants is imperative to allow States to find the innovative ways to combat this crisis.

I also appreciate the fact that the administration included Hyde Amendment pro-life protections in all proposed funding language. It is important to ensure that Federal funds are not used to perform abortions. And I hope as this subcommittee moves forward with reauthorizations and the Appropriations Committee puts together the bills for fiscal year 2021, they will maintain those protections.

Other important programs and policies are receiving increased funding, including: the Maternal and Child Health Block Grant, the Health Resources and Services Administration's Maternal Health in America initiative, and the 340B drug pricing program. Funding increases for the Centers for Disease Control and Prevention's influenza program are particularly important as we now face this worldwide coronavirus outbreak.

Which brings me to the novel coronavirus. And it has infected over 80,000 individuals worldwide, and proven to be more deadly than SARS. I appreciate the Trump administration's vigilance and rapid response efforts.

Mr. Secretary, let me just say, I was so heartened—I think it was four Fridays ago when you came on the air and said there was a limit to people being able to come into this country from China. And I thought it was important that the administration say that.

And I believe that is one of the central things—my thesis is that is one of the central things that has provided us at least a little breathing room as this virus erupts around the world. We are, fortunately, not as affected as some other countries. Now it is incumbent upon us to make sure that we utilize that time wisely.

Certainly, the Pandemic and All-Hazards Preparedness Act, which was worked on by this subcommittee in the last Congress and finally passed at the beginning of this Congress—important piece of legislation. I would have liked for us to have done real-time hearings updating, are we doing what was intended with that bill? Is the stockpile responding appropriately to the authorizations that we made?

And this is the type of information—rather then the political rhetoric back and forth that we have heard, this is the type of information that I think would be helpful and, indeed, reassuring to the American people.

You can't ignore the fact of what has happened to the markets. Today we are grateful that they have seemed to have rebounded a little bit. But, look, we all know China has not been forthcoming with information, and it is that uncertainty—that uncertainty—that I believe it is one of the negative forces driving the market.

Mr. Secretary, I appreciate you being here today. We will have multiple questions for you. I certainly look forward to your testimony.

Thank you. I yield back.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Thank you, Madam Chair. I want to thank Secretary Azar for being here today to discuss President Trump's Budget Proposal for fiscal year 2021 and the 2019 novel coronavirus, or COVID–19, outbreak.

I appreciate the Trump Administration's commitment to healthcare, especially lowering healthcare costs and the reducing the complexity of the healthcare system so that patients can more easily access care. One thing the Administration, particularly you, Secretary Azar, has led on is advancing kidney health for Americans. That trend continues in the Health and Human Services Budget Proposal's support for H.R. 5534, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019.

This bill would extend Medicare coverage of immunosuppressive drugs past the current 36-month limit for kidney patients who do not obtain other health coverage.

A patient with a kidney transplant must take their immunosuppressive drugs or their body will ultimately reject the kidney causing the patient to return to dialysis treatment. A kidney transplant is an investment into the future of the recipient patient. This bill will protect that investment. I have worked on this policy for nearly a decade, and I am thankful that this has been highlighted as a priority by the Administration. This Congress is the time to finally pass this common-sense legislation.

This budget also continues the work of the SUPPORT Act, by making clear that the opioid epidemic and response programs are a priority.

In the Oversight and Investigations Subcommittee we heard from various states about the efforts they are making to help those with substance use disorder. Funding for these State Opioid Response Grants is imperative to allow states to find innovative ways to combat the opioid crisis.

I also appreciate that the Administration included Hyde Amendment and pro-life protections in all proposed funding language. It is important to ensure that federal funds are not used to perform abortions, and I hope that as this subcommittee moves forward with reauthorizations and the Appropriations Committee puts together the bills for fiscal year 2021, that they will maintain those protections.

Other important programs and policies receiving increased funding including the Maternal and Child Health Block Grant, the Health Resources and Services Administration's Maternal Health in America Initiative, and the 340B Drug Pricing Program. Funding increases for the Centers for Disease Control and Preparation's influenza program is particularly important now as we face a worldwide coronavirus outbreak.

This novel coronavirus, named COVID-19, has infected over 75,000 individuals worldwide and has proven to be more deadly than SARS. I appreciate the Trump Administration's vigilance and rapid response efforts. The State Department issued a level 4 travel advisory for China and the Administration has been appropriately restrictive in allowing non-citizens who had traveled to China within the last 14 days from entering the U.S. It is a relief to know that our country is taking this outbreak very seriously and has successfully limited the number of cases in the United States; however, with increased global spread and community spread in countries such as Italy, COVID–19 will become more difficult to contain.

Our agencies have worked together to protect the American people from this outbreak and have been successful in limiting infection of those in the U.S. This is proof that the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 is working. Thanks to the work of this subcommittee in the last Congress and the leadership of Rep. Susan Brooks and Chairwoman Eshoo, our public health system is working as intended. I believe that our response efforts thus far have shown that our public health system has adapted and improved since the Zika

and Ebola responses. Throughout those responses, Chairman Upton ensured that we had robust hearings on those responses to ensure proper Congressional oversight and understanding of the situations. I hope that we will be able to stick to that tradition and hold a standalone hearing on COVID–19.

I do appreciate the CDC and other agencies' transparency in providing multiple telebriefings for Congressional staff each week so that Congress can be as informed with the most up-to-date information as possible. I look forward to learning more about COVID–19 and the challenges and successes of these response efforts.

Thank you for holding this important hearing. I yield back.

Ms. ESHOO. The gentleman yields back.

I want the ranking member to know the following. On January 30, I requested that, the following week, we have a hearing on the coronavirus with the heads of the agencies. The Secretary leaned in and said, "I head up the effort, and I want to be there with that team." And here we are today.

So this is not something, Dr. Burgess, that we have just casually overlooked or ignored. That is far from the fact.

I now would like to recognize the chairman of the full committee, Mr. Pallone, for his 5 minutes.

Mr. PALLONE Thank you, Chairwoman Eshoo.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Today's hearing serves two critical purposes: first, we will examine the Trump administration's proposed budget for the Department of Health and Human Services for fiscal year 2021, and, second, we will get a crucial update on the administration's ongoing response to the coronavirus.

I am disappointed, though not surprised, that the Trump administration budget proposal completely contradicts the healthcare promises that the President repeatedly makes to the American people.

When it comes to ensuring the American people have access to affordable and quality healthcare, the Trump administration has failed them, and this budget proposal continues that record.

Two years after showering the wealthy and large corporations with major tax breaks, the President's 2021 budget proposal slashes $100 billion from the Affordable Care Act, $500 billion from Medicare, and more than $900 billion from Medicaid over the course of years. And the President also wants to make it easier for States to take away people's coverage, undermine their care, and cut critical benefits.

And this puts the health and well-being of tens of millions of children, parents, pregnant women, and people with disabilities at risk. Medicaid is a lifeline for millions of working-class families, and it is unconscionable that the president wants to cut it to pay for tax cuts for millionaires.

Now, these budget cuts also fly in the face of President Trump's own words. He promised that, as President, he would not cut Medicare or Medicaid. And he promised in his State of the Union Address earlier this year that he would continue to protect the more than 130 million Americans with preexisting conditions. But, as Secretary Azar knows, this administration is now suing in the Fed-

eral courts to strike down the ACA and all of its consumer protections.

Overall, President Trump is proposing a 12-percent cut to the HHS's budget, one of the largest cuts to any Federal agency. The devastating cuts don't end at Medicare, Medicaid, and the ACA. The President's proposal cuts the National Institutes of Health by $3 billion and the Centers for Disease Control and Prevention by $675 million. And keep in mind that this is the very agency that is now responding to the coronavirus.

And I am also concerned by the proposal to move tobacco regulation out of the FDA's authority altogether. Instead, the administration would create a new, untested agency to oversee tobacco products while we are in the midst of a youth tobacco epidemic.

After years of regulatory uncertainty, the Tobacco Control Act clearly and unambiguously ensured that FDA would regulate tobacco products for the protection of public health, and, over the last decade, the agency has worked to develop the expertise, workforce, and scientific basis to effectively regulate these products.

So I am concerned that this proposal would only serve to further politicize tobacco regulation by stripping away FDA's sound, scientific, and evidence-based approach and replacing it at the whims of political appointees. And it is nothing more than a gift, frankly, to big tobacco companies.

Now, let me just move to the second topic at hand. After we discuss the budget, we will ask questions of the Secretary and other top public health officials on the administration's efforts to address the coronavirus outbreak. It is critical that we get an update on the scale of the outbreak, its repercussions in the U.S., and how we can work together to ensure the safety of all Americans.

I think we have one of the strongest public health infrastructures in the world, and it is more than capable of coming to an effective solution. And we should be supporting that system with all available resources.

So, again, Madam Chair, I thank you. And I think—well, actually, I have time left, if anybody wants it, but—everybody gets time, or should—does anybody want my time? I guess not.

All right. Thanks a lot. I yield back.

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today's hearing serves two critical purposes. First, we will examine the Trump Administration's proposed budget for the Department of Health and Human Services for fiscal year 2021. And second, we will get a critical update on the Administration's ongoing response to the coronavirus.

I am disappointed, though not surprised, that the Administration's budget proposal completely contradicts the healthcare promises that President Trump repeatedly makes to the American people.

When it comes to ensuring the American people have access to affordable and quality healthcare, the Trump Administration has failed them, and this budget proposal continues that sorry record.

Two years after showering the wealthy and large corporations with major tax breaks, the President's 2021 budget proposal slashes $100 billon from the Affordable Care Act (ACA), $500 billion from Medicare and more than $900 billion from Medicaid over the course of ten years. The president also wants to make it easier for states to take away people's coverage, undermine their care, and cut critical benefits. This puts the health and well-being of tens of millions of children, parents, pregnant women, and people with disabilities at risk. Medicaid is a lifeline for mil-

lions of working-class families, and it's unconscionable that the president wants to cut it to pay for tax cuts for millionaires.

These budget cuts also fly in face of President Trump's own words—promising that, as president, he would NOT cut Medicare or Medicaid. And promising in his State of the Union Address earlier this year that he would continue to protect the more than 130 million Americans with pre-existing conditions. As Secretary Azar well knows, this Administration is now suing in the federal courts to strike down the ACA and all of its consumer protections.

Overall, the President is proposing a 12 percent cut to HHS's budget—one of the largest cuts to any federal agency. The devastating cuts don't end at Medicare, Medicaid and the ACA, the President's proposal, cuts the National Institutes of Health (NIH) by $3 billion, and the Centers for Disease Control and Prevention (CDC) by $675 million. Keep in mind this is the very agency that is now responding to the coronavirus.

I'm also concerned by the proposal to move tobacco regulation out of the Food and Drug Administration's (FDA) authority altogether. Instead, the Administration would create a new, untested agency to oversee tobacco products while we are in the midst of a youth tobacco epidemic. After years of regulatory uncertainty, the Tobacco Control Act clearly and unambiguously ensured that FDA would regulate tobacco products for the protection of public health. Over the last decade, the agency has worked to develop the expertise, workforce, and scientific basis to effectively regulate these products. I'm concerned that this proposal would only serve to further politicize tobacco regulation by stripping away FDA's sound scientific and evidence-based approach and replacing it at the whims of political appointees. This is nothing more than a gift to big tobacco companies.

Now, let me move to the second topic at hand today. After we discuss the budget, we will ask questions of the Secretary and other top public health officials on the Administration's efforts to address the coronavirus outbreak. It is critical that we get an update on the scale of the outbreak, its repercussions in the United States, and how we can be working together to ensure the safety of all Americans. We have one of the strongest public health infrastructures in the world, and it is more than capable of coming to an effective solution. We should be supporting that system with all available resources.

Thank you, and I yield back.

Ms. ESHOO. The gentleman yields back.

Pleasure to recognize the ranking member of the full committee, Mr. Walden, for his 5 minutes for his opening statement.

OPENING STATEMENT OF HON. GREG WALDEN A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Madam Chair. Good afternoon.

And, Mr. Secretary, thank you for being here today. It is not the first time we have seen you here, I think, this year probably, but certainly, we appreciate the work you and your team have done dealing with the coronavirus.

I think I have been in every one of the roundtables and hearings that you and your team have provided for this committee and other committees. Chairman Pallone and I were the co-moderators of the first one in the Visitor Center, where every Member of Congress was invited, and I was at the last one, and I was at the Situation Room at the White House before the break. And, you know, I think you all have been very forthcoming with the facts.

And for whatever reason, we haven't had a hearing here. Maybe we wanted to wait until this one. But I think it is important that we hear from you and the team that you are leading.

And I think it is important to recognize the work that Mrs. Brooks did on reauthorizing the Pandemic and All-Hazards Preparedness Act in the last Congress. We had big fights about that, but thank goodness it is in place, because it is designed to do exactly what we are encountering today: have a lead person in the

administration—that is you—that is designated by the President, and a team ready to go.

And so I guess I have been to enough of those briefings that I saw Members kind of yawning at some point in those, quote/unquote, "closed-door briefings" because we were hearing it for the third time.

Now, we were gone a week, and a lot has changed. And we know what is happening in China is probably worse than we are being told. And I think the big issues there are the supply chain as well as public health.

We know it is spreading around the world, and we are trying to cope. And we know, and you have warned us, and Dr. Fauci has warned us, and others, expect it to—you know, this could well mutate, but that doesn't mean end of world. It can well expand; we should be ready for that. But, as Mr. Pallone said, we have a terrific public health system here in the United States.

A lot of that is driven at the local level. And it is important we have those communication links in place so that when we identify something, somebody coming in through an airport, the local health officials know about it at home and we are able to deal with it. And I think it is good to get this out in the public.

I would just point-out that we will hear from you and the CDC, FDA, and ASPR and NIAID to give us an update on the sidecar hearing. We have had now, what, 80,000 confirmed cases worldwide, 2,700 deaths. The outbreak has become a significant global health concern. Yesterday, Italy announced 300 individuals have been affected by the coronavirus; 11 have died.

There is still much we do not know about the outbreak, and so we will learn more, I guess, after this budget hearing.

But it is essential that we do everything we can and provide you the assistance. And I know, in the meetings I have been in with everybody else on this committee that was there to attend, you have made it clear, if you need more money, you will ask us, and we have made it clear, if you need more money, tell us, and we will work with you.

Now, we will want to get the specifics, obviously, but I know you have sent up a supplemental request for, I think, a total of a little over $2 billion, $2.5 billion. Some of that is reprogramming; some of it is additional money. No sooner had that left your office than some politicians were on the air, criticizing you for not asking for enough. And so we will be interested to get your response to that.

I do think it is also essential to look at perspectives in terms of what Americans are facing today with the traditional flu and that we have probably lost, what, 10,000 or more Americans have died from the annual flu. And we have vaccines for that and treatments for that. And so we have to think about that, as well, and practice good public health.

I was in Japan with a couple of other of my colleagues on the committee, and you can't go anywhere in Japan without the hand sanitizer being squirted in your hands. And it was a good lesson, I think, for all of us. But we ought to be doing a little bit more of that here and we would probably help with the traditional seasonal flu and spread of other diseases.

And so there is a lot we can learn from you; there is a lot we can learn from your team. And we will look forward to hearing from you directly on that, on the record here in the public.

So, with that, Madam Chair, I yield back.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Madame Chair, thank you for holding this important hearing. Secretary Azar, welcome back. Thank you for taking the time to be here today and the work you and your team continue to do.

Providing funding to essential health programs has been one of the priorities of this committee. Last year, we passed several important bills that reauthorized research funding for autism and the Emergency Medical Services for Children program. We also included provisions in the end-of-the-year spending bill that provide additional protections for CRT wheelchairs provided to Medicare beneficiaries. These provisions—that are now law—directly and positively impact the American people and show we are a committee that can continue to reach bipartisan agreements to help the public.

The President's budget continues to build on a number of proposals that increase health access to rural communities, combat the HIV epidemic, and provide states greater flexibility to engage in innovative programs—such as implementation of the Money Follows the Person demonstration, giving consumers the choice of where they live and receive services.

As the opioid epidemic continues to claim lives and other drug epidemics are arising, the budget also keeps vital grants in the budget for substance use disorder treatment.

The budget also integrates proposals that members of this committee have previously supported, such as providing lifetime coverage for immunosuppressive drugs for kidney transplant recipients as well as an extension of the Independence at Home demonstration program. These are good, bipartisan proposals that continue to build on the work this committee has done.

The budget also reiterates the President's commitment to providing greater price transparency, so patients know the cost of their services. Additional provisions remove regulatory barriers that hinder the ability to have more value-based care, such as modernizing the Stark Law and making site-neutral payment changes so that costs can be uniform for all Medicare beneficiaries.

It should also be noted that we are quickly approaching the May 22nd deadline to fund community health centers and other essential programs for the rest of the year. These are important programs and we need to make sure they are fully funded; it's also an opportunity to act on legislation to end surprise medical bills - a key priority of not only this committee, but also President Trump. Of course, the President's budget also emphasizes the need to engage in drug pricing reform to lower the cost of prescription drugs for consumers. I hope that we can work on bipartisan proposals that will do so and I continue to believe the Lower Costs, More Cures Act, that I introduced, has a path to the President's desk. This would provide savings to the American people, place the first out-of-pocket cap on America's seniors' drug costs, and prioritize innovation without sacrificing lifesaving cures—unlike Speaker Pelosi's alternative with estimates that up to 15 or even 100 fewer cures would be developed.

After we hear from Secretary After we hear from Secretary Azar, we're going to hear from representatives of the CDC, FDA, NIAID, and ASPR to give us an update on the coronavirus outbreak and responses to combat it. I thank Doctors Redfield, Hahn, Fauci, and Kadlec for taking the time to appear before us today. With over 80,000 confirmed cases and over 2,700 deaths, the outbreak has become a significant global health concern. Yesterday, Italy announced over 300 individuals had been affected by the coronavirus and 11 had died. There is still much we do not know about the outbreak given that public health authorities have been given limited access to Chinese patients. It is important to make sure that the CDC and other agencies have the necessary funding to further research and manage this outbreak. Earlier this week, the Administration requested emergency funds to combat the coronavirus outbreak and I think this Committee should do everything it can to assist public health officials with this crisis.

I thank both panels for taking the time to appear and I look forward to hearing from each of you.

Ms. ESHOO. The gentleman yields back.

I now would like to introduce our witness for today's first panel. One person, one person alone: the Nation's Secretary of Health and Human Services.

Welcome to you, Secretary Azar. You certainly are familiar with the lighting system around here, so you are now recognized for 5 minutes for your statement to the committee. Thank you for being here.

STATEMENT OF ALEX AZAR

Secretary AZAR. Great. Thank you very much.

Chairwoman Eshoo, Chairman Pallone, Ranking Members Walden and Burgess, thank you for inviting me to discuss the President's budget for fiscal year 2021.

I am honored to appear before the committee for budget testimony as the HHS Secretary for the second time, especially after the remarkable year of results that the HHS team has produced.

With support from this committee, this past year, we saw the number of drug overdose deaths decline for the first time in decades, another record year of generic drug approvals from FDA, and historic drops in Medicare Advantage, Medicare Part D, and Affordable Care Act exchange premiums.

The President's budget aims to move toward a future where HHS's programs work better for the people we serve, where our human services programs put people at the center, and where America's healthcare system is affordable, personalized, puts patients in control, and treats them like a human being and not like a number.

HHS has the largest discretionary budget of any nondefense department, which means that difficult decisions must be made to put discretionary spending on a sustainable path.

The President's budget proposes to protect what works in our healthcare system and make it better. I will mention two ways that we do that: first, facilitating patient-centered markets; and, second, tackling key, impactable health challenges.

The budget's healthcare reforms aim to put the patient at the center. It would, for instance, eliminate cost-sharing for colonoscopies, a lifesaving preventive service. We would reduce patients' costs and promote competition by paying the same for certain services regardless of the setting.

The budget endorses bipartisan, bicameral drug pricing legislation. And I want to thank this committee for your bipartisan work to pass legislation such as the CREATES Act to cut patient costs and save taxpayer dollars through lower drug prices.

The budget's reforms will improve Medicare and extend the life of the Hospital Insurance Fund for at least 25 years.

We propose investing $116 million in HHS's initiatives to reduce maternal mortality and morbidity. And we propose reforms to tackle America's rural healthcare crisis, including telehealth expansions and new flexibility for rural hospitals.

The budget increases investments to combat the opioid epidemic, including SAMHSA's State Opioid Response Program. This successful grant program grew out of this committee's creation of the State Targeted Response grants in the Cures Act, and we were pleased

to work with Congress to provide flexibility on the SOR grants for States to address stimulants like methamphetamines.

We request $716 million for the President's initiative to end the HIV epidemic in America by using effective, evidence-based tools. Thanks to support from Congress, we have already begun implementation of the initiative.

The budget reflects how seriously we take the threat of other infectious diseases, such as the novel coronavirus, by prioritizing the funding for CDC's infectious disease programs and maintaining investments in hospital preparedness.

As of this morning, we still had only 14 cases of the novel coronavirus detected in the United States involving travel to or close contacts with travelers. Coming into this hearing, I was informed that we have a 15th confirmed case, the epidemiology of which we are still discerning. Three cases also exist among Americans repatriated from Wuhan, and 42 cases exist among American passengers repatriated from the Diamond Princess cruise ship in Japan.

While the immediate risk to the American public remains low, there is now community transmission in a number of countries, including outside of Asia, which is deeply concerning. We are working closely with State, local, and private-sector partners to prepare for mitigating the virus's potential spread in the United States, as we expect to see more cases here.

On Monday, OMB sent a request to make at least $2.5 billion in funding available for preparedness and response, including for therapeutics, vaccines, personal protective equipment, State and local public health department support, and surveillance. I look forward to working closely with Congress on that proposal.

This year's budget aims to protect and enhance Americans' well-being and deliver Americans a more affordable, personalized healthcare system that works better rather than just spends more. I look forward to working with this committee to make that commonsense goal a reality.

Thank you very much.

[The prepared statement of Secretary Azar follows:]

PREPARED STATEMENT OF MR. AZAR

Sec. Azar Written Budget Testimony

The President's Fiscal Year (FY) 2021 Budget (Budget) is built around a vision for HHS and a vision for American healthcare. We are building toward a future where HHS's programs work better for the people we serve; where America's healthcare system is affordable, personalized, and puts patients in control; and where our human services programs put people at the center.

The Budget reflects the Administration's commitments to delivering on this vision and other important themes of HHS's work: advancing a patient-centered healthcare system, protecting the lives of the American people, promoting independence, and making HHS the healthiest organization it can be.

Over the past year, under President Trump's leadership, the men and women of HHS have delivered remarkable results. Beginning in 2018 and through 2019, the number of drug overdose deaths in America began to decline for the first time in nearly two decades, thanks to huge expansions, assisted by HHS, in access to evidence-based addiction treatment. The Food and Drug Administration (FDA) approved a record number of generic drugs and biosimilars in FY 2019. We launched new payment models in Medicare that pay for health and outcomes, rather than sickness and procedures. We finalized a requirement, effective January 2021, that hospitals provide patients with useful price information, and proposed measures to give patients control over their own health data through interoperability. We launched President Trump's initiative to end the HIV epidemic in America within ten years, and worked with Congress to secure funding for it. The Department played a vital role in responding to an Ebola outbreak in the eastern Democratic Republic of the Congo and the humanitarian crisis in Latin America. We took unprecedented steps to expand access to treatment for Americans with serious mental illness and worked to help seniors remain in their homes. The latest data from the Administration for Children and Families shows a record number of adoptions with child-welfare-agency involvement, and reductions in the number of children entering foster care. The Budget proposes to continue work on these priorities, while also identifying new areas for action, such as maternal and rural health.

The Budget proposes $94.5 billion in discretionary budget authority and $1.3 trillion in mandatory funding. Within our discretionary programs, it prioritizes funding for programs that have demonstrated effectiveness, proposes to end programs that have not, and focuses on direct services provided to the American people. On mandatory spending, the Budget proposes commonsense reforms that will pave a path to fiscal sustainability and make these important programs work better for the people they serve.

FACILITATE PATIENT-CENTERED CARE

Providing Price and Quality Transparency

President Trump's Executive Order on *Improving Price and Quality Transparency in American Healthcare to Put Patients First* directs HHS to make healthcare prices transparent, laying the foundation for a patient-driven and value-based health system. HHS has acted swiftly to require hospitals to publish the prices they negotiate with insurers and is working to do the same for issuers, so patients can understand their own out-of-pocket costs. CMS has also required Part D

prescription drug plans to develop tools that allow beneficiaries to determine plan benefits and formularies.

The Executive Order calls for the development of a Health Quality Roadmap that aligns and improves reporting on data and quality measures across Medicare, Medicaid, the Children's Health Insurance Program, and other Federal health programs. The Roadmap will include a strategy for establishing, adopting, and publishing common quality measures; aligning hospital inpatient and hospital outpatient measures; and eliminating low-value or counterproductive measures.

HHS legislative proposals increase price and quality transparency in Medicare. For instance, the Budget would eliminate coinsurance or copayments for a screening colonoscopy when a polyp is found, saving lives and supporting the President's policy to reduce out-of-pocket costs for this common procedure.

The Budget also invests funding in programs that promote transparency. The Budget requests $51 million for the Office of the National Coordinator for Health IT, which includes funding to develop, promote, and adopt common standards to integrate health information and product transparency while protecting privacy. In addition, the new National Institute for Research on Safety and Quality within the National Institutes of Health (NIH) supports the Administration's efforts to move healthcare organizations from volume to value by focusing on improving outcomes, reducing cost, and expanding choices for consumers. Research investments will focus on developing knowledge, tools, and data needed to improve the healthcare system.

Lowering the Cost of Prescription Drugs

The United States is first in the world in biopharmaceutical investment and innovation. But too often, this system has not put American patients first. We have access to the greatest medicines in the world, but access is meaningless without affordability. The Budget supports quick Congressional action to pass comprehensive legislation to address these flaws in our current drug pricing system and provide needed relief to the American people.

The Budget delivers on President Trump's promise to bring down the high cost of drugs and reduce out-of-pocket costs for American consumers by pursuing policies that align with the four pillars of the President's *American Patients First Blueprint*: increased competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs.

The Budget includes an allowance for bipartisan drug pricing proposals. The Administration supports legislative efforts to improve the Medicare Part D benefit by establishing an out-of-pocket maximum and reducing out-of-pocket costs for seniors. The Administration also supports changes to bring lower cost generic and biosimilar drugs to patients. These efforts would increase competition, reduce drug prices, and lower out of pocket costs for patients at the pharmacy counter.

The Budget includes an allowance for savings of $135 billion over ten years to support the President's commitment to lower the cost of prescription drugs.

Protecting and Improving Medicare for our Nation's Seniors

Over 60 million American seniors are in the Medicare program, and they are overwhelmingly satisfied with the care they receive through traditional Medicare and Medicare Advantage. The President is continuing to strengthen and improve these programs.

The Budget continues to implement the President's Executive Order on *Protecting and Improving Medicare for Our Nation's Seniors*, building on those aspects of the program that work well, while also introducing market-based approaches to Medicare reimbursement. The Administration seeks to protect and reform Medicare with proposals that strengthen fiscal sustainability and deliver value to patients. To drive reform, the Centers for Medicare & Medicaid Services (CMS) is modernizing the Medicare Advantage program, unleashing innovation, expanding telehealth options, and driving competition to improve quality among private Medicare health and drug plans. The Administration is expanding flexibility for these Medicare Advantage plans to maximize choices for seniors, and taking action to ensure fee-for-service Medicare is not promoted over Medicare Advantage.

President's Health Reform Vision Allowance

While Americans have the best healthcare options in the world, rising healthcare costs continue to be a top financial concern for many Americans. President Trump's Health Reform Vision will protect the most vulnerable, especially those with pre-existing conditions, and provide the affordability, choice, and control Americans want and the high-quality care that all Americans deserve.

The President's Health Reform Vision would build on efforts outlined in the Executive Order, "*Improving Price and Quality Transparency in American Healthcare To Put Patients First"* to provide greater transparency of healthcare costs and enshrine the right of a patient to know the cost of care before it is delivered. It focuses on lowering the price of medicine, ending surprise medical bills, breaking down barriers to choice and competition, and reducing unnecessary regulatory burdens. The Health Reform Vision will also prioritize Federal resources for the most vulnerable and provide assistance for low-income individuals. Medicaid reform will restore balance, flexibility, integrity, and accountability to the state-federal partnership. Medicaid spending will grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable.

The Budget includes savings of $844 billion over ten years for the President's Health Reform Vision Allowance.

Paying for Outcomes

The Administration is committed to advancing a personalized and affordable healthcare system that puts the patient at the center by ensuring Federal health programs produce quality outcomes and results at the lowest possible cost.

In part, this will be achieved by our continued focus on paying for outcomes rather than procedures. For instance, the Budget seeks to improve Medicare primary care services by ensuring payments more accurately reflect clinician time, resources, and outcomes. The Budget also implements a value-based purchasing program for hospital outpatient departments,

ambulatory surgical centers, and post-acute care facilities, offering incentives to improve quality and health outcomes. Finally, the Budget proposes a set of reforms that improve the physician experience and participation in the Quality Payment Program by eliminating reporting burdens for clinicians participating in the Merit-Based Incentive Payment System, CMS's largest value-based care payment program.

The Administration issued proposed rules to modernize key regulations that advance the movement to value-based care and paying for outcomes. Specifically, the Administration proposed reforms to the Anti-Kickback Statute, the Physician Self-Referral regulations (Stark Law), and 42 CFR Part 2. These proposed rules are part of HHS's Regulatory Sprint to Coordinated Care, which aims to reduce regulatory barriers and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination. These proposed rules reduce unnecessary regulatory burden on physicians and other healthcare providers while reinforcing their statutory intents of protecting patients from unnecessary services, and limiting fraud waste and abuse. This includes adding flexibilities with respect to outcomes-based payments and part-time arrangements. These rules would allow physicians and other healthcare providers and suppliers to design and enter into value-based arrangements that improve quality outcomes, produce health system efficiencies, and lower costs.

The CMS Center for Medicare and Medicaid Innovation (Innovation Center) launched a number of innovative payment and service delivery models to test ideas to shift our healthcare system toward payment for outcomes and health rather than sickness and procedures. This effort includes Direct Contracting and Primary Care First, a new suite of payment model options that will transform primary care to deliver better value for patients throughout the healthcare system. In addition, the Emergency Triage, Treat, and Transport Model provides greater flexibility to ambulance care teams to address emergency healthcare needs of Medicare beneficiaries following a 911 call, rather than delivering them to the hospital or emergency department for an unnecessary and expensive visit.

PROTECT LIFE AND LIVES

Combating the Opioid and Methamphetamine Crisis

In 2018, drug overdose deaths declined for the first time since 1990. A reduction in deaths from prescription opioid painkillers is almost entirely responsible for this decline. To maintain and build on this progress, HHS continues to advance the department's five-point strategy to:

- Improve access to prevention, treatment, and recovery services, including the full range of medication-assisted treatments;
- Better target the availability of overdose-reversing drugs;
- Strengthen our understanding of the crisis through better public health data and reporting;
- Provide support for cutting edge research on pain and addiction; and
- Improve pain management practices.

The Budget requests $5.2 billion to address the opioid overdose epidemic and methamphetamine use, including $169 million in new resources. Funding expands State Opioid Response grants in the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide treatment, recovery support services, and relapse prevention. The Budget provides funding to

the Health Resources and Services Administration (HRSA) for Addiction Medicine Fellowships to support approximately 60 fellows annually in underserved, community-based settings that integrate primary care with mental health and substance use disorder prevention and treatment services.

While opioids have been at the forefront of the drug landscape, the crisis continues to evolve and many public health experts believe we are entering into the fourth wave of the crisis, which is underscored by increases in overdose deaths involving cocaine and methamphetamine.

HHS is leveraging current efforts to address the opioid epidemic to combat the rising mortality and morbidity associated with methamphetamines and other stimulants. To allow flexibility to most effectively combat substance use in whatever form it takes, SAMHSA's State Opioid Response grant program has the flexibility to also address stimulants. HHS would direct $50 million within NIH for research to develop medication-assisted treatment and evidence-based psychosocial treatment for methamphetamines and other stimulants.

Ending the HIV Epidemic: A Plan for America

In the 2019 State of the Union, President Trump announced a bold new initiative to reduce new HIV infections by 75 percent in the next 5 years and by 90 percent in the next 10 years, averting more than 400,000 HIV infections in that time period. This initiative focuses on four key strategies:

- Diagnose all individuals with HIV as early as possible after infection;
- Treat the infection rapidly and effectively after diagnosis, achieving sustained viral suppression;
- Protect individuals at risk for HIV using proven prevention approaches; and
- Respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.

The Budget invests $716 million in dedicated funding for the second year of the *Ending the HIV Epidemic: A Plan for America* initiative, an increase of $450 million from FY 2020. This funding expands activities in the 57 target jurisdictions to increase HIV testing and access to prevention and treatment services.

With $371 million, the Centers for Disease Control and Prevention (CDC) transitions from planning to implementation and intensifies work begun in FY 2020 in the 57 target jurisdictions. CDC grants to affected communities will drive additional testing with the goal in the second year of doubling the number of new HIV diagnoses rapidly treated with antiretroviral therapy to maintain health and prevent additional HIV transmissions. Funded jurisdictions will use pharmacy data, telehealth, mobile testing, and new science-based networks to ensure individuals enter and adhere to care.

With $302 million, HRSA expands HIV prevention services to all community health centers in the targeted initiative areas and serves 28,000 additional HIV positive people through the Ryan White Program. HHS also requests $27 million for the Indian Health Service (IHS) to enhance HIV testing and linkages to care for American Indians and Alaska Natives.

NIH directs $16 million to leverage pilot data from 17 Centers for AIDS Research to design and evaluate effective, sustainable systems to implement HIV prevention and treatment interventions and rapidly implement strategies at scale that will be most effective.

These investments build on ongoing HIV activities supported across the Department and an announcement in 2019 to make pre-exposure prophylaxis medication available free of charge for up to 200,000 uninsured individuals each year for up to 11 years. The donation by Gilead Sciences, in partnership with HHS, will help reduce the risk of HIV infections, particularly for individuals that may be at the highest risk.

Improving Maternal Health

Approximately 700 women die each year in the United States from pregnancy-related complications and more than 60 percent of these deaths are preventable. In fact, women in the United States have higher rates of maternal mortality and morbidity than in any other industrialized nation – and the rates are rising. In addition to rising mortality rates, severe maternal morbidity affects more than 50,000 women and adds significant costs to the healthcare system.

Cardiovascular disease is now the leading cause of death in pregnancy and the postpartum period, constituting nearly 30 percent of pregnancy-related deaths. Chronic hypertension – which is diagnosed or present before pregnancy or before 20 weeks gestation – may result in significant maternal, fetal, and neonatal morbidity and mortality. The rate of chronic hypertension increased by 67 percent from 2000 to 2009, with the largest increase (87 percent) among African American women. CDC points to hypertensive disorders, cerebrovascular accidents, and other cardiovascular conditions as some of the leading causes of maternal deaths, all potentially preventable conditions. It is imperative to identify risk factors prior to pregnancy in order to prevent poor pregnancy and postpartum outcomes.

HHS's *Improving Maternal Health in America* initiative is addressing this significant public health problem. This initiative focuses on four strategic goals:

- Achieve healthy outcomes for all women of reproductive age by improving prevention and treatment;
- Achieve healthy pregnancies and births by prioritizing quality improvement;
- Achieve healthy futures by optimizing postpartum health; and
- Improve data and bolster research to inform future interventions.

The Budget provides a total of $116 million for this initiative across the National Institute for Research on Safety and Quality (NIRSQ), CDC, HRSA, and IHS. This includes $7 million for NIRSQ to improve service data, advance data evaluation, and expand medical expenditure surveys to ensure policy makers have timely and accurate data. The Budget also invests $24 million in CDC to expand the Maternal Mortality Review Committees to all 50 states and D.C. to ensure every case of pregnancy-related death is examined. The Budget provides $80 million in HRSA to improve the quality of maternal health services, expand access to care, and reduce disparities in care. The Budget invests $5 million in IHS to help improve health outcomes by standardizing care, increasing cultural awareness, and improving care for pregnant women.

Advancing American Kidney Health

Today's status quo in kidney care carries a tremendous financial cost. In 2016, Medicare fee-for-service spent approximately $114 billion to cover people with kidney disease, representing more than one in five dollars spent by the traditional Medicare program. In July 2019, the President signed an Executive Order launching an initiative to transform care for the estimated 37 million Americans with kidney disease. The *Advancing American Kidney Health* initiative tackles the challenges people living with kidney disease face across the stages of kidney disease, while also improving the lives of patients, their caregivers, and family members.

The Budget includes $39 million across multiple HHS agencies and requests new legislative authority in support of the initiative's three goals:

- Reduce the number of Americans developing End-Stage Renal Disease (ESRD) by 25 percent by 2030.
- Have 80 percent of new ESRD patients in 2025 receive dialysis at home or a transplant.
- Double the number of kidneys available for transplant by 2030.

This funding also supports transplantation activities for other organs.

To achieve these goals, HHS is scaling programs nationwide to optimize screening for kidney disease and educate patients on care options. HHS is also supporting innovation and groundbreaking research to inform the next generation of targeted therapies and accelerate development of innovative products such as an artificial kidney. New and pioneering payment models are also being developed to increase both value and quality of care for the patient.

The Budget also targets new funding towards HRSA's Organ Transplantation Program to remove financial disincentives for living organ donors. The Budget invests $31 million in HRSA for the Organ Transplantation program, including $18.3 million for the Organ Procurement Transplantation Network, Scientific Registry of Transplant Recipients, and public and professional education efforts to increase public awareness about the need for organ donation. In addition, the proposed rule to increase accountability and availability of the organ supply – announced in December 2019 – would improve the donation and transplantation rate measures, incentivize Organ Procurement Organizations (OPOs) to ensure all viable organs are transplanted, and hold OPOs to greater oversight, transparency, and accountability while driving higher OPO performance.

HHS is working to accelerate innovation in the prevention, diagnosis, and treatment of kidney disease through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between HHS and the American Society of Nephrology. The HHS Office of the Chief Technology Officer will continue the KidneyX competition in FY 2021 by challenging individuals, teams, and companies to build and test prototype solutions, or components of solutions, that can replicate normal kidney functions or improve dialysis access.

The Budget proposes to establish a new program within the Office of the Assistant Secretary for Preparedness and Response (ASPR) that will advance kidney health. The Preparedness and Response Innovation program will support advanced research and development, prototyping and

procurement of revolutionary health security products, technologies and other innovations. The program's first project will focus on portable dialysis equipment for emergency response. This will ensure that individuals with kidney failure have access to dialysis during a disaster.

The Budget also advances legislative proposals to revolutionize the way patients with chronic kidney disease and kidney failure are diagnosed, treated, and supported. This effort includes extensions of both the NIH Special Diabetes Program and IHS Special Diabetes Program for Indians to address chronic conditions, such as diabetes, that can lead to kidney disease.

For patients who lose Medicare coverage at 36 months post-transplant and who do not have another source of healthcare coverage, the costs of continuing immunosuppressive drug therapy may be prohibitive. Without these drugs, the patient's body rejects the transplant, reverts to kidney failure, and requires dialysis. To prevent transplant rejection and reversion to dialysis, the Budget proposes to establish a new federal program that provides lifetime coverage of immunosuppressive drugs for certain kidney transplant recipients until they are otherwise eligible for Medicare coverage. The Budget also proposes to increase competition among, and oversight over, Organ Procurement Organizations to improve performance and increase the supply of organs for transplant. In addition, the Budget advances new innovative kidney care payment models to encourage home dialysis, increase access to kidney transplants, and incentivize clinicians to better manage care for patients with kidney disease.

Transforming Rural Health

There are 57 million Americans living in rural communities. Rural Americans face many unique health challenges, including hospitals that are closing or in danger of closing; difficulty recruiting and retaining physicians, nurses, and other providers; and increased likelihood of dying from many leading causes of avoidable death such as cancer and heart disease.

HHS's *4-Point Strategy to Transform Rural Health* builds on current HHS initiatives in the following areas:

- Build a Sustainable Health Model for Rural Communities;
- Leverage Technology and Innovation;
- Focus on Preventing Disease and Mortality; and
- Increase Rural Access to Healthcare.

The Budget supports rural communities through programs such as the Rural Communities Opioids Response Program and the Telehealth Network Grant Program at HRSA, which supports substance use prevention, treatment, and recovery services, and promotes telehealth technologies for healthcare delivery in rural communities. Project AWARE (Advancing Wellness and Resiliency in Education) will increase mental health awareness training in rural communities. In response to American Indian and Alaska Native communities' demand for telebehavioral services, IHS expands the Telebehavioral Health Center of Excellence with funding for new space, updated equipment, and additional behavioral health providers.

Telehealth services strive to make rural health programs more effective, increase the quality of healthcare, and improve health outcomes. The Budget seeks to remove barriers to telehealth services in rural and underserved areas through a proposal to expand telehealth services in

Medicare fee-for-service advanced payments models with more than nominal financial risk. This proposal broadens beneficiary access to Medicare telehealth services and addresses longstanding stakeholder concerns that the current statutory restrictions hinder beneficiary access. The proposal expands the telehealth benefit in Medicare Fee-for-Service and provides authority for Rural Health Clinics and Federally Qualified Health Centers to be distant site providers for Medicare telehealth services. It also permits IHS and tribal facilities to be originating and distant site providers, even if the facility does not meet the requirements for being located in certain rural or shortage areas, and allows for coverage across state lines. The Budget also proposes to modernize payments to Rural Health Clinics to ensure equitable payment for these health clinics and help rural communities maintain access to these crucial services. Finally, the Budget proposes to allow Critical Access Hospitals to voluntarily convert to an emergency hospital that does not maintain inpatient beds.

Addressing Tick-borne Diseases

Tick-borne diseases, of which Lyme Disease is the most common, account for 80 percent of all reported vector-borne disease cases each year and represent an important emerging public health threat in the United States. With 59,349 reported cases in 2017, the annual number of reported cases has more than tripled over the last 20 years; due to under-reporting, this number substantially under-represents actual disease occurrence. The geographic ranges of ticks are also expanding, which leads to increased risk for human exposure to the bites of infected ticks. Most humans are infected through bites from very small young ticks, hosted by deer or mice.

To address critical gaps in knowledge, diagnostics, and preventive measures for tick-borne diseases, HHS is proposing an action plan that will prioritize and advance the most promising candidates and technologies for diagnosing and preventing Lyme and other tick-borne diseases. This plan, led by the Office of the Assistant Secretary for Health in partnership with NIH, CDC, and FDA, will address four primary areas: innovations in diagnosis and advanced detection, developing vaccine-based prevention, ensuring robust domestic surveillance of vector borne diseases, and providing additional knowledge to advance the best treatment and prevention options. These efforts will improve outcomes for those affected by Lyme Disease symptoms. This plan builds on the Kay Hagan Tick Act, enacted through the Consolidated Appropriations Act for 2020, to improve research, prevention, diagnostics, and treatment for tick-borne diseases.

The Budget requests $189 million, an increase of $58 million, to address tick-borne diseases. This amount includes $115 million for NIH to expand its research on of tick-borne disease, including in the prevention, diagnosis, and treatment; and $66 million for CDC to address vector-borne diseases, focusing on tick-borne diseases, including tick surveillance, insecticide resistance activities, and development of improved diagnostics. FDA will ensure the safety and efficacy of products developed to prevent, diagnose, and treat vector-borne diseases.

Focusing on Influenza

Influenza is a serious disease that can lead to hospitalization and sometimes death, even among healthy people. In the United States, millions of people are sickened, hundreds of thousands are hospitalized, and tens of thousands die from influenza every year. In September 2019, the President signed Executive Order 13887, *Modernizing Influenza Vaccines in the United States to*

Promote National Security and Public Health. The Executive Order recognized influenza as a public health threat and national security priority, and directed HHS to prepare and protect the nation.

The Budget invests $998 million to continue on-going influenza activities as well as targeted increases to support this directive. This amount includes $306 million for ASPR to modernize influenza vaccine manufacturing infrastructure and advance medical countermeasure research and development. Activities include additional clinical studies on licensure of pre-pandemic recombinant-based influenza vaccine and the advanced development of novel diagnostics, respiratory protective devices, and alternative vaccine delivery technology. The Budget also funds the Office of Global Affairs to support US leadership of international efforts on pandemic influenza preparedness.

The Budget requests $216 million for CDC's Influenza program, an increase of $40 million. CDC will expand influenza vaccine effectiveness monitoring systems and develop and characterize candidate vaccine viruses for vaccine manufacturers, and efforts to improve the evidence-base on non-egg-based vaccines. CDC will support whole genome characterization of more than 10,000 influenza viruses. All of these activities help build domestic capacity. CDC will also increase influenza vaccine use by removing barriers to vaccination and enhance communication to healthcare providers about the performance of influenza vaccines.

The Executive Order also calls for the development of novel technologies to speed seed vaccine development, targeted development of vaccines that protect against multiple types of virus for multiple years, and to improve adjuvants. In support of this goal, the Budget includes $49 million for FDA to support regulatory science research and clinical assessments to promote development and access to safe and effective influenza vaccines, and $423 million for NIH to accelerate influenza research, including universal flu vaccine development.

Emergency Preparedness

HHS plays a key role in supporting domestic and international preparedness and response to ensure our nation's safety. The Budget invests $2.6 billion in ASPR to expand efforts to prevent, prepare for, respond to, and recover from, the adverse health effects of public health emergencies. This amount includes $562 million for the Biomedical Advanced Research and Development Authority to maintain a robust pipeline of innovative medical countermeasures that mitigate health effects of infectious diseases and chemical, biological, radiological, and nuclear agents. It also includes $535 million for Project BioShield to support procurement of medical countermeasures against these threats, and $705 million for the Strategic National Stockpile to sustain and increase inventory of high-priority countermeasures such as antibiotics to treat anthrax exposure and vaccine to prevent smallpox. These investments will help HHS advance progress towards national preparedness goals.

NIH supports a robust research portfolio to develop vaccines and therapeutics that enable rapid response to public health threats including emerging microbial threats, such as extensively drug-resistant tuberculosis, emerging viral strains such as Zika, and viral hemorrhagic fevers such as Ebola. The Budget continues investments in NIH in scientific research on these new threats, and

invests $120 million in FDA to facilitate medical countermeasure development and availability to respond in the event of a microbial or other public health threat.

Strengthening the Indian Health Service

The Administration is committed to improving the health and well-being of American Indians and Alaska Natives. This population continues to experience significant health disparities, and the Budget includes key investments to ensure quality of care. The Budget invests $6.2 billion in IHS, which includes $125 million for electronic health record modernization, provides funding to support IHS Services, Ending the HIV Epidemic, and Maternal Health, and includes $125 million for high-priority healthcare facilities construction projects. The Budget proposes a new, indefinite discretionary appropriation and reforms for IHS to address Indian Self-Determination and Education Assistance Act section 105(*l*) lease costs.

Reforming Oversight of Tobacco Products

The Budget proposes to move the Center for Tobacco Products out of FDA and create a new agency within HHS to focus on tobacco regulation. A new agency with a mission focused on tobacco and its impact on public health would have greater capacity to respond rapidly to the growing complexity of new tobacco products. Additionally, this reorganization will allow the FDA Commissioner to focus on its traditional mission of ensuring the safety of our nation's drug, food, and medical products supply.

Providing Shelter and Services for Unaccompanied Alien Children

The Administration for Children and Families (ACF) provides shelter, care, and support for unaccompanied alien children apprehended by the Department of Homeland Security or other Federal Government department or agency. The number of unaccompanied alien children requiring care is inherently unpredictable. In FY 2019, ACF cared for 69,488 children, the highest number in the program's history. To ensure adequate shelter capacity and care in FY 2021, the Budget requests a total of $2 billion in discretionary funds to support capacity of 16,000 licensed permanent beds, depending on operational needs, and includes a mandatory contingency fund to provide up to $2 billion in additional resources if needed.

PROMOTE INDEPENDENCE

Promoting Upward Mobility

In the human services work at HHS, the overarching goal is to promote personal responsibility, independence, and self-sufficiency—to help Americans lead flourishing, fulfilling, independent lives. HHS programs for low-income Americans achieve this goal by supporting work, marriage, and family life. HHS seeks to better align our social safety net programs with the booming economy, and focus on work as the means to lift families out of poverty.

Many Americans are joining the workforce as the Administration's policies continue to strengthen the economy and produce historically low unemployment rates. The Administration supports working families by investing in child care, an important work support that helps families achieve independence and self-sufficiency. The Administration is working to implement policies that increase access to high-quality, affordable child care.

The Budget proposes to improve the Temporary Assistance for Needy Families (TANF) program by restoring its focus on employment and work preparation, and by targeting funds to low-income families. The proposal fundamentally changes the way the program measures success by moving to measures that focus on employment outcomes, phasing out the ineffective work participation rate. In addition, the Budget establishes Opportunity and Economic Mobility Demonstrations that allow for the streamlining of funding from multiple safety net programs to deliver coordinated and effective services. The Budget also seeks to improve consistency between work requirements in TANF and Medicaid by requiring that able-bodied individuals participate in work activities at least 20 hours per week in order to receive welfare benefits.

Supporting Child Care

Child care is an investment in both present and future generations of the workforce. However, it is also one of the biggest expenses for families and can be a barrier to work. Funding plays a critical role in helping families achieve self-sufficiency by providing parents access to a range of child care options. In FY 2018, the most recent year for which preliminary data are available, over 1.3 million children from about 813,000 low-income families received a monthly child care subsidy from the Child Care and Development Fund. The Budget provides $5.8 billion for the Child Care and Development Block Grant and $4.2 billion in mandatory child care funding for a total investment of $10.0 billion in child care. The mandatory funding includes a one-time $1 billion fund for competitive grants to states to increase child care services for underserved populations and stimulate employer investment in child care. The Budget will serve 1.9 million children.

Promoting Adoption

Adoption gives children stability and love during their childhood, and also a safe and stable environment in which to grow into responsible adults who flourish. Approximately 20,000 youth exit or "age out" of foster care each year without the safety net of a forever family, and their outcomes are often concerning. A longitudinal study found that only 58 percent graduated from high school, and only half found employment by age 24. More than a third of youth in one study had experienced homelessness at least once by age 26. Children and young adults in foster care cannot be expected to achieve the independence they need to thrive and flourish on their own—but finding them a loving forever family could change all that.

According to ACF, the number of children adopted with help from public child welfare agencies rose from 59,000 in FY 2017 to more than 63,000 in FY 2018. To sustain this momentum, ACF has launched a Call to Action for states and other stakeholders, which aims to develop and sustain key partnerships across public and private groups, including faith-based groups, with the goal of reducing the number of children in foster care and increasing the number of children who find a forever family, through adoption or otherwise.

The Adoption Assistance and Guardianship Assistance programs will provide $4.1 billion in FY 2021 in mandatory funding to provide monthly support payments to families adopting sibling

groups or other children with special needs. Under existing law, Adoption Assistance funding will keep pace with the number of qualifying children adopted each year.

HHS promotes adoption through administrative actions and funding incentives to promote adoption, and to identify and address barriers to adoption. Initiatives include family-finding programs, focusing on identifying the barriers that exist in the recruitment and development of foster and adoptive families, and the development and dissemination of court-related practice improvements addressing barriers to timely adoptions.

Supporting Families and Preventing the Need for Foster Care

Helping families receive the care and services they need before the involvement of a child welfare agency can help prevent a child from entering foster care. The Administration has focused on primary prevention, as well as adoption, and we are starting to see better results. HHS is implementing the Family First Prevention Services Act (Family First Act), which supports services to prevent child maltreatment and the need for foster care. This groundbreaking new legislation provides the opportunity for substantial improvements in outcomes for children and families. The Budget proposes to streamline the process for evaluating evidence-based prevention services programs under the Family First Act to give states and tribes access to more programs that help prevent the need for foster care and assist kinship caregivers.

The Budget invests $510 million for discretionary child welfare activities in ACF, including services that allow children to remain safely with their families and education and training vouchers for youth aging out of foster care. In collaboration with CMS, the Budget proposes that Qualified Residential Treatment Programs (QRTPs) be exempted from the institution for mental diseases (IMD) payment exclusion allowing children in foster care to have Medicaid coverage in these placements even if a QRTP qualifies as an IMD.

The Budget provides $197 million to ACF for child abuse prevention grants. These grants support increased use of evidence-based prevention programs, allowing states to explore new research opportunities and to adapt more rigorous evaluations of existing programs; demonstration projects to test the effectiveness of partnerships that strengthen family capacity and prevent child abuse through the co-location of services; and state plans for safe care of infants affected by substance use disorders.

The Budget also proposes to expand the Regional Partnership Grant program by $40 million each year, which will increase funding for grants that help courts, child welfare agencies, and other government and community entities work together and improve practices to address the impact of substance abuse, including opioids, on child welfare. The Budget proposes an increase of $30 million each year for the Court Improvement Program to help courts improve practices and comply with new mandates in the Family First Act.

Strengthening Efforts to Treat Serious Mental Illness and Serious Emotional Disturbances
In 2018, more than 11 million adults in the U.S. were living with a serious mental illness. More than 7 million children and youth experienced a serious emotional disturbance. They faced a greater risk of suicide and life expectancy 10 years shorter than the general population.

The Budget provides $1.1 billion to SAMHSA for serious mental illness and serious emotional disturbances, which includes funding to support Assertive Community Treatment for Individuals with Serious Mental Illness, Community Mental Health Services Block Grant, and Children's Mental Health Services. These programs provide comprehensive and coordinated mental health services for some of the nation's most vulnerable populations and increases access to mental health services in schools. The Budget will also provide targeted flexibility for states to provide inpatient mental health services to Medicaid beneficiaries with serious mental illness.

The Budget also invests in programs that address the nation's alarming rates of suicide. Suicide is the 10th leading cause of death in the United States – responsible for more than 47,000 deaths in 2017 – and suicide rates have increased steadily for individuals of all ages. The Budget provides $93 million for suicide prevention activities, including additional funding to expand Zero Suicide initiatives to focus on adult suicide prevention and allow communities and states to tailor strategies to prevent suicide in their local jurisdictions.

Supporting Independence for Older Adults and People with Disabilities
The Administration prioritizes community living for older adults and people with disabilities to ensure that they can maintain independence and live fully integrated in their communities. The Budget invests $1.5 billion in the Administration for Community Living for critical direct services that enable seniors and people with disabilities to live independently, such as senior meals, in-home chore assistance, independent living skills training, employment training, and information and referral services. These programs empower older adults and people with disabilities to live independently and make critical choices about their own lives.

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

HHS is responsible for more than one-quarter of total federal outlays. The Department administers more grant dollars than all other federal agencies combined. HHS is committed to responsible stewardship of taxpayer dollars, and the Budget continues to support key reforms that improve the efficiency of Departmental operations.

Advancing Fiscal Stewardship
The Administration recognizes its immense responsibility to manage taxpayer dollars wisely. HHS ensures the integrity of all its financial transactions by leveraging financial management expertise, implementing strong business processes, and effectively managing risk.

As the Department overseeing Medicare and Medicaid, HHS is committed to exercising proper oversight of these programs to protect the millions of impacted beneficiaries and the taxpayers in general. In accordance with the direction in the Executive Order on *Improving and Protecting*

Medicare, HHS is investing in the newest technological advancements, such as Artificial Intelligence, to enhance our ability to detect and prevent fraud, waste, and abuse.

The Department is committed to reducing improper payments in Medicare, Medicaid, and Children's Health Insurance Program (CHIP). HHS continues to enhance existing program integrity tools to address improper payments and prevent fraud, including provider screening, prior authorization, and auditing providers and plans. New methods and technologies will allow HHS oversight to reduce improper payments and adapt to the changes in healthcare as we shift from a fee-for-service to a value-based healthcare payment system.

The Budget advances new legislative and administrative proposals to strengthen the Department's ability to address weaknesses in Medicaid beneficiary eligibility determination processes, while providing tools to facilitate the recovery of overpayments made by states. HHS also continues to support updates to Medicaid information systems that offer critical support to program integrity efforts, including the Transformed Medicaid Statistical Information System (T-MSIS) and a new Medicaid drug rebate system. In addition, HHS includes proposals that enhance oversight of Medicare Advantage and Part D plans, increase the period of enhanced oversight on new providers, and expand Medicare fee-for-service prior authorization.

Implementing ReImagine HHS

HHS supports the President's Management Agenda through *ReImagine HHS*, the Department's robust reform and transformation effort, organized around core goals to streamline processes, reduce burden, and realize cost savings. The effort takes an enterprise approach, affecting activities across the Department. For example, the Buy Smarter initiative plans to use new and emerging technologies to leverage the enormous purchasing power of HHS and streamline the end-to-end procurement process. The Maximize Talent initiative addresses modern-day human capital management and human resources operational challenges, resulting in key achievements: HHS's simplified recruitment process resulted in a significant increase in the number of new hires on-boarded since implementation, and HHS was rated the "Best Place to Work in the Federal Government" out of all executive departments in 2019. As part of the Bring Common Sense to Food Regulation initiative, FDA is working to increase collaboration between food regulatory programs to minimize dual jurisdiction and improve state product safety. As a result, 48 states and territories participate in the Produce Safety Implementation Cooperative Agreement Program, which increased state large farm inspections over 400 percent in FY 2019.

ReImagine HHS efforts are also making HHS more innovative and responsive. Under the Optimizing Regional Performance initiative, HHS developed a Regional Facilities Utilization Model with $150 million in potential savings and a footprint reduction of more than 62 percent within ten years. For the first time since 1974, HHS completed a comprehensive assessment of regions to better align with Administration priorities and improve HHS's ability to serve Americans across the country. In addition, under the Optimize Coordination Across HHS initiative, HHS configured a new cloud environment for an administrative data hub to provide dashboarding capabilities for Operating Divisions, bringing together human resources, travel, and facilities data to inform better decision-making across the enterprise.

In FY 2021, all *ReImagine HHS* projects will reside in their permanent offices within HHS. This ensures that their work can sustainably continue going forward.

Grants Management

HHS continues to drive change for grants management government-wide. Leveraging the efforts and success of the HHS ReImagine Grants Management initiative. The Office of Management and Budget pre-designated HHS as the Grants Quality Services Management Office (QSMO) to create and manage a marketplace of solutions for grants management; govern its long-term sustainability; institute a customer engagement model; and drive the implementation of standards and solutions to modernize grants management processes and systems. Guided by a government-wide governance board, QSMOs are tasked with offering solutions that, over time, will improve quality of service and customer satisfaction; modernize and automate processes and supporting technology; standardize processes and data; and achieve efficiencies in government-wide operations and maintenance.

In FY 2018, the government awarded over $750 billion in grants to approximately 40,000 recipients across more than 1,500 programs.

Full designation as the Grants QSMO is contingent upon approval of a 5-Year Implementation Plan and budget estimate in alignment with the published QSMO Long-term Designation Criteria. HHS is developing a vision and strategy to inform the Grants QSMO 5-Year Implementation Plan, with significant engagement with stakeholders to ensure the Grants QSMO can meet their diverse needs.

Regulatory Reduction

HHS is committed to streamlining the regulatory process and evaluating necessary steps to eliminate or change regulations that impose unnecessary burden. Burdensome regulations can drive up costs of healthcare, while poorly designed regulations can come between doctors and patients, reducing the quality of care and the essential trust to that relationship. From FY 2017 to FY 2019, HHS succeeded in cutting the economic burden of its regulations by $25.7 billion through 46 deregulatory actions. HHS had the largest deregulatory impact of any Cabinet agency during this time period.

HHS is using the power of new cognitive technologies for greater operational effectiveness and research insights, including regulatory reduction. HHS used an Artificial Intelligence-driven regulation analysis tool and expert insight to analyze the Code of Federal Regulations, seeking potential opportunities to modernize regulations. HHS since launched a Department-wide Regulatory Clean-Up Initiative to implement changes based on these findings, by reviewing and – where a change is warranted – addressing incorrect citations and eliminating the submission of triplicate or quadruplicate of the same citation.

HHS is working to implement the provisions of the Executive Order on *Promoting the Rule of Law through Improved Agency Guidance Documents*. This Executive Order will accomplish important policy goals that will improve HHS guidance practices in the long term. Prior to the issuance of this Executive Order, several Federal agencies issued internal memoranda regarding the appropriate use of guidance. The Executive Order requires agencies to now go a step further

and codify certain good guidance practices and policies into Federal regulations. By August 27, 2020, each agency must finalize regulations to set forth processes and procedures for issuing guidance documents. In addition, by February 28, 2020, Federal agencies must establish a single, searchable database on its website that contains, or links to, all of the agency's guidance documents currently in effect. Any guidance document not included in the guidance website is deemed rescinded. HHS is committed to meeting the President's timelines.

Ms. ESHOO. Thank you, Mr. Secretary.

And we will now move to member questions. And I will recognize myself for 4 minutes, which will be the limit for questions to the Secretary.

Mr. Secretary, we know that on February 24, the Acting Director of OMB—what was requested, the appropriation of $1.25 billion for emergency funding for the virus. Is that what you requested of OMB?

Secretary AZAR. So the actual total supplemental authorization would be $2.5 billion. We proposed——

Ms. ESHOO. That I know, but——

Secretary AZAR [continue]. Half of that to be covered——

Ms. ESHOO [continue]. The new funding is 1.25.

Secretary AZAR. I do want to emphasize, as I have told the appropriators, that was meant as a suggestion of a way to fund half of it. But if Congress decides there are other approaches, we are not wed to that.

Ms. ESHOO. And what exactly does that cover? And is it anticipatory?

Now, yesterday, the CDC said we need to be prepared—essentially, we need to be prepared for a much larger spread of this virus in the United States. So is what has been requested in emergency funding to cover a broader plan, or is it on the figures that you just gave us?

Secretary AZAR. So it is to cover expenses that we believe are appropriate for 2020. So this would go through the end of 2020's fiscal year. And then we would work with appropriators on any adjustments to 2021 appropriations in the weeks and months ahead as we continue to learn on a daily basis about the spread of the disease.

Core investments. First, surveillance, expanding our surveillance system for novel——

Ms. ESHOO. Yes. I have some other questions, so——

Secretary AZAR. Oh, sure. But——

Ms. ESHOO. All right.

Secretary AZAR [continue]. I am happy to walk you through the five key basic——

Ms. ESHOO. And I read the entirety of your printed statement.

I want to turn to the status of drug pricing policy proposals. If you could just say "yes" or "no," it would be great.

Have you finalized a policy ending drug rebates to middlemen in Medicare?

Secretary AZAR. We did not move finally with that rule.

Ms. ESHOO. OK.

Have you finalized a policy tying drug prices to the lower costs, the reference pricing?

Secretary AZAR. We had an advance notice of proposed rulemaking, so that was not an actual formal proposal yet.

Ms. ESHOO. All right.

Have you finalized a proposal to make drug manufacturers put list prices in television advertisements?

Secretary AZAR. We did. And much to their shame, the pharma industry sued. And Congress has not passed explicit authorization

for that list price requirement in the statute that I wish they would do.

Ms. ESHOO. Are you planning to finalize or pursue any of these policies in the near future?

Secretary AZAR. We plan to finalize as soon as we can the importation program implementing section 804 of the Food, Drug, and Cosmetic Act to allow low-cost importation from Canada.

Ms. ESHOO. You know that the House passed H.R. 3. You also know that the President said that we are going to "negotiate, negotiate, negotiate so hard," or something like that. "We are going to negotiate like crazy." Do you support direct negotiations?

Secretary AZAR. We do not support H.R. 3 because we don't believe the negotiation framework in there is either a negotiation or actually practical and implementable. And it also just has no chance of passing in the Senate. The bipartisan package of Grassley-Wyden is struggling even to get to the floor there.

Ms. ESHOO. Well, H.R. 3 caps out-of-pocket, as you know, prescription costs for seniors. Do you support the capping of out-of-pocket costs for them?

Secretary AZAR. We have an important opportunity here——

Ms. ESHOO. Yes or no?

Secretary AZAR [continue]. Bipartisan——

Ms. ESHOO. Yes or no?

Secretary AZAR [continue]. To cap out-of-pocket spending and reduce what seniors——

Ms. ESHOO. Yes or no?

Secretary AZAR [continue]. Are you paying for Part D. So, yes, we do.

Ms. ESHOO. OK. Good.

Well, I think that I have asked all—let me just—well, H.R. 3 also limits drug price hikes to inflation. Do you support the inflation caps?

Secretary AZAR. So that is part of the Grassley-Wyden package also in the Senate, and we——

Ms. ESHOO. Do you support it?

Secretary AZAR [continue]. Have made clear that that is a package we can support it. It is not the only bipartisan package, but the price inflation penalties in Part D and B are acceptable to us as a means of getting list prices under control.

Ms. ESHOO. Thank you.

My time has expired. I now would like to recognize the ranking member of the subcommittee for his 4 minutes of questions.

Mr. BURGESS. Thank you.

Mr. Secretary, in December of 2018, the President signed two important bills into law that addressed maternal health and maternal mortality. The first bill, Representative Jaime Herrera Beutler's Preventing Maternal Deaths Act, established a grant program for States to establish or expand maternal mortality review committees. The other bill, Improving Access to Maternity Care Act, required HRSA to identify maternity care health professional target areas.

So how have you used these bills? How is your agency building on the success of those two laws to ensure access to quality maternity care and prevent maternal mortality?

Secretary AZAR. First, could I thank you for your leadership on immunosuppressive drugs? I hope you saw that we put in the budget what you have long advocated for in terms of that coverage.

On this——

Mr. BURGESS. Yes. Yes, you may say thank you. You are welcome.

Secretary AZAR. And on maternal mortality also, the work of Congress really focusing on this critical issue. Too many women are dying either in childbirth, preterm, at childbirth, or postpartum. And so we have made this a serious part of the President's agenda, with a $116 million initiative, with the $74 million increase, that focused on improving prevention, quality improvement, postpartum health, and improving the data collection on that, so a four-part strategy that we look forward to working with Congress on coming out of the budget.

Mr. BURGESS. Well, I thank you for that.

You know, Republicans on this subcommittee in 2017 sent your predecessor, Secretary Price, a letter asking for HHS to update and release the Pandemic Flu (Influenza) Plan. And it previously had not been updated since 2005.

Can you describe how you are using the Pandemic Influenza Plan as a guide in preparing for your response to this current outbreak of the coronavirus?

Secretary AZAR. So, as you know, I was one of the architects of the original pandemic plans back in the Bush administration. That work is foundational. That is what has set up our entire State, local, and Federal preparedness program for any type of viral outbreak like this.

And so it is really the blueprint for how we are operating today, including my role, leading through the Emergency Support Function 8 under the National Response Plan, which is the doctrine that we have had in place now for 15 years.

Mr. BURGESS. Let me just say, this committee did do work on H.R. 3 last October. There was concern from many of us that the negative effects on innovation and development would really be profound. And now we find ourselves confronted with this coronavirus outbreak, where we know we need new antivirals, we know we need new vaccines, we know we need new monoclonal antibodies to help people who become ill.

Can you just speak to the fact of, is innovation still important? Because we have heard several times in this subcommittee and in the full committee that maybe innovation wasn't so important as getting cheaper drugs into people's hands.

Secretary AZAR. Innovation is vitally important, and that is why two of the key legs of the supplemental request are to develop vaccines and therapeutics for this novel virus.

One of the challenges with H.R. 3 is the sheer amount of money it would pull out of the system. And I am not a believer that if you pull any money out of the drug industry——

Mr. BURGESS. Right.

Secretary AZAR [continue]. It is catastrophic or impossible. But the sheer amount would materially impact the bringing forward of drug therapies for Alzheimer's, for arthritis—just go through the list of therapies that you need to incent, or you won't get them.

Mr. BURGESS. Yes. And, you know, interestingly enough, the Alzheimer's drug that was withdrawn a year ago, I am reading, is now getting a new look at different dosing schedules. And, again, work like that, that is not going to happen if we don't value innovation.

Mr. Secretary, I thank you for being here and certainly look forward to the second part of this hearing.

I yield back.

Ms. ESHOO. The BARDA biodefense budget has also been cut.

Now, glad to recognize the chairman of the full committee for his 4 minutes of questions.

Mr. PALLONE. Thank you, Chairwoman Eshoo.

Mr. Secretary, I thank you for appearing before our subcommittee today. But I continue to be upset by the Trump administration's decision to ask the court to strike down the ACA in the Republican lawsuit that is seeking to declare the entire law invalid.

If the district court ruling is upheld, then the Trump administration will be responsible for the largest coverage loss in U.S. history. Over 20 million Americans would lose their coverage, raising consumer costs and making lifesaving healthcare unaffordable for American families. And it would eliminate protections for preexisting conditions, adversely impact the Medicare program, and end Medicaid expansion.

So I have sent you three letters now, including one in April of last year, requesting any analysis, study, assessment, or reports regarding the potential impact if the entire ACA is found to be unconstitutional. And for almost two years now, I have repeatedly asked for any documents relating to any contingency plans in place in the event the ACA is found unconstitutional.

Only last week, I received a 1- and 1.5-page response that answers none of my questions, frankly. And the documents produced so far to the committee answer none of these questions.

So I would like to submit, Madam Chair, my letters and the Department's response in the record. I would ask for unanimous consent.

Ms. ESHOO. So ordered.

[The information appears at the conclusion of the hearing.]

Mr. PALLONE. So, really—I have 2.5 minutes here, Mr. Secretary—I think the American people have the right to know what the administration's contingency plans are, given the President is asking that this entire law be declared invalid. Maybe you just have to answer "yes" or "no." We will see. I only have two minutes.

Secretary, has the Department conducted an analysis to evaluate the impact on individuals with preexisting conditions and their access to affordable health insurance if the ACA is found unconstitutional, yes or no?

Secretary AZAR. Well, of course, it is not going to be left just like that. We would replace it with something that would actually deal with preexisting conditions——

Mr. PALLONE. But have you done any kind of contingency plans for what would happen if the court struck down the ACA, yes or no?

Secretary AZAR. We are always considering different options, but it will depend on the nature of any ultimate court decision——

Mr. PALLONE. All right.

Secretary AZAR [continue]. If it even agrees with striking down all or part of the ACA.

Mr. PALLONE. All right. Well, it doesn't sound like there is such a thing.

Has the Department conducted an analysis to evaluate the impact on premiums and access to coverage in the individual market, particularly for individuals with preexisting conditions, if the ACA is found unconstitutional, yes or no?

Secretary AZAR. Well, it depends on what would be struck down, whether all of it is struck down, part of it, or none of it.

Mr. PALLONE. OK.

Secretary AZAR. We are years, possibly, away from a final court decision on all of these elements.

Mr. PALLONE. All right. Well, let me ask you this. Are there any contingency plans to ensure that the 20 million people who are covered under the ACA do not lose coverage? Anything at all? Any contingency plans?

Secretary AZAR. Well, first, we have been emphatic that we are changing nothing about how we administer this program during the pendency of the litigation. And at the time that there—if there is a final court decision striking down all or part of it, it will depend on the context of that decision and the politics, frankly, of who is in Congress and what we can work with to ensure the——

Mr. PALLONE. Well, I am trying to——

Secretary AZAR [continue]. Protection of preexisting conditions.

Mr. PALLONE. It sounds like the answer is, no; you don't have anything yet.

I would just like a commitment from you, basically, to respond to my request to provide any documents to the committee that relate to contingency plans in the event that the ACA is struck down. Can you give me that commitment?

Secretary AZAR. I am sure you will understand that deliberative processes regarding potential legislative proposals are some of the core of the internal executive departments' functions.

Mr. PALLONE. So it sounds like the answer is no. Well, I just think that it is unfortunate because, you know, our oversight responsibility is to make sure that, in the event we have this terrible situation, that there is some kind of contingency plan. And I don't think you have it. So I don't believe the administration has any kind of comprehensive plan to address the fallout that will occur if this Republican suit is successful in court.

Thank you, Madam Chair.

Ms. ESHOO. The gentleman yields back.

The Chair recognizes the ranking member of the full committee, Mr. Walden, for his 4 minutes.

Mr. WALDEN. Thank you, Madam Chair.

Mr. Secretary, again, thanks for being here.

I want to make a couple of points.

One is, on the opening day of this Congress, I led the effort on the House floor, now in the minority, trying to move an effort to protect people with preexisting conditions pending this lawsuit's decision.

Congress could act. This House could move legislation to put into law certainty to protect people with preexisting conditions, in addi-

tion to the laws that are already on the books dealing with preexisting conditions. But my colleagues have chosen not to do that.

So they could. And we would probably find common ground here on a preexisting severability language. There is a lot that could be done here.

Second, it was the Congressional Budget Office—independent, nonpartisan—that said, I believe 8 to 15 new medicines would never be invented because of H.R. 3, Speaker Pelosi's partisan drug pricing bill. As you said, that could be a cure for Alzheimer's. It could be a cure for the coronavirus. We don't know.

And that is just the first ten years. The further out you look, the more future innovation will be lost. California Life Sciences said upwards of 85 percent of what they invest in would go away. Eighty thousand U.S. jobs, 80,000 is what California Life Sciences said. We would lose the R&D. We would lose the innovation.

Now, no President that I have been around, Republican or Democrat, has ever leaned in harder on these issues of cost of care than President Trump. And I was with you and him when he announced the effort to get transparency in the hospital system. And before we got from the news conference to the Oval Office, I believe the hospitals had sued you. Is that correct?

Secretary AZAR. I believe it is, yes.

Mr. WALDEN. Yes.

And you talked about the drug disclosure in advertising. And what happened there?

Secretary AZAR. Rather disgustingly, the pharmaceutical industry sued us to conceal their list prices from their consumers.

Mr. WALDEN. And so then I want to talk about Medicare Part D. We were all working together on this committee, which we have a great reputation of doing—occasionally we fight, and that is all right; we know it. But we were working together to cap the out-of-pocket costs for seniors under Medicare Part D and modernize Medicare Part D when all that, unfortunately, came to an abrupt halt, driven, I am going to say, from the Speaker's office. Those discussions ceased.

But we agreed that we needed to cap out-of-pocket costs. We put that in our bill, H.R. 19. They put that in their partisan H.R. 3. But we all agree that it is time to cap the out-of-pocket costs for seniors in Medicare.

Does the administration support capping the out-of-pocket costs for seniors in Medicare?

Secretary AZAR. Absolutely.

Mr. WALDEN. Did the administration opposes H.R. 3?

Secretary AZAR. We do oppose H.R. 3.

Mr. WALDEN. Did the administration support the concepts of H.R. 19, our alternative?

Secretary AZAR. We support the elements of it, absolutely, including the notion of capping out-of-pockets and saving seniors money.

Mr. WALDEN. One of the big issues we have dealt with here, or tried to, is the high cost of insulin, not just for seniors but for others. But in our alternative, H.R. 19, that was all bipartisan legislation, we capped cost of insulin, I believe, at $50 a month was the maximum.

Does the administration support that concept?

Secretary AZAR. I believe so, yes.

Mr. WALDEN. So, going forward, are you hopeful that Congress and the administration can get together on a plan the President can sign, that can become law, that would actually reduce the costs of pharmaceutical drugs in America without driving innovation away?

Secretary AZAR. Yes. I have said the administration is the most flexible party here—Republicans, Democrats, Senate, House. Get list prices under control, lower out-of-pockets, and give the drug plans the real incentive to get drug prices down.

Mr. WALDEN. H.R. 19 contains about 80 or 90 percent of the Wyden-Grassley bill. We think we are with you, we think we can get there, if we can just put the partisan weapons away.

Thank you, Mr. Secretary.

And I yield back.

Ms. ESHOO. The gentleman yields back.

Pleasure to recognize the gentleman from New York, Mr. Engel, for his 4 minutes of questions.

Mr. ENGEL. Thank you, Madam Chair.

Secretary Azar, the State of New York was extremely disappointed to hear that CMS has denied the State's request for a renewal of its Delivery System Reform Incentive Payment Program, known as DSRIP.

When the program was first approved, CMS and HHS insisted that New York include targets for the State's Medicaid program that would incentivize providers to move away from fee-for-service, toward value-based payments.

New York's healthcare community has made progress in doing just that, receiving double-digit reductions in preventable hospital readmissions, while saving the Federal Government billions of dollars.

The request for additional time and continued investment of those savings in DSRIP was to move closer to exactly what CMS and HHS have been saying the Federal Government wants everyone to be doing. So, in light of that, why would CMS and HHS want to stop supporting these successful efforts to achieve the very goals that the Trump administration has been saying that it has for healthcare?

So will your department commit to meeting with the State of New York to discuss how these reforms are sustained into the future? And I would like a "yes" or "no" answer if I could get it.

Secretary AZAR. Yes. I am not familiar with that particular program, but you are right, we do support value-based transformation in our programs. I don't know the particulars of why CMS has had difficulty with New York, but, yes, we will be happy to sit with New York.

Mr. ENGEL. OK. And I would be happy to sit with you as well——

Secretary AZAR. Thank you.

Mr. ENGEL [continue]. And discuss it.

Mr. Secretary, we have mentioned it here, other members have mentioned it here, and you know it far too well, that Americans are suffering from the current epidemic of skyrocketing prescription drug prices. My constituents always tell me they are having to

make unconscionable choices between paying for food or filling a lifesaving prescription such as insulin.

The House has taken bold, decisive action to lower drug prices through H.R. 3, which provides a commonsense solution to this crisis by allowing the government to negotiate drug prices. That is a policy that the President supported as a candidate in 2016, saying—and I quote—"When it comes time to negotiate the cost of drugs, we are going to negotiate like crazy," unquote. That is from the President.

The administration has yet to deliver any meaningful solutions for the health crisis. In May 2018, your Department released a blueprint to lower drug prices, but many of those policies failed to materialize or provide minimal relief to patients. Other ideas, such as the International Pricing Index, have been shelved.

Despite these failures, President Trump claims to have reduced drug prices, when, in fact, a recent report showed that, on average, drug prices increased by over five percent at the start of this year.

Mr. Secretary, can you commit to me today that you will deliver on the President's promise to negotiate drug prices? I would like a "yes" or "no" also.

Secretary AZAR. So we support bicameral, bipartisan legislation that would get through. And there are many principles in H.R. 3 the President is supportive of, but it has to pass both houses of Congress, and, at the moment, H.R. 3 doesn't have a chance of seeing the light of day in the Senate. And so we need to work together to see if something can get through both chambers.

Mr. ENGEL. Well, I am sure if the President asked Mitch McConnell to put it on the agenda, he would.

Secretary AZAR. I don't think so.

Mr. ENGEL. There are plenty of things that we have passed in this House that, unfortunately the other body hasn't done, and the President seems to be right along with it.

So I just think it is another example of the administration's broken healthcare promises to the American people. I just think that we need to get those prices of drugs down, and we need to have not empty rhetoric but true facts.

And I yield back the balance of my time.

Ms. ESHOO. The gentleman yields back.

Pleased to recognize the gentleman who was the former chairman of the full committee, Mr. Upton of Michigan, for his 4 minutes.

Mr. UPTON. Thank you, Madam Chair.

Mr. Secretary, welcome. Big time.

So, as you know, this committee, on a unanimous vote, passed 21st Century Cures—"Cures," as we call it. When I was chair, we expedited the approval of drugs and devices, and I would suspect strongly that your testimony that we had a record number of generic approvals is a direct result because of what this committee did.

We also added some $45 billion in health research over a 10-year span. And, frankly, we asked the question of the agencies, as we worked on this legislation, what is it that we could do to help you make sure that we hit these targets of faster approvals of drugs

and devices. And so, whether it was the FDA, the CDC, and others, the NIH obviously, they gave us an answer, and we delivered.

And at the end of the day, for this crisis, we are going to find a vaccine to solve coronavirus. I know that we are. And I would like to think that what we did in this committee and then passed on the House floor will be a direct result of that.

And, frankly, it prompts all of us, I think, to ask the questions of what more can we do to get on a faster pace to find that vaccine and that cure. And, in fact, as you may know, Diana DeGette and I are again working on a 2.0 Cures bill, where we can take these three years since President Obama signed the bill into law and ask those questions to see what, constructively, we can do so that all hands are on deck. And I know—I don't have to ask you—I know that you will help us with ideas to do that.

A question that I have is: A containment is the very first step in responding to any outbreak of coronavirus. We have seen that around the world now. And statements from yesterday indicate that the CDC said it really isn't if but when it gets to larger numbers here in the United States.

I have always believed in the adage that if you are going to do something, you better do it right the first time because you are not going to find a second. And you want to make sure that—pay me now or pay me later. So we need to have the right numbers as it relates to fighting this terrible disease.

Is the $2.5 billion, is that a floor? Is that a suggestion, the $2.5 billion that you requested?

Secretary AZAR. We have described the request as at least $2.5 billion for 2020 money and then work on 2021 money as we see the situation develop over the weeks and months ahead.

Mr. UPTON. So I know that we are waiting to see the precise details of where it is going. Are any of those dollars envisioned to include the contingency of what China has done as it relates to regional quarantines?

Secretary AZAR. No, we don't envision that as a, kind of, practical step here in the United States. As Dr. Messonnier spoke about yesterday, in the event that we had community-level outbreaks, which might be small, just a town, a city, if we had that, we would take the pandemic playbook, which is community-based mitigation steps, social distancing.

It is very rare that those types of—that "cordon sanitaire" efforts around cities are effective. They usually promote more panic and cause people to actually leave and spread.

Now, China is a different government and culture than we have here.

Mr. UPTON. Of the 14,000 Americans that have died this flu season, do you know what percentage of those were not vaccinated?

Secretary AZAR. I do not have the numbers. Historically, our youth who die tend to not to have been vaccinated, which is a real tragedy.

Mr. UPTON. And last question: Has there been any query of those 55 Americans who currently have been diagnosed with the coronavirus—did any of them have the flu vaccine, do you know? Was that question asked of any of the 55?

Secretary AZAR. I don't know that that would have been asked. We don't, of course, have any evidence that the flu vaccine would have any properties related to the novel coronavirus. But I don't know if that was asked as part of the intake for the patients.

Mr. UPTON. OK.

I yield back.

Ms. ESHOO. The gentleman yields back.

It is a pleasure to recognize the gentlewoman from California, Ms. Matsui, for her 4 minutes of questions.

Ms. MATSUI. Thank you, Madam Chair, for holding this important hearing.

And welcome, Mr. Secretary.

Before I get into my line of questioning, I do want to express my deepest concerns about the Medicare, Medicaid, and other cuts included in the budget. At a time when we are dealing with the coronavirus outbreak, an addiction crisis, and a lawsuit that threatens ACA protections for preexisting conditions, the administration's cuts to critical safety-net programs target the most vulnerable in our communities and aim to further erode access to vital healthcare services.

We should be prioritizing primary comprehensive care, particularly in the mentally ill and people with addiction. I believe mental health is the area where we have an opportunity to work together and make progress.

Mr. Secretary, I appreciate the Department's strong support of the Certified Community Behavioral Health Clinic Medicaid demonstration. As you know, Representative Markwayne Mullin and I are working to further scale the program with our bipartisan legislation, the Excellence in Mental Health and Addiction Treatment Expansion Act.

For the eight States currently participating in the Excellence demonstration, we have studies showing that quality mental health services, outpatient care, and addiction treatment provided at these facilities are saving lives and money. People are avoiding jails and emergency rooms; instead, getting the comprehensive care they need in their communities.

We have 11 additional States that are ready to participate in an expanded Excellence program. Our bill has a bipartisan group of 88 cosponsors who support this full expansion, and the House has already voted to extend the program longer-term.

I was very pleased to see that the budget this year explicitly endorses extending this Excellence demonstration. And I believe we do all agree, Mr. Secretary, that adequate Medicaid resources around substance abuse treatment are essential to fighting the opioid and addiction epidemic.

Mr. Secretary, I have a question: Under the leadership of Chair DeLauro, $200 million was made available to HHS in fiscal year 2020 to help States prepare for eventual participation in the Excellence demonstration. How does HHS plan to obligate these resources?

Secretary AZAR. First, thank you for your personal leadership on the Certified Community Behavioral Health Clinic issue. You are right, the data is showing really positive results today, so thank you for that.

In terms of your work with Chairwoman DeLauro, SAMHSA is now accepting applications from States for these grants to increase access to and improve the quality of community mental and substance use disorder treatment services through the expansion of CCBHCs, and the deadline for States to apply is March 10.

Ms. MATSUI. OK. Thank you. The positive impacts of the demonstration make it clear that there is room to improve mental health and addiction care in this country by scaling this program.

In California, our county hospitals, public academic medical centers, and public children's hospitals rely upon financial arrangements that leverage public funds and partnerships as essential means of providing healthcare to the most underserved communities and patient populations in the State.

I have concerns about the administration's recent proposal to eliminate these sources of funding, particularly supplement payments. I worry that, if finalized, the Medicaid accountability rule would destabilize the whole system of care provided under Medi-Cal. Medicaid supplemental payments are an integral component of total Medicaid reimbursement that providers rely on for adequate reimbursement and financial stability.

Mr. Secretary, have you weighed the restrictions on supplemental payments against the adequacy of these base payments? Are there plans to make any corresponding adjustments to base payments for these providers?

Secretary AZAR. So we are hearing the very important feedback from you and others about that regulation, and we want to take that in as we look at how and whether to finalize at CMS the relationship of these intergovernmental transfers to supplemental payments and, also, if there are ways we can work with States to restructure payments in a way that would be consistent with the law. So we want to work with the States, not be adversarial to them, on this.

Ms. MATSUI. OK. Well, thank you, Mr. Secretary.

And I yield back.

Ms. ESHOO. The gentlewoman yields back.

Pleasure to recognize Mr. Shimkus of Illinois for his 4 minutes of questions.

Mr. SHIMKUS. Thank you, Madam Chairman.

Thank you, Mr. Secretary, for being here.

Coronavirus is a novel pathogen, as a lot of us know, but in your testimony you also mention emerging microbial threats.

And, Madam Chairman, I ask to submit in the record this news release from the World Health Organization on the 17th of January 2020.

Ms. ESHOO. So ordered.

[The information appears at the conclusion of the hearing.]

Mr. SHIMKUS. And in the 114th Congress, I joined with Gene Green on what we called the ADAPT Act. Last Congress, it was Tony Cárdenas and I, with the help of the now-chairman of the subcommittee, Anna Eshoo, who joined, and technical assistance by HHS, on what we call the REVAMP Act. And it is an attempt to address how, if you have this antimicrobial resistance, how public funding may not be the only way you can address this.

Can you talk about that challenge?

Secretary AZAR. Yes, I am very concerned about the drug development around antimicrobial resistance in terms of creating a sustainable market.

You know, we have had, actually, tremendous success from the efforts you have led and the Congress has led and BARDA at my agency have supported. We have supported the development of 16 novel antibacterial projects. I believe three have actually come to market.

What we are finding, though, is there is a market failure question here, where you are basically asking a company to develop a drug but then not to have it used much. And that is not a usually sustainable business model.

So I have actually commissioned my team to work on how we can possibly solve that; is that more like a bioterrorism chemical countermeasure and the approaches that we need there. Quite concerned about this.

Mr. SHIMKUS. And that is what we have tried to do legislatively, and, at sometime, one was the tradeable vouchers debate, which I think should have legs, especially in this concern of, as you put it, trying to have something on the shelf that you don't want to use. That is the key.

Scott Peters and I are also working on legislation that we call Ending the Diagnostic Odyssey. And it is an attempt to help DNA sequencing so that when there is a disease or some event you don't have to test, test, test; you can go just through the sequencing aspect of that.

Do you have any thoughts on or comments of what you all may be doing that we don't know about in trying to push more DNA identification?

Secretary AZAR. So I have not studied that particular issue. We are happy to get back to you on that. It certainly is at the fore right now as we deal with novel coronavirus and have the CDC diagnostic, but also hope that commercial innovators will develop physician bedside diagnostics for rapid insight testing.

Mr. SHIMKUS. Yes. And this is timely—well, it obviously is timely because of the threat that we are all concerned about now, but it is also Rare Disease Week. And a lot of that community is, you know, looking for this as a novel way, especially on what we call that diagnostic odyssey. And we see that with people who are struggling with just types of cancer and trying to identify the right treatment early versus what I would say sometimes is a trial-and-error method that is very damaging to the health of the patient.

And with 30 seconds left, I wanted to just briefly—and it has been asked a little bit before. You all do support Medicare D reform; is that correct?

Secretary AZAR. Oh, absolutely. It is a real opportunity for seniors.

Secretary AZAR. Well, you would cap catastrophic payment, the limit at $3,100. So a patient would never pay more than $3,100. And then, at least the Grassley-Wyden plan, the senior could actually opt into a program where they would pay no more than $258 a month for their drugs, no matter what their expenses are.

Ms. ESHOO. The gentleman yields back.

The gentleman from Maryland, Mr. Sarbanes, is recognized for his four minutes of questions.

Mr. SARBANES. Thank you, Madam Chair.

Secretary Azar, you certainly know that the popularity of e-cigarettes has recently led to an unprecedented surge in youth tobacco use, and it is bringing back a vengeance the tobacco epidemic in this country we have worked so hard to curb. It shows why we have to improve the law and something this committee has been working on.

Unfortunately, the Trump administration is now proposing, as I understand it from the budget, removing FDA's oversight of tobacco products in favor of an untested agency that will take years to get off the ground, which threatens to set us back even further. I am perplexed that the administration would decide to do this, remove FDA's authority, alter the agency's public health mission, which includes making, quote, "tobacco-related death and disease" part of America's past, not America's future, and by doing so, ensuring a healthier life for every family.

This latest move is kind of breathtaking. It makes no sense. It is a crazy thing to do by the administration, which unfortunately, hasn't taken significant action against big tobacco as more of our Nation's youth are becoming addicted.

In January, after heavy lobbying from big tobacco, as we understand it, and the vaping industry, and listening to partisan political consultants like Trump campaign manager Brad Parscale, the administration reversed course. We were on a trajectory where we thought everybody was on the same page.

The administration reversed course, and announced a policy which failed to ban all flavored e-cigarettes, allowing popular menthol cartridges to stay on the market, and allowing all flavored disposable e-cigarettes and open tank e-cigarettes to proliferate through our Nation's schoolyards, which is exactly what they are doing.

And I am concerned that removing this authority from the FDA, which is a part of the proposal, could lead to even more loopholes and more industry influence.

My question is this: When formulating the budget proposal to remove the FDA's tobacco oversight authority, did you, your agency staff, White House staff, or staff of the Office of Management and Budget, speak or meet with any lobbyists or other representatives of the tobacco industry, or, for that matter, political operatives who work for or are contracted by the President's reelection campaign?

Secretary AZAR. Well, I certainly—I can't speak for others. I am not aware of any such deliberations. The idea was that if we move the tobacco center out from under FDA, first, if it were a politically appointed—a presidential-appointed, Senate-confirmed leader, they would be more accountable to Congress. Second, as a direct report to me, or whoever is Secretary, elevating the role of tobacco control there.

It has always been a little bit of an odd connection. FDA is about safe and effective, whereas the tobacco center is about regulating a product that is undeniably bad. And so there is a——

Mr. SARBANES. It doesn't make any sense, does it?

Secretary AZAR. It would be subject to Congress if it was something——

Mr. SARBANES. I mean, we are at the height of it. We are at this tipping point on this epidemic when it comes to vaping.

I mean, there does reside, however you want to sort of carve up what you consider the appropriate mission of the FDA to be; there certainly exists, resides within the FDA now significant expertise and experience in terms of dealing with this issue. Why you would propose, at this moment in time, when this epidemic risk in a sense overtaking the dimensions of the previous tobacco epidemic we saw in this country, by zeroing out that authority and moving it to an untested new agency, which, by the way, I think would be more susceptible to political influence of the kind I was just recounting than it is now. It doesn't make any sense to me. I urge you to reconsider that. We are in the midst of this crisis, and we have to use every tool available to us here in the government to respond to it.

With that, I yield back.

Ms. ESHOO. The gentleman yields back.

There is 5 minutes and 22 seconds left on the clock. Any member that would like to leave to vote, when we get to—you can leave now. When we—when the clock goes to zero, they will hold the vote open for those that have not arrived from our subcommittee, and at that point, we will take a 20-minute break.

But now I would like to recognize the gentleman from Kentucky, Mr. Guthrie, for his 4 minutes of questions.

Mr. GUTHRIE. Thank you, Mr. Secretary.

I look forward to getting into the coronavirus. I will do that in my second rounds of questions. So the SUPPORT Act we passed last year included my bill, the Comprehensive Opioid Recoveries Act, to establish treatment centers that offer FDA-approved medications, and assistance treatments, all of them comprehensively. Currently, SAMHSA has the grant application open for entities to apply and I am glad HHS is moving fast in implementing the program. But my question is: How is HHS implementing other parts of the SUPPORT Act? And does HHS conduct any oversight on how the funds are actually being used?

Secretary AZAR. So, first, thank you for the SUPPORT Act, and it is so comprehensive we actually established a SUPPORT Act implementation leadership committee to track all of the different work streams needed under the SUPPORT Act. It is really enhancing our work across all five elements of our strategy on opioids, and so, we are just—we are driving forward, making progress on the opioid epidemics. We have got—the overdose deaths are down for the first time in decades as a result of our collaborative bipartisan efforts here, and we are implementing and using the SUPPORT Act authority. So thank you for those.

Mr. GUTHRIE. OK. Thank you.

And also, in 2018, Congress passed my bill, the bipartisan BOLD Infrastructure for Alzheimer's Act. Can you please provide an update on how this law is being implemented across the country?

Secretary AZAR. So, with that Act, I want to, if I could get back to you in writing on that, I don't have all the details on that particular program. I apologize, but if I could get back to you.

Mr. GUTHRIE. OK. Thank you.

And this is kind of technical from my role as ranking Republican on the Oversight and Investigations Subcommittee on this committee. This committee and Oversight and Investigations conducted extensive oversight, cybersecurity at HHS, including through technical audits conducted by GAO of cybersecurity controls at HHS operational divisions. So, as I said, it is very technical.

Last Congress, the Subcommittee on Oversight and Investigations held a closed hearing, in part, because HHS failed to properly identify and address certain vulnerabilities. We recently received preliminary results from the most recent audit of another HHS agency, though I can't go into details in this setting.

So my question is: Does HHS have a point person who coordinates corrective actions on cybersecurity among all HHS agencies, and, if so, will you direct that person to continue to work with the committee on improving enterprise cybersecurity at HHS, and ensuring that mitigations applied in one setting are consequently applied through all of HHS?

Secretary AZAR. Yes, we do. Our chief information officer, Jose Arrieta, who works directly with me, absolutely is in charge of those issues. If I could go back to your previous question, I had misheard on the BOLD Act.

Mr. GUTHRIE. On the BOLD Act, yes.

Secretary AZAR. So I apologize on that.

For fiscal year 2020, CDC will have two funding opportunities to carat ck word. I can't find it as a verb actions under the BOLD Act. So first, there will be the public health programs to address Alzheimer's disease and related dementias; and second, there will be the centers of—the Health Centers of Excellence to Address Alzheimer's Disease and Related Dementias. We expect both of those funding opportunities to be out in the coming month. And for fiscal year 2021, the President's budget for CDC includes $3.493 million to continue to support these Alzheimer's activities.

Mr. GUTHRIE. Because by 2050—that is when I will be 86, I believe—they believe it is going to be a trillion, estimated to be $1 trillion spent on Alzheimer's disease. Not only is it devastating to the individual who has it, the family that cares for that person, but also it would be devastating to the deficit and the budgets of our country. So this is something very important. Thanks for your leadership and effort, and I appreciate working with my colleagues here to move the BOLD Act forward and address it.

And I yield back.

Ms. ESHOO. The gentleman yields back.

A pleasure to recognize the gentleman from New Mexico, Mr. Luján, for his 4 minutes, and I will wait right here with you and then we will run over.

Mr. LUJÁN. Thank you, Madam Chair.

Secretary Azar, when Donald Trump was running for office four years ago, he famously said that he wouldn't cut Medicaid. He didn't say it once or twice, but claimed it at least five separate occasions, that he would not cut Medicaid but, in reality, no President and no administration in the last 50 years has done more to undermine Medicaid than Donald Trump.

In fact, his first major legislative effort to repeal the Affordable Care Act would have ended Medicaid as we know it, and put the healthcare of 70 million Americans at risk. And if my colleagues from the other side of the aisle want to protect people with preexisting conditions, they should drop the lawsuit. That could happen tomorrow.

After President Trump failed to cut Medicaid legislatively, he decided to try the same thing administratively, even though the law clearly does not allow it.

Secretary Azar, there has been some misreporting that the block grant guidance is limited to adults in the expansion population, but under the administration's guidance, States could block grant Medicaid for more than just expansion adults. Isn't that true?

Secretary AZAR. Congressman, I don't—I don't believe that is the case. I will ask did CMS administrator to get back to you on that, but my understanding was that it would be an optional demonstration for adults only, and that it would actually not affect coverage for our most vulnerable, our pregnant women, children, elderly adults, people on eligible on the basis of disability. But I will ask Administrator Verma to get back to you on that, because that is not my understanding.

Mr. LUJÁN. Let me jump into this. I am glad that you pointed that out, because I think that there is a concern here, and I hope that you would agree with me that, if that is your understanding, that you do something about it, Mr. Secretary, because the Center on Budget points out that people that are low-income parents, women who are pregnant, and people with disabilities who are covered through Medicaid expansion could be included in what I will describe as the President's illegal block grant guidance.

Is that something that you would agree with if that is the case? Would you stop it if, in fact, the guidance does allow for those vulnerable populations to be discriminated against?

Secretary AZAR. So I have been under the view that it does not affect coverage for our most vulnerable populations. It doesn't allow them to strip benefits, or strip eligibility. Essential health benefits have to be covered. You can't change eligibility. You can't cap or limit——

Mr. LUJÁN. Mr. Secretary, if I may, just for clarification, because it sounds like we are on the same page.

Secretary AZAR. What you are saying I am not—the concerns you are expressing——

Mr. LUJÁN. Mr. Secretary——

Secretary AZAR [continue]. I don't believe we are in the HOA, but we will get back to you on that.

Mr. LUJÁN. Let me ask you this pointed question.

Secretary AZAR. Yes.

Mr. LUJÁNN. If, in fact, the President's Medicaid block grant program does allow for those folks to be thrown off and get caught up in this, will you stop it?

Secretary AZAR. Well, we are not going to approve plans that allow people to be thrown off, because it can't change eligibility. I can't change eligibility.

Mr. LUJÁN. Let me ask it one more time, because it sounds like you are getting there.

Mr. Secretary, if, in fact, vulnerable populations like pregnant women, families, and those that are disabled, are subject to this rule where they could be block granted, will you stop it?

Secretary AZAR. I don't believe we would—I will not approve a plan that removes coverage for our most vulnerable citizens.

Mr. LUJÁN. So that is enough for me. You said you will not approve a plan.

Secretary AZAR. I will not approve—with very low-income parents, children, pregnant women, elderly adults, or people eligible on the basis of disability should not be affected in terms of their Medicaid coverage, is what I am informed. I will get back to you from Administrator Verma to confirm all of those details. I want to make sure that I am right on that, but that has been my understanding of the HOA program.

Mr. LUJÁN. What I am looking for is assurance that if what my comments are associated with being consistent with the Center on Budget points out, you, in fact, will not approve that plan and you will not allow for Medicaid block grant cuts, devastating cuts go into a place that will be subjected to pregnant women, families, and those with disabilities?

Secretary AZAR. The categories that I mentioned before are ones that I do not believe are subject to it, plans should not be approved if they would harm eligibility for those individuals.

Mr. LUJÁN. So if the Center on Budget's assessment is correct, you will not allow that to go into effect?

Secretary AZAR. I do not believe their assessment or description of the program is correct, and I have said I don't expect that I would approve any plan that would harm our vulnerable populations. It is a healthy adult opportunity under Medicaid expansion, but we will get you any clarification on that afterwards. Thank you for raising that to me.

Mr. LUJÁN. There is a reason that most of us in this Congress has—have opposed Medicaid block grants. These are devastating programs. It is another effort to undermine Medicaid, and to continue to cut the program which President Trump promised he would not. This is another example of where he is.

And with that, I yield back.

Ms. ESHOO. The committee will now recess for approximately 20 minutes. So hold on to your seats while you stand up and stretch and we race over and come back.

It sounded like the Secretary said yes, Ben Ray.

[Recess.]

Ms. ESHOO. The subcommittee will come to order. Thank you. Thank you, Dr. Azar, for your patience.

And I now would like to recognize the gentleman from Virginia, Mr. Griffith, for his—is it 4 minutes—4 minutes of questions.

Mr. GRIFFITH. Thank you, Madam Chair.

I appreciate you being here. Thank you so much. The President and your agency have expressed concerns with the middlemen in the drug supply chain, pharmacy benefit managers, PBMs. Over time, PBMs have morphed into under-regulated entities with opportunities to exploit their position in the middle of the drug transactions in the U.S. For example, according to a new report from XIL Consulting, which is run by former Express Scripts' executive,

PBMs benefit from an obscure fee known as direct and indirect remuneration, DIR—I know you are familiar with that—at a rate exceeding 500 percent per prescription as compared to the average administration fee. Last year, the administration proposed a rule to address these DIR fees, but later withdrew it.

Do you still have plans to implement accountability measures for PBMs?

Secretary AZAR. No.

Mr. GRIFFITH. And if so, what does that regulation look like?

Secretary AZAR. So I remain very concerned about the DIR fees and their impact, especially on America's community pharmacists, as well as independent specialty pharmacies.

So, the reason that we did not finalize that rule—and we were very transparent at the time—was the concern that by—if we forced the DIR fees to basically go through to the benefit of the patient, that that could cause an increase. The middlemen would jack up the part D premiums for our seniors, and that was the concern and the President just has been adamant that he does not want to run the risk of part D premiums going up.

We—so it remains a priority for the administration to deal with this issue. If we ever could legislatively, that would be useful also.

Mr. GRIFFITH. And as you know, I would love to have a legislative solution, but we thought this might be a good test case to do it with that.

Secretary AZAR. Maybe even through, if we could get bipartisan, bicameral drug pricing legislation, that might be a vehicle to have that in there.

Mr. GRIFFITH. It might be.

And let me ask you this: There has been some mention earlier today of H.R. 3. I raised the concern, and then later, it was raised by the Congressional Research Service that the bill, as written, is just blatantly unconstitutional. Have your lawyers advised you that that is the case in their opinion as well?

Secretary AZAR. I have not had anyone study the constitutionality issues on H.R. 3 about the penalty amounts and whether that would work. So I haven't seen any analytics on that.

Mr. GRIFFITH. Any time they want a discussion on it, I am more than happy to facilitate one.

Let's talk about opioids, because I only have a little bit of time left. Over the past few years, there has been a lot talk about how they are prescribed in America, and how pain is medically managed in general. And I will tell you, that I thought we were on the track of getting our healthcare professionals to back off of giving out so many opioids for pain, but I have a friend who is currently undergoing some procedures, and we were talking yesterday about how they had given her opioids, how she took it in the initial day after some painful procedures, but that after that, she turned it away but they—you know, she has got it sitting in her house. What has this administration and HHS done to reduce the overprescribing of opioids?

Secretary AZAR. So we have actually, through the CDC, put out guidance to professionals on appropriate prescribing. We continue to work on even further titrated by different pain areas on what the best guidance is to do that.

It is distressing to hear that. We have seen, though, an over-25 percent, I believe, decrease, maybe 30-percent decrease in the opioid prescribing of illegal opioids to date since the President took office. So we are making progress, but, of course, it is disturbing to hear any pockets like that.

Mr. GRIFFITH. Well, and—look, it is going take time but we can't—just because we have started to solve the problem, we cannot think it is solved, and we cannot take our foot off the gas pedal in trying to make sure that we don't overprescribe, and that we deal with this issue. It is very serious in my district and many others.

I thank you very much, and I yield back.

Ms. ESHOO. The gentleman yields back.

The Chair is pleased to recognize the gentleman from Oregon, Mr. Schrader, for his 4 minutes.

Mr. SCHRADER. Thank you very much, Madam Chair.

Thanks for being here, Secretary Azar. I appreciate it very, very much. I am going to leave my coronavirus questions to the next panel, but we do want to make sure the CDC is fully funded, and a little concerned about the original budget. Glad to see some changes coming forward.

My question, the first question, is on Medicare Advantage. It is a huge program in Oregon and many, many States. It leverages our Federal tax dollars to maximum advantage. Most Oregonians, most seniors get a lot of their prescription drug coverage from Medicare Advantage. Very concerned that this administration, and frankly, others, have tended to try and cut Medicare Advantage programs. I think that is foolhardy. The whole goal here is to actually make sure that the savings from the Medicare Advantage are plowed back into making sure there are more benefits that are covered, better prescription drug coverage, and expanding it to a larger universe.

So could you give me some assurance you are going to continue, this administration? You will try and continue to improve the Medicare Advantage program and not take away the savings that could be plowed into more benefits for folks.

Secretary AZAR. No, absolutely. So I am actually under direct orders of the President in his Medicare executive order to enhance and protect Medicare Advantage, exactly the things you are talking about: Offer more supplemental benefits, make sure people—make those plans as attractive as options for people as possible.

Mr. SCHRADER. Just saw guidelines on reducing caps and that sort of thing that made me nervous about what the intent was.

The second question is on the proposed Medicaid rule. Hear a lot about that back home. In many States, I was budget chair for my State back in the day, and it seemed like a great opportunity for our States to, again, leverage Federal dollars with State tax dollars, actually with private hospital dollars and long-term care dollars. So it was a really smart use, I thought, of taxpayers' limited ability to finance programs they want. This really made great use of the dollars.

I am very concerned with this new MFAR rule that you are going to—ostensibly it is, with all due respect, framed in the guise of transparency, when, indeed, it is a backdoor attempt to take away

matching funds, the ability for the provider tax to be leveraged in many States, including ours.

So, I guess, given the fact the executive order requires Federal agencies to perform this regulatory impact analysis to determine the effect of the impact of the proposed rule, but the proposed rule says the fiscal impacts of the Medicaid program from the implementation of the proposed rule is unknown. Do you consider that to be a comprehensive regulatory impact analysis?

Secretary AZAR. I haven't looked at the reg impact analysis there. So I just I don't know the specifics on that, but, certainly, I do want to assure you we are hearing the feedback from you and others and governors about this. We are looking at this not to be penal, but, rather, to make sure that those intergovernmental transfers are genuine State money that is getting matched and not funny money or schemes—that is really the intent—and to also be more prospective, not penal, looking backwards, as much as we can.

So we are—I appreciate getting this feedback. We are hearing a lot of it, and we are taking that in.

Mr. SCHRADER. Well, what some people would call funny money schemes, others would call smart financing in using the accounting system the way it has been established for decades to maximum advantage. It would really put a huge hundreds-of-million-dollar hole in the Oregon State HHS budget. So I would urge you to back down on that a little bit, or at least give it some more serious thought.

I yield back. I thank you, Madam Chair.

Ms. ESHOO. The gentleman yields back.

It is a pleasure to recognize the gentleman from Florida, Mr. Bilirakis, for his 4 minutes of questions.

Mr. BILIRAKIS. Thank you. Thank you, Madam Chair. I appreciate it very much.

Secretary Azar, thank you, first of all, for your leadership. I appreciate it very much. And thank you for your responsiveness to a lot of my constituents' concerns as well.

Again, we have begun to make progress, in tackling our Nation's opioid crisis, and HHS has played a key role in that effort. Thank you for your continued support, of course.

Do you feel—and this is a budget question; do you feel HHS has the necessary resources to continue to implement provisions of the 2018 SUPPORT Act and the 2019 HHS Pain Management Task Force recommendations?

Secretary AZAR. I do believe so. In fact, we have increased funding for opioids in this budget.

Mr. BILIRAKIS. OK. Very good.

Also, next, the community house centers, as you know, do a wonderful job. The funding is expiring soon. Now, we reauthorized it for an additional seven years, and that is a great thing. But, again, how do community health centers serve as a gateway to integrated care for individuals with mental illness and substance use disorder?

Secretary AZAR. You know, more than 28 million people rely on HRSA's community health centers that we fund. They are a critical part of our primary care network, of preventive care for individ-

uals, and they deliver high-quality service. And we are using them also as part of the Ending the HIV Epidemic program to reach the underserved and reach people that we need to bring into treatment and prevention.

You know, more than 93 percent of our 1,400 health centers provide mental health counseling and treatment. Sixty-seven percent of them provide substance abuse services. I believe the—I think the number 60 percent of the clients at the community health centers, I believe, are ethnic and racial minorities. I am always just so impressed when I visit them, the quality of care and the quality of service there.

Mr. BILIRAKIS. Absolutely. Do you have anything to add? Because I wanted to give you an opportunity to add, because this is a big issue affecting our constituents, obviously, on the insulin pricing. I know that this has been mentioned in the committee, but if you could maybe elaborate on that, I would appreciate it very much.

Secretary AZAR. I appreciate that. I did want to clarify one thing from Mr. Walden's question earlier regarding a piece of legislation. I misheard about, I guess, it is a proposal to cap out-of-pockets at $50 for insulin. The administration does not have a formal statement of administration position on that piece of legislation yet. Of course, we want to get out-of-pockets down. We want to deal with the insulin issue, and get insulin pricing down for everybody, but we don't have a formal statement yet on that issue.

The part D reforms the committee has worked on and that has a lot of bipartisan support though, that could be such a benefit to people, that catastrophic cap at $3,100, spreading that cap over 12 months, where no senior would ever pay more than 258 bucks a month for their prescriptions if they opted into that. What an incredible thing we could deliver for America's seniors if we could get bicameral, bipartisan action on that.

Mr. BILIRAKIS. Absolutely.

Well, thank you for clarifying that, and, of course, we will follow up with you, because, again, this is a big issue affecting our constituents.

How does the budget address school safety? I don't have much time, do I? How does the budget address school safety and the mental health needs of our students?

Secretary AZAR. So we fund Project AWARE in here, which is a really important school-based school safety program for those for mental health services. We have Healthy Transitions funded, which improves access to mental disorder treatment and related support services for youth. We have the Safe Schools Framework Implementation Toolkit to help educate teachers and administrators to identify kids in crisis who need mental health intervention. That is part of it.

Mr. BILIRAKIS. OK. Thank you very much.

I appreciate it, Madam Chair.

Ms. ESHOO. The gentleman yields back.

It is a pleasure to recognize the gentleman from Massachusetts, Mr. Kennedy, for his 4 minutes of questions.

Mr. KENNEDY. Thank you, Madam Chair.

Mr. Secretary, thank you for being here.

This week, DHS implemented their well test for immigrants nationwide. The earlier estimates show that the rule could lead to 4.7 million people withdrawing—excuse me—from Medicaid and CHIP alone, many of whom are legal immigrants, the children of immigrants, asylum seekers, and refugees. Yes or no, sir, nearly five million people are forced to forego their health coverage; is that a success?

Secretary AZAR. We do not believe that individuals who come to this country should be dependent on public taxpayers for healthcare or other services.

Mr. KENNEDY. So refugees having access to healthcare is a success?

Secretary AZAR. We do not believe that individuals who should come to this country to be dependent on public welfare programs. That is the—that is the—that is the basis for that——

Mr. KENNEDY. So, sir, you have frequently told the story of your grandfather arriving at Ellis Island from Lebanon as an impoverished teenager who spoke no English. You talk about him being met by a member of the United States Public Health Service. You speak proudly of that story. Under this rule, based on your own telling of that story, your grandfather would have been turned away. So I ask you, yes or no, are you proud of this public charge policy?

Secretary AZAR. So my grandfather came and worked his way through his bootstraps.

Mr. KENNEDY. Would he have gone—would he have had access to healthcare under this policy?

Secretary AZAR. No, he would not have.

Mr. KENNEDY. And do you——

Secretary AZAR. And he wouldn't have asked for it, because he would have wanted to make his own way.

Mr. KENNEDY. And so you are proud of this policy.

Secretary AZAR. I am proud of my grandfather and 100 years ago, he came to the United States——

Mr. KENNEDY. That was not the question.

Secretary AZAR [continue]. In Ellis Island.

Mr. KENNEDY. That was not the question. Are you proud——

Secretary AZAR. We supported this policy. It is—we——

Mr. KENNEDY. I am going to take that as a no.

Secretary AZAR. The American people don't support the idea that people should be coming to this country to be——

Mr. KENNEDY. Mr. Secretary, next question. Are you aware that under your leadership, the number of Americans without health insurance has risen for the first time in a decade in 2018 by roughly two million people?

Secretary AZAR. So actually, the numbers on the uninsured require a bit more depth than that. The—what is happening on the uninsured is actually the ACA has—most of the growth of uninsured is because the ACA priced individuals out of the individual markets.

Mr. KENNEDY. Sir, I am almost out of my 4 minutes.

Are you aware, sir, Mr. Secretary, that the percentage of uninsured children rose by .6 percent under your leadership? Would you consider fewer children with access to healthcare a success?

Secretary AZAR. So actually, in terms of children and coverage, we have SCHIP. We have reauthorized that for a long period of time. We have got the Medicaid program——

Mr. KENNEDY. So you contest the numbers?

Secretary AZAR. So in terms of the uninsured numbers there, the children that are uninsured are likely part of the coverage gap left by the ACA, as well as the pricing out of nonsubsidized——

Mr. KENNEDY. Sir, do you believe that it is the—so last month, we held a hearing here about an opioid epidemic where a representative from the Department of Health and Human Services of North Carolina stated that if North Carolina had expanded Medicaid, 415 more people would be alive in North Carolina today. Do you believe that this administration's opposition to Medicaid expansion that, according to that individual, has cost lives; is that a good policy choice?

Secretary AZAR. I am not going to validate that politician's statements. I don't know who it was——

Mr. KENNEDY. It was a representative of the Department of Health and Human Services of North Carolina.

Secretary AZAR. I don't know who they are. I don't know the basis for that. I haven't seen the evidence.

Mr. KENNEDY. So you are unaware of the fact that Medicaid has saved lives in North Carolina?

Secretary AZAR. No——

Mr. KENNEDY. The absence of Medicaid expansion——

Secretary AZAR. That is not what I am saying. I am saying I haven't seen the evidence basis for the assertions you are making and that he made.

Mr. KENNEDY. One last question for you. You have spoken about this administration's efforts to combat coronavirus and the so-called increased choice for healthcare. For one man, Osmel Martinez Azcue, those two things recently converged when he tried to be prepared after developing flu-like symptoms following a trip to China. He was left with a bill of well over $1,000, and a demand of proof that the flu he was tested for wasn't related to any preexisting condition, or else he would be forced to pay a few thousand dollars more.

So, please explain to me as we are staring down a potential pandemic, and the CDC is warning about fundamental changes to our way of life because of it, do millions of people that have signed up for junk insurance plans pushed by this administration, do they really have a choice?

Secretary AZAR. So the short-term limited duration plans are an option for individuals. We have been very clear that they may be the right choice for some, but they may not be the right choice for others who have preexisting conditions.

Mr. KENNEDY. Even people with thousands of dollars of uninsured claims in the midst of a potential pandemic, that is a good choice?

Secretary AZAR. So if an individual, if it is a choice between no insurance and some insurance at 60 percent lower than what the Affordable Care Act has priced them out of the market at, it is at least an option for individuals provided.

Mr. KENNEDY. Unless they expanded Medicaid.

I yield back.

Ms. ESHOO. The gentleman yields back.

It is a pleasure to recognize the gentleman from Indiana, Dr. Bucshon, for his 4 minutes of questioning.

Mr. BUCSHON. Thank you very much.

And thank you, Mr. Secretary, for being here today.

I am going to switch gears a little bit. 340B is a critical program, especially for rural hospitals, and I am just interested in what you think should be done, if anything, to continue to ensure that the 340B program, given its significant growth, is helping more patients get access to care?

Secretary AZAR. You put your finger right on it there when you mentioned the growth. It has grown from $7 billion of pharmaceutical sales in 2012 to $19.3 billion in 2017, and we believe in the 340B program, but we do believe those savings need to actually make their way to patients, not just subsidizing hospitals, but actually make their way to patients.

I mean, imagine, for instance, just take the issue of insulin. Hospitals often acquire their insulin at an extremely low price, but they don't have to necessarily pass those savings on to the patient that they are serving as an outpatient. That is partly why we would, part B, propose the changes and have tried to implement the changes that would reduce what seniors have to pay for part B—for—would have to pay in the Medicare program for their drugs.

Mr. BUCSHON. Do you think that more transparency in the 340B program would be part of the solution?

Secretary AZAR. Absolutely. We support transparency in the program. We support giving the regulatory authority as part of our budget, and also requiring that hospitals that want to get the benefit of those savings I just talked about, to retain that in the program, would have to dedicate one percent of their work towards delivering charity care which seems like a pretty low bar.

Mr. BUCSHON. So what you are saying is probably that HRSA does need probably more authority and more teeth to address the program. Would you agree with that?

Secretary AZAR. We need greater oversight, but we need regulatory authority to implement that oversight so that we can have—so we can actually do audits in an enforceable way and have that type of transparency.

Mr. BUCSHON. Thank you.

I would also like to thank you for making improvements in pain management a key component of the HHS opioid strategy plan. I mean, I firmly believe we will never successfully address the opioid epidemic unless we also improve pain management, and I am a physician, and patient access to non-opioid therapies, particularly FDA-approved medical devices, which have the greatest opioid-sparing potential.

Can you tell us what HHS is doing to promote pain management best practices and the status of various provisions in the SUPPORT Act to break down barriers to non-opioid therapies for pain?

Secretary AZAR. So one of my top priorities has been to leverage the Center for Medicare and Medicaid Innovations authorities to fight the opioid epidemic and that is why we developed the Mater-

nal Opioid Misuse, or the MOM Model, and we recently announced the participants in that model and that is going to address the fragmentation of care for pregnant and postpartum Medicaid beneficiaries with opioid use disorder by supporting care coordination and better integration. So that is part of that.

Mr. BUCSHON. Great. And earlier in the hearing, you were starting to give some bullet points on, I think, corona, your plan, the five-point plan or whatever. In the last 50 seconds, can you expand on that?

Secretary AZAR. You bet. First, expand our surveillance system so we have novel coronavirus surveillance comparable to what we have on the flu, because that is the bedrock of our public health response; second, money to support State and local public health departments are going to have to do a lot of work here; third, vaccine research and development; fourth, therapeutic research and development; and fifth, finally, strategic national stockpile acquisition, especially of personal protective equipment.

Mr. BUCSHON. Thank you for that.

And do you feel that we have had enough access to—in China to get the data that we need to help solve this problem? Has that loosened up?

Secretary AZAR. We have struggled. The World Health Organization GOARN team has now completed its mission. We are waiting for its report. The initial reports I have is that that team felt they were getting access to information and evidence, but I want to see the final results of that.

Mr. BUCSHON. Thank you, Mr. Secretary. I yield back.

Ms. ESHOO. The gentleman yields back.

Just for the record, HHS has existing oversight authority of the 340B, and it is my understanding that HRSA has conducted 1,500 audits of the program. So the question——

Secretary AZAR. The courts actually have said we do not have the ability to implement regulations. So that—and that——

Ms. ESHOO. We are not talking about that. We are talking about audits, and so that is why I wanted to get this on the record. Look at your audits and see what is in them. It is under the control of your department.

I now would like to call on, or recognize, the gentleman from California, Mr. Cárdenas, for his 4 minutes.

Mr. CÁRDENAS. Thank you very much, Madam Chair, and I appreciate the opportunity for us to have this oversight hearing.

Secretary Azar, thank you so much for being with us. This is an opportunity for to us ask you some essential questions in fulfilling our oversight duties. And last time you were here before us for our budget hearing, I asked you about your agency's role in the horrifying practices of separating children from their families. Today, I would like to ask you about other ways that the administration is impacting families, both in my district and throughout the country.

I would like to ask you about an issue that is frightening families in my own district. I am, of course, talking about the for-profit company's proposal for a detention center in my district, a proposal approved by HHS and that wants to use our Federal tax dollars to put a facility there to have children in a prison-like setting.

VisionQuest, the company that received these funds from your agency, has a history of alarming reports and stories of abuse within their programs right here in this country. These stories include descriptions of excessive use of physical restraints and isolation, verbal abuse, food deprivation, humiliation and intimidation, and even deaths and this is all about them having children in their care.

As part of the due diligence of your organization, would officials within the Office of Refugee Resettlement be aware of these types of violations before awarding a contract to such a company like VisionQuest?

Secretary AZAR. I don't want to endorse the statements that you have made regarding that entity, because I do not know the particulars of that entity or the allegations that are being made there. So I want to be careful I am not endorsing that, but——

Mr. CÁRDENAS. OK. Go ahead.

Secretary AZAR [continue]. I would expect it would be part of any grant review of any grantee to examine their past history, and treatment of children. I would absolutely expect that, yes.

Mr. CÁRDENAS. OK. If you could please report to this committee if any of the grantees, such as the one I was talking to, if there is any evidence within the Department of any valid situations with an organization such as—an organization that would be entrusted with Federal funds to house children.

Secretary AZAR. Sure.

Mr. CÁRDENAS. OK? Thank you.

But funds—these funds that you would be providing as of, unless you were to have such evidence; you would go ahead and contract with an organization?

Secretary AZAR. Well, that is how, as you know, the Unaccompanied Alien Children program runs, is we hire grantees that run permanent, hopefully, permanent State-licensed facilities that care for children until we can place them with sponsors. That is really what the system Congress set up. That is what we run.

Mr. CÁRDENAS. Thank you.

And the city of Los Angeles is in the process of solidifying their ordinances to whether or not they are going to allow private entities to use Federal funds to house children.

I have another issue I would like to discuss with you. I want to turn to the issue of impacting American families, especially vulnerable children throughout America. In your written testimony, you speak about the importance of promoting adoption to give children the stability and love during their childhood. You speak about prioritizing adoption, but you neglect to mention the fact that right now in America, the agencies are turning away qualified potential parents because they are either LGBTQ, or they happen to be of a religious minority here in America. This is in the—this is in spite of the fact that LGBTQ parents are seven times more likely to foster or adopt children than non-LGBTQ parents.

My question is, in your efforts to identify and address barriers to adoption, can you tell me how eliminating data collection and reporting on sexual orientation over fostering adoptive youth and parents is helpful to furthering that goal?

Secretary AZAR. So the AFCAR is what you are referring to, I believe, is the AFCAR's reporting system and the original regulation contain 270 individual data points, 153 of which were new, and the States, there was significant feedback about just the sheer volume of data collection and expense to States, all of which is money that, if we add more and more questions, more and more data collection, that is money the States can't use to actually assist with adoption and foster care placement. So it is really just an effort to streamline those data requests in there.

Mr. CÁRDENAS. My time has expired.

I yield back.

Ms. ESHOO. Is the gentleman yielding back?

Mr. CÁRDENAS. Yes.

Ms. ESHOO. I thank the gentleman.

It is a pleasure to recognize the gentlewoman—and that she is—from Indiana, Mrs. Brooks, for 4 minutes.

Mrs. BROOKS. Thank you, Madam Chairwoman.

And welcome, Secretary Azar. Thank you for being here.

And thank you for pointing out that just this past June, the President signed PAHPA, the reauthorization of PAHPA, of which this committee worked very hard on in the last Congress, and we finally got it done in this Congress.

And I worked particularly hard with the chairwoman and the ranking member of this committee to try to make sure we improved our readiness and our response, and because the question of a pandemic is really not a question of if, but when, I think most people, and obviously CDC is acknowledging that.

One thing I would like people who are listening to understand, the global security—Global Health Security Index was recently issued, and the United States of America was first in the world out of 195 countries for prevention, detection, response, and public health. And I also want to commend the administration for the National Health Security Strategy that was put in place for 2019 to 2022. I want to commend you for leading that work.

But with respect to PAHPA, I am curious. How are you leveraging, how is HHS leveraging all of the new things that we put into PAHPA? And then I have one—I would like to also ask you to address, because there are so many good things in your budget, but I am particularly concerned about a $200 million cut to BARDA, because BARDA has brought forth so many incredible innovations and the partnership that they have with the private sector. Given this proposed cut, what strategies are we going to put in place if BARDA is cut?

Secretary AZAR. So on the BARDA question, so that was, of course, in the budget before the coronavirus situation, and because Congress in the appropriations in December added, I think, $535 billion of Ebola funding available in 2020, we are pulling forward some of our acquisition strategies for BARDA into 2020 around, especially vaccine and therapeutics on Ebola.

So that created some offset. We may need to relook at that now, given some of the offsets proposed in the supplemental requests but that was meant to be somewhat because we had pulled forward some of those acquisition strategies to 2020.

Mrs. BROOKS. OK. But the private sector companies who are our partners in developing the diagnostics, the therapeutics, the vaccines, and because the government is the customer for those products, is it fair to say then that BARDA, and all of the BARDA professionals who are working in BARDA, is it fair to say that they should not anticipate, with what is happening right now a cut in their funding?

Secretary AZAR. We would—first, we would work with the appropriators as to whether the offset we proposed on the 535 Ebola to be part of the funding of the supplemental, if that happens. I can tell you from feedback this morning at the House Appropriations Committee, I think that may be unlikely from the appropriators.

Mrs. BROOKS. We still have Ebola in Africa. Is that correct?

Secretary AZAR. We do, although fortunately, it is on the downswing on the Epi Curve at this point but what we would do is use that money for acquisitions on Ebola, if that money remains there for Ebola in 2020 vaccines and therapeutics that we have got. But if not, we would work with appropriators on making sure BARDA is adequately funded certainly.

Mrs. BROOKS. And are there any other issues or any other strategies or framework that we provided in PAHPA that you are using specifically right now to combat the coronavirus?

Secretary AZAR. On the coronavirus, the—I can't trace directly to the PAHPA authorities but, for instance, our vaccine strategies are very much influenced by that in terms of recombinant DNA, the universal vaccine research that we are doing in the influenza case, as well as cell-based technology to bring domestic manufacturing capabilities here.

Mrs. BROOKS. I yield back my time. I thank you.

Ms. ESHOO. The gentlewoman yields back.

Just for the record, the gentlewoman asked about the $200 million cut to BARDA, and the Secretary responded.

The administration, Mr. Secretary, put out the budget ten days after, after, not before, after declaring a public health emergency. So your answer is really not correct on that.

Secretary AZAR. Well, I am sure you understand the budget is locked in December. So it is already probably was printed by the date of the coronavirus outbreak.

Ms. ESHOO. Well, you mean the administration doesn't have the ability to call it in and cross something out and say, N-O, we are the not cutting this, we need it? I mean, that is not—come on. Come on. All right.

Now the gentleman from Vermont, Mr. Welch, is recognized for 4 minutes.

Mr. WELCH. Thank you.

Thank you, Mr. Secretary. You have been here a while.

Drug importation, we are very happy that you are proceeding on that and, as you know, we have a Republican Governor in Vermont who is extremely interested in getting authority to do this. They hope to have everything that is required for you sooner than the deadline. So we think it is a great opportunity. Our Republican Governor and Democratic legislature wants to take advantage of this.

One of the concerns that the Governor has, in particular, but all of us, is including insulin and that is not included, and my understanding is that there have been some concerns raised as to whether that can be safely done. It really would make a huge difference to Vermonters and, as you know, a lot of people already drive across the border to get insulin, and even some companies do that.

Our view is that the concerns about safety are always legitimate, no matter where the source of drugs, but our real request is to accommodate insulin as one of the drugs that could be imported as long as it is done safely. I wish you could comment on that and tell us what we need to do to give some relief to folks that are desperate about the cost difference.

Secretary AZAR. So unfortunately, insulins as an injectable product are expressly excluded under Section 804 of the Food, Drug, and Cosmetic Act which is the provision for the Canadian importation regime that we are using. We have no objection to it. In fact, the second part of the importation program where a drug company could bring a product in with a new drug code and actually price it at their—price at a lower list price so that they could deal with their PBM, those middlemen contracts, that are open for all products, including insulin.

Mr. WELCH. So let me just understand. This is helpful. You are saying it is because the statute——

Secretary AZAR. Yes, we have—we did not——

Mr. WELCH [continue]. Not because of a concern that HHS has.

Secretary AZAR. It is the statute.

Mr. WELCH. So as far as you are concerned, if you felt there was authority under the law for insulin to be included, you would see no reason to object to that.

Secretary AZAR. That is correct. We would be supportive if the statute provided for that. We believe it can be imported appropriately, but the statute does not allow me to approve an importation regime under 804 with insulins in it.

Mr. WELCH. So if we did an amendment to the statute to allow for insulin to be an exception, you would be supportive of that, it sounds like.

Secretary AZAR. I can't formally state an administration position, but I can tell you the President wants importation. He wants it yesterday, and we are delighted the Governor is working, because we want shovel-ready importation programs that, when we finalize a rule that we could get to work on approving.

Mr. WELCH. All right. So who would I follow up within the administration? It probably sounds like you——

Secretary AZAR. Me.

Mr. WELCH [continue]. But if I talk to the President about supporting what statutory provision may need to be included in order to allow insulin to come in. That would be huge, huge, huge for the Governor of Vermont, and for the people of Vermont.

Secretary AZAR. Sure. Happy to work with you on that. Absolutely. Talk directly to the President with you.

Mr. WELCH. All right. Thank you.

And I yield back.

Thank you very much——

Secretary AZAR. You bet.

Mr. WELCH. [continue]. Mr. Secretary.

Ms. ESHOO. The gentleman yields back.

The gentleman from Georgia, Mr. Carter, is recognized for 4 minutes.

Mr. CARTER. Thank you, Mr. Secretary, for being here.

I want to follow up on Representative Griffith's questions about DIR fees by the pharmacy benefit managers and, of course, as you know, the PBMs have squeezed out almost $4 billion out of pharmacies that have retail pharmacies with these DIR fees. In a survey that was done by the National Community Pharmacists Association said that 58 percent of the independent retail pharmacists in this country don't expect to be in business in two years, the result of DIR fees which, of course, should be of concern to all of us, but particularly to HHS and delivery of healthcare services in our country.

I just wanted to ask you. I believe you responded to Mr. Griffith by saying that the concern was the higher premiums with the insurance companies. As you know, three PBMs account for almost 80 percent of the market share in this country, and all of those PBMs are owned by insurance companies. How can we—how can we answer the question of whether those rebates that they are getting, the PBMs they are giving, are going back to the insurance company that is also owned by the same company?

Secretary AZAR. Well, that is one of the real problems we have got, is we don't have PBM transparency. Absolutely. So we can't actually know where those monies are flowing.

Mr. CARTER. It would appear to me that that is just taking money out of one pocket and putting it in the other pocket. I mean, it is the same company and then it is extended even more than that to include the pharmacies as well. So you know, the vertical integration is something that has got to be addressed.

But what do you think we can do to address the DIR fees? Now the DIR fees have been associated with higher out-of-pocket costs for recipients, and that is certainly something we have to be concerned about, and I know you are concerned about and you have said in the past that you are. If we can lower out-of-pocket costs, would it help to have the rebates at the point of sale?

Secretary AZAR. Oh, yes, it would help to have rebates at the point of sale. That would lower out-of-pocket costs. And pushing through, so folks understand, the DIR is basically a penalty provision that the middlemen impose on the community pharmacists, but the patient is made to pay off of the full price when they buy the drug and the pharmacy later may get this callback of this penalty, but the patient doesn't get a refund of their out-of-pocket.

Mr. CARTER. Absolutely. And that callback can take place almost a year afterward——

Secretary AZAR. Exactly.

Mr. CARTER [continue]. And sometimes two years afterward.

Secretary AZAR. Very unpredictable to the community pharmacy. They are struggling from this. Absolutely.

Mr. CARTER. Absolutely.

Now I want to switch to the coronavirus and these are yes-or-no questions, if you could answer them for me. At this time, at this time, are you and others involved in preparing for a potential

COVID-19 outbreak, doing everything you can to prepare for such an event?

Secretary AZAR. We are indeed.

Mr. CARTER. At this time, if you and others involved in preparing for a potential COVID-19 outbreak felt like you needed more money, would you have asked for it?

Secretary AZAR. I would have and I have and that request is there.

Mr. CARTER. OK. At any time, if you and others involved in preparing for a potential COVID-19 outbreak need more money, will you ask for it?

Secretary AZAR. I will indeed.

Mr. CARTER. Absolutely. So it is not as to say that the amount of money that is asked for is proportional to the effort that is going to be put forth to prepare for this?

Secretary AZAR. Right. That is right. And the President has made very clear in my own discussions with him, as well as publicly, that we want to work with Congress on an appropriate supplemental proceedings here and we have said—it quite deliberately says at least $2.5 billion. We want to work with Congress. We got to get that money and make sure that Congress is satisfied with the funding also.

Mr. CARTER. As should be the case.

And, again, if you find out that you need more, you are going to come back to us, and we are going to approve it. We want you to have everything that is available that you need to prepare for this. And you are going to do that, correct?

Secretary AZAR. That is correct.

Mr. CARTER. Madam Chair, I yield back.

Thank you, Mr. Secretary.

Ms. ESHOO. The gentleman yields back.

The Chair recognizes the gentleman from California, Mr. Ruiz, for 4 minutes.

Mr. RUIZ. Thank you, Secretary Azar, for being here today.

As a father and a physician, I care very deeply about the physical and mental health of children and also children while in the custody of the Office of Refugee Resettlement. And I am glad my colleague Tony Cárdenas brought that up because I am also dealing with a similar situation in my district.

ORR's website says their unaccompanied children program, quote, "takes into consideration the unique nature of each child's situation and incorporates child welfare principles when making placement, clinical, case management, and release decisions that are in the best interest of the child."

So let me get this straight, because I definitely want answers. When determining appropriate housing for children in ORR custody, do you give grants to for-profit organizations with a documented history of child abuse?

Secretary AZAR. Again, I can't speak to that particular grant that was raised before. We would give grants to for-profit or nonprofit without discrimination, but——

Mr. RUIZ. OK. So the caveat is those with a documented history of child abuse.

I recently learned that, in addition to the facility in Arleta, California, ORR is providing a grant to VisionQuest to open a 130-bed shelter for unaccompanied children in the city of Hemet, California, which I represent. VisionQuest is a for-profit organization whose history suggests that their focus is to make money rather than care about the well-being of children.

This is exemplified by VisionQuest's very long history of keeping children in abusive and harmful conditions, which my colleague touched on. Dating all the way back to 1987, a report from the RAND Corporation found that, quote, "the treatment methods used by VisionQuest were unorthodox" and that "activities engaged in by the youths posed unnecessary risks to their health and safety."

Last year, the Associated Press reported that in 1994 the Department of Justice documented episodes of physical and mental abuse at a VisionQuest shelter in Franklin, Pennsylvania, including staffers pulling children's hair, using harsh restraints, choking minors, and even slamming them into walls.

And in 2017 the city of Philadelphia had to end a contract with VisionQuest after State inspectors found that staff members had choked, slapped, and injured children in the facility.

Secretary, as our providing Federal funding to a for-profit organization with a long history of child abuse is definitely not in the best interest of children, are you familiar with these reports?

Secretary AZAR. I am not familiar with all of those reports. Some of the allegations that you raised, I am familiar with.

Mr. RUIZ. Here is the report.

Secretary AZAR. Of course, whether for-profit or nonprofit is not the factor——

Mr. RUIZ. This is the RAND report.

Secretary AZAR [continue]. But we want to ensure that any grantee——

Mr. RUIZ. And this is a——

Secretary AZAR. Thank you.

Mr. RUIZ [continue]. Letter within the Department of Justice documenting

Secretary AZAR. Thank you. I appreciate that.

Mr. RUIZ. My question now——

Ms. ESHOO. Would the gentleman be seated and speak from the microphone so that what you say can be properly recorded?

Mr. RUIZ. Sure. Will do.

So, now——

Secretary AZAR. Of course, one of these is, I just noted, from 1994.

Mr. RUIZ. Of course. So that is why I mention a long history of abuse.

Secretary AZAR. But we will make sure any grantee is appropriate to the——but we need to make sure that——

Mr. RUIZ. And so that is why——

Secretary AZAR. Correct, and not——

Mr. RUIZ. That is why, when you look and review at these programs, I want to ask you, what is the process? Is there transparency? How do you determine and how do you open this up to communities to determine who is going to house children with the safety of these children in mind?

Secretary AZAR. So, for these permanent bedded facilities, which is our goal at the request of Congress, the grantees would actually have to be State-licensed. And so there is a State licensure procedure.

Mr. RUIZ. OK.

Secretary AZAR. That would be the community involvement.

Mr. RUIZ. Well, the State of Pennsylvania denied them their ability to take care of children because of those horrible——

Secretary AZAR. And then they would not be able to be a grantee in that case.

Mr. RUIZ. And they had to close that facility.

So the question is, when you look at those reports and you review the evidence, would you be open to reevaluating these grants and your relationship with VisionQuest——

Secretary AZAR. I will ensure——

Mr. RUIZ [continue]. And their care for ORR?

Secretary AZAR. I will ensure that ORR has looked at these and this was part of the evaluation criteria in looking at them.

Of course, just because an entity has—all of the behaviors you described are absolutely unacceptable. I just want to be very clear about that.

Mr. RUIZ. And I am glad you said it, because I——

Secretary AZAR. Absolutely unacceptable——

Ms. ESHOO. The gentleman's time has expired.

Secretary AZAR. Thank you.

Ms. ESHOO. The Chair recognizes the gentleman from Missouri, Mr. Long, for his 4 minutes.

We really need to move along, because we have another panel, and everyone knows it is a very important one. So let's stay within our time.

Mr. Long, 4 minutes.

Mr. LONG. Thank you, Madam Chairwoman.

And, Secretary Azar, I want to thank you for being here today. I know we tried to get together one time, and as soon as we sat down, my phone started blowing up that my house was on fire in Missouri, which it turns out it wasn't, but the alarm company people seemed to think it was and they sent the fire department. I am sure you remember that.

But I want to thank you for working so hard to advance the administration's health agenda on behalf of the American people.

As you note in your testimony, rural Americans face many unique health challenges. And, under your leadership, HHS created the Rural Health Task Force and is proposing a four-point strategy to transform rural health, which is vitally important in my area, as I represent a lot of rural areas.

Can you first speak to the Rural Health Task Force's role in identifying the needs of rural areas and how to meet those needs department-wide?

Secretary AZAR. You bet. Yes, absolutely. Thank you.

The Rural Task Force identified four key priorities for us. The first, we have to develop a sustainable model for rural healthcare. We can't just patch it over with money if it is not underlying economically viable. Second, we have to have prevention and health promotion in rural America. Third, we have to leverage technology

and innovation like telehealth. And, fourth, we have to get the next generation of providers out into rural America, and we have to allow nurse practitioners and P.A.s to practice to the full extent of their license in rural communities.

Mr. LONG. OK. Thank you.

And one area in rural health that has been seriously impacted over the last few years is durable medical equipment, as you are apprised of. I was pleased that CMS issued the interim final rule in May of 2018 that provided payment relief for durable medical equipment in rural areas and continued the relief in the 2019 end-stage renal disease final rule until the end of 2020.

Can you tell me if CMS plans to continue this relief in rural areas after 2020?

Secretary AZAR. So I am not able, obviously, to discuss a pending regulatory action, but I do know that that was a major priority, to get that payment fix in place through the interim final rule to ensure better equity for rural America. So that remains very much top of mind for us.

Mr. LONG. OK.

And in the President's fiscal year 2021 budget, there is a provision that would expand the competitive bidding program for durable medical equipment into rural areas in 2024. We have heard many complaints about the competitive bidding program over the years, really since its inception. Can you detail how you would like to reform the program and how it would impact rural areas?

Secretary AZAR. Yes. What we would like to do in the budget is, actually pay for durable medical equipment under the competitive bidding program and move that, though, from a single payment amount that is based on the maximum winning bid to actually paying suppliers on their own bid amounts and then expanding the competitive bidding to additional geographic areas, including rural areas.

We think that would actually enhance access to DME in rural areas by allowing competition there rather than simply having to depend on the payment result secured elsewhere. We think that can solve a lot of the access challenges that we saw that we had to work to fix with the interim final regulation.

Mr. LONG. OK.

And has CMS engaged with outside experts, economists, or consumer groups on this as it considers expanding the competitive bidding program?

Secretary AZAR. We do. We engage with stakeholders and experts before we consider any new policy. And, of course, the benefit when we do notice-and-comment rulemaking is to get that feedback.

Mr. LONG. Would you go forward with the proposal without the Congressional approval?

Secretary AZAR. I believe, for some of the regional elements on competitive business, I believe that we—I don't know if we require statutory authority. I want to get back to you on that, as to whether the budget has that as an administrative action or a statutory request. If I could get back to you, Congressman, on that.

Mr. LONG. If you would, I would appreciate it.

Secretary AZAR. You bet. Thank you.

Mr. LONG. And I yield back.

Ms. ESHOO. The gentleman yields back.

The Chair now recognizes the gentlewoman from Michigan, Mrs. Dingell, for her 4 minutes of questions.

Mrs. DINGELL. Thank you, Madam Chair.

Thank you, Mr. Secretary. I know it has been a long afternoon.

It has been nearly a month since you declared a formal public health emergency and response to the coronavirus global threat. On February 2, you sent a letter to Congress that you intend to use or transfer or reprogram authority to reallocate approximately $136 million from current programs.

Yesterday, we got the details of those transfers, and I would like to request unanimous consent to enter that into the record.

Ms. ESHOO. So ordered.

[The information appears at the conclusion of the hearing.]

Mrs. DINGELL. Thank you, Madam Chair.

These include $62 million transferred out of NIH, $37 million taken from the Low Income Energy Assistance Program, and $7.5 million from the Centers for Medicare and Medicaid.

Given that you plan to take $37 million from the Low Income Energy Program, do we have any estimates of how many people that is going to impact and who is going to go without heat this winter?

Secretary AZAR. So, for the transferred reallocation authority, that works out to a 0.2-percent change. And we did that across the Department evenly, but then, within different agencies, they selected various programs.

On LIHEAP, we are now late in the season, almost at the end of February. I don't have an analysis for you of——

Mrs. DINGELL. Can we get, for the record, please, what we think the impact will be? Because we obviously are worried about people who aren't going to have heat.

You are going to take—and I don't mean to be—I just have to go fast. I have 4 minutes. You are going to be taking—you took $62 million from NIH. Is that going to harm our ability to conduct medical research into new cancer treatments—I am happy, with you, that opioid deaths have gone down this year. There is no one who feels stronger. Maybe Annie. We are together—and meet other public health challenges. What is going to happen to those programs?

Secretary AZAR. So the NIH, in doing the reallocation and taking their allotment of the 0.2 percent, they firewalled off certain priorities, including, I know, opioid research and development is one of the primary areas——

Mrs. DINGELL. So it has not been cut?

Secretary AZAR [continue]. Pediatric cancer—right.

Mrs. DINGELL. All right.

Now, I know you talked about this yesterday, but you stated in your Senate testimony yesterday that the U.S. Currently has about 30 million stockpiled N95 respirators, which are masks that can help stop a person from inhaling infective particles, but that it might require 300 million for healthcare workers alone. This doesn't include masks, gloves, and personal protective equipment.

That was yesterday. We have heard about nearly 900 more cases worldwide, 60 more deaths. I am really worried, as I know the Chair is, about the supply chain in this country. Your own agency

has stated that 65 percent of N95 respirators are manufactured outside of the U.S., in China and Mexico. Yesterday, The Washington Post told us that a large group-purchasing organization says we may only have a 2-week supply.

I don't want to frighten anybody. We shouldn't be rushing off. But are we facing an imminent shortage of N95 respirators and other personal protective equipment?

Secretary AZAR. So I did want to clarify on the numbers that I told the appropriators this morning. After the hearing, I learned some additional information about the number of masks that we have. We have a higher number, but the mix is different. So we have 30 million surgical masks, the gauze masks. We have 12 million N95 NIOSH-certified masks, and then five that are not NIOSH-certified—5 million N95s. So I just wanted to clarify the data on that.

One of the things we are doing with the transfer money that we discussed earlier is contracting to get—get contracts started with domestic manufacturers of N95 masks so that we can scale up production——

Mrs. DINGELL. But how long is it going to take to scale up that production?

Secretary AZAR. It will take time because we do not have as much domestic manufacturing——

Mrs. DINGELL. Is it a national security threat that 90 percent of our generics are coming from China? We have this kind of shortage. What are we going to do—and I am out of time—to help bring the kind of production of these kinds of essentials to this country so we are not dependent on anyone else?

Ms. ESHOO. The gentlewoman's time has expired.

The Chair recognizes the gentlewoman from Delaware, Ms. Blunt Rochester, for 4 minutes.

Ms. BLUNT ROCHESTER. Thank you, Madam Chairwoman.

And, also, welcome, Mr. Secretary.

I have to express my deep concern and disappointment in the implementation of the Affordable Care Act, which is the law of the land. It appears that the Department of Health and Human Services has made it harder for Americans to access and afford the vital health insurance coverage that they rely on.

Your department recently proposed a rule that would discontinue the ACA subsidies for low-income families who do not actively reapply during the ACA's open enrollment period. These are low-income Americans who are currently enrolled in zero-dollar-premium plans.

Secretary Azar, your department's analysis acknowledges that there are 270,000 Americans who are reenrolled in these zero-dollar-premium plans that could lose their coverage. And yet you proposed ending auto-enrollment for these individuals, thereby endangering their coverage.

First, a "yes" or a "no" question: In deciding to propose this policy, did you consider the fact that it would result in American families losing coverage?

Secretary AZAR. I want to get back to you for the record, if I could. I don't know that we actually proposed it, as opposed to asking for comment on whether one should allow auto-reenrollment for

people that are 100-percent subsidized in the ACA exchange markets. I think we asked just for comment on that, as opposed to proposing that as the approach.

Ms. BLUNT ROCHESTER. So I am assuming, if you are asking for comment, it is something that you are considering?

Secretary AZAR. It is under consideration, if we should require someone to apply who is getting 100 percent of their subsidy paid for, their premiums paid for, should they affirmatively demonstrate that they continue to qualify on an income and wealth basis for that, as opposed to just rolling over and then pay and chase later if we find months later, they don't qualify.

Ms. BLUNT ROCHESTER. So can you guarantee that no individuals would lose coverage as a result of this policy?

Secretary AZAR. Well, if they don't qualify, then they wouldn't retain coverage at 100-percent subsidy——

Ms. BLUNT ROCHESTER. Meaning, if you changed the policy, then they wouldn't qualify and they could lose——

Secretary AZAR. They shouldn't qualify.

Ms. BLUNT ROCHESTER. I am particularly alarmed that your department would propose such a policy given that Congress statutorily directed you to establish automatic reenrollment for all individuals enrolled in the marketplace. That provision was signed into law by the President at the end of the year. This proposed policy goes against congressional intent.

Mr. Secretary, will you commit to the American people that you will not take any action that would cause American families to lose their health insurance? That is just a "yes" or "no."

Secretary AZAR. I believe that rider was with respect to 2020 moneys, and the request for information was regarding the 2021 plan year, which is not subject to that rider, is my understanding.

Ms. BLUNT ROCHESTER. The deep concern is that the Department now has a record of refusing to properly invest in robust advertising and outreach. The Department has drastically reduced funding for outreach and education activities. It has gutted the Navigator program, limited the time for enrollment, and is giving consumers less opportunity to make informed choices. Now the Department threatens to discontinue American families' subsidies who have become accustomed to being reenrolled every year.

Mr. Secretary, would you commit to working with me to ensure that Americans wishing to enroll in coverage will be well-informed about the opportunities to enroll?

Secretary AZAR. Well, I am always happy to work with you, Congresswoman, on any issue.

Ms. BLUNT ROCHESTER. Well, we have talked about working together before, so I just want to put it on the record on this particular issue.

Secretary AZAR. So, you know, just in terms of open enrollment, we put out a billion reminder emails, we had——

Ms. BLUNT ROCHESTER. It is just a "yes" or "no" question, because my time has expired. Yes?

Secretary AZAR. Happy to work with you.

Ms. BLUNT ROCHESTER. OK. We will follow up.

Thank you, Madam Chair.

Ms. ESHOO. The gentlewoman's time has expired.

The Chair recognizes the gentlewoman from California, Ms. Barragán, for her 4 minutes of questions.

Ms. BARRAGÁN. Thank you.

Thank you, Mr. Secretary, for being here today.

As we have heard from you, our U.S. Government has implemented aggressive measures to help prevent the spread of the coronavirus. There have been repatriation missions. There have been travel bans, airport restrictions, and additional travel notices issued. Many of these actions have impacted Los Angeles County and, in particular, my district.

On February 2, the President signed a proclamation banning foreign nationals who have traveled to China in the preceding 14 days and were not the immediate family of U.S. citizens and permanent residents. Over the course of a few weeks, 808 U.S. citizens were flown back to the United States, where they were quarantined for 14 days at military bases.

As of today, 37 countries have confirmed cases of coronavirus. Should we expect travel bans from countries, like Italy, who have confirmed cases of transmission but are on a different continent than current travel bans?

Mr. Secretary, how sustainable are quarantines and travel restrictions in holding the coronavirus at bay?

Secretary AZAR. It is an excellent question. And that is why, when we did the initial 212(f) China ban that you mentioned, we were very clear, we can't hermetically seal the United States off, and, at some point, there would be sufficient spread in other countries that measures like that would not be effective.

With China, of course, with the epicenter being in China and with the aggressive measures taken by China, that is what we felt was appropriate to do there. We will constantly look at other travel advisories, 212(f) restrictions, or surveillance and requests for home isolation as we gather more information. But it is a very fair point, absolutely.

Ms. BARRAGÁN. And so, following up on that, what resources are going to the quarantines that are happening?

Secretary AZAR. So——

Ms. BARRAGÁN. And should these be expanded? Should they be extended? You know, what additional resources do you expect are going to be necessary?

Secretary AZAR. So I would actually like to get us out of the Federal quarantine business. And I do want to commend California and the local governments there. They have really been a superb partner with us on the repatriation of American citizens. But it is quite expensive to maintain institutional quarantine.

We don't envision further repatriation flights that really has implicated that need for us to scale up this type of facilities-based quarantine. In the future, as I think Dr. Schuchat mentioned yesterday, we would envision more self-home-isolation activities, State- and local-based monitoring and quarantine activities.

Ms. BARRAGÁN. OK.

I want to drill down a little bit on this, because on Monday HHS issued a statement that revealed a Naval base in Ventura County, Point Mugu, may receive American travelers coming through LAX who would be quarantined to be monitored for symptoms of

coronavirus based solely on their travel history. Let me repeat that: based solely on their travel history.

Mr. Secretary, what are HHS's plans to quarantine Americans based on solely their travel history? And would those be voluntary or mandatory?

Secretary AZAR. So that would be the Hubei province travel. So an individual who within, the previous 14 days, has been in Hubei province in China, as an American or a permanent resident alien or family member, would be subject to mandatory quarantine.

We are seeing very, very few of those individuals. I think we had a family of three and then one individual is really all, I believe, that we have right now currently in quarantine.

So that is more of a backup concept there, the Ventura facility you are talking about, to know it is there. But we have, again, worked very well with the State and locals in California.

Ms. BARRAGÁN. Right. And we certainly know that the CDC has said that it is not a matter of if the virus is going to spread but a matter of when. You know, Congress wants to work with your agency to fund adequate and effective and sustainable public health responses. We can't do that without sufficient funding going forward to appropriate to State and local partners.

Secretary AZAR. Yes.

Ms. BARRAGÁN. I know that you will be seeing out of the Congress, especially out of the majority, a proposal on that.

Thank you, and I yield back.

Secretary AZAR. Thank you.

Ms. ESHOO. The gentlewoman's time has expired.

The Chair recognizes the gentlewoman from New Hampshire, Ms. Kuster, for her 4 minutes.

Ms. KUSTER. Thank you, Madam Chairman.

And, Secretary Azar, thank you for appearing before our committee. There is a lot going on both in your budget and with our concerns about the coronavirus, so I will move through this quickly.

The key to a public health crisis, as you well know, is trust and credibility. And my point is, it would be helpful for clear, easy-to-understand, credible updates from this administration to both us, as policymakers and Members of Congress, and to the American people. And it would be even more preferable if the statements by the President of the United States did not contradict the statements of the scientists and physicians at the CDC and in your department.

My time is limited. I want to jump right in on the administration's continuing efforts to undermine the Affordable Care Act's consumer protections for people with preexisting conditions.

The administration and your testimony today claims to support protections for preexisting conditions, but, with all due respect, the facts speak for themselves. This administration has repeatedly taken action, including court proceedings, to undermine protections for people, including my constituents, with preexisting conditions.

Your department finalized a rule to expand junk plans that do not provide protection for people with preexisting conditions and issued a 1332 waiver guidance creating new standards inconsistent with congressional intent. The guidance allows States to increase consumers' costs, reduce coverage, and undermine protections.

Simple "yes" or "no" question, Secretary Azar: Are you aware that the 1332 guidance could substantially raise costs for Americans with preexisting conditions?

Secretary AZAR. Actually, our 1332 guidance allowed me to approve reinsurance waivers for 11 States, causing 10- to 30-percent declines in premiums in the exchange market.

Ms. KUSTER. And in the other States, what would the result be?

Secretary AZAR. One other State was, I think—I forget if it was Hawaii that we approved a waiver allowing them to not have the SHOP. I think that was it, if I remember. Yes, in Hawaii. So that was at their request, to not have the State—I forget the exact terminology of what the SHOP is, but it is a technical aspect of the Affordable Care Act.

We have approved no other ACA 1332 waivers at this point.

Ms. KUSTER. And will you commit not to approve waivers that would jeopardize the health and well-being and the financial well-being of Americans with preexisting conditions?

Secretary AZAR. You can't waive the protection against preexisting conditions, under 1332 or otherwise.

Ms. KUSTER. And this administration is inviting States to make changes to the ACA subsidy structure and direct taxpayer dollars to junk plans. And those do indeed threaten and jeopardize individuals with preexisting conditions.

Yes or no, do you think it is appropriate to allow States to direct taxpayer dollars toward junk plans that do not provide protections for preexisting conditions?

Secretary AZAR. We think it is appropriate to allow States to support access to these short-term, limited-duration plans, which are plans that the Obama administration allowed to 12 months up until the end of the administration.

Ms. KUSTER. Well, let me dive right into that. Under the Obama administration, the short-term, limited-duration plans were for just three months.

Secretary AZAR. I——

Ms. KUSTER. You have now extended it to 12 months with three renewals. That is not the same condition.

Secretary AZAR. I am afraid that is actually not correct. The Obama administration had them for up to 12 months up until the very end of the administration, when they passed a midnight regulation shortening it to three months.

Ms. KUSTER. To three months. That is my point.

Secretary AZAR. Right at the very end. They were perfectly fine with the——

Ms. KUSTER. That is my point, is it was three months, and you have allowed for extensions for up to three times. That is four years.

And we had people testify here that they did not even have noticed that their preexisting conditions were not covered, and even insurers that said to them that if they didn't know they had a preexisting that they should have known.

So this is something we need much more work on. I aim to protect consumers with preexisting conditions.

Thank you. I yield back.

Secretary AZAR. Just one correction. It is 12 reinsurance waivers, not 11.

Ms. ESHOO. The gentlewoman's time has expired.

The Chair recognizes the gentlewoman from Illinois, Ms. Kelly, for 2 minutes.

And I just want to instruct the members; we have two more to question, and they have agreed to limit their time to 2 minutes each. We will then take a very short break, maybe 5 minutes, to reset the witness table for the next panel and allow the Secretary to take, you know, a few-minute break.

All right. So now we will recognize the gentlewoman from Illinois, Ms. Kelly, for 2 minutes.

Ms. KELLY. Thank you, Mr. Secretary, for being here.

I wanted to talk about two issues that I have paid a lot of attention to and that have actually ravaged communities of color across the Nation. One is maternal mortality, and the other is gun violence.

President Trump has expressed concerns about maternal deaths, and, following mass shootings last year, he called for bipartisan solutions to reduce gun violence. Well, we in Congress have come up with bipartisan solutions for both. I have worked with my colleagues on the other side of the aisle on a bill to expand Medicaid to provide postpartum coverage for a full year. And Congress appropriated and President Trump signed into law $12.5 billion in funding for the CDC to study gun violence.

Yet your administration seeks to slash funding to and block-grant Medicaid, implement more restrictive eligibility criteria for Medicaid recipients, and completely zero out funding for gun violence research.

Secretary, are you aware, yes or no, that the budget contains a proposal that would allow States to impose an asset test on pregnant women in Medicaid? It is pages 112 to 113 of the HHS Budget in Brief.

Secretary AZAR. I would want to look at that and get back to you on that. I am not aware of that particular provision.

Ms. KELLY. OK.

Secretary AZAR. We do have the proposal, similar to what you just mentioned for Medicaid, that would allow States an option to cover pregnant women for one year after birth if they are suffering from substance use disorder. So that is another part of the maternal mortality initiative.

Ms. KELLY. Yes. That proposal will cut Medicaid's funding by $2.2 billion. That is because it would cause a lot of people, including pregnant women, to lose their Medicaid coverage. So maybe you——

Secretary AZAR. That is a spending provision, the one I just mentioned. It would actually expand—right now, they can only get 60 days' coverage postpartum. This would allow that coverage for up to a year as a State option in a non-budget-neutral way, I believe.

Ms. KELLY. Well, my time is up.

Ms. ESHOO. The gentlewoman's time has expired.

That legislation that we took up here is awaiting floor approval. The gentlewoman has been a leader on this for long before the rest

of the members even knew that we had this horrible statistic in our country.

Last but not least, the gentlewoman from Florida, Ms. Castor, for her two minutes.

Ms. CASTOR. Thank you, Madam Chair.

Mr. Secretary, the administration is urging the Federal courts to strike down the Affordable Care Act in its entirety, including the protections for more than 130 million Americans who have a preexisting health condition.

I think my neighbors back home would want me to relay to you how dangerous that is, how angry they are about it. They do not want to return to the days when insurance companies could discriminate against them if they had asthma, a cancer diagnosis, some other preexisting condition. They don't want to return to the days where an insurance company can cancel them if they get sick.

And I think the coronavirus now highlights the importance of consistent health insurance coverage that has a floor of essential health benefits. And it really shines light on these junk plans. Your department has finalized a rule to expand the short-term, limited-duration junk plans. They are not required to cover preexisting conditions. You acknowledged that in your last budget hearing in front of this committee.

And a couple of studies have come out recently, a Georgetown Health Policy Institute study, one commissioned by Leukemia and Lymphoma Society, that kind of highlight the abuses here.

Is the Department conducting any oversight on the abuses of these junk plans, the abuses in marketing, and false promises? Are you conducting oversight of these?

Secretary AZAR. So the short-term, limited-duration plans are off-exchange, and so we don't actually regulate——

Ms. CASTOR. Could you just say "yes" or "no" quickly? Because——

Secretary AZAR. We don't——

Ms. CASTOR [continue]. The time is short.

Secretary AZAR. We don't regulate them directly. They are subject to State insurance regulation.

Ms. CASTOR. You do not—so it is, like, hands-off? You said, we are going to promote these junk plans, and you are not conducting any oversight? Is that true, yes or no?

Secretary AZAR. They are subject to State insurance regulations, as individual markets should be.

Ms. CASTOR. And you don't check in with the State and monitor the abuses in the junk-plan market that are raising costs on everybody and excluding preexisting conditions?

Secretary AZAR. So we——

Ms. CASTOR. Thank you.

Secretary AZAR. We do not support—we do not regulate State insurance commissioners.

Ms. ESHOO. The gentlewoman yields back.

Let's take a 5-minute break, and the staff can reset the witness table, and then we will resume. Thank you.

[Recess.]

Ms. ESHOO. The Subcommittee on Health will come back to order.

What we are going to do is, we are not going to have our witnesses do their formal public statements. We have them all in the record.

[The prepared statements follow:]

[The information appears at the conclusion of the hearing.]

Ms. ESHOO. We thank you for them. I have actually read them, and I am sure my colleagues have as well.

What I just want to do quickly, out of respect to each, is to just give a quick introduction. And then we will go to members with their questions.

And, first of all, thank you for being here. I think that the United States of America is so blessed—is so blessed—to have, I think, the finest public health professionals in the entire world. There is a reason why the world looks to us: Because we have you and your expertise.

So, Dr. Fauci, thank you to you. America can't live without you, really.

Dr. Hahn, welcome to you. I think this is the first time that you are before the committee?

Dr. HAHN. Yes.

Ms. ESHOO. And we will make it really pleasant for you.

Dr. HAHN. Thank you very much.

Ms. ESHOO. We won't do to you what we did to the Secretary.

Mr. Secretary, welcome back to the table.

Dr. Kadlec, welcome to you.

And to Dr. Redfield from the CDC, thank you for being here.

And thank you, collectively, for what you have done to help to brief the Congress during this.

Now, is it my turn to ask?

STAFF. Yes.

Ms. ESHOO. OK. Let me start, obviously, with the coronavirus.

I started out earlier today saying that confusion is the enemy of preparedness. I do not put confusion at the doorstep of Dr. Fauci, Dr. Hahn, Dr. Kadlec, and Dr. Redfield.

I think that you have done an excellent job in advising, briefing the Congress and for the work that you are doing.

I think we have some problems with the administration, because the professionals say one thing and then there is confusion on the other side.

I hope that something else will happen, too, and that briefings be held in public so the American people can hear you. I hope, as we move through this challenge, that the American people will come to know you the way we do, and that we elevate the level of confidence and trust that I know you can engender, but I don't think it is there now.

There is confusion; markets are roiling. It is not only because of confusion, but there are many matters at hand. But you, the scientists, the doctors—the American people couldn't be better served. They just couldn't be better served. So thank you to you for your especially important service right now.

What I want to get to—Dr. Hahn, let me start with you—is our drug supply. Are manufacturers being forthcoming with the FDA about potential shortages?

Dr. HAHN. Madam Chairwoman, thank you for the question.

We are being very proactive in our discussions with manufacturers. As you know, drug manufacturers are required to report to us when there are potential disruptions——

Ms. ESHOO. And how far in advance do they let you know that there will be a shortage?

Dr. HAHN. Typically those conversations occur in real-time. What we have done is——

Ms. ESHOO. Well, I know that—I think, usually, all of our conversations are in real-time. I am saying, how much—you know, in a trajectory of time, if they were talking to you today, would they be able to tell when the shortage would begin? How much runway do we have?

Dr. HAHN. We often do not——

Ms. ESHOO. For example, China and manufacturing. So we have a problem with that.

Dr. HAHN. So, just as an example, I can tell you that drug manufacturers are required to tell us when there is a potential disruption to the drug supply. When the applicants apply to the FDA, they might provide, for example, five different manufacturers for the precursors to the drug and then five manufacturers for the actual final drug form——

Ms. ESHOO. OK.

Let me ask you this. If the coronavirus outbreak is continuing three months from now—and I pray that it isn't—what do you estimate the American drug supply will be? Have you done——

Dr. HAHN. So we have looked at this.

Ms. ESHOO [continue]. Forward-leaning planning?

Dr. HAHN. There are 183 prescription drug manufacturers in China. Twenty are sole-source from China. That is both precursors as well as the final drug form. We have reached out to all of these manufacturers, and we have no shortages to those sole-source drugs.

It is the redundancy, Madam Chairwoman, that is most important, and if we have redundancy, then we can shift to other manufacturing sources.

Ms. ESHOO. Yesterday, the FDA said that—you mentioned this—the 20 drug products that are either solely sourced there for their active ingredients or finished drug products from China. Can you share that list with us, or is that proprietary?

Dr. HAHN. That is a proprietary list. We are internally compiling lists associated with all the questions that we have been asking of manufacturers.

Ms. ESHOO. Yes.

Dr. Redfield, how many coronavirus tests can the U.S. conduct as of today?

Dr. REDFIELD. How many cases?

Ms. ESHOO. Yes. How many tests——

Dr. REDFIELD. Oh, tests.

Ms. ESHOO [continue]. Can our country conduct as of today?

Dr. REDFIELD. I would have to get back to you with the exact number.

Ms. ESHOO. OK.

I kind of teased, but I was serious, Secretary Azar. We have some deep cuts to these agencies, the people that you are sitting

with. And it was mentioned by, I think, the ranking member that the budget was printed and it couldn't be changed because of the print and all of that.

I think, Secretary Azar, the $200 million in cuts at BARDA, $700 million in cuts at CDC, and $3 billion out of NIH, are you willing to reconsider that, given what our country is facing and what the American people need day-in and day-out from these agencies? They are the essentials.

Secretary AZAR. The proposals to the budget do not impact our ability to do the novel corona response. The CDC budget actually has a $135 million increase in the fields of infectious disease and global health security preparedness.

Ms. ESHOO. Do you think that, in other words, they deserve these cuts? These are healthy cuts? This is good for them, and it is good for our country.

Secretary AZAR. You asked me about impact related to novel coronavirus. These will not impact functioning related to that. And, of course, we have these emergency supplemental request on top of that.

Ms. ESHOO. Well, but if you wrote it in December, how do you know that?

Secretary AZAR. Because the changes that we make in the budget are not related to categories that will impact our ability to do the novel coronavirus response.

Ms. ESHOO. So there is nothing to reconsider?

Secretary AZAR. I don't believe there is, in terms of the existing budget proposal. We have——

Ms. ESHOO. Well, you know what?

Secretary AZAR [continue]. The emergency supplemental adding to accounts that we think are the relevant ones.

Ms. ESHOO. Today is February 26, 2020, and I certainly hope you are right, but I think that we are shortchanging the American people.

At this time, I recognize Dr. Burgess, the ranking member of the subcommittee.

Mr. BURGESS. I thank the Chair.

I would just point out, we are the United States House of Representatives. All spending bills originate in the United States House of Representatives. So it is certainly well within our power to provide the level of spending that you all request.

The House is just now doing its budget, several months after the administration did its budget. I will be testifying to the Budget Committee tomorrow. I think if people have concerns, they ought to bring them up to the Budget Committee. I just hope we will actually have a budget debate and vote on a House budget, because we haven't in several previous years.

But I do want to thank the panel for being here today. This is critically important. The Chair is correct that people do need to see and this needs to be public. That is why we have hearings, because hearings are on the record and are public, which is why, several weeks ago, I suggested we have this hearing, and I am glad we are having it today.

Secretary Azar, you were testifying on the budget before. You did take some questions on the issue of the Office of Refugee Resettle-

ment. Just off the topic of the corona, can I say, I have been fortunate enough to visit a number of your facilities provided by Office of Refugee Resettlement, and I think we are fortunate to have the men and women who are working in those facilities. And would you just please convey to them my thanks? Because I do think they do a good job, and we would be much the worse without them.

Secretary AZAR. I will. And that will mean a great deal to them. Thank you.

Mr. BURGESS. Dr. Hahn, you and I had talked a little bit, somewhat earlier, about the supply chain and the active pharmaceutical ingredients that we import from overseas. And the fact was that there was an adequate stockpile as, sort of, this story began to evolve several weeks ago.

To the extent that you can tell us, how are things looking now, as far as the stockpile that companies have available, as far as the active pharmaceutical ingredient?

Dr. HAHN. Thank you, Representative Burgess.

As we discussed before, we have received no reports of shortages and found no shortages in prescription drugs coming from China. And we have discussed this with manufacturers and pharma companies, and adequate supplies currently exist.

Mr. BURGESS. So can I just offer this observation? And I have been on this subcommittee for a long time, and we have had this discussion in other guises and other times. And if there is any silver lining to this cloud, it may be that we recognize that we need to bring some of that manufacturing back within our own shores so that we are responsible for our—we have the responsibility for those active pharmaceutical ingredients.

And I know this is something the President is focused on and part of his rebuilding of America. This is, I think, work that this committee, subcommittee, has done in the past. I think it is something that we really need to take very seriously.

We had some hearings on continuous manufacturing a few weeks ago, and I think that is another aspect of this, where—perhaps some attention to the continuous manufacturing, but the main thing is make it here so we are not dependent on a sole source from another country. Whether it be in difficulty from an infection or just simply out of sorts with the United States at the time, it does jeopardize our people, and I do think we need to recognize that.

And, again, that is not a criticism of this panel. We have known about that on this subcommittee for a long time, and it is just, we haven't acted. Now, perhaps we will.

Dr. Redfield, I would like to ask you, we have heard several times the World Health Organization was able to finally get into China and assist them. And now that report is going to be coming back. Are you satisfied with the level of interaction that you have had with your Chinese counterparts? Because the CDC itself was not allowed to go in. Is that correct? It was only as part of the World Health Organization?

Dr. REDFIELD. We were able to have a representative on the GOARN team that went to China to do the investigation. I have had regular conversations with my counterpart, the head of the CDC in China. We have had a good exchange of scientific informa-

tion. We do have a CDC office in Beijing, China, that is there, and they continue to have good interactions with those colleagues.

Mr. BURGESS. So you think there is, working with the State and local folks?

Dr. REDFIELD. There is good scientific interaction between us.

Mr. BURGESS. OK.

And, Dr. Hahn, let me just come back to you for a moment. And thank you for the work you are doing on getting a laboratory-developed test. That is critical. They can't all be done at the CDC. We are going to have to be able to get those tests done rapidly in the field for our people on the front lines.

But is there any evidence if there is any sort of hoarding behavior going on with things like personal protective equipment or pharmaceuticals? Is that something about which we need to become concerned?

Dr. HAHN. In terms of the supply for——

Mr. BURGESS. Yes.

Dr. HAHN. We have reached out to manufacturers, and we are aware that spot shortages can and have occurred. However, currently, we know of no overall shortage related to PPE. However, this is a very dynamic situation, as I mentioned at yesterday's press conference, that we are likely to see some pressure, particularly on the demand side here.

Mr. BURGESS. Is there anything——

Dr. HAHN. We are working very closely with manufacturers on this.

Mr. BURGESS. OK. Is there anything you can do to prohibit or prevent—not prohibit, but prevent hoarding activity by people who might just be buying up equipment?

Dr. HAHN. Well, the Department has led an all-Department effort to communicate to providers and hospitals regarding this issue. And we have recommended following CDC guidelines with respect to the use of particularly respirators, where it seems to be the most pressure.

Mr. BURGESS. OK. Thank you.

Ms. ESHOO. The gentleman's time has expired.

It is a pleasure to recognize the gentlewoman from Colorado, Ms. DeGette, for her 5 minutes of questioning.

Ms. DEGETTE. I thank the Chair for including some of the other subcommittees in this.

As four of the five of you well know, we have been having hearings in the Oversight Subcommittee for years on these issues. It is what keeps me up at night. The most recent hearing we had was on December 4 about seasonal flu and pandemic flu. And lo, here we are. And what I am concerned about is, we are still not any more prepared than we were on December 4. And so that is what I want to talk about.

Back in 2005, we had a National Blueprint for Biodefense—or 2015. Some of you recognize this document. Our now-colleague Donna Shalala had your job, Mr. Secretary. And in this blueprint for defense, what we they did was, they said, in case we have some kind of a pandemic, we need to have a clear line of authority to make these decisions.

Are you aware of that, Mr. Secretary?

Secretary AZAR. I wasn't aware of Secretary Shalala's recommendation in——

Ms. DEGETTE. But are you aware of this blueprint?

Secretary AZAR. More of the blueprint. I wasn't aware of——

Ms. DEGETTE. OK.

Secretary AZAR. I wasn't remembering that recommendation.

Ms. DEGETTE. Well, so this is what I want to ask you. Because I just got back from Japan on Monday, and so we were really looking at the Diamond Princess incident. And here is what I was concerned about, is, you had all these people sitting in this petri dish of a ship for a long time. The CDC said that people should not be flown back to the U.S. from that ship. And then, apparently, the CDC was overruled by the State Department.

So here is my question. You are the chairman of the President's task force on the novel coronavirus. Who is in charge? Are you in charge?

Secretary AZAR. I am in charge. But in Japan, the Deputy Chief of Mission, who is the Charge d'Affaires——

Ms. DEGETTE. Right.

Secretary AZAR [continue]. Who made that decision, has full authority of the President of the United States——

Ms. DEGETTE. Right.

Secretary AZAR [continue]. When in a foreign country.

Ms. DEGETTE. So that is the problem.

Secretary AZAR. No, that——

Ms. DEGETTE. Well, yes, it is, and I will tell you why that is the problem. Because you are the head of the panel, the health experts are saying you shouldn't be flying these people back in, and then there is another agency that basically overruled what you said.

If we have an outbreak in the United States, there are a number of other agencies that are going to have other interests. And I will just give you a couple of examples: the State Department, which we just dealt with; HHS is you; the State public health departments; various other agencies.

Who is in charge of the final verdict? Is it you?

Secretary AZAR. It depends on the circumstances. If it is——

Ms. DEGETTE. That is not going to work if we have a pandemic.

Secretary AZAR. No. If it is in a foreign country, the ambassador of the President is the final word on representing the United States' interests in that country.

Ms. DEGETTE. So what happened is, they flew back in 14 Americans, maybe more, who were infected with the coronavirus. That is why someone needs to be in charge. And you know what? I think it should be you.

Secretary AZAR. I just, with respect, I want to—the Deputy Chief of Mission had a very difficult decision to make there. They——

Ms. DEGETTE. I understand that. I don't need you to explain that to me. What I am saying, as this goes along, there needs to be someone who can overrule Homeland Security and State, who can make these decisions for the American public based on public health. And I am hoping we can have some more hearings to talk about that.

Secretary AZAR. I appreciate that.

Dr. Redfield, I want to ask you—because the Chair, Chairwoman Eshoo, asked you the question about the lab tests, and you said you didn't know how many lab tests are available—do we have lab tests that will accurately test for the coronavirus?

Dr. REDFIELD. Yes. I——

Ms. DEGETTE. OK. Now, what I heard was they are limited, and people have to send their tests to the CDC to be tested. Is that right?

Dr. REDFIELD. Presently, there are 12 jurisdictions that have the test up and running. Nine of——

Ms. DEGETTE. Twelve jurisdictions throughout the United States?

Dr. REDFIELD. Throughout the United States.

Ms. DEGETTE. And so people can send their tests there?

Dr. REDFIELD. They send their tests there.

Ms. DEGETTE. And when are we going to be able to put that everywhere?

Dr. REDFIELD. Well, we are working cooperatively with——

Ms. DEGETTE. I am asking you, when are you going to be able to put that everywhere?

Dr. REDFIELD. I was trying to say——

Ms. DEGETTE. Do you know?

Dr. REDFIELD [continue]. We are working with the FDA now. We are hoping that later this week——

Ms. DEGETTE. OK.

Dr. REDFIELD [continue]. Our tests will be such that the first one can go—all the laboratories that got it can execute the current test on the modification that we did with the FDA.

Ms. DEGETTE. OK.

Dr. Fauci, I know you are working on developing a vaccine. If we gave you more money, could we develop a vaccine more quickly?

Dr. FAUCI. We would need more money to take it for the next step. We are in a Phase 1 right now, and we are OK. When we get to——

Ms. DEGETTE. How much more money? How much more money?

Dr. FAUCI. For?

Ms. DEGETTE. I think you could probably get bipartisan consensus that we would give you the money.

Dr. FAUCI. Yes. How much would you need for it to get it over the hill?

Ms. DEGETTE. Yes. Yes.

Dr. FAUCI. About $140 million.

Ms. DEGETTE. $140 million. I think——

Secretary AZAR. And, Congresswoman——

Ms. DEGETTE. Yes?

Secretary AZAR [continue]. If you wouldn't mind, the emergency supplemental would actually dedicate a billion dollars for vaccines. That is part of the detail we will be working with the committee on.

Ms. DEGETTE. OK.

I just want to say one more thing, because my time is up, and I know that Congresswoman Schakowsky is going to ask you some questions about the supplemental. I just want to say that even Minority Leader McCarthy today said we need at least $4 billion. And

we shouldn't be shifting money away from Ebola and other diseases into trying to deal with this coronavirus. We need to work on all fronts at once.

And I thank you for your comment.

And I yield back.

Ms. ESHOO. The gentlewoman's time has expired.

The gentleman from Kentucky, Mr. Guthrie, is recognized for his time.

Mr. GUTHRIE. Thank you, Madam Chair.

And thank you for all being here.

And just so everybody knows, we have been having these meetings, if they have not been formal hearings, bipartisan, with several of you over time. And I remember, when we first started meeting about this, it might have been Dr. Fauci said—I don't want to put words in your mouth, but we were going to prepare for a pandemic. That is what the American people expect us to do. We are going to prepare for a pandemic. We are going to put things in place for a pandemic and hope and pray that it never comes. We are going to get ready. And as we prepare for it, people are going to see things, hear things, and maybe react that this pandemic is imminent, when it may not be, because we are doing what we are supposed to do.

The other thing is, I know the White House and the administration needs to reassure markets and marketplaces where we are and where we stand. And for everything that I have heard previously and what Larry Kudlow has said, it is not inconsistent with where we are.

But I know that the CDC came out and talking about the pandemic, to be ready for it. And, Secretary Azar, if you would like to explain this. I know the CDC warned that Americans should—and I will quote—"prepare for community spread" in the United States and should be ready for, quote, "significant disruption."

And would you explain what that means and what it means to the average person, what that means? And what is the most important message you would like for the American people to know about the current state of America and the coronavirus?

Secretary AZAR. Our messaging, from the President through to the career officials at the CDC, has been consistent, but it is striking a balance: America's risk is low at the moment. That could change quickly. We are working to keep that risk low, but we have always been transparent that we expect more cases in the United States with a rapidly spreading virus, especially with what we have seen.

For the average American, there is no change in their behaviors except what we always would advise, which is: to practice good public hygiene—washing your hands appropriately, coughing into your arm, not touching your face with unwashed hands—and appropriate preparedness activities at home. And you can go to CDC.gov for normal advice for flu seasons, hurricanes, and others. Good preparedness, and good thoughtfulness at home.

We are trying to be very transparent to people of the risks we face, even if we are at a low-risk situation now, so people aren't surprised, so that they know what we are dealing with and what uncertainties we are dealing with.

Mr. GUTHRIE. Thank you.

And so, Dr. Fauci and Dr. Redfield, for 50 days, we have learned much about the coronavirus, but much is still unknown. What is the current—this is what I know people want to know at home. What is the current scientific consensus about the transmissibility, infectiousness of the virus? And how long, once you are infected, if you are infected, how long can you pass it on?

And what are the other remaining known unknowns? What are the things you know that you would like to know the answer to?

With Dr. Fauci and Dr. Redfield and Dr. Kadlec, if that is in your world.

Dr. FAUCI. Well, first of all, we know it is a very transmissible virus. There are some viruses that are not efficient in going from human to human. What we learned early on and we are convinced now, given what we have seen in China and other countries, that it is a highly transmissible virus. That is the first thing.

The second thing, when you say how long a person is infected after they get infected, that is something that is still up in the air. And the way you get the answer to that is you try and isolate the virus, what we call, shedding for a period of time.

And we know that there are individuals who are actually able to transmit when they are without symptoms, before they get symptoms. What we don't know yet—and I think we are going to get information from the group, including the CDC individual and one of my people who was in China with the WHO group—what the extent of that transmissibility is from an asymptomatic person. Is it minor, part of the driving of the outbreak, or is it significant? That is going to be a very important thing that is currently an unknown.

And, Bob, do you want to take over?

Mr. GUTHRIE. Dr. Redfield?

Dr. REDFIELD. I concur with Dr. Fauci. I think the biggest challenge we have right now is, what is the relative infectivity, whether before you get sick—are you more infectious before you get sick, or are you more infectious after you get sick?

We are tracking these patients that we do have in this country to see how long they actually have a virus that can be isolated from their respiratory secretions. It is probably going to be longer than many of us originally anticipated. I think, at this stage, we have an individual who is out about 18 days from the time they initially actually got sick.

So I think these are key questions, and we continue to try to get the data to answer them.

Mr. GUTHRIE. So are there other things that you are looking to know that you don't—that you know that you don't know that you are trying to find the answers to?

Dr. REDFIELD. Well, I think one of the other areas from the CDC's point of view is trying to understand the methods of transmission. Is it all respiratory transmission through droplets? Is there fomite transmission? For example, can this virus survive on certain surfaces long enough for somebody else to come down, put their hand down, and then touch their face? You know, it is not clear right now what the relative components of, say, droplet transmission is to fomite transmission.

Mr. GUTHRIE. Thank you.

My time has expired. I will yield back.

Ms. ESHOO. The gentleman yields back.

The gentlewoman from Illinois, Ms. Schakowsky, is recognized.

Ms. SCHAKOWSKY. Thank you.

As all of you know, the World Health Organization has declared the coronavirus outbreak is a global health emergency, and our administration now has declared it a public health emergency. Yet, Secretary Azar—we have talked about this, you have heard about it—the Trump administration asked Congress for just $2.5 billion to combat the disease that the CDC's Director, Nancy Messonnier, warned could severely disrupt daily life and could cause severe illness in the United States.

So, in that request, you did not, as I understand, include—were not specific about surveillance for testing kits that actually work—because not all of them have—and for treatment. Instead, you suggested robbing $500 million from the United States response to the Ebola epidemic, which actually still is raging in places. So I find it incomprehensible that you are asking for a molehill when what we really need is a mountain of support here.

Secretary Azar, yes or no, do you agree with the President of the United States that the coronavirus is "very much under control" in the United States, unquote, and will, quote, "go away," unquote, by spring?

Secretary AZAR. He did not say the last part that you just said. He said we hope it will go away with warmer weather. I hope everybody here would hope it would go away with warmer weather.

The virus in the United States has been in a contained situation to date, but that can change. As Dr. Messonnier said, we expect more cases, and we expect that we will see at least limited community transmission of the virus in the United States.

Ms. SCHAKOWSKY. Let me ask you another question. My hometown of Chicago reported the first human-to-human transmission of the coronavirus in the United States. And though the Illinois and Cook County and Chicago Departments of Public Health have expertly, I would say, handled our two coronavirus cases; they have not received any reimbursement or financial assistance for the work they have done. I just met with the director of public health in Chicago, who said they are spending $150,000 per week to respond to this.

Will the United States be able, in the $2.5 billion, to help local and State health officials who have already spent lots and lots of money trying to deal with this?

Secretary AZAR. So, yes, that is actually part of the supplemental request, is to fund State and locals. In addition to the $675 million FEP money they already have received for many years, Illinois, of course, received each year $16.3 million for exactly these activities. But we want to give additional funding through the supplemental request for those activities.

Ms. SCHAKOWSKY. Well, that is really good news. Thank you.

Secretary Azar, will your $2.5 billion be enough to help healthcare workers in hospitals and nursing homes or the homecare workers who have to care for quarantined individuals?

Secretary AZAR. In what respect are you asking?

Ms. SCHAKOWSKY. Well, I mean——

Secretary AZAR. The salaries? Because they are already paid. I am just curious. I want to——

Ms. SCHAKOWSKY. No, I mean, I think——

Secretary AZAR. If there are elements we need to add to our request, we will be glad to——

Ms. SCHAKOWSKY. There may be a lot of additional costs that—people that work in hospitals, and they may have to hire more people. Is there any help that is going to be for staffing?

Secretary AZAR. Would you mind if Dr. Kadlec responds, Congresswoman?

Dr. KADLEC. I can address part of your question, ma'am, and that is, $350 million is dedicated for personal protective equipment that could be used by healthcare workers in many different settings. So we are stockpiling that to make it available should communities need that in addition to what they have on hand.

Ms. SCHAKOWSKY. OK.

Let me just finally say this. Last week, 45 of my colleagues and I sent a letter to President Trump, and what we were talking about is, are we going to be guaranteed affordable treatments or vaccines that are developed?

We are concerned that private pharmaceutical companies may end up having a role in this and raising the cost beyond the point that people could well afford it.

Secretary AZAR. We absolutely share your passion around ensuring affordable access to medicines, but the private sector must have a role in this. We will not have a vaccine; we will not have therapeutics without the private-sector candidates that they and we will have to invest in.

Ms. SCHAKOWSKY. But we have paid for all the R&D so far, right?

Secretary AZAR. No, that is not accurate. For instance, Gilead has a product, Remdesivir, that was originally NIH-funded basic research, I think, out of the University of Alabama, but they have carried forward with development. Moderna is using Dr. Fauci's——

Ms. SCHAKOWSKY. My time has expired, but if I could just reaffirm then, you are saying it will for sure be affordable for anyone who needs it?

Secretary AZAR. I am saying we would want to ensure that we work to make it affordable, but we can't control that price, because we need the private sector to invest. The priority is——

Ms. ESHOO. The gentlewoman's time has——

Secretary AZAR [continue]. To get vaccines and therapeutics. Price control won't get us there.

Ms. ESHOO [continue]. Expired, Mr. Secretary. Thank you.

I now recognize the gentleman from Michigan, the former chairman of the full committee, Mr. Upton.

Mr. UPTON. Thank you, Madam Chair.

I have a couple of questions that I hope to run through. And I guess the first question ought to be directed to—first of all, thank you all, 24/7, and for the briefings that we have had over the last couple of weeks as well.

I guess this ought to be directed first to Dr. Redfield. There is a report just published now in the last hour or two of apparently

there is a daily newspaper in Korea called the JoongAng Daily, and they reported that there is a Korean Airlines flight attendant who serviced a number of flights between LAX and Seoul, and she was confirmed to have coronavirus. They are not sure where she got it. There is some suspicion that she had also worked a flight to Israel with that apparent tourist group that came from Korea there in the previous week.

What do you know about this? Is there some communication? I hope you know something, but I know that it is recent news. But it was published Tuesday in Korea; it is Thursday now. So just wondering what you might know about this.

Dr. REDFIELD. I can say that I haven't been briefed on that, sir. Normally what we would do, if we had confirmed cases, obviously——

Mr. UPTON. Now, this is a Korean woman, 24 years old.

Dr. REDFIELD. Yes. So that would be—we are interacting—we actually sent someone yesterday to embed in the Korean CDC to help facilitate communications between Korea's CDC and our CDC. But I can tell you I haven't been briefed on that specific situation. But I will look into it and get back to you.

Mr. UPTON. OK.

And, second—and does anyone else know anything more?

Dr. Fauci, I know that China did publish, thank goodness, the genetic sequence, which has allowed the rest of the world to try and pierce the bubble here. Moderna Therapeutics is one of the companies—I think they are out of Massachusetts—that is actually working on, I want to say, a Phase 1, but I may be wrong.

Dr. FAUCI. Yes.

Mr. UPTON. If it is successful, how long? What can you tell us?

Dr. FAUCI. We are working with the company Moderna on a vaccine platform called messenger RNA. We are working at our Vaccine Research Center.

And we did exactly as you said. As soon as the sequence was put on a public database, we pulled the gene out for the spiked protein, which is the protein that you want to make an immune response against.

There are several steps in that that determine the success or failure of what you are doing. And we have been able to successfully express it in this particular platform that we are going to use for a vaccine. We have shown that it is immunogenic in mice. And very soon, within the next month and a half to two, it is going go into humans in a Phase 1 study.

But I think people need to appreciate—because there is often misunderstanding—a Phase 1 study, we will say, was three months from the go, which was about a month and a half ago. It will take about three months or four to determine if it is safe and induces the kind of response that you would predict would be protective.

Once you get there—it relates to the question that I was asked before—then you go to a Phase 2 study. The Phase 1 study has 45 people. A Phase 2 study has hundreds or maybe even low thousands of people. That would take at least six or eight months to show that it works. So, from the time you push the button to go to the time you even know it works, it is about a year to a year and a half.

Then, as the Secretary said, you have to partner with pharmaceutical companies to make millions and millions and millions of doses, which could also extend the time.

Mr. UPTON. And that would be a vaccine or a remedy?

Dr. FAUCI. That would be a vaccine——

Mr. UPTON. OK.

Dr. FAUCI [continue]. To prevent infection.

Mr. UPTON. OK.

The last question that I have, and I will save this for Secretary Azar. A couple of weeks ago, my colleague Debbie Dingell and I sent a letter to the administration—you were copied on it—as it relates to the supply chain of companies with operations in China, specifically Wuhan province.

A lot of us are concerned about products that are made there. Auto State, Michigan, we have a lot of different things that are there. I know Apple, as an example; they fessed up; their stock price collapsed and led to the market trouble that we had this week.

What type of outreach are—have you initiated outreach to companies large and small, particularly on the shortage questions as well? Because they may not want to tell you what they might know. Where are you all on that?

Secretary AZAR. So, as chair of the task force, we have directed a whole-of-government outreach to manufacturers and suppliers across not just healthcare but everywhere. And Dr. Hahn and Dr. Kadlec have led the effort with regard to pharmaceutical, generic and biologic, and device manufacturers in China.

And that is what Dr. Hahn was reporting on earlier, the results of that outreach. Very proactive. As you know, with drugs, they have to report to us potential shortages. Device, we don't yet have legislation on that, so we are proactively probing that system. As he reported, we don't yet know of any potential shortages, but we are on that because we share your concern about the risks there.

Mr. UPTON. Just to follow up, is the Secretary of Commerce—are they working on other things——

Secretary AZAR. Yes.

Mr. UPTON [continue]. Beyond just drugs and devices?

Secretary AZAR. Yes. With their regulated entities and their major manufacturing entities, they are working to gather information about potential shortages, as they might impact the economy. The National Security Council and the National Economic Council are leading those efforts.

Mr. UPTON. Thank you.

I yield back.

Ms. ESHOO. I appreciate what Mr. Upton raised overall but certainly the last part of it, the whole issue of our dependence on China and that 90 percent of the American people take generics and that those generic drugs are manufactured in China and, to a lesser degree, in India, but China controls the global market on the API, the active pharmaceutical ingredients.

But I met with Dr. Kadlec after—I think it was the classified briefing. He came to my office. What I wanted to know was, do we have an inventory? Do we have an inventory of who the manufacturers are? Are any of these plants shut down? I know we asked

questions about how long they can manufacture until they can't, because drug shortages are a part of this whole problem with the supply chain.

But when I met with Dr. Kadlec, we don't have that inventory. Is that in place now Mr. Secretary?

Secretary AZAR. Actually, I believe——I believe that is what Dr. Hahn briefed you on earlier.

Ms. ESHOO. We do have an inventory?

Dr. HAHN. We have reached out to the manufacturers. We have to do that proactively because there are not requirements, for example, state of operations that are required to report to us.

Ms. ESHOO. But if we inspect manufacturing plants, don't we know who they are?

Dr. HAHN. Yes, we do.

Ms. ESHOO. Don't we have a list of them?

Dr. HAHN. Yes, we do.

Ms. ESHOO. We do.

Dr. HAHN. Yes, we do.

Ms. ESHOO. What is the difference between that and the question I asked then?

Dr. HAHN. So we have a list of manufacturers that have been given to us by pharmaceutical companies who manufacture both precursor products and final drugs in China. But there may be five or six for each of these drugs, and they might be in different countries.

Ms. ESHOO. I see. All right.

The gentleman from Massachusetts, Mr. Kennedy, is recognized for his 5 minutes.

Mr. KENNEDY. Thank you.

I want to thank you all for being here. Thank you for being willing to be before this committee. I have some differences with some of you up there on our healthcare policy, but I am grateful for your presence here, and I wish you all success. So good luck to you, and good luck to us all.

First off, a bit of—just rapidly, sir, Dr. Redfield, if you can. I have a 2-year-old and a 4-year-old, and a lot of other parents of young children are nervous about this. Can you just give me a real quick answer, as to parents of young kids, is there anything people should be doing at this point or should be concerned about?

Dr. REDFIELD. I want to echo what the Secretary said. Right now, the risk to the American public is low, and we would argue that they go on with their life. Our containment strategy has been quite successful.

But that said, what was said also is that, in light of what has happened in the Republic of Korea and Italy and Iran and Japan and we have seen how fast this virus can move, we are encouraging people, again, to just think about being prepared.

Mr. KENNEDY. OK.

Part of being prepared is trying to make sure that there is as much and as clear communication as to what we are confronting and how the government is structured to be ready for this and to meet this challenge.

I do think, obviously, as some of my colleagues have noted, that, despite calls to strengthen our country's pandemic preparedness,

this administration did dismantle the Federal Government's pandemic response chain of command, including leadership structure at the White House through the National Security Council's global health security unit.

So when you flash-forward to this year and the coronavirus starts spreading throughout the world, there have been reports of this task force—and, Mr. Secretary, you indicated that you are, in fact, the head of it. I would ask just, if you can, to the greatest extent possible, communicate what that structure looks like so that people can have some understanding as to what is backing that up. You don't have to do it now, but just as you can. Just to get that information out would be helpful to all of us.

So, moving on a bit, though, to try to make sure that there is not just a structure put in place but that communication is, in fact, clear, Mr. Secretary, I would take a bit of an issue with the fact that the message is consistent. I think the message from you all up here on this panel, so far has been pretty consistent. I do have an ABC News story here that I am going to enter for the record which quotes the President as saying that it is, quote, "a problem that's going to go away," end quote.

The President is also quoted as saying, quote, "The virus we're talking about having to do, you know, a lot of people think it goes away in April with the heat, as the heat comes in. Typically that will go away in April. We are in great shape though," end quote.

Dr. Fauci, does this go away in April with the heat?

Dr. FAUCI. The history of respiratory viruses such as influenza and other coronavirus viruses tends to diminish and almost disappear as you get into the summer. That is just something that happens. Every year, we see that with influenza.

However—underline "however"—this is a new virus, so we don't know what this virus is going to do. If it acts like influenza, the heat will actually make it diminish in its impact. But we have no way of knowing how it is going to act.

Mr. KENNEDY. And I would say that there are different temperature gradients across this country by April. Fair enough?

Dr. FAUCI. Correct. And also in different hemispheres, because when we are having cold weather, others are having warm, and vice versa.

Mr. KENNEDY. Thank you.

He has also stated that we are, quote, "very close to a vaccine," end quote. But, Doctor, you just laid out that, best-case scenario, we are still 12 to 18 months away roughly. Is that right?

Dr. FAUCI. Correct.

Mr. KENNEDY. He said—congressional staff briefed folks yesterday in a press conference. Said, quote, "It's not a question of if but rather a question of when and how many people in this country will have severe illness." Almost at the exact same time, the President was saying that, quote, "it's going work out fine," end quote, "a problem that's going to go away."

Dr. Redfield, does the CDC agree that this is a problem that is going to go away without intervention?

Dr. REDFIELD. I think it is important to recognize that, from time to time, new pathogens come from animals and get into the human species. Clearly, this is one of those times when we have a new res-

piratory pathogen that has come into the human species. And I think it is prudent to assume that this pathogen will be with us for some time to come.

Mr. KENNEDY. Dr. Kadlec?

Dr. REDFIELD. And as——

Mr. KENNEDY. Dr. Kadlec?

Dr. REDFIELD. [continue]. Tony said, we don't know the cycle of it. We don't know how it is going to—if it is going to be impacted by humidity and heat. But I think we should assume that this virus is going to be a virus that we are going to be challenged with, similar to the other viruses that we have that are respiratory.

Mr. KENNEDY. Doctor, thank you.

I have ten seconds left. For the rest of the panel, "yes" or "no," agree with Dr. Redfield?

Mr. Kadlec?

Dr. KADLEC. I support Dr. Redfield's view.

Mr. KENNEDY. Mr. Secretary?

Secretary AZAR. The President is expressing confidence that this team, the public health infrastructure in this country, State and local, that we can deal with this. We will prepare for this. We will work together on this. He is trying to calm the public.

We see in China that panic can be as big of an enemy as the virus in these situations. And so there is always that balance——

Mr. KENNEDY. Mr. Secretary, I don't want to panic over this either. The stock market is crashing. He is trying to stop the stock market. He is not trying—he is outright contradicting everything that you all have just said. Outright contradiction.

Secretary AZAR. I think he is expressing confidence in——

Mr. KENNEDY. With no medical basis for it. That is what you have just expressed to us. Come on, sir.

Secretary AZAR. Well, no. He is expressing that the American people need to take a breath here, that there is no change to anyone's daily life from this, that the country has a plan, we have pandemic plans, there is a playbook for this, and we are executing against that. But we have to be realistic, also, and transparent that we will have more cases——

Mr. KENNEDY. And, sir, as head of HHS, do you agree with the President's statement, as I quoted, "The virus that we're talking about having to do, you know, that it will go away with the heat"?

Ms. ESHOO. The gentleman's time has expired.

Do you want to answer that quickly?

Secretary AZAR. No.

Ms. ESHOO. No. I didn't think so. You are doing a great job for the President, Mr. Secretary.

It is a pleasure to recognize the gentlewoman from Indiana, Mrs. Brooks, for her time.

Mrs. BROOKS. Thank you, Madam Chairwoman.

And thank you all so very, very much for being here and for your work day-in and day-out on behalf of not only our country but on behalf of the world.

And I would like to remind my colleagues that in November of 2019 the United States of America was ranked number one in global health security. The Global Health Security Index, conducted by Johns Hopkins, of 195 countries, we are leading the world.

Now, that doesn't mean that we can't always continue to improve. And that is what PAHPA, which was passed, signed into law in June, did. It actually took care—it focused on vulnerable populations, like children, like the elderly. We added a lot of new things to that.

One of the things, though, that I am concerned about is the flexibility of the funding and whether or not—we introduced an Infectious Disease Rapid Response Reserve Fund. Eighty-five million was put into that fund. We have $705 million in a Strategic National Stockpile fund. We have all of these.

How much flexibility is there? Or do we need to give you more authority, Mr. Secretary, very quickly, to have more flexibility to be able to not focus on Congress having to do supplementals all the time? How much more flexibility do you need?

Secretary AZAR. Well, the Infectious Disease Rapid Response Fund has been critical for us. The flexibilities in the Strategic National Stockpile, is critical to us. The emergency supplemental, is the most flexibility that you could give us there; as we deal with the situation as it evolves, we would appreciate that also.

The challenge with setting up long-term funding mechanisms that are indefinite is they can become slush funds for any other priority, as opposed to concrete, real public health emergencies. I think that has always been the challenge.

Mrs. BROOKS. And if you find that you need more funding for any of these funds, will you come back and ask for more funding?

Secretary AZAR. Absolutely. And I want to emphasize, the 2.5 is at least 2.5. It is for 2020 only. And we will come back if we need more. And we will work with Congress if Congress wishes to give more.

Mrs. BROOKS. Dr. Kadlec, with respect to the Strategic National Stockpile, which I believe you oversee in conjunction with the CDC—is that correct?

Dr. KADLEC. Yes, ma'am.

Mrs. BROOKS. What is the status of our Strategic National Stockpile?

Dr. KADLEC. Well——

Mrs. BROOKS. Can you quickly say what those are?

Dr. KADLEC. Sure. It is a variety of countermeasures that deal with chemical, biological, radio, and nuclear capabilities, as well as for pandemic influenza. We have a supply of personal protective equipment that we have on hand. We have sent out a solicitation to get more, but the answer is, we have a whole range of things that——

Mrs. BROOKS. And these are at undisclosed locations——

Dr. KADLEC. Yes, ma'am.

Mrs. BROOKS [continue]. Throughout the country, are they not?

Dr. KADLEC. That is correct.

Mrs. BROOKS. And, at this point, is the Strategic National Stockpile sufficiently funded?

Dr. KADLEC. Ma'am, I think the thing is, at this point in time, in light of what the requirements are, we have been given, at least in terms of what is in the supplemental request, another $400 million, that would be a great benefit to help us address any kind of shortfalls for this event.

Mrs. BROOKS. Last week, when I was home, I learned from a local public health official in Indiana that an individual from this county had traveled from China and, interestingly enough, had come through the Chicago airport. And the Chicago airport officials notified this public health official, said this person is coming home to quarantine, and she appeared at this individual's home within 24 hours of that person coming through the Chicago airport.

I thought that was awesome. It was excellent that that kind of coordination happened. How did that happen? And is that happening all across the country?

And this individual is going to cooperate with the local health official, and provide their temperatures for a couple of weeks. Is this happening all across the country?

Dr. REDFIELD. Yes.

Mrs. BROOKS. And who at the airports is notifying local health officials?

Dr. REDFIELD. So what happened, when the original travel restrictions were put in for China and Hubei, if you were coming into the United States, an American citizen or a family member or a permanent resident, on Hubei, you were required to go into 14 days of quarantine. That quarantine could either have been institutional or that quarantine could have been in your home, working with the health departments. And that is really how we have operationalized.

But if you had been from China, the requirement was that, when you came through; you were screened. You were given an education card, provided that you had no symptoms, telling you about the risk and what the symptoms are and the contact information with your local health department. And you, in conjunction with your local health department, were going into what we called voluntary monitoring and isolation.

And that woman that you gave the example of did exactly as we instructed and they were instructed as they went through Chicago O'Hare Airport.

Mrs. BROOKS. And so, actually, it was my local public health official that was incredibly impressed that she had received this information. The young man and his family are monitoring.

Madam Chairwoman, I would like to enter into the record—CSIS produced a report in November of 2019 about U.S. global health security, making sure we are ending the cycle, with a number of recommendations. You and I serve on that commission. I would ask that that be entered into the record.

Ms. ESHOO. So ordered.

[The information appears at the conclusion of the hearing.]

Mrs. BROOKS. With that, I yield back.

Ms. ESHOO. The gentlewoman yields back.

The gentleman from California, Mr. Ruiz, is recognized for 4 minutes.

And for those that are left, there is an agreement that it is 4 minutes because the panel is getting nervous about time. So let's honor that, OK? Thank you.

Mr. RUIZ. Thank you for being here today.

I want to discuss a very important issue for local agencies and that I know many other members are hearing as well, and that is

funding and reimbursement for moneys that our counties and public health departments have spent up front to help fight the spread of the coronavirus.

I am a disaster-trained emergency physician, and public health expert. And in disaster or epidemic preparedness, rapid reimbursement is a matter of readiness capacity.

I think we can all agree that a lot is being asked from the public health infrastructure in our States. They are stepping up. They are coordinating. They are doing the right thing.

On January 29, a flight carrying 195 Americans from Wuhan, China, was diverted to March Air Reserve Base in Riverside County, the county that my district is in. Riverside County responded efficiently and was effective in monitoring and quarantining all of these passengers for 14 days.

Over 40 county officials worked on this project. In addition, the county supplied food, transportation, quarantine supplies, screening, housing, a mobile health clinic, emergency management standby, and support services for ambulances. All told, these efforts are estimated at a little over $1.3 million.

And while that flight quarantine is over, the broader response continues in Riverside and in communities across the country. So receiving rapid reimbursement is critical to capacity readiness in the future. If you drain resources without replenishing them, you won't have necessary resources to fight this public health crisis, such as bedside diagnostics, personnel, and masks, just to name a few, and also having the resources to create preparedness plans, quarantine plans, et cetera, in the case of rapid transmission of this virus in the future.

So I want to ask a question. Dr. Redfield, what are the funds that are available to reimburse State and local officials for their efforts in responding to coronavirus?

Dr. REDFIELD. I will defer some of this to the Secretary, but I think he said, in the supplemental, a substantial portion——

Mr. RUIZ. OK. So you are telling me—the last time we spoke, you identified—somebody in your staff mentioned a few. Now you are saying those funds don't exist; we need to pass the supplemental to reimburse counties. Is that what I am hearing from you?

Secretary AZAR. So we have the FEP, which funds California at $41 million a year, but the supplemental has requested $757 million from CDC——

Mr. RUIZ. OK. So which funds——

Secretary AZAR [continue]. Which would have in that the State and local funding——

Mr. RUIZ. OK. Are there funds right now that counties can apply for?

Secretary AZAR. No, there are not. That is what the emergency——

Mr. RUIZ. There are no funds?

Secretary AZAR. No additional to the emergency——

Mr. RUIZ. OK.

Secretary AZAR [continue]. Funds that they get each year for these activities.

Mr. RUIZ. All right.

Secretary AZAR. That is what the supp is for.

Mr. RUIZ. Well, we are definitely——

Secretary AZAR. We agree.

Mr. RUIZ [continue]. Going to work on that. And that is an issue, right? Because we were under the impression that there were. And rapid reimbursement is a matter of readiness capacity. If we don't rapidly reimburse, our local agencies will not be ready to deal with a potential rapid spread of the virus.

Dr. Kadlec and Dr. Redfield, yes or no, can we get a commitment from you both here today that you will reimburse these expenses by local municipalities for the costs associated with containing the spread of the coronavirus?

Dr. REDFIELD. Well, we are clearly going to work to see how to get that done.

Mr. RUIZ. OK. So that is not a commitment.

Dr. Kadlec?

Mr. KADLEC. I think the thing is, we are committed to basically work with you to do that.

Mr. RUIZ. OK. Well, we need to reimburse because, especially in rural areas, where they don't have the resources, they don't have the hospitals, the quarantine spaces, the ability to get the supplies over to those areas, you are putting them in vulnerable situations if you don't respond.

Dr. Redfield, since 2008, local and State health departments have lost nearly a quarter of their workforce. Does this affect our Nation's ability to mount and sustain a response?

Dr. REDFIELD. I think it is one of the key core capabilities that we need to continue to improve for our public health ability—that is, the data modernization, which you all have helped with last year; the laboratory capacity, to build it and keep it fluid, as you see with the current diagnostic test; and the third, most important one——

Mr. RUIZ. Yes. Listen.

Dr. REDFIELD [continue]. Is the workforce.

Mr. RUIZ. Work within a team.

Dr. REDFIELD. We need to build that workforce.

Mr. RUIZ. Be consistent. No discrepancy. Discrepancy breeds anxiety. That brings panic. OK?

All right.

Ms. ESHOO. The gentleman's time has expired.

I wanted to get a commitment so that these agencies don't lose the money that they are losing. You are asking them to promise you even beyond where the cuts are. So I would be happy if that could happen, but the Congress has a job to do to restore the money in these agencies.

These cuts are really shameful. They really are. And when we have such premier agencies, people at the top that know what they are doing, and they are being cut, and the Secretary is telling us, "Well, we did $1.5 billion; everything is going to be fine," I don't think so.

Dr. Bucshon from Indiana.

Mr. BUCSHON. Yes, thanks for the 5 minutes. I appreciate it. No, 4 minutes. I am just kidding.

Ms. ESHOO. Four minutes.

Mr. BUCSHON. I mean, in reference to the funding, I just want to—I mean, the Congress provides funding for the agencies, and a the budget proposal is a budget proposal, no matter which President it comes from. So I am not too worried that this Congress won't provide the appropriate level of funding.

And I understand also that additional funding—if we could quickly bring up the supplemental and pass that, that clearly, in my opinion, it would help if Secretary Azar and all the people at this table do their job and get money to everybody.

The other thing is I just want to comment briefly on the criticism of the President and what he has said. If the President of the United States comes out and incites a panic in the United States; it incites a worldwide panic. And I see the role of the President as different than mine or Secretary Azar's or others. And even though, you know, the President says what he says, I do think having a calming effect in a situation like this is appropriate, and allow the professionals behind the scenes to do their jobs.

I just wanted to say that. And——

Secretary AZAR. And if I could, I agree entirely. I think the President's role has been actually critical in keeping the country calm in this situation. He has expressed the levels of doubt and uncertainty with his words that we have but also tried to be reassuring to the American public as we also try to be transparent about what the risks are coming forward.

We all have different roles to play here, as you said, and the President is a very important one, guiding towards balance, maturity, and calm in addressing a public health emergency.

Mr. BUCSHON. I would agree. I mean, if the President came out and incited a panic; he would be criticized for that.

So I guess, you know, we had this unprecedented containment strategy when things were in China. Now that we know we have had problems with person-to-person transmission in Italy and South Korea and maybe other places, does that change our current containment strategy?

And, Dr. Redfield, maybe you can address that.

Dr. REDFIELD. Yes. I would say first that we are maintaining aggressive containment. I want to say that, of all the strategies we have used in this multilayer strategy, the most important one we have is an astute medical and public health community in the United States. Of those 14 cases originally that were diagnosed, only one was picked up by the screening.

So we are now moving, obviously, to educate the American Medical and public health community that it is not just China; we have to worry about now; we have to worry about certain places of Italy and Iran and whether it is the Republic of Korea. So we are continuing with that.

And we are continuing to look at our travel alerts. You know, we have put the travel alert to Level 3 now for Korea and Level 2 now for Italy, Iran, and Japan, trying to let the American public know this may not be the time to go to those areas.

Mr. BUCSHON. OK. Great.

And, again, for you, Secretary Azar, do you have anything to add to that? OK.

Again, Dr. Redfield, as far as the testing goes, the CDC, 12 other public health laboratories have the testing, but I guess they had some difficulty with the third reagent in the test. And can you further explain the problems with the test? And have those problems been resolved?

Dr. REDFIELD. So, first, the test really measured three different—let's just say, three different nucleic acid pieces. And one of them had a control; the third one had a control. And, in that control, there was low-level contamination.

There was never any question about whether the test could tell positive——

Mr. BUCSHON. OK.

Dr. REDFIELD [continue]. Or negative. It just had a group of individuals that we had to say we didn't know.

Mr. BUCSHON. OK.

Dr. REDFIELD. Those samples, again, were at CDC. CDC has continued, we have doubled—I found out we are at 350 to 500 samples a day, when the question was asked earlier, that we are running right now.

Mr. BUCSHON. OK. So the problem has been resolved, basically?

Dr. REDFIELD. The problem is being resolved. We work with——

Mr. BUCSHON. OK.

Dr. REDFIELD [continue]. The FDA. And we have a fix that is supposed to be operationalized this week.

Mr. BUCSHON. One other quick thing. Have you guys conducted disease modeling for a potential COVID-19 outbreak in the U.S.?

Dr. REDFIELD. We do have modeling groups. It is a global modeling group that is looking at a variety of different models. And that is in process. As Tony said earlier, there is still a number of things we don't quite know about this virus to make those models available for prime time, but we are working it.

Mr. BUCSHON. You are working on it. OK. Thank you very much. I yield back.

Ms. ESHOO. The gentleman yields back.

I think that concludes the questions that we have for you today. Thank you to each one of you.

Mr. Secretary, you have been here for many hours, and, you know, throw a punch, take a punch, right? But we are all here for our fellow Americans—for our fellow Americans.

And I think if there is anything that has come out of this today, we want facts. We want to bring the temperature down. We want to bring the fear factor down. And anything and everything that you can do in order to achieve that, as we move on with Dr. Fauci's work, with larger distribution of the diagnostics through the CDC in partnership with what we have across our country, is going to go a long way.

So thank you to each one of you.

I am not going to adjourn. You can get up and leave while I read a very long record of items that need to be placed into——

Secretary AZAR. Thank you, Chairwoman.

Ms. ESHOO [continue]. The record.

Thank you. God bless you and your work on behalf of the American people. Thank you.

All right. I am going to request—I have a unanimous consent request to enter the following documents into the record:a June 28 letter from four House committees to HHS and CMS regarding the case Texas v. The United States; a December 2018 letter from four House committees to HHS and CMS regarding the case Texas v. The United States; an April 2019 letter from five House committees to HHS and CMS regarding the case Texas v. The United States; a February 2020 letter from HHS in response to the April 2019 joint letter from five House committees regarding the case Texas v. The United States.

The committee actually is still in order. I wanted the witnesses to be able to leave, but if anyone wants to gab, take it into the side room so that I can read these into the record, please.

A February 2020 letter from HHS in response to the April 2019 joint letter from five House committees regarding the case Texas v. The United States; an October 2019 Washington Post article entitled "Trump Campaign Urges White House to Soften Proposed Flavored Vape Ban," unquote; an October 2019 bicameral letter to HHS from two congressional committees regarding the increased number of uninsured children in the United States; June 2019 letter from the Energy and Commerce Committee examining HHS's administration of the Medicaid program; a statement from Johnson & Johnson regarding the company's response to the coronavirus outbreak; a statement from the American Society for Microbiology regarding the coronavirus outbreak; a February 2020 article from BioCentury entitled, quote, "Biopharma Industry, Academics Push Back Against Demands for Price Controls on COVID-19 Countermeasures," unquote; a January 2020 Wall Street Journal opinion piece entitled, quote, "Pharma to the Rescue," unquote.

Are there any objections?

Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Ms. ESHOO. And the subcommittee will now adjourn. Thank you, everyone.

[Whereupon, at 5:19 p.m., the subcommittee was adjourned.]

https://www.who.int/news-room/detail/17-01-2020-lack-of-new-antibiotics-threatens-global-efforts-to-contain-drug-resistant-infections

Lack of new antibiotics threatens global efforts to contain drug-resistant infections

17 January 2020
News release

Geneva

Declining private investment and lack of innovation in the development of new antibiotics are undermining efforts to combat drug-resistant infections, says the World Health Organization (WHO).

Two new reports reveal a weak pipeline for antibiotic agents. The 60 products in development (50 antibiotics and 10 biologics) bring little benefit over existing treatments and very few target the most critical resistant bacteria (Gram-negative bacteria).

While pre-clinical candidates (those in early-stage testing) are more innovative, it will take years before they reach patients.

“Never has the threat of antimicrobial resistance been more immediate and the need for solutions more urgent,” says Dr Tedros Adhanom Ghebreyesus, Director-General of WHO. “Numerous initiatives are underway to reduce resistance, but we also need countries and the pharmaceutical industry to step up and contribute with sustainable funding and innovative new medicines.”

The reports (*Antibacterial agents in clinical development – an analysis of the antibacterial clinical development pipeline* and its companion publication, *Antibacterial*

agents in preclinical development) also found that research and development for antibiotics is primarily driven by small- or medium-sized enterprises with large pharmaceutical companies continuing to exit the field.

Clinical development review

WHO in 2017 published the priority pathogens list, 12 classes of bacteria plus tuberculosis that are posing increasing risk to human health because they are resistant to most existing treatments. The list was developed by a WHO-led group of independent experts to encourage the medical research community to develop innovative treatments for these resistant bacteria.

Of the 50 antibiotics in the pipeline, 32 target WHO priority pathogens but the majority have only limited benefits when compared to existing antibiotics. Two of these are active against the multi-drug resistant Gram-negative bacteria, which are spreading rapidly and require urgent solutions.

Gram-negative bacteria, such as *Klebsiella pneumoniae* and *Escherichia coli*, can cause severe and often deadly infections that pose a particular threat for people with weak or not yet fully developed immune systems, including newborns, ageing populations, people undergoing surgery and cancer treatment.

The report highlights a worrying gap in activity against the highly resistant NDM-1 (New Delhi metallo-beta-lactamase 1), with only three antibiotics in the pipeline. NDM-1 makes bacteria resistant to a broad range of antibiotics, including those from the carbapenem family, which today are the last line of defence against antibiotic-resistant bacterial infections.

"It's important to focus public and private investment on the development of treatments that are effective against the highly resistant bacteria because we are running out of options," says Hanan Balkhy, WHO Assistant Director-General for Antimicrobial Resistance. "And we need to ensure that once we have these new treatments, they will be available to all who need them."

On a more positive note, the pipeline for antibacterial agents to treat tuberculosis and *Clostridium difficile* (which causes diarrhea) is more promising, with more than half of the treatments fulfilling all the innovation criteria defined by WHO.

Preclinical development review

The pre-clinical pipeline shows more innovation and diversity, with 252 agents being developed to treat WHO priority pathogens.

However, these products are in the very early stages of development and still need to be proven effective and safe. The optimistic scenario, the report indicates, is for the first two to five products to become available in about 10 years.

WHO on AMR

New treatments alone will not be sufficient to combat the threat of antimicrobial resistance. WHO works with countries and partners to improve infection prevention and control and to foster appropriate use of existing and future antibiotics.

In the area of research and development, WHO and the Drugs for Neglected Diseases Initiative (DNDi) have established the Global Antibiotic Research and Development Partnership (GARDP), a non-profit research and development organization accelerating the development of new and improved antibiotics to tackle drug-resistant infections. GARDP's strategy is to deliver five new treatments by 2025. GARDP is working with more than 50 public and private sector partners in 20 countries to develop and ensure sustainable access to treatments, promoting responsible use and affordability to all in need.

FY 2020 Secretary's Transfer for Coronavirus Response

Amounts to be Executed as Necessary

(In Dollars)

This table illustrates the maximum transfers allowable under the February 2, 2020 notification letter. Transfers to these accounts will be executed only as necessary to meet rapidly developing public health needs.

Operating Division Appropriation	FY 2020 Enacted /1	Planned Transfers Out	Planned Transfers In	Revised Level
Labor / HHS Appropriations				
Administration for Children and Families				
Low Income Home Energy Assistance	3,740,304,000	(37,403,000)		3,702,901,000
Children and Families Services Programs	12,426,652,000	(4,775,000)	-	12,421,877,000
ACF Total	**16,166,956,000**	**(42,178,000)**	-	**16,124,778,000**
Administration for Community Living				
Aging and Disability Services Programs	2,171,000,000	(4,198,000)	-	2,166,802,000
ACL Total	**2,171,000,000**	**(4,198,000)**	-	**2,166,802,000**
Agency for Healthcare Research and Quality				
Healthcare Research and Quality	338,000,000	(635,000)	-	337,365,000
AHRQ Total	**338,000,000**	**(635,000)**	-	**337,365,000**
Centers for Disease Control and Prevention				
Immunization and Respiratory Diseases	433,105,000	-	12,993,150	446,098,150
HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention	1,273,556,000	(801,000)	-	1,272,755,000
Emerging and Zoonotic Infectious Diseases	570,372,000	-	17,111,160	587,483,160
Chronic Disease Prevention and Health Promotion	984,964,000	(2,327,000)	-	982,637,000
Birth Defects, Developmental Disabilities, Disabilities and Health	160,810,000	(384,000)	-	160,426,000
Public Health Scientific Services/2	555,497,000	-	13,272,660	568,769,660
Environmental Health	196,850,000	(472,000)	-	196,378,000
Injury Prevention and Control	677,379,000	(426,000)	-	676,953,000
National Institute for Occupational Safety and Health	342,800,000	(820,000)	-	341,980,000
Global Health/2	442,422,000	-	-	442,422,000
Public Health Preparedness and Response (Center for Preparedness and Response)	850,200,000	-	25,506,000	875,706,000
CDC-Wide Activities and Program Support	113,570,000	-	3,407,100	116,977,100
Infectious Diseases Rapid Response Reserve Fund	85,000,000	-	2,550,000	87,550,000
CDC Total	**6,686,525,000**	**(5,230,000)**	**74,840,070**	**6,756,135,070**
Centers for Medicare & Medicaid Services				
Program Management	3,974,744,000	(7,514,000)	-	3,967,230,000
CMS Total	**3,974,744,000**	**(7,514,000)**	-	**3,967,230,000**
Health Resources and Services Administration				
Primary Health Care	1,505,522,000	(2,573,282)	-	1,502,948,718
Health Centers Malpractice Claims Fund - Tort Claims	120,000,000	(234,020)	-	119,765,980
Health Centers Malpractice Claims Fund - Free Clinics	1,000,000	(1,950)	-	998,050
Health Workforce	885,590,000	(1,727,045)	-	883,862,955
Health Workforce - Graduate Medical Education programs	50,000,000	(97,508)	-	49,902,492
Maternal and Child Heath	943,784,000	(1,785,928)	-	941,998,072
Health Care Systems	123,471,000	(187,063)	-	123,283,937
Health Care Systems - National Hansen's Disease Program	122,000	(238)	-	121,762
Rural Health	308,294,000	(128,923)	-	308,165,077
Rural Health - Rural Residency Development Program	10,000,000	(19,502)	-	9,980,498
Family Planning	286,479,000	(558,681)	-	285,920,319
Program Management	155,300,000	(302,860)	-	154,997,140
HRSA Total	**4,389,562,000**	**(7,617,000)**	-	**4,381,945,000**
National Institutes of Health				
NCI - National Cancer Institute	6,245,442,000	(12,316,000)	-	6,233,126,000
NHLBI - National Heart, Lung, and Blood Institute	3,624,258,000	(7,157,000)	-	3,617,101,000
NIDCR - National Institute of Dental and Craniofacial Research	477,429,000	(964,000)	-	476,465,000
NIDDK - National Institute of Diabetes and Digestive and Kidney Diseases	2,114,314,000	(3,620,000)	-	2,110,694,000
NINDS - National Institute of Neurological Disorders and Stroke	2,374,687,000	(4,183,000)	-	2,370,504,000
NIAID - National Institute of Allergy and Infectious Diseases	5,885,470,000	-	-	5,885,470,000
NIGMS - National Institute of General Medical Sciences	1,706,397,000	(3,472,000)	-	1,702,925,000
NICHD - Eunice Kennedy Shriver National Institute of Child Health and Human Develop	1,556,879,000	(2,612,000)	-	1,554,267,000
NEI - National Eye Institute	824,090,000	(1,729,000)	-	822,361,000
NIEHS - National Institute of Environmental Health Sciences	802,598,000	(1,619,000)	-	800,979,000
NIA - National Institute on Aging	3,543,673,000	(7,303,000)	-	3,536,370,000
NIAMS - National Institute of Arthritis and Musculoskeletal and Skin Diseases	624,889,000	(1,303,000)	-	623,586,000
NIDCD - National Institute on Deafness and Other Communication Disorders	490,692,000	(1,027,000)	-	489,665,000
NINR - National Institute of Nursing Research	169,113,000	(328,000)	-	168,785,000

Operating Division Appropriation	FY 2020 Enacted /1	Planned Transfers Out	Planned Transfers In	Revised Level
NIAAA - National Institute on Alcohol Abuse and Alcoholism	545,373,000	(1,082,000)	-	544,291,000
NIDA - National Institute on Drug Abuse	1,462,016,000	(914,000)	-	1,461,102,000
NIMH - National Institute of Mental Health	1,968,374,000	(2,926,000)	-	1,965,448,000
NHGRI - National Human Genome Research Institute	606,349,000	(1,263,000)	-	605,086,000
NIBIB - National Institute of Biomedical Imaging and Bioengineering	403,638,000	(846,000)	-	402,792,000
NCCIH - National Center for Complementary and Integrative Health	151,740,000	(318,000)	-	151,422,000
NIMHD - National Institute on Minority Health and Health Disparities	335,812,000	(601,000)	-	335,211,000
FIC - John E. Fogarty International Center	80,760,000	(119,000)	-	80,641,000
NLM - National Library of Medicine	456,911,000	(941,000)	-	455,970,000
NCATS - National Center for Advancing Translational Sciences	832,888,000	(1,610,000)	-	831,278,000
OD - Office of the Director /2	2,234,787,000	(4,303,000)	-	2,230,484,000
OD - Common Fund - Gabriella Miller Kids First Research Act	12,600,000	-	-	12,600,000
B&F - Buildings and Facilities	200,000,000	(420,000)	-	199,580,000
CURES Act, Innovation Account	492,000,000	-	-	492,000,000
NIH Total	**40,223,179,000**	**(62,976,000)**	-	**40,160,203,000**
Office of the Secretary				
General Departmental Management	284,729,000	-	8,541,870	293,270,870
Teen Pregnancy Prevention Community Grants	101,000,000	(190,518)	-	100,809,482
Sexual Risk Avoidance	35,000,000	(66,162)	-	34,933,838
Office of the National Coordinator for Health Information Technology	60,367,000	(114,000)	-	60,253,000
Office for Civil Rights	38,798,000	(74,000)	-	38,724,000
Public Health and Social Services Emergency Fund - lump sum appropriation	1,037,458,000	-	31,123,740	1,068,581,740
Public Health and Social Services Emergency Fund - Strategic National Stockpile	705,000,000	-	21,150,000	726,150,000
PHSSEF Subtotal	**1,742,458,000**	-	**52,273,740**	**1,794,731,740**
OS Total	**2,262,352,000**	**(444,680)**	**60,815,610**	**2,322,722,930**
Substance Abuse and Mental Health Services Administration				
Mental Health	1,444,974,000	(725,000)	-	1,444,249,000
Substance Abuse Treatment	3,756,556,000	(3,620,000)	-	3,752,936,000
Substance Abuse Prevention	206,469,000	(293,000)	-	206,176,000
Health Surveillance and Program Support	128,830,000	(225,000)	-	128,605,000
SAMHSA Total	**5,736,829,000**	**(4,863,000)**	-	**5,731,966,000**
LHHS Total	**81,949,147,000**	**(135,655,680)**	**135,655,680**	**81,949,147,000**

Note: Transfers to these accounts will be executed only as necessary to meet rapidly developing public health needs.

1/ Amounts shown in this column display the enacted amount for the contributing programs within these OpDivs, and do not necessarily sum to the total annual appropriations for that account.

2/ HHS will direct $13 million to the Public Health Scientific Services account instead of the Global Health account, to enhance domestic support for Coronavirus response activities. This change does not increase the total amounts to CDC under the use of this authority, as notified on 2/2/2020. This transfer will be executed after 15 days, per Section 205 of Title 2 of PL 116-94.

3/ The NIH Budget Authority reflects the $5 million transfer from NIH to OIG that was included in the FY 2020 Enacted L/HHS appropriations bill.

Congress of the United States
House of Representatives
Washington, D.C. 20515

June 13, 2018

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

We write to you with serious concerns regarding the U.S. Department of Justice's (DOJ) decision not to defend in federal court key patient protections contained in the Affordable Care Act (ACA), and to seek information regarding the U.S. Department of Health and Human Services' (HHS) and the Centers for Medicare & Medicaid Services' (CMS) involvement in DOJ's decision. The DOJ decision in *Texas v. United States* to decline to defend ACA provisions guaranteeing coverage regardless of health status ("guaranteed issue") and prohibiting insurers from charging higher premiums based on health status ("community rating") breaks with DOJ's longstanding tradition of defending laws enacted by the United States Congress, and constitutes yet another attempt by the Trump Administration to sabotage the ACA at the expense of consumers across the nation.[1]

Approximately 130 million individuals live with pre-existing conditions in the United States, such as cancer, diabetes, and asthma.[2] Prior to the ACA, insurers in the individual market could deny or charge these individuals more for insurance coverage—locking millions of Americans out of accessible health coverage. The guaranteed issue and community rating provisions of the ACA prohibited insurers from discriminating on the basis of these pre-existing conditions. In declining to defend these protections in the *Texas v. United States* lawsuit, the Trump Administration is seeking to invalidate these critical patient protections, and once again subject millions of Americans with pre-existing conditions to the discrimination they faced before the ACA.

Efforts by the Trump Administration and congressional Republicans to sabotage the ACA are already driving up the uninsured rate and costs for consumers across the nation.

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[1] Federal Defendants' Memorandum In Response To Plaintiffs' Application For Preliminary Injunction (June 7, 2018), *Texas v. United States of America,* N.D. Tex. (Civ. No. 4:18-CV-00167-O); 42 U.S.C. § 300gg-1, 300gg-3, 300gg-4(a), 300gg-(a)(1), 300gg-4(b).

[2] Center for American Progress, *Number of Americans With Pre-Existing Conditions By Congressional District* (Apr. 5, 2017).

According to the Congressional Budget Office, the Republican tax bill will increase premiums by an average of 15% for individuals in the individual market, and result in 3 million more uninsured.[3] HHS's ongoing efforts to erode the ACA's consumer protections through regulatory actions, such as short-term and association health plans, will also result in increased costs and reduced coverage.[4] The decision to decline to defend the law in *Texas v. United States* is just the latest attempt to accomplish what the Administration and the Republican Congress failed to accomplish through legislation—to repeal the ACA and take health care away from tens of millions of Americans.

Although this latest effort to target the constitutionality of critical patient protections is of dubious legal merit, it will nonetheless have a damaging impact on our nation's health care system and directly threaten the well-being of millions of Americans. While the case is pending, potentially for years, the legal uncertainty will result in additional instability in the individual marketplace, resulting in higher premiums and fewer choices for consumers. This is on top of the double-digit premium hikes Americans are already facing due to the Administration's ongoing sabotage of the law.

The potential implications of DOJ's decision raise serious concerns regarding how HHS and CMS under President Trump intend to fulfill their obligations "to enhance the health and well-being of all Americans."[5] Therefore, please provide the following documents by June 27, 2018:

1. Any analysis HHS and/or CMS has performed to evaluate the effects that the elimination of the guaranteed issue and/or community rating provisions of the ACA will have on cost and coverage of health insurance in the United States.

2. Any analysis HHS and/or CMS has performed to evaluate the effects that the elimination of the guaranteed issue and/or community rating provisions of the ACA will have on individuals with pre-existing conditions and their access to affordable health insurance.

3. Any analysis HHS and/or CMS has performed to evaluate the effects of the legal uncertainty from *Texas v. United States* on premiums in the individual market during the pendency of the lawsuit, including in the upcoming (2019) plan year.

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[3] Congressional Budget Office, *Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2018 to 2028* (May 2018).

[4] Urban Institute, *Updated: The Potential Impact of Short-Term Limited-Duration Policies on Insurance Coverage, Premiums, and Federal Spending* (Mar. 14, 2018).

[5] U.S. Department of Health and Human Services, About HHS (www.hhs.gov/about/strategic-plan/introduction/index.html).

4. Any analysis HHS and/or CMS has performed to evaluate how the elimination of the guaranteed issue and community rating requirements, which apply to both individual and small group health insurance issuers, will affect employer-provided health insurance.

5. DOJ's brief requests a declaratory judgment that the ACA's individual mandate, guaranteed issue, and community rating requirements be declared invalid beginning on January 1, 2019. Please provide all relevant documents and communications regarding HHS's contingency planning for the possibility that these changes could go into effect as of January 1, 2019, including answers to the following questions:

    a. If every individual who is eligible for subsidized coverage in the exchanges is to be individually underwritten and charged premiums based on their health status, how does HHS plan to designate the second-lowest cost silver plan upon which Advanced Premium Tax Credits are calibrated?

    b. How does HHS plan to conduct risk adjustment across the individual market and small group markets without community rating?

    c. If the community rating and guaranteed issue requirements are invalidated as of January 1, 2019, what will happen to coverage for individuals who sign up for Qualified Health Plans effective January 1, 2019, during the upcoming open enrollment season?

    d. Does HHS believe all of the other market reforms of the ACA, such as the limitations on age rating, are severable from the individual mandate? If DOJ prevails in its request for declaratory judgment, will HHS decline to enforce the limitation on age rating or any other ACA market reforms?

6. DOJ has taken the position that the individual mandate is not severable from the guaranteed issue and community rating provisions, arguing that Congress believed that the individual mandate requirement is essential to the operation of the guaranteed issue and community rating provisions when it originally passed the ACA in 2010. However, Congress also left both market reforms intact when it passed the Republican tax bill, which reduced the individual shared responsibility payment to $0. Moreover, it is clear from HHS's own proposed rules that the Department expects the individual market to continue to function beyond 2019, when the mandate penalty is zeroed out.[6]

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[6] See, e.g., Short-Term, Limited-Duration Insurance: A Proposed Rule by the Internal Revenue Service, the Employee Benefits Security Administration, and the Health and Human Services Department (Feb. 21, 2018) ("Given the prior trend and the recent increases in premiums in the individual market, the Departments anticipate that the rule, if finalized, would encourage more consumers to purchase short-term, limited-duration insurance for longer durations, including individuals who were previously insured and some who are currently enrolled in individual market plans, especially in 2019 and beyond, when the individual shared

a. Please provide HHS's view on whether the individual market can, in fact, function with the continued existence of the guaranteed issue and community rating requirements, but with the individual shared responsibility payment set at $0.

b. Has HHS changed its view regarding the effects of the reduction in the shared individual responsibility payment on the individual insurance market? If so, please provide any analysis prepared that led to this change in viewpoint.

c. If this viewpoint has changed, will HHS be withdrawing the proposed rule regarding short-term, limited duration health plans and reissuing it with an analysis that reflects the Administration's current position regarding the effects of reducing the shared individual responsibility payment?

7. Please provide all communications between HHS and/or CMS officials and officials from DOJ regarding the DOJ decision not to defend the guaranteed issue and/or community rating provisions of the ACA. Such communications should include, but not be limited to, emails, letters, faxes, and any other written materials, as well as a list of any meetings, calls, or other oral communications that took place between the aforementioned parties. In the case of meetings, calls, and other oral communications, please include the date, time, and location at which such communications took place, as well as a list of individuals who participated.

Thank you for your prompt attention to this matter. Should you have any questions, please contact Una Lee of the Energy and Commerce Committee's minority staff at (202) 225-3641, Melanie Egorin of the Ways and Means Committee's minority staff at (202) 225-4021, Arya Hariharan of the Judiciary Committee's minority staff at (202) 225-6906, or Udochi Onwubiko of the Education and the Workforce Committee's minority staff at (202) 225-3725.

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responsibility payment included in section 5000A of the Code is reduced to $0, as provided under Public Law 115-97."); *id.* ("Beginning in 2019, the individual shared responsibility payment included in section 5000A of the Code is reduced to $0, as provided under Public Law 115-97. This would compound the effects of the provisions of this proposed rule…").

Sincerely,

Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce

Richard E. Neal
Ranking Member
Committee on Ways and Means

Jerrold Nadler
Ranking Member
Committee on the Judiciary

Robert C. "Bobby" Scott
Ranking Member
Committee on Education and the Workforce

Congress of the United States
Washington, DC 20515

December 7, 2018

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

We are writing to request your immediate attention to an issue of critical importance to our healthcare system and to the millions of Americans living with preexisting conditions. Previously, we asked for your assistance in understanding the Department's involvement in the Administration's decision to decline to defend protections for individuals with preexisting conditions in the *Texas v. United States* lawsuit. To date, you have provided no substantive response to our inquiry.

On June 7, 2018, in the *Texas v. United States* lawsuit, the Department of Justice (DOJ) declined to defend the Affordable Care Act (ACA) and petitioned the Court to strike down the law's protections for individuals with preexisting conditions. The guaranteed issue, community rating, and preexisting condition exclusion provisions of the ACA prohibit insurers from discriminating on the basis of these preexisting conditions. In declining to defend these provisions, the Trump Administration is seeking to invalidate these critical patient protections, and once again subject millions of Americans with preexisting conditions to the discrimination they faced before the ACA.

On June 13, 2018, we sent the attached letter requesting documents and information to better understand the Department's role and involvement in the DOJ's decision. There is no legal basis to withhold information from Congress on the basis of the pendency of an ongoing lawsuit. We request a complete response to our June 13, 2018 letter by no later than December 31, 2018. We also request a briefing on the Department's document production schedule by December 17, 2018.

Thank you for your prompt attention to this matter.

Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce

Richard E. Neal
Ranking Member
Committee on Ways and Means

PRINTED ON RECYCLED PAPER

Robert C. "Bobby" Scott
Ranking Member
Committee on Education and the Workforce

Jerrold Nadler
Ranking Member
Committee on the Judiciary

Congress of the United States
Washington, DC 20515

April 8, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Secretary and Administrator Verma:

We are requesting information and documents regarding the involvement of the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) in the troubling decision by the Department of Justice (DOJ) not to defend the constitutionality of the Affordable Care Act (ACA).

On March 25, 2019, DOJ announced in a letter filed with the U.S. Court of Appeals for the Fifth Circuit that it would no longer oppose the judgment of the district court in *Texas v. United States*, which held that the ACA is wholly unconstitutional. Previously, DOJ had argued that although it believed that certain portions of the law should be held unconstitutional, the rest of the law should stand.[1] In a June 7, 2018 letter to Congress explaining DOJ's position in the litigation, then-Attorney General Sessions stated that he was acting "with the approval of the President of the United States."[2]

DOJ's sudden and significant reversal from its previous position was reportedly driven by officials inside the White House and the Office of Management and Budget (OMB)—including Acting Chief of Staff Mick Mulvaney, Acting Director of OMB Russ Vought, and Director of the Domestic Policy Council Joe Grogan—over the opposition of Attorney General William Barr and HHS Secretary Alex Azar.[3]

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[1] Letter from Attorney General Jefferson B. Sessions III, Department of Justice, to Paul Ryan, Speaker of the House (June 7, 2018) (online at www.justice.gov/file/1069806/download).

[2] *Id.*

[3] *White House Obamacare Reversal Made Over Cabinet Objections*, Politico (Mar. 26, 2019) (online at

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If the Administration's new legal position prevails and the entire ACA is struck down, there would be catastrophic implications for millions of American consumers and the United States health care system. Approximately 21 million Americans would be at risk of losing their health insurance—including 12 million individuals who gained coverage through Medicaid expansion and another nearly 10 million who receive federal subsidies to purchase plans on the individual market.[4]

Striking down the ACA would also have serious implications for the 133 million Americans with pre-existing conditions like asthma, diabetes, and cancer.[5] The ACA prohibits insurance companies from denying coverage or charging higher premiums to consumers for a pre-existing condition.[6] It also prohibits insurers from selling polices that exclude coverage for pre-existing conditions and from instituting lifetime and annual limits on benefits.[7]

This new legal position also runs counter to several of the Administration's own policy priorities, which HHS and CMS are charged with carrying out. President Trump has stated that he wants to use CMS's Innovation Center to test drug cost models as part of his initiative to lower drug prices, yet this center was created by the ACA and would no longer exist if the law was to be found unconstitutional. This Administration has praised initiatives to crack down on health care fraud, but the ACA provided stronger tools to fight Medicare fraud. The President's HIV plan relies on a number of provisions of the ACA to expand access to prevention and treatment for Americans with HIV and those at risk. It is not clear how this plan would operate if the law is repealed. The ACA significantly expanded access to substance use disorder treatment, which is an important part of the President's push to reduce opioid use disorder.

Although HHS has asserted that "Secretary Azar fully supports the Administration's litigation position in the ACA case, which bears his name," this statement is at odds with accounts of two individuals with knowledge of the Administration's internal deliberations.[8] Congress needs to understand what communications HHS and CMS had with White House, OMB, and/or DOJ officials regarding this decision, as well as what contingency plans are being developed to address the disruption that will inevitably occur in the event that the ACA is overturned by the courts.

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www.politico.com/story/2019/03/26/trump-obamacare-reversal-cabinet-1238359).

[4] Center on Budget and Policy Priorities, *Latest Republican ACA Repeal Plan Would Have Similar Harmful Impacts on Coverage Health as All the Others* (June 20, 2018) (online at www.cbpp.org/sites/default/files/atoms/files/6-20-18health.pdf).

[5] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Health Insurance Coverage for Americans with Pre-Existing Conditions: The Impact of the Affordable Care Act* (Jan. 5. 2017) (online at https://aspe.hhs.gov/system/files/pdf/255396/Pre-ExistingConditions.pdf).

[6] 42 U.S.C. §§ 300gg(a)(1), 300gg-1, 300gg-4(a), 300gg-4(b).

[7] 42 U.S.C. § 300gg-3; 42 U.S.C. § 300gg-11.

[8] *White House Obamacare Reversal Made Over Cabinet Objections*, Politico (Mar. 26, 2019) (online at www.politico.com/story/2019/03/26/trump-obamacare-reversal-cabinet-1238359).

The day after DOJ announced that it would reverse its legal position, President Trump pledged at a press conference: "If the Supreme Court rules that Obamacare is out, we will have a plan that is far better than Obamacare."[9] It is unclear whether any plan yet exists, though reports indicate that the White House has engaged several conservative think tanks to develop this plan.[10] The President now asserts that Congress will vote on a replacement plan immediately following the 2020 election.[11]

DOJ's decision raises serious concerns as to how HHS and CMS will fulfill their mission to "enhance the health and well-being of all Americans" if the ACA is overturned.[12] Congress is entitled to understand the communications that took place and pressures that were applied to achieve these troubling results. Further, there is no legal basis for withholding information from congressional oversight due to the pendency of an ongoing lawsuit. For these reasons, we request that you produce the following documents and information by April 22, 2019:

1. Documents sufficient to identify all HHS and/or CMS personnel—including but not limited to Secretary Azar and Administrator Verma—who were informed of DOJ's decision to support the district court's judgment in *Texas v. United States* prior to March 25, 2019. If no responsive documents exist, please provide a list of all HHS and/or CMS personnel who were informed of this decision prior to March 25, 2019.

2. Documents sufficient to identify when the HHS and/or CMS personnel identified in response to Request 1 were informed of DOJ's decision to support the district court's judgment in *Texas v. United States*. If no responsive documents exist, please provide a written summary of when each of the HHS and/or CMS personnel identified in response to Request 1 were informed of this decision, including the identity of the parties who relayed this information.

3. All communications dated between December 14, 2018, and March 25, 2019, between any personnel from HHS and/or CMS, and any personnel from the White House and/or OMB, regarding DOJ's decision to support the district court's judgment in *Texas v. United States*. If no responsive documents exist, please provide a written summary of all communications (whether telephonic, in-person, or otherwise) between any HHS and/or CMS personnel, and any White House

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[9] *Trump Vows to Have a Health Plan 'Far Better than Obamacare,'* Politico (Mar. 27, 2019) (online at www.politico.com/story/2019/03/27/trump-health-care-obamacare-1238927).

[10] *White House Working on Secret Healthcare Plan with Three Conservative Think Tanks,* Washington Examiner (Mar. 31, 2019) (online at www.washingtonexaminer.com/news/white-house-working-on-secret-healthcare-plan-with-three-conservative-think-tanks).

[11] *Trump, in Reversal, Says Replacing Obamacare Can Wait Until After Election,* Bloomberg (Apr. 2, 2019) (online at www.bloomberg.com/news/articles/2019-04-02/trump-in-reversal-says-replacing-obamacare-can-wait-until-2020?utm_campaign=pol&utm_medium=bd&utm_source=applenews).

[12] U.S. Department of Health and Human Services, *About HHS* (online at www.hhs.gov/about/strategic-plan/introduction/index.html).

and/or OMB personnel regarding this decision dated between December 14, 2018, and March 25, 2019, or state whether there were no such communications.

4. All communications dated between December 14, 2018, and March 25, 2019, between any personnel from HHS and/or CMS, and any DOJ personnel, regarding DOJ's decision to support the district court's judgment in *Texas v. United States*. If no responsive documents exist, please provide a written summary of all telephonic or in-person communications between any HHS and/or CMS personnel, and any DOJ personnel regarding this decision dated between December 14, 2018, and March 25, 2019, or state whether there were no such communications.

5. All analyses, studies, reviews, assessments, reports, memoranda, or opinions regarding the potential impact if the ACA is found unconstitutional as the result of a judicial decision in *Texas v. United State*s, including but not limited to potential impacts on health care insurance coverage, impacts on health care providers, and economic impacts of this change. If no such documents exist, please say so in your response.

6. All documents and communications relating to any plans or policies to initiate an alternative health care law in the event the ACA is found unconstitutional as the result of a judicial decision in *Texas v. United States*. If no such plans or policies exist, please say so in your response.

7. All communications regarding any plans or policies to initiate an alternative health care law in the event that the ACA is found unconstitutional as the result of a judicial decision in *Texas v. United States*. If no responsive documents exist, please provide a written summary of all telephonic or in-person communications between any HHS and/or CMS personnel, and any DOJ personnel regarding this decision dated between December 14, 2018, and March 25, 2019, or state whether there were no such communications.

Thank you for your attention this matter.

Sincerely,

Elijah E. Cummings
Chairman
Committee on Oversight and Reform

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce

Richard E. Neal
Chairman
Committee on Ways and Means

Robert C. "Bobby" Scott
Chairman
Committee on Education and Labor

Jerrold Nadler
Chairman
Committee on the Judiciary

cc: The Honorable Jim Jordan, Ranking Member
Committee on Oversight and Reform

The Honorable Greg Walden, Ranking Member
Committee on Energy and Commerce

The Honorable Kevin Brady, Ranking Member
Committee on Ways and Means

The Honorable Virginia Foxx, Ranking Member
Committee on Education and Labor

The Honorable Doug Collins, Ranking Member
Committee on the Judiciary

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

FEB 10 2020

The Honorable Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Richard E. Neal
Chairman
Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

The Honorable Robert C. "Bobby" Scott
Chairman
Committee on Education and Labor
United States House of Representatives
Washington, DC 20515

The Honorable Jerrold Nadler
Chairman
Committee on the Judiciary
United States House of Representatives
Washington, DC 20515

Dear Chairs Maloney, Pallone, Neal, Scott, and Nadler:

This letter supplements the Department of Health and Human Services' (HHS) ongoing document production in response to your April 8, 2019 letter requesting information concerning the ongoing litigation in *Texas v. United States*, No. 19-10011 (5th Cir.). We appreciate your interest in this significant case. HHS is committed to working towards satisfying the Committees' requests while also ensuring Executive Branch interests remain protected. To that end, HHS has produced 385 documents totaling 4,191 pages in response to your request. We will continue to produce additional responsive, non-privileged documents on a rolling basis.

On December 18, 2019, the United States Court of Appeals for the Fifth Circuit found that the individual mandate of the Affordable Care Act (ACA) was unconstitutional, but remanded to the district court to determine if the mandate is severable from the rest of the ACA. *Texas v. United States*, 945 F.3d 355 (5th Cir. 2019). The ruling did not halt any other provision of the law. HHS continues administering and enforcing all aspects of the ACA as it has before the court issued its decision.

We respectfully refer your requests for information concerning specific litigation decisions to the Department of Justice, which is responsible for handling litigation across federal agencies. We understand that the Department of Justice sent the Committees a letter responding to your inquiry on May 24, 2019.

Requests for documents outlining the details of internal deliberations regarding potential decisions HHS would make as a result of the lawsuit implicate the core deliberative process, attorney work product, and attorney-client privileges. These concerns are heightened given the ongoing nature of the litigation. To the extent the Committees request a number of confidential communications between the President or his close advisors concerning an executive branch litigation decision, White House counsel has previously explained why such a request cannot be accommodated. *See* Letter from Pat Cipollone, Counsel to the President, to Chairman Jerrold Nadler and Chairman David Cicilline (Apr. 15, 2019). Nonetheless, HHS's ongoing document production of responsive, non-privileged material illustrates the Department's continued commitment to working with Congress to satisfy its request for information while ensuring the Department and Executive Branch's interests remain protected.

We look forward to continue working with the Committees on reaching appropriate accommodations for this and other oversight requests. Please do not hesitate to contact this office if we may provide additional assistance regarding this or any other matter.

Sincerely,

Sarah Arbes
Acting Assistant Secretary for Legislation

Cc: The Honorable Jim Jordan, Ranking Member
Committee on Oversight and Reform

The Honorable Greg Walden, Ranking Member
Committee on Energy and Commerce

The Honorable Kevin Brady, Ranking Member
Committee on Ways and Means

The Honorable Virginia Foxx, Ranking Member
Committee on Education and Labor

The Honorable Doug Collins, Ranking Member
Committee on the Judiciary

The Washington Post
Democracy Dies in Darkness

Trump campaign urges White House to soften proposed flavored vape ban

By **Michael Scherer**, **Josh Dawsey**, **Laurie McGinley** and **Neena Satija**

Oct. 25, 2019 at 3:50 p.m. EDT

President Trump's campaign manager Brad Parscale has privately warned the president that his plans to reduce youth vaping by banning flavored e-cigarettes could backfire in the 2020 election — placing Trump's reelection campaign in the middle of a governmental debate over a major public health issue.

The political lobbying effort comes as the Trump administration is considering whether to continue allowing menthol- and mint-flavored e-cigarette products, according to three people familiar with the deliberations. Allowing these sales would mark a major retreat from a proposed ban announced in September on "all non-tobacco" flavors . Government data shows that nearly two-thirds of high schoolers who use e-cigarettes use mint or menthol flavors.

Parscale has commissioned internal campaign polling to argue that Trump supporters who use e-cigarettes could abandon the president if he follows through on a ban, according to a person familiar with the effort who spoke on the condition of anonymity to discuss internal deliberations.

AD

Instead, this person said, Parscale has suggested reframing the issue away from flavors to other steps that the government can take to prevent youth use of the products, including a ban on sales of e-cigarettes to anyone under 21, a requirement that stores limit access by locking the products up, and stiffer penalties for selling to underage consumers.

The White House is discussing allowing menthol and mint flavors — a position that would benefit the largest e-cigarette producer, Juul Labs — or allowing only menthol on the theory that it is less sweet and the sole flavor permitted in cigarettes, said two people familiar with the deliberations. No final decision has been made. Those discussions were first reported by Bloomberg News.

Anti-tobacco activists and health groups were livid about the prospect of the White House's backtracking on the flavors.

AD

"Excluding menthol would be huge — it means that kids will buy menthol," said Desmond Jenson, an attorney with the Public Health Law Center at the Mitchell Hamline School of Law in St. Paul, Minn. "If you give them one flavor, that's what they will buy. It doesn't solve the problem."

Scott Gottlieb, who served as Trump's first FDA commissioner, said Friday that the harm to youths of allowing mint and menthol flavors outweighs the benefit to adults of having flavored options.

"If mint and menthol e-cigs remain on the market, the biggest beneficiaries are tobacco companies like Altria and Reynolds which mass-produce these products, harming kids who are largely using these brands," Gottlieb said. "Data suggests that adults who use e-cigs to successfully quit smoking aren't using these same products."

AD

The Food and Drug Administration declined to comment on whether the administration is considering excluding mint and menthol from its proposed ban. In a statement, it said that the agency in coming weeks will finalize a policy that would "clear the market of unauthorized e-cigarette products in flavors that appeal to kids. The FDA plans to share more on the specific details of the plan and its implementation soon."

A spokeswoman for the Department of Health and Human Services said she could not comment on the policy while it is still being drafted.

Inside the White House, members of the president's family, including first lady Melania Trump and senior adviser Ivanka Trump, have been helping to lead the push for a crackdown on youth use of e-cigarettes. The first lady has called e-cigarette use by children a "growing epidemic" with an estimated 5 million underage users.

AD

"We need to be proactive before this gets out of control," Melania Trump announced at an Oct. 9 White House event with former teenage users of the products.

The first lady was also present for the Sept. 11 Oval Office announcement by HHS Secretary Alex Azar and acting FDA commissioner Norman "Ned" Sharpless about the proposed ban. Under the plan, flavored products would be required to come off the market and could not return unless specifically cleared by the FDA.

"The youth are drawn to flavored e-cigarettes, including mint and menthol," Azar said at the event, citing recent research.

Parscale reached out to President Trump after that event to say that the decision was being made too quickly and that Trump needed more data, according to a person familiar with the conversation.

AD

After the outreach from Parscale, Trump released a cryptic tweet on Sept. 13, which suggested the possibility of a different approach than the one Azar had announced in the Oval Office.

"While I like the Vaping alternative to Cigarettes, we need to make sure this alternative is SAFE for ALL!" Trump wrote. "Let's get counterfeits off the market, and keep young children from Vaping!"

A Washington Examiner op-ed written by a pro-vaping conservative activist, Paul Blair, with the headline "Banning flavored e-cigarettes might cost Trump reelection," was circulated at the White House and considered the "opinion of the campaign," according to a White House official involved in the process.

AD

"We were getting crushed by the e-cig industry that first 48 hours," said the official, who called Parscale's intervention "annoying."

Trump advisers compiled a binder of evidence supporting the idea of strong new measures to combat youth vaping, according to a person familiar with the effort. The documents included public polling, supportive editorials, statements from the scientific and medical community, and statements from elected leaders. White House officials have said that banning e-cigarette flavors could help Trump with voters outside his core base, including suburban moms.

At the same time, there have been public signs of a crack in White House support for banning all favors, as Azar and the White House press office originally announced.

AD

Senior White House adviser Kellyanne Conway suggested to reporters Friday that menthol could be viewed as a type of tobacco flavoring.

"I think the conversation is less about flavors and more about adults and youth," she said. "I recognize that menthol tastes like tobacco. Many adults like menthol."

Conservative activists and trade groups organized a protest by e-cigarette users at a recent Trump rally in Dallas and have said that any attempt to restrict flavors would take away the freedoms of adults.

"Flavors are vaping. Vaping is flavors," said Grover Norquist, the president of Americans for Tax Reform, who declined to say whether he or his group have received funding from the e-cigarette industry. "It is a vote-moving issue in the same way being a home-schooler is or concealed carry."

AD

Greg Conley, president of the American Vaping Association, said in a statement that while he is "heartened" to see the White House beginning to back off the flavor ban, "carving out certain flavors to benefit one company simply will not be effective at achieving any of the White House's goals."

Conley said in an interview Thursday that mint and menthol account for a relatively low proportion of the sales at vape shops and that exempting them would not save retailers from financial peril. "It won't satisfy the voters that Trump is trying to appease," he said.

Rather than a flavor ban, many in the vaping industry would prefer tougher sales restrictions that keep e-cigarettes out of the hands of kids, he said.

Juul, the largest e-cigarette company, has removed all flavors from the market except tobacco, menthol and mint, and it said recently that it was reviewing whether to suspend sales of the latter two. Mint and menthol accounted for almost 60 percent of Juul's $3.3 billion in retail sales in the United States last year, according to a Wells Fargo analyst report from last month.

Juul spokesman Austin Finan said the company will continue to refrain from lobbying the administration on its e-cigarette flavor policy and "will fully support and comply with the final policy."

The company has employed a number of former Trump White House officials, including former counselor to the president Johnny DeStefano, former vice presidential adviser Rebeccah Propp and former communications adviser Josh Raffel.

Altria, the tobacco giant that has a 30 percent stake in Juul, also has said that it is opposed to youth vaping and that it would not lobby against the administration's e-cigarette proposal. "We're not lobbying in opposition to the administration's current e-vapor proposal, and we look forward to reviewing the FDA's new e-vapor guidance when it is issued." Juul's top executive was replaced last month with a former Altria executive.

Jeff Miller, a lobbyist with close ties to Vice President Pence, reported that his firm was paid $60,000 by Altria from July through September 2019 to lobby HHS, the Executive Office of the President and the White House on "issues related to the regulation of tobacco products including . . . [the] WH Administration Initiative to ban flavored vaping products."

Altria reported paying its in-house lobbyists more than $2 million to lobby Congress, the FDA, the White House and the Office of Management and Budget on issues including "FDA Guidance on E-Vapor."

A person familiar with Altria's lobbying strategy said the disclosures reflect efforts to gather information — not to take a position on the White House proposed ban.

"They've been clear: Don't get involved in any of the flavor ban issues at all. They just want to know what's going on," said the person, who spoke on the condition of anonymity because they were not authorized to talk publicly. "We make calls to our contacts in government to say, 'Hey, what's going on with the issue, what are you hearing, what do you think they're going to do?' "

The intelligence-gathering has made clear, the person said, that "there's disagreement among folks in the White House. The concern is, there's a lot of adults that switched to mint and menthol to quit smoking. So how do you handle that?"

But Matt Myers, president of the Campaign for Tobacco-Free Kids, said any rollback of the ban to exclude mint and menthol would amount to a “get-out-of-jail-free card” for Juul and “represents the worst of special interest politics.”

Congress of the United States
Washington, DC 20510

October 29, 2019

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

As Ranking Member of the United States Senate Committee on Finance and Chairman of the House Committee on Energy and Commerce with jurisdiction over Medicaid and the Children's Health Insurance Program (CHIP), we write to you regarding our serious concerns with the continued and unprecedented increase in the number of uninsured children in the United States.

Last month, the U.S. Census Bureau released new data showing that for the second year in a row more children were uninsured. This is despite a strong economy and trends up until two years ago showing consistent health coverage gains for children. According to the data, 5.5 percent of children were uninsured in 2018, an increase of 425,000 children from 2017.[1] It also follows an alarming trend of declining child enrollment in Medicaid and CHIP. Over 830,000 children lost Medicaid and CHIP coverage in 2018 nationwide, and though some states with declining enrollment in 2018 have started to regain momentum in 2019, cumulative enrollment losses from December 2017 through May 2019 have now surpassed one million children.[2]

This is a disturbing trend that the Administration should be looking to correct, but, instead, your Administration has applauded the enrollment declines among children. And while you assert that

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[1] U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2018 (Sept. 10, 2019), *available at* https://www.census.gov/library/publications/2019/demo/p60-267.html.
[2] TRICIA BROOKS, GEORGETOWN UNIV. HEALTH POLICY INST. CTR. FOR CHILDREN & FAMILIES, WHAT HAS HAPPENED TO THE 1+ MILLION CHILDREN WHO HAVE LOST MEDICAID/CHIP COVERAGE? (Sept. 4, 2019), https://ccf.georgetown.edu/2019/09/04/what-has-happened-to-the-1-million-children-who-have-lost-medicaid-chip-coverage/.

they are the result of the improving economy,[3] that is simply not borne out by the evidence. If children were leaving Medicaid and CHIP and finding coverage elsewhere, then the number and percent of uninsured children would go down. There would also be a shift in the sources of coverage, showing a greater percentage of children with private and employer-sponsored insurance. This is simply not the case. As stated in the U.S. Census Bureau's findings, "the percentage of people with private coverage did not statistically change."[4] Instead, 400,000 more children are uninsured since last year, reversing decades of progress towards covering more children. These historic coverage losses have occurred under your leadership, and should not be celebrated with misleading claims.

We believe that these historic coverage losses among children are the result of overly burdensome and faulty eligibility and renewal processes, diminished resources for outreach and enrollment assistance, and policies that instill fear and confusion among immigrant and mixed status families, such as the Department of Homeland Security's public charge rule, that are leaving eligible children without the coverage they need.[5]

The Department of Health and Human Services (HHS) in coordination with the Centers for Medicare & Medicaid Services (CMS) must take immediate action to ensure that all eligible children are enrolled in Medicaid and CHIP. Please respond by November 30, 2019 with a detailed explanation of the specific actions HHS is taking to address these unprecedented coverage declines and increase Medicaid and CHIP child enrollment to once again reduce the share of children without health coverage.

In addition, in order to oversee your administration of a program that tens of millions of children rely on for their health and well-being, please also provide the following by November 30, 2019:

1. All briefing materials, including memoranda, PowerPoint presentations, or emails, relating to the decline in children's enrollment in Medicaid and CHIP.

2. A timeline indicating when you became aware that there was a decline in children's enrollment in Medicaid and CHIP, and specific action CMS took in response.

3. All analysis performed in support of your assertion that children who have lost Medicaid and CHIP coverage gained coverage elsewhere.

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[3] Administrator Seema Verma (@SeemaCMS) Twitter (Apr. 256, 2019 2:17pm), https://twitter.com/SeemaCMS/status/1121478298561912832.
[4] *See supra* note 1.
[5] KAISER FAMILY FOUND., ANALYSIS OF RECENT DECLINES IN MEDICAID AND CHIP ENROLLMENT, *available at* https://www.kff.org/medicaid/fact-sheet/analysis-of-recent-declines-in-medicaid-and-chip-enrollment/.

4. A description of the steps CMS plans to take to reverse the historic increase in children's coverage losses in Medicaid and CHIP.

Sincerely,

Ron Wyden
Ranking Member
Senate Committee on Finance

Frank Pallone, Jr.
Chairman
House Energy and Commerce Committee

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

June 27, 2019

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is examining the U.S. Department of Health and Human Services' (HHS) administration of the Medicaid program. Recent actions by the state legislatures in Utah and Tennessee suggest that one or both states may soon request waiver authority to cap their Medicaid programs, threatening access to care for millions of people in these states. I am deeply troubled by these developments, and with the reports that the Centers for Medicare & Medicaid Services (CMS) plans to release guidance to states on how they may cap spending on their Medicaid programs, either through a block grant, a per capita cap, or some other mechanism.[1] Equally troubling are reports that CMS Administrator Seema Verma "has urged [Alaska] to be the first state to receive Medicaid dollars as a block grant."[2] In view of these reports, and recent state action in Tennessee and Utah to request waivers to block grant their programs, I write to request additional information about HHS's actions related to block granting or otherwise capping the Medicaid program.

In 2017, Congress considered and rejected converting Medicaid to a block grant or per capita cap when such a change was a centerpiece of the failed Republican effort to repeal the Affordable Care Act. Capping Medicaid funding, whether through a block grant or a per capita cap, would be devastating to those who rely on the program. The President's budget estimates

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[1] Politico, *Trump wants to bypass Congress on Medicaid plan* (January 11, 2019).

[2] Letter from Michael Dunleavy, Governor of Alaska, to Donald Trump, President of the United States (March 1, 2019).

that such a change would cut $1.4 trillion from Medicaid over 10 years.[3] Cuts of that magnitude would threaten access to services for children with complex medical needs, people with disabilities, seniors, and others in the community who receive care from safety net providers that are largely financed by Medicaid. The American Hospital Association has said the deep cuts from such a proposal "would reduce federal Medicaid funding to unsustainable levels" and "will have serious negative consequences for communities across America."[4]

Congress recognized that changing the financing structure of Medicaid to implement a block grant or per capita cap requires a statutory change, and the President's 2020 budget acknowledges that legislation is needed to do so.[5] Moreover, federal law does not give the Secretary authority to change Medicaid's structure to a block grant or per capita cap through administrative action. In order to implement a block grant or per capita cap, the Secretary would need to effectively waive Section 1903 of the Social Security Act (the Act), which states that "the Secretary… shall pay to each State which has a plan approved under this title, for each quarter… an amount equal to the Federal medical assistance percentage… of the total amount expended during such quarter as medical assistance under the State plan."[6] Section 1115 authorizes the Secretary to waive certain enumerated sections of the law if doing so "is likely to assist in the promotion of the objectives of [Medicaid]"[7], which, according to the statute, is "to furnish medical assistance" to eligible individuals.[8] Therefore, for the Secretary to waive part of the Medicaid program, it must satisfy a two-prong test: first, it must be one of the enumerated sections listed in Section 1115, and second, it must promote the objectives of the Medicaid program.

Capping the Medicaid program fails both requirements. Section 1903 is not one of the enumerated sections listed in the statute the Secretary can waive. Congress never intended for the Secretary to have the ability to waive the federal funding provisions (financing requirements); if it had, the statute would clearly state it, as it does with other sections of the law. To argue otherwise defies the plain language and clear statutory framework of Section 1115. Furthermore, it defies logic to argue that limiting medical assistance promotes the objective of "furnishing medical assistance." Capping the Medicaid program would result in reduced or loss of benefits for individuals, loss of coverage, and imperil the financing of critical health care

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[3] Department of Health and Human Services, *FY2020 Budget in Brief.* (www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf).

[4] Senate Committee on Finance, Statement of the American Hospital Association, *Hearing to Consider the Graham-Cassidy-Heller-Johnson Proposal,* 115th Cong. (September 25, 2017).

[5] *See* note 3.

[6] Social Security Act, Pub. L. No. 74-271: § 1903(a).

[7] Social Security Act, Pub. L. No. 74-271: § 1115.

[8] Social Security Act, Pub. L. No. 74-271: § 1901.

providers. In other words, it would reduce the amount of medical assistance, not assist in furnishing it.

Recent reports suggest that you plan to take administrative action to make changes in Medicaid financing despite the fact that there is no statutory authority to implement a block grant or per capita cap through a section 1115 demonstration project, or "waiver."[9,10] Your recent approval of Utah's waiver already appears to exceed your authority in the statute.[11] It allows the state to cap enrollment based on available state appropriations and gives states the authority to deny coverage to people whenever it experiences budget pressures or simply decides it has spent enough on coverage for eligible adults without any accountability or oversight by CMS, in violation of the statute. An HHS spokesperson said that CMS believes "that only when states are held accountable to a defined budget can the federal government finally end our practice of micromanaging every administrative process."[12] This suggests that you are considering allowing states to cap state spending on Medicaid by limiting enrollment or otherwise changing eligibility or benefits to stay within their self-imposed spending caps. Like Utah's enrollment cap, this would undermine the fundamental structure of Medicaid, which provides a guarantee of coverage to all people who qualify.

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As the Chair of the Committee on Energy and Commerce with jurisdiction over Medicaid, it is my responsibility to ensure that the program is administered in compliance with

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[9] *See* note 1.

[10] Modern Healthcare, *Medicaid block grant waiver reports revive hospitals' funding worries* (January 16, 2019).

[11] Letter from Seema Verma, Administrator, Centers for Medicare & Medicaid Services, to Nathan Checketts, Director, Utah Department of Health (March 29, 2019) (www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ut/ut-primary-care-network-ca.pdf).

[12] *See* note 10.

[13] Social Security Act, Pub. L. No. 74-271: § 1115(d).

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federal law. Allowing states to cap their Medicaid spending based on their own budget decisions without regard to the adequacy of the funding to provide coverage and full benefits to all eligible individuals would have devastating consequences for those who rely on Medicaid for their medical care. The plain language of the statute prohibits the Secretary from approving a waiver that requests a block grant or per capita cap in Medicaid through a cap on federal funds. Legislative history and the Administration's own budget acknowledge that converting Medicaid to a block grant or per capita cap would require a statutory change. Other changes that allow states to develop their own caps are similarly outside your authority. Accordingly, it is troubling to learn that you are putting your radical agenda ahead of your responsibility to implement the law faithfully.

In order to oversee your administration of the Medicaid program, please provide the following no later than July 15, 2019:

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2. All cost and coverage estimates prepared by HHS, including the CMS Office of the Actuary, the Office of Management and Budget (OMB), or contractors or subcontractors for HHS or OMB, related to the State Medicaid Director Letter: Medicaid Value and Accountability Demonstration Opportunity, a Medicaid block grant, or Medicaid per capita cap.

3. A list of all personnel, and their titles, involved in approving the decision to draft or release the State Medicaid Director Letter: Medicaid Value and Accountability Demonstration Opportunity.

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6. All emails regarding the State Medicaid Director Letter: Medicaid Value and Accountability Demonstration Opportunity, block grants, per capita caps, or section 1115 waivers between Calder Lynch and Nathan Checketts, Utah Director of Medicaid and Health Financing.

7. All documents and communications regarding the State Medicaid Director Letter: Medicaid Value and Accountability Demonstration Opportunity; block grants, per capita

caps, or section 1115 waivers between Seema Verma, Calder Lynch, Brady Brookes, Mary Mayhew, and Christopher Traylor and officials in the states of Utah, Alaska, Georgia, and Tennessee, including but not limited to individuals in the office of the Governor and the State Medicaid Director.

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I appreciate your attention to this matter. If you have any questions, please contact Rick Van Buren with the Committee staff at 202-225-5056.

Sincerely,

Frank Pallone, Jr.
Chairman

Johnson & Johnson

WORLDWIDE GOVERNMENT AFFAIRS & POLICY

February 26, 2020

The Honorable Anna Eshoo
202 Cannon House Office Building
Washington, DC 20515

The Honorable Michael Burgess
2161 Rayburn House Office Building
Washington, DC 20515

Chairwoman Eshoo, Ranking Member Burgess and Members of the Committee:

On behalf of Johnson & Johnson, I am pleased to share information regarding the company's response to the threat of the novel coronavirus (COVID-19) outbreak. Throughout our more than 130-year history, Johnson & Johnson has had a legacy of coming to the aid of local and global communities during times of crisis, from natural disasters to health outbreaks. We believe we have a responsibility to step in and invest in solutions for global public health crises and are proud to be contributing to the global response to COVID-19.

In early January 2020, when the viral sequence became available, Johnson & Johnson began to rapidly mobilize our resources in response to the virus. As part of this work, we have initiated efforts to develop a vaccine candidate against COVID-19, which we hope can ultimately be deployed quickly and extensively to help combat this outbreak. Earlier this month, J&J announced a collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services, to further expedite our investigational coronavirus vaccine program as well as to accelerate the discovery of potential treatments for the virus. We remain open to collaborating with governments, healthcare professionals and others to ensure rigorous collection of data that will allow evidence generation to guide the use of effective medicines and support the best outcomes for patients affected by the outbreak.

The company has also mobilized quickly to provide crucial donations from across its businesses, as well as other support, to help those impacted. To date, J&J has made available 1 million surgical masks, 50,000 bottles of BAND-AID® Brand Isopropyl Alcohol, and 1 Million Renminbi to the Chinese Red Cross Foundation. Johnson & Johnson Medical Devices Companies China is also providing an electrosurgical generator and other devices to the Red Cross Society of China Wuhan Branch to help supply new isolation hospitals that were constructed quickly to address the growing outbreak.

We believe that global health security is everyone's responsibility and requires coordinated effort from governments, civil society and healthcare companies. We are proud to contribute to global efforts to combat the novel coronavirus through both humanitarian donations and the development of a vaccine and treatment for COVID-19.

Thank you for your attention to this critically important issue. If you have any questions, please e-mail Meghan Stone at mdstone@its.jnj.com or call 202-589-1425.

Sincerely,

Jane M. Adams
Vice President, Federal Affairs



Statement from the American Society for Microbiology
in response to the
House Energy and Commerce Subcommittee on Health Hearing:
"The Fiscal Year 2021 HHS Budget and Oversight of the Coronavirus Outbreak"
February 26, 2020

On behalf of our 30,000 members in the United States and around the world, the American Society for Microbiology (ASM) thanks Chairwoman Anna Eshoo, Ranking Member Michael Burgess and members of the House Energy and Commerce Subcommittee on Health for holding this hearing on the current novel coronavirus outbreak stemming from Wuhan, China. ASM also thanks Congress for reauthorizing the Pandemic and All-Hazards Preparedness and Innovation Act last year, and for its support through fiscal year 2020 appropriations for public health preparedness and response programs that are crucial to address any public health emergency, especially an international outbreak.

We urge Congress to continue its commitment in fiscal year 2021 to a global health security agenda that recognizes and supports cutting edge research, laboratory capacity, pandemic preparedness and public health response capabilities. The current coronavirus public health emergency illustrates exactly why continued investments are needed across multiple government agencies, including the NIH, CDC, BARDA and the FDA; and it underscores the importance of maintaining open and transparent communication with our international partners. We also urge Congress to ensure that the agencies have the resources to address the ongoing threat through supplemental appropriations.

As the situation continues to unfold, we offer the following additional points to the Subcommittee:

- **We are amidst an event that remains fluid and is changing on a daily, sometimes hourly basis.** It is essential that officials communicate accurate information in a timely manner to protect the public, mitigate spread of the disease and coordinate an effective international response.
- **The development of accurate and rapid diagnostics should be a priority.** Diagnostics enable and inform all aspects of infectious disease outbreak management—from surveillance and detection to response, containment and recovery. Advances in diagnostic technologies, such as next generation sequencing made possible through CDC's Advanced Molecular Detection program, will continue to be essential in our fight against both emerging and persistent infectious disease threats.
- **Laboratories play a critical role in identifying outbreaks and guiding resources for response and should be strengthened**. We are fortunate in the U.S. to have a robust laboratory surveillance system that can screen incoming travelers and identify—and potentially treat—individuals at high risk of spreading infection. This laboratory capacity does not exist in all countries and we must do more now to ensure its progress in low-resource countries.
- **International scientific and public health collaboration is essential.** ASM urges policymakers to ensure that an appropriate balance exists between protecting national security and allowing for continued, safe and legitimate collaboration across borders. Such a balance is necessary to preserve the public health, the public interest and the advancement of science.



As an organization with extensive global public health programs and with scientists and public health workers on the front lines in China and at the source of disease outbreaks around the world, ASM understands first-hand the importance of securing our borders against biothreats. Our world is more interconnected than ever, and microbes know no borders. ASM and its members stand ready to assist the Subcommittee, its members and the Congress as the U.S. continues to respond to the novel coronavirus outbreak.

More information from ASM on nCov2019:

https://www.asm.org/Press-Releases/2020/nCoV2019-Resources

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The American Society for Microbiology is one of the largest single life science societies, composed of 30,000 scientists and health professionals. ASM's mission is to promote and advance the microbial sciences. ASM advances the microbial sciences through conferences, publications, certifications and educational opportunities. It enhances laboratory capacity around the globe through training and resources. It provides a network for scientists in academia, industry and clinical settings. Additionally, ASM promotes a deeper understanding of the microbial sciences to diverse audiences.

BioCentury®

Biopharma industry, academics push back against demands for price controls on COVID-19 countermeasures

By Steve Usdin | February 20, 2020 | View Online

The biopharma industry and academics who are developing vaccines and therapies to prevent and treat COVID-19 pushed back Thursday against calls from members of Congress for price controls on medical countermeasures.

In a letter to President Donald Trump, 46 House Democrats asked him to "ensure that any vaccine or treatment developed with U.S. taxpayer dollars be accessible, available, and affordable." They added that this goal "cannot be met if pharmaceutical corporations are given authority to set prices and determine distribution, putting profit-making interests ahead of public health priorities."

BIO accused elected politicians of exploiting the outbreak to score political points, and PhRMA said the letter could deter companies from developing COVID-19 vaccines and therapies.

Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine, suggested that the lack of economic incentives for industry investment is a bigger concern than pricing.

The Democrats, including Reps. Jan Schakowsky (D-Ill.) and Lloyd Doggett (D-Texas), called on HHS to avoid granting exclusive licenses to private manufacturers for COVID-19 vaccines or therapies. They also urged Trump to "allow HHS to intervene if a manufacturer prices a COVID-19 vaccine or treatment at an excessive level."

PhRMA rejected the call to avoid exclusive licenses. "Current law permits exclusive licenses to be granted only when NIH determines the license is necessary to develop, manufacture and bring a product to market," said Holly Campbell, deputy VP for public affairs at PhRMA. "Obstructing that process does a disservice to Americans and people around the world who could benefit from new treatments or vaccines."

PHARMA DETERRED BY LACK OF RETURN

While the goal of ensuring access and affordability are laudable, the letter is aiming at the wrong problem, Hotez told BioCentury. He co-directs the Texas Children's Center for Vaccine Development at Baylor, which is developing vaccines to protect against COVID-19, SARS and several neglected tropical diseases.

Hotez agreed with congressional Democrats that "any coronavirus vaccine should be made available at an affordable price."

He added that "the real problem is that industry is mostly holding back from developing vaccines for neglected and emerging diseases, leaving it to smaller biotechs and academic-based product development partnerships like our Texas Children's Center for Vaccine Development at Baylor College of Medicine to carry the burden."

Two pharmas, Johnson & Johnson (NYSE:JNJ) and Sanofi (Euronext:SAN; NASDAQ:SNY), have started COVID-19 development programs (see "Sanofi Enters Vaccine Race with BARDA Collaboration").

The response to COVID-19 is an exception. The largest biopharmas, Hotez said, have been reluctant to invest in vaccine development for neglected diseases and emerging pathogens.

"In some respects the letter reflects a broader misunderstanding about vaccines for these diseases," Hotez said. "Except for a few committed non-profit organizations like ours driven by humanitarian goals, or biotechs using this an opportunity to get their platform technologies into the clinic so they can later license profit making vaccines, there's actually not much interest" in developing vaccines for neglected diseases and outbreaks like MERS, SARS and Zika.

SEEKING "GUARDRAILS"

The congressional Democrats singled out an HHS Biomedical Advanced Research and Development Authority (BARDA) partnership with Regeneron Pharmaceuticals Inc. (NASDAQ:REGN).

The letter, which echoed a report issued Wednesday by Public Citizen, said that the federal government has funded Regeneron's coronavirus R&D and stated that "there must be guardrails in place to prevent Regeneron from monopolizing the medicine and maximizing profits."

BARDA has agreed to fund 80% of R&D and manufacturing costs for promising treatments developed by Regeneron, which is developing mAbs to neutralize the virus.

Christos Kyratsous, Regeneron's VP of research for infectious diseases and viral vector technologies, told BioCentury last week that the company had started COVID-19 mAb discovery activities with DNA segments of the virus, created pseudo-particles for testing purposes, and was immunizing mice that have been genetically engineered to generate immune responses.

Regeneron provided BioCentury a statement in response to the congressional letter. The company said its "focus first and foremost is on doing the right thing for patients. For infectious diseases, we are particularly motivated by the public good, as we apply our unique scientific expertise, talent and technologies."

Regeneron said its scientists were working "around the clock" on COVID-19 therapies, and that the company is "committed to ensuring any potential medicines reach patients in need around the globe."

BIO EVP for public affairs Rich Masters blasted the congressional letter, telling BioCentury that "hundreds of scientists at companies large and small are working around the clock to develop vaccines and antiviral therapies to address the coronavirus."

He said members of Congress who signed the letter were "demoralizing the men and women on the frontlines trying to get medical innovations to the people whose lives depend on them," and, citing industry collaborations with NGOs and government agencies, suggested that Congress "should be focused on how they can best support and encourage these efforts."

PhRMA also reacted strongly.

Campbell highlighted the "enormous upfront costs and risks associated with vaccine development" and said "the signers of this letter could prevent a vaccine, therapy or cure for coronavirus from ever reaching patients."

WSJ | OPINION

- OPINION
- REVIEW & OUTLOOK

Pharma to the Rescue

Advances in drug research mean a vaccine for the coronavirus could be in human trials by April.

By The Editorial Board
Jan. 30, 2020 7:30 pm ET



The Johnson & Johnson campus in Irvine, California.

The World Health Organization on Thursday declared China's novel coronavirus a global health emergency, though governments and businesses have already been mobilizing against the contagion. And look who's on the front lines—evil U.S. drugmakers.

The coronavirus originated late last year in Wuhan but is rapidly spreading and has infected more than 8,200 people—more than the deadly SARS virus in 2002-2003. More than 15 countries have confirmed cases, and many airlines have suspended flights to China to limit the contagion.

The good news is that the coronavirus so far appears less deadly than SARS. Immunology has also advanced by leaps and bounds, so treatments and vaccines should be available much sooner. Several U.S. drugmakers including Johnson & Johnson, Moderna Therapeutics and Inovio Pharmaceuticals are already working with the National Institutes of Health on vaccines.

It took scientists 20 months to develop a SARS vaccine to test on humans, but the NIH hopes to have a vaccine ready for human trials by April. While tens of thousands more may get sick in the meantime, U.S. drugmakers are donating antiviral medicines that may fight the virus.

AbbVie and J&J are shipping HIV treatments to China while Gilead is studying whether an experimental antiviral drug that has worked on other coronaviruses in animal trials could help. Merck is also reviewing research to see if any of its drug compounds can be repurposed.

All of this is worth pointing out as politicians on both sides of the aisle denounce drugmakers as parasites on society. While hard to estimate, the public health dividends from drugmakers' research and development often exceed their commercial profits.

https://www.wsj.com/articles/pharma-to-the-rescue-11580430606

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

June 27, 2019

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is examining the U.S. Department of Health and Human Services' (HHS) administration of the Medicaid program. Recent actions by the state legislatures in Utah and Tennessee suggest that one or both states may soon request waiver authority to cap their Medicaid programs, threatening access to care for millions of people in these states. I am deeply troubled by these developments, and with the reports that the Centers for Medicare & Medicaid Services (CMS) plans to release guidance to states on how they may cap spending on their Medicaid programs, either through a block grant, a per capita cap, or some other mechanism.[1] Equally troubling are reports that CMS Administrator Seema Verma "has urged [Alaska] to be the first state to receive Medicaid dollars as a block grant."[2] In view of these reports, and recent state action in Tennessee and Utah to request waivers to block grant their programs, I write to request additional information about HHS's actions related to block granting or otherwise capping the Medicaid program.

In 2017, Congress considered and rejected converting Medicaid to a block grant or per capita cap when such a change was a centerpiece of the failed Republican effort to repeal the Affordable Care Act. Capping Medicaid funding, whether through a block grant or a per capita cap, would be devastating to those who rely on the program. The President's budget estimates

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[1] Politico, *Trump wants to bypass Congress on Medicaid plan* (January 11, 2019).

[2] Letter from Michael Dunleavy, Governor of Alaska, to Donald Trump, President of the United States (March 1, 2019).

that such a change would cut $1.4 trillion from Medicaid over 10 years.[3] Cuts of that magnitude would threaten access to services for children with complex medical needs, people with disabilities, seniors, and others in the community who receive care from safety net providers that are largely financed by Medicaid. The American Hospital Association has said the deep cuts from such a proposal "would reduce federal Medicaid funding to unsustainable levels" and "will have serious negative consequences for communities across America."[4]

Congress recognized that changing the financing structure of Medicaid to implement a block grant or per capita cap requires a statutory change, and the President's 2020 budget acknowledges that legislation is needed to do so.[5] Moreover, federal law does not give the Secretary authority to change Medicaid's structure to a block grant or per capita cap through administrative action. In order to implement a block grant or per capita cap, the Secretary would need to effectively waive Section 1903 of the Social Security Act (the Act), which states that "the Secretary… shall pay to each State which has a plan approved under this title, for each quarter… an amount equal to the Federal medical assistance percentage… of the total amount expended during such quarter as medical assistance under the State plan."[6] Section 1115 authorizes the Secretary to waive certain enumerated sections of the law if doing so "is likely to assist in the promotion of the objectives of [Medicaid]"[7], which, according to the statute, is "to furnish medical assistance" to eligible individuals.[8] Therefore, for the Secretary to waive part of the Medicaid program, it must satisfy a two-prong test: first, it must be one of the enumerated sections listed in Section 1115, and second, it must promote the objectives of the Medicaid program.

Capping the Medicaid program fails both requirements. Section 1903 is not one of the enumerated sections listed in the statute the Secretary can waive. Congress never intended for the Secretary to have the ability to waive the federal funding provisions (financing requirements); if it had, the statute would clearly state it, as it does with other sections of the law. To argue otherwise defies the plain language and clear statutory framework of Section 1115. Furthermore, it defies logic to argue that limiting medical assistance promotes the objective of "furnishing medical assistance." Capping the Medicaid program would result in reduced or loss of benefits for individuals, loss of coverage, and imperil the financing of critical health care

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[3] Department of Health and Human Services, *FY2020 Budget in Brief.* (www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf).

[4] Senate Committee on Finance, Statement of the American Hospital Association, *Hearing to Consider the Graham-Cassidy-Heller-Johnson Proposal,* 115th Cong. (September 25, 2017).

[5] *See* note 3.

[6] Social Security Act, Pub. L. No. 74-271: § 1903(a).

[7] Social Security Act, Pub. L. No. 74-271: § 1115.

[8] Social Security Act, Pub. L. No. 74-271: § 1901.

providers. In other words, it would reduce the amount of medical assistance, not assist in furnishing it.

Recent reports suggest that you plan to take administrative action to make changes in Medicaid financing despite the fact that there is no statutory authority to implement a block grant or per capita cap through a section 1115 demonstration project, or "waiver."[9,10] Your recent approval of Utah's waiver already appears to exceed your authority in the statute.[11] It allows the state to cap enrollment based on available state appropriations and gives states the authority to deny coverage to people whenever it experiences budget pressures or simply decides it has spent enough on coverage for eligible adults without any accountability or oversight by CMS, in violation of the statute. An HHS spokesperson said that CMS believes "that only when states are held accountable to a defined budget can the federal government finally end our practice of micromanaging every administrative process."[12] This suggests that you are considering allowing states to cap state spending on Medicaid by limiting enrollment or otherwise changing eligibility or benefits to stay within their self-imposed spending caps. Like Utah's enrollment cap, this would undermine the fundamental structure of Medicaid, which provides a guarantee of coverage to all people who qualify.

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I appreciate your attention to this matter. If you have any questions, please contact Rick Van Buren with the Committee staff at 202-225-5056.

Sincerely,

Frank Pallone, Jr.
Chairman

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