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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. KEITH LAWRENCE MIDDLEBROOK, Defendant.	No. 2:20-cr-00229-DSF GOVERNMENT'S MOTION *IN LIMINE* TO EXCLUDE DR. RAM DURISETI'S TESTIMONY AND, IN THE ALTERNATIVE, TO HOLD A *DAUBERT* HEARING; EXHIBIT A

Plaintiff United States of America, by and through its counsel of record, the United States Attorney for the Central District of California and Assistant United States Attorneys Kenneth R. Carbajal and Joseph S. Guzman, hereby files its Motion In Limine to Exclude Dr. Ram Duriseti's Testimony and, in the Alternative, to Hold a Daubert Hearing (the "Motion").

This Motion is based on the attached memorandum of points and authorities, supporting exhibit, the files and records in this case, and any further evidence or argument the Court may allow.

Dated: March 13, 2024

Respectfully submitted,

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/s/
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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

On February 28, 2024, defendant provided the government with an expert disclosure for Dr. Ram Duriseti. According to the disclosure, Dr. Duriseti is a clinical associate professor. (Rule 16 Expert Notice for Dr. Ram Duriseti ("Dr. Duriseti Notice."), Ex. A.) In summary, defendant proposes calling Dr. Duriseti to testify that there were hundreds of potential COVID-19 treatments and prevention measures in March 2020. (Id.) The government files this motion to exclude Dr. Duriseti's testimony because it would be irrelevant.

Expert opinion testimony may be objectionable where it is irrelevant. See Fed. R. Evid. 403; United States v. Spangler, 810 F.3d 702, 707 n.3 (9th Cir. 2016)(relevance is "folded into the Daubert standard under Federal Rule of Evidence 702"). The only COVID-19 treatment related issues in this case are whether the defendant created: (1) the cure to COVID-19 and (2) a COVID-19 prevention pill. Dr. Duriseti's proposed testimony would not aid the jury in resolving any factual dispute related to these two issues.

Should the Court be inclined to allow Dr. Duriseti to testify regarding potential COVID-19 treatments and prevention measures, the government respectfully requests a pre-trial Daubert hearing to determine the admissibility of the proposed testimony.

II. STATEMENT OF FACTS

The Indictment charges defendant with multiple counts of wire fraud, in violation of 18 U.S.C. § 1343. (Docket ("Dkt.") 40.) Three days after President Trump declared a national emergency due to the COVID-19 global pandemic, defendant — who has only a high school

diploma —stated on social media that he had developed the cure and a prevention pill for the virus. Defendant began to solicit investments into his companies, Quantum Prevention CV Inc., Quantum Cure CV 2020 Inc., and Quantum Immunity CV 2020 LLC, to further develop and market the cure and treatment he claimed to have developed. Defendant fraudulently made material misrepresentation to investors through phone calls, text messages, and emails, to induce those investors to wire-transfer money into bank accounts he controlled.

III. APPLICABLE LAW

Federal Rule of Evidence 402 provides, in part, that "evidence which is not relevant is not admissible." Fed. R. Evid. 402. Federal Rule of Evidence 702(a) provides that a witness may be qualified as an expert and provide an opinion if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. Id.; see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) (holding that expert testimony must be "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute") (internal quotation marks and citation omitted).

Expert testimony "is admissible under Rule 702 if the subject matter at issue is beyond the common knowledge of the average layman, the witness has sufficient expertise, and the state of the pertinent art or scientific knowledge permits the assertion of a reasonable

opinion." United States v. Winters, 729 F.2d 602, 605 (9th Cir. 1984). It is the proponent's burden to establish relevance and reliability by a preponderance of the evidence. See Lust v. Merrell Dow Pharmaceuticals, Inc., 89 F.3d 594, 598 (9th Cir. 1996).

The district court is the "gatekeeper" of expert witness testimony and the court is charged with assuring that the expert testimony "rests on a reliable foundation and is relevant to the task at hand." United States v. Harmanek, 289 F.3d 1076, 1093 (9th Cir. 2002) (citing Daubert, 509 U.S. at 592-93). This gatekeeping role "entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is . . . valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. The gatekeeping function applies not only to scientific testimony, but to expert testimony of any kind. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999).

The trial court's gatekeeping function is vital to ensure accurate and unbiased decision-making by the trier of fact. Kumho Tire, 526 U.S. at 147. Because expert testimony carries the "aura of special reliability and trustworthiness," it raises a substantial danger of undue prejudice and courts must pay particular attention in assessing its admissibility. See United States v. Amaral, 488 F.2d 1148, 1152 (9th Cir. 1973). District courts have wide latitude to exclude expert testimony and exercise their important gatekeeping role. See, e.g., United States v. Singaglio, 942 F.2d 581, 584 (9th Cir. 1991).

Daubert articulated a two-step guide for district courts to follow in executing their gatekeeping function: first, the trial

court must make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts in issue; second, the court must "ensure that the proposed expert testimony is relevant and will serve to aid the trier of fact." Daubert, 509 U.S. at 592-93.

IV. THE COURT SHOULD EXCLUDE DR. DURISETI'S TESTIMONY

A. Dr. Duriseti's Testimony Regarding Potential COVID-19 Treatments and Prevention Measures is Irrelevant

Dr. Duriseti's anticipated testimony regarding potential COVID-19 treatments and prevention measures is irrelevant and the Court should exclude it. Dr. Duriseti's notice states that Dr. Duriseti will testify that as of March 2020, there were hundreds of potential COVID-19 treatments and preventative measures. (Dr. Duriseti Notice at 4.) Such testimony is plainly inappropriate.

Dr. Duriseti's proposed testimony is full of irrelevant details that will confuse the jury. The testimony would state that early on in the pandemic there were various potential COVID-19 treatments, such as intubation, anticoagulants, convalescent plasma, remdesivir, hydroxychloroquine, ivermectin, and dexamethasone. (Id. at 4-6.) Dr. Duriseti further testify that there are still many potential COVID-19 treatments that have not been disproven or proven as effective, such as Vitamin C, Vitamin D, and Zinc, among other treatments. (Id. at 6.) Regardless of the validity of this claim, this line of testimony would not aid the jury in determining whether the defendant created: (1) the cure to COVID-19 in March 2020, and/or (2) a COVID-19 prevention pill. Indeed, Dr. Duriseti's testimony that Remdesivir or

Vitamin C and Vitamin D had existed for years and could potentially treat COVID-19 does nothing to prove or disprove whether the defendant had created a cure. (Id. at 8.) The testimony regarding Vitamin C and Vitamin D would merely state that these vitamins *could* be potential treatments for COVID-19, not that there is any concrete evidence showing that they are treatments. Dr. Duriseti's statement that "[a] person who takes such a supplement today, or took such a supplement at the start of the COVID-19 pandemic is not using a government-approved treatment for COVID-19. However, research may validate long-existing opinions that such supplements can treat or prevent COVID-19" demonstrates the speculative nature of Dr. Duriseti's potential testimony and proves that this testimony would provide little, if any, reliable evidentiary value to the jury. (Id.) Moreover, Dr. Duriseti has not analyzed whatever defendant purported was the cure, which is testimony that could conceivably be relevant.

B. Should the Court be Inclined to Allow Dr. Duriseti's Testimony, the Government Respectfully Requests an Evidentiary Hearing

For the reasons discussed above, Dr. Duriseti should be precluded from testifying about potential COVID-19 treatments and prevention measures. In the event the Court is inclined to permit any such testimony at trial, the government respectfully requests an evidentiary hearing. A Daubert hearing is necessary to assess the methodology, applicability, reliability, relevance, and impact of Dr. Duriseti's proposed testimony regarding potential COVID-19 treatments and prevention measures. United States v. Lukashov, 694 F.3d 1107, 1112 (9th Cir. 2012).

V. CONCLUSION

For the foregoing reasons, the Court should preclude Dr. Duriseti from testifying regarding potential COVID-19 treatments and prevention measures. In the alternative, the Court should hold a pre-trial Daubert hearing to assess the methodology, applicability, reliability, relevance, and impact of Dr. Duriseti's proposed testimony on that topic.

EXHIBIT A

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February 28, 2024

By Email Only

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Re: **Rule 16 Expert Notice for Dr. Ram Duriseti**

Counsel:

Pursuant to Federal Rule of Criminal Procedure 16(b)(1)(C), we are writing to disclose our intent to elicit expert testimony from Dr. Ram Duriseti, M.D., Ph.d. at the trial in this matter. Dr. Duriseti is a clinical associate professor in emergency medicine at Stanford University. His resume, publications list, and a list of the cases in which he has testified in the past four years are attached as exhibits A to this letter.

In addition to the qualifications listed in his resume, Dr. Duriseti has extensive professional experience regarding COVID-19. He has treated hundreds of COVID-19 patients. He has read and analyzed hundreds of journal articles on COVID-19 and related topics, and co-authored academic analyses of COVID mitigation policies and their impacts. He has published or has pending studies on COVID-19-related issues. He has also authored and co-authored opinion pieces on COVID-19 policy matters, co-authored documents to guide Congressional hearings on COVID-19 policy and response, testified before the California State Legislature Health Committee, and conferred with various California State Senators about COVID-19 policies.

The defense anticipates eliciting the following opinions from Dr. Duriseti at trial. In reaching these opinions, Dr. Duriseti relied on the indictment, discovery related to COVID-19

(Bates USAO 348-358), his experience and training as a medical doctor who has treated hundreds of COVID-19 patients, and his own research and publications regarding COVID-19.

1. From December 2019 to mid-2020, COVID-19 rapidly spread around the world, while knowledge and opinions regarding the disease developed and changed at a similarly rapid pace.

Coronavirus disease 2019, or COVID-19, is a disease caused by the SARS-CoV-2 virus. As shown in the below timeline, from the first reports of an atypical pneumonia-like illness in late 2019 to mid-2020, COVID-19 spread rapidly around the world. Similarly, knowledge, as well as rational opinions, regarding COVID-19 changed quickly and frequently.

December 12, 2019: Patients in Wuhan, China, experience symptoms of an atypical pneumonia-like illness that does not respond to standard treatment.

January 10, 2020: The Center for Disease Control ("CDC") and World Health Organization ("WHO") began publicly identifying the illness as a novel coronavirus, referring to it as "2019 Novel Coronavirus" or "2019-nCoV."

January 11, 2020: China reports its first death due to the 2019 Novel Coronavirus.

January 20, 2020: The CDC reports the first laboratory-confirmed case of the 2019 Novel Coronavirus in the U.S.

January 27, 2020: The U.S. Food and Drug Administration ("FDA") announces that it will take "critical actions to advance development of novel coronavirus medical countermeasures" with interagency partners, including the CDC.

January 31, 2020: The Secretary of the Department of Health and Human Services, Alex Azar, declares the COVID-19 outbreak a public health emergency.

February 4, 2020: FDA approves the emergency use authorization for the CDC-developed SARS-CoV-2 diagnostic test kit.

February 8, 2020: Some of the first CDC test kits for detecting the SARS-CoV-2 virus arrive at a public health laboratory in east Manhattan, New York City, N.Y. The laboratory reports that the tests produce "untrustworthy results."

February 11, 2020: WHO announces the official name for the disease that is causing the 2019 Novel Coronavirus outbreak: "COVID-19."

February 26, 2020: Then-President Donald Trump states at a press conference, "This is a flu. This is like a flu."

March 2, 2020: Then-President Donald President Trump states, "On average, you lose from 26,000-70,000 or so and even some cases more from the flu. … So far, we have six [COVID-19 deaths] here."

March 9, 2020: Then-President Donald Trump posts on Twitter (now. "X"), "So last year 37,000 Americans died from the common Flu. It averages between 27,000 and 70,000 per year. Nothing is shut down, life & the economy go on. At this moment there are 546 confirmed cases of CoronaVirus, with 22 deaths. Think about that!"

March 11, 2020: Media coverage and public attention intensifies after the National Basketball Association suspends play, and actor Tom Hanks announces that he tested positive for COVID-19.

March 13, 2020: The Trump administration declares a nationwide emergency due to COVID-19.

March 17, 2020: The University of Minnesota launches a clinical trial testing hydroxychloroquine, an already existing, FDA-approved Malaria treatment, for the treatment of COVID-19.

March 24, 2020: Then-President Donald Trump states, "You're going to lose a number of people to the flu. But you're going to lose more people by putting a country into a massive recession or depression." [1]

Through much of this time period—and especially from March 11, 2020 onward—media coverage of COVID-19 was constant, ubiquitous, and conflicting. News sources, especially those commonly thought of as particularly politicized, criticized each other's COVID-19 coverage, as well as the government's approach to the disease.[2]

[1] https://www.cdc.gov/museum/timeline/covid19.html https://www.forbes.com/sites/tommybeer/2020/09/10/all-the-times-trump-compared-covid-19-to-the-flu-even-after-he-knew-covid-19-was-far-more-deadly/?sh=6ad8449df9d2

[2] *See, e.g.*, https://www.vox.com/2020/3/24/21192222/fox-news-coronavirus-coverage-dan-patrick-drugs; https://www.washingtonpost.com/politics/2020/03/12/trump-coronavirus-timeline/

2. As of March 2020, there were hundreds of potential COVID-19 treatments and preventative measures.

In the first few months of COVID-19, hundreds of existing supplements, drugs, and therapies were identified as potential treatments or preventative measures for COVID-19.[3] Indeed, by April 2020, the National Institutes of Health launched the Accelerating COVID-19 Therapeutic Interventions and Vaccines ("ACTIV") partnership between U.S. and European health agencies and pharmaceutical companies in order to evaluate more than 100 potential preventatives and therapeutics.[4] These potential treatments included various classes of drugs, such as immune modulators, monoclonal and polyclonal antibodies, and blood thinners. Later, antidepressants and antiparasitic drugs, among others, were included for study as potential therapies.

3. In the early stages of the COVID-19 pandemic, various potential COVID-19 treatments cycled in an out of use with and without government approval.

With a new disease, like COVID-19 in late 2019 and early 2020, there is no scientific consensus about appropriate treatment. With little evidence about existing supplements, drugs, and therapies for COVID-19, doctors, government agencies, health organizations, and the general public had to make health decisions in the absence of complete knowledge. With COVID-19, this lack of information caused disputes among and between doctors, government agencies, and the general public as to best practices for treating and preventing the disease. Given the lack of information at the outset of COVID-19 and rapidly evolving information thereafter, any purported "consensus"—whether among government bureaucrats, doctors, or the general population—about actual or potential COVID-19 treatments or cures were subject to change at any given moment and, especially at the beginning of the pandemic, changed rapidly. Likewise, knowledge of efficacy of treatments for COVID-19 is constantly evolving. The following examples illustrate the point.

Intubation. By February 2020, physicians often recommended early intubation to reduce virus aerosolization and transmission to health care workers. However, by March 2020, physicians actively treating COVID-19 agreed that the rush to mechanical ventilation needed to be rethought. Nonetheless, in March 2020, the federal government invoked the Defense Productions Act to force General Motors to produce more ventilators. By June 2020, many were urging providers not to routinely intubate COVID-19 patients, citing emerging data that non-invasive methods were no more aerosolizing than mechanical ventilation. When the "consensus" was still settled on

[3] https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials

[4] https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options

intubation, Dr. Duriseti advocated for non-invasive ventilatory support whenever clinically safe and feasible, which later proved to be the preferable approach.[5]

Anticoagulants. Early in the pandemic, anticoagulants were used in COVID-19 patients after observations that some patients developed blood clots in their lungs or deep peripheral veins. By late 2020, however, research suggested that anti-coagulants did not protect against thromboembolic complications of severe COVID-19.

Convalescent Plasma. Convalescent plasma contains polyclonal antibodies obtained from individuals who have recovered from a COVID-19 infection. The FDA issued an emergency use authorization in August 2020, which is ongoing with several subsequent modifications. However, studies from late 2020 show that convalescent plasma does not treat COVID-19. Nonetheless, the FDA permits its use to this day.[6]

Remdesivir. Remdesivir is a patented anti-viral medication made by pharmaceutical company Gilead, which was first developed years before the COVID-19 pandemic.[7] On May 1, 2020, FDA approved its use for treating COVID-19 under an emergency use authorization. The FDA granted regular approval on October 22, 2020. Some Remdesivir trials supported its use as a COVID-19 treatment. However, the largest trial of Remdisivir from the WHO showed no beneficial effect.[8]

Hydroxychloroquine. Hydroxychloroquine is an anti-malarial drug that can treat arthritis and lupus. It is on the WHO's list of essential medicines. In March 2020, the FDA granted emergency use authorization of hydroxychloroquine to treat hospitalized COVID-19 patients. But that approval was revoked in June 2020. In addition, in June 2020, an NIH RCT (randomized controlled trial) of hydroxychloroquine was halted early after concluding that hydroxychloroquine was safe but ineffective for hospitalized COVID-19 patients. In October 2020, a larger WHO Solidarity Trial also showed that hydroxychloroquine does not benefit hospitalized COVID-19 patients if given during hospitalization. In February 2021, a Cochrane Review of these and other RCTs concluded that hydroxychloroquine had little or no effect for hospitalized COVID-19 patients.

Ivermectin. Approved by the FDA in 1996, ivermectin is an anti-parasitic drug on the WHO's list of essential medicines. In 2020, it was proposed as a potential drug for COVID. A systematic review published in June 2020 showed ivermectin to be effective against several viruses during in vitro experiments using cultured cells, including SARS-CoV2. A few smaller

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[5] https://www.wsj.com/articles/hospitals-retreat-from-early-covid-treatment-and-return-to-basics-11608491436

[6] https://www.covid19treatmentguidelines.nih.gov/therapies/antivirals-including-antibody-products/covid-19-convalescent-plasma/

[7] https://www.wsha.org/wp-content/uploads/RDV-development-fact-sheet-Final.pdf

[8] https://www.nejm.org/doi/full/10.1056/nejmoa2023184

human trials published in 2021-2022 showed faster SARS-CoV2 viral clearance in patients taking ivermectin compared to a placebo, but clinical endpoints were unaffected or not measured.[9] It was not until December 2022 that an NIH funded randomized controlled trial looking at a longer and higher dosing regimen of Ivermectin to treat COVID-19 was completed and released as a pre-print publication. No statistically significant benefit was detected, but trial enrollment was primarily after mass-infection with the Omicron variant in the winter of 2021 to 2022.[10]

Dexamethasone. Dexamethasone is a generic drug on the WHO's list of essential medicines. In 2020, UK researchers conducted the large randomized RECOVERY Trial, showing that dexamethasone improved survival of hospitalized patients. It is widely used in the U.S. to treat very severe COVID illness. A U.S. randomized trial, however, did not find a difference in hospitalized patients receiving dexamethasone plus remdesivir versus baricitinib plus remdesivir. An observational study of hospital patients not receiving supplemental oxygen found increased mortality after receiving dexamethasone, which could be an accurate finding or an artifact due to more serious COVID-19 patients being more likely to receive dexamethasone.

4. There are still many potential COVID-19 treatments that have not been disproven or proven as effective.

There remain many potential COVID-19 treatments that have not been disproven or proven to be effective. As of 2023, for example, the NIH acknowledged that, for many therapies, drugs, or dietary supplements that existed prior to COVID-19, the current evidence does not establish or refute any claim that such therapies may be effective for some COVID-19 patients. Such potential COVID-19 treatments include: (1) Vitamin C, (2) Vitamin D, (3) Zinc,[11] (4) high-titer COVID-19 convalescent plasma,[12] (5) interferon lambda,[13] (6) Anakinram (7), inhaled corticosteroids,

[9] https://www.norfolkgroup.org/downloads

[10] https://www.fda.gov/media/136534/download; https://www.medrxiv.org/content/10.1101/2022.12.15.22283488v1

[11] https://www.covid19treatmentguidelines.nih.gov/therapies/supplements/summary-recommendations/

[12] https://www.covid19treatmentguidelines.nih.gov/therapies/antivirals-including-antibody-products/covid-19-convalescent-plasma/

[13] https://www.covid19treatmentguidelines.nih.gov/therapies/antivirals-including-antibody-products/interferons/

(9) Vilobelimab,[14] (10) Apixaban, (11) thrombolytic agents, (12) antiplatelet therapy,[15] (13) inhaled budesonide in combination with fluvoxamine, and (14) Metformin.[16]

There have long been rational and legitimate grounds to support the opinion that such treatments can be effective against COVID-19. Taking Vitamin D as an example, the NIH provides the following rational for its potential use as a COVID-19 treatment:

> Vitamin D is critical for bone and mineral metabolism. Because the vitamin D receptor is present on immune cells such as B cells, T cells, and antigen-presenting cells, and because these cells can synthesize the active vitamin D metabolite, vitamin D also has the potential to modulate innate and adaptive immune responses. It is postulated that these immunomodulatory effects of vitamin D could potentially protect against SARS-CoV-2 infection or decrease the severity of COVID-19.
>
> Vitamin D deficiency (defined as a serum concentration of 25-hydroxyvitamin D ≤20 ng/mL) is common in the United States, particularly among people who identified as Hispanic or non-Hispanic Black. These groups are overrepresented among cases of COVID-19 in the United States. Vitamin D deficiency is also more common in older patients and patients with obesity and hypertension; these factors have been associated with worse outcomes in patients with COVID-19.[17]

Beyond these points, it is also notable that there is a long-standing debate in the literature, both inside and outside of COVID-19, as to whether low Vitamin D levels in severely ill patients is causal for a disease or simply a marker of poor health status and therefore only correlated without a causal link.

Moreover, similarly valid rationales support opinions that other supplements, drugs, and therapies can treat or prevent COVID-19.

5. The COVID-19-related documents provided by the government do not prove that any particular drug or other therapy was or was not a cure or treatment for COVID-19 in March of 2020.

The government produced three COVID-19 related documents authored by government agencies or health organizations: (1) a "Q&A on coronaviruses" by the World Health Organization

[14] https://www.covid19treatmentguidelines.nih.gov/therapies/immunomodulators/summary-recommendations/

[15] https://www.covid19treatmentguidelines.nih.gov/therapies/antithrombotic-therapy/

[16] https://www.covid19treatmentguidelines.nih.gov/therapies/miscellaneous-drugs/summary-recommendations/

[17] https://www.covid19treatmentguidelines.nih.gov/therapies/supplements/vitamin-d/

dated March 9, 2020 (the "WHO Document");[18] (2) a report titled "NIH clinical trial of remdesivir to treat COVID-19 begins" and dated February 25, 2020 by the National Institutes of Health (the "NIH Document");[19] and (3) an undated report titled "What you need to know about coronavirus disease 2019 (COVID-19)" by the Center for Disease Control (the "CDC Document").[20]

None of these documents establish that any particular drug or other therapy was or was not a cure, treatment, or preventative measure for COVID-19 in March of 2020. The NIH Document regarding the initiation of Remdesivir clinical trials demonstrates this point. As explained above, Remdesivir was developed years before the COVID-19 pandemic and was quickly identified as a potential COVID-19 treatment. The NIH Document correctly notes (as stated by Dr. Anthony Fauci) that, before the first COVID-19-Remdesivir clinical trials began in February 2020, Remdesivir had already been administered to COVID-19 patients due to rational and legitimate opinions regarding its potential as a COVID-19 treatment. Three months after the Remdesivir trials began, on May 1, 2020, the FDA gave emergency use authorization for Remdesivir as a COVID-19 treatment. And it later granted regular approval in October of 2020, which is still in effect even though Remidisivir is no longer recommended for the treatment of severe COVID-19 in many hospital systems. The fact that the FDA did not approve Remdesivir until May 2020 did not render prior use of Remdesivir invalid or otherwise negate Remdesivir's potential utility as a treatment prior to the FDA's approval. Rather, clinical trials and the FDA's approval process lagged behind rational and legitimate opinions that Remdesivir was a potential COVID-19 treatment. Moreover, those legitimate, pre-FDA approval opinions later found some support in clinical trials, as later recognized by the FDA.

The WHO and CDC documents do not change this analysis. They both claim that, at the time they were published, there was no treatment for COVID-19. This is incorrect. As discussed above, for example, Remdesivir had existed for years and had already been administered to COVID-19 treatments because there were legitimate and rational reasons to believe it could treat COVID-19. The same is true for other COVID-19 treatments or potential treatments that existed prior to COVID-19, such as Vitamins C and D. A person who takes such a supplement today, or took such a supplement at the start of the COVID-19 pandemic is not using a government-approved treatment for COVID-19. However, research may validate long-existing opinions that such supplements can treat or prevent COVID-19. It is worth noting that the use of Decadron for severe COVID-19 was initially discouraged despite decades of positive experience with steroids in severe respiratory infections to help decrease airway inflammation. This flew in the face of Dr. Duriseti's decades of clinical experience and that of many other physicians. Within months, physicians established that Decadron was one of the biggest reducers of mortality in severe COVID-19 patients.

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[18] USAO_00000354

[19] USAO_00000349

[20] USAO_00000348

At most, the WHO, CDC, and NIH documents stand for the proposition that, at the time they were published, there was no government-approved COVID-19 treatment. Nonetheless, doctors and individuals at the time the documents were published and earlier took rational steps to recommend and access potential COVID-19 treatments and preventative measures, including, *inter alia*, Vitamins C and D, hydroxychloroquine, and Remdesivir. For some such potential treatments, such as Remdesivir, the government (through the NIH) later found that clinical trials validated already existing opinions that they would be effective. For other potential treatments, such as hydroxychloroquine, the government has changed its position over time (at first granting emergency use authorization for hydroxychloroquine in March 2020 and then revoking it in June 2020).[21] For other potential treatments, such as Vitamins C and D, the government admits that there remains insufficient information to establish or refute their effectiveness. In a similar vein, it is worth noting that even while Paxlovid remains an FDA approved treatment for COVID-19, it has only demonstrated statistically significant efficacy in unvaccinated patients prior to the Omicron variant. Multiple trials since Paxlovid's approval, including EPIC-SR by Pfizer, are either confounded or have not demonstrated statistically significant benefit in many patient cohorts with rebound infection in 20%.[22, 23]

* * *

Please contact us if you have any questions or concerns about this notice.

Sincerely,

/s/J. Alejandro Barrientos
J. Alejandro Barrientos
Ijeoma U. Eke
Attorneys for Keith Middlebrook

Under Federal Rule of Criminal Procedure 16, approved and signed by:

Dr. Ram Duriseti

[21] Even at the time of revocation, there was no strong evidence to suggest that there was a clear trend to harm for the doses that were recommended.

[22] https://www.nejm.org/doi/full/10.1056/NEJMoa2204919?query=featured_home

[23] https://www.acpjournals.org/doi/10.7326/M23-1756