



# A "KNIFE FIGHT" WITH THE FDA: THE TRUMP WHITE HOUSE'S RELENTLESS ATTACKS ON FDA'S CORONAVIRUS RESPONSE

**STAFF REPORT** AUGUST 2022

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#### EXECUTIVE SUMMARY

The Select Subcommittee on the Coronavirus Crisis has been investigating the federal government's response to the coronavirus pandemic to ensure the American people receive a full accounting of what went wrong and to determine what corrective steps are necessary to ensure our nation is better prepared for any future public health crisis. The Select Subcommittee previously released the first installment of findings from its investigation into senior Trump Administration officials' rampant political interference in the pandemic response, which documented the Trump White House's embrace of a dangerous and discredited herd immunity via mass infection strategy well before vaccines were available.<sup>1</sup>

This report is the second installment of the Select Subcommittee's findings from its investigation. It documents three separate instances where Trump White House officials executed coordinated pressure campaigns that sought to bend the Food and Drug Administration's (FDA) coronavirus decision making to the White House's political will. Extensive evidence uncovered by the Select Subcommittee reveals how the Trump White House exerted extreme and inappropriate pressure on FDA to reauthorize hydroxychloroquine after it was shown to be ineffective and potentially dangerous; strongarmed FDA to deliver misleadingly positive news about convalescent plasma as a coronavirus treatment on the eve of the 2020 Republican National Convention (RNC); and blocked FDA from issuing guidance on coronavirus vaccine authorizations for weeks in an attempt to ensure that the first vaccine could be authorized before the 2020 presidential election.

Findings released by the Select Subcommittee in this report include the following:

# Senior Trump White House Adviser Peter Navarro Exerted Inappropriate Pressure on FDA to Reauthorize Hydroxychloroquine as a Coronavirus Treatment After It Was Shown to Be Ineffective and Potentially Dangerous

- Former FDA Commissioner Dr. Stephen Hahn acknowledged during a transcribed interview that White House Office of Trade and Manufacturing Policy Director Peter Navarro exerted inappropriate pressure on him to reissue an emergency use authorization (EUA) for hydroxychloroquine (HCQ) after FDA revoked a previous EUA for the drug on June 15, 2020, due to its inefficacy as a coronavirus treatment and potential safety issues.
- Newly released documents reveal that Mr. Navarro and Dr. Steven Hatfill—an adjunct assistant professor at George Washington University whom Mr. Navarro brought into the White House in January 2020 to work as a full-time volunteer on the coronavirus response—engaged in "constant fighting" with Dr. Hahn and other federal officials about hydroxychloroquine, according to Dr. Hatfill. In an email to an outside ally, Dr. Hatfill described an upcoming "knife fight scheduled with the FDA" over hydroxychloroquine, and said he and Mr. Navarro had direct access to Vice President Pence and President Trump, writing: "We see the VP on Friday" and have "a backchannel to DJT."

#### <u>Trump White House Officials Covertly Worked with Outside Groups to Attempt to</u> Reauthorize Hydroxychloroquine and to Fund Clinical Trials to Justify Its Use

- Mr. Navarro and Dr. Hatfill coordinated with representatives at the Henry Ford Health System (HFHS) in an effort to reauthorize hydroxychloroquine while obscuring the White House's involvement. Newly released emails show that Dr. Hatfill drafted "a new EUA request" at Mr. Navarro's direction, "selected" HFHS to be the submitting institution, and then "transferred the EUA reinstatement letter over to ... the Ford System," which allowed the EUA request to be submitted by HFHS instead of someone affiliated with the White House. HFHS submitted the renewed EUA petition to FDA on July 6, 2020, but FDA denied the petition the following month.
- Dr. Hatfill also courted researchers to pursue a study to show the purported benefits of hydroxychloroquine by dangling millions of taxpayer dollars in promised funding—doing so after the drug was shown to be ineffective and potentially dangerous for certain patients. Dr. Hatfill closely coordinated with Mr. Navarro on these efforts, telling Mr. Navarro that he was "ready to step in" to personally oversee one of the studies he pursued but wanted an outsider to run it "so there is no Conflict of Interest accusation from [National Institutes of Allergy and Infectious Diseases (NIAID) Director Dr. Anthony] Fauci."

## Mr. Navarro and Dr. Hatfill Forged Close Alliances and Coordinated Secretively with Outside Allies—Including Known Conspiracy Theorists—to Amplify External Pressure on FDA to Reauthorize Hydroxychloroquine

- Working from inside the White House, Mr. Navarro and Dr. Hatfill sought to generate outside support for hydroxychloroquine by engaging known extremists and prolific conspiracists like former White House Chief Strategist Steve Bannon, Dr. Jerome Corsi, and the Association of American Physicians and Surgeons (AAPS). Under Mr. Navarro's supervision, Dr. Hatfill coordinated with AAPS Executive Director Dr. Jane Orient and Mr. Bannon to gather support for a petition he drafted to "keep pressure on the FDA and the new EUA request" that he was spearheading with HFHS. According to Dr. Hatfill's internal notes, his "hydroxy petition" received at least "8000 signatures."
- Dr. Hatfill also engaged Senator Ron Johnson to push White House Chief of Staff Mark Meadows to pressure FDA into renewing the hydroxychloroquine EUA. Following a meeting between Senator Johnson and Mr. Meadows in late August 2020, Senator Johnson reported to Mr. Navarro and Dr. Hatfill that "Meadows said he would ask Sec Azar to issue whatever approval HHS can issue," but that "[o]ther than the President, Meadows, and Navarro, EVERYONE ELSE is [sic] Administration doesn't want to touch HCQ with a 100' pole."

• Dr. Hatfill and Mr. Navarro also coordinated on hydroxychloroquine with Dr. Paolo Zanotto, a virologist who the Brazilian Senate has since recommended be charged criminally for promoting false coronavirus cures. New documents obtained by the Select Subcommittee show that Dr. Hatfill was connected to Dr. Zanotto by Jack Maxey—a former co-host of Mr. Bannon's *War Room* podcast—in late July 2020, and that Mr. Navarro's office shipped a "donation of HCQ to Brazil."

## Mr. Navarro and Dr. Hatfill Took Steps to Conceal the White House's Involvement in Mobilizing External Support for Hydroxychloroquine—Including Conducting Official Business with Private Email Accounts

- Dr. Hatfill took steps to obscure his White House affiliation and instead "work from the shadows," as he described it, when building outside pressure on FDA to reauthorize hydroxychloroquine—using third party intermediaries, instructing his allies not to reveal where he worked, and regularly using only his personal email address to communicate about his efforts. For example, Dr. Hatfill instructed Dr. William O'Neill at HFHS not to disclose Dr. Hatfill's White House affiliation when discussing their work, admonishing him: "NEVER mention the White House together with my name[.]"
- Today's report includes more than 35 previously unreleased emails showing Mr. Navarro and/or Dr. Hatfill discussing the federal pandemic response using their personal accounts, including encrypted ProtonMail accounts, seemingly without copying an official government account or otherwise properly preserving these records.
- On August 3, 2020, the Department of Justice (DOJ) filed a lawsuit against Mr. Navarro for alleged violations of the Presidential Records Act (PRA), citing documents previously released by the Select Subcommittee showing Mr. Navarro communicated about the federal pandemic response using a private email account during his White House tenure. Evidence released today raises further questions about whether Mr. Navarro—and other Trump White House officials—violated the PRA by using private email accounts to conduct official business without taking steps to preserve those records.

## Mr. Navarro and Dr. Hatfill Aggressively Attacked Dr. Fauci, Dr. Hahn, and Other Public Health Officials Who Refused to Support Hydroxychloroquine—and Pushed for Them to Be Federally Investigated

- Mr. Navarro and Dr. Hatfill engaged in a coordinated effort to attack federal officials who stood in the way of their attempts to reauthorize hydroxychloroquine—including taking steps to publicly discredit these officials, to push for federal investigations into their actions, and to advocate for their termination. New documents obtained by the Select Subcommittee suggest that these efforts were done to benefit President Trump's political standing:
  - o Two days after *USA Today* published a July 14, 2020, op-ed by Mr. Navarro in which he attacked Dr. Fauci as being "wrong about everything I have interacted with him on," Dr. Hatfill told Garrett Ziegler, a Senior Policy Analyst working under Mr. Navarro, that he was gearing up to attack Dr. Fauci and Dr. Hahn,

- writing: "Peter and the DT [Donald Trump] need some ammunition. Im [sic] currently in the process of specifically outlining what Fauci and Hahn did wrong and the havoc it has caused."
- o Less than three weeks later, Dr. Hatfill told AAPS leadership that Mr. Navarro would attend an August 5, 2020, meeting of the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel—where Mr. Navarro was scheduled to present "Perspectives on Hydroxychloroquine," despite lacking any relevant scientific expertise. Dr. Hatfill said he anticipated that this meeting would devolve into "a sit-down drag out face-to-face fight with Fauci."
- o After the NIH meeting, Dr. Hatfill outlined a plan for Mr. Navarro to have DOJ "start an investigation of the Fauci Panel—their emails and other communications" in order to "shut them up for a bit," and then "pull Hahn in and ask him to re-establish the EUA," contending Dr. Hahn was "weak and will fold when he sees what is going on." Dr. Hatfill expressly tied the timing of these actions to when voting in the November presidential election would begin, assuring Mr. Navarro: "Within 10-14 days of the start of HCQ outpatient treatment—figures should start to decrease," concluding: "Is that not about the same time that some sort of voting goes on ??"
- Dr. Hatfill repeatedly advocated for launching federal investigations into public health officials who opposed hydroxychloroquine, including urging Senator Johnson in a letter for a public hearing record to call for "a combined HHS-IG and DOJ investigation into the entire HCQ matter." He also circulated a petition accusing Dr. Fauci and other senior federal officials of perpetrating "crimes against humanity" and "mass murder" for being "insubordinate to POTUS" by purportedly having "blocked HCQ"—and which called on the Trump Administration to "bring these criminals to justice."

# In the Days Leading Up to the Republican National Convention, President Trump Expressed "Dismay" About Perceived Delays in an EUA for Convalescent Plasma, While the White House Hastily Convened a Press Conference that Grossly Misstated the Data

- During his transcribed interview, Dr. Hahn recounted that NIH Director Dr. Francis Collins told him during a White House meeting in the weeks before the RNC that President Trump had "express[ed] dismay over NIH potentially putting up roadblocks" to the timeline for FDA's authorization of convalescent plasma as a coronavirus treatment, after NIH officials raised concerns about insufficient efficacy data to support an EUA.
- After President Trump accused FDA of being part of the "deep state" and deliberately stalling progress on therapeutics like convalescent plasma, Dr. Hahn said he called the president on August 22, 2020, and told him that "we either were nearing a decision or had made a decision" on an EUA. That same day, Dr. Hahn's Chief of Staff sent a text message to multiple senior political appointees at the Department of Health and Human Services (HHS), stating: "potus said a lot of false remarks with Hahn today about what this was, so we need to make sure POTUS talkers are correct." FDA issued an EUA for convalescent plasma the next day.

- On August 23, 2020—the day before the start of the RNC—the White House hastily convened a press conference to tout the convalescent plasma EUA. In an email previously released by the Select Subcommittee, FDA Associate Commissioner for Media Affairs Emily Miller advised Dr. Hahn on his talking points for the press conference, telling him to "[m]essage positive always" and to "phrase it in real language." Dr. Hahn grossly misstated the implications of the efficacy data on plasma during the press conference, after which he issued a public apology. Dr. Hahn told the Select Subcommittee that he did not seek to clear his apology through the "normal channels" of the Trump Administration.
- The Select Subcommittee obtained an August 28, 2020, agenda for a so-called "China Virus Huddle" meeting—which were attended by top White House officials—that listed as a discussion item: "COVID-19 Events/Messaging Post RNC." This document suggests that senior Trump White House officials discussed pandemic messaging and event planning in relation to the timing of the RNC.

## Trump Administration Political Appointees Blocked FDA Coronavirus Vaccine EUA Guidance Due to "Objections" Over How It Would Impact the Authorization Timeline Ahead of the Presidential Election

- Dr. Hahn told the Select Subcommittee that FDA sent a draft of its coronavirus vaccine EUA guidance to HHS and the White House in September 2020 for review and approval. The guidance advised vaccine manufacturers that they would need to submit phase three trial data in their EUA applications that included a median follow-up duration of at least two months (60 days) after the completion of the primary vaccination series. By that time, it was clear that the guidance would result in FDA not authorizing a vaccine until after the presidential election.
- According to Dr. Hahn, officials in HHS Secretary Alex Azar's office expressed concerns about whether it was "appropriate" for FDA's proposed vaccine EUA guidance to advise manufacturers to submit the amount of surveillance data specified. Beginning around mid-September 2020, Dr. Hahn said FDA had multiple meetings and calls with Secretary Azar, HHS Chief of Staff Brian Harrison, and HHS Deputy Chief of Staff for Policy Paul Mango—none of whom are doctors or otherwise specialized in immunology or vaccinology—regarding the "timeline" and the "scientific and clinical rationale for the guidance."
- After FDA's guidance was sent to the White House for review, Dr. Hahn said "[t]here were objections about it" from Mr. Meadows and other White House officials, including "pushback about the issue of the 60 days" of surveillance data. Dr. Hahn said he "objected" to attempts to change the guidance because "any changes would be obviously reported and would further reduce vaccine confidence." During a September 23, 2020, press conference, President Trump decried the guidance as "a political move" that "has to be approved by the White House," which "may or may not approve it. A new email obtained by the Select Subcommittee shows that FDA Center for Biologics Evaluation and Research Director (CBER) Dr. Peter Marks contacted Dr. Hahn on September 29, as the guidance languished at the White House, cautioning: "The ambiguity here is actually

creating more problems than a decision one way or the other" on whether the guidance would be approved.

• With its formal vaccine EUA guidance stalled for weeks by the White House, FDA unilaterally released an informal set of briefing materials on October 6, 2020, which included an appendix that summarized advice that the agency provided to industry regarding EUA applications—and which publicly revealed that the agency wanted two months of surveillance data, despite the ongoing "objections" from the White House. Dr. Hahn told the Select Subcommittee that FDA did not seek approval from HHS or the White House before releasing the informal document, but noted that he "proactively reached out to the White House to let them know that this was going." Later that day, Dr. Hahn said he was called by Mr. Meadows and was told that FDA's formal vaccine EUA guidance was now approved.

This report is based on a review of thousands of pages of internal correspondence from Trump White House officials, senior HHS officials, and other internal documents obtained by the Select Subcommittee that have not previously been released, as well as transcribed interviews with senior officials, including former FDA Commissioner Hahn, involved in the federal government's coronavirus response.

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## I. <u>Trump White House Officials Orchestrated Coordinated Pressure Campaigns to Reauthorize Hydroxychloroquine and Expand Its Use After It Was Shown to Be Ineffective and Potentially Dangerous</u>

## A. President Trump Championed Hydroxychloroquine Despite the Absence of Meaningful Evidence

Within days of declaring the coronavirus pandemic a national emergency on March 13, 2020, President Trump began touting the purported promise of hydroxychloroquine and chloroquine (CQ)—medicines that are approved to treat or prevent a number of diseases—as powerful coronavirus treatments.<sup>2</sup> As outbreaks first spiraled out of control across the country and thousands of Americans contracted a novel virus for which there were no known treatments or vaccines, early anecdotal reports that hydroxychloroquine might be effective against the coronavirus provided a rare source of optimism—tempered by the absence of rigorous scientific evidence showing that it actually worked.<sup>3</sup>

Members of the media quickly began to report on hydroxychloroquine's potential to prevent or treat coronavirus infections. Some conservative media figures, in particular, began championing the drug as likely having a high degree of efficacy. For example, on March 16, 2020, *Fox News* host Laura Ingraham devoted a significant portion of her nightly program to interviewing an attorney who claimed that "we have strong reason to believe that a preventative dose of hydroxychloroquine is going to prevent the virus from attaching to the body and just get rid of it completely." Two days later, Ms. Ingraham sent an email to White House Senior Adviser Jared Kushner: <sup>5</sup>

From: Laura Ingraham Sent: Wednesday, March 18, 2020 12:21 PM
To: Kushner, Jared C. EOP/WHO

Subject: [EXTERNAL] The treatment that is already working (also sent to Pat, Alex)

Have been trying to get people's attention since Monday on hydroxychloroquine.

I discussed this on Monday on air and last night as well. When I asked Dr. Fauci, he pretty much dismissed it as "anecdotal."

- 1. Below is the Chinese experience with the drug, a common, inexpensive anti-viral.
- 2. The French are ahead of us! Have one million doses out already.

 $\underline{>} https://www.connexionfrance.com/French-news/French-lab-Sanofi-hypothetically-offers-millions-of-doses-of-potential-Covid-19-Plaquenil-anti-malaria-drug<$ 

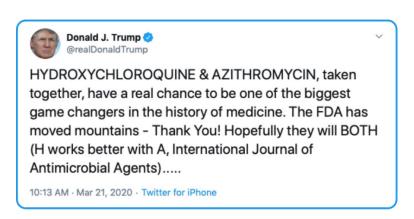
3. Internet presentation (in French) by two of the top French epidemiologists.

 $\underline{>} https://www.mediterranee-infection.com/coronavirus-diagnostiquons-et-traitons-premiers-resultats-pour-lachloroquine/\leq$ 

That same day, HHS Secretary Alex Azar sent an email to Assistant Secretary for Preparedness and Response (ASPR) Dr. Robert Kadlec and FDA Commissioner Dr. Stephen Hahn regarding "chloroquine," instructing them to "please be sure we are looking at both this and

hydrochloroquine [sic] and manufacturing" after "Laura Ingraham mentioned on her show" that the pharmaceutical company Sanofi manufactures the drug.<sup>6</sup>

President Trump repeatedly promoted hydroxychloroquine as a potentially significant coronavirus treatment during this period, despite scant supporting evidence. For instance, on March 19, 2020, he proclaimed—while standing alongside Commissioner Hahn at a White House press conference—that hydroxychloroquine "could be a game changer." On March 21, following the online publication of a French pre-print study on hydroxychloroquine that enrolled only 36 patients and was widely criticized for its small sample size and methodological issues, 8 President Trump cited the study in a tweet and proclaimed:9



In a follow-up tweet, the former president publicly commanded that hydroxychloroquine "be put in use IMMEDIATELY." That same day, the Centers for Disease Control and Prevention (CDC) released information on the use of hydroxychloroquine as a possible treatment for the coronavirus. In a March 24 email for Mr. Kushner, a director of Teva Pharmaceuticals acknowledged that there was "heightened demand for chloroquines after the President's press conferences."

Outside pressure from conservative media figures to deploy hydroxychloroquine continued to mount throughout March 2020. For instance, documents obtained by the Select Subcommittee show that daytime television talk show host Dr. Mehmet Oz wrote to White House Coronavirus Response Coordinator Dr. Deborah Birx on March 22, stating there was a "coronavirus drug shortage" that was impeding clinical trials, and previewing findings from the French researcher who conducted the small hydroxychloroquine study and purportedly "confirmed clinical benefits." Dr. Birx forwarded Dr. Oz's email to Dr. Hahn, who told Dr. Birx he wanted to speak with her about the matter later that day. <sup>13</sup> The next day, Dr. Oz sent a similar email to Mr. Kushner, urging him to have President Trump "push academic centers to move more expeditiously" on hydroxychloroquine. <sup>14</sup> On the morning of March 28, Dr. Oz again wrote to Dr. Birx about the small French study that President Trump referenced in his March 21 tweet, claiming "the treatment appears safe and results are better than expected," and asking for information on where to send patients for a clinical trial. <sup>15</sup> Within the hour, Dr. Birx forwarded the email to Dr. Hahn, saying: "We should talk." <sup>16</sup>

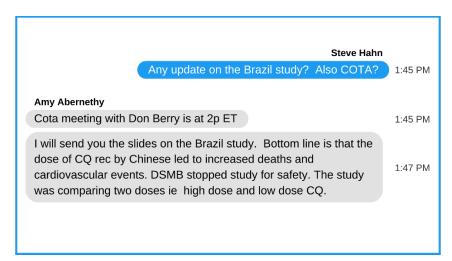
That same day, FDA granted an EUA for chloroquine and hydroxychloroquine, allowing the drugs to be administered to certain patients hospitalized with the coronavirus. <sup>17</sup> This

development was hailed by the president and his allies. <sup>18</sup> For instance, in early April 2020, President Trump held a meeting in the Oval Office with Ms. Ingraham, Dr. Hahn, and two hydroxychloroquine proponents who appeared on Ms. Ingraham's show to tout the drug as a coronavirus treatment. <sup>19</sup> Following this meeting, one of the hydroxychloroquine proponents in attendance, Dr. Stephen Smith, emailed Dr. Hahn directly, noting that "[t]he meeting the other day was…interesting" and urging Dr. Hahn to authorize higher doses of hydroxychloroquine for certain patients. <sup>20</sup> Dr. Hahn told the Select Subcommittee during a transcribed interview that Ms. Ingraham was contacting him directly around this time regarding coronavirus therapies or other "interesting scientific information." <sup>21</sup>

As President Trump and other figures hyped the drug, hydroxychloroquine prescriptions surged nearly 2,000 percent in March 2020.<sup>22</sup> The American Association of Poison Control Centers also reported an increase in hydroxychloroquine misuse during this period.<sup>23</sup> One couple in Arizona intentionally ingested a version of chloroquine phosphate used to treat aquarium fish—which is toxic to humans—under the mistaken belief that it was safe and would confer the same protection against the coronavirus that President Trump asserted that hydroxychloroquine would. They were both hospitalized, and the husband tragically died.<sup>24</sup>

#### B. FDA Revoked the EUA for Hydroxychloroquine After Evidence Mounted Showing the Drug Was Ineffective and Had Potentially Severe Side Effects

Within weeks of FDA's issuance of the EUA for chloroquine and hydroxychloroquine, evidence started mounting of its ineffectiveness and potential severe side effects in certain coronavirus patients. Previously released text messages obtained by the Select Subcommittee show that FDA Principal Deputy Commissioner of Food and Drugs Dr. Amy Abernethy expressed serious concerns to Dr. Hahn about chloroquine and hydroxychloroquine, which share similar toxicity profiles, in mid-April 2020. For instance, on April 13, Dr. Abernethy cautioned Dr. Hahn that a recent study found chloroquine potentially unsafe, writing: 26



On April 24, 2020, FDA issued a public warning about chloroquine and hydroxychloroquine, cautioning against the use of either drug outside of hospitals or clinical trials due to the "risk of heart rhythm problems." Despite this warning, President Trump continued promoting the drugs, claiming publicly the following month that he took

hydroxychloroquine as a prophylactic measure outside of the authorized settings.<sup>28</sup> Evidence continued to grow showing that the drugs were ineffective at treating coronavirus infections, leading to Dr. Fauci stating publicly on May 27: "The scientific data is really quite evident now about the lack of efficacy."<sup>29</sup> Following these statements, HHS political appointees scrambled to "urgently meet to discuss what secretary [Azar] and WH must say now."<sup>30</sup>

On June 15, 2020, FDA revoked its EUA for chloroquine and hydroxychloroquine, finding it was unlikely that the drugs were effective in treating coronavirus infections and that their known and potential benefits did not outweigh the risks of serious adverse events and other potential serious side effects.<sup>31</sup> According to Dr. Hahn, the doctors on the White House Coronavirus Task Force agreed at the time that FDA's decision to revoke the EUA "was the right thing to do."<sup>32</sup> Shortly after FDA's revocation of the EUA, NIH recommended against using hydroxychloroguine to treat coronavirus infections outside of a hospital or clinical trial, citing a large study that found "no evidence of benefit in patients with COVID-19" and in light of "documented serious dysrhythmias in patients with COVID-19 who were treated with chloroquine or hydroxychloroquine."33 In early July, FDA published a summary documenting the agency's review of safety issues with the use of hydroxychloroquine in patients hospitalized with the coronavirus, warning of "serious heart rhythm problems and other safety issues, including blood and lymph system disorders, kidney injuries, and liver problems and failure."34 By the end of July, the mainstream medical consensus was that hydroxychloroquine had not been shown to be an effective coronavirus treatment and may cause serious adverse events in certain patients.<sup>35</sup>

Despite FDA's revocation of the EUA and NIH's warnings about using hydroxychloroquine as a coronavirus treatment, a group of Trump White House officials continued to relentlessly push for the widespread use of the drug—pressuring FDA to reverse its decision on the EUA, diverting attention and resources from the coronavirus response to manufacture a basis for deploying the disproven treatment, coordinating with conspiracists to amplify misinformation about the federal government's rationale for not authorizing the drug for coronavirus patients, and lobbing meritless attacks aiming to discredit—and open federal investigations into—public health officials whom they viewed as impediments to widespread use of hydroxychloroquine.

#### C. Mr. Navarro and Dr. Hatfill Spearheaded an Effort from Inside the White House to Reauthorize Hydroxychloroquine

Leading the charge from inside the White House to pressure FDA to reauthorize hydroxychloroquine—and to expand its use to outpatient settings—was Peter Navarro who "served as a Senior Adviser to President Donald J. Trump during the former President's entire term in office," including as Director of the White House Office of Trade and Manufacturing Policy and Defense Product Act policy coordinator during the coronavirus pandemic. According to Mr. Navarro, he "was one of a small group of senior advisors 'who customarily meet with the President on a regular or frequent basis'" during his time in the White House.<sup>36</sup>

To wage this campaign, Mr. Navarro coordinated closely with Dr. Steven Hatfill, an adjunct assistant professor at George Washington University whom Mr. Navarro brought into the White House as his Senior Medical Adviser in January 2020.<sup>37</sup> Dr. Hatfill has acknowledged

spending "thousands of hours" working for the Trump White House during the pandemic, where he "had a front-row seat" for key decisions and provided "almost daily outside scientific considerations to the Executive Office of the President of the United States." The Select Subcommittee's investigation has revealed that Dr. Hatfill worked extensively on the pandemic during his White House tenure—where he was given an Executive Office of the President email address, appears to have had an office inside the White House, and had direct access to senior Trump Administration officials. In internal emails obtained by the Select Subcommittee, Dr. Hatfill stated that he spent "up to 18 hours a day, 7 days a week, working on the pandemic." Operating in tandem, Dr. Hatfill and Mr. Navarro devised multiple pressure schemes targeting FDA and federal officials who they contended were wrongly impeding widespread access to hydroxychloroquine.

Former Commissioner Hahn told the Select Subcommittee during a transcribed interview that he had repeated discussions about hydroxychloroquine with Mr. Navarro—who is not a medical doctor and has no scientific training—during which Mr. Navarro "was very demonstrative about his belief that hydroxychloroquine would work, and was working, and that it had met the statutory standard for an EUA," even after FDA revoked its authorization. According to Dr. Hahn, Mr. Navarro presented cherry-picked data and unreliable studies in an effort to convince FDA to reverse course and reissue an EUA, despite the fact that, according to Dr. Hahn, "it made no sense to continue the EUA in the setting of a Phase 1 trial that basically indicated that, in that setting, hydroxychloroquine didn't work."

Dr. Hahn further told the Select Subcommittee that he believed the type of pressure he experienced from Mr. Navarro was inappropriate:

Majority Counsel: Was there a time that perhaps that pressure was

inappropriate in any way?

Dr. Hahn: Meaning ever in my tenure?

Majority Counsel: Yes.

Dr. Hahn: Yes.

Majority Counsel: What happened?

Dr. Hahn: Well, it relates in part to the hydroxychloroquine issue....

And of course eventually we revoked that EUA, and then

we received an application for another EUA for hydroxychloroquine in the outpatient setting.

And there were discussions that I had with Mr. Navarro that I would say probably rose to the level of what you

just asked me with respect to pressure.

Dr. Hahn said Mr. Navarro's "persistence" in "asserting that the data were supportive," despite clear evidence to the contrary, contributed to what "I felt, was pressure." Consistent with these statements, text messages obtained by the Select Subcommittee show that the day after FDA revoked its EUA for hydroxychloroquine, Dr. Hahn's Chief of Staff, Keagan Lenihan, asked FDA Chief Counsel Stacy Amin to "Pls keep the WH being upset at SH [Stephen Hahn] between us." Stage of the Staff of Staff of

After FDA revoked its EUA for hydroxychloroquine, Mr. Navarro and Dr. Hatfill began coordinating with Dr. William O'Neill, a cardiologist at the Henry Ford Health System (HFHS) in Detroit, Michigan, on a renewed EUA request that petitioned FDA to reauthorize hydroxychloroquine and expand the scope of its authorized uses. <sup>44</sup> The two White House officials had been working with HFHS since as early as April 2020 to obtain hydroxychloroquine from the Strategic National Stockpile for HFHS to use in clinical trials studying the drug as a prophylaxis. <sup>45</sup> Dr. Hatfill had also discussed potential settings for hydroxychloroquine trials with HFHS, at one point suggesting to Dr. O'Neill that they perform a trial at a state correctional facility with a coronavirus outbreak: <sup>46</sup>

From: Steven Hatfill < @gwu.edu >
Sent: Thursday, April 16, 2020 2:04 AM
To: O'Neill, William < @hfhs.org >

Subject: Fwd:

Bill:

This just crossed my desk, there is a COVID prison outbreak at the Westville Correctional Facility in Indiana. The prison just got N-95 masks yesterday. Don't you think there must be a chain of infection already established there now, just like on the USS Roosevelt (never heard back from the DoD on that one and they have a huge number of infections there now.)

This prison might be a good place for a clinical prophylaxis trial-certainly the test subjects are not going anywhere and it could be made a double blind study.

See below

Steve Hatfill

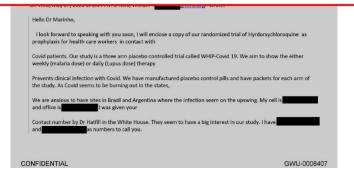
Mr. Navarro directed Dr. Hatfill "to prepare a combined EUA critique and EUA request" letter to FDA, which Dr. Hatfill worked on in late June 2020.<sup>47</sup> On June 29, Dr. Hatfill told Dr. O'Neill that he was actively "writing a new EUA request" and asked for "[u]rgent clarification" on the preliminary findings from a recent hydroxychloroquine study conducted by HFHS, emphasizing that "Peter is seeing the VP tomorrow." New documents obtained by the Select Subcommittee show that Dr. Hatfill sent a June 30 draft of a formal request to reauthorize hydroxychloroquine—which he personally signed—to Mr. Navarro, stating: "Please change anything you deem necessary to obtain a superior product. I think I have taken out all the words like 'idiot' and 'dumbass[.]"

It appears that Dr. Hatfill ultimately chose HFHS, an outside institution not formally affiliated with the White House, to submit the renewed EUA request to FDA. In emails obtained by the Select Subcommittee, Dr. Hatfill revealed to his outside collaborators that he was the one who "wrote the EUA calling for revesral [sic] of the ban on HCQ," appearing to incorrectly equate FDA's EUA revocation with a prohibition on the drug. He explained that he "selected" HFHS to be the submitting institution and "transferred the EUA reinstatement letter over to Dr. O'Neil [sic] and his collaboration at the Ford System," which allowed the EUA request to be submitted on behalf of HFHS instead of someone affiliated with the White House. Dr. Hatfill had instructed Dr. O'Neill in a prior email exchange not to reveal his White House affiliation in connection with their ongoing work on hydroxychloroquine, admonishing Dr. O'Neill:



PLEASE-NEVER mention the White House together with my name---I specifically asked that of you before---and it is certainly something not to be mentioned to a foreigner. I thought I related to you that I had already spoken with him when I linked you up by email. I am simply trying to help you out with your much needed study. Im not part of it, the WH is not part of it and this guy does not need to know anything about it other than you want to do a cooperation study on HCQ prophylaxis.

Steve

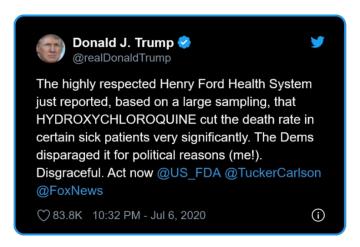


On July 1, 2020, HFHS released a study purporting to show benefits of hydroxychloroquine as a coronavirus treatment.<sup>52</sup> The study was swiftly criticized by the scientific community for containing multiple errors, flaws, and biases.<sup>53</sup> The next day, Dr. Hatfill pressed HFHS to expedite the renewed EUA submission, writing to Dr. O'Neill from a non-governmental email address:

I'm sitting here waiting for the EUA request signed by everyone to give to Dr Navarro for FDA EUA reauthorization. I should have had this last night . . . . I need the signed paper for the EUA on this civilian email address within the next hour. Time is a precious commodity here for this to work with maximum efficiency. <sup>54</sup>

Dr. Hatfill wrote to Dr. O'Neill: "We need to keep this communications chain simple for this to work," identifying only "William O'Neill, myself, then Dr Peter Navarro" as those who must be included on the chain and specifying that Assistant Secretary Kadlec should be excluded. 55 Dr. Hatfill then provided an update to Mr. Navarro on the status of the HFHS submission. 56 That same day, Dr. O'Neill sent Dr. Hatfill an EUA request signed by multiple HFHS representatives, petitioning FDA to authorize hydroxychloroquine as both a prophylaxis and a treatment for early coronavirus infections. 57

HFHS submitted the EUA request to FDA on July 6, 2020.<sup>58</sup> The next day, President Trump hailed the findings from HFHS's flawed hydroxychloroquine study on Twitter:<sup>59</sup>



President Trump remained fixated on hydroxychloroquine in the weeks that followed. During a transcribed interview, Special Advisor to the President Dr. Scott Atlas told the Select Subcommittee that President Trump asked him about hydroxychloroquine during their first one-on-one meeting in the Oval Office in mid-July 2020. President Trump tweeted a video on July 28 featuring members of a group called America's Frontline Doctors standing in front of the Supreme Court claiming, among other falsehoods, that hydroxychloroquine was a "cure for Covid."

FDA ultimately denied the renewed EUA request on or around August 10, 2020.<sup>62</sup>

## D. Senior HHS Officials Sought to Encourage Physicians to Prescribe Hydroxychloroquine Off-Label

Soon after FDA revoked the EUA for hydroxychloroquine, Mr. Navarro instructed FDA to contact Dr. O'Neill at HFHS. New documents obtained by the Select Subcommittee show that one of Commissioner Hahn's top aides, FDA Deputy Commissioner for Medical and Scientific Affairs Anand Shah, called Dr. O'Neill at Mr. Navarro's direction on or around June 16, 2020, to discuss hydroxychloroquine. After the call, Dr. O'Neill urged Dr. Hatfill: "Can you get them to [c]larify that FDA does not practice medicine and 'off [l]abel' use of medications is NOT regulated by FDA?" Dr. O'Neill claimed that he and fellow practitioners prescribing hydroxychloroquine "need cover" and expressed concern that "some Blue governors like Whitmer [w]ill try to ban its use again!" In the weeks that followed, as FDA stood firm in its position on hydroxychloroquine, senior HHS officials sought to promote the off-label use of

hydroxychloroquine—the exact type of "cover" that Dr. Hatfill and Mr. Navarro were urged to provide.

While HFHS's renewed EUA request was pending, on July 28, 2020, HHS General Counsel Robert Charrow circulated a document obtained by the Select Subcommittee to senior HHS officials, including Assistant Secretary for Public Affairs Michael Caputo and HHS Deputy Chief of Staff for Policy Paul Mango, titled, "FDA EUA Hydroxychloroquine and Chloroquine." The document included an "FAQ on off-label use of hydroxychloroquine" emphasizing that the drug could be prescribed off-label to treat coronavirus patients, while expressly acknowledging that FDA had revoked its EUA the prior month.<sup>64</sup>

Following Mr. Charrow's email, Mr. Caputo's Senior Advisor, Dr. Paul Alexander, wrote to the senior HHS officials on the email chain, saying, "The key message should be that as an off-label, it can be used for COVID contingent on the clinician's decisions." Dr. Alexander emphasized that it was "important" to include a statement that specified physicians may prescribe hydroxychloroquine "during COVID-19" irrespective of the EUA. Dr. Alexander also emailed Mr. Caputo's assistant, Madeleine Hubbard, seeking to tone down language warning about the risks of taking hydroxychloroquine, telling her that the word "serious' has to be removed before 'adverse events." HHS Deputy Chief of Staff for Operations and Strategy Judy Stecker later told the group that "Hahn needs to see" the document next. Ms. Stecker also suggested removing a line in the document specifying the exact amount of hydroxychloroquine in the Strategic National Stockpile—advising to instead "just make the point that it's available[.]"

It is unclear who in the Trump Administration directed senior HHS officials to draft a document encouraging physicians to prescribe hydroxychloroquine as an off-label coronavirus treatment more than a month after FDA revoked its EUA for the drug due to safety and efficacy concerns.

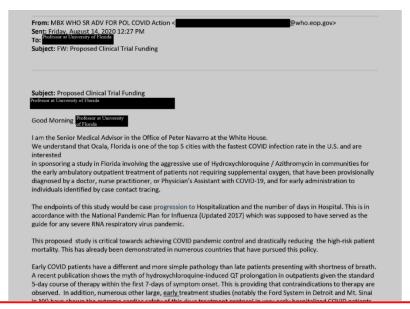
#### E. Trump White House Officials Sought to Direct Millions of Taxpayer Dollars to Fund Studies Aiming to Justify the Use of Hydroxychloroquine

From inside the White House, Dr. Hatfill and Mr. Navarro sought to route millions in taxpayer dollars to fund hydroxychloroquine trials in an effort to gather evidence that would justify use of the drug as a coronavirus treatment. In late May 2020, Dr. O'Neill at HFHS asked Dr. Hatfill if there were "any resources in the trillions allocated to Covid for a prevention trial" on hydroxychloroquine, while also inquiring whether Dr. Hatfill thought "any of Mr Trumps [sic] rich supporters would be willing to donate?" Dr. Hatfill replied: "I will ask and bust my butt to do what I can. One of the Assistant Directors of HHS Head of ASPR is a friend for over 20 years. I will take it directly there and plead the case." In a transcribed interview, Assistant Secretary Kadlec confirmed that he knew Dr. Hatfill since their time in the military in the 1990s, and said he was "stunned" when he saw Dr. Hatfill working in the White House, given Dr. Hatfill's "significant past where he was one of the persons of interest around the anthrax – 2001 anthrax event."

On May 23, 2020, Dr. Hatfill wrote to Dr. O'Neill saying that he "spoke with Peter and he thinks that there is BARDA [Biomedical Advanced Research and Development Authority]

money that can be used for your study," known as the WHIP COVID-19 study, which sought to determine whether hydroxychloroquine could prevent coronavirus infections in frontline workers. Dr. Hatfill provided HFHS information on how to initiate what he called an "unsolicited proposal" through Mr. Navarro's Office of Trade and Manufacturing Policy. Dr. Hatfill indicated that this funding mechanism was one of the "non traditional ways for funding for National Security issues," explaining that the submission "goes to the boss and if he is happy it goes off to BARDA in Trump Time." The WHIP COVID-19 study does not appear to have received federal funding, and it was ultimately terminated at the end of 2020 without producing any conclusive results on the efficacy of hydroxychloroquine as a coronavirus prophylaxis.

After FDA revoked its authorization of hydroxychloroquine, Dr. Hatfill continued pursuing a study that would show the purported benefits of the drug, advertising his access to millions in federal funding and diverting attention away from advancing the pandemic response. On August 14, 2020, Dr. Hatfill emailed a professor at the University of Florida about designing a clinical trial, noting: 75



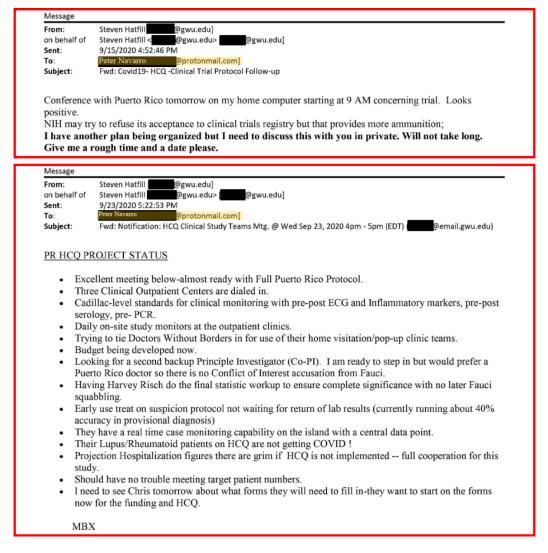
We expect to shortly have access to a large quantity of HCQ and azithromycin and 5 million dollars in BARDA funding for this purpose. Would you be interested in using this to design, IRB, and implement such a study?



Throughout August and September, Dr. Hatfill sent similar requests to researchers at Texas Tech University, to whom he claimed to "have 5 million dollars for a study and a truck full of medications to address this issue," and the University of Puerto Rico, representing that he had the ability to "fund" a rapid study, in coordination with other White House aides. <sup>76</sup> Dr. Hatfill explained to Mr. Navarro at the time that he was "ready to step in" to personally oversee the

study, but that he was "[1]ooking for a second backup Principle Investigator" and "would prefer a Puerto Rico doctor so there is no Conflict of Interest accusation from Fauci."<sup>77</sup>

On August 17, 2020, Dr. Hatfill sent himself at his official White House email address a draft request to use the Defense Production Act for, among other things, "a suitable supply of hydroxychloroquine, zinc, azithromycin and alternative doxycycline, together with 5 million dollars in funding." Days later, Dr. Hatfill contacted Christopher Abbott, an Associate Director in Mr. Navarro's office, to meet and discuss the forms needed to initiate the "PR HCQ PROJECT." Dr. Hatfill told Mr. Navarro that these forms were needed "for the funding and HCQ." Documents obtained by the Select Subcommittee show that Dr. Hatfill sent updates on his progress in setting up these trials and securing federal funding from his non-official email account to Mr. Navarro's personal ProtonMail account—raising alarming concerns about whether Dr. Hatfill and Mr. Navarro were deliberately attempting to evade transparency obligations and conceal their efforts to push hydroxychloroquine. Descriptions of the supplementation of



Despite these extensive efforts, including Dr. Hatfill repeatedly dangling access to millions of taxpayer dollars, it does not appear that public funds were used to pay for these initiatives.

On August 3, 2020, DOJ filed a lawsuit against Mr. Navarro for alleged violations of the PRA, citing documents previously released by the Select Subcommittee showing Mr. Navarro communicated about the federal pandemic response using a private email account during his White House tenure. 82 The Select Subcommittee has now identified more than 35 previously unreleased emails showing that Mr. Navarro and/or Dr. Hatfill discussed the federal pandemic response using personal accounts, including encrypted ProtonMail accounts, seemingly without properly preserving these records in accordance with the PRA. The PRA prohibits White House personnel from creating or sending a record "using a non-official electronic message account" unless the employee copies their official email account or "forwards a complete copy" to their official email "not later than 20 days" after sending or receiving the original email. 83 A February 2017 memorandum issued by the White House Counsel's Office made clear that all White House personnel were required to "conduct all work-related communications on your official EOP email account," specifying that "[a]ny employee who intentionally fails to take these actions may be subject to administrative or even criminal penalties."84 These documents raise further questions about the scope of potential PRA violations committed by Mr. Navarro and other Trump White House officials.

#### F. Dr. Hatfill Forged a Close Alliance with a U.S. Senator to Amplify Pressure on FDA to Reauthorize Hydroxychloroquine

After failing to get FDA to grant HFHS's renewed EUA petition,<sup>85</sup> Dr. Hatfill and Mr. Navarro sought to bolster their efforts by recruiting powerful allies outside the White House to pressure Dr. Hahn into reversing the agency's position on hydroxychloroquine.

By the time FDA denied the renewed EUA request, Dr. Hatfill had found an ally in Senator Ron Johnson, then-Chairman of the Senate Homeland Security and Governmental Affairs Committee (HSGAC). In August 2020, Dr. Hatfill fed documents and information pertaining to the purported benefits of hydroxychloroquine and alleged "long-standing FDA maleficence in many areas, not just with hydroxychloroquine" directly to Senator Johnson. As he explained in an August 9 email to an outside ally, Dr. Hatfill was actively working "to take the next step with Senator Johnson who will demand that Hahn produce a list of the published papers and other data that the FDA used to extend its HCQ ban to outpatients," after which Dr. Hatfill said "hopefully we are off to the races for some other more serious stuff to quickly happen in sequence."

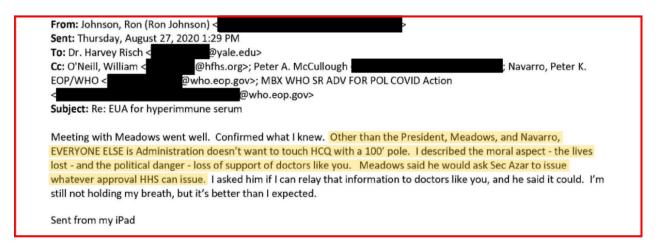
On August 18, 2020, Senator Johnson, along with fellow HSGAC Senators Mike Lee and Ted Cruz, sent a letter to Commissioner Hahn demanding an explanation for FDA's decisions to revoke the hydroxychloroquine EUA and to deny HFHS's renewed EUA request—a draft of which Dr. Hatfill appears to have reviewed and edited personally. 88 Consistent with Dr. Hatfill's August 9 email, the letter demanded, among other things:

any studies and data that informed the FDA's apparent determination that giving HCQ or CQ to COVID-19 infected outpatients within seven days from the onset of symptoms, under a doctor's supervision, will have no clinical effect and may be harmful to the patient. <sup>89</sup>

Three days before the letter was sent to Dr. Hahn, Dr. Hatfill sent a copy to Mr. Navarro's ProtonMail account, informing him that "[t]his letter from Senator Johnson should be going out on Monday to Hahn."<sup>90</sup>

On at least one occasion, Dr. Hatfill sought to use outside allies to covertly pass information to Senator Johnson. On August 16, 2020, Dr. Hatfill contacted former White House Chief Strategist Steve Bannon, the host of the podcast *War Room* which Dr. Hatfill appeared on both during and after his White House tenure. <sup>91</sup> Dr. Hatfill asked Mr. Bannon to "please pass this FOIA document to Senator Johnson," stating that the matter was "rather urgent" and provided a basis for why "[t]he FDA needs investigation urgently." Dr. Hatfill emphasized: "I dont want a WH connetation [sic] to it." Mr. Bannon told Dr. Hatfill that he was "On it."

Dr. Hatfill and Mr. Navarro also coordinated with Senator Johnson to press President Trump's Chief of Staff, Mark Meadows, to pressure FDA to reinstate the hydroxychloroquine EUA. Documents obtained by the Select Subcommittee reveal that Senator Johnson met with Mr. Meadows on or around August 27, 2020, to urge renewing the hydroxychloroquine EUA. Senator Johnson sent a readout of the meeting to Mr. Navarro and Dr. Hatfill at their White House email addresses, as well as to other hydroxychloroquine proponents with whom Dr. Hatfill was coordinating. Senator Johnson informed the group: 94



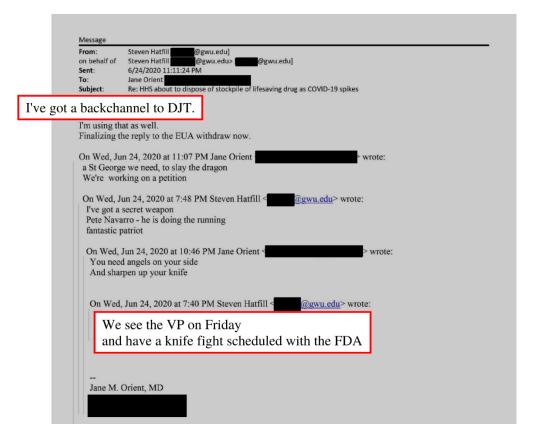
Dr. Hatfill also provided direct assistance to Senator Johnson for a November 19, 2020, hearing focused on hydroxychloroquine—the first of two Senate hearings chaired by Senator Johnson regarding the drug. <sup>95</sup> In an email to Senator Johnson days before the hearing, Dr. Hatfill sent a "[m]odified opening statement" and advised Senator Johnson on which individuals to trust as they pushed for hydroxychloroquine moving forward. <sup>96</sup>

Dr. Hatfill also pressed Senator Johnson to call for federal investigations into senior public health officials who opposed hydroxychloroquine. For instance, Dr. Hatfill sent Senator Johnson a letter to be submitted into the public hearing record—which cited only his George Washington University affiliation and made no reference to his White House role—urging for "a combined HHS-IG and DOJ investigation into the entire HCQ matter." In the cover email transmitting the letter to Senator Johnson, Dr. Hatfill specifically focused on Dr. Fauci, claiming, "I have a small 3-person team working on him," and telling Senator Johnson: "I did not know you were interested in him at this time."

#### G. Trump White House Officials Coordinated with Known Conspiracy Theorists to Build Pressure on FDA to Renew the Hydroxychloroquine EUA

White House officials sought to generate outside support for hydroxychloroquine by coordinating with individuals and a group known for promoting conspiracy theories. One such group was the Association of American Physicians and Surgeons, which, among other things, propagated the theory that President Barack Obama used a covert form of hypnosis to win the 2008 presidential election. AAPS became a vocal proponent of using hydroxychloroquine as a coronavirus treatment in 2020, and frequently engaged in overtly partisan conduct in support of then-President Trump. For instance, AAPS filed a federal lawsuit against FDA and other public health agencies on June 2, 2020, alleging "FDA officials from prior administrations acted contrary to the wishes of President Donald Trump, by arbitrarily limiting use of HCQ from the Strategic National Stockpile."

While working in the White House, Dr. Hatfill had been in contact with AAPS about the pandemic since at least March 2, 2020, when he sent an email to AAPS Executive Director Dr. Jane Orient—who would later testify during one of Senator Johnson's hydroxychloroquine hearings <sup>101</sup>—about "a crash program" inside the federal government to produce a drug for the coronavirus. <sup>102</sup> Following FDA's revocation of the hydroxychloroquine EUA, Dr. Hatfill contacted Dr. Orient on June 24, stating that he was "[f]inalizing the reply to the EUA withdraw." Dr. Hatfill told Dr. Orient that he planned to broach the issue at the highest levels of the government, stating: <sup>103</sup>



Dr. Birx testified during a June 23, 2022, hearing before the Select Subcommittee that "people were communicating with the President dangerous ideas" about hydroxychloroquine "on a daily basis from different individuals." <sup>104</sup>

In early July 2020, Dr. Hatfill continued to coordinate with AAPS as he sought to manufacture the appearance that the medical community opposed FDA's revocation of the hydroxychloroquine EUA. To that end, he drafted a public petition online calling on FDA to reinstitute the EUA, which he said was intended to "keep pressure on the FDA and the new EUA request" that he was working on covertly with HFHS. To garner support for the petition, Dr. Hatfill implored a group of AAPS members to promote his petition by getting "as many Doctor, Nurse, and other health care worker signatures on this as quickly as possible," and asking for their "help to get it rapidly circulated and signed." 105

As part of this effort, Dr. Hatfill worked on the petition with Joanna Miller, a Policy Analyst working under Mr. Navarro in the White House, keeping Mr. Navarro in the loop on his progress and providing Ms. Miller with an activity report documenting how many signatures the petition received. Dr. Hatfill also introduced Ms. Miller to Jeremy Snavely, the business manager of AAPS, on July 10, 2020, telling him that Ms. Miller "has an idea about promoting the signature sign in." Dr. Hatfill advised that Ms. Miller and Mr. Snavely "talk on the phone rather than email" about the petition. Ms. Miller replied that "Peter wants to do media stuff on it"—an apparent reference to Mr. Navarro. Ms. Miller proceeded to engage with AAPS to ensure the petition was accessible on federal officials' government devices, telling Dr. Hatfill "that's who it needs to reach." By mid-August, Dr. Hatfill said he was in contact with AAPS "every single day" as he worked on the pandemic response in the White House. 108

In addition to AAPS, Dr. Hatfill sought support for the hydroxychloroquine petition from Mr. Bannon, with whom Dr. Hatfill had been discussing hydroxychloroquine as early as April 15, 2020, when Mr. Bannon offered to introduce Dr. Hatfill to his colleagues who had access to "20 million hydroxychloroquine pills," at Mr. Navarro's request. On July 16, Dr. Hatfill sent Mr. Bannon a link to the petition, telling Mr. Bannon: 110

From:	Steven Hatfill @gwu.edu]
on behalf of	Steven Hatfill @gwu.edu> [ @gwu.edu]
Sent: To:	7/16/2020 5:09:00 AM  JACK MAXEY  Steve Bannon
Subject:	Fwd: Petition
Guys;	
I need help	advertising this !!!!
	to compart the resignation of hydrographics aring by the EDA
its a petition	T to support the re-issuance of hydroxychioroquine by the FDA.
	n to support the re-issuance of hydroxychloroquine by the FDA.  tion for reissuance has been put in by the doctors involved in the first early-use HcQ trial in Detroit
The applica	tion for reissuance has been put in by the doctors involved in the first early-use HcQ trial in Detroit
	tion for reissuance has been put in by the doctors involved in the first early-use HcQ trial in Detroit

That day, Dr. Hatfill updated Mr. Navarro on his progress, sending him a document titled, "Letter with 370 physician signers." According to Dr. Hatfill's internal notes, the "hydroxy petition" received "8000 signatures" as of August 19. 112

New documents obtained by the Select Subcommittee reveal how Dr. Hatfill's close coordination from inside the White House with a network of conspiracists resulted in the mainstreaming of a baseless theory for why the federal government was not reauthorizing hydroxychloroquine:

- On July 21, 2020, Mr. Snavely of AAPS forwarded Dr. Hatfill an "interesting FDA document" from "our ally" Dr. Harvey Risch, a Yale University professor whose colleagues declared in an open letter that they were "seriously alarmed" by his promotion of "misinformation about HCQ." In response, Dr. Hatfill told Mr. Snavely that "I want to arrange a call with Dr Risch [f]rom the [W]hite House," following Dr. Risch's appearance on Laura Ingraham's show where he suggested there was widespread corruption in the medical field for blocking hydroxychloroquine. 114
- On August 3, 2020, Dr. Hatfill contacted Dr. Risch, noting that "Navarro asked me to contact you" about hydroxychloroquine and saying, "I also suggested you for Bannon's first show." An episode of Mr. Bannon's *War Room* podcast featuring an interview with Dr. Risch and his pro-hydroxychloroquine commentary, as well as an interview with Senator Johnson, aired the same day. 116
- That evening, Dr. Risch contacted a producer of Mr. Bannon's podcast, claiming to "know why the FDA is balking at approving HCQ EUA." According to Dr. Risch, the criteria for issuing an EUA—which requires that "there are no adequate, approved, and available alternatives" to a medical product—"may mean that other agents, i.e., medications or vaccines, lose access to the EUA mechanism because HCQ got there first." Dr. Risch speculated that this caused "Big pharma pushback" on hydroxychloroquine and was the "explanation" behind FDA's EUA revocation. He also said, "I don't want to be the point person for this explanation" but advised that "anyone can talk about it, embarrass the FDA," and said it was "worth Steve seeing." The producer forwarded Dr. Risch's email to Mr. Bannon and Jack Maxey—a former co-host of Mr. Bannon's War Room podcast—who, in turn, forwarded it to Dr. Hatfill. 117
- That same day, Dr. Risch continued pressing this theory in an email to a group of hydroxychloroquine proponents, including the purported creator of the hydroxychloroquine coronavirus treatment regimen Dr. Vladimir Zelenko and prolific conspiracist Dr. Jerome Corsi. 118 Dr. Risch claimed that FDA was engaging in a "sinister" plot to block hydroxychloroquine in order to appease the pharmaceutical industry because, he speculated, "all those pharma drugs and vaccines get blocked from EUA access" if hydroxychloroquine received an EUA. 119
- The next day, Dr. Corsi told the group to "stress Dr. Risch's point" that "[i]f the FDA approves HCQ for COVID-19, that fact may block a EUA for the Big Pharma vaccine given the NIH rules for issuing a EUA." Dr. Orient of AAPS forwarded Dr. Corsi's email to Dr. Hatfill, asking him "might this be the real reason?" 120

• Months later, Senator Johnson advanced this unfounded theory in his opening remarks—which Dr. Hatfill personally edited—in the first Senate hearing on hydroxychloroquine, where he stated: "Could big PHARMA have played a role in discouraging less costly alternatives? The answer seems obvious, even though their methods will no doubt remain obscured." Dr. Risch testified at the hearing and advocated in support of widespread deployment of hydroxychloroquine. 122

While Dr. Hatfill was organizing and activating this conspiracist network to pressure the federal government to reauthorize hydroxychloroquine, he regularly took steps to conceal the White House's involvement in these efforts. For example, on August 9, 2020, Dr. Hatfill contacted Dr. Peter McCullough, a Texas cardiologist who later testified at the first Senate hearing on hydroxychloroquine and was disavowed by his former employer Baylor University Medical Center after spreading coronavirus misinformation. Dr. Hatfill asked Dr. McCullough to demand the retraction of two studies that "were argued by Fauci" in support of FDA's EUA revocation. Dr. Hatfill told Dr. McCullough that his assistance "would add greatly to a behind-the-scene effort that is now underway by others," explaining that the petition calling for these retractions would be funneled through "a third party organization to put up on the internet." Dr. Hatfill emphasized that it was important to conceal his involvement in this effort, and gave assurances that the authors' participation would not be publicly revealed, saying: 124

On Sun, Aug 9, 2020 at 10:49 AM Steven Hatfill < @gwu.edu> wrote: Hi Peter:

OK - Let me write a basic draft of the petition and then if you could pass it around, let everyone have some input, and send it back to me.

Best if I keep in the background for the time being.

Both Harvey and Bill O'Neill know where I am at ---if you need to check.

It's easier for me to work from the shadows.

I will then finalize the petition--- and then ensuring that it speaks for the group---- I will pass it to a third party organization to put up on the internet and a link can then be passed around to everyone that we know for signatures. We need only Doctors to sign it I would think. If that sounds reasonable-I will start on the petition today.

This signed petition will not only put some pressure on the journals and Boulware and sweat Fauci (because these are the journal papers he used for his determination), It will also allow me to take the next step with Senator Johnson who will demand that Hahn produce a list of the published papers and other data that the

.....Harvey and Dr. Watanabe can write their confidential analysis of this for the Senator (their participation will be kept mute)

Does this sound reasonable? Steve

On a separate occasion, Dr. Hatfill directed Dr. Risch to "use my GW email" on correspondence and "not link it to Peter's EOP email[.]" 125

Dr. Hatfill's secretive coordination with conspiracist allies on hydroxychloroquine extended outside the United States. Documents obtained by the Select Subcommittee show that Dr. Hatfill communicated on multiple occasions with Dr. Paolo Zanotto, a virologist in Brazil

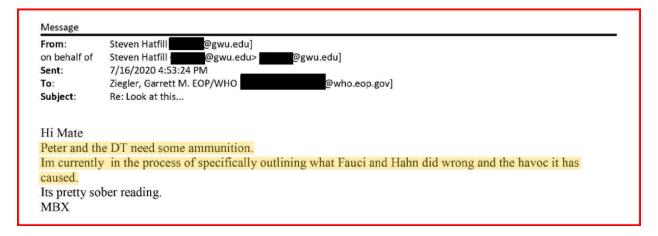
who worked closely with Brazilian President Jair Bolsonaro in formulating the country's pandemic response, which rejected basic scientific recommendations. <sup>126</sup> Brazil's Senate recommended criminal charges against Dr. Zanotto in October 2021 for his role in promoting false coronavirus cures, such as hydroxychloroquine. <sup>127</sup>

On July 31, 2020, Dr. Hatfill contacted Dr. Zanotto, noting that he had been introduced to the Brazilian virologist by Mr. Maxey from the War Room podcast. Dr. Hatfill made a veiled reference to his position in the White House, telling Dr. Zanotto, "Jack I think has filled you in where I work," and indicated that Mr. Navarro's office was responsible for sending a shipment of hydroxychloroquine to Brazil, writing: "it was our office that sent the donation of HCQ to Brazil several months ago where you and Jack were so helpful in getting it to the right place."128 Dr. Hatfill proceeded to outline how "[w]e here, have been fighting for HCQ since February" and had "now gone on the offensive and are implementing several strategies to get the EUA reinstated for HCQ here in the US." To support this effort, Dr. Hatfill requested that Dr. Zanotto coauthor a "good HCQ paper" and work to get a separate paper retracted. <sup>129</sup> Dr. Zanotto agreed to assist Dr. Hatfill in these efforts. <sup>130</sup> Days later, Dr. Hatfill updated Mr. Navarro on his conversations with Dr. Zanotto, telling Mr. Navarro that he learned from Dr. Zanotto "that all the HCQ we gave Brazil is still in a warehouse in Brazil slowly decaying because of heat." <sup>131</sup> Dr. Hatfill also reported to Dr. Risch that he was now "working with Dr Zonatto [sic] in Brazil" and that they could use "some data from there if it is needed" as they continued to press FDA to reauthorize hydroxychloroguine. 132

#### H. Mr. Navarro and Dr. Hatfill Aggressively Attacked Dr. Fauci and Other Federal Officials for Their Refusal to Support Hydroxychloroquine

As they were coordinating with conspiracists and waging a pressure campaign on FDA to reauthorize hydroxychloroquine, Mr. Navarro and Dr. Hatfill concurrently orchestrated an aggressive effort to attack and discredit Dr. Fauci, Dr. Hahn, and other senior officials who did not support the use of hydroxychloroquine to prevent or treat coronavirus infections. Newly released evidence shows that Dr. Hatfill and Mr. Navarro used their direct access to top public health officials in an attempt to strongarm them into supporting hydroxychloroquine. In emails obtained by the Select Subcommittee, Dr. Hatfill said he and Mr. Navarro were engaging in "constant fighting with Fauci and the FDA Commissioner Hahn," and other senior officials who did not support the use of hydroxychloroquine. In emails obtained by the Select Subcommittee, Dr. Hatfill said he and Mr. Navarro were engaging in "constant fighting with Fauci and the FDA Commissioner Hahn," and other senior officials who did not support the use of hydroxychloroquine in fections. Newly released evidence shows that Dr. Hatfill and Mr. Navarro used their direct access to top public health officials in an attempt to strongarm them into supporting hydroxychloroquine. In emails obtained by the Select Subcommittee, Dr. Hatfill said he and Mr. Navarro were engaging in "constant fighting with Fauci and the FDA Commissioner Hahn," and other senior officials who did not support the use of hydroxychloroquine in the properties of the use of hydroxychloroquine in the use of hydroxychloroquine in

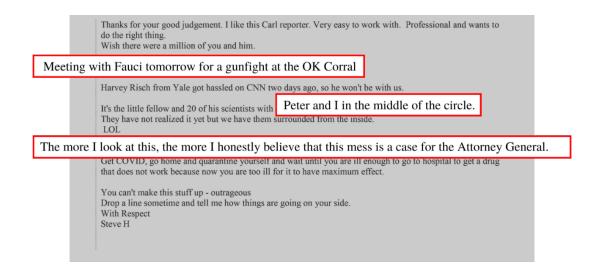
On July 16, 2020—two days after *USA Today* published an op-ed by Mr. Navarro attacking Dr. Fauci for being "wrong about everything I have interacted with him on," including the evidence for hydroxychloroquine <sup>135</sup>—Dr. Hatfill wrote to Garrett Ziegler, a Senior Policy Analyst working under Mr. Navarro who since leaving the White House has attacked Members of Congress on social media and been accused of doxxing federal agents who executed a search warrant on the former president's Mar-a-Lago property. <sup>136</sup> Dr. Hatfill said that he was searching for "ammunition" against Dr. Fauci and Dr. Hahn, and suggested that he was gearing up to attack the public health leaders at the direction of President Trump and Mr. Navarro, writing: <sup>137</sup>



On August 3, 2020, Dr. Hatfill contacted Dr. Risch—the pro-hydroxychloroquine professor whom Dr. Hatfill had recommended for Mr. Bannon's podcast—at Mr. Navarro's direction to strategize on a "2-phase approach" regarding Dr. Fauci. Dr. Hatfill proceeded to outline the contours of their plan: "I think the general concept is that Dr. Navarro wants a small team loosely put together that know each other a bit and can help reinforce each other, with each having their own particular area of practical expertise." Dr. Hatfill cited a paper Dr. Risch published on hydroxychloroquine and said, "I have no doubt that you are more than a match for Fauci in this area[.]" Dr. Hatfill later confided to an outside ally that he was working with a team of "underground cardiologists," whom Dr. Hatfill said he was using "to put more direct pressure shortly on the FDA and Fauci." 140

On August 4, 2020, Dr. Hatfill sent Mr. Navarro a draft "Letter for Fauci Reply," which detailed, among other things, Dr. Hatfill's disparaging "appraisal of the performance of yourself [Dr. Fauci] and Dr Hahn in supplying accurate advice to the President." That same day, Dr. Hatfill emailed leadership of AAPS, stating that tomorrow "I and 4 others will be in a sit-down drag out face-to-face fight with Fauci." Dr. Hatfill described this upcoming meeting as "the kick off to our formal fight over HCQ which is going to get really nasty." 142

Dr. Hatfill next contacted Sharyl Attkisson, a television host who used her Sinclair Broadcast Group-syndicated public affairs show to promote hydroxychloroquine, sharing a recent op-ed he authored attacking Dr. Fauci and Dr. Hahn for purportedly choosing "to ignore the ever accumulating and remarkable early-use data on hydroxychloroquine." Dr. Hatfill—who authored the op-ed without reference to his White House position—told Ms. Attkisson that he was gearing up for "a gunfight at the OK Corral" and pressed the notion that Dr. Fauci and other senior public health officials should be investigated over their position on hydroxychloroquine: 144



On August 5, 2020, Mr. Navarro tweeted a link to Dr. Hatfill's op-ed, calling it the "[b]est take down of anti-Trump Hydroxy Hysteria media" he had seen—without referencing the fact that Dr. Hatfill was working for him in the White House. 145

An agenda for an August 5, 2020, meeting of the NIH COVID-19 Treatment Guidelines Panel confirms that Mr. Navarro was invited to present "Perspectives on Hydroxychloroquine," despite being the only non-public health or medical expert listed in the agenda. He is we emails obtained by the Select Subcommittee reveal that Dr. Hatfill told Mr. Navarro after the meeting, "We were fed a load of bullshit." Dr. Hatfill proceeded to press for the immediate appointment of an "outside panel to review the Fauci Panel and the evidence they tried to feed us," and asserted that doing so would lay the predicate for a federal investigation, writing: "That would give ammunition for the AG [Attorney General] to start an investigation of the Fauci Panel—their emails and other communications. That would shut them up for a bit." Dr. Hatfill urged Mr. Navarro next to "pull Hahn in and ask him to re-establish the EUA based on the independent panel's findings and refutation of the Fauci panel. He is weak and will fold when he sees what is going on." Dr. Hatfill then expressly tied the timing of these actions to when voting in the November presidential election would begin, assuring Mr. Navarro: "Within 10-14 days of the start of HCQ outpatient treatment—figures should start to decrease," concluding: "Is that not about the same time that some sort of voting goes on??" 147

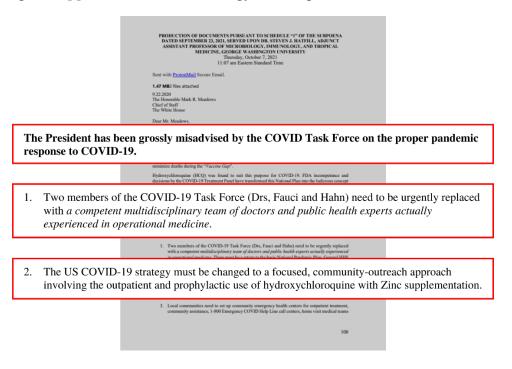
On August 7, 2020, Dr. Hatfill contacted Dr. Risch and continued to emphasize his call for a federal inquiry into his opponents, writing: "There are a bunch of things happening behind the scenes. There probably will be a time for the AG [Attorney General], but some other things have to happen first. Days later, Dr. Hatfill sent Ms. Miller in the White House an "Open Letter to Fauci Regarding the Use of Hydroxychloroquine for Treating COVID-19" that was signed by three doctors who were coordinating with Dr. Risch, in which they attacked Dr. Fauci for "reject[ing] the use of hydroxychloroquine." This letter was published online on August 13. 150

Dr. Hatfill's reckless attacks against those who opposed his views on hydroxychloroquine went beyond calling for federal investigations. In multiple instances during his White House tenure, Dr. Hatfill told Mr. Navarro and other White House officials that Dr. Fauci, Dr. Hahn,

and other public health officials were personally responsible for thousands of coronavirus deaths for their positions on hydroxychloroquine:

- In an email to Mr. Navarro, Dr. Hatfill claimed that Dr. Fauci, Dr. Hahn, and BARDA Director Dr. Rick Bright "have blood on their hands" for not supporting the widespread use of hydroxychloroquine. It appears Mr. Navarro forwarded this email to multiple White House officials, including Council of Economic Advisers Chairman Kevin Hassett.<sup>151</sup>
- Dr. Hatfill told Mr. Navarro on a separate occasion that "Fauci and Hahn have allowed thousands to die" for "blocking the early use of HCQ," contending "Americans will demand an explanation when this is realized." <sup>152</sup>
- Dr. Hatfill also forwarded to Mr. Snavely of AAPS a petition accusing Dr. Fauci and other White House Coronavirus Task Force members of perpetrating "crimes against humanity" and "mass murder" for being "insubordinate to POTUS" and purportedly having "blocked HCQ." The petition alleged that Dr. Fauci, Dr. Birx, Dr. Bright, and CDC Director Dr. Robert Redfield were responsible for "over 160k" deaths—and called on the Trump Administration to "bring these criminals to justice." 153

As the pressure campaign waged by Mr. Navarro and Dr. Hatfill failed to coerce FDA into reinstating its hydroxychloroquine EUA, Dr. Hatfill sought to remove those he viewed as impediments from the Administration altogether. In a letter to Mr. Meadows dated September 22, 2020, Dr. Hatfill called for Dr. Fauci and Dr. Hahn to be fired. In the letter, which was previously released by the Select Subcommittee, <sup>154</sup> Dr. Hatfill insisted that Dr. Fauci and Dr. Hahn had "grossly misadvised" President Trump and urged Mr. Meadows to make drastic changes to "[t]he US COVID-19 strategy," writing: <sup>155</sup>



Days later, Dr. Hatfill continued pressing for Dr. Fauci to be removed, forwarding Mr. Navarro an article about Dr. Fauci and writing, "You really need to consider what is likely to happen over the next 2 months if this little idiot and his COVID treatment panel is not fired." In an October 14 email to an HFHS representative regarding FDA's stance on hydroxychloroquine, Dr. Hatfill pledged that "[t]here will be a house cleaning after elections. [A] really good cleaning." 157

Many attacks against Dr. Hahn and Dr. Fauci were compiled in a manuscript that Dr. Hatfill and Mr. Navarro drafted over the course of the first year of the pandemic and circulated to other White House officials. The Select Subcommittee obtained copies of this report, titled, "Hydroxychloroquine Versus the China Virus and the High Costs of Hydroxy Hysteria," which ultimately spanned more than 50 pages in length. On December 15, 2020, Dr. Hatfill sent Mr. Navarro an updated draft of the report, stating that "Hahn and Fauci are going to find it is very lonely out there alone." Mr. Navarro sent a revised manuscript to his ProtonMail account days before the end of the Trump Administration, which assailed the purportedly "incorrect decisions by the FDA, Dr Fauci, and the COVID-19 Treatment Panel" for blocking widespread access to hydroxychloroquine and claimed: "Something more than medical science has been involved in the decisions that have been made concerning HCQ for early ambulatory treatment of patients with COVID-19." It concluded:

President Donald Trump, HHS Secretary Alex Azar, Dr. Robert Kadlec and the several dozen others who struggled behind the scenes to follow the National Pandemic Plan and enable the widespread outpatient access to an antiviral drug such as HCQ early in the outbreak, were 100% correct. <sup>160</sup>

During his transcribed interview with the Select Subcommittee, Assistant Secretary Kadlec denied that he was part of the effort to promote the use of hydroxychloroquine after the EUA was revoked, explaining that hydroxychloroquine "doesn't work." Dr. Kadlec stated that "hydroxychloroquine was a dead issue to me" after FDA revoked its EUA on June 16, 2020. 161

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HYDROXYCHLOROQUINE | CON

CONVALESCENT PLASMA

VACCINE GUIDANCE

## II. The Trump Administration's Push to Authorize Convalescent Plasma on the Eve of the Republican National Convention

While Trump White House officials pursued a self-described "knife fight" with FDA over hydroxychloroquine, another prospective coronavirus treatment caught the White House's attention, leading to additional conflict with senior public health leaders that ultimately left FDA's credibility further damaged.

Since March 2020, FDA had been interested in pursuing studies to determine whether convalescent plasma might be an effective coronavirus treatment, as it had been used to treat other infectious diseases and is generally considered to be a safe intervention. According to Dr. Hahn, FDA struggled to convince the academic community to perform randomized clinical trials, which would provide the type of data needed to reach a conclusive determination. As a result, FDA elected to initiate an expanded access program (EAP) with the Mayo Clinic in early April to gather real-world data on the efficacy of plasma as a coronavirus treatment.

Dr. Hahn told the Select Subcommittee during his transcribed interview that he spoke with President Trump directly about the status of a potential EUA for convalescent plasma, and that he and FDA CBER Director Dr. Peter Marks had discussions with officials working in Mr. Kushner's office about the timeline for FDA to issue an EUA. <sup>165</sup> Consistent with these statements, a text message obtained by the Select Subcommittee shows that Mr. Mango in HHS directed a senior FDA official to keep the White House communications team apprised of FDA's timing on an EUA, telling Ms. Lenihan on August 10, 2020, to "make sure Alyssa in WH comms understands the latest ETA on EUA for convalescent plasma." <sup>166</sup>

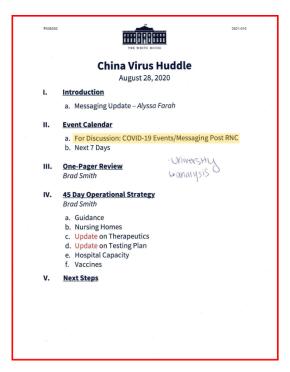
Although certain FDA officials were supportive of an EUA for convalescent plasma in the summer of 2020, concerns raised by other senior public health officials regarding what they perceived to be a lack of meaningful efficacy data on convalescent plasma as a coronavirus treatment led to what some Trump White House officials viewed as unnecessary—and politically motivated—delays. 167

#### A. NIH Officials Raised Concerns About Data on Convalescent Plasma, Delaying an EUA to the "Dismay" of President Trump

By the end of July 2020, FDA was considering a request to authorize convalescent plasma as a coronavirus treatment and was preparing to issue an EUA in or around the second week of August. On July 31, Assistant Secretary Kadlec sent FDA a letter of intent to "imminently submit" an EUA request for convalescent plasma. Less than two weeks later, Dr. Hahn was scheduled to brief members of the White House Coronavirus Task Force on the status of the EUA on the afternoon of August 12. However, some public health officials, including NIH Director Dr. Francis Collins, raised concerns about insufficient efficacy data on convalescent plasma for treating coronavirus infections. As a result, FDA elected to gather and review more data on the treatment before deciding whether to move forward with an EUA. 170

The Trump White House expressed anger at what was perceived to be an unnecessary delay in issuing an EUA. During his transcribed interview, Dr. Hahn told the Select Subcommittee that there was "a meeting at the White House about plasma, the data that we

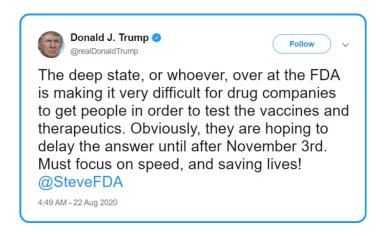
needed, this time schedule, et cetera," during which Dr. Collins said that President Trump had previously "express[ed] dismay over NIH potentially putting up roadblocks" to the timeline for FDA's authorization. According to reports, President Trump had told Dr. Collins, "You know, my polling numbers are looking really good.... But you doctors are killing me!" and called for the EUA to be completed by Friday, August 21, 2020—before the RNC was scheduled to begin on Monday, August 24—or else "it doesn't matter." A document obtained by the Select Subcommittee suggests that senior Trump White House officials discussed pandemic messaging and event planning in relation to the timing of the RNC: An August 28, 2020, agenda for a so-called "China Virus Huddle" meeting—where senior White House officials honed coronavirus messaging and discussed operational aspects of the response—listed as a top agenda item: "COVID-19 Events/Messaging Post RNC." 173



As senior FDA officials continued working to review the data on convalescent plasma, political appointees closely monitored the timing of a potential EUA. On August 19, 2020, Dr. Alexander, the Senior Advisor to Assistant Secretary Caputo, sent Dr. Hahn a table summarizing studies on convalescent plasma "as per our discussion today," telling Dr. Hahn that he was sharing this information in order "to help give us cover in our decisions" in granting an EUA. <sup>174</sup> Text messages obtained by the Select Subcommittee show that Ms. Lenihan contacted Ms. Amin, FDA's Chief Counsel, on August 21—President Trump's self-imposed EUA deadline—to convey Mr. Meadows's interest in FDA's timing on an EUA, telling Ms. Amin that she "[w]ould like to be able to tell Meadows it's done." <sup>175</sup> That same day, Dr. Marks informed Dr. Hahn that he expected to have the results of an analysis on new plasma samples completed by Sunday, August 23. <sup>176</sup>

When President Trump's deadline came and went without the issuance of an EUA, the president fired off a tweet on August 22, 2020, accusing FDA of deliberately stalling progress on

vaccines and therapeutics until after the presidential election and tagging Dr. Hahn's Twitter account: 177



Dr. Hahn told the Select Subcommittee that he was "disappointed" in President Trump's tweet, and that he reached out to Vice President Pence's Chief of Staff, Marc Short, for his advice on how to handle the situation. Dr. Hahn said that Mr. Short advised him to talk to President Trump directly. 178

Following this advice, Dr. Hahn told the Select Subcommittee that he initiated a call with President Trump on the afternoon of August 22, 2020, during which he told the president that "we either were nearing a decision or had made a decision" on the EUA. <sup>179</sup> That same day, Ms. Lenihan sent a text message to multiple senior HHS political appointees, stating: "potus said a lot of false remarks with Hahn today about what this was, so we need to make sure POTUS talkers are correct." Later that evening, Dr. Marks told Dr. Hahn via email that "the EUA should be signed off" by the following morning. Dr. Marks informed Dr. Hahn that the analysis of the plasma samples showed that "there is a 35% improvement in survival" after seven days for non-intubated patients under 80 years old who were treated within three days of diagnosis with high titer convalescent plasma. <sup>181</sup> Although not expressly stated in this email, the statistic cited by Dr. Marks reflected patients' relative improvement in survival as compared to those who were treated with lower titer convalescent plasma. <sup>182</sup>

Ultimately, the final decision was made to issue an EUA for convalescent plasma on the morning of August 23, 2020—the day before the start of the RNC. $^{183}$ 

## B. The White House Hastily Convened a Press Conference to Tout Convalescent Plasma, Grossly Misrepresenting the Data

Seeking to tout the EUA as a significant breakthrough before the start of the RNC, the White House quickly arranged a press conference in the White House briefing room on Sunday, August 23, 2020, featuring President Trump, Secretary Azar, and Commissioner Hahn. 184 FDA's press release announcing the EUA called it "Another Achievement in [the] Administration's Fight Against the Pandemic," even though Dr. Hahn later said in a public interview that the available data showed only a "small" survival benefit. 185

To prepare for the press conference, FDA's communications team—including Emily Miller, a political appointee and former reporter for One America News Network—drafted talking points for Dr. Hahn's use. <sup>186</sup> Days earlier, at the White House's insistence, Ms. Miller was appointed FDA's Assistant Commissioner for Media Affairs—a position that is typically filled by a career government official, not a political appointee. <sup>187</sup> Dr. Hahn told the Select Subcommittee that "it wasn't clear at the time whether the agency and I could say no" to the White House's recommendation to hire Ms. Miller. <sup>188</sup>

Hours before the start of the White House press conference, Dr. Hahn discussed with his team, including Ms. Miller, how to frame the data FDA had relied upon in deciding to grant the convalescent plasma EUA. In an August 23, 2020, email discussing his draft talking points previously released by the Select Subcommittee, Dr. Hahn told his team, "I like 35% increase in survival"—an apparent reference to the data cited by Dr. Marks the prior day. In response, Ms. Miller told Dr. Hahn to "[m]essage positive always" and to "phrase it in real language[.]" 189

At multiple points during the White House press conference, Commissioner Hahn, President Trump, and Secretary Azar each grossly misrepresented the efficacy data on convalescent plasma:

- Commissioner Hahn incorrectly stated the implications of the data: "What that means is—and if the data continue to pan out—100 people who are sick with COVID-19, 35 would have been saved because of the administration of plasma."
- President Trump falsely stated that the data from the Mayo Clinic showed that convalescent plasma "had an incredible rate of success" and "has proven to reduce mortality by 35 percent."
- Secretary Azar overstated the data, claiming: "We dream, in drug development, of something like a 35 percent mortality reduction. This is a major advance in the treatment of patients. This is a major advance." <sup>190</sup>

This press conference was met with severe backlash from leading public health experts. <sup>191</sup> As Dr. Eric Topol, the founder and director of the Scripps Research Translational Institute, detailed in an open letter to Dr. Hahn, "[e]very part" of the Commissioner's statement regarding the efficacy of convalescent plasma was "incorrect and a blatant misrepresentation of the data." One of the scientists at the Mayo Clinic who worked on the EAP told reporters that he had no idea where the statistic cited by Dr. Hahn during the press conference came from. <sup>193</sup> Despite the swift condemnation by the public health community, FDA continued pushing this grossly inaccurate statistic after the press conference, posting on an official Twitter account controlled by Ms. Miller: "Convalescent plasma has shown to be beneficial for 35% of patients."

Dr. Hahn told the Select Subcommittee that he recognized he needed to correct the false statements and issue a public apology soon after the press conference ended. On the advice of Wayne Pines—an FDA communications consultant who Dr. Hahn knew before he came to the agency—Dr. Hahn issued a series of tweets on August 24, 2020, 195 stating in part: 196



Dr. Hahn told the Select Subcommittee that he acted on his own accord in issuing this apology, and that it was not cleared through the "normal channels" in the Trump Administration. Dr. Hahn also said that he unilaterally decided to reassign Ms. Miller to a different position following the press conference, because she "became a story" and there was "a substantial amount of turmoil in the team," which was detracting from FDA's "ongoing efforts[.]" <sup>197</sup>

Dr. Hahn's apology caught many Trump Administration officials by surprise. Some expressed anger about the apology and rejected the notion that it was warranted. The next day, Dr. Alexander in HHS sent an email to Dr. Hahn and other senior FDA officials, asserting that "Dr. Hahn has no correction to make" because:

Dr. Hahn's statement on the 35% reduction is a **correct** one but it is based on relative risk reduction...that's the only clarification if needed but the doctors and scientists out there today in media stating that there are mistakes are **wrong**[.]<sup>199</sup>

HHS soon thereafter directed FDA to cancel its consulting contract with Mr. Pines, possibly in retaliation for his role in advising Dr. Hahn to issue the apology and correct the record.<sup>200</sup>

Neither President Trump nor Secretary Azar ever issued an apology or sought to correct the record following their statements during the August 23, 2020, press conference. During a hearing before the Select Subcommittee on October 2, 2020, Secretary Azar declined to accept responsibility for his role at the press conference.<sup>201</sup>

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## III. The Trump White House Attempted to Derail FDA's Vaccine Guidance Ahead of the Presidential Election and Pressed Commissioner Hahn on Vaccine Authorization

Heading into the fall of 2020, President Trump called repeatedly for a coronavirus vaccine to be authorized before the November 3 presidential election. Among other things, President Trump publicly acknowledged that "[i]t wouldn't hurt" to have a vaccine available before election day and told his supporters that a vaccine would be authorized "maybe before a special date. You know what date I'm talking about." Inside the White House, Mr. Meadows was acutely focused on FDA's timing for authorizing the first coronavirus vaccine. In a transcribed interview, Dr. Hahn told the Select Subcommittee that he had "multiple discussions with Mr. Meadows about the timeline" for a vaccine EUA, during which Mr. Meadows stated that he wanted FDA to "try to shrink this as much as possible." Dr. Hahn also told the Select Subcommittee that "President Trump expressed his desire for these to be approved as quickly as possible to save lives." 203

## A. The Trump White House Blocked FDA's Vaccine EUA Guidance for Multiple Weeks Due to "Objections" Over Its Impact on the Authorization Timeline

One of FDA's most consequential decisions on coronavirus vaccines concerned how long it would ask vaccine manufacturers to monitor clinical trial participants for any adverse events. Dr. Hahn told the Select Subcommittee that FDA decided in the summer of 2020 that it would issue guidance advising vaccine manufacturers to submit data from phase three clinical studies that included a median follow-up duration of at least two months (60 days) after the completion of the primary vaccination series. Dr. Hahn explained that FDA evaluated which duration to select based on a review of "the literature and our own experience with when toxicities would manifest themselves," after which the agency "came to the conclusion that 60 days was an appropriate measure for that." According to Dr. Hahn, FDA informally conveyed the substance of this surveillance guidance to manufacturers as they were constructing their phase three trials in the summer. But rather than endorsing FDA's gold-standard review process for ensuring vaccine safety, Trump White House officials blocked FDA from issuing the formal guidance for multiple weeks, resulting in an extended showdown with the agency.

After FDA informally conveyed to vaccine manufacturers the type of safety data they would need to collect in their clinical trials, FDA sent a draft of its formal vaccine EUA guidance, which included the recommended surveillance data, to HHS and the White House in September 2020 for review and approval. That month, nine pharmaceutical companies developing coronavirus vaccines issued a rare joint pledge to submit an EUA request only "after demonstrating safety and efficacy through a Phase 3 clinical study," as concerns grew surrounding Trump Administration officials' potential interference in FDA's review and authorization processes. At the time, only three companies had begun a phase three trial in the United States. It was increasingly evident that a median follow-up duration of 60 days after the primary vaccination series (which consisted of two doses spaced weeks apart for the vaccine candidates then in phase three trials) would result in FDA not authorizing a vaccine until after the presidential election. <sup>207</sup>

In a September 18, 2020, text message obtained by the Select Subcommittee, Ms. Lenihan at FDA indicated that she believed the Trump Administration would approve FDA's vaccine EUA guidance before Dr. Hahn testified before the Senate Committee on Health, Education, Labor, and Pensions later that month. Ms. Lenihan asked Ann Abram, FDA Deputy Commissioner for Policy, Legislation, and International Affairs, "How about vaccine guidance release Wed for the hearing." Ms. Abram asked if "SH [Stephen Hahn] on board?," to which Ms. Lenihan replied, "Yes[.]" Additional text messages from Ms. Lenihan indicate that the draft guidance was then sent to Mr. Mango in HHS on September 21, and that he was expected to "take a quick look and clear." However, the vaccine EUA guidance was not approved by the Trump Administration in September, and Dr. Hahn did not reference the surveillance data that FDA would request from vaccine EUA sponsors when he testified before the Senate on September 23. <sup>210</sup>

The Select Subcommittee's investigation has confirmed that the guidance was not approved at this time because multiple senior Trump Administration officials objected to the surveillance data called for by FDA. Dr. Hahn told the Select Subcommittee that officials in Secretary Azar's office at HHS and at the White House expressed concerns about whether two months of surveillance data was "appropriate." Beginning around mid-September 2020, Dr. Hahn said that FDA had multiple meetings and calls with Secretary Azar, Mr. Harrison, and Mr. Mango—none of whom are doctors or otherwise specialized in immunology or vaccinology—regarding the "timeline" and the "scientific and clinical rationale for the guidance." <sup>211</sup>

After the guidance was reviewed by the White House, Dr. Hahn said "[t]here were objections about it and there were suggestions made about adding additional language," including "pushback about the issue of the 60 days" of surveillance data. Dr. Hahn told the Select Subcommittee that these objections were lodged by multiple White House officials, including Mr. Meadows, who directed Dr. Hahn to discuss the guidance with a team at the White House and HHS, including Mr. Mango. Dr. Hahn said he met with this team on multiple occasions to discuss the guidance, during which "folks wanted us to consider making changes to it." Dr. Hahn said he "objected" to these requests because he believed the content of the guidance "needed to stay in the scientific and clinical domain" and because "any changes would be obviously reported and would further reduce vaccine confidence." 213

On September 23, 2020—the same day that FDA initially wanted to release the vaccine EUA guidance, according to Ms. Lenihan's text messages—Mr. Meadows reportedly called Dr. Hahn during a White House Coronavirus Task Force meeting to tell him that the White House would not sign off on the guidance because it would delay the timeline for when a vaccine could be authorized.<sup>214</sup> That evening, during a White House press conference, President Trump decried FDA's pending guidance as "a political move" that "has to be approved by the White House," which "may or may not approve it."<sup>215</sup>

With the fate of the guidance in serious doubt, Dr. Marks sent Dr. Hahn the World Health Organization's (WHO) proposed vaccine surveillance criteria that weekend, which called for manufacturers to accumulate more safety data than what FDA was proposing in its guidance. Dr. Marks told Dr. Hahn that "one could actually say that we are not as stringent" as the WHO's

criteria, and he asked to be kept informed if "anything develops over the weekend with the guidance." <sup>216</sup>

Nearly a week after President Trump publicly attacked the guidance as "a political move," the White House had still refused to sign off on its release. On September 29, 2020, Dr. Marks sent an email to Dr. Hahn and Ms. Lenihan, writing:

From: Marks, Peter <	@fda.hhs.gov>			
Sent: Tuesday, September	29, 2020 9:10 AM			
To: Lenihan, Keagan <	@fda.hhs.gov>; I	Hahn, Stephen	a.hhs.gov>	
Subject: Vaccine guidance				
Dear Commissioner and Ke	eagan,	14		*
	guidance? It would really be creating more problems that			
Best Regards,	i e			

Ms. Lenihan told Dr. Marks that Dr. Hahn was "continuing to push and call colleagues at WH and HHS" regarding the guidance. Dr. Marks proposed that they "make a decision to call this DOA or not" by the end of the day.<sup>217</sup>

Later that day, Dr. Marks sent Ms. Abernethy at FDA "an early draft of the vaccine surveillance plan," which was included in an appendix of a draft FDA briefing document for an upcoming meeting of FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), an outside group of experts that advises FDA on vaccine authorizations. The draft briefing document detailed a "Summary of Advice" that FDA had provided to vaccine manufacturers, which specifically noted that FDA had advised sponsors of a vaccine EUA request to submit phase three trial data "that includes a median follow-up duration of at least two months after completion of the full vaccination regimen to help provide adequate information to assess a vaccine's benefit-risk profile"—the same language that was contained in the formal guidance being blocked by the White House. <sup>219</sup>

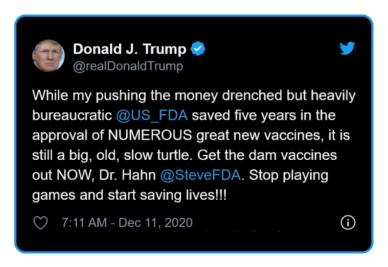
In the face of persistent White House stonewalling, FDA quietly released an informal set of VRBPAC briefing materials on October 6, 2020, which included the appendix summary of advice that Dr. Marks had circulated days earlier specifically acknowledging that the agency was calling for two months of surveillance data.<sup>220</sup> Dr. Hahn told the Select Subcommittee that FDA did not seek approval from HHS or the White House before issuing the briefing documents, but noted that he "proactively reached out to the White House to let them know that this was going."<sup>221</sup> Text messages obtained by the Select Subcommittee show that Ms. Lenihan contacted Mr. Mango on October 6, stating that the media would likely "link this release to the guidance we couldn't get out. Because it's the process and expectations on BLA [Biologics License Application] and EUA." Ms. Lenihan also indicated that Dr. Hahn had "just spoke with Meadows" about the release of the briefing documents.<sup>222</sup>

Dr. Hahn said he received a call from Mr. Meadows after FDA released these briefing materials to say that FDA's formal vaccine EUA guidance was now approved.<sup>223</sup> In a tweet that same day, President Trump explicitly tied FDA's authorization timeline for a vaccine to his political standing, calling FDA's guidance "another political hit job" that would "make it more difficult for them to speed up vaccines for approval before Election Day," tagging Dr. Hahn once again in the tweet.<sup>224</sup>

## B. The Trump White House Pressed Commissioner Hahn on Vaccine Authorization

Pfizer and BioNTech (Pfizer) announced on November 20, 2020, that it would submit an EUA request that day to FDA for its vaccine candidate—marking the first coronavirus vaccine EUA request filed in the United States. On December 1, as FDA's review of Pfizer's EUA application was ongoing, Fox News reporter John Roberts told Dr. Hahn: "WH is saying that you 'weren't taken to the woodshed' over the pace of EUA approval – but there was a vigorous discussion on the timeline and what could be done to further expedite it." Dr. Hahn forwarded the message to Mr. Meadows, who claimed it was "Totally made up." The next day, Dr. Hahn informed Mr. Meadows that "we received notice that the UK will issue a temporary authorization of the Pfizer vaccine," becoming the first Western country to authorize a coronavirus vaccine. In response to this news, Mr. Meadows directed Dr. Hahn and Dr. Marks to come to his office that day.

In the days that followed, Dr. Hahn and Mr. Meadows communicated regularly regarding FDA's progress on the Pfizer vaccine EUA application. On December 10, 2020, FDA's VRBPAC held a meeting to review and discuss Pfizer's EUA request. That evening, after the VRBPAC meeting concluded, Mr. Meadows sent Dr. Hahn a text message asking him to "Give me a call." Later that evening, Dr. Hahn told Mr. Meadows that "we made the decision to move forward with the EUA," and that the "[v]accine can be administered after EUA issued." Early on the morning of December 11, prior to any FDA announcement on the Pfizer EUA, President Trump sent a tweet demanding that Dr. Hahn "Get the dam [sic] vaccines out NOW...." 232



Following this tweet, Mr. Meadows sent three text messages to Dr. Hahn that day, repeatedly telling the Commissioner to call him: <sup>233</sup>

	(b)(6) Messages]	
From: To: Date:	Mark Meadows (b)(6) messages"> Stephen Hahn (b)(6) messages"> Fri, 11 Dec 2020 07:59:42 -0500	
Give me a d	call	
2020-1	2-11 17:13:25 UTC: (b)(6) (b)(6) Messages]	Messages ->
From: To: Date:	Mark Meadows (b)(6) messages"> Stephen Hahn (b)(6) messages"> Fri, 11 Dec 2020 12:13:25 -0500	
Call me		
2020-1	2-11 19:20:51 UTC: (b)(6) (b)(6) Messages]	Messages ->
	Mark Meadows (b)(6) messages">	

In a transcribed interview, Dr. Hahn told the Select Subcommittee that he received a call around this time from Mr. Meadows, who emphasized in a "very demonstrative" manner that he wanted FDA to issue an EUA for the Pfizer vaccine as quickly as possible. Dr. Hahn said that Mr. Meadows also made a "truncated statement" during the call that he thought "could be perhaps related to my position" as FDA Commissioner. Dr. Hahn said he asked Mr. Meadows for "clarification about my position," but Mr. Meadows hung up without elaborating. These statements are consistent with press reports documenting that Mr. Meadows demanded Dr. Hahn's resignation if FDA did not authorize Pfizer's vaccine by the end of the day on December 11, 2020. Dr. Hahn said he had another call with Mr. Meadows later that day, during which they discussed media reports regarding their initial call, which "had already been leaked to the press." FDA ultimately issued an EUA for Pfizer's vaccine on December 11. 238

Based on his experience leading FDA during the Trump Administration, Dr. Hahn told the Select Subcommittee:

I think strong consideration needs to be made for the independence of FDA from Health and Human Services. That ultimately, at the end of the day, an agency that is in a situation where scientific decisions can be reversed, I've always been – it's problematic to me. <sup>239</sup>

\* \* \*

The Trump Administration's nearly year-long crusade against FDA resulted in damaging consequences for the coronavirus response: Morale inside the agency cratered, and public confidence in FDA's scientific integrity was shaken in the midst of a once-in-a-century pandemic. <sup>240</sup> In his transcribed interview with the Select Subcommittee, Dr. Hahn elaborated on the concerns he held regarding the public's waning confidence in FDA's work during the pandemic:

I was concerned about the entire environment: A presidential election, bitter divisions in the country and in Congress. And, to me, it was a pretty significant combination of factors that led to a decrease in science and confidence in science and medicine, et cetera.<sup>241</sup>

Reflecting on President Trump disparaging FDA scientists as being part of the "deep state"—when they were, in reality, working tirelessly to ensure that safe and effective coronavirus vaccines, treatments, and diagnostics would be made available to the American people as quickly as the science allowed—Dr. Hahn explained the toll these relentless attacks had taken on the civil servants inside his agency:

[T]hey had been working really hard, our workload had doubled, and they also were worried about the potential impact that it would have on the public perception of the agency. There's a lot of pride at the agency and what they do.<sup>242</sup>

The open hostility displayed by President Trump and his allies toward the historically non-political agency served not only to diminish the long-term standing of the nation's public health institutions, it catalyzed a broader anti-science movement throughout the country. Long after President Trump left the White House, unfounded conspiracy theories about coronavirus vaccines and junk science touting disproven cures continue to proliferate, particularly on the internet. This type of misinformation needlessly prolonged the most acute phase of the pandemic and is still pushing countless Americans to reject science-based tools that would greatly decrease their chances of experiencing serious coronavirus outcomes. The anti-science movement that spreads these dangerous misconceptions is now taking hold in state legislatures across the country: According to one analysis, legislators in at least 30 states have introduced bills seeking either to limit the ability of health boards to penalize providers who promote disproven coronavirus treatments like hydroxychloroquine, or to explicitly authorize providers to prescribe and dispense disproven drugs for coronavirus patients.

If not meaningfully addressed, this hyper-politicization of public health—and reflexive embrace of anti-scientific dogma pushed by those who have trusted President Trump, his top advisers, and his most prominent supporters—will continue to constrain the country's ability to overcome public health threats, especially from a novel highly infectious disease that requires a concerted, collective response.

\* \* \*

- <sup>3</sup> See, e.g., Fact-checking Trump's Claims About Hydroxychloroquine, the Antimalarial Drug He's Touting as a Coronavirus Treatment, StatNews (Apr. 6, 2020) (online at www.statnews.com/2020/04/06/trump-hydroxychloroquine-fact-check/).
- <sup>4</sup> Trump Administration Not Ruling Out Domestic Travel Restrictions Amid Coronavirus Pandemic, The Ingraham Angle, Fox News (Mar. 16, 2020) (online at www.foxnews.com/transcript/trump-administration-not-ruling-out-domestic-travel-restrictions-amid-coronavirus-pandemic).
- <sup>5</sup> Email from Laura Ingraham to Jared Kushner, Senior Adviser, The White House (Mar. 18, 2020) (010P-R000014086\_0001) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.03.18\_010P-R000014086\_0001\_Redacted.pdf).
- <sup>6</sup> Email from Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services, to Alex Azar, Secretary, Department of Health and Human Services, Stephen Hahn, Commissioner, Food and Drug Administration, and Brian Harrison, Chief of Staff, Department of Health and Human Services (Mar. 18, 2020) (SSCC-0037728) (online at <a href="https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.03.18\_SSCC-0037728">https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.03.18\_SSCC-0037728</a> Redacted.pdf).
- <sup>7</sup> The White House, *Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing* (Mar. 19, 2020) (online at https://web.archive.org/web/20200319223012/https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-6/).
- <sup>8</sup> Philippe Gautret, et al., *Hydroxychloroquine and Azithromycin as a Treatment of COVID-19: Results of an Open-Label Non-Randomized Clinical Trial*, International Journal of Antimicrobial Agents (Mar. 20, 2020) (online at https://doi.org/10.1016/j.ijantimicag.2020.105949); *see e.g.*, 'This is Insane!' Many Scientists Lament Trump's Embrace of Risky Malaria Drugs for Coronavirus, Science (Mar. 26, 2020) (online at www.science.org/content/article/insane-many-scientists-lament-trump-s-embrace-risky-malaria-drugs-coronavirus). The academic organization that published this study later said it "does not meet the Society's expected standard, especially relating to the lack of better explanations of the inclusion criteria and the triage of patients to ensure patient safety." International Society of Antimicrobial Chemotherapy, Statement on IJAA Paper (Apr. 3, 2020) (online at www.isac.world/news-and-publications/official-isac-statement).
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- <sup>10</sup> The American Presidency Project, *Donald J. Trump: Tweets of March 21, 2020* (Mar. 21, 2020, at 14:13:09) (online at www.presidency.ucsb.edu/documents/tweets-march-21-2020) (accessed Aug. 20, 2022).

<sup>&</sup>lt;sup>1</sup> Select Subcommittee on the Coronavirus Crisis, *The Atlas Dogma: The Trump Administration's Embrace of a Dangerous and Discredited Herd Immunity Via Mass Infection Strategy* (June 21, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.06.21%20The%20Trump%20Administration%E2%80%99s%20Embrace%20of%20a%20Dangerous%20and%20Discredited%20Herd%20Immunity%20via%20Mass%20Infection%20Strategy.pdf).

<sup>&</sup>lt;sup>2</sup> See, e.g., Trump's Aggressive Advocacy of Malaria Drug for Treating Coronavirus Divides Medical Community, New York Times (Apr. 6, 2020) (online at www.nytimes.com/2020/04/06/us/politics/coronavirus-trump-malaria-drug.html); The White House, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020) (online at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/); Centers for Disease Control and Prevention, Medicines for the Prevention of Malaria While Traveling - Hydroxychloroquine (Plaquenil) (Jan. 4, 2013) (online at https://stacks.cdc.gov/view/cdc/27956); Centers for Disease Control and Prevention, Medicines for the Prevention of Malaria While Traveling - Chloroquine (Aralen) (Jan. 4, 2013) (online at https://stacks.cdc.gov/view/cdc/27954).

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- <sup>12</sup> Email from Roberto Mignone, Director, Teva Pharmaceutical Industries Ltd., to Nitin Saigal, Founder, Kora Management(Mar. 24, 2020) (010P-R000014085\_0001) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.03.25\_010P-R000014085\_0001\_Redacted.pdf).
- <sup>13</sup> Email from Stephen Hahn, Commissioner, Food and Drug Administration, to Deborah L. Birx, Coronavirus Response Coordinator, The White House (Mar. 22, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.03.22\_NoBates\_Redacted.pdf); see also Email from Mehmet Oz to Deborah L. Birx, Coronavirus Response Coordinator, The White House (010P-R000014077\_0001) (Mar. 22, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.03.22\_010P-R000014077\_0001\_Redacted.pdf).
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- <sup>17</sup> Letter from Denise M. Hinton, Chief Scientist, Food and Drug Administration, to Rick Bright, Director, Biomedical Advanced Research and Development Authority, Office of Assistant Secretary for Preparedness and Response, Department of Health and Human Services (Mar. 28, 2020) (online at www.fda.gov/media/136534/download).
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- <sup>20</sup> Email from Stephen M. Smith to Stephen Hahn, Commissioner, Food and Drug Administration (Apr. 5, 2020) (SSCC-0037735) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.04.05\_SSCC-0037735 Redacted.pdf).
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- <sup>26</sup> Text message from Amy Abernethy, Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration, to Stephen Hahn, Commissioner of Food and Drugs, Food and Drug Administration (Apr. 13, 2020) (SSCC-0036432) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.04.08%20-%20SSCC-0036429%20%5bText%20Messages%20from%20Dr.%20Abernethy%5d%20FN%203%20+%20FN%204.pdf); see also Text messages from Amy Abernethy, Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration, to Stephen Hahn, Commissioner of Food and Drugs, Food and Drug Administration (Apr. 8, 2020)

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.04.08%20-%20SSCC-0036429%20%5bText%20Messages%20from%20Dr.%20Abernethy%5d%20FN%203%20+%20FN%204.pdf).

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- <sup>36</sup> Defendant's Motion to Dismiss the Indictment, 1 (Aug. 17, 2022), *United States v. Navarro*, D.D.C. (No. 1:22-cr-00200); *see also* Letter from Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis, to Peter K. Navarro, Former Director of the White House Office of Trade and Manufacturing Policy (Sept. 14, 2021) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021-09-14.Clyburn%20to%20Peter%20Navarro%20re%20Production%20Request.pdf).
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- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021.09.23%20Memorandum%20from% 20Chairman%20Clyburn%20re%20S.%20Hatfill%20Subpoena.pdf); see, e.g., Email from Steven J. Hatfill to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Mar. 6, 2020) (GWU-0009118) (Dr. Hatfill providing a list of "Suggested Urgent Actions" to Mr. Navarro regarding the coronavirus in early March 2020).
- <sup>38</sup> Dr. Steven Hatfill, *How a Single Point Failure Destroyed the National Pandemic Plan* (Apr. 28, 2021) (online at https://drstevenhatfill.com/how-a-single-point-failure-destroyed-the-national-pandemic-plan/); Dr. Steven Hatfill, *Open Letter to America* (June 8, 2021) (online at https://drstevenhatfill.com/open-letter-to-america/); Dr. Steven Hatfill, *Single Point Failure II: The Role of Dr. Anthony Fauci in the Destruction of the National Pandemic Plan* (May 25, 2021) (online at https://drstevenhatfill.com/single-point-failure-2-the-role-of-dr-anthony-fauci-in-the-destruction-of-the-national-pandemic-plan/).
- <sup>39</sup> Dr. Hatfill used an Executive Office of the President email account named "MBX WHO SR Adv for Pol COVID Action" during his tenure in the White House. *See, e.g.*, Email from Steven J. Hatfill (Aug. 19, 2020) (GWU-0003574) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.19%20-%20GWU-0003574\_Redacted.pdf); Email from Steven J. Hatfill (Aug. 14, 2020) (GWU-0004305) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.14 GWU-

0004305\_Redacted.pdf). Dr. Hatfill periodically signed emails sent from his other email accounts with the initials "MBX." *See, e.g.*, Email from Steven J. Hatfill to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Aug. 4, 2020) (GWU-0006804) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.04 GWU-

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(July 16, 2020) (GWU-0012524) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.16\_GWU-0012524 Redacted.pdf).

<sup>40</sup> See, e.g., Email from Steven J. Hatfill (May 24, 2020) (GWU-0005120) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.05.25%20-%20GWU-0005120\_Redacted.pdf) ("I made a quick trip to [sic] up to Washington DC in Mid January --- and have now been stuck here working at the White House since then, and I mean stuck here-up to 18 hours a day, 7 days a week, working on the pandemic."); Email from Steven J. Hatfill (June 2, 2020) (GWU-0007967) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.06.02%20-%20GWU-0007967\_Redacted.pdf) ("Working 14h /7 / 365 since mid January[.] They fly me around sometimes on private jets to sort shit out. Seeing the good and the bad and what needs to be fixed."); Email from Steven J. Hatfill (Aug. 19, 2020) (GWU-0003574) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.19%20-%20GWU-0003574\_Redacted.pdf) ("I am at the White House working in an Office to fix this problem. I have been working there for the last 5 months, an average of 10 hours a day, 7-days a week, unpaid, as the senior medical advisor to one of the President's Senior Advisors. My email there is [Redacted]@who.eop.gov."). See generally Memorandum

of the President's Senior Advisors. My email there is [Redacted]@who.eop.gov."). See generally Memorandum from Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis, to Members of the Select Subcommittee on the Coronavirus Crisis, Issuance of Subpoena to Dr. Steven J. Hatfill (Sept. 23, 2021) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021.09.23%20Memorandum%20from% 20Chairman%20Clyburn%20re%20S.%20Hatfill%20Subpoena.pdf).

<sup>41</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf); see also Email from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration (May 5, 2020) (FDA-OC\_FOI\_2020-6423\_003672) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.05.05\_FDA-OC\_FOI\_2020-6423\_003672.pdf) (text messages from Ms. Lenihan to Dr. Hahn informing him that "Navarro wants to chat with you" regarding "HCQ").

- <sup>42</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%20Stephen%20Hahn%20-%20Redacted.pdf).
- <sup>43</sup> Email from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Stacy Amin, Chief Counsel, Food and Drug Administration (June 16, 2020) (FDA-OC\_FOI\_2020-6423\_003299) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.06.16\_FDA-OC\_FOI\_2020-6423\_003299.pdf).
- <sup>44</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf); Email from Steven J. Hatfill to William O'Neill, Cardiologist, Henry Ford Health System (May 20, 2020) (GWU-0006089) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.05.20\_GWU-0006089\_Redacted.pdf); Henry Ford Health, *Find a Doctor or Provider: William W. O'Neill, MD* (online at www.henryford.com/physician-directory/o/o-neill-william).

<sup>45</sup> Email from William O'Neill, Cardiologist, Henry Ford Health System, to Steven J. Hatfill (Apr. 9, 2020) (GWU-0014014) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.04.09 GWU-

0014014\_Redacted.pdf); see also Email from Steven J. Hatfill, to William O'Neill, Cardiologist, Henry Ford Health System (Apr. 9, 2020) (GWU-0014026) (online at

0014026\_Redacted.pdf); Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%20Stephen%20Hahn%20-%20Redacted.pdf).

- 46 Email from Steven J. Hatfill to William O'Neill, Cardiologist, Henry Ford Health System (Apr. 16, 2020) (GWU-0015061) (online at https://eoronavirus.house.gov/files/democrats.coronavirus.house.gov/files/2020.04.16. GWI
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.04.16\_GWU-0015061 Redacted.pdf).
- <sup>47</sup> Email from Steven J. Hatfill to Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House (July 6, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.06\_Hatfill%20p.217-246\_Redacted.pdf); *see also* Email from Steven J. Hatfill to Steven J. Hatfill (June 26, 2020) (GWU-0004949) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.06.26\_GWU-0004949 Redacted.pdf).
- <sup>48</sup> Email from Steven J. Hatfill to William O'Neill, Cardiologist, Henry Ford Health System (June 28, 2020) (GWU-0012103) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.06.29\_GWU-0012103 Redacted.pdf).
- <sup>49</sup> Email from Steven J. Hatfill to Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House (July 6, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.06\_Hatfill%20p.217-246 Redacted.pdf).
- <sup>50</sup> Email from Steven J. Hatfill (July 3, 2020) (GWU-0011516) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.03\_GWU-0011516\_Redacted.pdf); Email from Jeremy Snavely, Business Manager, Association of American Physicians and Surgeons, to Willie Soon (July 8, 2020) (GWU-0004583) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.08\_GWU-0004583 Redacted.pdf).
- <sup>51</sup> Email from Steven J. Hatfill to William O'Neill, Cardiologist, Henry Ford Health System (May 28, 2020) (GWU-0008407) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.05.28\_GWU-0008407 Redacted.pdf).
- <sup>52</sup> Samia Arshad, et al., *Treatment with Hydroxychloroquine, Azithromycin, and Combination in Patients Hospitalized with COVID-19*, International Journal of Infectious Diseases (July 1, 2020) (online at https://doi.org/10.1016/j.ijid.2020.06.099); *see also* Email from William O'Neill, Cardiologist, Henry Ford Health System, to Steven J. Hatfill (June 29, 2020) (GWU-0012103) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.06.29\_GWU-0012103\_Redacted.pdf); Email from Steven J. Hatfill to William O'Neill, Cardiologist, Henry Ford Health System (July 1, 2020) (GWU-0011795) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.01\_GWU-0011795\_Redacted.pdf).
- <sup>53</sup> Select Subcommittee on the Coronavirus Crisis, *Hearing on "The Urgent Need for a National Plan to Contain the Coronavirus"* (July 31, 2020) (online at https://coronavirus.house.gov/subcommittee-activity/hearings/hybrid-hearing-urgent-need-national-plan-contain-coronavirus); *Researchers Publish Scathing Critique of a Hydroxychloroquine Study Touted by the White House*, CNN (July 31, 2020) (online at www.cnn.com/2020/07/31/health/hydroxychloroquine-study-henry-ford-letters/index.html); *After Fauci Criticism, Henry Ford Health Clams Up on Hydroxychloroquine Study*, Detroit Free Press (Aug. 3, 2020) (online at www.freep.com/story/news/health/2020/08/03/henry-ford-fauci-trump-hydroxychloroquine-covid-19/5573656002/).

<sup>54</sup> Email from Steven J. Hatfill to John McKinnon, Senior Staff Infectious Diseases, Henry Ford Hospital, Marcus Zervos, Infectious Disease Specialist, Henry Ford Health System, Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House, and William O'Neill, Cardiologist, Henry Ford Health System (July 2, 2020) (GWU-0011749) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.02\_GWU-0011749 Redacted.pdf) (emphasis in original).

<sup>55</sup> *Id*.

- <sup>56</sup> Email from Steven J. Hatfill to Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House (July 2, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.02\_Hatfill%20p.273-274 Redacted.pdf).
- <sup>57</sup> Email from John McKinnon, Senior Staff Infectious Diseases, Henry Ford Hospital, to Marcus Zervos, Infectious Disease Specialist, Henry Ford Health System, Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House, William O'Neill, Cardiologist, Henry Ford Health System, and Steven J. Hatfill (July 2, 2020) (GWU-0011749) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.02\_GWU-0011749 Redacted.pdf).
- <sup>58</sup> FDA Denies Henry Ford Health Request to Use Hydroxychloroquine for COVID-19 Patients, Detroit Free Press (Aug. 13, 2020) (online at www.freep.com/story/news/health/2020/08/13/henry-ford-health-hydroxychloroquine-covid-fda/3360940001/).
- <sup>59</sup> Trump Tweets Support of Henry Ford Study, Doctors Warn Against Politicizing Medicine, Detroit Free Press (July 7, 2020) (online at www.freep.com/story/news/health/2020/07/07/trump-support-henry-ford-hydroxychloroquine-study/5389515002/); see also Text from Stacy Amin, Chief Counsel, Food and Drug Administration, to Keagan Lenihan, Chief of Staff, Food and Drug Administration, and Stephen Hahn, Commissioner, Food and Drug Administration (July 8, 2020) (FDA-OC\_FOI\_2020-6423\_004298) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.08\_FDA-OC\_FOI\_2020-6423\_004298.pdf).
- 60 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Scott Atlas (Jan. 7, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Transcribed%20Interview%20of%20Scot t%20Atlas.pdf). Despite having embraced a number of other discredited theories about the coronavirus, Dr. Atlas told the Select Subcommittee that he informed President Trump at the time with respect to hydroxychloroquine that "there's no proof that it works" and that he "did not think it was advisable to say that it worked, because it wasn't proven to work." *Id.*
- <sup>61</sup> Trump Retweeted a Video with False COVID-19 Claims. One Doctor in It Has Said Demons Cause Illnesses, Washington Post (July 29, 2020) (online at www.washingtonpost.com/technology/2020/07/28/stella-immanuel-hydroxychloroquine-video-trump-americas-frontline-doctors/). Facebook, YouTube, and Twitter all removed the video from their respective platforms for violating policies against spreading misinformation. Id.
- <sup>62</sup> FDA Denies Henry Ford Health Request to Use Hydroxychloroquine for COVID-19 Patients, Detroit Free Press (Aug. 13, 2020) (online at www.freep.com/story/news/health/2020/08/13/henry-ford-health-hydroxychloroquine-covid-fda/3360940001/).
- <sup>63</sup> Email from Steven J. Hatfill to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House (June 16, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.06.16\_Hatfill%20p.321-322\_Redacted.pdf).
- <sup>64</sup> Email from Robert Charrow, General Counsel, Department of Health and Human Services, to Judy Stecker, Deputy Chief of Staff, Strategy and Operations, Department of Health and Human Services, Laura Pence, Senior Advisor, Department of Health and Human Services, Michael Caputo, Assistant Secretary for

Public Affairs, Department of Health and Human Services, Paul Mango, Deputy Chief of Staff for Policy, Department of Health and Human Services, and Carol Danko, Department of Health and Human Services (July 28, 2020) (SSCC-0042085) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.28\_SSCC-0042085\_Redacted.pdf).

<sup>65</sup> Email from Paul Alexander, Senior Advisor, Department of Health and Human Services, to Michael Caputo, Assistant Secretary for Public Affairs, Department of Health and Human Services, et al. (July 28, 2020) (SSCC-0040801) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.28\_SSCC-0040801\_Redacted.pdf); see also Email from Paul Alexander, Senior Advisor, Department of Health and Human Services, to Stephen Hahn, Commissioner, Food and Drug Administration (July 20, 2020) (SSCC-0040905) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.20\_SSCC-

0040905\_Redacted.pdf) (Dr. Alexander urged Dr. Hahn to "put provisos in an EUA" for hydroxychloroquine that stated "this is up to a doctor and their patient on a case by case basis...").

<sup>66</sup> Email from Paul Alexander, Senior Advisor, Department of Health and Human Services, to Judy Stecker, Deputy Chief of Staff, Operations and Strategy, Department of Health and Human Services, and Laura Pence, Senior Advisor, Department of Health and Human Services (July 28, 2020) (SSCC-0042085) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.28\_SSCC-0042085) Redacted.pdf).

<sup>67</sup> Email from Paul Alexander, Senior Advisor, Department of Health and Human Services, to Madeleine Hubbard (July 28, 2020) (SSCC-0040804) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.28\_SSCC-0040804 Redacted.pdf).

<sup>68</sup> Email from Judy Stecker, Deputy Chief of Staff, Strategy and Operations, Department of Health and Human Services, to Laura Pence, Senior Advisor, Department of Health and Human Services, et al. (July 28, 2020) (SSCC-0040901) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.28 SSCC-

0040901\_Redacted.pdf); see also Email from Joanna Miller, Policy Analyst, The White House, to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House, and Steven Hatfill (Sept. 10, 2020) (GWU-0009538) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.10\_GWU-0009538\_Redacted.pdf) (White House officials circulating an interview of Dr. Hahn where he stated FDA "does not regulate the practice of medicine"); Email from Steven Hatfill to Joanna Miller, Policy Analyst, The White House (Sept. 10, 2020) (GWU-0009604) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.10\_GWU-0009604\_Redacted.pdf).

<sup>69</sup> Email from Judy Stecker, Deputy Chief of Staff, Strategy and Operations, Department of Health and Human Services, to Laura Pence, Senior Advisor, Department of Health and Human Services, et al. (July 29, 2020) (SSCC-0040814) (online at

 $https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.29\_SSCC-0040814\_Redacted.pdf).$ 

<sup>70</sup> Email from Steven J. Hatfill to William O'Neill, Cardiologist, Henry Ford Health System (May 21, 2020) (GWU-0005786) (online at

 $https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.05.21\_GWU-0005786~Redacted.pdf).$ 

<sup>71</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Robert Kadlec (May 19, 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/TI%20Excerpts%20Kadlec.pdf). *See generally Scientist Is Paid Millions by U.S. in Anthrax Suit*, New York Times (June 28, 2008) (online at www.nytimes.com/2008/06/28/washington/28hatfill.html).

- <sup>72</sup> Email from Steven J. Hatfill to William O'Neill, Cardiologist, Henry Ford Health System (May 23, 2020) (GWU-0005584) (online at
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.05.23\_GWU-0005584\_Redacted.pdf): National Institutes of Health National Library of Medicine Clinical Trials
- 0005584\_Redacted.pdf); National Institutes of Health, National Library of Medicine, ClinicalTrials.gov, *Will Hydroxychloroquine Impede or Prevent COVID-19 (WHIP COVID-19)* (Apr. 10, 2020) (online at https://clinicaltrials.gov/ct2/show/study/NCT04341441).
- <sup>73</sup> Email from Steven J. Hatfill to William O'Neill, Cardiologist, Henry Ford Health System (May 25, 2020) (GWU-0005114) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.05.25 GWU-
- <sup>74</sup> Henry Ford Study on Hydroxychloroquine for COVID-19 Quietly Shut Down, Detroit Free Press (Jan. 11, 2021) (online at www.freep.com/story/news/health/2021/01/11/henry-ford-study-hydroxychloroquine-covid-19/6625541002/); see also John E. McKinnon, et al., Safety and Tolerability of Hydroxychloroquine in Health Care Workers and First Responders for the Prevention of COVID-19: WHIP COVID-19 Study, International Journal of Infectious Diseases (March 2022) (online at https://doi.org/10.1016%2Fj.ijid.2021.12.343).
- <sup>75</sup> Email from Steven J. Hatfill (Aug. 14, 2020) (GWU-0004305) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.14\_GWU-0004305 Redacted.pdf).

0005114\_Redacted.pdf).

- <sup>76</sup> Email from Joanna Miller, Senior Policy Analyst, The White House, to Steven J. Hatfill (Aug. 15, 2020) (GWU-0003996) (online at
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.15 GWU-
- 0003996\_Redacted.pdf); Email from Steven J. Hatfill to Joanna Miller, Senior Policy Analyst, The White House (Aug. 15, 2020) (GWU-0001417) (online at
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.15 GWU-0001417-
- 1423\_Redacted.pdf); Email from Steven J. Hatfill to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Sept. 15, 2020) (GWU-0001415) (online at
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.15\_GWU-0001415 Redacted.pdf).
- The White House (Aug. 23, 2020) (GWU-0005341) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.23\_GWU-0005341 Redacted.pdf).
- <sup>78</sup> Email from Steven J. Hatfill to Steven J. Hatfill (Aug. 17, 2020) (GWU-0003662) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.17\_GWU-0003662\_Redacted.pdf); *see also* Email from Steven J. Hatfill to Harvey Risch, Professor Emeritus of Epidemiology, Yale School of Public Health (Aug. 24, 2020) (GWU-0007689) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.24\_GWU-0007689 Redacted.pdf) (Dr. Hatfill noting he "applied for 5 mil for a study").
- <sup>79</sup> Email from Steven J. Hatfill to Christopher J. Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Sept. 23, 2020) (GWU-0005338) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.23\_GWU-0005338\_Redacted.pdf).
- <sup>80</sup> Email from Steven J. Hatfill to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Sept. 23, 2020) (GWU-0005341) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.23\_GWU-0005341\_Redacted.pdf).
- <sup>81</sup> Email from Steven J. Hatfill to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Sept. 15, 2020) (GWU-0001415) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.15 GWU-

- 0001415\_Redacted.pdf); Email from Steven J. Hatfill to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Sept. 23, 2020) (GWU-0005341) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.23\_GWU-0005341 Redacted.pdf).
  - 82 See Complaint (Aug. 3, 2022), United States v. Navarro, D.D.C. (No. 1:22-cv-2292).
  - 83 44 U.S.C. § 2209(a).
- <sup>84</sup> Memorandum from Stefan C. Passantino, Deputy Counsel to the President, Compliance and Ethics, The White House, et al., to White House Personnel, Presidential Records Act Obligations (Feb. 22, 2017) (online at https://www.archives.gov/files/foia/Memo%20to%20WH%20Staff%20Re%20Presidential%20Records%20Act%20 (Trump,%2002-22-17) redacted%20(1).pdf).
- <sup>85</sup> FDA Denies Henry Ford Health Request to Use Hydroxychloroquine for COVID-19 Patients, Detroit Free Press (Aug. 13, 2020) (online at www.freep.com/story/news/health/2020/08/13/henry-ford-health-hydroxychloroquine-covid-fda/3360940001/).
- <sup>86</sup> Email from Steven J. Hatfill to Senator Ron Johnson (Aug. 16, 2020) (GWU-0003885) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.16\_GWU-0003885 Redacted.pdf).
- <sup>87</sup> Email from Steven J. Hatfill to Peter A. McCullough, Baylor University Medical Center (Aug. 9, 2020) (GWU-0004841) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.09\_GWU-0004841 Redacted.pdf).
- <sup>88</sup> Email from Garrett Ziegler, Senior Policy Analyst, The White House, to Steven J. Hatfill (Oct. 16, 2020) (GWU-0006344 at 0006372) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.10.16\_GWU-0006344%20at%200006372 Redacted.pdf).
- <sup>89</sup> Letter from Senator Ron Johnson, Senator Mike Lee, and Senator Ted Cruz, to the Honorable Stephen Hahn, Commissioner, Food and Drug Administration (Aug. 18, 2020) (online at https://www.hsgac.senate.gov/imo/media/doc/2020-08-18%20RHJ%20Letter%20to%20FDA%20on%20HCQ%20+%20CQ.pdf). In an April 11, 2020, email to Dr. Hahn and other senior FDA officials, Patrizia Cavazzoni, Director of FDA's Center for Drug Evaluation and Research, explained that the Center did not support an EUA for hydroxychloroquine in an outpatient setting "due to the heightened risk of serious or fatal arrhythmias in the outpatient setting" as compared to hospitalized patients. Email from Patrizia Cavazzoni, Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Steven J. Hatfill and Keagan Lenihan, Chief of Staff, Food and Drug Administration (Apr. 11, 2020) (SSCC-0037720) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.04.11\_SSCC-0037720.pdf).
- <sup>90</sup> Email from Steven J. Hatfill to Peter Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Aug. 15, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.15\_Hatfill%20p.17-20 Redacted.pdf).
- 91 See, e.g., Bannon's War Room, Episode 15: Practical Preparedness (Feb. 12, 2020) (online at https://warroom.org/2020/02/12/ep-15-practical-preparedness/); Bannon's War Room, Episode 1,701: Chernobyl Comes to America; Bio Weapons in Ukraine (Mar. 11, 2022) (online at https://warroom.org/2022/03/11/episode-1701-chernobyl-comes-to-america-bio-weapons-in-ukraine/). Mr. Navarro has also made frequent appearances as both a guest host on Bannon's War Room. See, e.g., Bannon's War Room, Episode 264: Pandemic: Hydroxy Hysteria (July 3, 2020) (online at https://warroom.org/2020/07/03/ep-264-pandemic/); Bannon's War Room, Episode 1,441 Malone, Navarro on Vaccine Resistant Variants/Supervirus (Nov. 26, 2021) (online at https://warroom.org/2021/11/26/episode-1441-malone-navarro-on-vaccine-resistant-variants-supervirus/).

- <sup>92</sup> Email from Steven J. Hatfill to Steve Bannon (Aug. 16, 2020) (GWU-0003900) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.16\_GWU-0003900 Redacted.pdf).
- <sup>93</sup> Email from Steve Bannon to Steven J. Hatfill (Aug. 16, 2020) (GWU-0003884) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.16\_GWU-0003884 Redacted.pdf).
- <sup>94</sup> Email from Senator Ron Johnson to Harvey Risch, Professor Emeritus of Epidemiology, Yale School of Public Health, et al. (Aug. 27, 2020) (GWU-0001122) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.27\_GWU-0001122 Redacted.pdf).
- <sup>95</sup> Senate Committee on Homeland Security & Governmental Affairs, *Hearing on "Early Outpatient Treatment: An Essential Part of a COVID-19 Solution"* (Nov. 19, 2020) (online at www.hsgac.senate.gov/hearings/early-outpatient-treatment-an-essential-part-of-a-covid-19-solution); Senate Committee on Homeland Security & Governmental Affairs, *Hearing on "Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II"* (Dec. 8, 2020) (online at www.hsgac.senate.gov/early-outpatient-treatment-an-essential-part-of-a-covid-19-solution-part-ii).
- <sup>96</sup> Email from Steven J. Hatfill to Senator Ron Johnson (Nov. 15, 2020) (GWU-0001582) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.11.15\_GWU-0001582\_Redacted.pdf); Email from Steven J. Hatfill to Senator Ron Johnson (Nov. 15, 2020) (GWU-0001584) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.11.15\_GWU-0001584\_Redacted.pdf); Email from Steven J. Hatfill to Senator Ron Johnson (Nov. 16, 2020) (GWU-0000421) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.11.16\_GWU-0000421\_Redacted.pdf); see also Email from Steven J. Hatfill (Aug. 19, 2020) (GWU-0003570) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.19\_GWU-0003570 Redacted.pdf) (Dr. Hatfill noting he wrote hearing questions for Senator Johnson).
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- <sup>108</sup> Email from Steven J. Hatfill (Aug. 19, 2020) (GWU-0003574) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.19\_GWU-0003574 Redacted.pdf).
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- <sup>154</sup> See Memorandum from Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis, to Members of the Select Subcommittee on the Coronavirus Crisis, *Issuance of Subpoena to Dr. Steven J. Hatfill* (Sept. 23, 2021) (online at

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156 Email from Steven J. Hatfill to Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Sept. 27, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.27\_Hatfill%20p.127-128 Redacted.pdf).

157 Email from John McKinnon, Physician, Henry Ford Health System, to Steven J. Hatfill (Oct. 16, 2020) (GWU-0006287) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.10.16\_GWU-0006287\_Redacted.pdf); see also Email from Steven J. Hatfill (Dec. 30, 2020) (GWU-0000510) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.12.30\_GWU-0000510\_Redacted.pdf) (Dr. Hatfill noting in December 2020 that he "was unable to get Fauci removed and I lost the fight for the time being, but have not given up"); Email from Steven J. Hatfill (Dec. 12, 2020) (GWU-0000752) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.12.12\_GWU-0000752\_Redacted.pdf) (Dr. Hatfill writing that "[t]he FDA is a walking disaster" and stating there should be a "controlled burn to get rid of the deadwood. An example at the NIH is Fauci and his team").

158 See Email from Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House, to Steven J. Hatfill (Jan. 15, 2021) (GWU-0001067) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021.01.15\_GWU-0001067\_Redacted.pdf); Email from Steven J. Hatfill to Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Dec. 15, 2020) (GWU-0000564) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.12.15\_GWU-0000564\_Redacted.pdf); Email from Steven J. Hatfill to Steven J. Hatfill (GWU-0007341) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.06.09\_GWU-0007341\_Redacted.pdf); Email from Steven J. Hatfill to Joanna Miller, Policy Analyst, The White House (June 7, 2020) (GWU-0007520) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.06.07\_GWU-0007520\_Redacted.pdf); see also Email from Steven J. Hatfill to Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Dec. 13, 2020) (GWU-0000722) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.12.13\_GWU-0000722\_Redacted.pdf) (Navarro inquiring into the status of the "Hydroxy draft").

159 Email from Steven J. Hatfill to Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House (Dec. 15, 2020) (GWU-0000564) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.12.15\_GWU-0000564 Redacted.pdf).

160 Email from Peter K. Navarro, Director, Office of Trade and Manufacturing Policy, The White House, to Steven J. Hatfill (Jan. 15, 2021) (GWU-0001067) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021.01.15\_GWU-0001067\_Redacted.pdf). A manuscript titled, "Hydroxychloroquine Use for Covid-19 in the United States," which lists Mr. Navarro and Dr. Hatfill as the authors, was published on Dr. Hatfill's personal website in "Winter 2022." It presents much of the content contained in the draft reports obtained by the Select Subcommittee. *See* Peter Navarro & Steven Hatfill, *Hydroxychloroquine Use for Covid-19 in the United States* (Winter 2022) (online at https://drstevenhatfill.com/wp-content/uploads/2022/01/Baseline-HCQ-Document-Draft.pdf).

161 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Robert Kadlec (May 19, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/TI%20Excerpts%20Kadlec.pdf).

<sup>162</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2

- 0Stephen%20Hahn%20-%20Redacted.pdf). See generally Convalescent Plasma Therapy, Mayo Clinic (online at www.mayoclinic.org/tests-procedures/convalescent-plasma-therapy/about/pac-20486440) (accessed Aug. 22, 2022).
- 163 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
- <sup>164</sup> Id.; see also Food and Drug Administration, Press Release: FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID–19 Treatment, Another Achievement in Administration's Fight Against Pandemic (Aug. 23, 2020) (online at www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment) (detailing the Mayo Clinic EAP).
- 165 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
- 166 Text from Paul Mango, Deputy Chief of Staff for Policy, Department of Health and Human Services, to Keagan Lenihan, Chief of Staff, Food and Drug Administration (Aug. 10, 2020) (2020.08.10\_FDA-OC\_FOI\_2020-6423\_003839) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.10\_FDA-OC\_FOI\_2020-
- <sup>167</sup> See In the Bubble with Andy Slavitt, Lemonada (Feb. 8, 2021) (online at https://lemonadamedia.com/podcast/inside-trumps-fda-with-stephen-hahn/) ("So we felt back in June and July, that we had met the standard for an EUA for convalescent plasma."); Yasmeen Abutaleb and Damian Paletta, Nightmare Scenario: Inside the Trump Administration's Response to the Pandemic that Changed History (2021).
- <sup>168</sup> Email from Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services, to Stephen Hahn, Commissioner, Food and Drug Administration (July 31, 2020) (SSCC-0037869) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.07.31\_SSCC-0037869 Redacted.pdf).
- <sup>169</sup> White House Coronavirus Task Force Agenda (Aug. 12, 2020) (P002880) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.12\_P002880.pdf).

6423 003839.pdf).

- <sup>170</sup> See, e.g., F.D.A. 's Emergency Approval of Blood Plasma Is Now on Hold, New York Times (Aug. 19, 2020) (online at www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html).
- 171 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
- 172 Yasmeen Abutaleb and Damian Paletta, *Nightmare Scenario: Inside the Trump Administration's Response to the Pandemic that Changed History* (2021); *see also Trump's Focus as the Pandemic Raged: What Would It Mean for Him?*, New York Times (Oct. 26, 2021) (online at www.nytimes.com/2020/12/31/us/politics/trump-coronavirus.html). Dr. Collins since acknowledged that President Trump pressured him to support unproven coronavirus treatments. *NIH Director Says Trump, Republicans Pressured Him to Back Unproven COVID-19 Remedies*, The Hill (Dec. 20, 2021) (online at https://thehill.com/homenews/administration/586539-nih-director-says-trump-republicans-pressured-him-to-back-unproven/).
- 173 The White House, China Virus Huddle (Aug. 28, 2020) (P008303) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.28\_P008303.pdf); see Select Subcommittee on the Coronavirus Crisis, The Trump Administration's Embrace of a Dangerous and Discredited Herd Immunity via Mass Infection Strategy (June 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.06.21%20The%20Trump%20Admi nistration%E2%80%99s%20Embrace%20of%20a%20Dangerous%20and%20Discredited%20Herd%20Immunity% 20via%20Mass%20Infection%20Strategy.pdf) (describing the White House "China Virus Huddle" meetings).

- 174 Email from Paul Alexander, Senior Advisor, Department of Health and Human Services, to Stephen Hahn, Commissioner, Food and Drug Administration, et al. (Aug. 19, 2020) (SSCC-0015402) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.19\_SSCC-0015402 Redacted.pdf).
- 175 Text from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Stacy Amin, Chief Counsel, Food and Drug Administration (Aug. 21, 2020) (FDA-OC\_FOI\_2020-6423\_003453) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.21\_2020.08.21\_FDA-OC\_FOI\_2020-6423\_003453-58.pdf).
- 176 Email from Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration, and Keagan Lenihan, Chief of Staff, Food and Drug Administration (Aug. 21, 2020) (SSCC-0038079) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.21\_SSCC-0038079 Redacted.pdf).
- <sup>177</sup> Donald J. Trump (@realDonaldTrump), Twitter (Aug. 22, 2020) (online at https://web.archive.org/web/20200823082006/https://twitter.com/realdonaldtrump/status/1297138862108663808).
- 178 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
  - <sup>179</sup> *Id*.
- 180 Text from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Michael Caputo, Assistant Secretary for Public Affairs, Department of Health and Human Services, et al. (Aug. 22, 2020) (FDA-OC\_FOI\_2020-6423\_004367) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.22\_FDA-OC\_FOI\_2020-6423\_004367.pdf).
- 181 Email from Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration (Aug. 22, 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.22\_FDA%20FOIA\_Redacted.pd f).
- 182 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf); see also F.D.A 'Grossly Misrepresented' Blood Plasma Data, Scientists Say, New York Times (Jan. 6, 2021) (online at www.nytimes.com/2020/08/24/health/fda-blood-plasma.html).
- 183 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf); Food and Drug Administration, News Release: FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID—19 Treatment, Another Achievement in Administration's Fight Against Pandemic (Aug. 23, 2020) (online at www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment).
- 184 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2

0Stephen%20Hahn%20-%20Redacted.pdf); The White House, *Remarks by President Trump in Press Briefing* (Aug. 23, 2020) (online at https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-press-briefing-august-23-2020/); *see also* Text from Paul Mango, Deputy Chief of Staff for Policy, Department of Health and Human Services, to Keagan Lenihan, Chief of Staff, Food and Drug Administration (Aug. 11, 2020) (FDA-OC\_FOI\_2020-6423\_003851) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.11\_FDA-OC\_FOI\_2020-6423\_003851.pdf) (Mr. Mango noting in a text message to Ms. Lenihan that he was guessing that "the WH will want to have potus announce this").

185 Food and Drug Administration, *Press Release: FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID—19 Treatment, Another Achievement in Administration's Fight Against Pandemic* (Aug. 23, 2020) (online at www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment); *In the Bubble with Andy Slavitt*, Lemonada (Feb. 8, 2021) (online at https://lemonadamedia.com/podcast/inside-trumps-fda-with-stephen-hahn/) (Dr. Hahn: "Ultimately, we had data which demonstrated that there was a benefit and a survival benefit, although small, related to the administration to inpatients seeking patients convalescent plasma."). During a transcribed interview, Dr. Hahn appeared to contradict this assertion, claiming "[t]hat a 35 percent relative increase – relative increase in survival is a substantial treatment effect." Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%20Stephen%20Hahn%20-%20Redacted.pdf).

<sup>186</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf); Email from Emily Miller, Assistant Commissioner for Media Affairs, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration, et al. (Aug. 23. 2020) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.23%20FDA%20FOIA.pdf).

- 187 'She Couldn't Even Pronounce Convalescent Plasma': FDA Ousts Spokesperson After 2 Weeks, Politico (Aug. 28, 2020) (online at www.politico.com/news/2020/08/28/fda-top-spokesperson-leaves-404422); Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
- <sup>188</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%20Stephen%20Hahn%20-%20Redacted.pdf).

- <sup>189</sup> Email from Emily Miller, Assistant Commissioner for Media Affairs, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration, et al. (Aug. 23. 2020) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.23%20FDA%20FOIA.pdf).
- 190 The White House, *Remarks by President Trump in Press Briefing* (Aug. 23, 2020) (online at https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-press-briefing-august-23-2020/); *see also* Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf) (acknowledging "it was inaccurate the way I presented" the data); *Dear Commissioner Hahn: Tell the Truth or Resign*, Medscape (Aug. 31, 2020) (online at www.medscape.com/viewarticle/936611).

<sup>191</sup> See, e.g., F.D.A. 'Grossly Misrepresented' Blood Plasma Data, Scientists Say, New York Times (Jan. 6, 2021) (online at www.nytimes.com/2020/08/24/health/fda-blood-plasma.html).

- <sup>192</sup> Dear Commissioner Hahn: Tell the Truth or Resign, Medscape (Aug. 3, 2020) (online at www.medscape.com/viewarticle/936611).
- <sup>193</sup> F.D.A. 'Grossly Misrepresented' Blood Plasma Data, Scientists Say, New York Times (Jan. 6, 2021) (online at www.nytimes.com/2020/08/24/health/fda-blood-plasma.html).
- <sup>194</sup> FDA Spokesperson ARCHIVED (@FDASPox\_Archive), Twitter (Aug. 23, 2020) (online at https://twitter.com/FDASpox\_Archive/status/1297706985039835136).
- <sup>195</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%20Stephen%20Hahn%20-%20Redacted.pdf).
- <sup>196</sup> Dr. Stephen M. Hahn (@SteveFDA), Twitter (Aug. 24, 2020) (online at https://twitter.com/stevefda/status/1298071620414824452).
- <sup>197</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%20Stephen%20Hahn%20-%20Redacted.pdf).
- <sup>198</sup> See Yasmeen Abutaleb and Damian Paletta, Nightmare Scenario: Inside the Trump Administration's Response to the Pandemic That Changed History (2021); Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
- 199 Email from Paul Alexander, Senior Advisor, Department of Health and Human Services, to Brad Traverse, Senior Advisor to the Assistant Secretary, Office of the Assistant Secretary for Public Affairs, Department of Health and Human Services, and Gordon Hensley, Senior Public Affairs Adviser, Department of Health and Human Services (Aug. 25, 2020) (SSCC-0040890) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.08.25\_SSCC-0040890 Redacted.pdf) (emphases in original).
- <sup>200</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
- <sup>201</sup> See Select Subcommittee on the Coronavirus Crisis, *Press Release: At Hearing, Secretary Azar Refuses to Accept Trump Administration Responsibility for Deaths of Over 200,000 Americans* (Oct. 2, 2020) (online at https://coronavirus.house.gov/news/press-releases/hearing-secretary-azar-refuses-accept-trump-administration-responsibility-deaths).
- <sup>202</sup> Trump Says Coronavirus Vaccine Possible Before Nov. 3, Reuters (Aug. 6, 2020) (online at www.reuters.com/article/us-health-coronavirus-trump-vaccine/trump-says-coronavirus-vaccine-possible-before-nov-3-idUSKCN25221Q); Vaccine-Makers Promise Safety Amid Shaky Public Confidence in Covid Developments, Politico (Sept. 8, 2020) (online at www.politico.com/news/2020/09/08/vaccine-makers-safety-pledge-409784); see also Trump's Den of Dissent: Inside the White House Task Force as Coronavirus Surges, Washington Post (Oct. 19, 2020) (online at www.washingtonpost.com/politics/trumps-den-of-dissent-inside-the-white-house-task-force-as-coronavirus-surges/2020/10/19/7ff8ee6a-0a6e-11eb-859b-f9c27abe638d story.html).
- <sup>203</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf). When asked if President Trump ever expressed a specific desire to have a vaccine approved before the election, Dr. Hahn replied in the negative. *Id.*

- <sup>204</sup> *Id*.
- <sup>205</sup> *Id.*; *see also* Text from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Ann K. Abram, Deputy Commissioner for Policy, Legislation, and International Affairs, Food and Drug Administration (Sept. 21, 2020) (FDA-OC\_FOI\_2020-6423\_004191) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.21\_FDA-OC\_FOI\_2020-6423\_004191.pdf) (FDA officials discussing sending vaccine guidance to Mr. Mango in HHS for review).
- <sup>206</sup> Press Release: Biopharma Leaders Unite to Stand with Science (Sept. 8, 2020) (online at www.businesswire.com/news/home/20200908005282/en/Biopharma-Leaders-Unite-to-Stand-with-Science).
- <sup>207</sup> See AstraZeneca's Coronavirus Vaccine Becomes Third to Begin Phase Three Trials in the United States, CNN (Sept. 9, 2020) (online at www.cnn.com/2020/08/31/health/astrazeneca-vaccine-phase-3-trial/index.html).
- <sup>208</sup> Text from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Ann K. Abram, Deputy Commissioner for Policy, Legislation, and International Affairs, Food and Drug Administration (Sept. 18, 2020) (FDA-OC\_FOI\_2020-6423\_004166) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.18\_FDA-OC\_FOI\_2020-6423\_004166.pdf).
- <sup>209</sup> Text from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Ann K. Abram, Deputy Commissioner for Policy, Legislation, and International Affairs, Food and Drug Administration (Sept. 21, 2020) (FDA-OC\_FOI\_2020-6423\_004191) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.21\_FDA-OC\_FOI\_2020-6423\_004191.pdf).
- <sup>210</sup> See Senate Committee on Health, Education, Labor and Pensions, Hearing on "COVID-19: An Update on the Federal Response" (Sept. 23, 2020) (online at www.help.senate.gov/hearings/covid-19-an-update-on-the-federal-response).
- <sup>211</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
  - <sup>212</sup> *Id*.
- <sup>213</sup> *Id.*; *see also* Explanation for Median Two Month Follow-Up After Completion of COVID-19 Dosing (SSCC-0037991) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Undated%20SSCC-0037991.pdf) (document produced by Dr. Hahn outlining FDA's rationale for the two-month follow-up safety data).
- <sup>214</sup> How the F.D.A. Stood Up to the President, New York Times (Oct. 20, 2020) (online at www.nytimes.com/2020/10/20/health/covid-vaccines-fda-trump.html); see also White House Coronavirus Task Force Agenda (Sept. 23, 2020) (P010938) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.23 P010938.pdf).
- <sup>215</sup> The White House, *Remarks by President Trump in Press Briefing* (Sept. 23, 2020) (online at https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-press-briefing-092420/).
- <sup>216</sup> Email from Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration, and Keagan Lenihan, Chief of Staff, Food and Drug Administration (Sept. 26, 2020) (SSCC-0037773) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.26\_SSCC-0037773\_Redacted.pdf). According to Dr. Marks, WHO's proposed criteria called for three months of data beginning two weeks after the final vaccination for the entire trial population, not just the median follow-up duration. *Id.*

- <sup>217</sup> Email from Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration, and Keagan Lenihan, Chief of Staff, Food and Drug Administration (Sept. 29, 2020) (SSCC-0038009) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.29\_SSCC-0038009\_Redacted.pdf).
- <sup>218</sup> Email from Amy Abernethy, Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration (Sept. 30, 2020) (SSCC-0037994) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.30\_SSCC-0037994\_Redacted.pdf); see Vaccines and Related Biological Products Advisory Committee, Charter of the Vaccines and Related Biological Products Advisory Committee (Jan. 3, 2022) (online at www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/charter-vaccines-and-related-biological-products-advisory-committee) (describing mission of VRBPAC).
- <sup>219</sup> Compare Email from Amy Abernethy, Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration (Sept. 30, 2020) (SSCC-0037994) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.09.30\_SSCC-0037994\_Redacted.pdf), with Food and Drug Administration, Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry (Oct. 2020) (online at https://web.archive.org/web/20201010184451/https://www.fda.gov/media/142749/download); see also Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf) (noting that the content of the final guidance matched that of the draft guidance FDA submitted to the White House).
- 220 Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf); see also Email from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Stephen Hahn, Commissioner, Food and Drug Administration (Oct. 5, 2020) (SSCC-0038023) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.10.05%20SSCC-0038023\_Redacted.pdf); FDA Releases High Coronavirus Vaccine Standards Despite White House Resistance, Roll Call (Oct. 6, 2020) (online at https://rollcall.com/2020/10/06/fda-releases-high-coronavirus-vaccine-standards-despite-white-house-resistance/).
- $^{221}$  Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%20Stephen%20Hahn%20-%20Redacted.pdf).
- <sup>222</sup> Text from Keagan Lenihan, Chief of Staff, Food and Drug Administration, to Paul Mango, Deputy Chief of Staff for Policy, Department of Health and Human Services (Oct. 6, 2020) (FDA-OC\_FOI\_2020-6423\_003916) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.10.06\_FDA-OC\_FOI\_2020-
- https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.10.06\_FDA-OC\_FOI\_2020-6423\_003916.pdf).
- <sup>223</sup> Select Subcommittee on the Coronavirus Crisis, Transcribed Interview of Stephen Hahn (Jan. 28, 2022) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2022.01.28.SSCC%20Interview%20of%2 0Stephen%20Hahn%20-%20Redacted.pdf).
- <sup>224</sup> *Trump's Den of Dissent: Inside the White House Task Force as Coronavirus Surges*, Washington Post (Oct. 19, 2020) (online at www.washingtonpost.com/politics/trumps-den-of-dissent-inside-the-white-house-task-force-as-coronavirus-surges/2020/10/19/7ff8ee6a-0a6e-11eb-859b-f9c27abe638d story.html).

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- <sup>231</sup> Text Message from Mark Meadows, Chief of Staff, White House, to Stephen Hahn, Commissioner, Food and Drug Administration (Dec. 10, 2020) (FDA-OC\_FOI\_2020-6423\_003092) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020.12.01-12.11\_FDA-OC\_FOI\_2020-6423\_003092.pdf).
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