Politics, Private Interests, and the Biden Administration's Deviation from Agency Regulations in the COVID-19 Pandemic

Interim Staff Report of the

Subcommittee on the Administrative State, Regulatory Reform, and Antitrust
of the Committee on the Judiciary

Representative Thomas Massie, Chairman

U.S. House of Representatives

June 24, 2024

EXECUTIVE SUMMARY

The Subcommittee on the Administrative State, Regulatory Reform, and Antitrust of the Committee on the Judiciary has jurisdiction over administrative law and is charged with oversight of the ever-expanding federal bureaucracy. The very idea of executive agencies staffed by experts to tackle the complexities of the modern world is a concept that took root a century ago. But since then, Congress has implemented procedures and rules designed to limit agency authority and generate uniformity and certainty among agency actions. The COVID-19 pandemic, and the actions of public health agencies during that time, is an area that requires Congressional oversight to inform potential legislative reforms.

On March 11, 2020, the World Health Organization declared the novel coronavirus outbreak to be a global pandemic.[1] In March 2020, the Trump Administration relied on laws such as Project BioShield Act of 2004 to implement a total-government solution to the emerging pandemic.[2] The Trump Administration response centered around the Federal Emergency Management Agency (FEMA), which possesses the experience for managing emergencies and disasters, and the Department of Defense (DOD), which has expertise in managing logistics and distributing resources in crisis.[3]

In April 2020, the Trump Administration initiated Operation Warp Speed (OWS) as a government-wide solution to rapidly bring to market vaccines and other disease countermeasures to address the pandemic.[4] Under OWS, the Trump Administration facilitated the development of multiple vaccines through the Emergency Use Authorization (EUA) process.[5] The effort was so instrumental that even the Biden Administration's senior pandemic leadership now refers to the Trump Administration's implementation of OWS and the initial response as "[t]he great success of the pandemic."[6]

By contrast, from the beginning of the pandemic, the Biden-Harris campaign sought to politicize and undermine the federal COVID-19 response, for apparent political reasons. As a candidate, then-former Vice President Biden questioned all efforts to return the country to normal.[7] He recommended mandating social behaviors and called into question COVID-19 testing and mobilization efforts in the federal response.[8] Effectively calling into question

[1] *See WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 - 11 March 2020*, WHO (Mar. 11, 2020).
[2] *See* Robert P. Baird, *Can Trump Really Speed Approval of Covid Treatments?*, N.Y. Times (Oct. 12, 2020); *see generally* FRANK GOTTRON, CONG. RSCH. SERV., R41033, PROJECT BIOSHIELD: AUTHORITIES, APPROPRIATIONS, ACQUISITIONS, AND ISSUES FOR CONGRESS (2011); *see also* Project BioShield Act of 2004, 42 U.S.C. § 247d(a)–(f) (2004).
[3] *See* Brett P. Giroir, *Memoir of a Pandemic* 163 (2023); *see also id.* at ix–xvii.
[4] *See* Transcribed Interview of Peter Marks, Director, FDA Center for Biologics Evaluation and Research (Apr. 15, 2024) at 50:14–51:17.
[5] *See, e.g.*, Letter from Peter Marks to Leslie Sands (Sept. 11, 2023).
[6] *See* Adam Cancryn, *Biden's Top Covid Adviser Wishes He Had Tangled with Tucker Carlson*, Politico (Feb. 6, 2023).
[7] *See* Alice Miranda Ollstein, *Inside Biden's Plan to Take on Coronavirus*, Politico (Aug. 20, 2020).
[8] *See id.; see also* Joe Biden for President 2020, *Biden Campaign Press Release - Fact Sheet: Donald Trump's Utter Botching of the COVID-19 Response*, The American Presidency Project (Aug. 26, 2020) (archived).

research being done at the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), and the National Institutes of Health (NIH) to address the crisis, then-Senator Kamala Harris said she would not trust President Trump that a vaccine developed during the Trump Administration was safe.[9]

After the 2020 presidential election, President Biden and his administration flipped to not only endorsing and taking credit for rolling out a vaccine—the one it had impugned during the campaign—but also they later sought to mandate that Americans take the vaccine.[10] On January 21, 2021, President Biden appointed Janet Woodcock to be the Acting FDA Commissioner.[11] The Biden Administration pressured agencies to go beyond their legal authorities while, as discussed in this report, it ignored risks revealed in the initial release of the EUA vaccine and required that the vaccine be given to the military and federal employees.[12] The Biden Administration encouraged agencies and states to use liberty-taking tactics not supported by science (such as universal mask mandates, vaccine mandates, social-distancing mandates, school closures, and censorship[13]) and to force Americans to take the vaccine.[14]

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[9] *See* Evan Semones, *Harris Says She Wouldn't Trust Trump on Any Vaccine Released Before Election*, Politico (Sept. 5, 2020).

[10] *See* Vinay Prasad & Alyson Haslam, *COVID-19 Vaccines: History of the Pandemic's Great Scientific Success and Flawed Policy Implementation*, Monash Bioethics Review 12–13 (Mar. 9, 2024); *see also* Amanda Seitz and Calvin Woodward, *AP Fact Check: Biden Overstates his record on COVID vaccine*, Associated Press (Oct. 22, 2021) (explaining that the Trump administration had "set the stage" and had begun the vaccine roll out which continued under the Biden Administration).

[11] *See* Shannon Muchmore, *Biden Appoints Janet Woodcock as Acting FDA Chief, Plans COVID-19 Testing Board*, MedTech Dive (Jan. 21, 2021); *see also* Beth Snyder Bulik, *FDA Veteran Woodcock Takes Over as Acting Commissioner in Biden Administration*, Fierce Pharma (Jan. 20, 2021); Beth Snyder Bulik, *Woodcock to Step up to Interim FDA Chief as She and Scharfstein Are Vetted for Permanent Jobs*, Fierce Pharma (Jan. 14, 2021) (discussing how President Biden was considering Woodcock for the permanent role).

[12] *See cf.* H. COMM. ON JUDICIARY AND SELECT SUBCOMM. ON THE WEAPONIZATION OF THE FED. GOV'T, 118TH CONG., INTERIM STAFF REP. ON THE CENSORSHIP-INDUSTRIAL COMPLEX: HOW TOP BIDEN WHITE HOUSE OFFICIALS COERCED BIG TECH TO CENSOR AMERICANS, TRUE INFORMATION, AND CRITICS OF THE BIDEN ADMINISTRATION 1–5 (May 1, 2024) (discussing how the Biden Administration through government agencies pressured big tech to censor speech); *cf.* H. COMM. ON JUDICIARY AND SELECT SUBCOMM. ON THE WEAPONIZATION OF THE FED. GOV'T, 118TH CONG., INTERIM STAFF REP. ON THE WEAPONIZATION OF THE FEDERAL TRADE COMMISSION: AN AGENCY'S OVERREACH TO HARASS ELON MUSK'S TWITTER (Mar. 7, 2023) (discussing how the Biden Administration weaponized the FTC to harass Elon Musk for revealing the pressure the Administration put on Twitter to censor critics).

[13] *See, e.g.*, *Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members*, Sec'y of Def., U.S. Dep't of Def. (Aug. 24, 2021); *Statement by President Joe Biden on COVID-19 Vaccines for Service Members*, The White House (Aug. 9, 2021). *See generally Examining Our COVID-19 Response: An Update from Federal Officials: Hearing Before S. Comm. on Health, Educ., Lab., & Pensions*, U.S. S. Comm. on Health, Educ., Lab., & Pensions (2021). Dr. Anthony Fauci has described this conundrum: when the government through a mandate makes "it difficult for people in their lives, they lose their ideological bullshit, and they get vaccinated," mandating a vaccine can also increase public hesitancy in the vaccine. *Hearing Wrap Up: Dr. Fauci Held Publicly Accountable by Select Subcommittee*, U.S. H. Comm. on Oversight & Accountability (June 4, 2024). *See* Forbes Breaking News, *'Ideological Bulls--t': Rich McCormick Grills Fauci on Audio of Him Discussing Vaccine Requirements*, YouTube (June 3, 2024), https://www.youtube.com/watch?v=2GgpKRoRYGE.

[14] *See Hearing Wrap Up: Dr. Fauci Held Publicly Accountable by Select Subcommittee*, *supra* note 13.

The EUA vaccine was not perfect, but good public policy related to EUA authorizations suggests that this rapid response to the emerging pandemic would need ongoing evaluation.[15] Thus FDA policy was that manufacturers and the government monitor and communicate findings as to the effects of a product being rolled out under that lower, emergency-response standard.[16] The Biden Administration, however, pivoted away from this important requirement and sought to ensure the EUA vaccine received full licensure as a way to support vaccine mandates.[17] While the vaccine approval process can be robust and lengthy, the Biden Administration through Acting Commissioner Janet Woodcock sought to move on an arbitrary political timeline and pressed the FDA to ignore its regulations in the approval process.[18] During this time, the Administration ignored or silenced voices that questioned the merits of universal vaccination and downplayed the serious injuries from the EUA vaccine.[19]

At the direction of Subcommittee Chairman Thomas Massie, the Subcommittee has examined the FDA's process to fully license the Pfizer vaccine in August 2021 and how the CDC characterized the efficacy of the vaccines. Chairman Massie sent four letters to the Department of Health and Human Services (HHS) and its component agencies seeking material related to the FDA's licensing efforts in 2021, the FDA's active promotion of the vaccine in 2021 and 2022, and the CDC's conduct related to reporting on the safety and efficacy of the vaccine.[20] The Subcommittee also conducted transcribed interviews of FDA officials responsible for vaccine approval, which revealed that the FDA rushed the vaccine licensing and subsequent recommendations for vaccine boosters. The Subcommittee's oversight also revealed that the administrative state mishandled reports of vaccine injury, despite requirements to actively obtain, synthesize, and report feedback on the safety and efficacy of the EUA vaccine.[21] Biases seemed to emerge that discounted evidence of vaccine injury.[22]

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[15] *See* U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF PUB. HEALTH EMERGENCY COUNTERMEASURES, OFF. OF PUB. HEALTH EMERGENCY PREPAREDNESS, PROJECT BIOSHIELD: ANNUAL REPORT TO CONGRESS, JULY 2004 THROUGH JULY 2006 11–12 (July 31, 2006); *see also* Transcribed Interview of Marion Gruber, Former Director, FDA Center for Biologics Evaluation & Research, Office of Vaccines Research & Review, 22:2–19 (July 18, 2023).

[16] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 22:2–24:16.

[17] *See* Food and Drug Admin., *FDA Approves First COVID-19 Vaccine*, News Release (Aug. 23, 2021), *see also* FDA-OC-2021-5574-000331–59; *see also* Transcribed Interview of Peter Marks, *supra* note 4, at 89:19–24; Transcribed Interview of Marion Gruber, *supra* note 15, at 66:23–68:20.

[18] *See generally* FDA-OC-2021-5574-000331–000359 (FDA emails detailing how senior leadership ignored warnings of experts related to the licensing approval process).

[19] *See generally*, *e.g.*, HOW TOP BIDEN WHITE HOUSE OFFICIALS COERCED BIG TECH TO CENSOR AMERICANS, TRUE INFORMATION, AND CRITICS OF THE BIDEN ADMINISTRATION, *supra* note 12, at 1–5.

[20] *See* Letter from Thomas Massie, Chair, Subcomm. on the Administrative State, Regulatory Reform, and Antitrust, to Dr. Mandy K. Cohen (Oct. 20, 2023); Letter from Thomas Massie, Chair, Subcomm. on the Administrative State, Regulatory Reform, and Antitrust to Dr. Mandy K. Cohen (Dec. 6, 2023); Letter from Thomas Massie, Chair, Subcomm. on the Administrative State, Regulatory Reform, and Antitrust to Dr. Mandy K. Cohen (May 16, 2024); Letter from Thomas Massie, Chair, Subcomm. on the Administrative State, Regulatory Reform, and Antitrust to Dr. Robert Califf (Oct. 25, 2023).

[21] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 123:24–134:19; *see generally COVID-19 Vaccines: History of the Pandemic's Great Scientific Success and Flawed Policy Implementation*, *supra* note 10.

[22] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 124:19–134:19; *see generally COVID-19 Vaccines: History of the Pandemic's Great Scientific Success and Flawed Policy Implementation*, *supra* note 10.

The transcribed interviews and internal FDA documents revealed that, despite evidence of harms from the EUA vaccine, the Biden Administration sought to fully approve the Pfizer vaccine through the Biologics Licensing Application (BLA) process. Under the leadership of then-Acting FDA Commissioner Dr. Janet Woodcock, a long-time FDA staffer who the Biden Administrative promoted to Acting Commissioner, and Dr. Peter Marks, head of the FDA's Center for Biologics Evaluation and Research (CBER), the agency cut corners in its usually rigorous BLA process to brand the Pfizer EUA vaccine as the only fully licensed "safe and effective" COVID-19 vaccine on the market at the time.[23] The BLA approval occurred despite the objections of the FDA's experts in vaccine development who were concerned about risks for healthy young people caused by the Pfizer vaccine, particularly the risk of myocarditis.[24]

The decision for the FDA to rush the Pfizer BLA vaccine review process comported with pressure to mandate the vaccine. Dr. Marks testified to the Subcommittee that he was seeking to appease outsiders who wanted to have an approved vaccine that gave them "more confidence" in a vaccine, even though it was the exact same vaccine already on the market under the EUA.[25] Dr. Marks also explained that the Biden Administration could not mandate any COVID-19 vaccine unless the FDA first approved a BLA, and in this case, the Pfizer BLA.[26] Standing in the way were indications of EUA vaccine injuries in some patients, and approving the BLA by the deadline being demanded and in the face of these injuries would require lowering standards.[27] To ensure a quicker approval, Acting Commissioner Woodcock and Dr. Marks removed the experts who voiced concerns during the BLA process.[28] Acting Commission Woodcock and Dr. Marks proceeded, despite the concerns, and completed the approval to meet the deadline that the Biden White House had set.[29]

The Subcommittee's oversight also revealed internal CDC steps taken to undermine efforts by members of Congress to clarify the CDC statements about the vaccine's efficacy. Clarity by the CDC on the impact of the vaccine could have prevented injury.[30] Instead, CDC documents reveal that the CDC engaged in conduct that undermined public confidence by actively censoring speech and disregarding attempts from Americans' elected representatives in Congress to clarify the CDC's representations about the vaccines.[31] By late 2021, the FDA and Dr. Marks, and not the CDC, became advocates for the Pfizer vaccine—a role for the FDA that was unprecedented before the pandemic and outside the proper function of the FDA as authorized by Congress.[32]

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[23] *See FDA Approves First COVID-19 Vaccine*, *supra* note 15; *see also* FDA-OC-2021-5574-000331–59.
[24] *See* FDA-OC02021-5574-000335–36; *see also* FDA-OC02021-5574-000340.
[25] *See* FDA-OC02021-5574-000347–50.
[26] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 89:19–21, 90:21–23.
[27] *See* MG000001–02; *see also* FDA-OC-2021-5574-00346–50
[28] *See* FDA-OC02021-5574-000335.
[29] *See id.*
[30] *See generally COVID-19 Vaccines: History of the Pandemic's Great Scientific Success and Flawed Policy Implementation*, *supra* note 10.
[31] *See, e.g.*, HJC_CDCMMWR000429–36.
[32] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 76:3–79:21, 84:17–24.

Numerous harms resulted from the FDA's actions in evaluating the Pfizer vaccine. Countless Americans suffer from side-effects of the vaccine.[33] The morale and well-being of the military under the Biden Administration deteriorated due to harsh vaccine mandates.[34] Unless changes are made to restore credibility to the FDA's once-robust vaccine approval process, future vaccines approved by the FDA may be met by an American public with increased skepticism and elevate the potential for higher vaccine hesitancy.[35]

This episode is an example of the administrative state engaging in dangerous behavior beyond its authority and without accountability. Dr. Marks testified that he believed his actions were justified because people wanted more confidence in the vaccine, but by ignoring warnings, his actions served to reduce confidence in the entire FDA approval program.[36] Dr. Marks testified that he was justified in his decisions made in July 2021 because of increases in COVID-19 deaths,[37] but the data at the time show lower levels of hospitalizations and deaths.[38] Reflecting on the FDA's handling of the vaccine approval process three years later, now-former Acting FDA Commissioner Woodcock said she is "disappointed in [her]self" and her involvement as it relates to vaccine-related injury as the FDA did not do enough to address this important concern.[39]

Congressional oversight, including investigative work performed by the Select Subcommittee on the Coronavirus Pandemic, has already revealed how the NIH and the Biden Administration misled the public and exacerbated the effects of the COVID-19 pandemic through mandates and misinformation.[40] This interim report reveals that where the Trump Administration organized a total government solution and generated vaccines under EUA, the Biden Administration politicized the administrative state to do things beyond the agencies' legal authority that, in turn, undermined the federal effort. Reasonable minds may disagree about the size and scope of the federal administrative state. But all Americans should agree that when a federal agency acts in the interest of public health, it do so in a way that generates confidence in the result. The Subcommittee will therefore continue its oversight of the administrative state and the response to the COVID-19 pandemic.

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[33] *See generally COVID-19 Vaccines: History of the Pandemic's Great Scientific Success and Flawed Policy Implementation*, *supra* note 10; *see also* Apoorva Mandavilli, *Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?*, N.Y. Times (May 3, 2024).
[34] *See generally COVID-19 Vaccines: History of the Pandemic's Great Scientific Success and Flawed Policy Implementation*, *supra* note 10.
[35] *See* MG000001–02.
[36] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 76:3–79:21, 84:17–24.
[37] *See id.* at 92:17–21.
[38] *See id.* at 76:3–79:21, 84:17–24.
[39] *See* Apoorva Mandavilli, *Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?*, N.Y. Times (May 3, 2024).
[40] *See generally Hearing Wrap Up: NIH Refutes EcoHealth's Testimony, Tabak Reveals Federal Grant Procedures in Need of Serious Reform*, U.S. H. Comm. on Oversight & Accountability (May 17, 2024).

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I. INTRODUCTION

The COVID-19 pandemic likely leaked from a virus testing program partially funded by the National Institute of Allergy and Infectious Diseases (NIAID).[41] When COVID-19 reached the United States in early 2020, the Trump Administration shifted management of the federal response to the Federal Emergency Management Agency (FEMA), which possesses the experience for managing emergencies and disasters, and the Department of Defense (DOD), which has expertise in managing logistics and distributing resources in crisis.[42] The Trump Administration also used authorities granted in the Project BioShield Act, a law enacted in 2004 to implement rapid total government solutions and countermeasures to biologic threats.[43]

HHS and its subagencies— NIH, CDC, and the FDA among others—are responsible for overseeing the science behind the virus, and the methods for developing countermeasures to the threat.[44] The FDA is the HHS component that evaluates the safety of drug products before they come to market, but it does not develop, manufacture, or test drugs.[45] By comparison, the CDC is charged with protecting the public health, and it does so, in part, by providing information to help the public from health threats.[46] It is the role of the FDA to describe the efficacy of drug products and the role of the CDC to inform the public—an important distinction to note during a public health emergency when clarity of communication is of paramount importance.

By April 2020, to protect America's most vulnerable citizens and support safe operations of businesses and schools, the Trump Administration made it a priority to promote public awareness, testing, and development of a potential COVID-19 vaccine.[47] The Trump

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[41] *See Hearing Wrap Up: Dr. Fauci Held Publicly Accountable by Select Subcommittee*, note 1313; *see generally*, C-SPAN, *Dr. Fauci Testifies on U.S. Response to COVID-19 Pandemic* (June 3, 2024). After the Department of Defense's Defense Advanced Research Projects Agency rejected a grant request to fund this project because it was too dangerous, Dr. Anthony Fauci authorized NIAID to award $3,748,715 to Ecohealth Alliance Inc., which sought to establish a high-risk program at the Wuhan Institute of Virology (WIV) for "Understanding the Risk of Bat Coronavirus Emergence." *See* Christi A. Grimm, *The National Institutes of Health and Ecohealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies* 6, DHHS Office of the Inspector General, A-05-21-00025, (2023); *see also Hearing Wrap Up: NIH Refutes EcoHealth's Testimony, Tabak Reveals Federal Grant Procedures in Need of Serious Reform*, *supra* note 40; *see also* Bill Gertz, *COVID Virus Made in Chinese Lab as Bat Vaccine, Marine Researcher Says*, Wash. Times (Jan. 12, 2022); *see also* Ed Browne, *Fauci Was 'Untruthful' to Congress About Wuhan Lab Research, New Documents Appear to Show*, Newsweek (Sept. 9, 2021). The program was deemed risky because it sought to manufacture a "gain-of-function" virus to test its resistance to vaccines when spread from animals to humans. *See* Patrick Berche, *Gain-of-Function and Origin of Covid19*, PubMed Central (June 2, 2023); Alina Chan, *Why the Pandemic Probably Started in a Lab, in 5 Key Points*, N.Y. Times (June 3, 2024); *see also* Letter from James Comer, Chairman, Comm. on Oversight & Jim Jordan, Chairman, Comm. on the Judiciary, to Francis Collins & Anthony Fauci (May 28, 2021).

[42] *See Memoir of a Pandemic*, *supra* note 3, at 163.

[43] *See generally* Frank Gottron, *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, *supra* note 2.

[44] *See President Donald J. Trump Directs FEMA Support Under Emergency Declaration for COVID-19*, FEMA (2020) (archived); *see Memoir of a Pandemic*, *supra* note 3, at 94–96, 107–08; *see also* Transcribed Interview of Peter Marks, *supra* note 4, at 25:1–26:21 (concerning working with General Perna).

[45] *See Examination & Sample Collection*, Food & Drug Admin. (Sept. 26, 2018).

[46] *See About CDC*, Ctrs. for Disease Control & Prevention (Feb. 12, 2024).

[47] *See Memoir of a Pandemic*, *supra* note 3, at 167–79, 271–72.

Administration developed Operation Warp Speed (OWS), which was an effort to rapidly bring to market vaccines and other treatments to address the COVID-19 crisis.[48] Relying on the Project BioShield Act, the Trump Administration invited private vaccine developers to seek an emergency use authorization (EUA) to make vaccines available to the public faster than under the FDA's standard BLA process.[49]

The differences between EUA and BLA approval are significant. The usual BLA approval process robustly evaluates biologic products, such as vaccines, to ensure that they are safe, effective, and can be trusted to present a low likelihood of risk to the person taking the product.[50] The process, however, can take at least eight months, and often ten months to a year, for the FDA to review and determine if it is fully safe and effective when used as directed.[51] This process allows the FDA to provide adequate disclosures as to the potential side effects of the product, which are critical to inform health care providers treating patients. Strict adherence to this process allows the public to have confidence in the FDA's BLA approvals.

An EUA, on the other hand, is meant to allow for a rapid response to an immediate biologic threat, and is a means to bring a product to market that is still being tested as a disease countermeasure until a fully licensed product is available.[52] In this way, the EUA product is riskier than a BLA-approved product and is only used in case of an emergency when no alternatives are available, such as during the COVID-19 pandemic when no vaccines were available.

A key attribute of the EUA process requires ongoing post-marketing analysis to assess the safety and efficacy of the EUA product in real-world settings.[53] This effort, when properly implemented, informs the public of the risks from the disease countermeasure and allows product developers to make adjustments to improve the product. In this way, the EUA process does not supplant the BLA process; while EUA post-marketing studies can inform BLA evaluators, they do not necessarily replace the same clinical data that is examined in a BLA evaluation. With respect to the vaccines developed in response to the COVID-19 pandemic, the Trump Administration facilitated the development of multiple vaccines and other treatments through the EUA process, while EUA post-marketing analysis largely fell to the Biden Administration.[54]

As the Trump Administration sought to use its authorities to develop life-saving treatments, the campaign of then-former Vice President Joe Biden challenged the effectiveness

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[48] *See* Transcribed Interview of Peter Marks, *supra* note 44, at 50:14–15, 84:7–10.
[49] *See* FDA, *Emergency Use Authorization* (May 21, 2024); Transcribed Interview of Peter Marks, *supra* note 4, at 50:14–51:10; Transcribed Interview of Marion Gruber, *supra* note 15, at 16:13–18:16 (July 18, 2023).
[50] *See Biologics License Applications (BLA) Process (CBER)*, Food & Drug Admin. (Jan. 27, 2021); *see also* Transcribed Interview of Marion Gruber, *supra* note 15, at 15:23–16:10.
[51] *See Biologics License Applications (BLA) Process (CBER)*, Food & Drug Admin. (Jan. 27, 2021); *see also* Transcribed Interview of Marion Gruber, *supra* note 15, at 27:15–21; *see also Priority Review*, Food & Drug Admin. (Jan. 4, 2018).
[52] *See* Carrie MacMillan, *Emergency Use Authorization vs. Full FDA Approval: What's the Difference?*, Yale Medicine (Mar. 7, 2022).
[53] *See id.*
[54] *See, e.g.*, Letter from Peter Marks to Leslie Sands, *supra* note 5.

of the COVID-19 federal response and made the pandemic into a political issue.[55] The Biden-Harris campaign alleged that federal agency efforts to respond to the pandemic were "botch[ed]," [56] "almost criminal," [57] and "incompetent," [58] claiming that the joint efforts of the agencies amounted to surrender.[59] Then-Senator Kamala Harris, Biden's running mate, repeatedly cast doubt on the efficacy of the vaccines being developed through OWS—the same vaccines that she and President Biden ultimately made mandatory for servicemembers and millions of other Americans.[60] Then-former Vice President Biden, too, cast doubt on Trump Administration's pandemic response policies, insisting instead the government should require mask-wearing and resisting a return to school and work.[61]

When President Biden assumed office on January 20, 2021, the new administration immediately moved to take people's freedoms. Progress made under the Trump Administration to rein in the inefficiencies in the administrative bureaucracies were abandoned and replaced by mask mandates, vaccine mandates, social-distancing mandates, closed schools, and censorship[62] to advance its political agenda, even though some of these approaches were not supported by science.[63]

II. UNDER THE BIDEN ADMINISTRATION'S MANAGEMENT OF THE COVID-19 PANDEMIC, THE FDA SUCCUMBED TO OUTSIDE INFLUENCE AND RISKED PUBLIC SAFETY TO APPROVE THE PFIZER BLA

On August 20, 2021, over the concerns of some of the FDA's world-renowned vaccine experts during the BLA review, the FDA granted Pfizer the first fully licensed COVID-19 vaccine. While BLA review ordinarily may take as long as ten months to a year, or six to eight months if "prioritized," the FDA licensed the Pfizer COVID-19 vaccine less than four months after Pfizer filed its application.[64] The fully licensed vaccine approved in August 2021,

[55] *See Memoir of a Pandemic*, *supra* note 3, at xii.
[56] *See Biden Campaign Press Release - Fact Sheet: Donald Trump's Utter Botching of the COVID-19 Response*, *supra* note 8.
[57] Lauren Gambino, et al., *Joe Biden Decries Trump's 'Almost Criminal' Covid Response*, The Guardian (Sept. 10, 2020).
[58] Arlette Saenz & Sarah Mucha, *Biden Campaign Makes Push to Paint Trump's Coronavirus Response as 'Incompetent' and 'Corrupt'*, CNN (May 12, 2020).
[59] Annie Linskey, *Biden Escalates Criticism of Trump on Coronavirus as Cases Grow Nationwide*, Wash. Post (June 30, 2020.
[60] *See Harris Says She Wouldn't Trust Trump on Any Vaccine Released Before Election*, *supra* note 5.
[61] *Inside Biden's Plan to Take on Coronavirus*, *supra* note 7.
[62] *See Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members*, *supra* note 13; *Statement by President Joe Biden on COVID-19 Vaccines for Service Members*, *supra* note 13; *see generally Examining Our COVID-19 Response: An Update from Federal Officials: Hearing Before S. Comm. on Health, Educ., Lab., & Pensions*, *supra* note 13. Separately, Dr. Anthony Fauci has described this conundrum: when the government through a mandate makes "it difficult for people in their lives, they lose their ideological bullshit, and they get vaccinated," mandating a vaccine can also increase public hesitancy in the vaccine. *Hearing Wrap Up: Dr. Fauci Held Publicly Accountable by Select Subcommittee*, note 13; *see also 'Ideological Bulls--t': Rich McCormick Grills Fauci on Audio of Him Discussing Vaccine Requirements*, *supra* note 13.
[63] *See Hearing Wrap Up: Dr. Fauci Held Publicly Accountable by Select Subcommittee*, *supra* note 13; *Memoir of a Pandemic*, *supra* note 3, at 241–42 (on natural immunity).
[64] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 27:4–23; *see also Priority Review*, *supra* note 51.

according to Dr. Marks, was the same vaccine as the EUA vaccine released under OWS in December 2020.[65]

During the Pfizer BLA review process, the FDA vaccine experts expressed concerns about injuries reported during the Pfizer EUA vaccine post-marketing evaluations, and warned that rushing the BLA review would result in lowering its robust standards, which would undermine public confidence.[66] Testimony and FDA internal communications obtained by the Subcommittee reveal that Acting FDA Commissioner Dr. Janet Woodcock and CBER Director Dr. Peter Marks were influenced by outside pressures to rush the BLA approval, that Dr. Marks promised to deliver a BLA in the four weeks needed to meet the Biden Administration's deadline (which was necessary step for the Biden Administration to issue vaccination mandates), and he would do so by operating as he did when evaluating the EUA vaccines in OWS.[67] The FDA's experts both resigned, after explaining publicly how the Biden FDA was not following science or good public policy related to vaccination and boosters.[68]

A. To force mandates on Americans, the Biden Administration rushed the BLA process for the Pfizer vaccine despite warnings from FDA scientists.

Following his inauguration, President Biden and his Administration turned from casting doubt on the vaccines developed during the Trump Administration[69] to encouraging people to take the just-released EUA vaccines, expanding the federal supply of the vaccines,[70] seeking boosters for the vaccine,[71] encouraging mask mandates, [72] social distancing, remote learning, and ultimately mandating vaccines. By the early summer of 2021, the Biden Administration announced various mandates related to the federal COVID-19 response, and had discussed mandating the vaccine.[73] Because full FDA BLA approval was necessary for the government or other organizations in the United States to require vaccination, by the spring of 2021 senior leadership at the FDA began discussing the importance of licensing the Pfizer vaccine.[74] People working on the project knew that an FDA license would be needed for the government and other

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[65] *See* Transcribed Interview of Peter Marks, *supra* note 44, at 172:14–20.
[66] *See, e.g.*, MG000001–02; *see generally* FDA-OC-2021-5574-000331–59.
[67] *See* FDA-OC02021-5574-000335; *see also* Transcribed Interview of Marion Gruber, *supra* note 15, at 101:18–102:5 (on mandates).
[68] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 115:11–117:3.
[69] *See* Sean Sullivan, *Biden Questions Whether a Vaccine Approved by Trump Would Be Safe*, Wash. Post (Sept. 16, 2020); Sydney Ember, *Biden, Seizing on Worries of a Rushed Vaccine, Warns Trump Can't Be Trusted*, N.Y. Times (Sept. 15, 2020) (updated Jan. 15, 2021).
[70] *See Fact Sheet: President Biden Announces New Steps to Boost Vaccine Supply and Increase Transparency for States, Tribes, and Territories*, The White House (Jan. 26, 2021).
[71] *See generally Examining Our COVID-19 Response: An Update from Federal Officials: Hearing Before S. Comm. on Health, Educ., Lab., & Pensions*, *supra* note 1362 (testimony of Dr. David Kessler, Chief Science Officer, COVID Response, DHHS, regarding boosters and other behaviors) (testimony of Dr. Peter Marks, Director, FDA Center for Biologics Evaluation and Research).
[72] *See Executive Order on Protecting the Federal Workforce and Requiring Mask-Wearing*, The White House (Jan. 20, 2021).
[73] *See* Transcribed Interview of Philip Krause, Former Deputy Director, FDA Center for Biologics Evaluation & Research, Office of Vaccines Research & Review (Sept. 7, 2023), at 125:11–14.
[74] *See* Transcribed Interview of Philip Krause, *supra* note 7373, at 125:9–18.

institutions to issue vaccine mandates.[75] That is, even though the Pfizer EUA vaccine was still undergoing post-marketing surveillance and review to evaluate its safety, efficacy, and impact on different populations, political pressure began to mount early in the Biden Administration to issue a fully licensed Pfizer vaccine.[76]

Pfizer submitted the BLA for its COVID-19 vaccine on May 12, 2021.[77] The Biden Administration wanted everyone to be vaccinated, but needed the FDA to approve a license under the BLA protocol to mandate vaccination.[78] The standard timeline to approve a BLA is ten to twelve months, but a BLA may be given priority and that timeline may be reduced to six to eight months when, "if approved, [there] would be significant improvements in the safety and effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications."[79] Dr. Marks testified that the Pfizer EUA and BLA vaccines were "the same vaccine;"[80] meaning he gave the Pfizer vaccine unprecedented priority even though it was the same as the "standard application" being delivered under the EUA.

The law requires rigor in the FDA BLA approval process to protect the public from taking unsafe, dangerous, or ineffective vaccines.[81] These rigorous criteria necessarily require that the vaccine evaluation process consider nuances in demographic groups and factors for health care professionals to consider before administering the vaccine.[82] This process informs health care providers in making decisions as to the best health care solutions for patients.[83] The testing process is iterative and requires constant back-and-forth between the manufacturer and FDA, as the manufacturer continues to study the safety and efficacy of the product to continue to update the package inserts and information for health care providers.[84]

At the FDA, Dr. Marion Gruber had been the ultimate decision-maker for vaccine BLAs for several years as Director of the Office of Vaccines Research and Review (OVRR).[85] She served on committees with the World Health Organization (WHO), including six years on the Global Advisory Committee for Vaccine Safety.[86] Dr. Gruber oversaw vaccine research for the

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[75] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 60:16–25; Transcribed Interview of Philip Krause, *supra* note 73, at 132:11–20; Transcribed Interview of Peter Marks, *supra* note 4, at 89:19–21.
[76] *See Remarks by President Biden on the COVID-19 Response and the State of Vaccinations*, The White House (Mar. 29, 2021).
[77] *See Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older*, Pfizer (Aug. 23, 2021).
[78] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 61:23–64:2; Transcribed Interview of Peter Marks, *supra* note 4, at 89:15–24; *see also Press Briefing by White House COVID-19 Response Team and Public Health Officials*, The White House (June 22, 2021).
[79] *See Priority Review*, *supra* note 51*; see also* Transcribed Interview of Marion Gruber, *supra* note 15, at 27:15–16.
[80] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 172:14–20.
[81] *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA (2017); *see also* 21 C.F.R. § 600–680 (describing the high standards of production and agency review for a BLA); *see also* https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 ("Ensuring the safety and effectiveness of vaccines is one of FDA's top priorities.").
[82] *See* Integrated Summary for Effectiveness: Guidance for Industry 2–12, FDA (Oct. 2015).
[83] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 181:5–182:6.
[84] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 34:5–35:20.
[85] *See id.* at 7:22–9:1.
[86] *See id.* at 13:20–25.

2009 H1N1 pandemic and the Ebola outbreak of 2014 to 2016—experiences that gave her particular insights on how to approach, streamline, and accelerate vaccine license reviews in the face of public health emergencies.[87] As the OVRR Director, Dr. Gruber oversaw the efforts under OWS involving risk and investment for the vaccine manufacturing process, which helped bring COVID-19 vaccines to the market in remarkable speed under a less-stringent EUA.[88] Dr. Gruber had several meetings with WHO during the pandemic, at which she exchanged the scientific information being learned about the vaccines under development around the world.[89]

Dr. Gruber worked closely with Dr. Philip Krause, who was the Deputy Director at OVRR.[90] A long-time scientist at FDA, Dr. Krause published more than 100 peer-reviewed articles on vaccinology, virology, epidemiology, vaccine safety, and biostatics.[91] During the pandemic, Dr. Krause was also assigned as a liaison from the OVRR to the WHO.[92] Early in the pandemic, Dr. Krause became the chair of the WHO expert working committee on COVID-19 vaccines.[93] Like Dr. Gruber, Dr. Krause also ran frequent meetings on the topic of COVID-19 vaccine development around the world, helped to coordinate international and WHO scientific responses to the pandemic, and reviewed vaccine applications at the FDA.[94] Dr. Krause also worked with the Coalition for Epidemic Preparedness Innovations (CEPI), a non-profit non-government organization aimed at promoting vaccine development to prepare for pandemics.[95]

By the spring of 2021, reports of myocarditis in healthy young males following vaccination surfaced, suggesting that while the vaccine would be a good choice for an unvaccinated immunocompromised person, it may in fact be on net harmful for an otherwise healthy, young person.[96] Further, as Dr. Gruber told the Subcommittee during her transcribed interview, it was not clear whether the vaccines were more effective than natural immunity for healthy people with prior COVID-19 infections.[97] Despite the Biden Administration's insistence for everyone to get vaccinated immediately, there was no evidence to warrant vaccination for healthy individuals with prior infection, particularly ahead of those in high-risk groups.[98]

Pfizer's EUA post-marketing analysis was particularly important because, as Dr. Marks explained in his transcribed interview, the Pfizer BLA vaccine reviewed under the BLA was the same as the Pfizer EUA vaccine.[99] For the BLA approval, the FDA relied on different data that included the EUA post-marketing data, Pfizer data related to vaccine manufacturing facilities and processes, and other evidence from ongoing drug trials.[100] The BLA process also required

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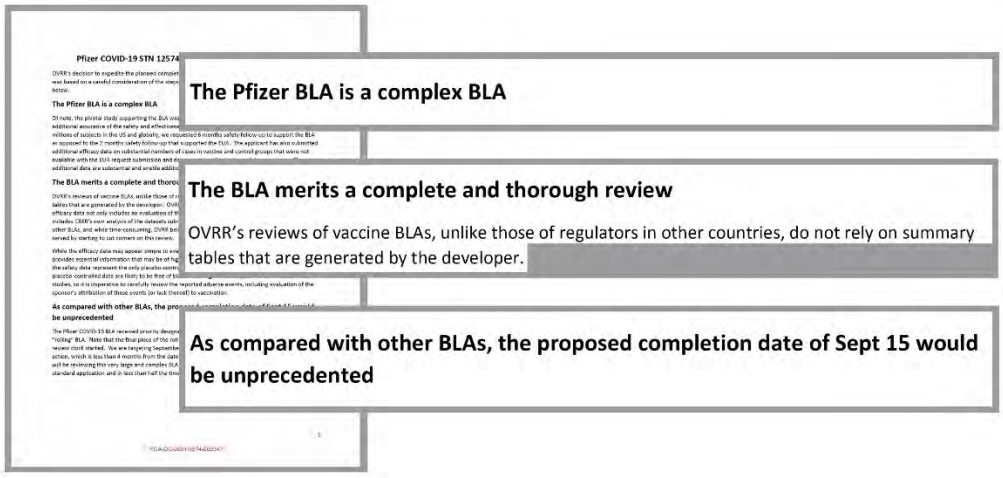
[87] *See* Kristen Abboud, *Marion Gruber, Changemaker*, International AIDS Vaccine Initiative (Nov. 9, 2023).
[88] *See id.*
[89] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 15:2–17.
[90] *See* Transcribed Interview of Philip Krause, *supra* note 73, at 12:2–13:8.
[91] *See id.*
[92] *See id.*
[93] *See id.*
[94] *See id.*
[95] *See id*.
[96] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 65:22–66:20.
[97] *See id.* at 17:10–18:17.
[98] *See* HJC_CDCMMWR000429–34.
[99] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 172:14–20.
[100] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 34:5–35:3.

updating fact-sheet disclosures to accompany the vaccine.[101] One issue that has come to light through the Subcommittee's oversight is that Pfizer sometimes reported serious adverse events to the FDA in misleading ways, though this did not concern Dr. Marks who relied on others to assess the claims of serious adverse events.[102]

When Pfizer filed a BLA, and the Biden FDA decided to grant priority to its review.[103] Although the BLA "was longer than [they] thought," Dr. Krause explained that the normal prioritized BLA review would have set an "action due date" (ADD) for approval at about January 18, 2022.[104] After this initial review, Drs. Gruber, Krause and Marks initially agreed to speed up the process with a target ADD of mid-October 2021,[105] which would have eliminated three months from the typical priority BLA approval.[106] Dr. Marks subsequently changed course and asked that the ADD be moved up another month, to September 15, 2021, telling Drs. Gruber and Krause that mid-October would be "taking too long."[107]

Dr. Marks and Acting Commissioner Woodcock asked again that the ADD be moved up even further, and Dr. Marks asked Dr. Gruber to "justify" the September 15, 2021 ADD.[108] Both in conversations and in an email dated July 15, 2021, Dr. Gruber informed Dr. Marks that the September 15, 2021 ADD was feasible for the BLA review, but anything earlier would require "cutting corners" and lowering their review standards.[109] Dr. Gruber made clear to Dr. Marks that she could not support any action requiring the FDA to cut corners or lower its standards.[110] She provided an analysis to Dr. Marks explaining that the Pfizer vaccine BLA was "complex," warranted "complete and thorough review," and even the September 15, 2021 ADD, "would be unprecedented."[111]

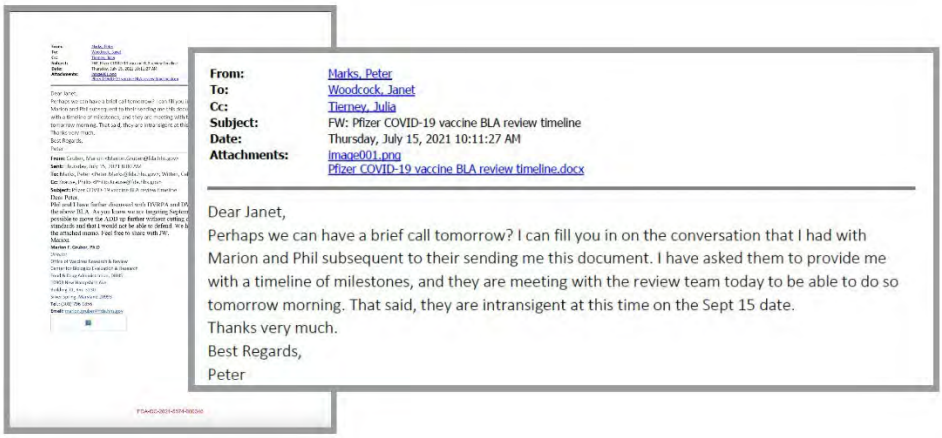
[101] *See id.* at 22:4–23:1.
[102] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 123:11–127:5.
[103] *See Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older*, Pfizer (Aug. 23, 2021).
[104] *See* Transcribed Interview of Philip Krause, *supra* note 73, at 87:9–88:3.
[105] *See id.* at 104:18–24.
[106] FDA-OC-2021-5574-000347–50.
[107] *See* Transcribed Interview of Philip Krause, *supra* note 73, at 85:6–10.
[108] *See* FDA-OC-2021-5574-00346; FDA-OC-2021-5574-00351.
[109] *See* FDA-OC-2021-5574-00351.
[110] *Id.*
[111] *See, e.g.*, FDA-OC-2021-5574-000346–49.



Drs. Gruber and Krause both testified to the Subcommittee that they felt pressure to rush the review for the licensing of the Pfizer vaccine despite the need for further review related to the efficacy and safety of the vaccine.[112] Dr. Gruber explained that the risk of myocarditis in young men was "evident" under the EUA, and that risk required close evaluation under the higher BLA review standards.[113]

Nonetheless, the Biden Administration decided to push the approval process for an earlier completion date. Dr. Marks went back to Drs. Gruber and Krause and explained that they would "need" to complete the review faster than the September 15 target date.[114] In a separate email on July 15, 2021, Dr. Marks told Acting Commissioner Woodcock that Drs. Gruber and Krause were "intransigent at this time on the Sept[ember] 15 date."[115]

[112] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 61:13–15, 65:22-66:20; Transcribed Interview of Philip Krause, *supra* note 73, at 54:14–24.
[113] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 23:5–24:15, 65:22–66:20.
[114] *See* Transcribed Interview of Philip Krause, *supra* note 73, at 86:2–7.
[115] FDA-OC02021-5574-000346.



From: Marks, Peter
To: Woodcock, Janet
Cc: Tierney, Julia
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Date: Thursday, July 15, 2021 10:11:27 AM
Attachments: image001.png
Pfizer COVID-19 vaccine BLA review timeline.docx

Dear Janet,
Perhaps we can have a brief call tomorrow? I can fill you in on the conversation that I had with Marion and Phil subsequent to their sending me this document. I have asked them to provide me with a timeline of milestones, and they are meeting with the review team today to be able to do so tomorrow morning. That said, they are intransigent at this time on the Sept 15 date.
Thanks very much.
Best Regards,
Peter

Dr. Gruber testified that the reasons she was given for FDA leadership's demand to move up the ADD were vaccine hesitancy and a desire for a "vaccine mandate."[116] Dr. Gruber testified that both Dr. Marks and FDA Acting Commissioner Woodcock expressed interest in the vaccine mandates, and it was common knowledge that, absent FDA approval, the federal government and states could not require mandatory vaccination.[117] Dr. Gruber explained that in her career, the subject of a mandate had never been a factor in a vaccine licensure review.[118] Dr. Marks explained that historically, the FDA does not get involved in policies related to mandates.[119] Yet for the Pfizer BLA, the pressure was on to rush the review to meet the desire to get a licensed vaccine that the Biden Administration could require Americans to take.

B. The Biden FDA removed the experts who raised concerns during the Pfizer BLA review.

Senior leadership at the Biden FDA worked behind the scenes to undermine the vaccine experts as they were counseling caution in rushing the vaccine approval. Following Dr. Gruber's July 15, 2021, email to Dr. Marks explaining why moving the ADD up would compromise the integrity of the BLA, Dr. Marks forwarded the email to Dierdre Hussey, Director of the Office of Management in the Center for Biologics and Research to "document" the issue. [120] In the email to Hussey, Dr. Marks claimed he verbally requested a timeline to "justify" the already aggressive ADD.[121] Dr. Marks emailed Hussey in an apparent attempt to create "human resources consequence[s]," in the words of Dr. Krause, for Dr. Gruber's principled stand that a date before September 15 was not possible.[122]

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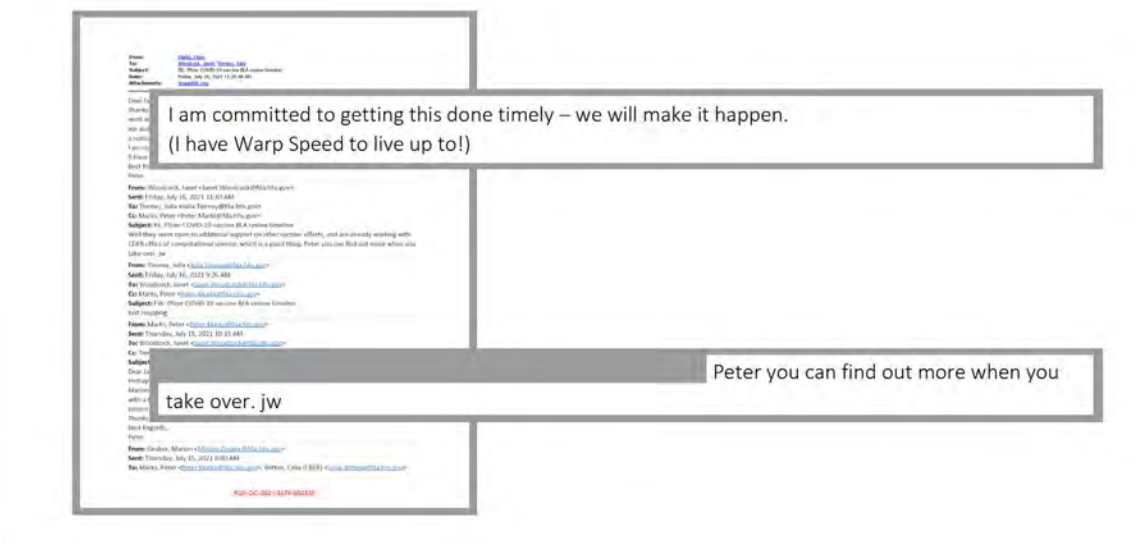
[116] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 101:21–102:8.
[117] *See id*. at 60:18–62:15.
[118] *See id*. at 67:7–12.
[119] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 90:15–20.
[120] *See* FDA-OC02021-5574-000351.
[121] *See id.*
[122] *See* FDA-OC-2021-5574-000351; *see also* Transcribed Interview of Philip Krause, *supra* note 73, at 130:19–24.

Other documents reveal that Acting Commissioner Woodcock and Dr. Marks decided on or about July 15, 2021, that rather than heed Drs. Gruber and Krause's advice and warnings about the BLA review, to remove them from the review altogether.[123] Dr. Marks sent to Acting Commissioner Woodcock Dr. Gruber's detailed explanation as to why rushing the Pfizer BLA review was a bad idea, adding that the experts were "intransigent."[124] Acting Commissioner Woodcock responded to Dr. Marks that he could simply "find out more when you take over."[125] Dr. Marks thanked Acting Commissioner Woodcock for this, committing to put all available assets on the Pfizer vaccine review for "four weeks"—a period that coincided with the Biden Administration's timeline for a vaccine mandate.[126] Dr. Marks told Acting Commissioner Woodcock that he was "committed to getting this done timely," and added, "I have warp speed to live up to."[127]



Three days later, on July 19, 2021, Acting Commissioner Woodcock and Dr. Marks met with Drs. Gruber and Krause and informed them that OVRR management and oversight of the BLA review was being transferred to Dr. Marks.[128] In a departure as to how substitutions of project leadership are handled at the FDA, Acting Commissioner Woodcock informed the group that Dr. Krause would not be filling in during Dr. Gruber's planned absence (for a family event), which she had already planned prior to the BLA in-fighting.[129] Based on opinions expressed during this meeting, Drs Gruber and Krause later testified separately to the Subcommittee that they believed Acting Commissioner Woodcock shared Dr. Marks' desire to expedite the BLA process and ADD.[130]

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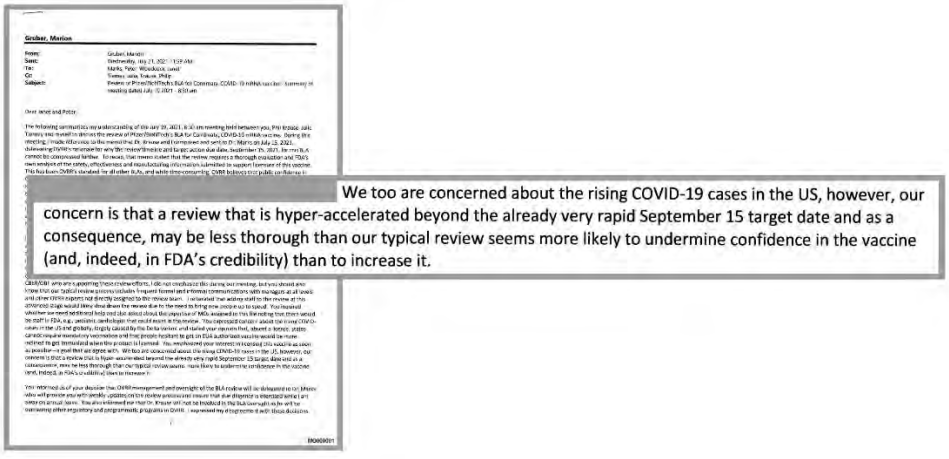
[123] FDA-OC02021-5574-000335.
[124] *Id.*
[125] *Id.*
[126] *Id.*
[127] *Id.* (cleaned up).
[128] *Id.*; *see also* MG000001–02; *see also* HJCVaccine00003–5 (reflecting FDA internal notes of the same meeting).
[129] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 68:16–69:14.
[130] *See id.* at 69:7–14; *see also* Transcribed Interview of Philip Krause, *supra* note 73, at 132:9–18; *see* also MG000001–02; HJCVaccine00003–5.

In the meeting on July 19, Dr. Gruber explained again to both Acting Commissioner Woodcock and Dr. Marks that there were significant risks with the deadline and raised concerns with BLA "becoming increasingly complex in light of increasing evidence of association of this vaccine and the development of myocarditis (especially in young males but also other ages included in the BLA indication.)"[131]

In an email to Acting Commissioner Woodcock and Dr. Marks following the July 19, 2021 meeting, Dr. Gruber noted that the driving factors for the rushed review, as expressed by Acting Commissioner Woodcock and Dr. Marks, were "mandates" and the increase in COVID-19 cases stemming from the emerging Delta variant.[132] She explained that, "our concern is that a review that is hyper-accelerated beyond the already very rapid September 15 target date and as a consequence, may be less thorough than our typical review seems more likely to undermine confidence in the vaccine (and, indeed, the FDA's credibility) than to increase it."[133]


Gruber, Marion

We too are concerned about the rising COVID-19 cases in the US, however, our concern is that a review that is hyper-accelerated beyond the already very rapid September 15 target date and as a consequence, may be less thorough than our typical review seems more likely to undermine confidence in the vaccine (and, indeed, in FDA's credibility) than to increase it.

Despite Dr. Gruber's clear warning that moving the ADD earlier could undermine the FDA's BLA program, Dr. Marks deferred to the Biden-appointed Acting Commissioner Woodcock, that he could proceed as he had done under the EUA standard in OWS.[134] In the end, Dr. Marks would approve the vaccine in time for the Biden Administration to mandate it to the healthy young men and women serving the United States armed services.

C. FDA experts sought to expose inaccurate information about vaccine boosters.

In addition to mandating the vaccine, the Biden Administration also suggested that vaccine booster shots would be required. During her transcribed interview with the

[131] *See* MG000001–02; *see also* HJCVaccine00003–5
[132] *See* MG000001–02; *see also* HJCVaccine00003–5.
[133] *See* MG000001–02; *see also* HJCVaccine00003–5.
[134] *See* FDA-OC02021-5574-000335; FDA-OC02021-5574-000338.

Subcommittee, Dr. Gruber emphasized that the extra layer of oversight in BLA review was necessary given that safety in vulnerable populations, such as children, was even more important to avoid vaccinations that may do more harm than help for some people.[135] Dr. Gruber saw multiple media publications writing about booster shots and how the booster was necessary for the general population, so she and Dr. Krause decided to write an article in the *Lancet* expressing their difference in opinion.[136] Dr. Gruber testified that she thought boosters were necessary for the elderly and the immunocompromised but did not think a booster was necessary for the general public.[137] She also raised concern that the abbreviated BLA process could undermine the credibility of the FDA and the administrative approval process and pressing for boosters to the vaccines for the general public could deepen vaccine hesitancy because it signaled that the vaccine was not necessarily effective alone.[138]

Dr. Gruber expressed that to curb the pandemic she believed it would be better to provide vaccines to people who did not have the vaccine yet on a global level and to limit the boosters to the elderly and immunocompromised.[139] Dr. Gruber testified that she did believe there was not an increased benefit for a "young healthy person" who had received the primary vaccination to receive the booster at that time.[140]

D. Dr. Marks's testimony is inconsistent with contemporary emails and the facts about the state of the pandemic when he made key decisions.

Dr. Marks testified during his transcribed interview that he rushed the BLA review because of COVID-19 hospitalizations and deaths in the late summer of 2021.[141] However, neither his email exchanges with Dr. Woodcock nor Dr. Gruber's contemporaneous memorialization of their conversation in mid-July 2021 make any suggestion of such a rise of hospitalizations or deaths as motivating the drive for cutting corners in the BLA process.[142]

Dr. Marks's claims that rising death and hospitalization rates in July 2021 pushed the vaccine review also seems implausible because the death and hospitalization rates at that point were the lowest at any time during the pandemic until 2023. Contemporaneous CDC data showed death and hospitalization rates were down, though they began to rise in August 2021.[143]

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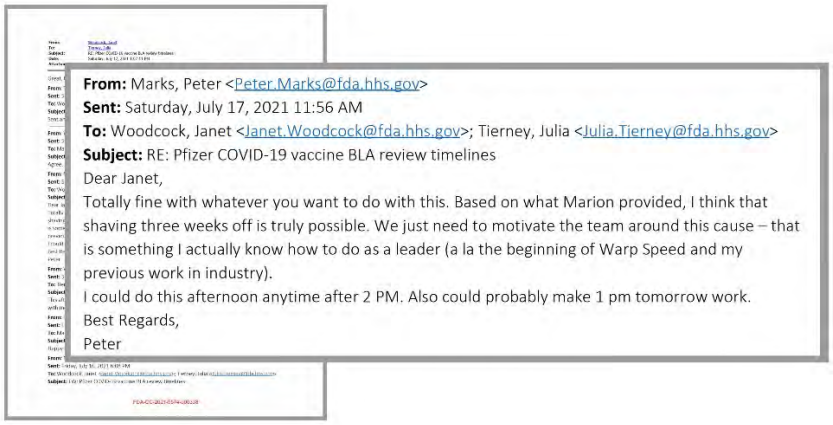
[135] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 65:4–66:21.
[136] *See id*. at 79:2–23; *see also* Philip R. Krause, MD, et al., *Considerations in Boosting COVID-19 Vaccine Immune Responses*, Lancet, vol. 398, no. 10308, 1377–80 (Oct. 9, 2021).
[137] *See id; see also* Transcribed Interview of Marion Gruber, *supra* note 15, at 79:13–16.
[138] *See* MG000001–02.
[139] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 79:17–20.
[140] *See id*. at 80:8–10.
[141] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 91:14–92:1.
[142] *See, e.g.*, FDA-OC-2021-5574-000335–59.
[143] *See* FDA-OC-2021-000335; *see also Trends in United States COVID-19 Deaths, Emergency Department (ED) Visits, and Test Positivity by Geographic Area*, COVID Data Tracker, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00 (last accessed Jun. 19, 2024); *COVID-NET Laboratory-confirmed COVID-19 Hospitalizations*, COVID Data Tracker, Ctrs. for Disease Control & Prevention, https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network (last visited June 19, 2024).

In fact, the data show a significant spike in hospitalizations *after* the Biden FDA cut corners in the BLA process and the Biden Administration started mandating the vaccine.

According to documents and testimony, Dr. Marks's other reason for rushing the Pfizer BLA was vaccine hesitancy.[144] When Dr. Marks testified, he described to the Subcommittee how "vaccine hesitancy" was a problem, and that the government was sending divergent messages related to the vaccine.[145] Dr. Marks testified that he received "hundreds" of emails from people wanting an FDA-approved vaccine.[146] Dr. Gruber explained to Dr. Marks and Acting Commissioner Woodcock in an email dated July 15, 2021, and again in a meeting on July 19, 2021, however, that cutting corners on the BLA approval simply to be able to give the public more confidence in the vaccine would, in fact, undermine that confidence and exacerbate vaccine hesitancy.[147] Dr. Marks' response to Dr. Gruber, as far as the Subcommittee can discern, was to inform Acting Commissioner Woodcock that he was "totally fine with whatever you want to do with this," as the two ignored Drs. Gruber and Krause's warnings.[148]



From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Saturday, July 17, 2021 11:56 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Dear Janet,
Totally fine with whatever you want to do with this. Based on what Marion provided, I think that shaving three weeks off is truly possible. We just need to motivate the team around this cause – that is something I actually know how to do as a leader (a la the beginning of Warp Speed and my previous work in industry).
I could do this afternoon anytime after 2 PM. Also could probably make 1 pm tomorrow work.
Best Regards,
Peter

During his transcribed interview, Dr. Marks testified that the Pfizer EUA and BLA vaccines were "the same vaccine."[149] When pressed why, if the two drugs were the "same vaccine," he did not simply encourage the use of the EUA vaccine to address vaccine hesitancy, Dr. Marks acknowledged that it was a "[r]eally good point," but that "people would feel more

[144] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 54:6–55:6, 88:6–14; *see also* MG000001–02; FDA-OC-2021-5574-000351 ("In my opinion, the recurrent recent deterioration during the current public health emergency necessitates that we fully mobilize all center resources in order to approve a BLA for a COVID-19 vaccine as rapidly as possible.").
[145] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 180:17–182:6 ("And finally, I'd just say that it also helps if we could have consistent messaging, because I think there were divergent message [*sic*] from different places that were tougher.").
[146] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 88:6–14.
[147] *See* FDA-OC-2021-5574-000335–36; *see also* MG000001.
[148] FDA-OC-2021-5574-000338.
[149] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 172:14–20.

comfortable than [taking a vaccine] that was felt to be experimental by some."[150] Dr. Gruber warned that Dr. Marks' approach could have the opposite effect.[151] Dr. Gruber expressed concern that rushing the fully licensed vaccine would undermine that confidence in the vaccines.[152]

III. THE CDC FOUGHT CONGRESSIONAL OVERSIGHT AND PUT FORWARD UNSUPPORTED JUSTIFICATIONS FOR ITS ACTIONS WHILE THE FDA ABUSED ITS AUTHORITY TO PROMOTE THE PFIZER VACCINE.

On December 12, 2020, the CDC issued guidance on the recently approved EUA vaccine.[153] Immediately concerns were raised about the accuracy of the CDC's claims and Members of Congress, including Subcommittee Chairman Massie, began asking questions of the CDC.[154] The CDC's response was to push back and, in some cases, try to squelch the speech of its critics.

Later, the FDA decided to become the voice advocating for the vaccine, without coordinating with the other HHS entities. Dr. Marks started hosting a series of short videos designed to convince Americans to take the vaccine, without providing the same disclaimers drug providers are required to provide in their marketing materials. The CDC's and the FDA's actions reflect how the administrative state became both unaccountable for and out of control in their messaging, likely putting Americans in danger.

A. The CDC sought to thwart Congressional oversight.

When the FDA released the Pfizer EUA vaccine in December 2020, the CDC represented that it was effective in stopping the spread of COVID-19, even on people who were already infected.[155] The CDC Morbidity and Mortality Weekly Report (MMWR) asserted that with the Pfizer EUA, "[c]onsistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection."[156]

On December 16, 2020, Chairman Massie called the CDC to ask if there was an error in the MMWR of December 13, 2021.[157] Chairman Massie was concerned that the evidence provided during an FDA Vaccines and Related Biological Products Advisory Committee

[150] *See id.* at 138:18–139:2.
[151] MG000001–02.
[152] *Id.*
[153] *See* Sara E. Oliver et al., *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine – United States, December 2020*, 69 Morbidity and Mortality Weekly Report 1922–24 (Dec. 12, 2020).
[154] *See generally* HJC_CDCMMWR000429–36.
[155] *See generally id.*
[156] *See* HJC_CDCMMWR000240.
[157] *See* HJC_CDCMMWR000240–41.

(VRBPAC) meeting did not support the CDC's claim.[158] The CDC checked internally, and initially assessed that the data supporting the claim was limited, but the agency did not follow up with Chairman Massie until he reached out to the CDC again in January 2021.[159]

On January 19, 2021, Chairman Massie contacted the CDC again, explaining that he was concerned that people with prior infections were being misled and receiving the vaccine ahead of people who needed the vaccine more.[160] Chairman Massie reached out to the primary author of the MMWR recommendation, which prompted CDC career staff to address Chairman Massie's concern.[161] Another CDC employee directed third-party scientists who evaluated the vaccine not to engage with Chairman Massie or respond to his questions.[162] One CDC employee even apologized to others that Chairman Massie was reaching out with questions about the CDC's claims.[163]

On January 20, 2021, Chairman Massie again spoke with CDC staff, explaining that he thought the CDC would have clarified its confusing messaging.[164] Internal CDC notes concerning Chairman Massie's call show that the CDC was aware that there was "not sufficient information to [support the CDC's claim in MMWR,]" but that the information was only written for the general public, as "opposed to what is in the detailed [Advisory Committee on Immunization Practices] review of the data."[165] These same internal notes reflect the CDC's belief that "while there is an ability to get an erratum out there" to clarify the language for the public, "doing so is a matter of competing priorities."[166] In short, despite making an unsupported claim about vaccine efficacy—and being called out on the claim by Chairman Massie—the CDC refused to be transparent, insisting against issuing an erratum to correct the error.[167]

As the Committee on the Judiciary and the Select Subcommittee on the Weaponization of the Federal Government have revealed, the Biden Administration sought to censor speech online—as well as books sold on online platforms—that raised concerns about the safety and efficacy of the Pfizer vaccine on certain patients.[168] The administrative state at the Biden CDC has sought to slow Subcommittee oversight, with requests for documents still outstanding, refusing to acknowledge or address confusing and misleading communications, or declining to make efforts to improve on the messaging related to the risks of the COVID-19 vaccines.[169]

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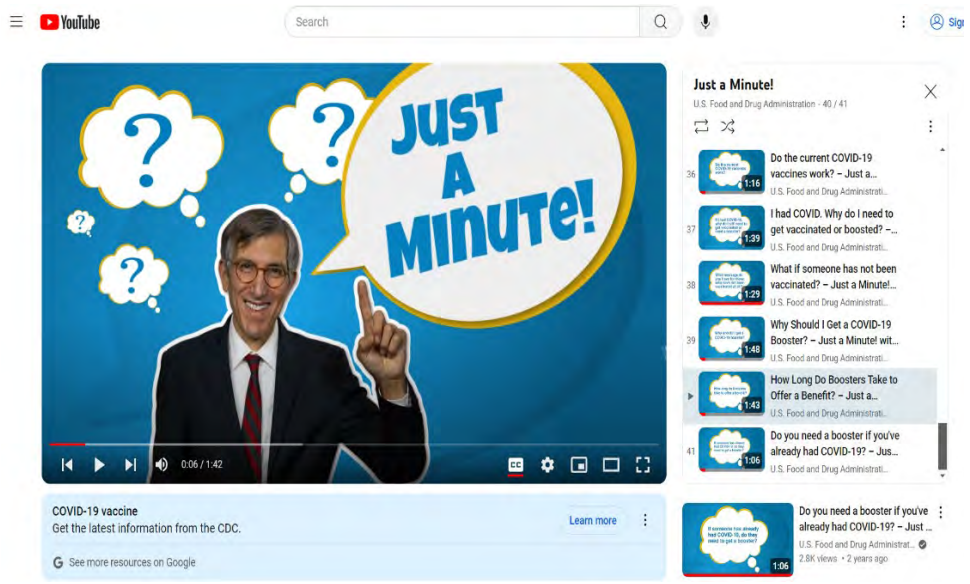
[158] *See* HJC_CDCMMWR000240.
[159] *See* HJC_CDCMMWR000239.
[160] *See* HJC_CDCMMWR000214.
[161] *See id.*
[162] *See id.*
[163] *See id.*
[164] *See* HJC_CDCMMWR000001-002.
[165] *Id.*
[166] *Id.*
[167] *See* HJC-CDCMMWR00000451.
[168] *See* INTERIM STAFF REP. ON THE CENSORSHIP-INDUSTRIAL COMPLEX: HOW TOP BIDEN WHITE HOUSE OFFICIALS COERCED BIG TECH TO CENSOR AMERICANS, TRUE INFORMATION, AND CRITICS OF THE BIDEN ADMINISTRATION, *supra* note 12, at 1–5.
[169] *See* HJC_CDCMMWR000429–59.

B. Dr. Marks became an active advocate for the Pfizer vaccine after approving the Pfizer BLA.

By late 2021, Dr. Marks became a public advocate promoting the Pfizer vaccine in his role at the FDA.[170] The FDA began a media campaign of promoting videos entitled "Just a Minute," with Dr. Marks hosting, during which Dr. Marks promoted the vaccine.[171]



In this public relations campaign for the vaccine, comprised of 41 videos in total, Dr. Marks actively promoted the vaccine—a role that the FDA is not authorized to do.[172] This effort may have assuaged concerns among an unknowing public, but it has the long-term effect of undermining confidence in the FDA as an impartial government agency. In some cases he failed to provide important information and disclaimers related to the vaccine.[173] When asked on what authority he and the FDA produced these videos, Dr. Marks testified that the unique nature of the pandemic and the need to address vaccine hesitancy required the exceptional actions, even though such advertising is something the manufacturers may only do under strict regulations as to the representations that may be made.[174] This is another instance where the administrative state engaged in conduct for which it is unaccountable and which it would never accept from a regulated entity.

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[170] *See* FDA, *How Long Do Boosters Take to Offer a Benefit? – Just a Minute! with Dr. Peter Marks*, YouTube (Dec. 23, 2021).
[171] *See, e.g.*, *id.*
[172] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 83:10–85:6.
[173] *See id.* at 81:7–82:7.
[174] *See id.* at 78:16–79:24.

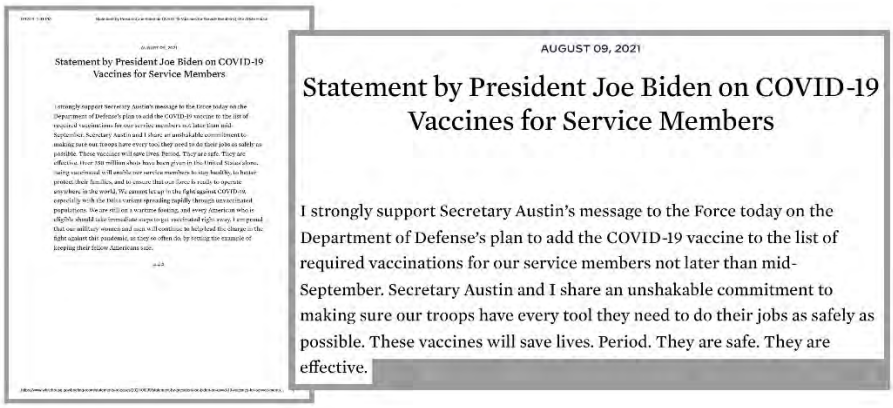
IV. THE RUSHED AND POLITICIZED PROCESS RESULTED IN REAL AND AVOIDABLE HARM TO AMERICANS.

With the stroke of a pen, the Biden Administration struck a deep blow to readiness of the United States armed services. In just 16 months over 8,400 servicemembers were involuntarily forced out of the military through the imposition of the Administration's COVID-19 vaccine mandate.[175] The exodus of these 8,400 service members from our military likely represents only the tip of the iceberg relative to the harm, as countless other service members resigned their commissions, opted not to reenlist, or retired before they otherwise would have.[176] In the last three years, the Army shrank by 40,000 soldiers, the Air Force by 13,475 airmen, the Navy by 10,000 sailors, and the Marine Corps by 8,900 Marines.[177] Even with these drastic reductions of military strength, the Department of Defense still failed its Fiscal Year 2023 recruitment target by more than 41,000 troops.[178]

A. The Biden Administration used the administrative state in ways that hurt the U.S. armed services.

In the summer of 2021, the Biden Administration made the political calculation that it needed to be seen as doing something about the threat of a new COVID-19 variant. To achieve the desired political appearance, the FDA had to deliver in two ways. First, the FDA needed to authorize boosters, but this could only be done by politicizing science. The "inescapable conclusion" of the scientific data at the time, according to the FDA's top vaccine expert, was "that a booster was not going to have a significant impact on people's protection against severe disease."[179] The second thing was that the FDA had to approve a BLA for a COVID-19 vaccine—not necessarily because it warranted licensure—but to increase American's confidence in the vaccine and because licensure of the vaccine was seen as a "prerequisite to mandates."[180] At the same time the Biden Administration was developing this strategy, according to a contemporaneous news accounts, a "study of U.S. service members found higher than expected rates of heart inflammation following receipt of COVID-19 vaccines. It's a finding Defense Department researchers say should call attention to the condition, known as myocarditis, as a potential side effect."[181]

[175] *See, e.g.*, Lara Seligman, *Pentagon Mulls Back Pay for Troops Kicked out Over Covid Vaccine Mandate*, Politico (Jan. 13, 2023) (noting that more than 8,400 service members were discharged for refusing the vaccine).
[176] *See, e.g.*, Oren Liebermann, *Only 43 of More Than 8,000 Discharged from US Military for Refusing Covid Vaccine Have Rejoined*, CNN (Oct. 2, 2023) (noting that only 43 service members discharged for refusing to take the vaccine sought to rejoin, and that the Biden Administration dropped its vaccine mandate amid concerns that the mandate hurt "recruiting and retention efforts").
[177] *See* Timothy Frudd, *US Military 41,000 Troops Short of Recruitment Goal*, Am. Military News (Dec. 19, 2023).
[178] *See id.*
[179] *See* Transcribed Interview of Philip Krause, *supra* note 73, at 69:3–4.
[180] *See id.* at 125:11–18.
[181] *See* Patricia Kime, *DoD Confirms: Rare Heart Inflammation Cases Linked to COVID-19 Vaccines*, Military.com (June 30, 2021).

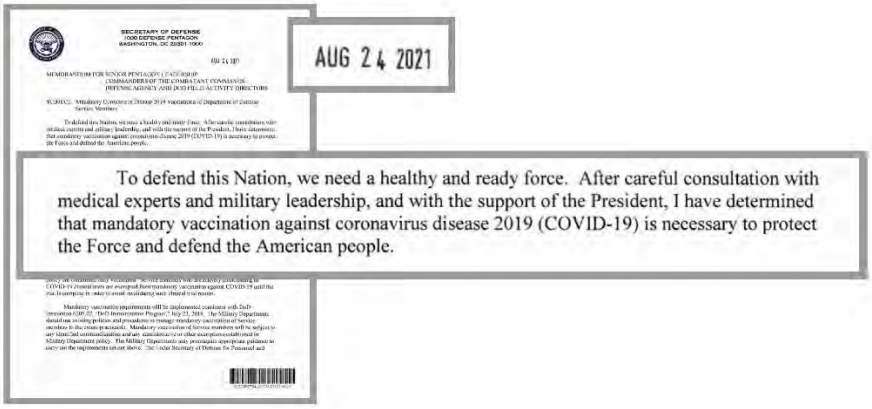


AUGUST 09, 2021

Statement by President Joe Biden on COVID-19 Vaccines for Service Members

I strongly support Secretary Austin's message to the Force today on the Department of Defense's plan to add the COVID-19 vaccine to the list of required vaccinations for our service members not later than mid-September. Secretary Austin and I share an unshakable commitment to making sure our troops have every tool they need to do their jobs as safely as possible. These vaccines will save lives. Period. They are safe. They are effective.

The Biden Administration did not allow this inconvenient science to derail its political plans to mandate the vaccine.[182] The FDA ultimately gave full approval to the Pfizer-BioNTech COVID-19 vaccine on August 23, 2021, and on August 24, 2021, Secretary of Defense Lloyd Austin mandated COVID-19 vaccination for all service members.[183] In a memorandum outlining the vaccine mandate, Secretary Austin wrote that the services "should impose ambitious timelines for implementation" and that they must "report regularly on vaccination completion" within their respective branches.[184]



SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

AUG 24 2021

To defend this Nation, we need a healthy and ready force. After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people.

[182] *See* The White House, *Statement by President Joe Biden on COVID-19 Vaccines for Service Members* (Aug. 9, 2021).
[183] *See Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members*, *supra* note 13.
[184] *Id.*

In the absence of a large-scale war in which to distinguish themselves from their peers, military commanders sought to demonstrate their leadership ability by outpacing each other in how quickly they achieved complete compliance with the mandate within their respective units.[185] As this was a practice that had nothing to do with actual military competence, commanders of all abilities could compete for the first time on a playing field that ignored military ability and favored an anything-goes approach to achieve compliance. Empowered by the Secretary of Defense, some commanders took personal offense to service members in their units who were reluctant to be vaccinated, resorting to reprehensible coercion to achieve their ends.[186] The military adopted a vaccination strategy, akin to the one explained by Dr. Anthony Fauci, focused on arming organizational leaders with legal protections that empowered those leaders to embrace tactics of coercion: "It's been proven, when you make it difficult for people in their lives, they lose their ideological bull[****] and get vaccinated."[187]

In practice, the protections touted by Dr. Fauci amounted to an endorsement for commanders to wrongly discriminate, isolate, harass, and ultimately separate service members who did not comply with their mandates. In one such example, a Naval Special Warfare Operator (SEAL) was repeatedly denied by his commander the medically essential treatment he sought for a traumatic brain injury he suffered in service because he was unvaccinated.[188] In another case, a young female minority airman was threatened by her commander with dishonorable discharge for not getting the vaccine. When she refused to cave to threats from her commander, she was subjected to a sort of "forced solitary confinement" through her commander's weaponization of quarantine protocols.[189] The quarantine assignments were 14-day stints and "consisted of being isolated to a barracks room with zero in-person communication with human beings, and meals delivered three times a day from people wearing hazmat suits."[190] During the first week of quarantine, servicemembers were totally isolated and confined to their rooms; during the second half, servicemembers were permitted a mere 45 minutes per day outside but were still confined in a "small guarded and taped off area outside the quarantine barracks."[191] This young airmen was routinely subjected to back-to-back assignments in quarantine and ultimately spent a total of 140 days in forced isolation before being involuntarily separated from the service and stripped of benefits associated with her veteran status.[192]

The insidious nature of the administration's mandate enforcement strategy perverted the sacred bond that must exist between military commanders and the servicemembers under their charge. A former Commandant of the Marine Corps described the relationship between officers

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[185] *See* Robert A. Green Jr., *Defending the Constitution Behind Enemy Lines* 44 (2023).
[186] *See* Danielle Runyun, Written Testimony provided to the Select Subcommittee on the Coronavirus Pandemic, (Jul. 27, 2023) [hereinafter "Runyun Testimony"].
[187] *See 'Ideological Bulls--t': Rich McCormick Grills Fauci on Audio of Him Discussing Vaccine Requirements*, *supra* note 13.
[188] *See* Runyun Testimony, *supra* note 186.
[189] Robert A. Green Jr. @RobGreen1010, X (May 14, 2024, 9:22 AM), https://x.com/RobGreen1010/status/1790372061283528965. Green is an active-duty Navy Commander that has written extensively on the ramifications associated with the COVID-19 vaccine mandate on the armed services.
[190] *Id.*
[191] *Id.*
[192] *See id.*

and enlisted "to in no sense be that of superior and inferior nor that of master and servant, but rather that of teacher and scholar. In fact, it should partake of the nature of the relationship between father and son, to the extent that officers, especially commanding officers, are responsible for the physical, mental, and moral welfare" of the servicemembers entrusted to them.[193] Despite this responsibility for the welfare of their troops, military commanders not only issued blanket denials of service member's religious accommodation requests, but they also violated their informed consent rights.[194] It may be no surprise then that as a result, Americans' trust in military leadership has cratered.[195]

B. COVID-19 Vaccine injury is real, preventable, and still largely ignored by the Biden Administration.

A critical aspect of the EUA is the imperative for the administrative state to continuously evaluate in real-time the safety and effectiveness of the vaccine, and to possess the humility to constantly reassess that risk and adjust its response.[196] In short, the policy justifications supporting EUA anticipate that the federal government would need to constantly evaluate data, and, if necessary, admit that the solution being administered may not be the optimal solution for all people and remove the authorization.[197]

As the Pfizer EUA vaccine was being administered, reports came in of adverse effects including myocarditis, pericarditis, and severe neurological events.[198] As the Biden Administration took over in early 2021 the message turned to promoting the need for vaccination, even though risks were being reported.[199]

The culture inside the FDA in 2021 did not allow the agency to objectively consider that its advocacy for a mandatory COVID-19 vaccine may not have been optimal. It was clearly difficult for Dr. Marks, who appeared in 41 videos promoting the vaccine, to adequately address concerns about injuries relating to a vaccine with which he was so closely involved. It is far easier to simply suggest that the symptoms after receiving the vaccine were coincidental; as Dr.

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[193] *See* Richard Swain & Albert C. Pierce, *The Armed Forces Officer* 59, Nat'l Def. U. (2017).
[194] *See* Robert A. Green & W. Dean Lee, *The Institution or the Constitution*, Real Clear Defense (Mar. 25, 2024).
[195] *See id.*
[196] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 120:12–126:8.
[197] *See* Carrie MacMillan, *Emergency Use Authorization vs. Full FDA Approval: What's the Difference?*, Yale Medicine (Mar. 7, 2022) (describing how through post marketing surveillance the FDA found evidence to revoke the EUA for hydroxychloroquine because it learned that the treatment could pose a risk without offering a significant benefit).
[198] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 123:25–126:2; *see also* Apoorva Mandavilli, *Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?*, N.Y. Times (May 3, 2024).
[199] *See* President Joseph Biden, *Remarks by President Biden on the COVID-19 Response and the State of Vaccinations*, The White House (Mar. 29, 2021); *see also* Transcribed Interview of Marion Gruber, *supra* note 15, at 123:25–126:2; *see also Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?*, *supra* note 198; Transcribed Interview of Peter Marks, *supra* note 4, at 43:9–44:17, 127:24–132:1 (on discounting the relationship between harm and the vaccine).

Marks testified the FDA evaluated the evidence from Pfizer and in several cases did not find correlation or causation between vaccination and the onset of certain symptoms soon after.[200]

Reflecting on the FDA's handling of the vaccine approval process three years later, now-former Acting Commissioner Woodcock says today that she is "disappointed" with her involvement as many people suffered from "serious" and "life-changing" reactions to the vaccine- and that the FDA has not done enough to understand and address this important concern.[201]

V. CONCLUSION

The Biden Administration sought to mandate vaccines.[202] To do so, the FDA first needed to license the vaccines.[203] Two former FDA scientists, Drs. Gruber and Krause, testified to the Subcommittee that the pressure they felt to rush to cut corners on the vaccine review was due to pressure to mandate vaccines.[204] In his transcribed interview, Dr. Marks testified to other reasons (such as his claim that there were increased deaths when he made his decisions in mid-July 2021, that he received outside pressure for the FDA to give a full approval to a COVID-19 vaccine, and his personal concerns over the abilities of Gruber and Krause to complete the review on his abbreviated timeline), none of which were realistic or justifiable reasons to alter the FDA's procedures.[205] The only plausible conclusion, based on the testimony and contemporaneous documents, is that the FDA licensed the Pfizer vaccine BLA in the way it did to comport to the Biden Administration's anticipated mandate on August 24, 2021.[206] In doing so, and in then becoming an active proponent for the vaccine, the FDA succumbed to the Biden Administration's pressure to do things beyond its authority which may have long-term impacts on the agency's ability to confidently serve the American public.[207] Today former Acting FDA Commissioner Woodcock says that her involvement as it relates to vaccine-related injury that she is "disappointed in myself" and that the FDA did not do enough to address vaccine-related

[200] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 43:9–44:17, 127:24–132:1 (on discounting the relationship between harm and the vaccine).
[201] *See Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?*, *supra* note 198; *see also* Apoorva Mandavilli, *Covid Vaccine Side Effects: 4 Takeaways From Our Investigation*, N.Y. Times (May 3, 2024).
[202] *See generally COVID-19 Vaccines: History of the Pandemic's Great Scientific Success and Flawed Policy Implementation*, *supra* note 10.
[203] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 61:23–63:21; Transcribed Interview of Philip Krause, *supra* note 73, at 132:16–24; Transcribed Interview of Peter Marks, *supra* note 4, at 89:19–21.
[204] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 61:14–16, 102:21–103:5; Transcribed Interview of Philip Krause, *supra* note 73, at 132:16–24.
[205] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 76:3–79:21, 84:17–24.
[206] *See* James Garamone, *Biden to Approve Austin's Request to Make COVID-19 Vaccine Mandatory for Service Members*, DOD News (Aug. 9, 2021) (archived).
[207] President Joseph Biden, *Remarks by President Biden on the COVID-19 Response and the Vaccination Program*, The White House (Aug. 23, 2021) (speech transcript) (praising Acting Commissioner Woodcock as a "true professional" and ironically commending the FDA for concluding "without question" the Pfizer vaccine was safe and effective.).

injury.[208] This poor policy by the Biden Administration reveals many significant problems related to accountability and good decision-making in the administrative state that warrant legislative reform.

On June 17, 2024, the State of Kansas, under the leadership of Attorney General Kris W. Kobach, sued Pfizer in the District Court of Thomas County, Kansas, alleging that "Pfizer misled the public that it had a 'safe and effective' COVID-19 vaccine . . . even though it knew its COVID-19 vaccine was connected to serious adverse events, including myocarditis and pericarditis, failed pregnancies, and death," and that "Pfizer concealed this critical safety information from the public."[209]

Dr. Marks, who has been credited by some with naming OWS based on his affinity for the television science fiction series *Star Trek*,[210] motivated his FDA team using stories about the Apollo-13 crisis, Star Trek, and the space race.[211] But it is the Challenger disaster in January 1986 that should remind policymakers about the devastating effects of an inadequate or rushed process in government.[212] When asked if he ever discussed the decision-making that led to the Challenger disaster (and, accordingly, the bureaucratic failures in the decision-making that killed seven astronauts and set back the space program) as a cautionary tale for his team in cutting corners and lowering standards, Dr. Marks simply said, "I didn't share that particular story."[213]

* * * * *

This interim report aims to present the information as is known now to inform potential legislation that will improve procedures and accountability the administrative state and prevent federal agencies from discounting adverse consequences for the sake of administrative expediency. The Subcommittee will continue its oversight and supplement this report as necessary.

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[208] *See also* Apoorva Mandavilli, *Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?*, N.Y. Times (May 3, 2024); *see also* Apoorva Mandavilli, *Covid Vaccine Side Effects: 4 Takeaways From Our Investigation*, N.Y. Times (May 3, 2024) (describing challenges the government has had in detecting COVID-19 vaccine related injuries).

[209] *See* Compl., *State of Kansas v. Pfizer, Inc*. (Kan. Dist. Ct., 2024).

[210] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 26:25–27:3.

[211] *See id.* at 26:25–27:3, 92:6–12.

[212] *See, e.g.*, *Report to the President by the Presidential Commission: On the Space Shuttle Challenger Accident, NASA* 105, NASA (June 6, 1986) (In the wake of the Challenger disaster of January 23, 1986, the Rogers Commission found that "[t]here was a serious flaw in the decision making process leading up to the launch," and that "a well-structured and managed system emphasizing safety would have flagged the rising doubts about the Solid Rocket Booster joint seal. Had these matters been clearly stated and emphasized in the flight readiness process in terms reflecting the views of most Thiokol engineers and at least some Marshall engineers, it seems likely that the launch . . . might not have occurred when it did").

[213] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 137:11–138:3.

APPENDIX A: FDA INTERNAL CORRESPONDENCE DECIDING TO CUT CORNERS TO MEET THE DATE OF THE BIDEN VACCINE MANDATE

Appendix Table of Contents

COMMITTEE ON THE JUDICIARY,

U.S. HOUSE OF REPRESENTATIVES,

WASHINGTON, D.C.

INTERVIEW OF: DR. MARION GRUBER

Tuesday, July 18, 2023

Washington, D.C.

The interview in the above matter was held in room 164, Cannon House Office Building, commencing at 10:02 a.m.

Present: Representatives Jordan, Biggs, and Massie.

Appearances:

For the COMMITTEE ON THE JUDICIARY:

[redacted], SENIOR PROFESSIONAL STAFF MEMBER

[redacted], DEPUTY GENERAL COUNSEL

[redacted], COUNSEL

[redacted], DIGITAL ASSISTANT

[redacted], CHIEF COUNSEL FOR OVERSIGHT

[redacted], CLERK

[redacted], DIGITAL DIRECTOR

[redacted], MINORITY CHIEF OVERSIGHT COUNSEL

[redacted], MINORITY PROFESSIONAL STAFF MEMBER

For DR. MARION GRUBER:

HILARY LOCICERO, ESQ.

LLOYD LIU, ESQ.

BLL, LLP

[redacted] We will go on the record.

Good morning. This is a transcribed interview of Dr. Marion Gruber. The committee has requested this interview as part of the committee's oversight of the FDA and administrative practices and procedures.

Would the witness please state your name for the record?

Dr. Gruber. My name is Dr. Marion Gruber.

[redacted] We encourage witnesses who appear before the committee to freely consult with counsel if they so choose, and it is my understanding that you are appearing today with personal counsel. Is that correct?

Dr. Gruber. That is correct.

[redacted] Could counsel place state your name for the record?

Ms. LoCicero. Yes. Good morning. My name is Hilary LoCicero from BLL LLP on behalf of Dr. Marion Gruber.

Mr. Liu. And I'm Lloyd Liu from the same firm.

[redacted] Great. Thank you.

On behalf of the committee, I want to thank you for appearing here today to answer our questions. The chairman also appreciates your willingness to appear voluntarily.

My name is [redacted], and I work with Chairman Jordan's staff.

I will now have everyone else from the committee who is here in the room introduce themselves as well.

[redacted] My name is [redacted], and I am here with Chairman Jordan's staff.

Mr. Massie. I am Congressman Thomas Massie from Kentucky.

Mr. Biggs. Congressman Andy Biggs from Arizona.

[redacted] with the Democratic staff.

[redacted]. I am the chief oversight counsel for the House Judiciary Committee, Democratic staff.

[redacted], Chairman Jordan's staff.

[redacted], law clerk on Chairman Jordan's staff.

[redacted], Chairman Jordan's staff.

[redacted] I would like to now go over the ground rules and guidelines that we will follow during today's interview.

Our questioning will proceed in rounds. The majority will ask questions first for 1 hour. Then the minority will have an opportunity to ask questions for an equal period of time if they so choose. We will alternate back and forth until there are no more questions and the interview is over.

Typically, we take a short break at the end of each hour, but if you need to take a break at any other time, just please let us know, and we're happy to accommodate that.

As you can see, there is an official court reporter taking down everything we say to make a written record, so we ask that you give verbal responses to all questions. Do you understand that?

Dr. Gruber. I do.

[redacted] So the court reporter can take down a clear record, we will do our best to limit the number of people directing questions to you at any given hour to just those people on the staff whose turn it is.

Please try and speak clearly so the court reporter can understand and the folks down at the end of the table can hear you as well.

It is important that we don't talk over one another or interrupt each other if we can help it, and that goes for everybody present at today's interview.

We want you to answer our questions in the most complete and truthful manner as possible, so we will take our time. If you have any questions or you do not understand one of our questions, please let us know. Our questions will cover a range of topics, so if you need clarification at any point, just say so.

If you honestly don't know the answer to a question or do not remember, it is best not to guess. Please give us your best recollection, and it is okay to tell us if you learned information from someone else. Just indicate how you came to know the information.

If there are things you don't know or can't remember, just say so, and please inform us who, to the best of your knowledge, might be able to provide a more complete answer to our question.

You should also understand that, by law, you are required to answer questions from Congress truthfully. Do you understand that?

Dr. Gruber. Yes.

[redacted] This also applies to questions posed by congressional staff in an interview. Do you understand this?

Dr. Gruber. Yes.

[redacted] Witnesses that knowingly provide false testimony could be subject to criminal prosecution for making false statements under 18 U.S.C. Section 1001. Do you understand this?

Dr. Gruber. Yes.

[redacted] Is there any reason you are unable to provide truthful answers to today's questions?

Dr. Gruber. No.

[redacted] Finally, I'd like to make note that the content of what we discuss here today is confidential. We ask that you not speak about what we discuss in the interview

to any outside individuals to preserve the integrity of our investigation.

For the same reason, the marked exhibits that we will use today will remain with the court reporter to go into the official transcript and any copies of those exhibits will be returned to us when we wrap up the interview.

All right. That's the end of my preamble.

Is there anything my colleagues on the minority would like to add?

[redacted] We just thank you for taking time out of your day to come in today.

[redacted] And I understand your attorney has a statement she would like to make on the record.

Ms. LoCicero. Yes. Thank you.

On behalf of Dr. Gruber, Dr. Gruber is here today as a former FDA employee. She has been authorized to speak about matters that the committee wishes to learn about, but she is not authorized to speak about anything that would impinge on the agency's deliberative process privilege. So if there are questions what would impinge on that privilege, I'll raise an objection at that time.

[redacted] Thank you.

The clock now reads 10:07 a.m. We'll start with the first round of questioning, and I'll turn it over to my colleague, [redacted]

EXAMINATION:

BY [redacted]:

Q Good morning, Dr. Gruber.

Are you currently employed?

A Yes.

Q Where do you work?

A I have a remote office position. I work from home. My employer is the

International AIDS Vaccine Initiative.

Q And how long have you been working there?

A I started working with IAVI in January of 2022.

Q And what is your title?

A My title is vice president for public health and regulatory science.

Q And in this role, what are your responsibilities?

A I oversee the Regulatory Affairs Division in IAVI. I also present IAVI at global committees and agencies, WHO, for instance, but also other not-for-profit organizations and, of course, our funders.

Q And where did you work before IAVI? Did I say that correctly?

A Yes. IAVI is correct. It stands for International AIDS Vaccine Initiative. I worked at the U.S. Food and Drug Administration in the Office of Vaccines.

Q Did you work anywhere in between those two?

A No.

Q And when did you first join the FDA?

A I joined the FDA as a government employee, and that was in 1992.

Q And what did you do before working at the FDA?

A I was a postdoc. I had a postdoc position at the FDA from 1989 to 1992. And prior to that, I had a postdoc position at the Oklahoma Medical Research Foundation, and that was from 1986 to 1989.

Q And can you walk us through the positions that you held at the FDA?

A Yeah. So when I started in 1992, I worked as a CMC reviewer. CMC stands for chemistry, manufacturing, and control information. So I was part of a team which looked at the manufacturing process for biological products that were regulated by the office. At that time, that was the Office of Therapeutic Research and Review. So that was

not the Office of Vaccines.

Then -- and I actually worked there, as I said, as a CMC reviewer, and I also did bench research because these positions -- it was supporting to our role at the FDA.

In 1995, I decided to take a full regulatory position in the Office of Vaccines Research and Review. There, I worked what they referred to as primary reviewer. I was responsible for communicating decisions made by review teams to the vaccine manufacturers. I also was part of the review team, working alongside with the medical officers, with the CMC reviewers, facility experts, et cetera. I did that for 10 years.

And then in 2005, a position came open in the Office of the Director at the Office of Vaccines Research and Review, and that was associate director for regulatory and policy decisions. And I was selected for that position. And at that time, my primary responsibility was looking at guidance documents, taking part in writing guidance documents, involved in policy decisions, looking at proposed and final rules to see how they could be implemented.

And I did this -- I think it was 2008 when the, at that time, deputy director of the Office of Vaccines retired from the office, and I served as acting deputy and then was selected deputy director of the Office of Vaccines. But I don't -- I cannot give you the exact date on that.

And then in 2007, the, at that time, office director, Dr. Norman Baylor, resigned -- not resigned. He decided to retire and take another position outside the agency. And because I was his deputy director at that time, I served as acting office director and had applied for office director position.

So the acting office director, I did from -- it was fall of 2011. So when Dr. Baylor left. I can't really recall. Was it October, November? I don't know. And in May 2012, I was selected office director of the Office of Vaccines, and I served in that position until I

decided to retire from the FDA in October of 2021.

Q And so your last position at the FDA was director of the Office of Vaccines Research and Review. Is that correct?

A That is correct.

Q Can you describe for us your roles and responsibilities in that position as director?

A As director of Office of Vaccines, it was my responsibility to oversee the review activities conducted by the different disciplines. I also, in collaboration with the division directors, decided on the research program because the offices in the Center for Biologics Evaluation and Research have research responsibilities.

So -- and I also closely collaborated with office directors in the other offices: Office of Biostatistics and Epidemiology. Office of Compliance, for instance. Office of Communication. And, of course, you know, I had to report my activities -- the activities of my stuff -- to the center director.

Q Other than vaccines, were there other subject matter areas that you worked on in this position?

A There were certain other biological products. Allogenic products.

Q What are those products?

A Allogenic products? Well, these are -- were developed -- actually, they have been on -- around for decades. Way before I became office director. And they are really to treat people with certain allergies, such as allergies against grass and pollen, for example.

Q Okay. And who was your director supervisor in this position when you were director?

A At first, it was Dr. Karen Midthun. She was center director when I became

office director. And when Dr. Midthun retired, Dr. Peter Marks was, at that time, her deputy and took over as acting center director and then to center director. So I reported to him.

Q When did that change happen? When did Dr. Marks join? Do you remember?

A I don't quite remember the year, but I can tell you he served as the deputy director -- center director -- to Dr. Midthun. And I think Dr. Midthun retired 2000- -- 2016 or 2017.

Q And did you have more than one direct supervisor other than Dr. Marks?

A It was Dr. Marks at that time. I mean, when Dr. Midthun left.

Q How many people directly reported to you when you were director?

A It varied slightly between -- 15 and 17 were my direct reports.

Q Was one of those direct reports Dr. Philip Krause?

A Dr. Philip Krause was my deputy director.

Q And how long had he been your deputy director?

A As I stated, I became office director in 2012, and he was chosen deputy office director of Office of Vaccines -- I want to say 2013 or 2014.

Q Did you have regular interactions with Dr. Peter Marks?

A Yes. Yes. We had weekly one-on-one meetings where, you know, I summarized the activities of the Office of Vaccines.

BY [redacted]:

Q Can you help us understand the organizational structure of the Office of Vaccines? The 15 to 17 people, were they split into teams? Did they all work on one vaccine? Or what was the setup of the office?

A Okay. So that's going to be a little bit long of an answer.

The Office of Vaccines, when I was office director, was organized into the Office of the Director. And the Office of the Director were, at that point, seven people. It was the deputy office director. I had an associate director for regulatory policy, an associate director for medical policy, an associate director for medical countermeasures and scientific affairs, and then an associate director for epidemiology, postmarketing surveillance. Then I had an assistant.

Let me see if I'm going to be complete here. Yeah. There were two assistants. One was because I also had overview, of course, of the Budget Division.

And so that was the immediate Office of the Director. And the other people reporting to me were the division directors. So Office of Vaccines is organized, again, Office of the Director and then the Budget Office and then the Division of Bacteria and Allogenic Products. And that was, at that time, about 70 people plus postdocs. So 70 FTEs plus postdocs. Then the Division of Viral Products and Division of Vaccines and Related Product Applications. So that was the Applications Division, which administered the incoming submissions by the vaccine manufacturers and completed correspondence, et cetera.

So each of these divisions was headed by two directors, the director and the deputy director. My direct reports were the division directors. So three division directors. So now I have to see. 10, 11 -- yeah. So it amounted to 15 people. Yeah.

Q And how many people worked under the director and deputy director of the Division for Viral Products?

A About the same. It always fluctuated a little bit. People are hired. People leave and retire. So it was about 70 people. That was the average. Again, plus postdocs.

Q Okay.

A And the Division of Vaccines and Related Product Applications, DVRPA, that

also had about 70 people.

Q Okay.

A Medical officers, toxicologists, and then the administrative people were all in DVRPA.

Q Okay. Thank you.

A And, of course, let me be complete. The DVRPA division director also reported to me.

Q Okay.

BY [redacted]:

Q Now, with your interactions with Dr. Marks, did the frequency of your interactions change throughout the COVID-19 pandemic versus beforehand?

A There was more frequent interaction, yes.

Q And what was his exact title at the beginning of the COVID-19 pandemic?

A Well, he was the director of the Center For Biologics Evaluation and Research.

Q Did that ever change at all during your time there? Was he always in that specific position?

A Yeah.

Q And did you have regular interactions with FDA Commissioner Janet Woodcock?

A Direct regulatory interactions?

Q Yes.

A One time.

Q One time.

And so you didn't have regular interactions, like, weekly meetings or monthly?

A No.
Q Is that normal for someone in your level position at the FDA?
A Yes.
Q Generally speaking, did you have regular interactions with Dr. Krause?
A Yes.
Q Yes?
A He was my deputy, yes.
Q How often would you say you interacted with him?
A Every day.
Q Every day.
In your line of work at the FDA, did you find that there were common disagreements between you and your supervisors?
A Define common disagreements.
Q Maybe just on research or analyzing data. Just, I think, common, everyday discussions about a product.
A No. There were no common disagreements as defined by you.
Q Did you have any common disagreements between you and your subordinates?
A No.
Q Due to the size of your agency and your parent agency HHS, who did you regularly interact with outside of the FDA in your line of work?
A I did committee work. So as I mentioned at the beginning, I -- there was interaction with the WHO, the World Health Organization. But there were also, you know, other ad hoc committees within HHS where I was sent to represent the Office of Vaccines.

Mr. Biggs. Can I ask a question? A follow-up question? I don't want to break the flow. You guys are doing well.

But the common disagreements question -- maybe I read too much into your answer. Were there times that there were extraordinarily -- you know, extraordinary or anomalous times where you'd have a disagreement with either a supervisor or subordinate over any of these areas that you were previously asked about?

Dr. Gruber. There were no common disagreements in the line of work that I did for the 10 years that I was office director.

Mr. Biggs. I get the no common disagreements.

But was there ever a disagreement over an exceptional way to handle something or to look at research that you recall?

Dr. Gruber. On the way research was handled? No.

BY [redacted]:

Q And you spoke about how you had interactions with the World Health Organization. How regular were those interactions?

A I served, at the time I was office director, for 6 years on the Global Advisory Committee for Vaccine Safety, the GACVS, WHO. These were in-person meetings that I had to attend twice a year.

And in addition, there were ad hoc working groups, for instance, during the Ebola outbreak. That was something that the WHO concerned itself with and, of course, required interaction with the global public health community. So I served on some committees such as guidance finding committees.

Q Did your service on these committees continue during the COVID-19 pandemic?

A I rotated off the GACVS committee -- I want to say 2019 or 2020. I would

have to double-check that.

Q Did you have any interactions with the WHO during the COVID-19 pandemic?

A Yes. Yes. There were.

Q Can you describe some of those interactions?

A Well, you know, it was -- the WHO, of course, was interested in making vaccines available for the global community, and so there had been meetings on how to address that. Yeah.

Q And what was your role in these meetings?

A A regulatory advisor. Yeah.

Q And can you describe what you would do as a regulatory advisor?

A So during the pandemic, as you know, there were several -- several -- many, many vaccine candidates evaluated by the Office of Vaccines and, by far, not restricted to the vaccines that one heard about in the news or were eventually authorized.

And so what we discussed in these committees was really the progress of the development of these products. And then when we assumed regulatory review of the data for these products, we had scientific exchanges.

BY [redacted]:

Q Can you define for us what a biologic license is?

A What a biologic license is? So there is -- and you'd have to look this up in the CFR, the Code of Federal Regulations. There is a long and very old definition for biologic product.

And vaccines are part of biologic products. And if a manufacturer develops a vaccine, the Public Health Service Act states that, in order to obtain a license, the vaccine has to be shown to be safe and pure and potent, and the manufacturing facility in which

the product is made has to be complying with standards to assure the safety and purity and potency of the product.

And if -- so we had the responsibility of reviewing the information submitted by the vaccine manufacturer to support safety, purity, and potency. And when we made the regulatory decision that these standards are met, we would issue a license. A biologic products license.

Q Why is a biologic license needed, in your opinion?

A Before you make available a biological product such as a vaccine to potentially millions of healthy individuals, there has to be oversight by an independent agency to assure that the product meets standards of safety, purity, and potency.

Q And are you familiar with the FDA's Emergency Use Authorization process?

A Yes.

Q Can you explain the difference between a typical vaccination approval process and an EUA approval process for us?

A So in order for an Emergency Use Authorization to occur, there are certain requirements laid out in statute that need to be met. First of all, there has to be a declaration by the health secretary that there is a public health emergency that could adversely affect the well-being of American citizens. There has to be a requirement that the biological product or other product -- emergency use authorizations are also for drug products -- that there's a standard of "may be effective." So there needs to be supporting data to demonstrate that the biological product may be effective.

There has to be lack of available alternate therapy, and a decision has to be made that the known and potential benefits of the product outweigh the known and potential risks of the product.

So these are statutory requirements under an EUA authorization. And the

statutory requirements pertaining to a license, I already explained.

Mr. Massie. On the known and potential benefits outweighing the risks, is that done for certain age-groups, or is it uniformly done for the entire population? That calculation?

Dr. Gruber. So typically, the vaccine manufacturer has to do clinical trials. And the population for which the vaccine then is authorized and the EUA is typically the population that was studied in the clinical trial. So in an Emergency Use Authorization -- just an example. If it's for 16 years of age and older, there has to be data to authorize the biological product for that age-group.

Mr. Massie. If someone already had COVID and, as a result, had been conferred some natural immunity and have recovered, would they be considered separately in that risk-versus-a-benefit calculation?

Dr. Gruber. At the time that the clinical trials for these vaccines were conducted during the pandemic in 2020, the clinical trials at that time excluded people already exposed to COVID. So an inclusion criteria was COVID-naive -- naive to COVID or a new exposure to COVID.

Mr. Massie. But some of them, once they entered the study, they did -- it was found out that they had had prior exposure. Is that correct? In the Pfizer study, I think there were about 1,300 or 1,200 roughly distributed between the placebo group and the vaccine group.

Dr. Gruber. I don't recall the exact number, but yes.

Mr. Massie. Could that change the potential benefit versus the risk -- that calculation, that threshold -- if somebody had already had COVID?

Dr. Gruber. So, as you know, these studies were large studies. The Pfizer vaccine, it was, like, 44,000 people included in that study. And the analysis of efficacy was really

done on the population that was specified who were naive individuals. There were also separate analyses conducted in looking at other subpopulations included in the study, but typically, these studies were not powered, you know, to look at each subgroup individually.

Mr. Massie. So given that there weren't enough people who had already been exposed to COVID in that very large study to make -- to draw reliable conclusions about the benefit, is it wise to say that it conferred the same benefits to the COVID-naive -- the benefits that were conveyed to the COVID-naive were the same benefits that were conveyed to those who had already had COVID? That was sort of -- that was the CDC's position in the MMWR they did in December of 2020.

Dr. Gruber. The CDC is a recommending body. It's not a regulatory agency. We made our decision that the potential known -- that the known and potential benefits outweighed the known and potential risks of the vaccine made based on the data that we analyzed, the data coming out of the efficacy studies.

Mr. Massie. Which was based almost exclusively on a COVID-naive population?

Dr. Gruber. Most of them, yes.

Mr. Massie. Okay. Thank you.

BY [redacted]:

Q In your position at the FDA, specifically with the vaccine approval process generally, did you exercise any discretion? Was that permitted in your role to do that?

A I don't understand the question. Can you give me an example?

Q Of course. In deciding the overall -- for the overall decision to license a vaccine or -- you know, you had discussed just a bit ago about the risk-benefit analysis.

Were any of your decisions in the vaccine approval process -- were you able to exercise discretion?

A So first of all, let's separate Emergency Use Authorization from the biologic license. What I can tell you is, in both situations, in order to grant a license or an EUA, Emergency Use Authorization, I did not exercise discretion. I based my decision to authorize or approve the product based on the data submitted to support an EUA for a license.

And, of course, that was discussing it with the experts tasked with reviewing that information in the Office of Vaccines, but also the other offices that are included in making these decisions.

BY [redacted]:

Q And who is the ultimate decision-maker in granting a license or granting an EUA?

A Well, the EUA is not signed off by the office director. That was an HHS position at that time.

Q Okay. And who was that? Or what position was that?

A I don't recall that position. But you are able to check by just looking at the signature. Yeah.

Q Okay. And what about the regular license?

A That is the office director in concert with the -- so in this case, for a vaccine, it would be the office director of vaccines. So there was me and the office director of the Office of Compliance and Biologics Quality. For a new vaccine licensure, both office directors have to sign off on that license.

Q And so with the COVID-19 vaccinations, were those signed off by HHS, then?

A Can you repeat the question?

Q For the COVID-19 vaccinations, were those signed off by an HHS official, or were they signed off by the -- by you and the director?

A Are you referring to the biologic product licenses?

Q Yes.

A I only signed off on one of the biologic product licenses. That was the Pfizer mRNA vaccine community. I was no longer in the agency when Moderna's product was licensed.

Mr. Massie. Do you know when you signed off on that?

Dr. Gruber. On the Pfizer mRNA? Yes. In August of 2021.

BY [redacted]:

Q Who was the office director in the other office that you mentioned who would normally make a decision for a BLA?

A Yeah. The Office of Compliance and Biologics Quality. It's the OCBQ. That's what it stands for. And the office director at that time was Mary Malarkey.

Q How often did you work with Dr. Malarkey?

A Well, her office had oversight of the facility information that also needed to be reviewed in order to grant a biologic product license. And so we interacted in meetings on the products where we looked at progress review. Are there any issues that need to be followed up? Are there other information requests that we need to send to the manufacturer while the BLA, the biologic license application, review is ongoing?

And so we, you know, exchanged information and kept each other informed if there were any, you know, issues coming up during the review process.

Q Can you explain some of the post-vaccine rollout studies that need to be made before a booster vaccine is approved?

A I was not part of the booster vaccine approvals.

Q Had you ever worked on a booster vaccine in the past during your time as director?

A Yeah. Not as part of director, but deputy director. There was a Hib vaccine, influenza type B, for boosting of toddlers that I was involved in. Yeah. So that -- yeah. That would be it.

Q Are the possibilities that post-rollout research could uncover -- and this could be for any vaccines. What would be important findings that you or your team would look at?

A So we got -- let's go back to biologics license application, and I'll give you an example.

The sponsor or the vaccine manufacturer -- actually, it's referred to as an applicant when a biologics license application is in. They have to have conducted, during the development of the product, studies to demonstrate the immunogenicity and the safety and the efficacy of the product. And we, the regulators, look at the data derived from the efficacy and the safety studies and the immunogenicity studies.

And if there are adverse events -- uncommon adverse events observed in a clinical efficacy study, based on the severity of that adverse event, the sponsor may be required -- and that is a requirement to evaluate this adverse event further in the postmarketing space.

Many times, when I was in the Office of Vaccines, there were no required studies because the profile of the vaccine, the safety profile, was good. But many times, applicants still do so-called postmarketing commitment studies to further look at the safety of the product.

And it is not only the manufacturers. It's also the CDC, the Center for Disease Control, and also experts in the Office of Biostatistics and Epidemiology at CBER would, you know, have a system by which they can further evaluate the safety as well as the effectiveness of the product once it's licensed.

Q Are there benefits to doing these postmarketing studies for the FDA or for the applicant? Like, there are usually benefits versus any risks for this being done, in your opinion?

A I consider postmarketing studies of important -- importance because they usually can enroll many, many, many thousands, sometimes hundreds of thousands of people. And, you know, if there are events that you may not pick up in a prelicensure trial of a couple of thousand or sometimes many thousands, you may see that when you roll out the vaccine to a large population.

And the reason why this is important is that surveillance for safety and effectiveness of a product does not stop when the product is licensed. It continues. That is referred to as life cycle management.

And so, let's say, there is an event that is observed in the postmarketing space. The package insert that is approved when the vaccine is licensed needs to be updated to include that information. But the package insert will also be updated if further studies are conducted that perhaps have not been conducted in the prelicensure space, such as coadministration studies with other vaccines, for example. And once these data are available, the package insert is also updated. So it's a life cycle management of the product.

Mr. Massie. Was there a package insert for the EUA product?

Dr. Gruber. No. There are no package inserts, but there are fact sheets. So you refer to it as a fact sheet. And there are fact sheets for the healthcare providers, and there are fact sheets for the recipients of the vaccine.

And these fact sheets make it very clear that this is not a licensed product, but that the agency has determined that the known or potential benefits outweigh the known or potential risks of the product. But the people -- persons have, of course, a choice of

taking the vaccine or not to take the vaccine.

Mr. Massie. Would a package insert for a licensed product include potential side effects?

Dr. Gruber. Yes. And so do the fact sheets.

Mr. Massie. Do the fact sheets mention myocarditis? Or what were the side effects mentioned on the fact sheets?

Dr. Gruber. So, for example, for the Pfizer vaccine community -- or, at that time, it was not called community because it wasn't licensed -- there weren't events of myocarditis in the clinical efficacy study. I think there was one event of pericarditis in the vaccine group and one event of myocarditis in the placebo group.

So the risks of myocarditis became evident when the vaccine was rolled out once there was an Emergency Use Authorization. So it was the post-EUA safety surveillance systems by the CDC and by the FDA that -- where this increased risk was observed.

The fact sheets had to be updated. And, of course, when we license a community, there is a section in the approved package label -- package insert that is referred to as section 5.2, warnings and precaution, where this risk is described.

Mr. Massie. Was there ever a period of time where the EUA product was distributed with a fact sheet, that after the license was issued -- where the fact sheet on the EUA product did not disclose everything that the insert did if the licensed product had been distributed?

The reason I'm asking this question is, it was a year, it seems, before the licensed product with the insert was distributed. I'm not even sure if it was maybe longer than that.

So in the interim, there must have been a period of time where EUA products were being administered with a fact sheet. What I want to know is, did the fact sheet

have all the things on it that the insert did that you approved?

Dr. Gruber. Okay. When we developed the fact sheets for these EUAs -- and it was the first time that the Office of Vaccines had to develop fact sheets for vaccines because there wasn't an Emergency Use Authorization of that scale before -- we followed closely the organization of the package insert.

And the safety events and the efficacy data that were known at the time that the fact sheets were issued once the EUA was granted were based on the information known to us at that time.

And, of course, with the Pfizer vaccine, the Emergency Use Authorization occurred in December of 2020. The vaccine was licensed in August of 2021. So there was a period of 8, 9 months during which the vaccine was rolled out. And, of course, the additional information became apparent, such as the myocarditis risk that we just talked about. And then, of course, the data were written into the package insert because we became aware of that risk as a result of the post-authorization surveillance that was conducted by CDC and FDA.

Mr. Massie. Let me ask the question differently and more specifically.

Dr. Gruber. Yeah.

Mr. Massie. In November of 2021, it was not possible to get Comirnaty vaccine at CVS or any provider. Yet -- because they were still providing the EUA vaccine. So at that point, we wouldn't have known about myocarditis and other things that were -- would have been described on the package insert for the licensed product.

But were consumers who were receiving still the EUA product after the product Comirnaty had been licensed but was not available -- were they made aware on this fact sheet, let's say, 2 months after the license was issued for Comirnaty -- were they aware on the fact sheet of the same things that were in the enclosure or the insert?

Dr. Gruber. So people that received the vaccine on the EUA in November of 2021 -- that was after I had left the agency. I mean, I made sure, of course, as part of the license, that there was a package insert that included the safety information, and that was also available then on the FDA website. So there was that information.

As far as I am aware, there is a requirement to update the fact sheets as new safety information becomes available, but I didn't have authority over that at that point in time anymore.

Mr. Massie. And did you anticipate it would be so long between when the license was given for the product and when the licensed product would actually be available?

Dr. Gruber. We should look at the fact sheets because, again, there is a requirement to update the fact sheets with safety information as we became aware.

And I do recall -- although I do not recall the specifics -- that during 2021, once the vaccines were authorized -- the Moderna vaccine and the Pfizer vaccine -- that there were several rounds of fact sheets that we had to update, and the updated versions then had to be made available.

Mr. Massie. Did they include myocarditis as a side effect on the fact sheet?

Dr. Gruber. It could have only been included once CDC and FDA became aware of that increased risk of myocarditis.

Mr. Massie. Were you aware in August of 2021?

Dr. Gruber. Yes, I was aware in August of 2021 because, at that time, while the BLA for the Pfizer vaccine was under review, information from these post-EUA surveillance systems became available to us and pointed to this risk of myocarditis.

And this is why the FDA did a -- did a benefit-risk assessment. And we concluded that the benefits of the vaccine outweighed the risks, but we included myocarditis as an adverse event in section 5.2, warnings and precautions, on the package insert.

Mr. Massie. On the insert.

And I know you left almost as soon as the license was issued.

Dr. Gruber. Correct.

Mr. Massie. Within a month or two.

Dr. Gruber. Yes.

Mr. Massie. But the reason I'm asking this is not to catch you up in something here. But I just wonder -- for the year that everybody was told it was a licensed product, but when they went to get it, they were given the EUA product, I wonder in that period of a year, were they getting the same information?

I mean, you may not know since you were not in charge after that, but you might know if you had updated the fact sheet before you left to include the same things that the insert had.

Dr. Gruber. As I said, we were required to update the fact sheets for the EUAs as we became aware of safety.

Mr. Massie. Okay. Thank you.

Can I go down another line of questioning?

[redacted] Absolutely of course.

Mr. Massie. When compared to the typical review process for a vaccine prior to authorization or licensing, how was the process different for the COVID-19 vaccine?

Dr. Gruber. Are you referring to the process of the license application review or the overall development?

Mr. Massie. The authorization and then the licensing.

Dr. Gruber. Okay. So --

Mr. Massie. But I think you already told us that you had -- you really hadn't done an EUA before for a vaccine.

Dr. Gruber. Right.

Mr. Massie. So let's focus on the license.

Dr. Gruber. On the license.

What was similar in terms of the biologics license application review is that we assigned priority review to this application. The agency can assign priority review studies to a vaccine product if it is believed that it will treat or prevent a serious and life-threatening disease for which there's no available alternative therapy. And we had done that several times before, be granted priority review.

The difference between a priority review and a standard review is the time that the FDA has to take regulatory action either in approval, a license, or what we refer to as a complete response letter. That is when the information submitted was not sufficient to grant a license.

And there is a standard BLA review application that is 12 months from submission and a priority review application that is 8 months. So we would have to review the application in two-thirds of the time.

For community, it was yet different because I recall that -- I cannot give you the exact date, but I think the biologics license application was submitted somewhere in May of 2021. So do the math. 8 months later, the action due date would have been somewhere in January of 2022.

But because of the public health emergency, we decided we will do what we can to review this vaccine and the more compressed timelines without sacrificing our standards for safety, purity, and potency. And so we decided on a September 15th date, which would have been a third of the time usually allowed for a standard approval.

Mr. Massie. Were there -- would it be required to skip steps or collect less information to meet that deadline?

Dr. Gruber. No. I would not have supported that. I would have not signed off an approval letter. Skipping steps was out of the question.

What helped is the fact that we already had the efficacy data because the vaccine was approved and an EUA. So the efficacy study had been completed, and we already had reviewed the data under the EUA.

What we needed to focus on during the BLA review for the community are the updated information, including safety information that came in because the vaccines were used under EUA.

And there are other requirements that we have to meet in order for a product to license. We had to make sure -- and I referred to that before -- that the facility have certain standards and MGMP compliance, and we also had to make sure there is -- for every biologics license application, there has to be a pediatric assessment plan. These are studies -- if the applicant has not conducted them prior to licensure, that they will need to be required to study the product further in pediatric populations if there is no reason to grant a waiver. And there have been examples. We have done that before for other vaccine products.

So that had to be taken care of in that review time.

[11:03 a.m.]

Dr. Gruber. And then, of course, as our reviewers looked at the safety information that were submitted with the BLA and the updated information that came in, there were very, very close interactions with Pfizer, with the vaccine manufacturer.

We had, for example, medical offices may have a point of clarification on a certain dataset. They send a question to Pfizer. Sometimes it takes Pfizer a day to turn it around, sometimes a week or 3 weeks. And that happened during this timeline. There could be, you know, additional information requested to make sure that the facility meets all the standards required for licensure.

So there are a lot of information requests going back and forth on a daily basis during the BLA review. And it's not even, you know -- that goes for vaccines in general for vaccine BLA reviews.

Mr. Massie. My next series of questions is longer, so I can save it for the next portion.

Mr. Jordan. Can I have one quick question?

Dr. Gruber. Can I ask, can we take a break? I mean, I'm happy to answer your question but --

Mr. Jordan. I think the time is up in like 3 minutes.

Dr. Gruber. Okay.

Mr. Jordan. We'll be happy to do that and take a break every hour or more if you need.

I'm just going back to something you said much earlier when you were asked did you have regular interactions with FDA Commissioner Ms. Janet Woodcock and you said no. Is that right?

Dr. Gruber. That is correct.

Mr. Jordan. And then we asked, did you have any interactions with her? How often? I think you said one.

Dr. Gruber. I did have one direct interaction with her, yes.

Mr. Jordan. I'm just curious, what was that about?

Dr. Gruber. That was about the topic that Dr. Woodcock and Dr. Marks had informed the Office of Vaccines that it was necessary to speed up the approval process for COMIRNATY faster than the September 15 deadline that we all had agreed upon.

Mr. Jordan. You just discussed with Mr. Massie that deadline?

Dr. Gruber. Yes. And I -- because -- and I explained the interactions that were ongoing at that time, the frequent communication, the information requests going out. And we, of course, at that time were not in control of when the sponsor would provide responses.

I was concerned about wrapping up the approval faster because when -- and I had written a memo in the middle of July laying out my concerns.

Mr. Jordan. Tell me the beginning dates. Is it September of '21?

Dr. Gruber. Yes, September 15 of 2021.

Mr. Jordan. If I remember right, you just told Congressman Massie that you had already moved that up from a normal timeframe of January.

Dr. Gruber. That's right.

Mr. Jordan. Eight-month timeframe. So you had already moved it up to September.

Dr. Gruber. Yes.

Mr. Jordan. And then the updated mission was saying go even faster.

Dr. Gruber. That's right.

Mr. Jordan. And this is approving the license for the vaccine?

Dr. Gruber. Yes.

Mr. Jordan. Okay. That's the one time you talked to her. Did she come to you, or did you go to her?

Dr. Gruber. No. I had written a memorandum in July of 2021 laying out my concerns about that. I said: This is going to be very ambitious. I am not in control of when and how fast Pfizer would respond with information requests.

And I told her that we should not further compress the approval timeline. This is when she called me into a meeting. And we had the meeting.

Mr. Jordan. And what did she say?

Ms. LoCicero. I believe this would impinge on the deliberative process. So she is not authorized to answer that question.

[redacted] So your instruction is for the witness to not answer the question. Is that correct?

Ms. LoCicero. Correct, based on the guidance given to us by the FDA.

[redacted] We'll go off the record.

[Recess.]

[redacted] It is 11:18. We can go back on the record.

EXAMINATION

BY [redacted]:

Q So my name is [redacted]. I'll be asking some of the questions for the Democratic side along with Christina.

I wanted to start. We talked a little bit about your background as a public health official. I know that you were at the FDA in Office of Vaccine Research and Review for almost two -- over two decades. Is that right?

A Yes.

Q So did you -- I know you're here because of your work on the COVID-19 vaccine, but did you work on other vaccines in that time?

A Yes. Yes. I worked on numerous vaccines during these -- yes, between '95 and '21. And, again, in varied positions with different levels of authority, but, I mean, we had the pneumococcal conjugate vaccines that we licensed, Prevnar 13, Prevnar 20. Then there were 20-valent vaccines by other manufacturers, such as Merck, the licensure of Shingrix, the licensure of the Dengue vaccine. Licensure of the Ebola Zaire vaccine, meningococcal type B vaccines. Licensure of combination vaccines, you know, with childhood vaccines, human papillomavirus vaccine type, the nonavalent, et cetera. So lots of them, yeah.

Q Did you win any awards during your tenure as the Director of Office of Vaccine Research and Review?

A Awards? Yeah. I received awards, yes.

Q Can you talk about them?

A Well, the -- I got an award that probably was the biggest in 2008, when I was Deputy Director. That was awarded by the Secretary of Health and Human Services. You know, that was a big award. I got several policy awards.

Q What was that award for in 2008?

A That was just for -- for the work I was doing, you know, a general award. But then there were awards for the policy work I've done. We had awards that we received as a team that say for licensure of certain vaccines.

There were individual awards during, you know, my tenure as office director for leading the Office of Vaccines. And I think there was a group award too about the licensure of the Ebola vaccine. I mean, it goes on and on. Yeah, they -- they award or reward people for government service done.

Q Did you win the FDA Innovator Award in 2021?

A I think I did, yes. I forgot to say that, right?

Q Do you remember what that award was for?

A You know, I think that was just for, you know, the work we've done over the last couple of years in the approval of these, you know, pandemic vaccines and then the endemic vaccines, yeah.

Q Would it be accurate to describe you as a vaccine expert?

A Yes.

Q I wanted to talk about OVRR's processes more generally. So OVRR refers to the Office of Vaccine Research and Review. Is that right?

A Yes.

Q And it's part of the Center for Biologics Evaluation and Research?

A That is correct.

Q And that's CBER?

A Yes.

Q The mission of OVRR is to ensure that vaccines and related products are safe, effective, and accessible to U.S. consumers in order to protect public health. Is that right?

A Yes.

Q Is it fair to say that OVRR has both a regulatory and a research mission?

A Yes.

Q And there are three broad categories that OVRR's work falls into. Would you say that?

A Well, there's the preventive vaccines. There are the allergenic products, and then there is, we refer to it as catchall, the fecal microbiota products, for instance, phage

therapy. So yeah.

Q And OVRR reviews products for approval. Is that right?

A Yes.

Q What does that entail?

A Well, it is -- entails providing regulatory oversight of all the prelicensure activities. So we don't start interacting with vaccine manufacturers at the time they submit a biologics license application to us.

We actually start interacting at very early stages. We refer to this as pre-IND meetings, pre-Investigational New Drug Application meetings, where a vaccine developer comes in and informs us that they want to develop a preventive vaccine against a certain pathogen.

They will share with us their development plans, the type of preclinical data they need to sometimes show and demonstrate that the vaccine has preclinical safety. They tell us about the manufacturing process, and they inform us about the proposed clinical development plan.

And, as they go through the stages of clinical development or overall development, there will be interactions. So there's sort of like certain stages they come and talk to us again.

For instance, if they have data from a phase 2 safety and immunogenicity study, and then they want to know is the data supportive of starting a big study to demonstrate the safety and the efficacy of the product. So just as an example.

But there are also lots of other meetings where vaccine developers sometimes have technical questions, or there is to be a new assay that needs to be developed to measure the immunogenicity, let's say, of the products.

So CBER experts will sit with the vaccine manufacturer and develop a path

forward. And then, if data are accrued to support the safety and efficacy of the product and to support the adequacy of the facility, then they can submit a biologics license application. Then we review all the data in one big submission, as I described.

I mean, do you want me to go through this again?

Q Yeah, we're going to come back to that. Yeah.

So who develops the policies and the procedures that govern the review process? Does OVRR do that themselves or does somebody else tell them how to do reviews?

A So we, of course, need to start with the statute, right, the PHS ACT, and that is, of course, Congress. And then it's up to the FDA to really implement the statutory requirements, and that's in the form of regulations. And this is where FDA has authority for rulemaking, introducing a new regulation or even introducing a revocation of an old or outdated regulation.

And then there is guidance. And guidance basically takes the regulations and interprets them and provides then guidance and advice to manufacturers how to comply with the regulations and the statute.

And there are experts in the FDA who concern themselves with policy work or rule writing, and they will often reach out to subject-matter experts in the different offices of the FDA to help them with the rule writing, you know, and/or guidance writing. So people, based on their experience and expertise, may be asked to sit in on these working groups.

Q So OVRR's role is sort of a subject matter expert?

A Yes, that is correct.

Q And then OVRR also conducts bench research. Is that right?

A Yes.

Q Can you talk about that mission and what that entails?

A So the bench research that is conducted is really supporting the mission of OVRR, which is, again, to make available safe and effective products. And, in order to really develop the subject-matter expertise and the expertise to look at the chemistry manufacturing process, our researchers do often research in this area.

So we have subject-matter experts for let's say filovirus vaccines. That is the group of the Ebola vaccines. There are subject-matter experts for the flavivirus vaccines. That is the dengue vaccine, for instance. There are subject matter experts for certain bacterial pathogens, like the meningococcal type B and C, the pneumococcal or shigella, cholera.

And people will perform research in these areas. It is not basic research as it is performed by the NIH, for instance. It is what they refer to as mission-oriented research.

So they may help develop a certain assay to measure the immunogenicity induced by a new vaccine candidate against a certain pathogen.

Q You said that word "immunogenicity" a couple times. Could you explain what that means?

A Immunogenicity is the response that the body makes to a vaccine that the human receives. And so the immune response, that is a very comprehensive response and there are a certain type of cells in the human body that are being activated in response to the vaccine antigen that is injected.

And, basically, what that means is that the body develops a protective effect or reaction to the vaccine, so the next time the human may see the pathogen, it is protected because the vaccine induced this protective immune response.

Q Could you explain the difference between immunogenicity and efficacy?

A Yes. Immunogenicity refers to measuring the immune response that is induced to a vaccine. That is very commonly the antibodies that are made and that are

measured.

Efficacy is determined, in the traditional sense, by a clinical disease endpoint efficacy study in which the endpoint that is measured is prevention of morbidity or mortality that may be induced by the pathogen.

So, you know, for -- let me give you an example. When Prevnar 7 was licensed, it was prevention of invasive streptococcal disease due to serotypes contained in the vaccine.

And, however, the effectiveness or efficacy can also be demonstrated through an immunogenicity trial if the biomarker that is being measured, typically an antibody response, is a well-established biomarker that has been shown to be predictive of protection. But traditionally what the agency likes to see is a clinical disease endpoint efficacy study because it provides a very robust past demonstration of efficacy or not, depending on the vaccine. Yeah.

Q That makes sense. So, in your 25 years at OVRR, did you see the vaccine approval process change over time?

A Yeah. It changed in the sense that, through the Prescription Drug User Fee Act, or PDUFA, the agency had to comply with certain review timelines. When I started back in the early nineties or even late eighties as a post-doc, there was -- this concept of a managed review process wasn't there. That came into effect with the Prescription Drug User Fee Act, the first one, because the first one was in '92, when I had just started at the FDA.

And so certain timelines, you know, for which we had to take regulatory action, you know, were instituted. And, with the years, that was revised and further revised. For instance, not only did we have to meet timelines as part of the management review process. We also had to have meetings with -- official meetings with the sponsors as part

of the review process, as part of the BLA review process.

There were also then additional provisions, such as the Pediatric Research Equity Act, PREA, which then required us to really work with the applicant on a pediatric assessment that I mentioned before.

So, yes, over the years the review process was modified.

Q In your opinion, did you see those as improvements to the process?

A Yes.

BY [redacted]:

Q Can you say anything more about that? Why did you think that was an improvement to the process?

A Because it afforded more structure in the process and it was, you know -- and I think it facilitated interactions and collaborations between the vaccine manufacturer and the reviewers. And there was a clear establishment of roles and responsibilities.

Q And, looking at those interactions between the manufacturers and the FDA, you mentioned earlier in the approval process it sounds like there could be dozens of interactions. Is that fair to say?

A Hundreds of interactions.

Q Hundreds. And that -- in your opinion, that's beneficial for the process?

A I think it does facilitate reaching a regulatory decision because sometimes information that is submitted may be a bit vague or unclear, and that in and of itself should not result in a complete response action, which is the vaccine is not approved.

You should have the opportunity to ask questions during the review process. And it's not only just email or picking up the phone, but it is also writing what the agency refers to as discipline review letters.

So, when the medical officers do their -- perform their review and it's completed, while the review clock is ticking -- that's what we say -- they can send a letter to the vaccine manufacturers. And it could say: You know, your data are encouraging. However, we need this additional information.

And the same for CMC with facilities. And so that's why there is so much interaction during the BLA review process.

Ms. [redacted] Thank you.

BY [redacted]:

Q You worked through a couple of epidemic illnesses at OVRR, swine flu, Ebola, and then COVID. Do you think that these increased interactions helped you respond more quickly to those epidemic illnesses?

A I think they were learnings. There were learnings from each and every, you know, pathogen's pandemic potential, H1N1, and also, you know, the Ebola outbreak.

I think we've learned to communicate and foster more global interactions too. For instance, during the COVID pandemic, we had frequent interactions with other national regulatory authorities, such as the European Medicines Agency, Health Canada, PGA, global regulators from Asia, from Africa to really exchange regulatory reviews because the submissions made by these vaccine manufacturers, of course, they were the same.

And I think public health benefited from these interactions because there was sort of an alignment of what we would be, you know, requiring, requiring or also what may not be so necessary. Yeah.

BY [redacted]:

Q And is it fair to say that all of these global interactions meant that, in the case of the COVID-19 review specifically, you were able to gather more information because you were interacting with the European vaccine --

A Agencies.

Q -- regulatory agencies, agents at these agencies, et cetera?

A Yes, that is correct. Yes.

BY [redacted]:

Q The FDA has also been described as somewhat unique in that you analyze data for yourselves rather than take data analysis from the companies. Is that fair?

A Yes. That sets the FDA apart from other regulatory agencies. Even the European Medicines Agency, they do not require the raw data, the datasets from the vaccine manufacturer. We typically do request that information.

So that would be line listings, you know, of course, subjects identifiable we dequalify. We don't know who the subject, of course, is, but it will be line listings of, you know, for instance, the immune response induced in every subject or safety data, you know, injection site reactions, fever.

And, of course, these data, they are then used by the CBER statisticians, and they perform their own analysis of the data. So they would not rely on the output provided by the vaccine manufacturer. And that is another reason why there is so much interaction during an application review.

BY [redacted]:

Q Because you're looking for additional data?

A Well, because let's say the analysis and the outcome of the analysis done by CBER statistician is not -- is different than, you know, provided by -- by the vaccine developer. That's cause for discussion, right? So it doesn't happen all too often, but there are situations, you know, where this is -- you know, where this needs to be addressed. Yeah.

BY [redacted]:

Q And can that make the review process take a longer time if --

A You know what it means, that people just have to work more hours to get this work done. And that was the case during the COVID pandemic.

Q I want to turn to the COVID pandemic.

Do you remember when you first learned about the emerging novel coronavirus?

A When I learned about that? It was January of 2020, when my Deputy Director came in and said: You know, you heard about this new pathogen out of China?

And I said: Yeah.

And he said: The Coalition for Epidemic Preparedness Innovation, CEPI, wants to make that its pathogen X.

And that is a coalition that really, you know, with the mission to really expedite the availability of vaccines against these pandemic pathogens. So this is how I heard about that. And, well, but that was just the start, right? Pretty soon we knew that, you know, there was a real global health emergency.

Q What does designating something as pathogen X mean?

A Well, that is a term that CEPI uses, okay? So that they are trying to be proactive and really, you know, making sure that the vaccines are developed even to a future, you know, pathogen which you don't really know what it is. Is it a new coronavirus? Is it another Ebola virus? Is it a new form of, you know, viral species that you haven't -- that one hasn't seen before.

Q So, when you first learned about the emerging coronavirus, it sounds like your first thought was a vaccine for it?

A Yes. And the concern was what vaccines, right? So we didn't have any at that time. However, you know, things happen fast due to the new technology. And rather than months or years, you know, they had the sequence of the virus in a couple of

weeks and could express the antigen using the mRNA technology. And I remember meeting with the one company already in the beginning of March.

Q So that was going to be my next question. What steps did you take?

A Yeah. So what we -- what we realized very quickly is that the usual process -- and I describe this as the manage review process, where we have to, you know, meet certain timelines but also have a certain amount of time to review a data package.

Let me give you an example. A new vaccine -- a vaccine manufacturer knocks at FDA's door and says: I would like to, you know, develop this vaccine.

We have 2 months until we have to meet with that vaccine manufacturer.

In the meantime, they have to submit us -- to us a briefing document that we then review the available data. We formulate questions. We formulate guidance. And these timelines we realized are not doable to address this global public health emergency.

And so we met. Leadership in Office of Vaccines met and also with the Center Director. And we said business as usual in terms of having these timelines, you know, are no longer available to us. We have to have an all hands on deck. Our people have to realize that the submissions that are coming in need to be reviewed thoroughly. Scientific standards cannot be compromised. We have to make sure that there's compliance with regulations and applicable law, but work needs to be done as expeditiously as possible.

And we achieved that by -- first of all, it was tremendous dedication of our people. They canceled their vacation. They worked through weekends. Statisticians put in night shifts. We also enlisted help.

SARS-CoV-2 was a viral pathogen. The vaccine was a vaccine against a viral pathogen. But we enlisted the help of subject-matter experts in the -- in other disciplines, such as bacterial products, to help with other important work that was ongoing in the Office of Vaccines at that time. So that the group of people charged with the review of

SARS-CoV-2 vaccine candidates could fully, fully concentrate on that.

And, when I referred to an all-hands-on-deck approach, that's what it was. I mean, we made sure, between my deputy and myself, that we had coverage almost around the clock. I was at my desk at 6 o'clock in the morning. He started a little later, but was on call until midnight. So we had maybe 5, 6 hours where there was not, you know, immediate answering of emails and phones, but other than that that's what we did at that time.

And this is how we could accelerate the review and the decisionmaking. And, again, it was due to the tremendous dedication of the people. And many had been working in the Office of Vaccines for a long time. It was a very experienced staff, and we could apply learnings from other pathogens.

Q I know it feels kind of obvious, but could you explain why you felt such a sense of urgency in early 2020?

A You know, I think it felt very different. And you saw the news responding to the death counts on a daily basis, right? The curve, about people succumbing to SARS-CoV-2. I mean, by the day, you know, the curve skyrocketed. And people were falling ill. Neighbors were falling ill. I had people in my own office, their family members died of COVID.

So it was there, and we knew we had to do our part. And that is not to say that we didn't do our part during the Ebola pandemic because it was in Africa. We worked very hard too. But this, this was -- this happened on a very different scale.

Q Can you speak to -- do you know the number of people that were involved in this effort in your office and the other offices that you pulled in?

A So the Office of Vaccines at that time had about 250 full-time employees. Post-docs cannot be doing regulatory work, so there are restrictions.

I would say at least half of it. And that was also happening in the other offices. And there was a true commitment of leadership too. I mean, I remember helping with writing briefing documents or, you know, statements. Usually other people did this, and I just reviewed them.

And so I really -- it was a real team effort, you know. It was not the team did it and then presented it to the office director. We had to be part of it so that we could also make decisions and provide guidance in real time. It was a very different, you know, environment. And, yeah, again, our PDUFA timelines went straight out the window.

BY [redacted]:

Q You mentioned a couple minutes ago that you would get in the office at 6 a.m. and then your deputy would get in, and you basically had coverage at the office from 6 a.m. to midnight at the administrative level.

A Yes, yes.

Q How long did that schedule go on? How long did you do that?

A Started in January 2020, and it lasted till I left.

Q So a year and three-quarters?

A Yes.

BY [redacted]:

Q In 2020, the decision was made that COVID vaccines would be eligible for consideration under an Emergency Use Authorization. Is that right?

A In fall of 2020.

Q Yes.

A Yes, that is correct.

Q What was the -- you said that you don't sign the EUA, so what is your office's role in reviewing the vaccines for EUA?

A I -- I sign off on the memorandum that is put together by the Office of Vaccines, which provides a summary of the data and the results of the studies conducted and the product characterization performed. And so that's what I'm signing off on. But the EUA per se, that's not at my level. That was the HHS level.

Q In your memorandum, are you making a recommendation for a EUA?

A Yes. Yes, we recommended that. Basically, it's not a recommendation. We determined that the known and potential benefits outweigh the known and potential risks. We had to determine that at that time there was no available therapy. We basically have to make sure that all these requirements under the statute are being met.

Q So, when a manufacturer submits an EUA request, does OVRR still look at the safety profile of that vaccine?

A Yes. That is part of the review. So we had met frequently during 2020 with the vaccine manufacturers that were developing SARS-CoV-2 vaccines, and we had provided guidance on the clinical studies that needed to be conducted to demonstrate the safety and the efficacy of the product.

And, once the efficacy data came in, I mean, there was a lot of optimism, because the vaccines were so effective. But at that time, we did not have the safety information. So we could not authorize the vaccine based on demonstrated efficacy alone. We had to assure the safety and the circumstances of a public health emergency.

And this is what we did. And we also discussed our approach with the Vaccines and Related Biologic Products Advisory Committee in October of 2020. I remember that because we said we cannot just take 7-day safety data. You know, like you inject the vaccine. The primary series was two doses and then you wait 7 days and, oh, it's fine. No.

We said we wanted a minimum of 2 months of safety followup. That meant half

of the subjects had to have at least 2 months of safety followup. And that was a bit difficult to address during that time. And we had to hold the line to make sure that safety -- you know, the safety of the vaccine was favorable. Again, it's an EUA standard. That is different than a license standard. It says may be effective and the benefits, known and potential benefits need to outweigh the known and potential risks. And, in order to make that assessment, you have to look at the safety data.

Q How did that 2-month followup compare to the standard safety followup that you might require for a vaccine?

A It's shorter. It is -- usually, it is at least 6 months' safety followup.

Q How did you determine that 2 months was appropriate in this case?

A Again, we had to make a decision that the benefits of the vaccines in terms of protecting COVID-induced death, ICU admissions, hospitalization, that these benefits did outweigh, you know, the known and potential risks. And because we had a raging pandemic and people falling ill and dying, that benefit-risk ratio changed.

Q Can you explain a little more about how that changed?

A Well, we had to make a determination what the safety followup, what is -- what do we need in order to make that decision?

And we knew from experience working at the FDA and licensing lots of other preventive vaccines, we knew that if adverse events occur that are due to the vaccine -- I mean, there are many other adverse events that can just happen during the time. It's called incidental.

But we knew for those adverse events that happen that -- for other vaccines that are attributable to vaccines, they happen usually between, you know, the first 1, 2 months after the vaccine is injected. And this is how we came up with we need to have at least a minimum of 2 months of safety followup.

BY [redacted]:

Q So your determination, the reference you just made to the adverse effects, adverse events usually take place in the first 1 to 2 months, that's based on your years of vaccine research?

A That was the experience that we had at that point. And, you know, if you look at the Vaccine Injury Compensation Act, you have the data there, yeah.

Q And you talked a little bit about the benefits kind of broadly, decreasing ICU admissions, things like that. Can you talk a little bit more about what went into the benefits side of that equation?

A Well, as I said, we did the efficacies. We did review the efficacy data. And that was protection from severe -- from COVID vaccine. And the case definition said, protection from hospitalization, and then there were a series of secondary endpoints. And these endpoints were met. There were far more cases in the placebo group -- because these were a placebo-controlled trial, right? -- than in the vaccine group, so that we could conclude the efficacy of the vaccine. It was over 90 percent. It was a relatively tight confidence it evolved to.

Q So the benefit isn't just that fewer people got COVID, though. It's that the people that got COVID were not as sick. Is that fair to say?

A That was caught in terms of secondary endpoints, yes. And, you know -- well, you can debate what that means, being less sick, right? And then -- yeah.

Ms. [redacted] So you mentioned that October 2020 guidance. I want to introduce that for the record as exhibit 1.

[Gruber Exhibit No. 1
Was marked for identification.]

BY [redacted]:

Q This is the October 2020 FDA guidance about Emergency Use Authorizations for vaccines to prevent COVID-19. Are you familiar with this guidance?

A Yes.

Q Before I talk about this one in detail, could you first just broadly explain what are FDA guidance documents?

A Well, FDA guidance documents interpret a certain regulation. And so, you know, in this case, we knew what the requirements were under the statute to be able to grant an Emergency Use Authorization.

And, for instance, take the standard it may be effective. And so, in this guidance document, then, we tried to interpret what it means, you know, what sponsors had to demonstrate to meet this standard of may be effective.

And we did -- at that point wanted to apply stringent criteria because we knew, if an EUA would be granted for a COVID vaccine that it had the potential to be administered to millions of people. And so we wanted to make sure that the vaccines that we would authorize on the EUA would need to meet a certain effectiveness standard.

And we said: You know, at least 50 percent in the lower bound, you know, of greater than 30 percent. But we also told the sponsors what we would like to see in terms of safety data. And this is not something that we just came up with overnight.

As we discussed with the vaccine manufacturers since spring of 2020, the development of these COVID vaccines, we already had conversation there with the vaccine manufacturers. They asked us for guidance, what would be the standards. And we communicated this to them, and then we formulated it in terms of a guidance document. And -- yeah.

Q What role did OVRR play in developing this guidance?

A We played a very central role. Our -- our subject matter experts really

described, for instance, what chemistry manufacturing and control information would be required, what safety and effectiveness information that was ruled by the medical officers, you know, in terms of preclinical data. These were our toxicologists. And, yeah, so it was a concerted effort.

But that is not to say that only the Office of Vaccines worked on that, right? There were other offices that took part of it, such as the Office of Biostatistics and Epidemiology, again, the Office of the Compliance.

And, of course, you know, the -- the Center Director's Office and their policy people, you know, looked at this as well. So it was a concerted effort. However, it's fair to say that OVRR played a very central role.

Q Did you have a role in approving this guidance?

A I agreed to this guidance. Formal signoff is within the Director's -- Center Director's Office.

Q And, generally, not just for this guidance, but generally what approval processes do FDA guidance have to go through before they can be issued?

A Well, usually guidance writing takes longer than the guidances that we issued June 2020. I mean, one was the Emergency Use Authorization, and the other one was a clinical development and licensure of SARS-CoV-2 vaccines, right? We had two guidance documents.

Usually, there is a drafting group, the usual process. The drafting group consists of subject-matter experts and policy people, and they are addressing a certain issue for which, you know, guidance needs to be developed.

And so there is a draft. That draft is then being put out in the Federal Register for public comment. Depending on the comments that are received, it takes a couple of weeks or a couple of months to finalize the guidance document.

And so, once the comments are received they are addressed, but the agency has a certain discretion. So that's the difference to a rulemaking, where we have to address every comment. Here, we have a certain flexibility for guidance documents. Usually, we try to look at all the comments.

And then, you know, the guidance is finalized and being made available. That is not to say that final is final. The guidance can be updated. You know, entities, stakeholders have -- have opportunity to continue to submit their comments to the docket. And then if -- you know, if -- if it's felt that the guidance needs to be updated then that takes place.

Q This specific guidance was updated multiple times after October 2020.

A Yeah. Yeah, it was. Yeah, because it addressed other issues, right? Yeah.

Q Does the White House have a part to play in the approval process of guidance?

A It usually doesn't. In this case, that was different. The White House wanted to clear the guidance document.

Q We'll come back to that point. But, before we go there, I want to turn to page 5 on section 5 of this guidance. That section is entitled "Recommendations Regarding Information and Data to Be Included in a Request for an EUA for a COVID-19 Vaccine."

Would you say that the information and the data laid out in these recommendations was important for the OVRR to review before authorizing a COVID-19 vaccine for emergency use?

A Yes.

Q Section A looks at regulatory information. Is that right?

A Yes.

Q So, looking at A3, the guidance talks about a discussion of risks and benefits, including information about -- available information about the threat.

Why is that important for the EUA request to include a discussion of risks and benefits? I know we've talked about this a little bit before, but specifically for the EUA request.

A Because if you look at the beginning of the guidance document, and that is on page III, Roman III, criteria and consideration for the issuance of the guidance, it states: Based on this declaration and determination, FDA may issue an EUA after FDA has determined that the following statutory requirements are met.

And then there are four bullets. One of them is: The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweighs the known and potential risks of the product.

Q So, when EUAs were eventually issued for COVID-19 vaccines, were -- was there a discussion of risks and benefits in the requests that were made?

A In the -- by the vaccine manufacturers?

Q In the review process, was there a discussion of risks and benefits?

A Yes, of course, the review team looked at that and did a benefit-risk assessment. And, in doing so, of course, it took into consideration the data derived from the clinical disease endpoint efficacy studies that were conducted with these vaccine candidates.

Q And you mentioned the clinical endpoint is things like was the person infected; did they get severe disease?

A Yeah. It was prevention of COVID disease. It wasn't so much prevention of infection. It was really prevention of COVID disease and, you know, severe disease.

Am I allowed to make one statement? There was a lot of miscommunication that the vaccines were not effective. They were effective in terms of preventing against severe disease. They kept people out of the hospital. They didn't prevent infection or transmission. And that was -- this is an important distinction to make when talking about the vaccine efficacy.

Q Next I want to look at the safety and effectiveness information that is in this guidance. It's on page 9 in section C3. And then the actual safety and effectiveness data is detailed on pages 10 and 11.

So subsection b on page 10 talks about phase 1 and 2 studies and safety data in those studies. What are phase 1 and 2 studies?

A Typically, when a vaccine is developed, phase 1 studies are the first in human clinical trials. And they are there to primarily look at the safety. Looking at very common adverse event, of course, because these phase 1 studies are small studies, usually not more than a hundred subjects. And you sort of look at the initial safety of the product, and you look at the initial immunogenicity profile of the product.

And, when things look favorable, then phase 2 studies are started. These are typically randomized. That means there's a vaccine arm and a control arm, usually placebo. They include a couple of hundred subjects. And, again, there is safety that is evaluated and immunogenicity. Sometimes these phase 2 studies are even large enough to get a signal of efficacy, but usually that is not the case.

And then, if these data are favorable -- and usually it's not only one phase 1 and one phase 2. There are several studies that can be conducted, depending on what the data show.

And then there is a phase 3 study that is the what we refer to as pivotal study to demonstrate the safety and the efficacy. And that study data, if favorable, usually

supports licensure of the product.

But, of course, during the review process we would look at all the clinical studies conducted. And, during COVID, these -- there were not discrete stages of phase 1 and 2 and 3. The sponsors started with larger -- with smaller populations.

And when the vaccines were first tested in the first in human clinical trial part, it was healthy younger individuals. And then -- and they looked at different doses, different vaccine candidates. So different formulations of the vaccine, I mean.

And then they met with us and said: We have data here to suggest that this is immunogenic and tolerable.

And so they went then and expanded the study into phase 2, and then again expanded the study into phase 3.

And that, again, accelerated the accrual of critical safety and efficacy data, because -- because the clinical development, because of the pandemic, did not occur in stages.

Q When reviewing the COVID-19 vaccines for EUA, did OVRR review the safety data from this range of studies?

A OVRR did review the safety data available from all studies, yeah, and every subject that was receiving the vaccine.

BY [redacted]:

Q So you just talked about the phase 1, phase 2, phase 3 studies. In a normal process -- in a normal non-health emergency, let me put it that way, it would be the phase 1, and then there would be some review of data and then phase 2, then phase 3.

Is it fair to say that, with respect to COVID in particular, it was more of like a continually expanding process?

A That's right.

Q And that you said helped you accelerate the approval process, right?

A Yes.

Q And can you talk a little bit about how that helped you reach a regulatory decision more quickly with respect to this vaccine?

A Well, that in and of itself facilitated, you know, getting the critical safety and efficacy data needed to authorize the vaccine, but there was one thing that you usually do not have if you develop a preventive vaccine. And that is, when Pfizer, for example, started its safety and efficacy study, the large -- expanded to the large 44,000-subject trial, it was in the end of July.

And, at that time, the COVID cases like August-September started to rise. And they were able -- not only were they able to enroll these subjects in a matter of weeks, because people wanted to get the vaccine to protect themselves -- that was a fact.

The enrollment was much faster than you typically see with a vaccine, and you had an incidence rate. That means many, many cases of COVID, so that you could -- you know, your statistical criteria -- you need so many cases to declare efficacy -- was reached much faster because of the pandemic. Sometimes that can take years to accrue a sufficient number of cases due to disease incidence being very low. And this was not the case in this situation.

Q So, in a way, even though, obviously, the pandemic was horrible, also because it was so bad it made it easier to do the research here?

A Yeah. I am reluctant to phrase it that way, but yeah, uh-huh. Because it was very sad, seeing so many people dying. Yeah.

BY [redacted]:

Q And other parts of this guidance talk about the chemistry manufacturing and control data that you also talked about earlier. It talks about nonclinical and clinical data.

So is it fair to say that, during the EUA review process, OVRR reviews the regulatory information, the CMC information, and nonclinical and clinical safety and efficacy information?

A Yes. And facility information.

Q Facility.

A Well, OVRR, in concert with its colleagues from the other offices, right? For instance, our -- the statisticians here played a key role. They're not in the Office of Vaccines. They're working closely with the medical offices who are in Office of Vaccines, but they are responsible to do the statistical evaluation.

And our OVRR had the subject-matter experts for the CMC information, but the facility information is yet with a different office. And the office director of that office is Mary Malarkey, as I said before.

Q So FDA did review all of this information for the COVID-19 vaccine before issuing EUAs?

A Yes.

Q I want to turn to section VII. It's on page 11. It's titled "Consideration of an EUA for a COVID-19 Vaccine By an FDA Advisory Committee." Could you explain this consideration?

A Typically, if we -- if we have a Biologic License Application for a new vaccine product, we convene the Vaccines and Related Biologic Products Advisory Committee, which consists of experts in different disciplines from across the country. And we do this to have a public discussion and a public vetting on the safety and efficacy information that is available for this vaccine product.

And, even though FDA has reviewed the data and has also -- you know, has a perspective, of course, at that point when they convene the committee on the safety and

the efficacy of the product, they usually want to hear the advice of these public experts.

So the safety information and the efficacy information is presented during a day's deliberation, you know, for the specific vaccine. And the committee is typically asked with questions: Do you agree that the safety information submitted, or you heard about today supports the safety of the product under the condition of use? It's always like that, okay? And under the condition of, you know, what the recipient has to undergo because of exposure to the disease, or do the data support the efficacy of the vaccine?

And the committee then can vote. And there are sometimes also discussion points. So please discuss what additional data may be necessary. Do you think? So -- and so that's meetings that we have to really have a transparent process too so that people know about the products licensed. Everybody can call into these meetings.

We felt it was important to have this very transparent process also, you know, set in place during the COVID pandemic and before the Emergency Use Authorization, because we wanted to know if VRBPAC agreed with the criteria that were laid out in this guidance document. And that's why we convened the meeting. And, yes, they agreed with the criteria that we laid out.

And then we had two more advisory committee meetings that year, and that was presenting the data accrued with the Moderna mRNA vaccine and the Comirnaty mRNA vaccine, and both of these committee meetings took place within a week of each other in December, where the committee was again asked, you know, do you agree that the known and potential benefits outweigh the known and potential risks of this?

[12:16 p.m.]

BY [redacted]:

Q So you're saying VRBPAC did meet before the EUAs of both the Moderna and the Pfizer vaccine?

A Yes. Yes.

Q Do you have confidence in the OVRR review of the Pfizer and the Moderna COVID-19 vaccines for Emergency Use Authorization?

A Yes.

Q Were all the necessary procedures followed during the review process?

A Yes.

Q Were the review methods reliable?

A Yes.

Q Did OVRR make its decisions based on reliable evidence?

A OVRR made its decision based on the safety and efficacy information that was before them and found that the known and potential benefits did outweigh the known and potential risks of the product.

Q Did you have confidence in the safety and the efficacy of the COVID-19 vaccines when the EUAs were issued in late 2020?

A I had confidence that the requirements, as laid out by the statute, were met, and as I said before, may be effective, and the potential -- known and potential benefits would outweigh the known and potential risks. Yes.

Ms. [redacted] Thank you.

We can go off the record.

[Recess.]

[redacted] We'll go back on the record.

Dr. Gruber, at the end of the first hour, we were talking about your interaction with Commissioner Dr. Woodcock. So I want to enter a couple of exhibits, and then I'm going to turn it over to Congressman Massie.

So I'll offer as Exhibit No. 2 an email from you Wednesday, July 21st, 2021, at 11:59 a.m., to Drs. Peter Marks and Janet Woodcock.

[Gruber Exhibit No. 2
Was marked for identification.]

[redacted] Then, as Exhibit No. 3, an email chain between Dr. Gruber and Dr. Marks and Dr. Krause from July 15th, 2021, 8:00 a.m., with an attached memorandum titled, "Pfizer COVID-19 STN 125742.0 BLA target AD: 9-15-21."

[Gruber Exhibit No. 3
Was marked for identification.]

[redacted] And we'll give you a moment to review.

Dr. Gruber. So this is not -- you passed this out as well. Do you want me to review this right now as well or just this email?

BY [redacted]:

Q Just start with the email because we'll get to the memo a little later.

A Okay.

Q I just wanted you to have both in case you needed to reference either of them.

Mr. Massie. There's a reference in your email to a memo on July 15th, and we believe that's the memo that's referenced.

Dr. Gruber. Yeah. I'll take a moment to memorize it.

Thank you for giving me the time to look through this memo.

[redacted] Of course. I'm going to enter one more exhibit just so you can have it,

too, while we're questioning.

This will be Exhibit No. 4. It is an email from Dr. Marks to Dr. Woodcock and Julia Tierney from Friday, July 16th, 2021, at 6:08 p.m., with an attached timeline. And that will be Exhibit No. 4.

[Gruber Exhibit No. 4
Was marked for identification.]

Dr. Gruber. Okay.

Mr. Massie. I'll primarily be asking about the email.

Dr. Gruber. Okay.

Mr. Massie. Exhibit No. 2.

Dr. Gruber. Yes. I have that email. Thank you.

Mr. Massie. Dr. Gruber, did you have a meeting on July 19th, 2021, with Krause, Woodcock, and Marks to discuss the timeline of the BLA review for Pfizer's COVID-19 vaccine?

Dr. Gruber. Yes. That is true. The meeting took place between Dr. Woodcock, Dr. Marks, Dr. Krause, and Julia Tierney, was, I think, Dr. Woodcock's acting chief of staff at the time.

Mr. Massie. Were there any other people present?

Dr. Gruber. No.

Mr. Massie. And were there any other communications about this meeting other than your email?

Dr. Gruber. I had received -- I need a second. Yes. So I had written -- leadership in Office of Vaccines had written the July 15th memorandum to Dr. Marks explaining why we felt at that time that the review timelines cannot be compressed further. And I did not hear back from Dr. Marks in response to that memo of July 15th.

But then I received an email from Dr. Woodcock. It was a meeting invite to meet with her -- it was a Zoom meeting -- to meet with her on July 19th. I believe that was even a Monday. I got that, you know, meeting request, I think, the Friday before the specific instructions to appear at 7:30 a.m. or 8:00 -- 7:30 -- it was early in the morning -- to discuss the BLA review timelines. Yes.

Mr. Massie. And did you tell them in that meeting that they cannot be -- that the timeline cannot be compressed further?

Dr. Gruber. In the meeting of July 19th, I did recapitulate the content of my July 15 memo. Yes. That included my assessment at that time not to compress the timelines further.

Mr. Massie. Was there any recording of that Zoom meeting?

Dr. Gruber. Not that I remember.

Mr. Massie. Okay. And did you feel pressured in that meeting to change the timeline?

Dr. Gruber. Yes.

Mr. Massie. Did they say -- well, I don't want to lead you or trip you up or anything, so I'll draw your attention to this email.

You say in here about two-thirds of the way down in the second paragraph, quote, "You expressed concern that the rising COVID cases in the U.S. and globally, largely caused by the Delta variant, and stated your opinion that, absent a license, States cannot require mandatory vaccination."

Your email is addressed to both Marks and Woodcock, and here you say "you." Was it Woodcock or was it Marks or was it both of them that expressed their opinion that a license would be needed for vaccine mandates?

Dr. Gruber. It was both of them. Yeah.

Mr. Massie. So I'll introduce this into the record later, but on August 8th, the Secretary of Defense -- and I have that document, but I got a New York Times article, and I'll just -- I don't have other copies. I'll introduce all that later.

But on August 8th, the Secretary of Defense said that the vaccine mandate for the military would happen as soon as the FDA licensed the product. And then on August 9th, the New York Times reported that.

Were you -- other than in this meeting where Dr. Marks and Dr. Woodcock told you that the vaccine mandates would be conditioned or needed to have the full FDA approval before they could happen -- in addition to them telling you that here, were you aware that the Defense Department was awaiting an issuance of a license, the BLA, so that they could do the mandate?

Ms. LoCicero. And I just want to caution Dr. Gruber that you are not to speak about any deliberative process internal to the agency on that topic.

[redacted] And just to get it clear for the record, is that an objection for deliberative process?

Ms. LoCicero. Yes.

[redacted] Okay. And you're instructing her not to answer, or --

Ms. LoCicero. I'm instructing her to answer if she can, but to avoid providing information that is covered by the deliberative process within the agency.

[redacted] Okay. Thank you. Just wanted to get it clear for the record.

Dr. Gruber. Can you repeat the question for me?

Mr. Massie. Yeah. Let me repeat the question.

Did you know that the military was going to issue a mandate as soon as the licensure happened?

Dr. Gruber. No, I did not.

Mr. Massie. Are you aware that the day after your -- the license was issued, that the mandate was handed down from the Secretary of Defense?

Dr. Gruber. No.

Mr. Massie. Okay. What specifically did Woodcock or Marks tell you about -- or can you elaborate on your sentence here where they said that, "Absent a license, States cannot require mandatory vaccination."

Do you believe they were telling you that because they were trying to increase a sense of urgency?

Dr. Gruber. I cannot speculate as to why they told me that. I just recall that both of them said, absent a mandate -- a mandate requiring mandatory vaccination -- right. People would not be getting the vaccine.

And they also made the point, as I state here in the email, that they feel that people have a tendency to get a vaccine that is authorized, but they may be hesitant and would be more likely to receive the vaccine if it would be licensed. These two arguments were made during that meeting, yes.

Mr. Massie. Was it predetermined that the vaccine was going to be licensed at the point of that meeting?

Dr. Gruber. At that point of the meeting, the review was still ongoing. No determination had been made whether this vaccine would be licensed because we were busy reviewing critical information, as I had outlined in the July 15 memo.

Mr. Massie. What would have prompted a denial of licensing? What information would you have collected, possibly, in that period of time or were discovered?

Dr. Gruber. Several reasons. Multiple reasons. For instance, there could have been lack of information supporting that the facility would be in compliance with good manufacturing standards. There could have been information that incoming safety data

during the review of the BLA -- safety data that resided from the post-EUA surveillance system, where -- of such concern that a license would not be possible. There could have been, you know, an analysis by our statisticians not verifying the efficacy of the BLA.

So many, many reasons that could have prevented licensure of the product.

Mr. Massie. So was there a threshold for efficacy that you were looking for to approve the product?

Dr. Gruber. The efficacy standard -- the criteria had been published in the guidance for industry documents on development and licensure of SARS-CoV-2 vaccines.

In that guidance, we said the point estimate of vaccine efficacy has to be at least 50 percent as a lower bound of the suggested confidence interval of equal or greater of 30 percent. This was the efficacy standard that had to be met. And results showed that the vaccine far exceeded that efficacy standard. The point estimate was in the nineties rather than the 50th percentile, and the lower bound of the confidence interval was -- I think it was in the eighties or nineties.

And so, yes, the statistical criteria had been met to deem the vaccine efficacious.

Mr. Massie. Were there reports in the -- weren't there reports in the news that the efficacy was waning or that it wasn't effective for the predominant strain at the time?

For example, there was a CDC report about an outbreak in Barnstable, Massachusetts. Were you aware of that outbreak? Here, let me find a date on it. It was in early August. Or the Wisconsin -- oh, I'm sorry.

Where Walensky said on August 5th that what the vaccines can't do anymore is prevent transmission?

Dr. Gruber. I am not aware of that newspaper article. What I can tell you is the vaccines were developed to prevent severe COVID disease. It was evident that these vaccines would not prevent transmission. Many vaccines do not prevent transmission or

infection.

So when we discussed with the vaccine manufacturers the case definition that they needed to use to demonstrate efficacy, it was not transmission.

Mr. Massie. Were you ever concerned about public statements from government officials that these vaccines would reduce transmission, given that the Pfizer clinical trial was designed -- was not designed to test that and that your approval wasn't conditioned on it?

Dr. Gruber. In our regulatory documents, we clearly described the end points and case definitions that the vaccine was tested for to meet. There were a lot of different publications and statements made at that time.

Mr. Massie. So what the test didn't -- or the trials didn't determine is whether it prevented infection?

Dr. Gruber. That's right.

Mr. Massie. So -- but there was statements from the CEO of Pfizer that would indicate that -- that would suggest that it did. Were you concerned about that?

Dr. Gruber. I could not and wasn't able to control the statements made by public health officials or CEOs of the company in terms of, you know, the vaccine efficacy. All I could do is, in our regulatory documents, describe how the vaccine was tested and what efficacy was demonstrated against.

Mr. Massie. So you had given them a September 15th date, which you considered to be, I think, very aggressive compared to prior timelines for other vaccines. Is that correct?

Dr. Gruber. That is correct.

Mr. Massie. And who was pushing you to move that date up?

Dr. Gruber. It was Dr. Marks.

Mr. Massie. You said that, in your email, there are very important regulatory issues that need to be settled, and as an example, you mentioned a pediatric plan.

Can you explain what that means and what needed to be settled? Why was the BLA approval dependent on the pediatric plan?

Dr. Gruber. Because it is required by law that a vaccine manufacturer will assess the vaccine further in the pediatric population if they have not been tested as part of the efficacy study. And as I recall, in the efficacy trial, there were adolescents and children, I think, down to 12 years of age, but the vaccine was not tested in children less than 12 years of age as part of this efficacy study.

So a vaccine manufacturer then has to put a document together describing -- even though the vaccine was ready for approval in an older population or the adult population, that it would conduct further studies to evaluate the safety and the effectiveness of the product in pediatric subjects. So that is a -- that's the Pediatric Research Equity Act, PREA, that is a law that vaccine manufacturers and, by implication, FDA has to comply with.

So we had to review the documents that Pfizer submitted delineating the type of studies they would be conducting in pediatric subjects. And that, of course -- and this is what I stated in my email -- was important because safety in younger populations is even more paramount than in older populations.

Mr. Massie. You mentioned that the pediatric plan was becoming increasingly complex. What was complex, and how did the FDA and your team adapt to those complexities?

Dr. Gruber. So, by definition, pediatric subjects go until age 17, including age 17. And as we discussed earlier on this morning, we had become aware of data suggesting a risk of myocarditis. And this data became apparent because the vaccine was rolled out and the EUA. And, of course, there were post-EUA surveillance systems in place by the

CDC and the FDA, and they showed it was for myocarditis and pericarditis in younger adults but also adolescents, young males. And 12- to 17-year-olds includes the pediatric population.

So we had to discuss with a sponsor, given that identified risk, what further studies did need to be conducted if we were to license the product in the postmarketing space to further assess that risk. And this is referred to as postmarketing-required studies.

Mr. Massie. And that is complex in a way different from prior vaccine approvals? What is --

Dr. Gruber. The difference was that we became aware of this risk of myocarditis. If there would not have been this information and this data, there would not have been a need to require Pfizer to conduct a postmarketing-required study to further evaluate the safety signal as the regulations prescribe.

And so we also had to review proposed protocols for that further postmarketing-required study. And that also comes with -- they have to give us a date when they're going to initiate this trial and when they're going to conclude these studies. So this is where review activities were ongoing at that time.

Mr. Massie. And that's part of the timeline that Dr. Marks was asking you to compress?

Dr. Gruber. Yeah.

[redacted] So is it fair to say that you were the -- it had been raised to you the data regarding myocarditis or other -- the pericarditis side effects, that was -- you determined that based on the data before this July 19th meeting? Is that timeline accurate? Or could you elaborate on when you had found out about the myocarditis side effect in relevance to this meeting?

Dr. Gruber. The vaccines were rolled out under EUA, and the decision to authorize the Pfizer vaccine was made in December of 2020. The FDA and the CDC set in place a post-EUA safety surveillance system. And as the vaccine was rolled out and administered to a large number of subjects in the United States, these safety surveillance systems picked up this risk of myocarditis. And, of course, the sponsor was aware of this as well.

Mr. Massie. So you -- sorry to jump around.

You mentioned that Dr. Marks and Dr. Woodcock both mentioned mandates -- vaccine mandates to you. Is that something inside of the FDA's purview, and should that be a consideration that you have to take into effect when you're deciding whether to issue a license or not?

Dr. Gruber. I was never made aware that this is a requirement, and as a matter of fact, that subject had never come up in vaccine licensures before.

Mr. Massie. So is that why you memorialized it in this letter, that they were, I mean, mentioning mandates, and that wasn't really part of your job?

Dr. Gruber. Yes.

Mr. Massie. When you left, who was appointed to take over your responsibilities?

Dr. Gruber. That was Dr. Marks.

Mr. Massie. And who appointed him?

Dr. Gruber. Dr. Woodcock.

Mr. Massie. Did you express dissatisfaction with that decision?

Dr. Gruber. At the time of my departure in October -- on October 31st, 2023, I did not.

Mr. Massie. Who would you have expected to assume your position when you left?

Dr. Gruber. Dr. Krause.

Mr. Massie. You mentioned in your email the importance of a thorough and credible review by OVRR. Did you have concerns that what they were asking you to do would not be thorough and credible?

Dr. Gruber. At the time I wrote this memo on July 15th, and as I stated and tried to document in the July 15th memo, there was many activities going on, including information requests, requests for data to Pfizer.

And my experience as office director and my decades of experience in the Office of Vaccines had told me that one cannot predict when a vaccine manufacturer would respond to an information request. It could be in a couple of days, weeks, or months.

And so for me, I did not think that I could say, at that time, in the middle of July, where I knew so much review and regulatory activity was ongoing, that, yes, we can approve earlier. I also would like to add that I had concerns because I felt I needed to protect my people.

Mr. Massie. When was the decision finally made to shorten the timeline from September 15th to what eventually was August 23rd?

Dr. Gruber. At the time, I -- not about the memo, but when this meeting happened on July 19th, I had to go out of town. My daughter, whose wedding had been canceled twice due to COVID, had finally given a date for the marriage on August 1st in Germany, and I wasn't going to miss that wedding.

And, of course, that date, I didn't know when the BLA was submitted. I had no time of planning in advance. But what I did during -- during this time, during the BLA review, I discussed that -- with Kraus, my deputy, and I said, listen. I need to be -- you know, I want to go to attend my daughter's wedding. Can you take over at that time for me?

And he says, well, of course. That's what a deputy office director is for.

I also should say that Dr. Krause, you know, being a medical officer, knew the clinical data very well. The review team, the medical officers, asked him for guidance. He was very knowledgeable about all the data, and I felt he was the perfect person to oversee the review activities for the time that I was gone. I also indicated to Dr. Woodcock that I would be having my telephone and my telephone number. If something is the matter, I can be reached at any time.

She informed me in this meeting on July 19th that Dr. Marks would take over the review of the BLA activities -- or the BLA review activities. I'm sorry. And that Dr. Krause would be assigned to other OVRR programs. And they had -- and she indicated this to me in an email that she wrote me after she received my memo on July 21st that she had tasked Dr. Marks with looking at where efficiencies can be gained and if it was possible to move up that date.

So the decision was not made when I left, but it had been made when I came back.

Mr. Massie. And what did they assign Dr. Krause to? Was it other COVID vaccine tasks?

Dr. Gruber. Other COVID vaccines, other files because, of course, work in OVRR had to continue on bacterial products or, you know, allogenic products and -- yes, that sort of --

Mr. Massie. So they took somebody who was intimately familiar with the problem that needed to be solved and took him out of that decision position?

Dr. Gruber. I have to say yes.

Mr. Massie. And when you came back from your daughter's wedding, is that when you found out the new timeline was going to be August 23rd?

Dr. Gruber. No. There was no set timeline. It was, we will achieve an approval

faster than September -- or regulatory action faster than September 15th.

And I have to say, I give credit to the team because they did what they could. They -- as I indicated earlier, they were there day and night. Day and night to perform these review activities. Also, the sponsor did not delay responding to information requests. I was informed that they, you know, submitted the answers day and night.

And that is how, in the end, it was possible to move up the regulatory action of that BLA to the end of August. It was because my people gave it their best and they gave it their all.

Mr. Massie. What was the date that you returned?

Dr. Gruber. I think it was August 7th.

Mr. Massie. Would you like to ask questions?

[redacted] Yes.

BY [redacted]:

Q I would like to ask, how big was your team that was assigned to work on this -- on the BLA while you were out, and had they been previously working on it as well?

A So when a BLA is submitted, a review team is assigned, and the review team is put together from the different offices which have authority to review and then license the product. Office of Compliance, Office of Biostatistics and Epidemiology, and Office of Vaccines. And I cannot give you the exact number, but usually these committees are -- I would say 70, 80 people. Yeah.

Q And so is it fair to say, of those committees, they only took a few people from those committees to work on this BLA review team, or are you saying 70 to 80 people worked on it?

A Well, not everybody in all the review committee has, you know, a very central function. I mean, the most -- the most important people are the people that

perform the clinical data review. And there, we have said we need help. It's not usually -- it's one medical officer working with their supervisors in a typical BLA. Here, we had two people. Instead of one statistician, we had three statisticians.

But then, of course, the CMC reviewer -- they're working, you know, as a team, too. One has the primary responsibility of writing the memo, and others will help, you know, look through it. Yeah.

Q And the reason I ask is because I believe in -- I'm trying to exactly figure out which email it was, if it was the one from you. Oh, yes.

So in Exhibit 2, midway through paragraph -- the second paragraph, you wrote, "I reiterated that adding staff to this review at this advanced stage would likely slow down the review due to the need to bring new people up to speed."

So I was curious as to the number that had existed at the time before you left and then if that number did increase, or what number they were proposing to increase your team size to.

A I recall that the number did not increase. No. And I had made the point that I didn't think it was productive to add at such late stage in review new people because they have to familiarize themselves with the file, and there was really nobody who had time to bring somebody up to speed. I mean, I said either we try to get this done, or we start to train other people.

Q And to your knowledge, they did not bring on anybody new?

A No. To my knowledge, they did not bring on any new people, no.

Q Do you know if Dr. Marks and Dr. Woodcock -- if they had received instruction from outside the FDA to move this timeline up further from the September 15th, 2021 action due date?

Ms. LoCicero. I'm going to object to that to the extent it impinges on the

deliberative process privilege.

[redacted] Okay. So are you instructing the witness not to answer?

Ms. LoCicero. I am instructing her not to answer that question.

[redacted] Okay.

BY [redacted]:

Q What was your reaction to Dr. Marks' and Dr. Woodcock's goal to move up the timeline from September 15th to several weeks earlier?

A Well, I think I did describe this in my memo.

Q Would you say -- did Dr. Krause share those concerns that you described in your memo?

Ms. LoCicero. I'm going to instruct her also not to answer that question based on the objection.

BY [redacted]:

Q Did you draft your July 15th -- or whenever it was actually drafted, but it was in that July 15th email that was Exhibit 3 -- that memo, did you draft that yourself, or was there multiple people that helped you draft that?

A Several people helped draft it.

Q Now, on that Exhibit 3, with the July 15th, 2021 email, you also included Celia Witten. Can you tell us who she is?

A Celia Witten was, at the time, the deputy center director.

Q Of which center?

A Sorry. Center for Biologics Evaluation and Research. So Dr. Marks' deputy.

Q And in that email, that Exhibit 3 email, you wrote -- and I believe it's at the bottom of that page.

You said, "Phil and I further discussed with DVRPA and DVP management the

review timeline for the above BLA. As you know, we are targeting September 15th as the ADD. It will not be possible to move the ADD up without further cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW."

I wanted to just ask clarification what DVRPA and DVP stand for.

A Yeah. Where is that? I mean, I can tell you what it is. It's the Division of Viral Products, which was -- oh, in the email. I thought it was in the memo. I'm sorry. Yeah. Okay. Here it is.

Yeah. That was July 15th at the time I wrote the memo because I did consult with management, with the division directors of the Division of Viral Products, which is one of the divisions in the Office of Vaccines responsible for the review of chemistry, manufacturing, and control information.

And DVRPA is the Division of Vaccines and Related Product Applications. That is the division that is responsible for not only the administrative processing of the files, but it's the division where the medical team resides.

And so I -- obviously, when I was instructed to move up the approval date, I went to the management of these divisions because it is their people who performed the review activities. If they would find it reasonable, could they do it? And they cautioned for moving up the date further.

So this was not a decision single-handedly made by myself or by Phil.

Q Thank you for that clarification.

And if corners were indeed cut in the BLA approval process, would you personally be responsible for something going wrong, or would it be your team? Would it be the FDA generally? Or what is your understanding of who would be personally responsible?

Ms. LoCicero. I'm going to object. She's not going to answer hypothetical

questions.

Ms. Ferguson. Are you going to instruct her not to answer the question?

Ms. LoCicero. I'm instructing her not to speculate. If she would be happy to insert a different question --

Ms. Ferguson. Okay. We don't really recognize, you know, typical objections.

Ms. LoCicero. I'm instructing her not to answer that question.

Ms. Ferguson. Okay.

[redacted] Going to your memo that's attached to that July 15th email --

Ms. LoCicero. Can I just raise one issue? Just to note for the record that these Bates numbers are not consecutive.

[redacted] Correct.

Ms. LoCicero. So we are not -- we have never seen this document before today, which is fine. But I want to make it clear that it doesn't appear that this memo you've attached to it actually follows this email.

[redacted] Those documents -- just for clarification, they were produced under FOIA, and they were available on the FDA's website, and they had redacted any privileged information. And there was a couple different copies --

Ms. LoCicero. Okay.

[redacted] -- of some of these emails, and so it might have just been the way that we stapled it was -- that particular memo was attached to -- that's what it's referring to from the attachment. It just was in there a different order.

Ms. LoCicero. Okay.

BY [redacted]:

Q And going back to that memo -- and just for the sake of usual practice, is it fair to say that the FDA usually evaluates and analyzes BLAs separate and apart from any

analysis provided by a sponsor? That's the normal practice that the FDA --

A The FDA does perform its own analysis of the raw datasets submitted by the sponsor. We request those datasets to perform our analysis.

Q And how long does this dataset analysis usually take?

A That depends on the complexity of the BLA, the size of the clinical trial.

Q How long had it taken for this particular Pfizer vaccine?

A I cannot give you an exact timeline on that.

Q Can you explain how the FDA's own analysis of a developer's data affects the public's confidence in the vaccine?

A The primary reason for FDA to perform its own analysis is really to verify the accuracy of the data and information submitted by the vaccine manufacturer because, in the end, we have to make the determination that the vaccine is safe and pure and potent for its intended use, and we want to make sure that the data are accurate.

Q And further in this memo, you discuss that this BLA is a rolling BLA, and I just wanted to note for the record or get clarification what a rolling BLA is.

A Yeah. I mentioned earlier that a biologics license application can be assigned priority review, so the -- the review time is about 4 months -- 4 months shorter than a standard review. And there is an additional program.

So this -- this vaccine also received breakthrough therapy. It's an expedited program by the FDA. And that means a sponsor does not have to wait until they have all pieces of the BLA ready and submit this, but if they have pieces of the BLA already completed, such as the preclinical data and datasets, such as the CMC data and datasets, such as the clinical data, they can submit them, and FDA will start reviewing these sections, but the official review clock only starts when all the pieces are available.

So in this case, as I recall, the preclinical data were already available earlier than

the clinical data, and so we started reviewing that. And that, of course, is another mechanism by which you can accelerate, you know, the time it usually takes to review a BLA application.

Q Thank you for the clarification.

Mr. Massie. On August 17th, you e-mailed Dr. Marks and shared the current draft of the clinical review memo for Pfizer's BLA, and you stated that there was work that still needed to be completed, and therefore, the date of August 20th was not possible.

You know, 6 days later, the BLA was approved. What happened between your August 17th email to Dr. Marks and August 23rd, and do you agree with that decision?

Dr. Gruber. Congressman, is it possible -- is there an exhibit? Can I take a look at that?

Mr. Massie. I'll get that later. Yeah. I'll put this on hold and then give you those exhibits and ask you about it.

Dr. Gruber. Okay. Thank you.

Mr. Massie. When Pfizer submits safety data and categorizes adverse events that occurred during the trial, what level of review does the FDA conduct on those adverse events?

Dr. Gruber. As I mentioned, the FDA will request the raw datasets. So in this situation, there was data from 44,000 subjects, line listings, because -- and these people were followed for safety, right? 7 days and then 28 days. And so daily records are being put into these raw datasets. Injection site reaction, fever, malaise. And so these are line-by-line listings of every subject included in this clinical trial.

The sponsor then analyzes the data and says, okay. What was the percentage of fever? What was the percentage of headache, for example? And FDA then does the same analysis and says, let's see. Let's verify if what they state is correct.

Mr. Massie. Does the FDA independently check the medical records to confirm the characterization of the adverse event?

Dr. Gruber. The charts? The medical charts? For those where we see a more serious adverse event, we typically want to look at this and perform a chart review.

Mr. Massie. Does the FDA do its own analysis to determine whether every adverse event reported by the sponsor is related to the vaccine?

Dr. Gruber. That is clinical judgment. When the medical reviewers look at the adverse event, they look not only at, you know, what happened, but also, they look at the timely association between vaccination and occurrence of this adverse event.

They also look at the health status of the subject. Is it a person who is 75 years old with underlying medical conditions? Is it a young, healthy person? So they look at all this information.

And then there is a certain -- you know, of course, there are data effects, but then there is also clinical judgment that is applied to make a determination that the vaccine was related or if it was in accordance with that finding.

I should add that, for these clinical trials, there is also something that is called a Data Safety Monitoring Board, DSMB. That is an independent committee that also will look at data and do a safety review.

Mr. Massie. Just a week after the FDA approved the vaccine, you announced your retirement. Is that correct?

Dr. Gruber. Yes.

Mr. Massie. Why did you decide to retire from the FDA at that time?

Dr. Gruber. Congressman, I was eligible to retire from the FDA in summer of 2020. And I actually had made plans, and my husband and I talked about it, that I would put in my retirement paperwork by the time I would turn 62, which was in June of 2020. And I

was ready to do so, and then, as we all know, the pandemic hit. And I did not think, at that time, it was responsible of me to leave this important position during this time.

And we worked very hard that year to authorize these vaccines to make them available to people who wanted to be vaccinated to protect themselves from COVID-19. And in 2021, of course, there was still a lot of activity. There was -- and we -- you know, the submission, as we discussed, of the Pfizer BLA.

But at that time, I decided that my contribution to help the public health community out of the pandemic was done. I also admit there was a certain burnout, and I decided I will now move on with my retirement plans, and this is what I did.

[1:39 p.m.]

Mr. Massie. The press reported that your disagreement over the booster shots with other people in the FDA contributed to that. Is that true or false?

Dr. Gruber. That is false.

Mr. Massie. Okay. Thank you. Did you have concerns about booster shots being the policy of giving them to everybody or recommending them for everybody?

Dr. Gruber. During the year of 2021, there were various type of publications that evaluated the efficacy of the vaccine, expressed concerns about waning antibody titer. And there were people who were of the opinion that boosters to be given to the general population was necessary.

I had a different perspective. And I was part of a group on a paper published by the WHO that expressed a different perspective.

I want to be clear. I was not against boosters being administered. I thought boosters were necessary for the elderly, those with, you know, fragile immune systems, but I did not think, based on the data and the publications that I had read and reviewed at that time, that it was necessary to provide booster immunizations to the general public.

And I also was of the opinion, shared by colleagues of mine in the WHO, that, in order to curb the pandemic, that it would be better to provide vaccines to those unvaccinated or people that did not have access to vaccines, and not just necessarily in the United States but globally.

So, yes, I thought boosters were indicated for the frail, for the elderly, for the immunocompromised, based on the scientific information that I had reviewed at that time. I didn't think it was necessary to provide boosters to the general population.

Mr. Massie. In addition to the availability of vaccines, was it your concern that the risk-benefit was different for somebody who had already had the vaccine with respect to

getting a booster?

Was it purely -- was it purely a decision about vaccine distribution, or did you think the risk-reward changed for somebody receiving a benefit versus -- receiving a booster versus their initial vaccine?

Dr. Gruber. Any time we make a decision of authorizing or licensing a vaccine either for primary or for booster immunization, you have to be certain that the vaccine's benefit would outweigh the risks.

And my conclusion from the data that I had reviewed was that there wasn't increased benefit for let's say a young healthy person who had received the primary vaccination series to receive a booster at that time.

Mr. Massie. Did your concerns fall on deaf ears at FDA? Did they listen to your concerns and offer -- that would be my last question because we're out of time.

Dr. Gruber. I was not involved in the booster authorizations. I -- I was involved in writing a briefing document for Pfizer's supplement to authorize boosters for people 16 years of age and older, Congressman, but I was informed by my Center Director that my objectivity had been compromised due to the publication of the Lancet article and that, therefore, I could not preside over this advisory committee discussing the need for booster immunization.

Mr. Massie. Thank you.

[redacted] We'll go off the record.

[Recess.]

[redacted] It is 2:01. We can go back on the record.

BY [redacted]:

Q I want to pick up where we just left off about the Comirnaty BLA and then talking about what happened then.

During the pandemic, did the BLA build on the data that you already had from the EUA?

A Yes, yes. I mean, it contained the data from the EUA, the efficacy data and the safety data, but, of course, there was the -- the trial was continuing and there was continued safety followup and also continued efficacy followup, because, you know, the pandemic went on, and the trial continued. And so these were additional data that were submitted by Pfizer and were part of the BLA.

Q Is it fair to say that that made the review process a little bit faster, because you didn't have to analyze all of the data at once, but were able to do the EUA data first and then the additional data?

A That is correct. That is correct, yes.

Q And did the BLA approval account for any concerns that came up between the EUA and the BLA approval?

A Can you clarify your question?

Q Yes. So, we talked about how between -- after the EUA the FDA and CDC conducted post-EUA surveillance and found this risk of myocarditis and pericarditis.

Did the BLA account for that risk and did -- was that risk considered during the review process?

A Absolutely. We -- Pfizer submitted data, but also we became aware of the data from the post-EUA safety surveillance system that CDC and FDA had put in place.

And so the FDA experts, that was people in the Office of Biostatistics and Epidemiology that did a quantitative risk assessment, looking at the benefits afforded by the vaccine, in terms of protecting against COVID death, ICU admissions, and hospitalizations versus looking at the risk of myocarditis and hospitalizations there.

They came to the conclusion that even -- there were some severe cases of

myocarditis requiring hospitalization. Most of them, however, reacted to conservative management. And so when they also looked at the hospitalizations due to myocarditis versus COVID, that, of course -- you know, COVID -related hospitalizations were much more -- you know, they were longer, you know, intensive care units, et cetera.

So the overall benefit-risk assessment conducted by the FDA experts resulted in their conclusion that, despite of this increased risk seen, the benefits afforded by the vaccine far outweighed the risks.

But, in order to be conservative, the package insert for this vaccine that needs to be approved as part of the BLA approval stated the risk of myocarditis in section 5.2 warnings and precautions of the package insert. And, also, the sponsor was required to perform postmarketing-required studies to further evaluate that risk.

Q Are you confident in the review that your office did for the full licensure of the Pfizer vaccine?

A I am very confident.

Q Was the review based on reliable methods?

A The review was based on reliable methods and processes, yes.

Q And did those methods and processes consider reliable evidence?

A Yes.

BY [redacted]:

Q I want to turn to the events of August 2021 specifically that we talked through when this decision was made to accelerate the timeline.

So you said that you returned from your daughter's wedding on August 7. Is that correct?

A Yeah. I think it was August 7. My husband would know, but I know it was about a week after the wedding, which was August 1st. So yeah.

Q So you came back and you learned that the decision had been made to accelerate the timeline, correct?

A I think the decision was made during that time, but it was pretty much decided even before I left, because I had received word, right, to compress the timelines.

Q So the decision had actually been made even -- had been made before you left. It wasn't like they waited for you to leave the country and then issued a decision.

A No, no.

Q And what was the actual decision? Was it this vaccine needs to be released by -- or the -- sorry, the BLA needs to be approved by a certain date, or is it just we're going to speed things up?

A It was we do -- the review committee needs to do what it possibly can do to move up the action due date from September 15 to an earlier time point.

Q But they didn't say it needs to be moved up to August 23rd specifically?

A No. I did -- I was not informed of that, no.

Q So it wasn't like you -- like you returned from vacation and between -- you learned on August 7th that, within 2 weeks, this approval would have to be done?

A No.

Q I want to look through the memo that we talked through. It's exhibit No. 3. And start out on what is Bates stamped 347. So it's the actual memo, not the email itself.

A Yes.

Q And I want to -- this is the memo that you sent on July 16, 2021. I want to talk through this kind of page by page.

A July 15th, right?

Q I'm sorry. July 15th, correct, the email was sent. So you sent this on July 15, 2021.

A Uh-huh.

Q To Peter Marks, Celia Witten, copying Dr. Krause.

But the second boldfaced item on this page, it says: The BLA merits a complete and thorough review.

Can you briefly explain why you wrote that? Why did you believe this merited a complete and thorough review?

A It really was not a statement that pertained to this very BLA only. I mean, every BLA would merit a complete and thorough review.

Q And, in your opinion, at the time the BLA was approved, so on August 23, 2021, was a complete and thorough review done?

A Absolutely, yes.

Q The second -- or I'm sorry, I guess the third boldfaced headline there: As compared with other BLAs, the proposed completion date of September 15th would be unprecedented.

We talked through in the first hour -- or our first hour of questioning, I guess it was the second hour overall, that COVID-19 itself was fairly unprecedented. It was all hands on deck. Is that fair to say?

A That is fair to say, yes.

Q So the timeline here was unprecedented, but it's also an unprecedented public health emergency situation, right?

A Correct.

Q Turning the page to what's Bates stamped 348, it says: This is possible only with deprioritization of other reviews, including some related to COVID, and reassignment of work to other experienced medical officers."

Were there, in fact, other reviews deprioritized?

A We had deprioritized other reviews. We had deprioritized submissions related to other vaccines, non-COVID vaccines. We had received instructions to continue to prioritize COVID vaccine applications, not only restricted to the Pfizer and the Moderna, but all COVID, and of which there were, I don't recall, but at least a hundred.

And so we deprioritized the work on other important files. So, to give you an example, if a vaccine manufacturer submitted a meeting request -- and usually these can, depending on the type of the meeting -- most of them are type B meetings. That means we have to have the meeting held within 60 days.

We would say, we can't do that. It's deprioritized. It's going to take us another 2 months. So not 2 months but 4 months. And we had to do this the entire year of 2021 in order to cope with the workload.

Q And that was my point is that, to the extent it was all hands on deck to prioritize the response to COVID, it wasn't just this particular Pfizer BLA. It was across the board you were focused, your office was focusing on COVID and on addressing the response to that and deprioritizing other.

A That is correct. The deprioritization was not unique to this BLA.

Q Okay. Then the next bullet here or the next boldfaced topic is: Additional support from outside OVRR will not speed up the review.

And I think we talked through in the prior hour how it would have taken time to bring people up to speed and to have them read the files, right?

A Yeah. And that is it. I mean, a lot of review had been already taken place on the efficacy data, on the safety data, on the statistical evaluation, on the CMC information.

And so I disagreed with the note that putting in additional reviewers would speed up the timeline, because if I give you this book of a hundred pages, and I have read

through it, and I will ask you, please continue your review, what do you have to do? You have to review this hundred pages. You have to ask all kinds of questions, right, in order to come up to speed.

And I felt very strongly that I could not afford that at that time or at that stage of the BLA review. And, again, that was not a decision I made single-handedly. I discussed that with the supervisors of the different disciplines. And they said: No, not at this point.

Q Understood. What I want to look at in this paragraph, though, is your discussion of what the team that was already assigned and already up to speed on this review had to do.

So, for example, it says: The safety review encompasses a critical evaluation and interpretation of solicited and unsolicited safety data and SAES and clinical AEs of interest, including, but not limited to, the myocarditis signal that has been observed following the administration of the Pfizer COVID-19 vaccine under EUA.

So halfway through that paragraph.

We just talked through how at the end of the day, by August 23rd you, in fact, were able, your team was, in fact, able to do that review and to account for the concerns regarding myocarditis, correct?

A Correct. Yes.

Q And it says then: We are also performing subgroup analyses of safety and effectiveness data for race, ethnicity, and subjects with underlying condition.

A Uh-huh.

Q By August 23rd, was the team that was working on this project able to perform all of those subgroup analyses?

A They were. They were able to perform the subgroup analysis. And see, the next sentence is important: Completion of these reviews may require additional

correspondence with the sponsor.

That was the concern. If this would have had to take place, and then we would have had to wait for the sponsor's responses, additional analysis would have needed to be conducted. But that was not the case. We didn't -- we didn't have to do this. We didn't have to ask for additional information.

Q So, at the end of the day, it says: Completion of these reviews may require additional correspondence with the sponsor.

To the extent that there was correspondence, Pfizer was forthcoming. This happened more quickly than you might have been able to anticipate when you wrote this memo. Is that fair to say?

A That is -- that is a fact. At the time I wrote this memo, I wasn't in the position to make that assertion. I did not know how -- you know, what the extent of additional information requests would be, how fast Pfizer would be able to respond. And, again, I said this before, I took a bit of a conservative stance here, yeah.

Q And it says, it continues on: We hope that reviewers will be able to complete their detailed review memos of the various review activities by the beginning of September, as planned.

Were those -- what are those? Briefly, what are detailed review memos? What do those entail?

A So a clinical review memo is not simply here like a 2- or 3-page memo. It is a very comprehensive account for the review activities and the data, the data reviewed and looked at and assessed.

It can be -- I don't recall the exact pages of this review memo, but I think it was a hundred pages, at least. I predict it probably was more, but I can't recall. I've seen clinical review memos exceeding 400 pages.

It will give you the background of the disease. It will give you a summary of preclinical data submitted. It gives you a summary of the statistical evaluation, in addition to separate memos written by statisticians.

It will then walk through the individual clinical studies, describes the design, the subject disposition, how many people were of what race, what age, gender. All of this is going to be recorded, and then it will give you a discussion of the endpoint, the case definition, and will summarize the efficacy data.

And the same then goes for the safety evaluation. There will be tables and tables listing the adverse events that have been analyzed and shown. And so all of that is going to be recapitulated in that clinical review memo.

And then, at the very end, it has sort of an integrated assessment of risk. We'll be looking at what are the benefits, what are the -- what are the risks? And all of this has to be listed.

Q Okay. So those what sound like very comprehensive review memos, for this particular approval, were all of those comprehensive memos completed by August 23rd, when the BLA was approved?

A They were.

Q And then this says that, even after those very comprehensive reviews were completed, there were additional review activities to be completed, including legal negotiations, supervisory review, SBRA preparation, et cetera.

Were all of those additional approval requirements that are listed here, were all of those completed by August 23rd?

A They were. And it's -- that does not really happen in timely sequence.

Q Right. Okay.

A While a clinical review memo is written, label negotiations will start, for

instance because the applicant is required to send in the draft label with its initial BLA submission and reviews already start.

It's just that you need the conclusion and the assessment made by the medical officer to make a final determination that the data as shown and illustrated in the package insert are correct.

Q Understood.

A That's why you can't really get the label done before the clinical review memo is done. It is -- it is a parallel activity.

Q Okay. And, at the end of the day, all of these parallel activities, they were, in fact, completed to your satisfaction by August 23rd, right?

A That is right, yes.

Q Okay. I want to turn to -- it's part of the memo. It's page 350 of the Bates stamp. It's just the next page.

It says: Additional support from outside OVRR, if effectively used, might reduce the need to deprioritize certain submissions.

And there's a number of bullet points underneath that.

So I know we talked through that assigning additional staff to this particular -- to the Pfizer BLA wouldn't have been helpful, but you did think that it could be helpful for staff to be assigned for other areas, right?

A That's right. That is -- that was work that had to be addressed for other files, bacterial products, allergen products, other products that the Office of Vaccines was regulating, yes.

Q And even for like IT things, correct, IT staff?

A Including IT staff, yes. And we were saying -- because, of course, it was a compromise to be made. Prioritizing SARS-CoV-2-related submissions required

deprioritization of other submissions.

But we thought if we can get more people, experts to help with the SARS-CoV-2 unrelated files, it would not necessitate to keep deprioritizing those submissions.

Q Were you able to get additional staff for any of these areas?

A You know, that was at such late stage of my tenure at FDA that I did not see that through.

Q Okay. I want to return to something else you said in the earlier hour. You said -- and so it sounds like -- sorry, just to wrap up this line quickly.

So you did have concerns when you wrote the memo on July 15th about this potential accelerated timeline, but at the end of the day when -- and nobody actually said everything has to be done by August 23rd. It was just we're going to try and accelerate it even further.

A Yes.

Q At the end of the day, by August 23rd, you were fully confident in the decision to approve the BLA?

A I was. And I signed the approval letter, yes.

Q Okay. You said in the first hour -- the prior hour that you needed to protect your people. What did you mean by that?

A I -- I knew that my people -- and that did not only pertain to people in the Office of Vaccines but also the other offices -- that were part of the review team had worked many hours, had canceled vacations, while away from the office to attend events of their little children took their computers, their -- the computers, they couldn't take those, but the work phones, you know, to be -- to be available for questions to -- for phone calls.

So it was really -- people worked through many, many hours and situations. And

that had been ongoing for over a year. And I saw the dedication of people to wrap that BLA up and review it by September 15th, and I had discussed that with the division directors of the respective units, is it a possible date. And, at that time, I was informed by my division directors that it is ambitious, but it can be done.

When I heard that I have to move up the regulatory action date even further, I was concerned about my people, because there were signs of burnout. I had received phone calls of my staff. And I had to encourage them to move on and said: This is okay if you do that.

So, knowing that, knowing that and then being asked move this up, I felt I had to protect them and say: We have to put boundaries around what can be done.

But that was really just one argument. I want to clarify this. The other reasons were, as I stated in the memo: July 15th was a time where there were a lot of review activities ongoing. There were information requests to the sponsor, as we went over. And I didn't feel that I can give a certain point by which I can do this even faster.

And this was why I, you know, took a conservative stance and said: This cannot be done.

But I talked to my people. I talked to the division directors. We worked very closely with Pfizer. And the committee did get it done.

Q Are you proud of the work that your team did?

A I was -- I am tremendously proud. This was a team effort. I do not take credit for that. It was to the credit of the team. They were just wonderful. But it took its toll, yeah.

[redacted] Thank you.

BY [redacted]:

Q I want to move on and briefly talk about the booster shots that we've talked

about a little bit in the last hour.

The day after the Pfizer BLA was approved, Pfizer submitted a supplemental BLA to administer a booster dose to all individuals aged 16 and older. Does that sound right?

A Yeah. This supplement for a booster dose was submitted very shortly after approval of the BLA, yes.

Q Did your office follow its normal procedures when reviewing the supplement to the BLA?

A We did. I recall at that time that we discussed the necessity to go to an advisory committee meeting. And when we did. And people were assigned with reviewing of the supplement.

Q You mentioned that you didn't preside over the advisory committee, but the advisory committee did meet on September 17 to consider the supplemental BLA?

A That is correct. And I was participating in that meeting, but I didn't actively contribute.

Q What does that mean, that you didn't actively contribute?

A Well, usually if there are questions to the FDA, there are situations when the medical officer or the CMC reviewer doesn't want to speak up because it is at a certain level.

And then you have a -- you have an FDA official, a senior FDA official presiding over that, and they will answer questions. And this is what had been my responsibility. And that wasn't the case at that advisory committee.

BY [redacted]:

Q But you said you still participated in the meeting. What does "participate" mean?

A I did participate in the sense that I listened on Zoom. I listened to --

Q You're familiar with the results of the meeting and what happened?

A Yes. Yes, I was, uh-huh.

BY [redacted]:

Q Do you remember what the committee concluded at that meeting?

A I do remember.

Q Could you tell us?

A Yes. They did not recommend an approval for booster immunizations for people 16 years of age and older. They said, at that point, there wasn't sufficient data to support that, but that the -- not even an approval, it was an authorization again, an EUA should be considered for people 65 years of age and older and people with certain immunocompromised conditions.

Q That aligned with your opinion on --

A Well, it so happened.

Q And that exactly is what the FDA ended up doing, is that right, on September 17th? Sorry, on September 22nd, the FDA amended the Pfizer EUA to allow booster doses for the elderly and those at risk of severe disease from COVID-19?

A That happened, yes, on the EUA.

Q Are you confident in the amending of that EUA in that way? Are you confident in the review that happened for the amending of the EUA that way?

A Again, I wasn't entirely involved in that anymore. I participated in the writing of the briefing document for the committee, but, as stated, I did not preside over this committee as a senior FDA official and -- that's what I have to say to that.

Q I want to now move back in time, back to 2020. We were talking about the October 2020 guidelines, and you mentioned -- I had asked if the White House is usually involved in those guidelines, and you said they usually weren't, but in this case, they

were.

Could you talk a little bit more about that? What did you mean by that?

A Well, there was, of course, an interest to get vaccines out as soon as possible to protect people from SARS-CoV-2. And there was, you know -- the administration at that time, of course, also had the goal of making these vaccines available soon. And we all agreed with that stated goal.

I found it unusual that the White House said that they would need to clear this guidance document, because that was not usually the case.

BY [redacted]:

Q Who at the White House said that?

A Well, there were public announcements by President Trump at that time, right, that he said: We may or may not clear the guidance document.

He never said: We will not clear the guidance document.

He said: We may or may not, you know, clear it.

Q And when he -- how did you -- how did you hear that he had said that?

A By watching the news.

Q And what was your reaction when you saw that on the news?

A I was concerned because I felt that the recommendations made in this guidance document were reasonable. We already, you know, had in writing this guidance document considered the public health emergency and the serious risk, you know, caused by SARS-CoV-2. And, in Office of Vaccines, we were not willing to compromise any standards for safety and effectiveness in the interest of getting vaccine out even faster than we thought we could make them available.

Q And so your impression of what President Trump had said is that he may be pressuring you to compromise safety to get the vaccine out more quickly?

A I don't want to speculate about that.

Q Okay.

A I just know that he said: We may or may not approve, you know, the guidance document.

Q Have you ever had a situation before where a President had commented on any guidance document your team was involved in?

A No.

[redacted] So I'd like to introduce for the record a tweet from former President Trump dated October 6, 2020. It is timestamped 9:09 p.m.

[Gruber Exhibit No. 5
Was marked for identification.]

BY [redacted]:

Q This tweet reads: New FDA rules make it more difficult for them to speed up vaccines for approval before election day. Just another political hit job.

And then he tags an FDA official.

Were you aware that former President Trump wanted COVID vaccines to be authorized for emergency use before the election day in 2020?

A I was not directly informed of that. I knew that it was the desire to make the vaccines available as fast as possible, but I never got direct, you know, instructions to make them available prior to October 6 by nobody within FDA.

Q Had you heard at the time that the former President had called the FDA's guidelines a political hit job?

A I didn't pay attention to that.

Q What is your reaction to that?

A You know, during my tenure at the FDA, I really didn't focus on -- on politics

or, you know -- I wanted to make sure that my decisions were grounded in science and supported by the available data and in compliance with applicable law and regulation.

And so, you know, there were at this time so many tweets, so many newspaper articles. And I deliberately wanted to stay away from that, just do my job.

BY [redacted]:

Q The reference here to "just another political hit job," did political considerations play any part in the guidance that you drafted or that you -- I guess that your team drafted and that you cleared?

A No. As I explained earlier, the criteria in that guidance document that we advised manufacturers to follow in order to support an EUA were really based on -- on scientific and regulatory standards and not political motivations.

Q And, to be clear, you were a career civil servant, correct?

A Yes.

Q You never held a political appointment at the FDA?

A No.

[redacted] I'd like to introduce for the record another tweet from President Trump dated August 22, 2020. It's timestamped 7:49 a.m., and this will be exhibit 6.

[Gruber Exhibit No. 6

Was marked for identification.]

BY [redacted]:

Q This tweet reads: The deep state, or whoever, over at FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd. Must focus on speed, and saving lives.

And then it tags an FDA official.

Were any of the regulatory decisions you made related to the COVID vaccine an effort to delay vaccine authorization until after the 2020 election?

A Absolutely not.

BY [redacted]:

Q There's a reference in here to the deep state. What's your understanding of what the deep state is a reference to?

A My native language is German. I have to say, when I looked at that, I had no idea what "deep state" is and refers to.

Q Some people have said that the "deep state" refers to civil servants who are working to prevent the agenda of a political party from going forward.

With that definition, do you consider yourself to have been part of the deep state?

A No.

BY [redacted]:

Q I'm going to move on to another topic. I'm going to bring up some claims about vaccines, and I apologize in advance that some of these might be offensive, but I just want to make sure we have on the record, with you as a vaccine expert, the facts about vaccines.

Do childhood vaccinations cause autism?

A No.

Q How do you know that?

A Because I was at the time in the mid to end '90s, later even, beginning of the thousands, the 2000s, involved in reviewing a lot of the data and the information, specifically, you know, about a certain preservative in the vaccine. And the evidence suggested, the scientific evidence, that vaccines are not the cause of autism.

And, together with my colleagues, I spent a lot of time reviewing the evidence and came to the conclusion that vaccines are not the cause of autism.

Q Can the misconception that childhood vaccines are linked to autism be detrimental to public health?

A If parents decide not to immunize their children because of these claims, of course, in certain situations it could be detrimental to public health.

BY [redacted]:

Q Do you think it's generally accepted among the scientific community that vaccines are not the cause of autism?

A I think it is generally accepted in the scientific community, yes.

BY [redacted]:

Q There have been claims that Black children or Black people more generally should not be vaccinated because people with African blood react differently to vaccines than people with Caucasian blood. They are much more sensitive. Is that claim true?

A I am not aware of data that would suggest that.

Q There is a conspiracy that the government's promotion of widespread COVID vaccination was a way to hide vaccine injuries by eliminating the control group. Is that true?

A No.

Q Could you explain why that's not true?

A Because the studies conducted, the efficacy studies were placebo-controlled trials.

BY [redacted]:

Q Can you explain why that -- can you explain that a step further? The fact that they were placebo-controlled trials, why does that matter?

A Because if you enroll subjects in the clinical study, and one arm, study arm of people gets the investigational vaccine and the other group gets placebo, like a saline injection. And so how?

Q I think the theory behind this claim is that, if so many people got vaccinated, you couldn't possibly know if any particular injury was related to the vaccine, but you stated that there are a number of surveillance, ongoing evaluations that take place.

So it is possible to know if an injury is due to a vaccine, correct?

A So, as part of the clinical trials, where there is safety followup, there will be a determination if there is an adverse event whether it is plausibly due to the vaccine or not. And, as I explained earlier, that takes into consideration the timely association from the injection to the occurrence of the adverse event, the condition of the recipient, et cetera.

BY [redacted]:

Q There are claims that the COVID-19 vaccine is the deadliest vaccine ever made. Is that true?

A No.

Q There is a conspiracy that the COVID vaccine implanted microchips into the people who received it. Is that true?

A No.

[redacted] What's your reaction to that claim?

Dr. Gruber. I think that's a little bit far from science.

BY [redacted]:

Q I know that you have studied maternal vaccination. There are claims that the COVID vaccine isn't safe in pregnancy or even causes miscarriage. Is that true?

A I'm not aware of data that would suggest that the COVID vaccine is not safe

in pregnancy.

Q Recently, a conspiracy surfaced that COVID-19 was engineered to harm Black and White people while protecting Jewish and Chinese people.

In your opinion, is that true?

A No.

Q Are you familiar with the death of Hank Aaron, the baseball player, at the beginning of 2021?

A I don't recall.

Q Can false narratives about vaccines be detrimental to public health?

A Yes. I think yes.

Q How?

A Well, if it's false narratives, they convey the wrong facts. And that could lead to people hesitating to get the vaccine.

BY [redacted]:

Q Why is that a problem?

A That is a problem if you take SARS-CoV-2, which is a pandemic that caused a lot of death and serious disease in this country and globally, but can be prevented by using vaccines.

Q In your opinion, was vaccination an effective tool against COVID-19, the COVID-19 pandemic?

A There is no doubt in my mind that, without these vaccines, there would have been -- many more people would have suffered, would have suffered from the serious consequences of SARS-CoV-2.

Q Do you think many more people would have died without the vaccine?

A Yes.

[redacted] We can go off the record.

[Recess.]

[redacted] We will go back on the record, and the time is 2:55.

To begin, we are going to enter this exhibit, an email from Dr. Peter Marks to Commissioner Janet Woodcock, as exhibit 7.

[Gruber Exhibit No. 7

Was marked for identification.]

[redacted] And please take your time review if you need it.

Dr. Gruber. Okay.

Mr. Massie. Okay. I want to base some of my questions on this document. So, on August 17th, you emailed Dr. Marks, who shared the current draft of the clinical review memo for Pfizer's BLA. You stated that there was work still needed to be completed, and, therefore, a date of August 20th was not possible.

Had the date of September 15th been moved to August 20th?

Dr. Gruber. There was not an official email or instruction to move the September 15 date to August 20th. There was just repeated instruction of approving this BLA as soon as possible.

Mr. Massie. In the email characterizing the July 19th -- or, sorry, yes, July 19th meeting, you said that vaccine mandates were one of the reasons that were given for the importance of having an earlier date.

Were there other reasons given for moving up the date? Given that the EUA was still available, that people could get the vaccine, there seems to be a great sense of urgency placed on the approval, the final FDA approval. And one of the reasons was, as you stated in your email, the vaccine mandates.

Were there other reasons they gave, or could you determine why they had such a

sense of urgency to get this?

Dr. Gruber. The reason given to me was the vaccine mandate. And the second reason that I also mentioned in my email was that people hesitant to take a vaccine that is authorized but not approved may be inclined to take the vaccine if it's licensed. These two reasons were provided to me.

Mr. Massie. Dr. Fink, who is Doran Fink?

Dr. Gruber. Doran Fink was at that time the clinical Deputy Director in the Division of Vaccines and Related Product Applications, which, as you recall, is the division that -- in which the medical officers reside and the toxicologists and the administrative people.

Dr. Fink was responsible for overseeing the clinical review activities and had to -- was given responsibility to make sure that the clinical review is accurate.

Mr. Massie. He shared an email with you on August 17th in which he explained to Dr. Marks the status of the clinical review in the memo. Is that correct?

Dr. Gruber. Yeah. That is correct. That can be concluded from this email, yeah.

Mr. Massie. He noted that the benefit-risk considerations are complex. Do you agree with that?

Dr. Gruber. Yes.

Mr. Massie. Do you believe those considerations were adequately and thoroughly addressed in the ultimate review and regulatory decision 6 days later?

Dr. Gruber. The work on the benefit-risk analysis and assessment had been ongoing. I see here that Dr. Fink mentioned Rich Forshee's group. That's number 4. That was the Division of Biostatistics and Epidemiology.

And that group was responsible to perform a benefit-risk assessment of the vaccine, because that is the group that was analyzing the pos-EUA surveillance safety information and, thus, included the observed risk of myocarditis.

Mr. Massie. On the front page at the top of this in the email to Janet Woodcock from Peter Marks, he says: I'm not fully optimistic that we will make it, particularly because the supervisors seem to be treating this like a conventional review/learning exercise, rather than an all hands on deck, work together to get it done.

When he says, "I'm not fully optimistic we will make it," what was "it"? Was that a deadline that he had imposed?

Dr. Gruber. I do not know what he is referring to. I can just speculate.

Mr. Massie. Do you disagree with his assertion to the director that supervisors were treating it like a conventional review/learning exercise?

Dr. Gruber. I resent that statement.

Mr. Massie. He goes -- the next sentence, he says: I am going to provide context this a.m. that in the setting of this public health emergency adhering to our usual standards for safety and efficacy means just that -- it does not mean that we are bound by our usual process.

What do you think he meant by that?

A Again, I would need to speculate. I do not know what he meant by that because the sentence, as phrased, does not make sense to me.

Mr. Massie. It seems to contradict itself, that -- or implies that, because there's a public health emergency, you don't have to go by your usual process.

Dr. Gruber. I do not know what he meant by this sentence, Congressman. I do not know.

Mr. Massie. It seems like you can -- you know, emergency use authorization has one set of standards, but would you agree that just because this is an emergency you -- on the final approval, not the authorization, the emergency authorization, but, on the final approval, shouldn't you follow your process, your usual process that's been put in

place?

Dr. Gruber. If we had followed our usual process, we would have adhered to the PDUFA prescribed timelines: Priority review approval 8 month, standard review, you know, 12 months.

And we did not follow these timelines because of the public health emergency, and we wanted to approve the product as soon as that was possible without compromising our standards for safety and effectiveness.

Mr. Massie. You mentioned earlier in our last exchange that you have been told that, because you published a paper that was recommending against indiscriminate widespread boosters, that you were, therefore, biased and could not participate in the booster decision.

Is that correct or -- I don't want to mischaracterize.

A I was told by my supervisor at that time that because I am a co-author, I was a co-author on this Lancet paper, that my objectivity had been compromised.

[3:05 p.m.]

Mr. Massie. Who was your supervisor that told you that?

Dr. Gruber. Dr. Marks.

Mr. Massie. Was his objectivity compromised?

Dr. Gruber. I don't know.

Mr. Massie. I mean, by the standard he applied to you, he went on YouTube before the vaccine was approved and recommended that everybody take it. He made videos and public statements. Yet, he's part of the agency that's supposed to be the unbiased -- I mean, he's directing your efforts.

Can somebody remain unbiased in that final approval process and be publicly promoting the vaccines and saying they're safe and effective?

Ms. LoCicero. I'm going to raise an objection to that question. She is unable to speculate about that.

[redacted] In the last hour, Dr. Gruber was able to answer a few speculation questions, hypotheticals, made from the Democrat staff. So I just want to note that for the record that she has previously answered several questions.

Ms. LoCicero. Okay.

Mr. Massie. Let me rephrase it.

Do you think he was unbiased?

Dr. Gruber. It is true that, when he made a public statement, that one would have come to the conclusion that there was not perfect objectivity on his part.

Mr. Massie. I'll let you ask some questions now.

[redacted] Absolutely.

BY [redacted]:

Q So, Dr. Gruber, going back also to the last hour, our colleagues in the

minority discussed some statements made by President Trump leading up to the approval of the vaccine in 2020.

I also wanted to discuss some additional comments that were made in approval for the booster shots. I'm going to label this article from The New York Times dated August 27th as Exhibit 9.

Oh, I'm sorry. I apologize. I take that back. It is Exhibit 8. Thank you. I missed that sticker.

[Gruber Exhibit No. 8

Was marked for identification.]

BY [redacted]

Q Here you go.

And we don't have to walk through the full article. I just wanted to direct your attention primarily to -- I believe it is the fourth paragraph down. There is a comment from President Biden from this meeting with the Israeli Prime Minister, Naftali Bennett, from -- as I mentioned, I think it was August 27th, 2021.

He mentioned, "We were going to start around mid-September, but we're considering the advice you've given that we should start earlier," Mr. Biden said.

"The question raised is, should it be shorter than 8 months? Should it be as little as 5 months? That's being discussed." And this is in regards to approval of the booster vaccine.

Now, I just wanted to know, were you aware of President Biden's statement at this point in time?

A I may have read this article, The New York Times article, at the time, but I do not recall this now.

Q Do you have any reaction to him saying that the booster could potentially be

approved in as little as 5 months versus 8 months?

A You know, give me a minute to read this because I don't think he is referring to the approval time. Let's see.

From the second paragraph, where it says, "Just 9 days earlier, the President announced that his administration would begin offering third shots the week of September 20th to adults who had received the second dose of the Pfizer or Moderna vaccines at least 8 months ago," I believe they're referring in this paragraph to the booster immunization interval since primary vaccinations are not to approval times.

Q So is that different from the BLA? Is that a different booster? Is that what you're referring to?

A The BLA was approved not for booster shots. The BLA was approved for the primary vaccination. The primary vaccination of the mRNA vaccines was two doses. It was 21 days for one and 14 days for the other. That was a primary vaccination.

Q So do you know what he's referring to when he says the advice that the Prime Minister gave him was that there should be an approval shorter than 8 months or as little as 5 months? Do you know which shot he's referring to at that point in time?

A He's not specific, isn't he? So, you know, I would have to speculate here.

Q I wasn't sure what you meant -- if you understood when he said "offering third shots the week of September 20th to adults who had received their second dose."

What would that line up with-wise as far as the deadline goes?

A I don't believe I understood your question. As far as the deadline goes?

Q When originally you had mentioned that the BLA approval deadline before you went on leave was September 15th. And then at this point in time, August 27th of 2021, this had been after you got back from your leave?

A Uh-huh.

Q And at that point, in the last hour, you had said that the decision was pretty much made that the timeline would get moved up, but it hadn't been formalized.

My question is, which deadline is this referring to when they're talking about third shots?

A I think we have to separate. This is talking about booster administration, and that has nothing to do with BLA action due dates.

Q So were you a part of these discussions that they're referring to the booster shots?

A No.

Q Okay. Even though you were still there at this point in time in August of 2021, you were not a part of the approval process as far as the timeline goes?

A Of the booster authorization, you're saying?

Q Yes.

A Well, I stated earlier I was part of the group that wrote the briefing document that discussed the booster data that Pfizer had submitted on August 25th to support boosting the general population because the indication for the BLA was people 16 years of age and older. And the supplement that is submission to a licensed vaccine -- to a BLA -- now was seeking approval for a booster shot in people 16 years of age and older.

And I, at that time, was part of the group that prepared for the advisory committee to discuss these booster shots. And the people in the Office of Vaccines did review the supplement to the BLA, but that came to a halt on September 13th when I was told that I cannot preside over this for that happened on September 17th.

Q Okay. Thank you for the clarity. I was confused on the timeline.

Mr. Massie. Who is Maddie de Garay? Do you know in this case?

Dr. Gruber. I do not know.

Mr. Massie. Okay. I'll have to get this. But I think Doran Fink copied you on an email to Pfizer inquiring about Maddie. But if you don't remember that, I'll have to find it.

Dr. Gruber. No, I don't recall. I'm sorry.

Mr. Massie. Maddie was a participant in the children studies of 12- to 15-year-olds.

And when Pfizer submitted its EUA for 12- to 15-year-olds, they classified Maddie's injuries as follows: The SAE of neuralgia was reported in one female participant, 12 years of age, who had three emergency room visits beginning one day after the second dose. She reported concurrent nonserious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive workup, including serial, physical, and laboratory examinations and was diagnosed with functional abdominal pain. She was referred to psychology and physical therapy after which symptoms were reported as gradually improving.

During its initial review of the EUA request from Pfizer, what did the FDA do to confirm this SAE was reported accurately by Pfizer?

Dr. Gruber. That child was how old?

Mr. Massie. Between 12 and 15.

Dr. Gruber. During the initial review, the medical officers would have requested additional information. In this case, it is very likely that they would have conducted a chart review.

Mr. Massie. I'm sorry. I don't have the documents to show you. I'll have to get those. But I believe that there are some documents and some emails that were sent to you and Doran with an updated narrative concerning -- Pfizer sent you and Doran an updated narrative concerning Maddie on June 30th, 2021. I'll get you those documents.

Let me ask you a separate question since the other side went a little far field of the vaccine approval process. I'll ask you some general questions.

On December 10th, 2020, the FDA put out a slide deck characterizing the review of efficacy and safety of the Pfizer BioNTech COVID-19 vaccine Emergency Use Authorization request. This is Susan Wollersheim, FDA/CBER. Do you know her?

Dr. Gruber. Yeah. She was a medical officer in charge of the review of that -- the clinical data.

Mr. Massie. Did she work in your department?

Dr. Gruber. Yeah. She worked in the Division of Vaccines and Related Product Applications, and she reported to Dr. Fink.

Mr. Massie. So you and I discussed earlier that the vaccine was designed -- in fact, they tried to pick -- it wasn't designed to test whether it had benefit to those with prior exposure to COVID, but that they did have a few people that showed up in the study -- roughly 12- to 1,300 -- just over -- just about 1,100 finished the study. Of the many thousands who were in the study, I'm saying 1,100 had evidence of prior exposure to COVID.

And in this slide deck that Susan Wollersheim -- Dr. Wollersheim produced, there was one case of COVID in the placebo group and one case in the vaccine group. I'll show you this. This is the entire slide deck, but it's on page 25 there. Sorry.

[redacted] Do you have a copy for us?

Mr. Liu. Are we going to mark this as an exhibit, this slide deck? Can I get a couple other copies?

[redacted] Can we go off the record for a moment?

[Discussion off the record.]

[redacted] We will go back on the record.

Mr. Massie. While you were at the FDA, did you -- were you asked to do any approval or EUA for a more conventional kill-virus-type vaccine?

Dr. Gruber. No. No. It was something that was called pre-EUA requests, you know, where the CDC, for instance, submitted, you know, requests for certain vaccines. And I cannot even recall them now. Was it the anthrax vaccine? I don't know. I cannot say for sure. But that is very different from an EUA request. So we didn't do any EUAs for any other vaccines, at least not during my tenure.

Mr. Massie. Okay. Thank you.

BY [redacted]:

Q I'd like to turn back to Exhibit 4, if we could. And that is Bates stamped at the bottom on the FOIA document. The last digits are 355.

A The timeline document?

Q Yes. But I'd like to first discuss the email itself.

A Uh-huh.

Q In this email, you copied Mary Malarkey, Steven Anderson, and Dr. Philip Krause.

You had mentioned who Mary Malarkey was. Could you remind me what her title was again?

A Yes. She was, at that time, the director of the office -- OCBQ. Okay. The Office of Compliance and Biologics Quality.

Q And who is Steven Anderson?

A Steven Anderson was, at that time, the director of the Office of Biostatistics and Epidemiology.

Q Are either of them still working at the FDA, to your knowledge?

A I do know that Mary Malarkey retired. And to my knowledge, Dr. Anderson

is still in CBER. Yes.

Q Why did you choose to copy them to this email?

A Because I had to discuss the approval timelines and the time that it would need to take to bring this vaccine to approval not only with the people and supervisors in the Office of Vaccines Research and Review, but also, I had to discuss it with the office directors that were overseeing the Division of Epidemiology, the Division of Biostatistics, because they played an integral part, you know, in the review of the data, and then, of course, the Office of Compliance and Biologics Quality.

These are the people that look at the facility information. These are the people who would do a lot of this testing of the vaccines. And these are the people -- Mary Malarkey also did oversee the people looking at the labeling to see if that is -- so they collaborated with other medical officers to assure that.

So my point is that these timelines -- they're not only driven by review activities in the Office of Vaccines, but also in the Office of Biostatistics and Epidemiology and the Office of Compliance and Biologics Quality. And that's why I cc'd these people on the email because I also discussed these timelines with them.

Q And you had mentioned in the last hour, too, that, at this point in time, in this mid-July timeframe, there was a concern by you that there would not be able to be a complete and thorough review on the Pfizer BLA. But then you said by October 23rd, in your opinion, that there had been a complete and thorough review. Is that accurate?

A By October 23rd?

Q I'm sorry. August 23rd of 2021. That there had been a complete and thorough review. Is that correct?

A I knew there was because people really gave it their all and made sure that all the data that needed to be reviewed were reviewed and assessments were made.

Q And that includes all of these moving parts with Dr. Malarkey's office and Dr. Anderson's office?

A Yeah.

Q And I guess my question is, what do you think changed between your concern in mid-July and then once you had returned from your leave? How was your concern alleviated that there would be able to be a complete and thorough review?

A Yeah. Again, my concerns that I expressed in the July 15th memo were centered around the fact that, at that time, we had outstanding information requests through Pfizer. I could not be sure at the time how fast Pfizer was able to submit the required data and documentation to the FDA.

I also did know that, at that time, we received additional safety information that had to be factored into the benefit-risk assessment, and it was difficult for me to guess in the middle of July when these review activities could be completed.

And, again, it was able -- we were able to do so because Pfizer was very responsive and submitted, you know, data in a very timely manner. And, again, the people -- the reviewers who did the job were extending their working hours through weekends, canceled holidays, to address that request from the center director and acting commissioner to speed up the approval.

Q And you had mentioned that you were concerned about the burnout of these hardworking and dedicated individuals who were working to get this BLA approved. And you had mentioned just now that they had, like, you know, worked very long hours and through holidays.

Was that any concern of yours at the time that it was approved that there could have been a misstep somewhere in the process or that data wasn't fully reviewed?

A No, because there was sufficient oversight at the different levels. So you

don't really just rely on a clinical review memo. It is being reviewed by a team leader. It is being reviewed by the branch chief. It is being reviewed by the division director. It is being reviewed at the office level. So there are all these different steps.

So as you hear, it wasn't only the reviewers. It was everybody else.

Q And noting back in Exhibit 4, in the email you initially sent on Friday, July 16th of 2021, to Dr. Marks, you had said -- and I just want to understand what these acronyms mean and ask a couple questions about that.

You had said, "The target AAD is September 15th. Note that the DBSQC DS and DP testing will not be completed at that time because of reagent shortage."

Now, my question to you is, what does DBSQC DS and DP stand for? That's my first question.

A DBSQC was the acronym for a division in the Office of Compliance responsible for doing -- DS and DP refers to drug substance and drug product testing. So that division -- and I will tell you, I do not recall if it was the division of biologics standard and quality something, but I -- you know, I need to verify this, okay?

But I do know that that division is part of the Office of Compliance and Biologic Product Quality headed by Mary Malarkey at that time. And they usually do testing -- certain tests on the drug substance and the finally formulated drug product to basically verify the testing conducted by the vaccine manufacturers. But it is not the entire battery of testing. That's not what is required, so...

Q And can you elaborate on what you were saying would not be completed at that time because of reagent shortage?

A Because of reagent shortage?

Q Yeah. I didn't know what that meant.

A Yeah. You need, you know, to do, let's say, a potency test to verify the

individual strength of a vaccine. You need certain reagents. And that pertains to other tests as well. There was obviously a reagent shortage, so that -- not the entire battery of testing that the division usually did -- could do in a timely manner.

But, again, that is confirmatory testing. It's not that the vaccine didn't undergo lot release testing. The manufacturer had done that and had submitted the data to the agency. They have to do that.

We also have to review and approve a lot release protocol, and that all was done. Just this confirmatory testing by that division was not done. It's entirely because of a shortage of a particular reagent that was part of the assay -- the individual assay. But I do not recall what test and what reagent that was at this time.

Q Okay. And then I'd like to just turn generally back to -- when you submitted your resignation at the agency, what conversations did you have with Dr. Krause regarding your resignation?

A I informed Dr. Krause that I would inform Dr. Marks that I would retire from the FDA, and that meeting with Dr. Marks took place the end of August. I don't recall the exact date. Was it August 27th? I don't know. If that was a Friday, it probably was that day.

And because Phil was my deputy -- and usually, when an office director leaves, as was the case when Dr. Baylor had left when I was the deputy director, in the interim period before a new office director is selected or appointed, the deputy office director takes on the position of acting office director. And so I felt that I needed to inform Phil of my decision.

Q What was his reaction?

A Well, he didn't want to let me go. But he understood because we -- both of us actually had discussed, you know, retirement age and eligibility for retirement. And for

me, that had been the prior year. So it didn't come as a big surprise to him, I would think.

Q Do you think your decision influenced Dr. Krause's decision to also submit resignation and retire?

A I do not know.

Q What response did you receive from Dr. Marks regarding your resignation?

A Well, I met with him. I actually did ask for a face-to-face meeting. I put my mask on and waved to my dog, and I informed him of my decision to retire. He was very professional, very cordial.

Q And do you know what Commissioner Woodcock's reaction was to your resignation?

A I do not know.

Q Did anyone else on your OVRR team leave the FDA for the same reason you did? Did they retire? Did they resign?

A There was a person leaving, but that person already had looked for other opportunities in industry. That was their desire, and I think it was just coincidence. Yeah.

Mr. Massie. Was that Dr. Krause?

Dr. Gruber. No. That was Dr. Roberts.

Mr. Massie. Did Dr. Krause also leave or announce that he was leaving soon after you did?

Dr. Gruber. Yes, he did. It was on that following Monday.

Mr. Massie. Did you have discussions with him before you announced that you were leaving?

Dr. Gruber. I had informed Dr. Krause that I would -- that I had scheduled a meeting with Dr. Marks in which I was going to inform Dr. Marks that I would retire from the FDA. Yeah. That discussion took place between Dr. Krause and myself.

Mr. Massie. Did Dr. Krause tell you that he was also leaving?

Dr. Gruber. No. No. That was an announcement made on that Monday, and I recall he sent an email to Dr. Marks and cc'd me on it.

Mr. Massie. I'm waiting for my copies.

[redacted] All right.

We'll go off the record for a moment.

[Discussion off the record.]

Mr. Massie. So what we're submitting is Exhibit 9, which is an MMWR in December of 2020, obviously, from CDC.

[Gruber Exhibit No. 9
Was marked for identification.]

Mr. Massie. And then Exhibit 10 is a correction that they issued, and the back page of Exhibit 10 is an errata that goes with -- that's part of Exhibit 10.

[Gruber Exhibit No. 10
Was marked for identification.]

Mr. Massie. Exhibit 11 is the slide deck from Dr. Wollersheim at the FDA/CBER dated December 10th, 2020.

[Gruber Exhibit No. 11
Was marked for identification.]

Mr. Massie. And then Exhibit 12 is a study -- this is Pfizer's funded study, and I'm not sure of the date on it. I believe this is a research summary.

But the date on the Pfizer data, which is -- all this is is the cover page for the document that's very thick. And then the page of interest, which is the reported cause of death in the Pfizer trial as of July, I believe.

[Gruber Exhibit No. 12

Was marked for identification.]

Mr. Massie. So let me start, if that's okay. Okay. I'm going to start with Exhibit 12, the one we're all holding. The second page is the page of interest.

This is the reported cause of death broken down by individuals in the placebo group and individuals in the Pfizer vaccine group. And it shows that there were 15 deaths in the vaccine group and 14 in the placebo group. Are you aware of these results, Dr. Gruber?

Dr. Gruber. Yeah. We -- as part of every BLA submission, we look at the safety data. And, you know, when a study is that large -- 40-, maybe 44,000 subjects -- it is expected that there will be reported cases of death. And, yes, we were aware of these deaths. 15 in the vaccine group and 14 in the placebo group.

Mr. Massie. Is mortality something important to look at during a randomized control trial of a drug or vaccine?

Dr. Gruber. That is part of the analysis.

Mr. Massie. Did you or anyone else at FDA have concerns about the fact that there were slightly more deaths in the vaccine group than the placebo group?

Dr. Gruber. I would not interpret the data that beforehand CNP analyzed to suggest that there were more deaths in the vaccine group than in the placebo group.

I should also say that every time that we have a reported death and the cause thereof, which is listed here, the medical officers will perform an analysis to try to discern if the death was caused by the vaccine or if it was caused due to other reasons, such as underlying conditions.

And what this table does not really separate out here -- it just says safety population greater or equal of 16 years old. It would have been more helpful to have a stratification by age. Often what you see listed as the cause of death is events that

happen, you know, in the elderly with underlying medical conditions.

So, again, to answer your question, I am not concerned, and the data do not suggest to me that there were a higher number of deaths in the vaccine group compared to the placebo group.

Mr. Massie. But there were -- there were 15 deaths in the vaccine group and 14 in the placebo.

Dr. Gruber. Yes.

Mr. Massie. Wasn't one of the end points or one of the benefits of the vaccine supposed to be that it would protect you from hospitalization, severe illness, and death?

Dr. Gruber. Due to COVID, but not due to other conditions. And this table does not speak to that.

Mr. Massie. Wouldn't you -- I mean, if that was the end point, should -- you know, I know you like to have this stratified by age, but even so, on the whole, it shows that there were more deaths in the vaccine group than in the placebo group. But you have methods to eliminate that concern?

Dr. Gruber. So the efficacy estimation is driven by the primary end point, and that was prevention of symptomatic COVID disease. And when you look at the efficacy data, you would have seen that there was a substantially higher number of COVID cases presented -- prevented in the people who received the vaccine compared to people who got the placebo.

There are always death in these clinical disease end point efficacy studies. And this table here just calls reported causes of death. It doesn't say, you know, that all these deaths are due to COVID. Look, if you look at COVID-19, even here, you have zero cases in the vaccine group and two cases in the placebo group.

Mr. Massie. Uh-huh.

Dr. Gruber. But the numbers are also, you know, very, very low considering the size of this trial.

Mr. Massie. But as far as the ages of the two groups go, didn't they assemble these -- this study such that the groups would have relatively the same average age and the same number of participants in the different --

Dr. Gruber. That is true. In this trial, the groups were fairly balanced between vaccine and placebo groups with regards to demographics, age, et cetera.

Mr. Massie. So there are two columns, as you -- or at least -- let's see -- one column here, COVID-19, where it indicates there were two deaths in the placebo group and none in the vaccine group. But COVID-19 pneumonia, there was one in the vaccine group and zero in the placebo group.

But I think the concern is not whether this demonstrates efficacy. There were lots of public health officials saying, if you get this, you won't die. Was that an efficacy -- was that an end point that you took into consideration when giving the approval? Was efficacy of keeping you alive part of it, or was it just the symptomatic COVID within a period of time?

Dr. Gruber. It was symptomatic COVID. And, you know, if you look at COVID-19 pneumonia, there was one case in the vaccine group, and I note that this vaccine was not 100 percent efficacious, right? There were some, you know, cases of COVID in the vaccine group, just much, much less than in the -- much less cases of death and severe disease compared to the placebo group.

Mr. Massie. One of the concerns that people have when they look at this chart is not necessarily does it prove efficacy or not efficacy of keeping you from dying, but that there may be -- if there is efficacy, they may be offsetting deaths because of adverse reactions to the vaccine.

You would think if the vaccine is keeping people alive, there would be more deaths in the placebo group, but the fact that they're equal leads one to wonder if there are adverse effects that cause death that weren't captured.

Dr. Gruber. But these weren't causes of death from dose one to underlying. It doesn't say causes of death due to COVID.

Mr. Massie. Uh-huh.

Dr. Gruber. This is just a listing of all death that occurred as part of this clinical study. And these are causes that -- or the causes of these deaths had different reasons than COVID. So this is not what this table shows, that the number of deaths in the vaccine group was likely higher; therefore, the vaccine caused more death. That is not how you interpret this data.

Mr. Massie. Uh-huh. Okay. Well, thank you.

My next questions involve Exhibits 9, 10, and 11.

[redacted] Yes.

Mr. Massie. And I note you were over at Vaccines at FDA and not at the CDC, but I would like your scientific opinion because the CDC was basing their report on data that -- or characterization, I should say, of the Pfizer trial that was prepared by the FDA.

That would be the document that we're -- what number is that?

[redacted] Eleven.

Mr. Massie. Yeah. 11. The slide deck. With Dr. -- who is the doctor on that one?

Dr. Gruber. Dr. Wollersheim, right? She was the medical officer that performed the review of the efficacy data for this vaccine.

Mr. Massie. So on page 25 of that document --

Dr. Gruber. Yeah.

Mr. Massie. It shows that in the two groups, the placebo group and the vaccine

group, they found a bit over 500 people in each of those groups who had evidence of prior COVID exposure. And what they discovered in this very short trial with limited data was that there was one case of symptomatic COVID in each of those groups of 500.

The CDC published in December of 2020 -- just a few days after that, they published an MMWR and characterized that -- and that would be Exhibit 9. If you could look at Exhibit 9, the highlighted area, and I'll read that part.

"Consistent high efficacy greater than or equal to 92 percent was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection."

Now, when I read this in December, the day it came out or the day afterwards, I was interested myself in whether I should take the vaccine because I had already had COVID and -- proved through an antibody test, which is fairly reliable.

So I read this MMWR, and what -- I found it somewhat incredible that they could make a claim of 92 percent efficacy among those who had already had COVID because, as you said earlier, the study itself wasn't designed to prove that. In fact, the study was trying to involve only participants who had not had COVID before. But they were basing this statement on the slide deck and the FDA characterization of the Pfizer data.

And so what it is -- I called them. I called up the CDC, and I told them that I think they have a typo in their MMWR. And they agreed to change it.

And my concern at the time was that, if you promoted 92 percent efficacy for those who had already had COVID -- there was a limited number of vaccines, if you remember -- a very limited number in December or January. December of 2020 and January of 2021, February of 2021.

And my concern was that there would be more people -- based on the CDC guidance, there would be people who -- honestly, it wasn't proven that they could benefit

from this vaccine -- who would go get the vaccine in place of people who would benefit from it according to the data.

So what the CDC did is -- and I will refer you to Exhibit 10, which is the one with this mark on the front.

Dr. Gruber. Uh-huh.

Mr. Massie. The very last page of that is -- that Exhibit 10 is a modified version of their document. They changed it, but they didn't really change it. If you look at the highlighted part -- I'm sorry -- on page 2 of that. There you go.

Here, they limit their claim of 92 percent efficacy to being observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions.

Now, they -- but their correction was to change and say efficacy was similarly high in a secondary analysis, including participants both with or without evidence of previous SARS-CoV-2 infection. So you see they didn't really change it.

And if you go to the last page of that document that's in front of you, the very last page --

Dr. Gruber. Forty-four

Mr. Massie. Keep going. There it is.

Dr. Gruber. Right here.

Mr. Massie. They published this errata, and they said -- they said what it should have read. And then here's the sentence.

"Although numbers have observed hospitalizations and deaths were low, the available data were consistent with reduced risk for those severe outcomes among vaccinated persons compared with that among placebo recipients."

They basically -- in both their original MMWR and their correction to it, they

claimed that the Pfizer data, which your group had already evaluated and found that there was no efficacy that could be proven with the Pfizer data -- they claimed -- the CDC claimed it was 92 percent efficacious or highly efficacious.

Do you find any support for that claim at that time, which would have been December of 2020? December 18th of 2020 is when they made the claim. And the only available data they had to make that claim on was your characterization of the Pfizer trial.

Do you think the Pfizer trial supports that claim?

Dr. Gruber. So I was reading this article as you were talking, and yes, it does say that the body of evidence for this vaccine was primarily informed by one large randomized placebo-controlled study and 43,000 participants. In the preceding paragraph, they're talking about systematic review of literature.

However, the FDA did not come to the conclusion that similar high efficacy, you know, could have been derived from the data that came out of this efficacy study. And the study was powered for the overall population. There was some analysis done in the very elderly and people with comorbidities. Here, baseline SARS-CoV-2 race. But the number of people were just not large enough to really make an efficacy estimate.

Now, what's stated here does not mean that the vaccine is not efficacious in people with positive SARS-CoV-2 status. But we also cannot deduce from this data efficacy in the subpopulation because these are subgroup analyses, and the number of subgroups -- the sample size is just not high enough. So I cannot tell you why this wording was chosen in the MMWR report.

Mr. Massie. I'm not asking you to speculate, but I'm going to.

I think there was -- there was a concerted effort to get everybody vaccinated, whether they had immunity from prior exposure to COVID or not. And I think from the very beginning, that was an effort at the CDC to do that. And I think they were wrong to

mischaracterize the data that I believe you all correctly characterized in just the basic presentation of the numbers.

I have one last question, and feel free to answer it or not. Did you take the booster?

Dr. Gruber. I took the booster, yes. And that was in May of 2022. I had already left the agency. My primary vaccination was 1 and a half years before, and I took the booster.

Mr. Massie. I have no other questions.

[redacted] Neither do I. We can go off the record.

[4:16 p.m.]

[redacted] It is 4:16. We can go back on the record.

At the outset, I just want to note there was a comment made in the prior hour about the minority staff asking speculative questions.

We dispute that characterization of any of our questions or any of our lines of questioning as asking for speculation or being speculative in nature.

BY [redacted]:

Q Dr. Gruber, I want to -- it feels like I think it was an hour ago at this point. At the very early part of the last hour of questioning, there was a discussion about the VRBPAC, the booster-related VRBPAC.

A Yeah.

Q And there was a discussion about somebody commenting on your objectivity. Do you recall that discussion?

A Today?

Q Just today.

A Yes.

Q And I'm sorry, I can't remember right now. Who -- was it Dr. Marks who said that he wasn't sure of your objectivity?

A Yes.

Q Did he say what he meant by "objectivity"?

A Yes. That was on the very same day that the WHO publication in the Lancet in which we asserted that, at that time, booster immunizations were not necessary for the general population.

At that time, he called me, and he was very upset that I had signed on as a co-author of that publication. And he said that concerns were expressed that my

objectivity has been compromised and that I there -- regarding necessity of booster shots, and that, because of that, I could no longer take an active role in the September 17th VRBPAC that discussed the Pfizer supplement and the request by Pfizer to get a booster approval in people 16 years of age and older.

Q Understood. But he didn't actually explain "objectivity." He didn't define that term for you, did he?

A He did.

Q So did he say, for example, if by "objectivity," for example, if he meant that if the VRBPAC voted to decline a broad authorization and you were on that panel, that might, you know, call into question that outcome? Because that is actually what happened, right, it ultimately declined to recommend a broad recommendation?

A Yes. He said my objectivity was compromised because I had already taken a stance regarding booster immunizations.

Q And the purpose --

A By way of the publication.

Q And the purpose of the meeting is to have the information presented to you at that meeting, right?

A Yes. Although the purpose of the -- I mean, we knew the data because we do the review of the data then, right? And then the VRBPAC serves the purpose to have a public discussion of the data and for the VRBPAC to weigh in on the question. You know, at that time, it was, should boosters be administered to the general population?

Q There were questions raised in the earlier hour about whether Dr. Marks was objective. Was he on -- was he a voting member of that panel?

A No, no, no. FDA officials are not voting members, no.

Q So he may have participated, but he was not -- he didn't have a role in

making the final decision?

A No. He was called upon to make -- to answer questions, you know, by the committee.

Q Okay. I want to turn back to what's been marked as exhibit No. 7. This is the email from Peter Marks to Janet Woodcock, 8/18/21, 6:54:21 a.m.

[redacted] The one with highlights.

Dr. Gruber. Oh, this one. 6:54 a.m., right?

[redacted] Yes.

Dr. Gruber. On August 18?

[redacted] Yeah.

BY [redacted]:

Q So you were asked a number of questions about the very first email in that chain. You weren't on -- you weren't an original recipient of that email, right?

A That is correct. I was not an official recipient of that email. I was made aware of this email by Dr. Fink. And, at that point, you know, I felt that I had to support him --

Q Oh, understood.

A -- and supervise him.

Q I'm sorry. I should be clear. I'm looking at the very, very first email in that chain. I realize that you were included later in the chain.

[redacted] You mean the last, chronologically.

BY [redacted]:

Q Sorry, chronologically. The one at the very top. Sorry. The last in time, the one that's dated 6:54.

A Yes. I'm sorry. Yes.

Q The first one on the page, the last in time.

That email, you weren't on that email, correct?

A No.

Q Okay. So you were asked a number of questions about what was meant in this email, but you weren't one of the original recipients, and you weren't the sender, correct?

A That is correct.

Q So the questions about -- so, for example, there was a question made earlier about "it does not mean that we are bound by our usual process." Here, the term "process" you don't know what the term "process" means in this context, right?

A As I stated earlier, I wasn't clear what the whole sentence meant.

Q And so I think there was -- after you said that, there was a suggestion made by one of the questioners that this referred to the approval process. We just don't know that. You weren't on this email, and you don't -- any comment on that would be speculation, right?

A Any comment on that would be speculation because it is not clearly spelled out in this email what is meant here.

BY [redacted]:

Q I want to turn to the CDC MMWRs that were introduced. Based on your reading of that MMWR, is it exclusively based on the data that is presented in the December 10th slideshow that was introduced?

A Well, it says the body of evidence for the Pfizer vaccine was primarily informed by this one large double-blind placebo-controlled study. And that is the subject of that PowerPoint presentation here. This -- this is -- this is all the data from that study.

Q Looking at slide 25 of the PowerPoint, the overall efficacy concluded on that

PowerPoint is 94.6, with a confidence interval of 89.6 to 97.6, right?

A Yeah.

Q And, in the CDC publication, it says that the efficacy was 95.0 with a confidence interval of 90.3 to 97.6. Do you see that? It's above the highlighted sentence "the CDC has efficacy data."

[redacted] It's on page 2.

[redacted] You're looking at the other version.

A No, I see it.

BY [redacted]:

Q So do you see that clearly CDC was using different numbers, if not -- it might not be exactly clear why they're different, but clearly these numbers are not the same as the ones in the PowerPoint?

A Well, because it says it was primarily informed, but further up here they're talking about surveillance data and, you know, I don't know what other information they put in there.

Q In fact, it says that the COVID-19 vaccine's work group, which comprised of experts, held 27 meetings to review surveillance data, evidence for vaccine efficacy and safety and implementation, including the Pfizer vaccine. So it's possible that this CDC data, though primarily based on the Pfizer trial, includes information from other sources?

A That is possible, yes.

Q Finally, I want to turn to the conversation that we had again at the beginning of the last hour about the BLAs versus the booster.

So the Comirnaty BLA approval process was unrelated to the booster vaccines, correct?

A Yes.

Q And the BLA approval was not undertaken as a prerequisite to recommending vaccines -- or booster shots? I can clarify.

A Yes, can you please clarify.

Q So the BLA wasn't a necessary prerequisite for booster shots? Pfizer didn't need to get their BLA approved to then be able to recommend booster shots?

A Potentially, there could have been an emergency-use authorization of booster shots.

Q And there was an emergency --

A And that was eventually done, yeah.

Q And the majority referred to a part of this New York Times article that said that the President announced his administration would be offering third shots the week of September 20th to adults.

Do you remember that?

A Uh-huh.

Q That didn't happen, correct?

A Well, we went to the VRBPAC on September 17, right? And they recommended not boosting the general population, but restricting the boosters to people -- to the elderly and people with underlying conditions. So yeah. Let's see. What did it say here? When you said that didn't happen, what are you referring to?

Q Third shots were not offered to adults, all adults during the week of September 20th.

A That is correct, they were not offered.

Q The FDA followed the VRBPAC's recommendation?

A Yeah.

[redacted] We can go off the record. Thank you.

[redacted] We have no further questions.

[Whereupon, at 4:27 p.m., the interview was concluded.]

Certificate of Deponent/Interviewee

I have read the foregoing ____ pages, which contain the correct transcript of the answers made by me to the questions therein recorded.

_____

Witness Name

_____

Date

COMMITTEE ON THE JUDICIARY,

U.S. HOUSE OF REPRESENTATIVES,

WASHINGTON, D.C.

INTERVIEW OF: PHILIP KRAUSE, M.D.

Thursday, September 7, 2023

Washington, D.C.

The interview in the above matter was held in room 6400, O'Neill House Office Building, commencing at 10:01 p.m.

Appearances:

For the COMMITTEE ON THE JUDICIARY:

[redacted], SENIOR PROFESSIONAL STAFF MEMBER

[redacted], SENIOR COMMUNICATIONS ADVISER

[redacted], DIGITAL DIRECTOR

[redacted], COUNSEL

[redacted], DIGITAL ASSISTANT

[redacted], SENIOR SPECIAL COUNSEL

[redacted], PROFESSIONAL STAFF MEMBER

[redacted], MINORITY INTERN

[redacted], MINORITY OVERSIGHT COUNSEL

For PHILIP KRAUSE, M.D.:

THOMAS KRAUSE, ESQ.

[redacted] Okay. Let's begin.

This is a transcribed interview of Dr. Philip Krause. Chairman Jordan has requested this interview as part of the committee's oversight.

Would the witness please state your name for the record?

Dr. Krause. Well, my name is Philip Krause.

[redacted] Could your counsel please state your name and law firm for the record?

Mr. Thomas Krause. My name is Thomas Krause. I work for a U.S. Government agency, the U.S. Patent and Trademark Office. I'm here in an unofficial capacity with respect to them, but I have their permission to represent my brother.

[redacted] Okay. And just to be clear, are you representing solely your brother's interest unrelated to your agency affiliation?

Mr. Thomas Krause. That's absolutely correct.

[redacted] Do you understand this, Dr. Krause?

Dr. Krause. I do, yes.

[redacted] And you said that your attorney is your brother as well? Did I understand that correctly?

Dr. Krause. That is correct.

[redacted] Okay. On behalf of the committee I want to thank you for appearing here today to answer our questions. The chairman also appreciates your willingness to appear voluntarily.

My name is [redacted], and I am with Chairman Jordan's staff. I'll now have everyone else from the committee who is here at the table introduce themselves as well.

[redacted] I'm [redacted]. I'm with Chairman Jordan's staff.

[redacted], Chairman Jordan's staff.

[redacted], Chairman Jordan's staff.

[redacted] I'm [redacted], oversight counsel with the Democrats on the Judiciary Committee.

[redacted], I'm a legal intern of the Democrats, Judiciary Committee.

[redacted], Chairman Jordan's staff.

[redacted], Judiciary Committee.

[redacted] I'd like to now go over the ground rules and guidelines that we'll follow during today's interview.

Our questioning will proceed in rounds. The majority will ask questions first for 1 hour, and then the minority will have an opportunity to ask questions for an equal period of time if they choose. We will alternate back and forth until there are no more questions and the interview is over.

Typically we take a short break at the end of each hour, but if you would like to take a break before that, just let us know.

As you can see, there's an official court reporter taking down everything we say to make a written record, so we ask that you give verbal responses to all questions.

Dr. Krause, do you understand that instruction?

Dr. Krause. I do understand.

[redacted] So the court reporter can take down a clear record, we will do our best to limit the number of people directing questions at you during any given hour so that -- withdrawn.

Please try and speak clearly so the court reporter can understand and so the folks down at the end of the table can hear you. It is important that we don't walk over -- we

don't talk over one another or interrupt each other if we can help it, and that goes for everybody present at today's interview.

We want you to answer our questions in the most complete and truthful manner as possible, so we will take our time in today's interview. If you have any questions or if you do not understand one of our questions, just let us know.

Our questions will cover a wide range of topics, so if you need clarification at any point, Dr. Krause, just let us know. We're happy to rephrase the question or ask it in some similar fashion.

If you honestly do not know the answer to one of our questions or do not remember, it is best not to guess unless we expressly ask you to speculate. That's rare, but it could happen. But generally speaking, if you don't know the answer or you are at a loss to remember, just let us know.

Please give us your best recollection, and it is okay to tell us if you learned information from someone else. Just indicate how you came to know that information and from whom you came to know that information.

If there are things you don't know or can't remember, just say so, but please inform us, to the best of your knowledge, who you believe may have that information.

Can I get a commitment from you to do that, Dr. Krause?

Dr. Krause. Yes.

[redacted] You should also understand that by law, you are required to answer questions from Congress truthfully. Do you understand that?

Dr. Krause. I do.

[redacted] This also applies to questions posed to you by congressional staff in this interview today. Do you understand that?

Dr. Krause. Yes, I do.

[redacted] Witnesses that knowingly provide false testimony could be subject to criminal prosecution for making false statements under 18 United States Code, Section 1001. Do you understand that?

Dr. Krause. I do.

[redacted] Okay. Is there any reason today you are unable to provide truthful answers to today's questions.

Dr. Krause. No reason.

[redacted] Okay. And, Dr. Krause, we give everyone that admonishment about what the law is.

Dr. Krause. I understand.

[redacted] Finally, I'd like to make a note that the content of what we discuss here today is confidential. We ask that you not speak about what we discuss in this interview to anyone else -- to any outside individuals to preserve the integrity of this congressional investigation.

Can I get a commitment from you to do that, Dr. Krause.

Dr. Krause. Yes.

[redacted] For the same reason, the marked exhibits that we will use today will remain with the court reporter so that they can go into the official transcript. Any copies we use to show you we will ask that you return those.

All right. This is the end of the preamble. Is there anything that my colleagues from the minority would like to add?

[redacted] No. Just thank you for coming voluntarily today. We appreciate your time.

Mr. Thomas Krause. And I have a couple of statements to make first if you don't mind.

[redacted] Oh, yeah. Just about to go on the record, and then we'll take your statement.

Mr. Thomas Krause. All I wanted to say was --

[redacted] Then we'll go back on the -- yeah.

Mr. Thomas Krause. Oh, I thought this was on the record.

[redacted] We're on the record. I apologize. I'm about to give a final statement and then --

Mr. Thomas Krause. I can wait for your final statement.

[redacted] The clock now reads 10:06 a.m. We will start the first hour of questioning, but, of course, Mr. Krause, if you have a statement to make.

Mr. Thomas Krause. Yes. As [redacted] just noted, Mr. Krause -- Dr. Krause is here voluntarily. He's seeking to cooperate with the committee.

We do have two points that I'd like to make.

You mentioned that he is not to disclose the contents of this subcommittee meeting to anybody to protect the integrity of the investigation.

Can we get a reciprocal commitment from the subcommittee that you will not disclose the contents of this outside the subcommittee, that nobody with access to it will compromise this investigation that way?

[redacted] Mr. Krause, we're not in a position to make any representations one way or the other, but it's in everyone's interest to keep these things confidential and quiet, is what we can say on behalf of the committee.

Mr. Thomas Krause. Okay. Our concern is that parts of the transcript perhaps, or the videotape, would be used in certain manners, and we request that if that is to be done outside the committee, we receive a copy of the transcript prior to that release. Can I get your commitment on that?

[redacted] The transcript is committee property, and while we allow your client and you to come and review it, we do not disclose it. And any other requests -- and this is all on the record -- we will take to the chairman for consideration.

Mr. Thomas Krause. Okay. Well, we've just agreed that this is a confidential subcommittee meeting, and it's not normally to be disclosed outside the subcommittee.

I'm just asking in the extraordinary event that you see a need to disclose it outside the subcommittee, that we get access to the transcript so we can check to make sure that it's accurate and also provide context.

[redacted] So again, we will take all requests to the chairman for his ultimate ruling. He'll make those decision. But so you know, upon receiving the transcript of this interview, you will be notified, and you and your client can come and review the transcript.

Mr. Thomas Krause. Okay. But we understand we're not allowed to take it with us or --

[redacted] Correct. Correct. That's committee --

Mr. Thomas Krause. Just completely understand that. So it's important to us to get a copy of the transcript in the event the transcript is to be used outside the committee, which you've kind of assured me it won't be.

[redacted] The committee's investigation is confidential. Your request will be taken to the chairman, but to be clear, I have not assured you that the transcript will be given to you. You will be permitted to review the transcript in its entirety in our offices when -- at a mutually convenient time.

Mr. Thomas Krause. Totally understand. Just phrase the request, in the event the committee sees a need to breach the confidentiality of this hearing, then we request that we get advance notice of that and a copy of the transcript.

[redacted] We'll take that request to the chairman.

Mr. Thomas Krause. And, please, you'll report back to me what the chair says on that.

[redacted] Happy to do so in the event -- yes, happy to do that.

Mr. Thomas Krause. Thanks. And you've also seen the letter from the Food and Drug Administration, HHS, setting limits on what Mr. Krause's purpose of this -- Dr. Krause, Mr. Krause -- Dr. Krause's purpose at this transcribed interview is.

They've also asked us separately to respect their claims of deliberative process privilege. We'll attempt to do that. We ask that you try to frame your questions so as not to elicit deliberative process-privileged information.

If you do, I may find myself objecting to your questions and asking my question not to answer.

[redacted] I'll defer to my colleague on the letter from the agency, but I will tell you this: We don't -- the committee doesn't recognize the deliberative privilege process.

In the event you feel compelled to direct your client not to answer a question, you're welcome to do -- this is a voluntary interview. You're welcome to do that. You make a brief record as to why you're doing that, but we will also admonish that the committee reserves the right, if they deem that answer necessary for the committee's oversight work, to have your client come back in, perhaps under subpoena, to get that answer.

Mr. Thomas Krause. Appreciate it. Thank you very much. That's all I have.

[redacted] Okay. I'll get started then.

EXAMINATION

BY [redacted]:

Q Dr. Krause, are you currently employed?

A Yes. By myself.
Q Okay. And what is the name of your business?
A It's called Logics.Bio, LLC, but it's a consulting business.
Q Okay. You said Logics.Bio?
A Yes.
Q LLC?
A Yes.
Q Do you also work with Mesoblast, Incorporated?
A Yes. I'm on the board of directors of Mesoblast.
Q Okay. And how long have you been working in your consulting business?
A Since I left the FDA.
Q And how long have you been on the board of directors for Mesoblast?
A I don't remember exactly when I started, but a year, give or take.
Q Okay. And what is your title with Mesoblast?
A I'm just a member of the board of directors.
Q Okay. And what are your responsibilities on the board?
A Well, as a member of the board of directors of any company, I help provide direction to the company in strategic matters, as well as obviously oversight of what the CEO is doing.
Q And in your consulting business, Logics.Bio, LLC, what kind of work do you do?
A I do consulting for companies that are interested in developing biological products. I also do consulting for the World Health Organization. Yeah, those two things.
Q And did you work anywhere between your consulting business and Mesoblast and the FDA?

A No.

Q When did you first join the FDA?

A I joined the FDA in 1991. I did not bring a copy of my CV, and so I -- I've been admonished not to guess if I can't remember something, but I'm pretty sure 1991 is right.

Q Completely okay, give or take.

A Yes.

Q And what made you want to work at the FDA?

A The FDA is an important public health agency. The FDA also offered me a position as a research scientist where I could run a research laboratory, and gave me the resources necessary to do that, and of course, it was appealing.

I trained at the National Institutes of Health and so was already in the area. So it was appealing not to have to move. And so these were all factors that made it a good place for me to start my career.

Q And I know you'd mentioned -- you said not having your CV in front of you. To your best recollection, can you walk us through the positions you've held with the FDA?

A I can. Would you mind if I gave you a little bit of background what I did before I got to the FDA?

Q Absolutely.

A Because that will put things in context perhaps.

Q Of course.

A So I grew up in Urbana, Illinois. I received a -- well, I ultimately went to medical school at Yale. I became board certified in internal medicine and in infectious diseases.

I then did training in virology at the National Institutes of Health, and then ended

up going to the FDA from there.

While at the FDA -- I'll give you the big picture first, and if you need more detail, I'm happy to provide it -- I worked in a number of different capacities, ranging from running a laboratory to being the deputy director of the Division of Viral Products -- actually, being the acting director of that same division for a year, being in the Office of Vaccines Research and Review, the associate director for vaccine safety and medical policy.

Then ultimately in around 2013, the deputy director of the Office of Vaccines, which is the position I held until I left the FDA.

During the COVID pandemic, I was the -- the highest-ranking infectious diseases physician in the Center for Biologics. During the COVID pandemic -- well, and while at the FDA, I published over 100 peer-reviewed articles on topics that ranged from vaccinology, virology, epidemiology, vaccine safety, and even biostatistics.

While at the FDA during the COVID pandemic, I also was assigned as a liaison from the Office of Vaccines to the WHO, and in that capacity, very soon after the pandemic began, the World Health Organization made me the chair of their expert working committee on COVID vaccines, which entailed running frequent meetings on the topic of COVID vaccine development, helping to coordinate international and WHO scientific responses in addition to the work that I was doing for W -- or for FDA.

And then in addition to that, through this time, starting in -- well, there was an organization called the Coalition for Epidemic Preparedness Innovations, CEPI, which was founded in 2017, but I was involved in -- even before the organization was formed, also as part of my duties at FDA in helping to advise them how to set themselves up.

It's a nonprofit NGO with a goal of trying to promote the development of mostly vaccines to prepare for epidemics and pandemics. And so, I've been on their scientific

advisory committee since then.

Since I left the FDA, I have still continued to do consulting work with the WHO and have remained on the scientific advisory committee of CEPI.

Q And you said you were with CEPI since 2017. Is that right?

A In one capacity or another, but mostly as an adviser on the scientific advisory committee, so not employed by, but as an unpaid, senior, scientific adviser.

Q And you had mentioned the WHO in there. How long had you been doing work with them, like during the FDA and post?

A Well, as far as the WHO is concerned, while I was at the FDA, I intermittently helped different offices at the WHO on different things, especially regarding stability of vaccines, which is a big problem, of course, especially in the developing world, and how to make sure the vaccines are adequately stable.

So I did that for many years, using a combination of my regulatory, scientific, and mathematical background.

Oh, I didn't mention that I also have a master's degree in computer science and an MBA, which played a role, obviously, in that mathematical background.

And -- but then, starting around 2016, they started requesting my help in preparing for pandemics and for emerging infectious diseases. And so since 2016, give or take, I've been involved in various consultations with the WHO in one way or another to help them think about how they will prepare for different kinds of outbreaks in the developing world and around the world.

And then, of course, when the COVID pandemic came, I was on many of their early calls and was soon then asked to chair their expert working group.

Q And what kind of -- what topics, or like, what was the focus of that working group that you were the chair of?

A The expert working group included a lot of people who were working around the world, on an ad hoc basis, to provide advice to the WHO, but also to provide advice, using the WHO as a forum to the entire international community.

So the WHO would sponsor, or would convene meetings where they brought people together who were experts to answer critical questions that might come up about how vaccines should be developed, how people around the world could collaborate to make better and faster COVID vaccines, what are good ways to evaluate COVID vaccines, and all of those kinds of things.

Most of that work centered around clinical evaluation, but there was also a fair amount of science involved there too, and immunology, because understanding the immunology of a disease like COVID is obviously an important component of thinking about what one is up against.

Q And is there a reason -- and there might not be, but is there any significance to you being the acting director, not just the director? Like, did you not hold that position the entire time that that working group existed?

A Oh, I'm sorry. I think you must've written something down wrong. So I was the chair of the --

Q Oh, the chair.

A -- committee for WHO. I was the acting director of the Division of Viral Products at FDA for a year or so. And I would guess this was around 2009 or 2010, but I don't remember exactly what year that was.

Q I did get that mixed up. Thank you. Sorry. You've held a lot of positions.

And primarily, it sounds like you did work on virology, immunology, and vaccinations. Is there any other science subject matter that I missed.

A Well, clinical trials.

Q Clinical trials.

A So I'm viewed as -- I'm viewed as -- I'm fairly well-known as an expert around the world in all those topics.

Q Great. And while you were at the FDA and you were in your role with the Office of Vaccine Research and Review, your direct supervisor was Dr. Marion Gruber, correct?

A Correct.

Q And did you have more than one direct supervisor?

A No. Dr. Gruber was my sole direct supervisor while I was the deputy director of the office. Of course prior to that and prior to the time that she became the office director, I had other supervisors.

Q Okay. And then how long would you say that you worked with Dr. Gruber, not even necessarily in that capacity but in total?

A In terms of working with -- so, of course, I knew who she was for many years. I remember working closely with her probably when we were on a committee together in around 2010, but that's a -- that's also a guess. So I would say a dozen years or so.

Q Yeah. And how many people directly reported to you when you were deputy director?

A So the way that the office was structured, the -- a number of people reported directly to the office director. And the role of the deputy director was obviously to advise the office director but also to sit in for the office director when the office director wasn't present.

And so, when the office director wasn't present, the same direct reports that Dr. Gruber had were reporting to me when I was then the acting director during periods of time when she was not around or available.

I also was running a laboratory for much of this time, and while I was running the laboratory, I had a small number of direct reports who were involved in doing laboratory work.

Q How often would you say that you had to step in for Dr. Gruber when she wasn't present?

A It was intermittent. Normally would occur if she was on vacation or -- or needed to go to a meeting or something like that.

Q Did that ever happen during the pandemic?

A During the pandemic we all tried to maintain an all-hands-on-deck posture, and, of course, we were all also operating remotely. And so, I don't recall a time when it was impossible to reach Dr. Gruber in that capacity. Is it -- is it possible that she needed to leave town? I don't remember. It's possible.

Q And did you have regular interactions with Dr. Marks?

A "Regular" would be a strong word, but I certainly interacted with him quite a bit in -- at senior staff meetings. Normally, the office directors and the deputies were invited.

And then, of course, occasionally I would see him at other times as well. I would probably see Dr. Marks normally once every -- once or twice a month.

Q And did the frequency of your interactions change throughout the COVID-19 pandemic?

A Yes. Obviously through the pandemic, there were more interactions between the Office and the Office of the Center Director, and I was in a position to be in meetings with Dr. Marks more often.

Q What was his title during the pandemic starting at the beginning of it, March 2020?

A Dr. Marks --

Q Yes.

A -- was the director of the Center for Biologics Evaluation and Research.

Q And how long did you work for him -- I'm sorry. Let me take that back.

You worked for Dr. Gruber, and was your office, OVRR, underneath his purview? I'm trying to understand the structure a little bit better.

A That's exactly right. So the Center for Biologics Evaluation and Research has three product offices -- or at that time, had three product offices, and still does, but the names have changed in the meantime.

But it was the Office of Vaccines Research and Review, which was responsible for vaccines and certain allergenic products.

There was the Office of Tissues and Advanced Therapies called OTAT, which was responsible for cell therapies and gene therapies and tissue therapies.

Then there was the Office of Blood Research and Review, which was responsible for blood-related products.

So all of those types of products comprise biological products, which again, are regulated by a separate center within CBER.

There are additional offices within CBER that included an Office of Biostatistics and Epidemiology which -- in which most of the statisticians and a lot of the epidemiological -- epidemiology expertise resided.

There was an Office of Compliance and Biologics Quality, which was responsible for -- well, compliance, and certain kinds of quality testing and -- and often, certain kinds of -- of review of assays that companies might use to characterize their product.

There was an Office of Management that included people whose job it was to facilitate the work of the rest of the center. And it wouldn't shock me if I'm forgetting an

office right now, but those are the main ones I'm remembering right now.

Q No, I appreciate your explanation. Yeah, I know that there's a lot there.

How long would you say that you worked for him in his capacity as director of CBER, you said, C-B-E-R.

A CBER.

Q CBER?

A Yeah. Well, the entire time that I was the deputy director -- well, actually, when I first became the deputy director, Dr. Karen Midthun was the director of CBER, and Dr. Marks was her deputy director.

And I do not remember what year Dr. Midthun left. This is something I could look up on my phone. But when -- when she left, Dr. Marks took over as the center director. I would guess that was somewhere around 2015 or 2016, but I could have that wrong.

Q I appreciate it. Estimations are fine, too.

Did you have regular interactions with the FDA Commissioner, Janet Woodcock?

A Regular interactions, no. I sort of knew who Janet Woodcock was. She, of course, for most of my tenure at FDA was the director of the Center for Drug Evaluation and Research, CDER. She was the acting commissioner for a while during COVID.

You recall Dr. Stephen Hahn was the commissioner for a while, and then Dr. Woodcock became the acting commissioner before she was replaced by Dr. Califf.

Because I'd been at the FDA a long time, I certainly knew who Dr. Woodcock was. I think she knew who I was. If we were to see each other in the cafeteria, we would be cordial, but we didn't really have serious interactions on substantive issues.

And the only time I had a direct interaction with her during the COVID pandemic was at a meeting on July 19th, 2021.

Q Okay. And we'll get to that meeting a little bit later on, but you had said,

other than that one direct meeting, you had probably just passed her in the hallways but nothing -- no other direct contact?

A Yeah. And of course during the pandemic there were no hallways because the FDA had everybody working from home.

Q Okay. Perfect.

How often would you say that you interacted with Dr. Gruber?

A I would say daily. She and I talked about everything that was going on in the office. I gave her advice. We often went back and forth to try to figure out what the right solutions to problems were, and obviously, two heads are better than one usually.

And so my sense is that she valued my advice and I also felt as though I was often able to positively influence decisions that the office needed to make.

Q Did you ever have disagreements with her over certain studies or certain products that had come out of OVRR?

A So, you know, of course it's not possible to be a scientist at FDA and not have somebody who -- and not occasionally disagree with somebody, but you know very often, what I find is that when there are major disagreements that people have, it's because the people are approaching the problem from somewhat different perspectives, and perhaps value systems, and that if ultimately the organization decided to do something that wasn't what I recommended, often it was a very reasonable decision when approached from -- from a perspective that was held by -- by somebody else.

Q Generally speaking, how often would you say that maybe you'd ever disagreed with Dr. Marks regarding your research or review of vaccines?

Mr. Thomas Krause. I'd caution you to use your judgment and not disclose any deliberative process information, but she's asking a general question. You can provide a general answer.

Dr. Krause. Yeah, I think I can answer that generally. So occasionally, I would disagree with Dr. Marks. I was involved with the research program and saw myself as an advocate for the research that was being done within the center.

Dr. Marks wasn't always a -- he often appeared to question the value of some of the research that was going on where it seemed more obvious to me that that research was of high value, and so, I would attempt to explain those kinds of things to him.

BY [redacted]:

Q Did that happen around the time with the COVID vaccines?

A No, not around that time. So I remember some discussions with Dr. Marks about key issues where it appeared that he might disagree with what I thought was the right thing to do at the beginning, but after discussing them with him, he ultimately ended up agreeing with what I thought was the right thing to do.

Q What about Commissioner Woodcock? I know that you didn't have direct interaction, but did you -- were you aware of any disagreeing opinions that she might have about OVRR?

A I was not.

Q Okay.

A I was not.

Q In your line of work at the FDA, did you find that there were any common disagreements amongst your staff or anybody helping you work on the vaccines?

A Well, you have to understand that regulation is a complicated business and that it's people -- different people with different backgrounds may approach regulation from different perspectives, and some might be more or less conservative than others about how they might think a certain problem should be solved.

And so, I wouldn't say there were disagreements, but there were robust

discussions in which everybody's point of view was heard, and it then became possible to make a decision that ultimately everybody agreed with, based on an understanding of everybody's perspective -- well, everybody's opinion and the perspective from which those opinions came.

And to me, that was a really important part of the review process to have those kinds of robust discussions. If everybody walks in a room and thinks that they know what the right thing to do is, probably they're missing something.

And so, that's not -- you then -- as a leader, I felt it was my job to try to elicit almost sometimes some disagreement to try to understand how different people were reviewing things.

There's also always the risk that if somebody walks into a room and states a position, that you end up having some people who will just agree with that position for the sake of agreement or not -- not arguing.

And so I think it's an important part of the regulatory process to have those kinds of robust discussions. So I don't think I would call them common disagreements, but they -- they need to be discussions of different perspectives.

Q And due to the size of your agency and your parent agency, HHS, who did you regularly interact with outside of the FDA in your line of work? I know you've mentioned WHO. I didn't know if -- I can't remember if you mentioned anyone else.

A So I didn't. And depending on what was going on, I had fairly frequent interactions with people at the National Institutes of Health.

One of the things that I did as deputy director was, I organized, often in conjunction with NIH, various scientific meetings to address important questions that came up in the context of needing to understand the science.

And so, this is not like an advisory committee meeting, but it -- it's -- because no

advice was requested in these meetings, and yet, it's very important for an organization like FDA to be operating with the most current and most cutting-edge science, and to hear, from the scientific community, what is actually going on in an area.

So to give you an example, I -- with NIH, I organized and chaired a meeting on cytomegalovirus vaccines, and CMV is a virus which causes devastating congenital disease. And there were companies that were interested in studying that, but they actually also needed more scientific perspective from scientific leaders in the field.

And so having a meeting to discuss that helped move the field forward and then also had the byproduct of bringing some of those -- that scientific expertise, or scientific thinking, into the FDA on those vaccines.

Even early in the development of some of the vaccines -- and, of course, we still don't have a licensed vaccine -- and I repeated these kinds of things for other viruses too.

I did this for Ebola with NIH. I did this for Zika with NIH. I was a co-chair of a meeting on Dengue virus, which I believe also involved NIH. So I had fairly quick interactions with NIH in the context of convening and sharing those kinds of scientific meetings.

I also, during various kinds of emergencies, although not during COVID, went to NIH to provide regulatory advice on various studies that NIH wanted to do.

So, for example, during the Zika virus outbreak, NIH was very interested in developing Zika vaccines and funding Zika vaccines, and so they wanted to understand what the regulatory landscape looked like for those vaccines and how ultimately FDA might evaluate those.

And so, in collaboration with a sister agency, we listened to what they had to say and -- and gave them general advice on -- on -- on these regulatory issues. So I went to NIH, for instance, for those kinds of meetings as well.

Q Did you give that -- or have those types of meetings with the CDC as well?

A So I did have occasional meetings with CDC, usually less formal. So the CDC plays, obviously, an important role in studying epidemiology and in recommending which vaccines should be given. And so, during the COVID pandemic, I found myself on more calls with CDC.

During the 2009 H1N1 flu pandemic, I found myself on a lot of calls with CDC as we were trying to understand the epidemiology of these diseases.

Obviously during COVID there also was concern over safety issues, like myocarditis. The CDC was generating data that was relevant to that, as were other parts of the FDA.

The chief epidemiological component in the Center for Biologics is in the Office of Biostatistics and Epidemiology, and so, they were having the primary interactions with CDC.

Again, I was often invited to those meetings to provide the perspective of -- of somebody who understood the products, and understood the way that they'd been clinically evaluated, and also had, actually, a very strong understanding of epidemiology and could contribute to those discussions.

Q Do you feel that they listened to your advice when it came to the -- you explaining the regulatory landscape or any of your discussion and your background on these particular issues? Did you feel that the CDC listened to your advice on that?

A In general, I found that wherever I went, people valued my advice, or at least they said that they did, and very often they -- it appeared that they were also listening to it.

Q And you had mentioned that during the pandemic you found yourself on more calls with the CDC than previously. Did that -- was that also the case with the WHO

and the NIH? Like, did your interactions with each of those agencies increase?

A Well, my interactions with WHO increased quite a bit because that was a direct assignment that I had as part of my duties at FDA.

There were other people who were assigned to work more with NIH, so I did not interact as directly with NIH during the COVID pandemic.

Q I'm going to switch gears a little bit, talking a little bit about the vaccine approval process. You're probably very familiar with the FDA's biologic license application process, correct?

A Yes. That's fair to say.

Q Could you give us a brief overview of what it's used for and why it's important?

A Sure. So the biologics license application process is a process that a developer goes through in order to obtain a marketing license for a biological product, or, in this case, a vaccine, which allows them to market the product in the United States.

There -- so fundamentally the BLA is a marketing authorization. But another equally important part of what the FDA does in the review of a BLA is to evaluate all of the claims that the developer wants to be able to make about that product, and to determine the veracity of those claims.

And that then ends up showing up in what is in the package insert for that product and -- and then it constrains what advertisements the developer is allowed to make, because they're only allowed to advertise things that the FDA has reviewed and determined to be correct.

So the FDA, through its biologics licensing process, serves as an independent and objective reviewer of fact. The FDA employees are expected not to have any conflicts of interest, and thus, can look at the license applications from a perspective that nobody

else can and do their -- do their best to challenge the claims that the developer will make and make sure that those are correct.

So let me just finish -- give you one final sentence. So in -- which maybe was your next question anyway. But so in reviewing a biologics license application then, the FDA has to determine that the product is safe, pure, and potent, is what the statute says.

And what that means is that the FDA has to independently evaluate the safety of the product, and make sure it's safe. They have to independently evaluate its efficacy, which is how the word "potency" is then interpreted from the very old language.

And they have to independently evaluate its purity, which really means an evaluation of the chemistry, manufacturing, and controls and evaluation of the facility that is manufacturing the product to make sure that all of the controls that are used by the company or by the marketer, by the developer, to manufacture the product will assure that the product is the same many years after it's been licensed as it was during the clinical trials before it was licensed.

So I think you can understand that if it's safe and effective, that's fine, but if the manufacturer can't make that safe and effective product in the future, that doesn't help you. So really, the BLA stands on those three key elements that the FDA has to evaluate.

And then, of course, there's a benefit-risk decision that accounts -- that brings all of that together and summarizes that assessment.

Q And I'm going to jump back to something else first, but while you touched on it, can you briefly explain the benefit-risk analysis that you do at the FDA? I've briefly read on it, but to get a little bit more of a better understanding of why that's important.

A Well, obviously, any product needs to have -- that is going to be marketed to people -- needs to have more benefits than it has risks. And in vaccines, traditionally, because vaccines are given to healthy people who aren't otherwise sick at the time they

get the vaccine, that benefit-risk ratio should be highly favorable, because otherwise, you might be giving people, who are otherwise healthy, some substantial risk without knowing whether or not they will later encounter the disease that the vaccine is protecting against.

Q Now, going back to what you had mentioned with the FDA independently evaluating a product's safety, it's purity, and its potency, did you feel that the FDA was able to fully evaluate those three elements with the COVID vaccines?

A So the -- maybe if I could digress to make this easier, let me describe the emergency use authorization process which was also used to make many of the COVID vaccines available.

Q That was my next question. Please do.

A Okay. So -- sorry for taking you out of order.

Q No, that's perfect. Not a problem.

A You see I'm a very cooperative witness.

All right. So in the emergency-use-authorization process, the FDA has to make a determination that the product may be effective and that the known and potential benefits outweigh the known and potential risks.

And so there's also a risk-benefit determination for the EUA, but the EUA standard is not nearly as substantial as the BLA standard is.

The EUA standard, as it's written, of course involves the FDA looking at the efficacy data and the safety data and the CMC data, but allows the FDA to take all of that and integrate it into a -- an overall assessment of whether the known and -- known and possible benefits exceed the known and possible risks.

And so -- and whereas for BLA, the requirement is substantial evidence of efficacy. For the EUA, it's that the product might be effective.

So the FDA, in issuing an EUA, has to be -- has to be careful, but also needs to think about this -- these different elements in the context of the actual situation.

And so, for example, when the vaccines were first authorized -- and I'm going to try to be careful in spite of the fact that many people get this wrong. So I'll say this right now, is an emergency-use authorization means that the vaccine is authorized, but licensure means that it's approved.

And yet, many people mistake this and say approved when they mean authorized. So I'm going to try and keep this straight, but even I sometimes slip up.

So when the vaccines were first going to be authorized, the FDA then had to think about, in the context of the pandemic, how can one meet this requirement of believing that the known and possible benefits outweigh the known and possible risks for a vaccine.

And there were a number of concerns early in the pandemic which included that many vaccines were being developed at once, that if there were a vaccine that turned out not to be effective, that that could actually do considerably more harm than good, because that could then prevent better vaccines from being used or evaluated.

And so, in thinking about the standard and the way that the pandemic was unfolding, the FDA set a standard for efficacy of vaccines that required a 50 percent efficacy estimate and a 30 percent, 95 percent lower confidence in that efficacy estimate.

So that's a statistical way of saying that the -- we'll accept a vaccine as long as we have a high degree of confidence that it will reduce the incidence of disease by at least 30 percent.

Now, if we had said we would accept a vaccine that, for example, appeared to be better than nothing, we would be accepting, if multiple vaccines were authorized under that standard, some significant risk when you do it with many vaccines, that some of

those vaccines might not work at all.

And so, given the pandemic and the need for public confidence in what was done, the FDA set what some people might say was a fairly high efficacy standard. And yet, this was a similar efficacy standard to that which was set elsewhere around the world which the WHO ultimately recommended, and which many countries ended up using too.

So what that meant was when the vaccines were originally approved under emergency use authorization, we actually had very solid data on the efficacy of those vaccines.

We -- it turned out that the vaccines blew away those criteria anyway, right? The vaccines were about 95 percent effective, and the lower bound was in the high 80s or even above 90 percent for one of the vaccines.

And so, the public could have very high confidence that those vaccines worked.

At that point, though, we had only very short-term follow-up of these vaccine -- of people who received these vaccines, and so, what I would say is that we had some uncertainty about safety.

But of course, because we had great certainty about efficacy, you could state that the benefits were clearly outweighing the risks, even though we had follow-up that was much shorter than one would normally want for a BLA.

So in a BLA, we actually, at the beginning of the pandemic, issued a guidance document describing what we would want to see, what the FDA would want to see for a BLA, and that included 6 months of safety follow-up.

But, of course, as the pandemic wore on and as it seemed like it was likely that we would come to a vaccine, it was clear that we could not wait 6 months to gather all the safety data to license a vaccine.

And so, the question came up, what's the minimum amount of safety data that

one could contemplate using, as well as what's the minimum amount of efficacy data that one could contemplate using.

And so a subsequent guidance was ultimately published that described a median of 2 months' follow-up for safety and efficacy, and so -- but that 2 months' follow-up didn't meet the standard that one would've wanted for a BLA at the time that the vaccines were first authorized in December of 2020, if that makes --

Q Who had made that determination of the -- of the amount of data that was required?

A Well, so that -- that decision arose organically through discussions within the Office of Vaccine, and I think also with the Office of the Center Director, and was consistent with the kinds of decisions that were being made elsewhere in the world as well.

Q And who was the center director at the time?

A Peter Marks.

Q And you said, This was around the beginning of the pandemic that they set a standard for BLA. That was --

A That would've been in June of 2020, I think, that the guidance document was published that said that for a BLA, 6 months of safety data would be required.

Now, of course for BLA, one also would've needed the manufacturing data -- the chemistry, manufacturing, and controls data, and that data wasn't at a level during the original emergency-use authorization that one would've wanted during a BLA either.

And so, the initial emergency use authorization then, just to summarize, actually had the level of efficacy data that one was either equivalent to or close to, but I would say equivalent to that, which one would normally want for a BLA, because we had a very high standard in the efficacy study.

It did not have quite as much safety data as one would want for a BLA, but it had enough safety data that one clearly determined that the benefits, you know, substantially outweighs the risk, it turned out.

Q How much safety data did you have versus how much you wanted?

A Well, at the time that the vaccines were originally authorized, it was roughly a median of 2 months, which meant that half of the people in the study had been followed for more than 2 months, and half had been followed for less than 2 months.

And then of course with every additional month, additional safety data became available. But, of course, the desired amount of safety data was around 6 months of safety data.

And of course if one is doing this, you would like to follow everybody who's in the study for 6 months. So you don't come up with that answer 6 months after the first person is vaccinated.

You come up with that answer 6 months after the last person is vaccinated and, in this case, probably 6 months after the last person in the study has had two vaccinations, right?

And so -- so -- and then, of course, the EUA also didn't have the same standard, I think I said, of CMC data that one would expect to have in a BLA.

Q Now, were the standard EUA procedures followed throughout the COVID-19 vaccine approval process for as long as you were with the FDA?

A So there were several additional EUAs that were done while I was at the FDA. Some of these involved expansion of the age group for vaccines, and there generally the standard procedures were followed.

And -- and then in the fall of 2021, or August of 2021, there were two additional EUAs that were -- that were authorized by the FDA for -- for immunocompromised

individuals who were to receive either the COVID or the Moderna vaccine or for -- ultimately for individuals at -- of certain ages and in certain occupations to receive booster doses.

And so, under those circumstances, arguably one could still say that those authorizations met the statutory requirement for an EUA, but at that point, the reason they met the statutory requirement for the EUA was quite different.

So for the immunocompromised, for example, the efficacy data was based on a couple of published papers.

For a BLA, FDA always reviews the individual data and is in general not so trusting of published papers because they can't see the data.

And there are many cases where FDA has seen published papers that are published even in very prestigious journals and have rejected some of the conclusions from those papers when they've had a chance to actually see the data.

So if the FDA relies on a published paper, one could still say that the product may be effective, and one could still say, especially by that point, because we had a fair amount of data on vaccine safety, and especially, for instance, if you're giving a vaccine to the immunocompromised who were at great risk of getting very severe disease -- one could say that the benefits, or the known and possible benefits outweigh the known and possible risks.

At that point, one is shooting in the dark almost on how effective it is, but what has more confidence in the safety. So I think it would be fair to say that if you looked specifically at the EUA requirements, some people could interpret those EUA requirements to have been met, but that -- but they would've been met for different reasons.

And the same, of course, is true ultimately -- and this was after I left the FDA for

some of the booster vaccine EUAs, where, in August -- and I think you'll probably ask me more detailed questions about this later, and so I don't want to go through that entire story right now, but in August of 2021, there were announcements about the availability of booster vaccines by September 20th.

And the intent, I think, was to make the vaccines available for everybody. The discussions at the FDA's advisory committee ultimately supported making them available only in a subset of people.

And in that subset of people, it's probably fair to say that that criterion was met, but later on, one could have greater doubt as to whether that criterion was met when the EUA was expanded -- for boosters was expanded to the entire population, for example, above age 16.

Q And you said "one could say." Did you personally believe that there was grounds to expand it to all age groups, or to everybody, however -- whatever the classification would be?

A Well, there's is a lot of detail in the story, but I had, you know, co-authored -- or was the first author, so I had written the first draft of an article in September 2021 that laid out the data that supported giving boosters. And that article fairly definitively showed that most people would be unlikely to receive substantial benefit from a booster.

And so, my opinion was that there were probably some subgroups who would receive benefit from getting a booster, but that for everybody it -- I did not think at that time that one could say that the known and potential benefits exceeded the known and potential risks for everybody.

Q And you're right, we will touch a little bit on that a little bit later, too. And before I finish up my hour, I had just a -- one other question too.

You had said that the FDA had relied on a couple of published papers in

determining their -- the EUA for immunocompromised, and I believe you said for the -- was it the immunocompromised and the booster, or did you say it for --

A Oh, I said it for the immunocompromised, but for the booster, there was an advisory committee meeting at September 17th, 2021. And at that meeting, Dr. Marks invited scientists from Israel to present data that had never been provided to the FDA for review. So the first time anybody was seeing it was at that advisory committee meeting.

And Pfizer presented the results of a study that was -- had been briefly available in preprint form, but also was not -- had not been submitted to the FDA for review.

So there, in contrast to typical advisory committee procedures for BLAs, at least, data that FDA reviewers had never had a chance to look at was being presented to the advisory committee to -- to, on the one hand, let them know the latest breaking news, but at the same time, an important part of the advisory process, at least for BLAs had been to allow the FDA to review those data.

So I can't say that that's an inappropriate thing to do in the context of an EUA, because the standard for an EUA is much lower, and yet, it -- I think it highlights how different the standard is.

And I know that your committee is interested in figuring out how to do better in the next pandemic. And so, the one thing that I think could possibly be done would be to require the FDA to, if they're going to issue an EUA, to explain for that given EUA why it isn't a BLA, in other words, their independent assessment of the safety data, the efficacy data, the CMC data, and what would need to be done.

And that way, people who are looking at an authorization would know, for example, in the case of the -- one of these booster authorizations, that the efficacy data was weak, but they also would've known, in the context of the original EUA, that the efficacy data was strong.

And then, it would've provided a basis for a clearer interpretation of what the FDA's assessment was.

I don't think it would require the FDA to do more work because they do these assessments anyway, but it would be a different way of communicating which would allow the lay public, the prescribing physicians, and other policymakers to really understand in greater depth what the results of the FDA review was.

[redacted] Well, that is very helpful, but -- and I think that at this time, we'll go off the record.

[Discussion off the record.]

[11:11 a.m.]

BY [redacted]:

Q Good morning again, Dr. Krause. If I could start just with a couple of --

A Actually, could I ask --

Q Yeah. Sure.

A I'm wondering if I could just clarify two things quickly that I just said --

Q Yeah, of course.

A -- to make sure that I got them right.

So, of course, what I -- I said that the Israeli data was presented, the Advisory Committee had not been reviewed by FDA, but of course, I can't be certain that no one at FDA saw those data, but those were not reviewed by the Office of Vaccines --

[redacted] Okay.

Dr. Krause. -- which was what I was aware of -- would've been aware of at the time.

And just to be clear, when I was talking about the boosters meeting the EUA standard, this referred to the original booster application, where Pfizer came in and wanted a booster and everybody above age 16, and I disagreed that it met the EUA standard in that age group, and, in fact, the Advisory Committee also disagreed it that met the EUA standard for that group. And, ultimately, it wasn't -- it was authorized for a more limited subset of people.

Later on, the FDA authorized boosters for broader groups of people, and in those cases, I don't know what additional data the FDA had.

I actually, together with a colleague, published an editorial lamenting the fact that the FDA did not convene an Advisory Committee to discuss that decision, so I don't know what data they used to ultimately make that decision or if they had more data than they

had at the time when I was there and when the Advisory Committee recommended against authorizing it that broadly.

BY [redacted]:

Q Okay.

A Sorry. Go ahead.

Q Oh, no worries. That's good. You're a very technical expert here, and I want to defer to your expertise, and if you ever feel that you need to clarify something, please absolutely feel free, because I myself am not a doctor, and I don't think anyone else here is but you.

So I just wanted to back up a little bit before we get into the -- kind of the stuff that you were discussing in the first hour. Can you just talk a little bit more broadly about vaccines, and what are they, and do you believe that they're beneficial and why for most people?

A Sure. So vaccines are regarded, at least in medicine, as one of the most important inventions of all time in terms of their ability to prevent disease. And so, it's because of vaccines that we've eradicated smallpox from the Earth; we have come close to eradicating polio, although we're now failing again due to some problems, mostly related to vaccine hesitancy; we have, I believe, unless this has changed, eradicated rubella, or German measles, from the -- from this hemisphere.

And so, vaccines have had an enormously positive impact on human life and on the quality of life, and quantity of life, around the world.

I can tell you a little bit about what vaccines are and how they work, if that's all right.

Q Sure.

A I'll keep going.

Q You can keep going, and I'll keep asking.

A All right. Sounds good. So vaccines work by stimulating an immune response against what is called an antigen. The antigen is the vaccine component that is administered to a person. And so, the vaccine antigen provokes the same kind of immune response that that person would get if they were infected with the organism that that component came from.

And that immune response then, depending on the vaccine, can provide a lot of protection. And many vaccines will protect you for life, even with a single dose; other vaccines may require some additional doses to protect. Some vaccines are better at protecting against certain outcomes than other vaccines are.

But at the heart of this is this idea of mimicking an infection for the body so that the body then responds to it as though it were infected, so that when a person actually gets infected they treat the real infection as though it were a second infection. And because the immune system is ready for that, the severity of disease is normally less, if the vaccine works, or the infection might be prevented all together.

Q Okay. So fair to say that there are both risks and benefits involved with vaccination, generally speaking?

A That is true. While vaccines are generally very, very safe, vaccines also can have side effects, and it's very important to pay close attention to people who receive vaccines and to make sure we understand what side effects those vaccines might be causing.

One of the biggest advances in vaccinology over the last 15 years or so has been the ability to look at large databases of people who've received vaccines and compare them with people who did not receive vaccines and to understand what even rare side effects vaccines might be causing.

And so our ability to find even very rare side effects is much, much greater now, and this ability keeps increasing every year than it has ever been at any time in history. And so if these databases are not finding substantial side effects, that can give us a great deal of confidence in the safety of a given vaccine.

Q And that's because of the advances in data analysis and just the way you can see more statistically?

A That's exactly right, yes, so you can compare people who are vaccinated/who are not vaccinated. You can look much more -- in a much more granular way at time-dependent effects. So because many vaccine-associated adverse events appear shortly after vaccination, things that occur in a certain time window after vaccination might be more likely to be vaccine related than those that occur in a different time window.

And so, all of these different ways in which very clever scientists have learned to look at the epidemiology of vaccines has given us greater confidence in vaccine safety than we've ever had.

Q Okay. And fair to say then, because you can see more from the data in terms of the potential risks for vaccine, your standard might actually change, because you have the capacity to understand these risks. You may expect more of yourselves as public health advocates when you make a recommendation, because the information is available to you, you need to analyze it and balance it all, as you've described?

A I think -- I see the FDA's primary role there as in being a fair presenter of information, and of course they need to do this in the context of how the public is going to look at vaccine side effects.

And so, an example of this, for instance, is that back when there was a lot of polio everybody was very happy to take the oral polio vaccine, and even though the oral polio

vaccine carried with it a very small risk, maybe one in a million, of causing a disease that was very similar to polio. But the risk of getting polio was so much greater, and the devastating consequences for families and for children of getting polio were such that nobody doubted that that small risk was worth getting the vaccine.

Over time though, a -- well, a killed polio vaccine became sort of used more, because that vaccine did not carry even this one-in-a-million risk. And so -- and eventually the oral polio vaccine, which carried that risk, was withdrawn from use in the U.S., although it is still used in a few parts of the world. And so, the -- it's a combination of things that play into the public's and regulators' willingness to accept risks.

The J&J vaccine against COVID became associated and was found using these kinds of methods to cause a very rare but sometimes fatal disease. And I'm blanking on the acronym, but it -- involving a clotting disorder and -- TTP -- no, it's not TTP. Anyway, it'll come to me probably during [redacted] time or at lunch, then I'll come back to you.

But in any event -- and, of course, the availability of other vaccines that didn't have that side effect played a role in people's willingness to do without the J&J vaccine, and eventually the J&J vaccine was withdrawn from the market here in the U.S.

And so this is just an example of how well these safety systems work and how they can move us towards using the very safest vaccines.

Q Okay. So when you're talking about the risk-benefit analysis, just to be clear, you've talked about the risks and that can be seen in the data, especially the big data that is now available to scientists.

But on the benefits side, that is like the severity of disease, right? Like you have some diseases that can be a very serious, life-threatening risk, and then you have others that might not be so serious.

Can you talk a little bit about how the benefit fits into the analysis?

A It's an enormously important component of this. You know, one of the important parts of the BLA analysis that the FDA needed to do for the Pfizer vaccine was a formal and quantitative benefit-risk analysis of the myocarditis signal that had been observed. And so, it was clear that, at that time, that a small percentage of people who got either the Pfizer or the Moderna vaccine, the mRNA vaccines, carried a low risk of a disease called myocarditis.

Now, myocarditis is an inflammation of the heart, which, in theory, should be something that you would worry very much about, and in fact, this was the case. When people started coming in with myocarditis, they were very carefully observed, and it was very important to figure out what happened to them.

And over time, various things were learned about the myocarditis that was associated with COVID vaccines. It tended to be more common in males than in females; it tended to be more common in younger people; and the peak seemed to be roughly the 16- to 18-year age group. And you could find different reported rates of that myocarditis by changing the age span that one was looking at.

But it was common enough that it was very important to think about how to put that in the context of the benefits of vaccination, especially from we're thinking about approving a vaccine also for males in that particular age group.

And so, the analysis that the FDA did included an examination of myocarditis that is caused by COVID itself, because COVID can also cause myocarditis.

Q Right.

A And, of course, one has to make assumptions of how quickly the population would've gotten infected with COVID. But it became clear that even for the -- this young male age group that had the highest risk of myocarditis, the benefits in terms of preventing severe disease, hospitalization, and COVID-induced myocarditis greatly

exceeded the number of cases of myocarditis that the vaccine could possibly cause. So that particular benefit-risk analysis was performed formally as part of the BLA.

Now, even then, when the BLA was ultimately approved, the FDA required that Pfizer continue additional studies on myocarditis to understand more about what happened to people who had myocarditis and to better define the frequency of myocarditis. And so, the responsibility to keep looking at this didn't end with the licensure of that vaccine.

What became known over time, and actually was already known at the time the vaccine was licensed also, is that COVID-vaccine-induced myocarditis is much milder than the typical case of myocarditis that I would've seen when I was an intern or that a typical doctor would see.

And very often, while there would be some EKG abnormalities and there would be chest pain and there would be clear evidence of an inflammation of the heart, it would resolve fairly quickly and wouldn't have the same kinds of sequelae that myocarditis was associated with other causes would've had.

And so that also helped play a role in this benefit-risk analysis by gaining a better sense of what the risk side of that equation really looked at. But you really need to do these kinds of quantitative analyses when one -- when you're looking at that kind of an adverse event to understand how to put it into the context of the vaccine benefit.

Q And I don't want to digress too much, but because you brought up that particular analysis with respect to myocarditis, I think what I heard you just say is that COVID itself, there's evidence that COVID itself, the disease, causes myocarditis, correct?

A Correct.

Q And then there was this evidence that you discuss that the vaccine might cause it in a mild form in some population, particularly younger men, correct?

A Right.

Q But because, you know, the decisions that the FDA and other people, individuals are making when they decide to take a vaccine or not are actually affecting the course of the disease. Fair to say? Like when people start to have access to the COVID vaccine, people were -- more people were -- were being prevented from getting the disease, correct? Like as the vaccine became more available --

A No, there's no doubt the vaccine was saving lives, yes.

Q Okay. But the end point, or the objective of this vaccine was not necessarily to prevent infection, but to prevent COVID disease. Is that correct?

A Well, so that's an interesting question. The original clinical trials showed that the vaccine prevented COVID disease, and that's what they were designed to do. What people always care the most about with vaccines, though, is will they prevent severe disease? Will they keep people out of the hospital?

And for COVID this was particularly important, because we were worried about the hospitals getting overwhelmed.

Q Right.

A And if everybody got infected all at once and the hospitals got overwhelmed, that could lead to worse consequences even for the people who didn't have COVID. And so, hospitalization is actually the end point, and of course, death, that society probably cares about the most.

The difficulty is, is that hospitalization is a pretty rare end point. And so, for example, in the Pfizer vaccine trial, which enrolled around 43,500 total people, half in the placebo group and half in the vaccine group, there were -- and now, since I'm under oath, I could get the numbers wrong, but -- well, the efficacy was around 95 percent, which means that there were, I think, over 160 cases in the placebo group, and a handful in the

group that had the vaccine of COVID disease.

If you looked at the number of people who had hospitalization due to COVID, or severe COVID disease, and I don't remember exactly which one this is, it was nine to one. There were nine people in the placebo group who had that and one in the vaccine group that had severe disease. And that's not a big enough difference to statistically say that the vaccine clearly protects against severe disease.

So we're stuck with a system that allows us to look at and to understand the efficacy of a vaccine against milder disease. But, of course, what we care the most about is its ability to prevent severe disease. And then, of course, we also care, if we can achieve that, about its ability to prevent transmission to additional people.

But there's a general rule in vaccinology that, to my knowledge, is followed by every vaccine, and as I've told you, I've been in this field for more than 30 years, and that is that vaccines are always more effective at preventing severe disease than they are preventing mild disease. I don't know of any counter example to that rule.

And they're also always more effective in preventing mild disease than they are preventing infection. And, in fact, many vaccines, especially at times remote from vaccination, don't prevent infection at all. One might be able to get evidence that the person was infected, but they might not even know they were infected because they had such mild disease, but these infections can occur. If an infection occurs or if a person has mild disease, they probably have at least some theoretical risk of transmitting the disease. And so, the efficacy against severe disease is also likely to be greater than the efficacy against transmission.

But -- so, if you put this together for the Pfizer vaccine, for example, as it was evaluated in December 2020, with evidence that there was prevention of any disease, which included mild disease of 95 percent reduction, there would've been fairly high

confidence that it would also reduce severe disease by that much as well.

But -- so I'm just putting a little bit of a finer point on your statement, which is that the goal really -- the number one goal has to be to keep people out of the hospital, and in a pandemic like COVID, that had to be the number one goal. But a way of proving that we were likely to reach that goal was by demonstrating efficacy for mild disease, for symptomatic disease.

Q Okay.

A Does that make sense?

Q I think so. So telling you what you were looking at, it was helping you to see what might be the case as you get more data?

A Right. Yes.

Q Okay.

A So if the vaccine was going to be highly effective against mild disease, we likely had a good vaccine. But that wasn't necessarily the goal of vaccination, per se.

Q Okay. I want to go back a little bit to where I was trying to get to before, again, with the general risk-benefit analysis that you do with any vaccine. You mentioned that, especially I think in your example, the polio, one concern of public health officials is what happens when people stop taking what is considered a safe and healthy vaccine, and vaccine hesitancy is introduced into a population.

Now, when you have, you know, a population like in the United States or anywhere else in the world, most of us don't understand vaccines and virology the way that you do, we don't have that technical knowledge, and so we rely on experts like you and agencies like the FDA to help make large public health decisions.

And can you tell us a little bit, just broad view, what is your concern, if any, about vaccine hesitancy, like on the other end of the spectrum here? Is there any concern that

this committee should have in terms of the message that's sent when, you know, politicians and other people with a pulpit are talking about this highly technical, you know, subject? Do you think there's a risk on the side of promoting vaccine hesitancy with respect to public health?

A There absolutely is. And vaccine hesitancy is obviously a danger, because what it means is that people who would benefit from vaccines might be misinformed and choose not to take those vaccines.

And there are, of course, many things that can contribute to vaccine hesitancy. And overall, the public's confidence in the public health agencies overall, and in the quality of decisions that are coming out of the public health agencies, whether it's the FDA or the CDC, can play a role in vaccine hesitancy.

It's also the case that if people say that there are problems with vaccines that don't exist, that can also contribute to vaccine hesitancy.

So there are -- the difficulty is that there are many contributors to vaccine hesitancy, and I know that the public health agencies have spent a lot of effort trying to figure out how to combat vaccine hesitancy, but it's a difficult thing to do, as I'm sure you know.

Q Have you, since you were in the FDA or after you've left, have you followed sort of the public debate that is in the news or in other media settings about the safety of COVID vaccines? Do you pay attention to that?

A To some degree I do, yes.

Q And tell me what it is -- what is your reaction to that on, like, a high level? What are your concerns, if any?

A So, of course, there have been some people who have misled some of the data and have concluded that the vaccine has caused many deaths.

And the difficulty is that if you look at these databases, these are enormous databases that include many, many people in them, and they include many people who are vaccinated.

And it's not hard, if you include people who are vaccinated on every day of the year, and you also know that people die every day of the year --

Q For any cause, right?

A -- for any cause, whether it's a traffic accident or something else, it won't be difficult to find somebody who died of some cause within, in some proximity, to receiving a vaccine.

And that's why these very rigorous statistical methods that I was talking about for looking at these databases are so important, because they can tease that out and ask whether the risk of dying or of something bad happening after vaccination is truly different from the risk of what would have happened if one hadn't received the vaccine.

And so really, in the end, it's this aggregation of data and the ability to do these kinds of statistics which is the only reliable way to figure out when one is looking at this kind of data, whether it's showing a true vaccine adverse effect or something that is spurious.

But I'll give you an example from my experience also, which -- since you're asking about vaccine hesitancy, and maybe you'll come to this question anyway, but when I was the associate director for medical policy and vaccine safety at -- in the Office of Vaccines, I had the occasion to go to meetings where I would talk with parents and would hear from parents of children who believed that autism had been caused in their child by a vaccine.

Q Right.

A And what would happen is that these were parents whose child had received a vaccine, and some period of time not long after getting the vaccine, their child would

start behaving in a way that caused them to suspect autism.

And there would be nothing you could do to shake the belief of these parents that this vaccine was somehow associated with autism in their child, because they saw it happen in close proximity to each other.

But if you look at the entire population and ask how often are children receiving autism diagnoses, and how often are they receiving vaccines, and are we seeing more children receiving autism diagnoses in proximity to vaccines than not in proximity to vaccines, the answer is that there isn't an association.

But if you're the one person who sees that, and especially if you're a parent, I mean, that's something that has changed your life and you see the change in the life of your child.

And so, that parent is always going to believe that that vaccine was associated with autism and that there's nothing that you can do to shake that belief, in spite of the fact that all of the most sophisticated methods that can be used will show that that vaccine had nothing to do with autism.

And so, that's what one is up against when one is dealing with vaccine hesitancy, people who have very real stories that they have lived and that are, for them, are completely true and from their perspective represent unshakeable beliefs.

Q But as a scientist, with respect to that example, are you confident with your position that those vaccines are not causing autism?

A 100 percent confident. That's exactly right, because the data that the scientists can look at that becomes more powerful and stronger every year gives us assurance that there is no association between the vaccines and autism, and that these kinds of events are coincidences.

So likewise, the same thing is true about deaths after COVID, where if -- there may

be examples of people who got a COVID vaccine and might have died some period of time thereafter, or may have had some other adverse event sometime thereafter.

But unless this is looked at in the aggregate to see whether other people who got vaccines had the same thing happen to them and then had it happen more frequently among people who received vaccines than people who didn't, then you simply can't say that the vaccine caused that.

Q So when somebody, say this unfortunate parent, makes that association for reasons that you can imagine because it's personal to them, that decision really becomes problematic, I guess, when it's broadcast population-wide and people then have vaccine hesitancy. They're worried that their child might get autism, even though they haven't had the experience of the parent with the autistic child. They're hearing this message kind of filtered through culture or media or whatever, and they're thinking there's a danger here that really doesn't exist. There's no evidence that there's a causal connection between the vaccine and autism, and so --

A That's exactly right, and of course those kinds of problems are amplified through social media as well, because the reach of these stories ends up increasing.

Q And so it takes away -- this fear that's not based in science takes away from the benefit that vaccines could provide to the population writ large. Is that fair to say?

A That is fair to say, yes.

Q And with respect to COVID, as you followed the kind of disinformation/misinformation that has sort of proliferated in conversations, do you have concerns about the way the general public, in this country in particular, but elsewhere around the world, sees the risk benefit of COVID vaccines?

A So I'm less concerned now than I was before, because at this point many people have been vaccinated and many people have already been infected. And we know

that even now getting vaccinated, even with just the original two doses, is still pretty highly protected against severe disease.

And of course getting infected, the evidence suggests, is even more protective than getting vaccinated, and many people who have been both vaccinated and infected, many people have been infected multiple times.

So the urgency of COVID vaccines right now is nowhere near the level that it was in 2020, for example. I think, overall, though, to the extent that the population or the public starts believing that COVID vaccines are associated with adverse events, I'm almost more worried that they will carry that over to other vaccines and that we'll have a broader public health impact, because if they believe that COVID vaccines are causing adverse events, it means that they've lost confidence in our public health apparatus, it means that they don't believe what the CDC is telling them, and it means that they don't believe what the FDA is telling them, and that disbelief is going to extend beyond COVID.

So, I'll say, I'm less worried about the ramifications for COVID itself than for other diseases.

Q Okay. Let's talk about that. Actually, that is another subject I wanted to get into. And you as a scientist, but also as a FDA government regulatory official have a unique perspective in terms of, you know, how experts like yourself can affect the public health. Like there's an element here of trust that the American people need in their government in order to receive the expertise that people like you have with respect to virology and vaccines.

Is that fair to say?

A It is fair to say, yes.

Q And what, in your opinion, is dangerous, if that is your opinion, about undermining trust in Federal officials like yourself, and in regulatory agencies like the

FDA?

A So I'm a believer in transparency and openness, and so, to the extent that I hope that Federal agencies can do a better job in a future pandemic, it's not that I intend to undermine confidence in those agencies now. On the other hand, I do think it's important to take stock of where we've been and figure out what can be done better and see whether there were things that were done that themselves might have undermined confidence in these agencies.

Q Now, you were at the FDA under multiple presidential administrations, correct?

A Correct, yes.

Q And you've seen the operation of that agency with Republicans in control and also with Democrats in control, right?

A That is correct.

Q Have you ever observed political influence from either party affect scientists' ultimate decision-making at the FDA in a way that would affect the safety of the American people?

A I need a moment to think about that, also because I have to go to the restroom. Can I just take a couple minutes to run out?

[redacted] Sure. We can go off the record.

[Discussion off the record.]

BY [redacted]:

Q We can go back on the record.

A Can I ask you to just repeat the question so I have it, if you can read it back.

Q Yeah. My question is, like, after having been at the FDA through various administrations and both political parties, are you concerned, first of all, about the

motivation of FDA employees and their ability to make decisions that are based on science and based on the motive of helping Americans outside of political influence? Are you concerned about the employees at the FDA making the right choice?

A I have no concerns about that.

Q Do you have confidence in people in your position and the people around you that they're doing their job with the motive of keeping Americans safe?

A I think -- I can certainly speak for myself, and my sense is that most people at the FDA have that as their primary motivation.

Q If you had experienced something at the FDA that you thought, like, say, an employee or somebody who was ordering you to do something, that would risk the health of Americans that you thought was wrong, like asking you to make a decision that was wrong, or to hide some information from the American people, what would have been your response?

A If they asked me to do that, I would've said we can't do that.

Q Have you ever had to say that?

A No.

Q Okay. And as you sit here today, do you have confidence in the FDA as it's constituted now under the current administration to make decisions with the well-being of the American people in mind?

A Yes.

Q Okay. Let's go back to COVID.

A So, of course, before I took the break you actually did ask me a slightly different question, which I'm happy to answer if you want me to.

Q Okay. Sure. Go ahead.

A Well, that was the question I asked you to repeat.

Q I'm sorry. I don't know how you characterized the first versus the second, but if you had something else that you wanted to add.

Mr. Thomas Krause. The court reporter probably has the question.

Dr. Krause. You had asked a question about whether any administration had done something that had some impact on FDA decisions, didn't you?

BY [redacted]:

Q On your decision-making, yes.

A Is that what she said, on my decision-making? I mean, I'm happy to answer.

Q Well, you can answer whatever you -- if you have something you want to share, just go ahead and answer.

A No, no. I was puzzled by the question, so --

Q Okay.

Mr. Thomas Krause. It was about any administration whether political pressure could affect the health of the American people.

Dr. Krause. I think -- is that right? It was a broader question.

BY [redacted]:

Q You can answer whatever you would like to answer. Like, you can, if you have something that you want to share, share it.

A Okay. Well, so, I think it's been reasonably well-documented that there was suspicion that political pressure led to certain decisions being made at the -- just to start, at the FDA, early in the COVID pandemic.

So, for example, without very much data, hydroxychloroquine --

Q Right.

A -- was authorized by the Center for Drugs under the same EUA rules that I was talking about earlier. And there, if you sort of follow the analysis that I described, the

hydroxychloroquine, although I was not in the Center for Drugs and wasn't involved in evaluating drugs, there was very shaky, if any, there was zero credible data that that would be effective in the thing it was being authorized for, which was COVID.

Q Can you just explain that a little bit further. So I didn't even realize that that was the case. So hydroxychloroquine was authorized for --

A Hydroxychloroquine was an antimalarial --

Q Right. And --

A -- which was authorized by the FDA in early 2020 to treat COVID.

Q Under the Trump administration, correct?

A That is correct, yes.

Q Okay. And tell me how that decision was made, from your knowledge.

A Well, from my knowledge, I only know what I read in the papers, but it seemed that political pressure led to that authorization because the President was touting that as a cure for COVID, and soon afterwards the FDA authorized it.

Q Was there any data, to your knowledge, that supported the President's view that hydroxychloroquine was an effective treatment for COVID?

A I was not aware of any such data. And ultimately, a couple of months later, the FDA revoked that.

Now, also, later that year, the FDA authorized convalescent plasma to treat COVID. So convalescent plaza is blood or plasma that is taken from people who have recovered from COVID, and it was authorized to be used to treat people with COVID.

And this was viewed at the time as being very suspicious because the announcement of this authorization, to which the NIH strongly objected, and I remember looking at the data myself at the time, although it was not in my part of the Center for Biologics, I did not think that the data suggested that it was really working at all.

And yet -- and I believe that people at the NIH also didn't think it worked. And yet it was authorized, and people found the timing suspicious because it was authorized on the eve of the Republican National Convention. And --

Q When was that? Do you recall the year?

A That would've been August 2020, I think.

Q Okay.

A No, August? No, no, earlier, I think.

Q Trump administration as well?

A That was the Trump administration.

Now, so those are certainly situations where political pressure influenced things that the FDA did. So the question then is, was there political pressure applied also during the Biden administration in the context of the BLA for COVID vaccines, or the booster vaccination?

And, of course, in the context of the BLA, there was -- I have no direct evidence of pressure applied specifically by the administration, but it certainly -- and we'll probably get into this later, is that there is certainly evidence that there was applied from -- pressure applied from outside of FDA to speed up that evaluation.

Q Where -- was that from a position you were in that you could feel that pressure?

A Yes, absolutely.

Q Okay. And so what was your response to that pressure?

A Well, when that pressure occurred, initially, Dr. Gruber and I resisted that pressure, but then as the history will show, we were both relieved of responsibility for directing that review when we resisted that pressure.

Q And so what was the ultimate result -- I mean, I want to be very specific

about the decision. Now, with respect to the BLA for the COVID vaccine, are you talking again about what you were saying in the first hour, the boosters for the particular -- for the general population, or are you talking about --

A No. No, the boosters for the general population was an EUA not a BLA.

Q Okay. So you're talking about the licensing later?

A The licensing that occurred in August of 2021, yes.

Q Okay. And what were your concerns?

A Well, the -- the concerns there related to the speed with which the vaccine needed to be evaluated, and --

Q And can you just map out the difference, like what your view was and what the, you know, view was from the outside that was being advanced?

A So let me be clear, I'm not saying that this led to a safety problem for the American people, but I am saying that this led to a credibility problem for the FDA.

Q Okay. Can you explain the difference. Like how can you be confident that it didn't lead to a safety problem?

A Well, because to the questions that you've asked me, we've established that when the FDA loses credibility that then potentially increases vaccine hesitancy.

Q Yes.

A And so, if the FDA behaves in a way that suggests that it is subject to outside influences, whether it's through authorizing hydroxychloroquine or authorizing convalescent plasma, or speeding up the review of a BLA and what came along with that or speeding up a review, and actually having the FDA Commissioner before the FDA was -- even conducted review and before one of the companies even submitted any data say that a vaccine is going to be available for the American people in a month's time, these things strongly suggest external pressure on the FDA. And this is not lost on the American

public.

Q So that concern --

A And the American public will lose confidence in the ability of the FDA to make good and independent and science-based decisions.

Q So just so I understand, the concern that you're describing right there is about the public perception of the FDA and how -- how able they are to resist outside political pressure and let science prevail. Is that correct?

A Correct, yes.

Q Okay. And then you also said that there is this other potential concern, which is safety itself. And I think that you said that your concern is more about the public perception of the FDA's integrity, if you want to put it that way, and not so much that there was actually a decision made at the FDA that ultimately sacrificed the safety of the American people. Can you distinguish between those two?

A So the difficulty is I'm struggling with your definition of the safety of the American people, because you started off with the correct proposition that the safety of the American people depends on people's confidence in vaccines.

Q I see what you're saying, yeah.

A And so, if things happen that cause confidence in the public health agencies to decline --

Q Okay.

A -- that does have an impact on the safety of the American people.

Q Okay. But is there a distinction in your mind between that kind of risk to safety, which has to do with public perception and the ability to rely on the FDA in the future, and an immediate threat to safety with respect to a specific vaccine, for example, like COVID?

A And a recipient of a vaccine, of course those are different things, yes.

Q Okay. And do you think in the case of COVID vaccines that there was ever -- that --

A And then -- so, by the way, what I'll say, though, is that for the examples I gave under the Trump administration, my major concern there also was the hit to the credibility of the FDA.

Q Yeah.

A Not that these fundamentally ineffective treatments necessarily led to major safety concerns for recipients.

Q Right. Because if you took hydroxychloroquine, you're not going to die most likely. You're just not going to help --

A Well, it turned out over time that when a lot of hydroxychloroquine was given, there were more side effects than people expected.

Q Okay.

A But nonetheless, that's right. So I'm putting these on roughly the same level --

Q Got it.

A -- where, to me, the concern is not that the political pressure is going to cause a person who goes out and gets a vaccine to have a worse outcome because they got the vaccine, but I do think that a perception of political pressure, whether it exists or not, will affect the public's confidence in the public health agencies, which will then also have an impact on vaccine hesitancy.

Q Okay. Because if they don't trust the FDA then they're not going to take the next vaccine when we have another pandemic, right?

A Right. And as we said before, right, the same people who believe that COVID

vaccines are causing side effects or deaths or whatever, they're open to that proposition because they don't trust the public health agencies. If they trusted the CDC and the FDA, they wouldn't believe that.

Q Right.

A And so vaccine hesitancy is, at its heart, built on the credibility of the public health agencies, as well as other things, so it's not just up to experts like me.

Q Right. And, you know, here's another level of analysis that I'm curious about your opinion. So the FDA is regulatory agency, it's going to give recommendations to Americans based on highly technical expertise, that frankly no one can understand if they're not a doctor or an expert. But above the regulatory scheme, the FDA is Congress itself, and the people that are organizing this interview here today.

And, in theory, we're here to try to get information from you that will help in terms of the FDA being -- any kind of legislation that might affect the FDA in the future.

But also, like Congress, in my opinion, and I'm curious about yours, is not completely outside of that process of either undermining or supporting faith in the FDA. Like, do you have any thoughts or opinions that you would like to share about what this investigation itself, and the information that is derived from this investigation and sent to the public, what affect that could have on this problem that we might see in the future with people not trusting the FDA?

A So, my sense is that there are people who already are not trusting the public health agencies, which is why it is that we see people believing things that could not possibly be true.

And so, I think it's important for the people in charge of the public health agencies and the people who interact with them, to keep the importance of that credibility in mind.

And I think that is a lesson learned that I don't mean to be applied more to one party than another. It's -- and, of course, it would be unrealistic to imagine in a pandemic that politicians would have no interest in these kinds of decisions when people are dying due to a disease.

But my goal here obviously is to answer questions truthfully and to help as a citizen, who has been asked by Congress to provide whatever information I can, to help figure out what happened so that we can do a better job next time.

So I'm approaching it from that perspective, which is why I'm a -- I'm here voluntarily. The --

Q So could you answer that question that you just posed to yourself? I mean, what if anything could the FDA do differently or --

A Well, so the one thing I suggested to [redacted], and I do think that this would help, is if the FDA needed to provide more detail about the nature of their evaluations of products that are made available, especially under EUA, I think there's something about the EUA process where the standard for an EUA is, of necessity, somewhat ambiguous. In an emergency, it may be necessary to get something out with very, very little data if there really is no choice, and that's a decision that needs to be made at that time.

And so, I don't think one can change the way that the EUA standard is written, although other experts might disagree. But what I do think is that when the EUA standard is used, the public physicians, actually even Albert Bourla, who tweeted out that the Pfizer vaccine had been approved rather than it had been authorized, don't really always understand the difference between an EUA and a BLA.

And, in fact, many of the questions that you guys are asking me here today come down to what does it mean if something is authorized versus licensed, what level of confidence do we have in the authorized versus the licensed product, and so forth.

And it seems to me as though just because the EUA process has this intrinsic ambiguity, it also makes it a process that whether a politician intends to or not, can be perceived to be influenced by politics.

And so if there were a way of making sure that when an EUA is used, the standard that was applied for that EUA were made clear that the FDA's true assessment of why it is that this is an EUA and not a BLA were made clear, then the public and physicians and other public health authorities would have more to go on.

So, for instance, if under hydroxychloroquine, rather than simply say we think that the product might be effective and that the known and potential benefits outweigh the known and potential risks where somebody might say, well, this is a person who might die anyway, so any theoretical benefit might outweigh any risk --

Q Right.

A -- somebody could look at that standard and say that hydroxychloroquine met that standard.

Even though once the FDA authorized it, it almost certainly shouldn't have been authorized based on what was known about its likely efficacy, and the fact this was an antimalarial drugs, and antimalarial drugs don't have, in general, efficacy against these kinds of viruses.

And so, if the FDA would've been -- would've needed to say with that authorization, Well, we actually don't have any evidence for efficacy, and we're authorizing this because we see this as a Hail Mary pass, then people might have viewed that authorization differently from if it just came through as, the news report today, the FDA authorized hydroxychloroquine. And then people go out and seek a drug that isn't helping them and maybe keeps them from seeking things that might actually help them.

And so I do think that finding a way to convey better and stronger information

about the nature of any individual EUA could go a long ways to reduce the temptation, if there were temptation for politics to influence the outcome.

But I also think that it would go a long ways to reduce a perception of political interference as well, because if there -- if the data were very weak, and the FDA were forced to say what the data were in that sense and divide it up in this way and provide a clear explanation of why it doesn't meet the standard for licensure, why is it an EUA instead, then it would make the EUA a less-tempting target for -- well, for politicians, but then it also would decrease the likelihood that people would mistakenly believe that the process had been politicized.

Q Right. Do you have any concerns -- this reminds me of another question that, have you been following some of the work of this committee and other committees in Congress that seek to deregulate lots of the American bureaucracy, but in particular, the FDA and other agencies? Have you followed that effort?

A Not closely, but -- and, again, if you're asking for an opinion --

Q I am.

A Okay. So if this is an opinion, I'm safe under oath here, right? I believe that regulation is a very important aspect of the American economy that distinguishes the U.S. economy from the economy of many other countries, because what regulation allows is for people to know the facts about the products that they're using; it allows, well, for instance, people who buy stock to know the facts about the company they're buying stocks in; it helps us assure that various safety standards are met. If you buy a car without regulation, you don't know, for instance, if the airbags are going to work or not, and but maybe you care about that.

And so, confidence in the economy does depend on having some level of regulation, but it also requires on having very clear communication that surrounds what

that regulation is. And so, I feel as though I think getting rid of regulations for the sake of getting rid of regulations will probably harm the U.S. economy, although I'm not an economist. I do have an MBA.

Q I'm talking about the FDA in particular. Like, what if we had no FDA when COVID hit, and how would -- how can you imagine that the American people would've navigated this very technical cost-benefit analysis with respect to COVID?

A Well, we wouldn't have vaccines if there were no FDA, because without an FDA there would've been no basis for a company to make credible claims that a vaccine worked. And so, vaccines or purported vaccines that didn't work, would have just as easy a time market -- being marketed as vaccines that did.

Q So do you think that the danger to the American people, if there is any, is more from the people who work inside bureaucracies like the FDA, the sort of technocrats who are making decisions based on their expertise, or from some other place outside?

A I mean, there are plenty of dangers to the public, for sure. And so, maybe I can ask you to be more specific. I don't think that the people who were working at the FDA, by and large, are a major hazard to the American public, and yet you're giving me a very vague and anonymous comparator. So it's hard to answer the question specifically.

[redacted] Okay. I have no more questions, and we can go off the record.

[Discussion off the record.]

[12:29 p.m.]

[redacted] We can go back on the record.

BY [redacted]

Q Let's see. Now, Dr. Krause, I know that we touched on this a little bit because you've clarified before that Dr. Marks had brought in a group of Israeli physicians to review data by the FDA -- or to review data, but it had not been reviewed by the FDA. Can you clarify what you had said? I think you said the Office of OV --

A Right. So at the advisory committee meeting on September 17th, where the boosters were discussed, data that had not been reviewed by the Office of Vaccines was presented to the advisory committee. And if this had been a BLA, surely the Office of Vaccines would've reviewed those data.

The question always is, in the advisory committee process, you know, what are the expectations of the advisory committee members, and how does this kind of data that the FDA hasn't had a chance to carefully review, how should it play a role in ultimate decisionmaking.

Q Did it play any role?

A Well, in the end, the advisory committee recommended against the full authorization of boosters for everyone over age 16. They limited their authorization to the elderly and people in certain -- certain jobs.

The immunocompromised had previously already had a booster dose authorized for them, and so, the authorization at that meeting added the elderly and some additional people, but was not an authorization for universal boosting which is what Pfizer had requested and what had been announced previously by the Commissioner, the CDC Director and the NIH Director, NIAD Director, as well as the President.

Q And whose idea was it to bring in the Israeli physicians? Was that a decision

made by Dr. Marks, or was it made by someone else, you know, above him, to your knowledge?

A To my knowledge, what had happened prior to that advisory committee meeting was that Dr. Gruber, who normally would've been in charge of the advisory committee, was relieved of responsibility for that advisory committee by Dr. Marks.

And so, it would be reasonable to assume that it was Dr. Marks who brought in those speakers, but -- but I do not know.

And I'll point out, right, it was -- and I think I said this before, that the data had not been reviewed by the Office of Vaccines. It's quite possible that Dr. Marks or someone else at the FDA had seen the data.

Q Okay. Perfect.

And kind of switching gears back to what we were talking about before during our first hour, in your position at the FDA, specifically within anything with the vaccine approval process for a BLA or an EUA, is it fair that -- or, I'm sorry. Scratch that.

Did you exercise any discretion, like, was it ever permitted by your role for licensing, in licensing any of these products?

A I have to understand what you mean by "discretion." I'll give you a partial answer, and you can tell me if that covers what you need. So, for example, early in the pandemic, the FDA issued guidance documents that described what it was that the FDA would expect to see for a licensed COVID vaccine, and then later in the pandemic, for an EUA for a COVID vaccine. Excuse me.

And so that involved interpretation of the underlying regulations in the context of FDA's understanding of vaccines and the situation, and those guidance documents that I think ultimately were signed off on by Dr. Marks.

So, if by "discretion" you meant that the FDA had the ability to define how it was

interpreting the regulations, to me, that's an intrinsic component of what the FDA does, is, if there's a regulation where they need to provide guidance to sponsors, it needs to be done in context, and that was the purpose of providing those guidance documents.

But of course, once the FDA provided that guidance, they, in essence, take any discretion away from themselves. And so it was important to put those -- that guidance out early on in the pandemic so that everybody would know what to expect.

And of course, the guidance documents themselves are subject to public comment and to further discussion as well. And so, it's not as though the FDA just picks something, puts it in a guidance document, and that's the final word.

Q No, that does answer my question. That's exactly kind of what I was wanting to know.

And can you explain, you know, based on some research -- cursory research I had done, anything, what would be important to see in maybe post-vaccine rollout studies? Like, what kind of role did you play in reviewing post vaccine rollout studies and why they're important?

A So, are you talking about post-vaccine rollout studies after the original EUA authorizations in December 2020?

Q Any of them. EUAs or BLAs in general.

A Well, so the FDA, of course, was very interested in making sure that there was good and increasing safety data on these vaccines, because that obviously was something that they did not have as much of, as one would have for a BLA right at the time that the EUA was -- was done.

So some of these studies were conducted by the company, and some of these studies were done by FDA and CDC. And of course, international health authorities were also doing safety studies as well, and so FDA needed to keep tabs on those.

In addition, of course, there were missing data on pediatric use, and so it was important to understand how well these vaccines might work in children as well. And so those -- those studies needed to be designed and executed once the vaccine was made available.

There were important studies that were -- were done, although perhaps not quite under FDA's authority, to look at how well the vaccine was working during that rollout, and to look over time at what was happening.

And I had the opportunity in the article that was published in The Lancet in early September 2021, to summarize almost all of those studies. So I can tell you a little bit more about that paper now if you want --

Q Yeah, we can talk about it.

A -- or you may have a separate question about that.

Q Absolutely. I've got it actually right here. We'll enter it as exhibit 1 for the record.

[Krause Exhibit No. 1.
Was marked for identification.]

BY [redacted]:

Q There you go, sir. And if you want to continue on with what you were just saying in reference to this article, feel free, and I can jump to any of my other questions about this.

A Sure. So -- so what we did in this article was we looked at all of the data that had been published on how well vaccines were working. And so we looked at every published study that included information, both about vaccine efficacy against severe disease, and vaccine efficacy against mild disease.

And what I can say is, if you look at the co-authors, there's a long list of them, and

these include, well, myself, they include Dr. Gruber, they include colleagues from the WHO, they include people from other countries who had contributed to WHO consultations on this matter, and they also include people from -- who participated in the Cochrane Collaboration.

And the Cochrane Collaboration is a highly respected group that aggregates data from clinical studies in order to provide advice to doctors about the nature and quality of -- of the medical literature and what conclusions can be drawn from that.

And so, this was a fairly highly trained and experienced group of co-authors, also included people who, in my view, are some of the best statisticians in the world.

And together we looked at every study that had been published that could possibly lay -- provide any -- any insight into whether vaccine-induced immunity was waning over time.

And, of course, there had been some studies suggesting that vaccine-induced immunity was waning, and this was one of the big questions that came up in this issue of whether or not a booster might be needed.

Because in deciding that a booster should be given, it's important first to figure out, is the booster needed? And then to figure out, you know, does it work, because you really need both of those. If it isn't needed, then "does it work?" becomes a meaningless question.

And so this was just looking at these -- these studies that had been published. And you can look at these -- these four figures here that sort of summarize the findings of the paper, which is that, on the X axes there, you have vaccine efficacy against any infection, and at each of these four graphs on the Y axis, you have vaccine efficacy against severe disease -- or against -- so we have any disease versus severe disease.

And what you can see is that in panel A, even in vaccines that had fairly much

lower efficacy against mild infections -- that's the 26 reports to the left -- the efficacy against severe disease was still quite high, was close to 90 percent, based on a study aggregation method -- actually, two different methods were used to put all of the data together.

And, of course, if the vaccine continued to work very well even against mild disease in these studies, they also continued to work very well against severe disease.

So this is showing that vaccine efficacy in all of these reports together was retained against severe disease as being quite high.

And then panel B shows that regardless of which variant you looked at -- Alpha, Beta, or Delta, and the Gamma perhaps a little bit lower, but for Alpha, Beta, and Delta variants especially, which were the only ones which had been published at that time, vaccine efficacy against severe disease was retained as being very high, even if it appeared that vaccine efficacy against mild disease had started to decline.

Then panel C shows that this same finding is true regardless of what kind of vaccine it is.

In the U.S. we only had mRNA vaccines at that time, and we had the J&J vaccine which are the vector vaccines, but what you can see is, even for other kinds of vaccines which were used in other parts of the world, the vaccine efficacy against severe disease was, in general, retained much better than efficacy against milder disease.

And, of course, you see the inactivated vaccines were the least of the vaccines against mild disease or severe disease. But you see the mRNA vaccines, especially when you put all the 32 studies on mRNA vaccines together, you could see that when you aggregated that data, that these vaccines were continuing to work well, no matter where in the world you were looking.

Q So ultimately that's what you and these other doctors were trying to argue in

your article, that because the efficacy remained high after the initial vaccines, against severe disease, that the booster would not be needed? Is that correct?

A Well, so, that was the inescapable conclusion, that a booster was not going to have a significant impact on people's protection against severe disease.

And then the final panel, some people had said, well, people who got vaccinated early in the pandemic were having greater infection rates than people who were vaccinated later in the pandemic, suggesting that immunity might be waning.

But the difficulty with all these kinds of studies -- and here you see there was also no difference in impact on severe disease -- but that difference could also have been because people who were vaccinated early in the pandemic were, in general, people who were already perceived to be at higher risk, because we tried to vaccinate the higher risk people early in the pandemic.

So if that -- the difference even in mild disease there could've been just due to differences in who was vaccinated.

So what's interesting is that we actually cited early data from the Israeli study that was ultimately presented at the vaccines and related biological products advisory committee, even in this study, which had a very small amount of data by the time we wrote this article, had a little more data by the time they presented it at the vaccines and related biological products advisory committee.

And we pointed out that this study actually could have significant biases in it that were making it look like a vaccine was needed when it wasn't.

And what that Israeli study had shown -- well, reported, was that if you looked at people who had received a booster dose, they seemed to do better than people who didn't receive a booster dose.

Q And you're saying that study was biased?

A Well, we pointed out that that study could be biased.

Q Could be.

A What's interesting is that just a month or so ago, there was a letter to the editor of the New England Journal of Medicine by a group from San Francisco, which pointed out that this and several other studies from Israel were biased, because they were able to go back and look at some of the primary data, and they showed that the people who happened to get booster doses in Israel were fundamentally different from people who did not have access to booster doses.

And the people who had access to booster doses were people who were perhaps wealthier, had access to better healthcare and other things.

And you could find things that had absolutely nothing to do with COVID that also distinguished those groups, which is proof of -- in that study, of what we call healthy vaccinee bias, which means that if the people who get the vaccine, the booster, are fundamentally healthier than the people who don't, it makes it look like the booster helped those people.

But in fact -- so this was one of the main studies that had been relied upon in deciding that boosters might be needed in the U.S.

And what was interesting was that the advisory committee, in considering this, did not give huge weight to that, but nonetheless that was something that we pointed out in this article.

So the conclusions that we came to were that -- that a booster probably wasn't necessary in most people. These studies can't rule out the possibility there are some people whom a booster would help, and indeed, probably did help the immunocompromised and older adults.

Although the immunocompromised, it's a hard question. They were getting

COVID at a very high rate, but one of the reasons is because they didn't respond well to the vaccine in the first place.

And so an additional booster might not have helped them that much either, but it was certainly a reasonable thing to try.

[redacted] Can I ask?

[redacted] Go ahead.

[redacted] Why would -- in your experience, why -- either you know the answer or in your experience -- why would the advisory committee not take into account the potential for this biased model, as you put it?

Dr. Krause. Well, but they did, in the sense that they ultimately came up with a recommendation not to recommend booster vaccination in everybody.

[redacted] Okay. I --

Dr. Krause. So when they met, they actually came to conclusions not so different from the ones that my co-authors and I had come to in this paper.

[redacted] Okay.

[redacted] You also -- oh, I'm sorry. Go ahead.

Dr. Krause. Can I just finish?

[redacted] Yeah.

Dr. Krause. There were sort of just a couple of things that we pointed out as consequences of this. And, of course, this paper was published on September 9. This was actually based on a meeting at the WHO that was held on August 13th that brought together experts from around the world.

I mean, you can see that this collaboration of people who were putting this data together didn't arise out of nowhere, but it really came out of a lot of robust and international scientific discussions to try to come up with a clear-eyed answer of what the

data was showing.

And so, we concluded that probably boosters were not needed for most people. We pointed out that if given that boosters were not going to help many of the people who might otherwise take them, that giving doses of vaccine, regardless of where in the U.S. or in other countries or whatever, that one would be using as boosters as primary vaccination shots would clearly save a lot more lives, because the first two doses of vaccine is really what it took to get people that high level of protection, and that high level of protection against severe disease.

So we pointed out that we could save more lives if -- if the booster doses -- well, if doses that people wanted to use as both boosters were doses that might otherwise be unnecessarily used as boosters, were purposed differently.

And the other thing we pointed out was that, given that difference, it seemed that to the degree that public health authorities, the media focused on boosters, that actually might undermine confidence in the original vaccines in the first place.

Because if the message is, you need to go out and get a booster, and the message also is, you should get your first two shots, you're sort of telling people, well, these first two shots aren't expected to work that well.

And so -- so the booster message may actually have even undermined, to some degree, the message that was clear, which was that the first two doses were going to be highly protective and would save lives.

And so, these were the points we made in the article, and honestly, I think these points are, you know, turned out to be correct because it was based on very solid science with good scientists, excellent scientists, who did a very comprehensive study.

So this is not really an opinion piece. It's -- it's data and an effort to then figure out what the sequences of those data are.

BY [redacted]:

Q And you also mentioned, I see like at the bottom of the first page of this article, you noted that there could be risks if boosters are widely introduced too soon. Is that concurrent -- or is that kind of what you were suggesting before, that the booster message could undermine the original vaccination messaging if people weren't all vaccinated yet, or were there possibly other risks if boosters were introduced to the public too soon?

A I don't recall whether we said that explicitly in this article.

Q Oh, I'm sorry. It's at the bottom of page 1, and it's a piece of -- it's at the bottom of page 1 in the first column. It says, Although the benefits of primary COVID-19 vaccination clearly outweigh the risks, there could be risks if boosters are introduced too soon or too frequently, especially with vaccines, that can have immune-mediated side effects, such as myocarditis, which is more common after the second dose of some mRNA vaccines or GB Syndrome -- I can't fully --

A Guillain-Barre, right.

Q Yeah.

A Right. Just so -- so I couldn't remember if we'd raised those specific outcomes. But yeah, so the myocarditis at that time was believed to be potentially immune-mediated, which might have suggested that the more you stimulated someone's immunity, the greater the risk of myocarditis.

Likewise, Guillain-Barre syndrome is an immune-mediated side effect, and so, there might have been some risk that with additional doses of vaccine, one might have an increased risk of that.

The Guillain-Barre syndrome was observed mostly with the J&J and Astrazeneca vaccines, which weren't used very much in the U.S., and so it's not clear whether that

came to pass. It turned out with additional data that additional doses of the -- of the mRNA vaccines didn't lead to a higher risk of myocarditis.

Although there was still some small risk of myocarditis even with additional doses, so -- but time there was -- at the time there was no way to know whether, if one were to give a lot of extra doses of mRNA vaccines, what the safety of that would be, and so this was just a cautionary note.

Q And you had mentioned the J&J vaccine. Can companies like Johnson & Johnson and Pfizer and Moderna ultimately be held liable, like, from American citizens if they suffered those types of injuries from a vaccine produced by them, from your experience?

A So --

Mr. Thomas Krause. If you know. It's a legal question.

BY [redacted]:

Q If you know. From your experience.

A So it is a legal question, and so I'm not deeply familiar with the liability laws, and yet, one of the things that makes these vaccines feasible are the protections under the rules that make EUAs feasible in the first place.

And so, whether the company can be held liable or not, I'm not sure, but I believe that the companies have some protections against liability under these circumstances.

Q And kind of going back to this article, too, do you believe that the data collected since you published this article, do you think that vindicates the concern you expressed in 2021 which may, at that time, have not been popular? People, at that time, I think people were expressing the need for boosters, but it sounds like you and Dr. Gruber and some of these other physicians might've been in the minority at that time for thinking that boosters weren't needed? Am I wrong in understanding this?

A Well, at the time that we published this, at least the advisory committee ended up mostly agreeing with what we were saying.

You know, the difficulty is that at that time, we had -- well, the Delta variant, which had people very concerned because it seemed to be causing severe disease. Although, as you can see from this paper, not so much in people who had received the vaccine, but was causing severe disease in people who had not been vaccinated.

And there was some worry, I would say, among people who hadn't done this careful an analysis that if vaccination efficacy was going to wane against mild disease, that waning efficacy against severe disease might be far behind -- might not be far behind.

And so the worry there was that -- that the Delta virus, or, perhaps, ultimately the Omicron virus might change the equation.

The -- my own opinion at the time was that it was unlikely that that would be an issue because it seemed that longer-term protection was mediated by cell-mediated immunity, which is a kind of immunity where the cells in your body attack cells that are infected with the virus and controls the infection that way.

That's different from what scientists call humoral immunity, which is where antibodies attack the virus and can sometimes control the infection even before it gets started.

Q Not to interrupt you, but which of those two is what is commonly referred to as natural immunity, do you know? Like, I know how everyone's just like natural immunity can be equal --

A Both.

Q They're both?

A Both.

Q Okay.

A So -- so natural immunity is a term that as I understand how it's been used, is simply meant is simply meant to describe the immunity that somebody has after they've been infected.

And after somebody's been infected, they have a combination of antibodies, humoral immunity, and cell-mediated immunity.

And so, the -- it seemed the humoral immunity was more important in protecting against mild disease, and the cell-mediated immunity, once the humoral immunity had waned, was more important in protecting against severe disease.

And so, if you have only humoral immunity, you would've been protected against both, but it's just that the cell-mediated immunity would take over once the humoral immunity started to wane. And people would have both anyway that would contribute to controlling an infection.

So, that's a biological explanation for why it is that people had reduced experience over time, reduced efficacy against mild disease, because the antibodies started waning, but the cell-mediated immunity did not. So that continued to protect them against severe disease.

So it's even deeper immunology then to think about what it is that is being protected against by humoral versus cell-mediated immunity. And the cell-mediated immunity was directed at parts of the virus that didn't change as much, and so, the cell-mediated immunity is longer lived than the humoral immunity and is much more resistant to variants because those parts of the virus aren't changing when new variants evolve.

Q So those -- the natural immunity, which obviously covers both the cell -- the term just escapes me. Is the cell immunity versus the --

A Humoral.

Q -- humoral, both of those fall under the category of natural immunity?

A But they also both fall under the category of vaccine-induced immunity. The mRNA vaccines also induce both.

Q Okay. And do all of -- I guess any of the data that was collect over the last -- or over the last 2 years, does that -- I don't know the word I'm thinking of is -- like, does that kind of fit in and agree with this article that you've published as far as the need for boosters?

A Overall, the data is pretty consistent with what we published here and is pretty consistent that the cell-mediated immunity protects people against infection.

Now, over time, even the cell-mediated immunity can wane, but certainly at this time, it was very clear that there was no need for boosting --

Q And --

A -- in most people.

Q And you said the people that it would be needed in -- or at that time, the data suggested that it would be needed for the elderly and the immunocompromised. Were those the two main categories that were needed?

A Those are the main categories where the data suggested that a booster might save lives, yes.

Q Okay. And then I'm briefly going to touch on something before I switch gears again because we've already discussed a little bit about the September 17th advisory committee meeting.

Do you recall during that meeting conveying skepticism about Pfizer's possible misrepresentation of data or withholding any data?

A So "misrepresentation" is a strong word. During that meeting I did have an

opportunity to briefly, for probably just 2 or 3 minutes, talk about one of the studies that Pfizer had presented at the meeting. And this was also a study in which Pfizer claimed showed waning of immunity.

And this was also a study which had not been provided to the Office of Vaccines at least, for review prior to that meeting. So this was an analysis that -- I presented an analysis during this meeting that I generated on the fly during the meeting.

But it seemed as though there were inconsistent results within different pieces of data that were presented there.

Pfizer requested that the authors of the studies come on, and the authors insisted that they had used completely standard methods to generate those results, but nonetheless without having the ability to understand exactly how those results were generated, without having the ability to actually review those data in advance, it's -- even to this day, it is not clear to me that their analysis was correct.

Q Did that happen often throughout this time in the pandemic where maybe any of these pharmaceutical companies if they had presented data -- was this a rare occurrence that, like, Pfizer presented data that the FDA, or at least the OVRR had not had the chance to review prior to, that you guys were expected to?

A So -- so the first time I saw changes in the type of data that were being presented to support the EUAs, was with the EUA for the immunocompromised, where that EUA was based almost exclusively, at least for the Moderna vaccine, on published articles.

And one of those published articles was actually not with the Moderna vaccine. I believe it was with the Pfizer vaccine. So I think there was one article about the Moderna vaccine in the immunocompromised with a relatively small number of people.

And yet, I, at that point, given the situation in the immunocompromised who

otherwise did not have much that they could use to help them, and the fact that many of them were ending up in intensive care units if they got infected, in spite of the fact that they'd received two doses of vaccine, it seemed almost as a Hail Mary that it was reasonable to give that specific population a -- an opportunity to get another dose of vaccine because they otherwise had nothing.

And so, I think that although that EUA was based only on published papers, it did meet the EUA standard. It was reasonable to assume that the -- well, that it might be effective, of course, which is a very low standard, and that the known and likely benefits, or known -- not likely -- known and possible benefits exceed the known and possible risks.

Well, the known and possible risks in that population were low, but the possible benefit was potentially life-saving because so many of these people were getting very, very ill.

And so that was a population in which it seemed like the EUA standard was met even when the quality of the data was not at the level that the FDA would've requested for a BLA. So that appropriately was an EUA.

Q Who made that determination, though, to your knowledge, that even if the data wasn't as -- the word you said, like if it wasn't as, you know, broad of a data set, or if it wasn't something that you all didn't get the chance to evaluate, it was just based on published papers -- how often did that happen, and also, who made the determination that, yep, just because we're going to rely on these published papers for, you know, our decision, an EUA would be given?

Mr. Thomas Krause. You can use your judgment on deliberative process privilege on that one.

Dr. Krause. So --

BY [redacted]:

Q You mentioned the Moderna ones. That's why I was thinking if there were other instances.

A So -- so that particular one was not reviewed at all within the Office of Vaccines, I'll say that. And so those decisions were made -- that final decision was -- so -- but I actually don't remember who signed that.

Q Okay. And then, but other than that instance with Moderna where you had to rely on -- or I guess where the FDA, not saying you necessarily, but whoever would make that final decision on if an EUA should be granted based on the data presented from these published papers, but not from, you know, your office's ability to study and evaluate, you did it yourself, how often had that happened to your recollection, or was that the only time?

A At that time that was the only time I was aware of, but then of course at least some of the data that was presented in favor of boosting the more general population also was of a different standard.

Q And it was of a different standard for the EUA or --

A Well, so it's in -- Pfizer originally submitted the booster dose as a supplemental BLA, with the idea that that might be included under their license. But in the end, FDA authorized the booster in the elderly and in people with certain occupational situations as an EUA.

Q What's the difference? And this is purely coming from, again, as we've discussed, like none of us are doctors, but like the difference between a supplemental vaccine under the BLA versus an EUA, like, is there a difference in those considerations?

A So a BLA is still a license application. So a supplemental BLA has to reach the licensure standard whereas the -- which is as I described, right -- safe, pure, and potent -- whereas under the EUA, it just needs to meet the EUA standard, which is, may be

effective and known and possible benefits outweigh the known and possible risks.

And so, the FDA somewhere in there, and I do not recall where, decided that this booster, even just in the elderly, could be authorized but not approved because they didn't think that the data met the standard for approval.

Q Well, I'm going to switch gears a little bit, going back to a little bit about the BLA approval process, and this is going to go into talking a little bit about, during the summer of 2021, do you recall working with Dr. Gruber on a timeline update for the Pfizer COVID-19 BLA in July of 2021?

A I do recall that, yes.

Q Okay. And we're going to admit this as exhibit 2.

[Krause Exhibit No. 2.
Was marked for identification.]

Dr. Krause. Can I just take like a 3-minute bathroom break?

[redacted] Absolutely, of course.

We'll go off the record.

[Discussion off the record.]

[redacted] We'll go back on the record.

BY [redacted]:

Q Going back to where we were just getting ready to discuss a time in July of 2021 --

A Sorry. Let me mute this.

Q Oh, of course.

A It's a junk call anyway, a scam likely.

Q I get those too.

A All right.

Q We were just getting ready to talk about a time when you and Dr. Gruber were asked to provide a timeline update for the Pfizer COVID-19 BLA in July of 2021, and I had just passed out what we've marked as exhibit 2.

And this is a previously FOIA'd email from Dr. Marks to Dr. Gruber -- oh, I'm sorry. One moment, actually.

A Is that the right one?

Q I'm going to make sure it is.

Oh, yes, this is correct.

Okay. So this is a timeline that you all had provided, and it's marked at the bottom, Bates-stamped FDA-OC-2021-5574-000355 through 000357.

Do you recall being copied on this email -- or I'm sorry -- yes.

A Yes, I do.

Q In this email, Dr. Gruber also copied Mary Malarkey and Steven Anderson. Who is Mary Malarkey?

A Mary Malarkey, at that time, was the director of the -- of OCBQ, which, if I'm remembering the acronym correctly, is the Office of Compliance and Biologics Quality, and I described the function of that office earlier.

Q Yes. And then who is Steven Anderson?

A At that time, and possibly still, Steven Anderson is the head of the Office of Biostatistics and Epidemiology, another office which I described earlier today.

Q Do you know if either of them are still working at the FDA?

A I know that Mary Malarkey retired because she invited me to her retirement party. I do not know if Steven Anderson is still at FDA or not.

Q Why, to your knowledge, would they be copied to this email on the timeline for the BLA, out of curiosity, if you're aware?

A The -- the two of them would've contributed to the development of the timeline, because the review of the BLA would've depended -- or did depend on activities in multiple FDA offices. So the full review of the BLA depended on, for instance, a benefit-risk epidemiological analysis of the myocarditis, which was being spearheaded by people in Dr. Anderson's office.

And the approval of the BLA -- not -- yes, the approval -- sorry, I'm using the correct word here -- would've depended, or did depend, on activities within Mary Malarkey's office as well in terms of certain aspects of the chemistry, manufacturing, and controls review, inspections, and things like that.

Q And to this email, Dr. Gruber had attached a document that was the updated Pfizer COVID approval timeline, and it started in May of 2021, and ended on September 15th of -- September 15th, 2021. Is that correct?

A That's correct.

Q Now, in her email -- and feel free that if you need to take any time to review it as we're walking through it, you absolutely can do so -- in her email, she had wrote that the bar graph reflects target completion dates. Some of these pending timely sponsor response to information requests which we have been and are sending as we review the info contained in the submission.

Can you explain what that means?

A So maybe to explain this graph, I need to take you back in time some weeks, and explain what the action due date is and all of these things in the context of the BLA --

Q Absolutely.

A -- which will give you sort of a bigger picture of what this is, which then may enable you to ask more specific questions.

Q And while you walk us through that, I'll actually take this moment to

introduce another email exhibit that I think it includes a memo that maybe will help you with what you're possibly going to walk us through.

A Sure.

Q And feel free to get started if you would like. I'm going to admit this into the record as exhibit 3 --

A Sure.

Q -- while I get it, but feel free to start.

[Krause Exhibit No. 3.
Was marked for identification.]

Dr. Krause. So what you can see on the left here is that the first part of the BLA submission came to FDA on May 6th. The so-called roll 2 of the BLA's mission, which means that as of that point the submission was complete, came in on May 18th.

Now, according to the normal Prescription Drug User Fee Act deadlines for a priority review -- and this is the requirements that FDA agrees to -- a priority review like this would be completed within a total of 8 months.

So, of those 8 months, the first 2 months are consumed with a filing review to determine whether the application is materially complete, and the remaining 6 months are spent on the review.

So if you take those 8 months from the May 18th date that the BLA was considered complete or was considered completely filed, when Pfizer asserted that everything had been submitted, that would give a -- a PDUFA, which is how we say Prescription Drug User Fee Act, a mandated action due date of January 18th, 8 months from May 18th.

The -- it was clear, based on the COVID situation, that January 18th would be -- was longer than what we thought -- and this would be Dr. Gruber and I -- would want to

wait to take action -- final action on this BLA.

And so -- and I do not recall exactly how this happened, but we reached an agreement with Dr. Marks that we would target completion in mid-October. And I can't remember exactly when we reached that agreement with him, but it would've been -- well, sometime probably in late June, give or take.

Dr. Marks agreed with that, but then, not long afterwards, he came back and said, I think mid-October is taking too long for this, I'm worried about -- whatever he was worried about. I don't know what -- I'm quoting something I don't know that he said, but he said, Can you do it faster than that? And he suggested that we try and complete it by September 15th.

And so, Dr. Gruber and I went back and we talked with the people in the Office of Vaccines, as well as the people in these other offices and asked whether they thought if we worked very hard at this, we could finish it by September 15th.

And keep in mind that when we're telling Dr. Marks that we can finish it by September 15th, that doesn't mean that's necessarily how long it must take, but we assumed that he was going to take whatever date we gave him, and he was going to tell other people that it will be done by that date. And other people might do things relying on it being done by that date.

[redacted] Who might those other people be?

Dr. Krause. Hard to know but people outside the center perhaps who maybe needed to figure out how to distribute vaccine, for instance, or things like that. It's -- it's -- so -- so we were nervous about providing a date that we were not 100 percent sure that we could meet.

And so we, after going back to the various people within the office and in other offices, gained confidence that we could agree to complete the review by

September 15th.

Well, not long afterwards, he came back again and said, we are going to need this to be done faster than September 15th but on an earlier date. And based on that, Dr. Gruber and I, again, looked to see what might be feasible, but of course we already had an idea what everybody was telling us about what they thought was feasible, and we came back to him and told him, based on the memo that is exhibit 3, which I don't think I have a copy yet of --

[redacted] Oh, I'm sorry. It's over there.

Dr. Krause. Oh, there it is. There it is. Okay. There it is, yes -- which we sent on July 15th, explaining why it was why we didn't think we could promise that this could be done faster than September 15th.

So -- and, of course, this was -- but of course the timeline that it actually would take to complete a review was dependent on many things that were outside the control of the Office of Vaccines, including what might happen in these other offices, including, in particular, very often during a BLA review, there's very robust communication between the reviewing offices and the sponsor.

And so, in fact, what Dr. Gruber's email that you asked me about says, was that there were some pending sponsors requests for information.

So in other words, FDA had sent information requests to the sponsor to interpret what Pfizer had sent in, and we did not yet have answers back from Pfizer on those information requests.

BY [redacted]:

Q And those were needed in order to determine the --

A Well, those were needed to complete the review, but the concern was there would be additional information requests too, and the Office of Vaccines had no control

over how long it would take Pfizer to respond to those.

And so, this just gets to this point where it was very difficult to predict in advance how long it would take to complete the review and -- but when asked to promise a date, obviously that had to include a worst-case scenario in terms of what else needed to be done, how long it took to do the overall benefit-risk analysis, coordinating the dozen or so different reviews which needed to be done in order to complete the BLA review, as well as then what the company was going to provide in response to requests for information and how quickly they would be able to do it.

Q And who was asking you to make a promise on a deadline?

A Dr. Marks was requesting that we -- that's what the ADD is. So it's an -- in this case, it's -- the action due date, as entered in the computer, would've been January 18th. But the question is, what is the intent, when are we actually going to get this done?

And so Dr. Marks was requesting that it be done sooner than September 15th and -- but he did not provide a suggestion of how quickly he wanted it done. But he said sooner than the 15th.

Q And is that ADD, that action due date you've described, is that something that's normally publicized to, you know, to the American public, or is that something that's, like you said, something for your all --

A That's intended to be something that is kept within the FDA.

Q Was it, in this situation, to your knowledge?

A I do not know whether that was kept within the FDA. Although I note that CNN, in Marion Gruber's email to Dr. Marks, announced on that very day -- and actually, I saw this email from a Judicial Watch F-O-I, so I actually was able to find the CNN article where they said that it will be completed within 2 months of July 15th, which is a pretty

sure way of saying September 15.

So it seemed that the September 15th ADD, as had been agreed prior to this email with Dr. Marks, had found its way outside of the center.

Q Is that -- was that common, or was that something that -- was that happening, where this information about a projected timeline for when the vaccine would be approved, was that common, or was that -- did that seem like a rare occurrence to you for your time in the FDA?

A So I -- I would say that was -- from my time at the FDA was very rare. Within COVID, I'm less certain, but I can't give you a specific example.

Q No, that's okay.

[redacted] Do you have a personal opinion on who -- on how or who may be responsible for this ADD-projected date being leaked to the public or the media?

Dr. Krause. Well, I'm 100 percent sure that it was not leaked from within the Office of Vaccines, and I can't speak to where else it might've been leaked. It's conceivable that this was -- information was provided to the acting commissioner. It's conceivable that it was provided to the White House task force.

So figuring out where -- I don't know who else knew this, so I can't hazard a guess as to who -- who would've leaked that information.

[redacted] Now, what, if any, effect does this sort of public exposure place on your office at the time?

Dr. Krause. Well, at the time, at that moment, we were pretty confident that the review could be completed by September 15th, and so thought that by following our usual processes, that could be -- could be done.

Although one possible exception to that is, is that if it were going to be completed by September 15th, it would not have been possible to take this to an advisory

committee. And I don't recall what discussions we had internally on whether this should go to an advisory committee.

This, however, is the type of thing that, in order to gain public confidence in FDA's process, one might prefer to send to an advisory committee. And so, even the September 15th date would not have allowed sufficient time for that.

[redacted] Is that an important step in making your determination for a BLA, having an advisory committee?

Dr. Krause. So not all BLAs go for advisory committees. And, of course, if there are critically important issues that require outside advice, it's essential for those to go to the advisory committee.

My sense is that we already had very strong efficacy data. We had a substantial amount of safety data at this point, in some studies, almost an entire -- more than a year's. And we had the CMC data that we had, but advisory committees don't deal with CMC data.

So the other reason to go to an advisory committee would be to maintain and build public confidence in what we're doing.

So there wasn't a problem that the FDA would've needed to send to an advisory committee. But by opening the process and making it more transparent, an advisory committee might have, nonetheless, been viewed as an important thing to do.

Of course, there is -- there is a trade-off between taking it to an advisory committee and the total amount of time that it would take to complete the review.

[redacted] Okay. Well, I think we've reached our hour for now. We'll touch back, pick back up on that, next round.

But we'll go off the record.

[Discussion off the record.]

[2:17 p.m.]

[redacted] We can go back on the record, please.

BY [redacted]:

Q Okay. Dr. Krause, in the last hour, we talked a little bit about the September 17, 2021 meeting. Do you recall those questions?

A More or less, yes.

[Krause Exhibit No. 4.
Was marked for identification.]

BY [redacted]:

Q I just wanted to introduce -- since it wasn't introduced before, I just want to introduce, for the record, the summary minutes from that -- from that meeting. And this is, I guess, going to be marked as Exhibit 4. I'll give you a minute to just look at it so you can remind yourself.

Mr. Thomas Krause. Have you seen this before?

Dr. Krause. I haven't read it, no.

BY [redacted]:

Q Take some time to look at it if you need to.

A Okay.

Q The only reason I'm introducing this is just for the completeness of the record. Can you just tell us, like, what was the objective of this meeting?

A So the initial objective of the meeting was to have a public discussion to describe and present in a transparent way the data that -- that pertained to whether boosters, in particular, the Pfizer vaccine, should be made available to everybody, age 16 and up, which is what Pfizer had requested.

Q Okay. And you mentioned earlier in the last hour that there was some data

from Israel that was discussed or introduced at this meeting. Is that right? Is that when this -- that data was introduced?

A That's correct, and that's consistent with the line here: This was followed by a presentation by Dr. Sharon Alroy-Preis with the Ministry of Health, Israel, and Dr. Ron Milo with the Weizmann Institute" --

Q Okay.

A -- "made a presentation titled, 'Booster protection against confirmed infections and severe disease- data from Israel.'"

Q You're reading from exhibit 4 on page two, the second-to-last paragraph. Is that right?

A Correct.

Q Okay. And you said in the previous hour that you had noted some concerns about that data. Is that fair to say?

A Well, in The Lancet article we pointed out ways in which that data might be misleading.

Q Okay. And the ways in which you found the data potentially misleading, was that discussed at this meeting?

A Not to my recollection.

Q Okay. Did you bring it up at the meeting?

A I wasn't in a position to bring it up. Dr. Gruber was not running the meeting, and Dr. Marks was. I did get an opportunity, right after the committee returned from a break, to ask a question, and so I asked the question about the study that Pfizer presented.

Q Is that the data that we're referring to, or is that study something else?

A No, that's a different study.

Q Okay.

A That was -- that was -- I don't know if they mentioned that here. That was related to the, well, the Pfizer presentation, but they -- this doesn't -- doesn't describe -- the minutes, in general, represent a very, very abbreviated summary of these meetings, and so it -- that doesn't describe those specific data or the concerns that I raised.

Q Okay. But when you say that you raised the concerns, are you saying you raised the concerns in your article or that you raised them in the meeting or something else?

A No, actually at the meeting I raised them, because Pfizer was citing the data prominently as though that created an open-and-shut case that boosters were needed.

Q Right.

A And I pointed out that the study itself was -- had not been reviewed by FDA and itself seemed to have some internal inconsistencies that needed to be understood before one could interpret the data.

Q Okay. And raising concerns like that, that's your role as an expert, correct, to share your opinion or concerns about?

A It's a little bit unusual to be in a position where I need to raise those concerns in an Advisory Committee meeting, because normally when a company presents something in an Advisory Committee they're presenting data that they've already submitted to the FDA --

Q Right.

A -- and that the FDA has had a chance to review.

Q Okay.

A So -- but one of my roles was to try to make the office be as good as it could be, and if I saw something that I thought could be improved to point it out to somebody.

Q Okay. And can you see, I guess it's beginning on page three of exhibit 4, there's the numbers one and the number two down below, and I take it that those were the questions that were presented for vote to the committee. Is that correct?

A That's exactly right, yes.

Q Okay. And question one, it says, quote: Do the safety and effectiveness data from clinical trial C4591001 support approval of a COMIRNATY booster dose administered at least 6 months after completion of the primary series for use in individuals 16 years of age or older," end quote. Did I read that right?

A Yes, you did.

Q And COMIRNATY, for the record, that's the Pfizer vaccine?

A That's the trade name of the Pfizer vaccine, yes.

Q Okay. And then the members of the Advisory Committee were asked to vote yes or no, right?

A Correct.

Q And the results of the vote are listed there. It says that two people on the committee or on the Advisory Committee voted yes, and 16 voted no. Is that right?

A That's correct.

Q Is that consistent with your recollection?

A It is, yes.

Q Okay. So ultimately, the result of this Advisory Committee was that this particular booster for that subset was not approved or authorized?

A Exactly, yes.

Q Okay. And then if you look below, I guess it's number two, the question presented to the advisory group was, quote: Based on the totality of scientific evidence available, including the safety and effectiveness data from clinical trial C4591001, do the

known and potential benefits outweigh the known and potential risks of a COMIRNATY booster dose administered at least 6 months after completion of the primary series for use in individuals 65 years and older. Did I read that right?

A Yes.

Q And was that the question presented to the advisory group?

A It was, to the best of my recollection.

Q Okay. And then you see below that the results of that vote were yes, 18, and no, zero, correct?

A Correct.

Q Okay. And that's consistent with your recollection?

A Yes, it is.

Q Okay. With respect to those results, like the yes and the no and ultimately the authorization for the group 65 years or older, let's start with that, did you agree with that recommendation?

A I thought that was a very reasonable recommendation.

Q Did you vote on that, or is that some other member?

A No, no, FDA employees don't vote.

Q Got it.

A So it's an external advisory committee that is meant to reflect what the general scientific community and outside experts would think.

Q Okay. And then back to the first question, the vote was yes -- two people voted yes and 16 members voted no, with the ultimate result being that it was not authorized for use in individuals 16 years or older. Did you agree with that ultimate recommendation?

A I thought that was the right vote based on the data that were presented,

yes.

Q Okay. And those were the only two questions that were presented to the Advisory Committee at that meeting, is that right, in terms of the vote?

A These were the only two voting questions.

Q Okay.

A There was some additional question -- discussion after these questions were voted on regarding whether there might be some value to making the vaccine available to some additional populations.

Q And so --

A But this is my recollection. It's not obviously listed in these minutes.

Q Okay. Was that discussion -- I don't know if you can explain, but why was that not voted on, that second or third question?

A Normally, the FDA puts a lot of time into thinking about what the voting questions are, the exact wording, because they have such importance. And this additional discussion was, as I recall, induced by a question from Dr. Marks that he would like to have some additional discussion about whether there were other groups in which there might be some value to a booster dose.

Q Okay. So he was just looking for the Advisory Committee's thoughts?

A Informal thoughts, yes.

Q Understood. You can set that aside.

A Okay.

Q That's the only question I had about our exhibit 4.

A couple questions about just the COMIRNATY BLA approval process generally. Ultimately, that licensing authorization was approved on August 23, 2021. Is that correct?

A That's -- just to clarify the language --

Q Yeah, please.

A -- the license was approved. So normally, when I say approved, I mean, and people at the FDA mean, but this is hard language to enforce, approve means that the license or the BLA was approved. When you say "authorized," or "authorization," you're talking about emergency use authorization --

Q Yep.

A -- as a way of keeping these distinct from each other.

Q Okay. So --

A So the BLA was approved.

Q Okay. On August 23rd --

A On August 23rd, yes.

Q -- 2021. Is that right?

A Correct.

Q Got it. With respect to the BL -- the COMIRNATY BLA review process, was it thorough, in your opinion, as it went through the approval process with OVRR?

A The review was thorough. The review addressed all of the critical issues needed to come to the conclusion that it was appropriate to approve a BLA.

Q Okay. And are you confident that in that review in total that it was based on reliable evidence?

A Yes.

Q Okay. And did you -- in your opinion, did you find that the review utilized reliable methods?

A Yes.

Q You said that normally a BLA review process would take about 8 months if it

was priority. Is that right?

A That's correct.

Q Okay. And in this case, it was priority review, right?

A Correct.

Q Is that determined by statute, or what is the priority determination?

A There are several different criteria, but it has to do with the urgency for the product, how unusual it is, and also how lifesaving it is, and various other criteria that are written in the statute that are designed to assure that products that are really needed get reviewed faster.

Q Okay. To your knowledge, was there any dissenting opinion with respect to that COVID vaccine being a priority review under the statute?

A No, I don't think so.

Q And to your knowledge, what factors allowed OVRR in this case to finish the review, the BLA review faster than it would have in other cases that might have taken 8 months?

A So -- well, I'm just trying to think -- so, well, one reason is that the review involved a larger team of people and experts. So this really was an all-hands-on-deck situation where OVRR, especially as its review was prioritized, put all -- as many resources as it could into this review. And so, that was one thing.

Of those who were playing critical roles in this review, many of them put in extra hours, including nights, weekends, and really worked very, very hard on the review. It surely contributed to the review that Seiber had been involved in -- well, in discussing the studies before they were conducted, looking at the study results in the context of evaluating the EUA based on that same study. And so, having that experience with this data set probably also sped things up over who would otherwise have happened.

It's also the case that even when there's a priority review, reviewers often have multiple simultaneous tasks because that's the nature of business at the FDA. There's a lot of work to do and a lot of things are priorities. In this case, there was a desire to complete this even faster than the normal priority review timeline, which meant that the people who were working on it couldn't be working on other things.

Q So the desire that you spoke of to review the process more quickly, was that a desire that was shared among the FDA's scientists?

A Well, I can't speak for other specific FDA scientists. The -- we haven't gone through all of these exhibits yet obviously, but Dr. Woodcock and Dr. Marks indicated from their perspective the great importance of rapidly reaching the conclusion of this review. And the organization ultimately is responsive to its leadership, and so if people -- and so the reviewers did what they were asked and told to do.

Q In the -- you're talking about the review process, the BLA review process writ large?

A Well, and the individual reviewers --

Q Right.

A -- who put in a lot of extra time and a lot of extra effort to make it possible to review this BLA so quickly.

Q Okay. Is it fair to say that, you know, these employees who are working extraordinarily hard under these circumstances are motivated at least in part because they have their own concerns about the COVID pandemic and as it was unfolding in the country?

A I think that everybody who was working there at the time, myself included, had concerns about the COVID pandemic and how it was unfolding in the country. And we all wanted to in general do what we could to facilitate the availability of products that

would help.

Q Okay. And I think some of this is extremely obvious, but I'm just going to ask it anyway, but why were you concerned about the COVID pandemic at that time?

A Well, so many people, of course, had already died of COVID. The vaccines had been available since December of 2020. There were new variants that were evolving at that time, including the delta variant. The delta variant was actually well-protected against by the vaccine, but there -- I think some people had concerns that the -- that not enough people were getting the vaccine.

Q Like getting any version of the vaccine?

A Getting any vaccine, yes.

Q Okay.

A And they're -- motivating some people was the hope that if the vaccine were approved, that might motivate more people to get the vaccine.

Q And you mentioned this I think in the context of the booster authorization that there were some people in your position or tangent to you that were concerned about the messaging around boosters because they were worried ultimately that it might undermine people getting the original vaccine?

A Yeah, that was certainly a statement that I made that was The Lancet article and that I also made in a Washington Post op-ed that was published in late November.

Q And what was your concern, just if you could summarize it?

A The basic concern was that to the extent that all of the discussion and public discussion centered around boosting people, it meant that the energy that was needed in order to communicate with people who hadn't yet been vaccinated didn't exist. Many of the public -- official public communications really were led off with boosters, and if they mentioned getting the primary series, the first two doses, at all, it, in some cases,

appeared as an afterthought.

And the -- and so, there was a question of how did that impact the messaging, but then there also was the question that I think I -- I mentioned in the previous interview that to try and simultaneously give people the message that they need to get two doses of vaccine in order to save their lives, but if they had two doses of vaccine they needed a booster to stay alive, is difficult messaging to be giving at the same time, because if the same people hear both of those messages, they're not -- they sound contradictory.

Q Right. Is it also a concern -- correct me if I'm wrong, but the booster dose at the time is literally the same product as what somebody would've gotten in part of the original series?

A That's correct, yes.

Q Was there a scarcity issue in terms of the product itself, or does it depend on what part of the world you were in?

A That depended largely on what part of the world you were in. There were large numbers of doses of EUA-authorized vaccine in the U.S. around that time, so there was no -- no shortage of vaccine in the U.S.

Q So your concern at that point for the United States was just about messaging more than anything in terms of undermining the message that the original series was important?

A Well, both of those things. It was potentially undermining the message that the original dose was important, and that -- that the -- I'm sorry, I don't remember what my other thing was. This is the lunch catching up.

Mr. Thomas Krause. Do you want to take a minute?

Dr. Krause. Yeah, let me just take 1 minute.

[redacted] Sure, of course.

Dr. Krause. Okay. Sorry.

[Discussion off the record.]

Dr. Krause. Yeah, so I'm sorry, I was -- well, we have to resume, don't we?

BY [redacted]:

Q We're back on the record -- or we stayed on the record.

A Okay. So I was a little confused by the question.

Q I'm sorry.

A And so, were you asking about issues that came about with boosters overall or --

Q Yeah. I'm sorry, yes. I was talking about the previous discussion that we had where you were raising the concern or you had raised the concern that --

A So -- right. So one part of this is, of course, that the boosting message undermined the message to get the first vaccine series, but aside from that, is all of the data that I showed that the boosters themselves weren't needed.

Q For the general population?

A For the general population, exactly. And the further point made in The Lancet article that boosters would save more lives if those doses were actually given as primary doses.

Q Okay. That -- thank you for that clarification. That makes sense. Is there more to it?

A No. I think that covers what I believe the question was though.

Q Yes. I didn't want to cut you off.

Mr. Thomas Krause. Just to clarify, you had switched topics from the BLA approval to boosters, and that kind of --

BY [redacted]:

Q Yeah. Well, one of the reasons -- I was asking about -- I just -- I wondered, when you were talking earlier about the booster and that particular concern about it undermining the original series, I just wondered how it related to -- if scarcity was an issue. And I think you cleared that up. It was just a separate question.

A Correct. Scarcity was not the issue there.

Q Okay. I'm sorry. So let's just -- I'll try to stay more focused on the -- one process at a time so it's less confusing.

You said that the -- back to the COMIRNATY BLA procedure, one of the reasons you indicated that it was possible for the FDA to complete that review in less than 8 months was due to staffing and, I guess, choices that the agency made in terms of workload. Is that --

A Prioritization, exactly.

Q Okay. Who made those decisions about prioritization and staffing?

A So the decisions about prioritization and staffing for the BLA review were made by Dr. Gruber, who, together with me, wrote, for instance, the September 15th memo that described why we thought we could not --

Mr. Thomas Krause. July 15th.

Dr. Krause. Oh, sorry, July 15th memo that described why we thought that we could not further accelerate the BLA promise to action date. And so the -- and of note, when Dr. Marks relieved Dr. Gruber and me of being in charge of that BLA review, he did not add additional staff to that review. So the team was the right team, and it did not need further augmentation.

BY [redacted]:

Q Oh, I see what you're saying. So when you and Dr. Gruber left, there.

Was no additional staffing to --

A Sorry. We haven't been through all of these events, but there's a memo from July 21 that I found a copy of online that describes the meeting on July 19th during which Dr. Woodcock and Dr. Marks relieved Dr. Gruber and me of responsibility for directing the BLA review.

Q Right.

A And so -- and put Dr. Marks in charge of managing that BLA review. And so after that point --

Q Do you know when that was?

A I just said. So that memo was on July -- or that meeting was on July 19th.

Q So at the meeting that's when the staffing changed, at the same day?

A Dr. Marks said he was taking over right then, yes.

Q Okay.

A Yes.

Q Go ahead.

A And so there was no subsequent change in staffing for the review of that BLA.

Q So the staffing, I guess the building of the staff happened before that when you were still --

A That's exactly right, because the BLA came in according to the timeline May 6th, and the final submission that started the review clock was on May 18th, so by mid-July the review was already -- had already been underway for 2 months.

Q Okay. When did the staffing change occur?

A There was no staffing change.

Q Oh, I'm sorry. I thought you added people or prioritized their work in different ways so that people were more focused on the review.

A No. We initially put a robust team on this.

Q Is that May, then?

A Yes, right from the beginning, yes.

Q Okay. So that was a decision that you and Dr. Gruber made during the BLA review process in May?

A Or even slightly in advance of it, yes.

Q Okay. And can you say, like, did that -- how many people did that -- did it involve actually assigning people who were not working on this, or did it just involve taking the people who would otherwise be looking at it and telling them you're going to work on this only or both?

A A little bit of both.

Q Okay.

A But the total number of people who were engaged in the review of this BLA was certainly over 50, maybe even more.

Q From the beginning -- or May, from May --

A Well, had some responsibility. Not everybody had responsibility on the first day, but who had some responsibility associated with this BLA.

Q Okay. What was it that motivated you and Dr. Gruber to make those staffing decisions to have people prioritize this?

A We viewed it as an important BLA, and we knew that a BLA required a much more thorough review than an EUA did, and so -- and we already started off with the idea that we were going to try to finish this BLA that was originally due on January 18th by mid-October. So we knew that we would have to devote substantial resources to rapidly completing that BLA.

Q Okay. And was that because you felt pressure from leadership, or was there

some other reason, or both?

A Early on, no. Early on I think everybody agreed that we didn't know what was going to happen in the pandemic, that this BLA was going to need to be reviewed anyway, and so, that it would be useful and important to complete the BLA review faster than the original January 18th priority review timeline.

Q Okay. Was there resistance from staff members when being asked to work these extraordinary hours or to focus exclusively on this matter?

A So I do not know that directly, because the additional acceleration in the review occurred after Dr. Marks took over that review. And so, there's no doubt that people on the team worked very, very hard; and without that additional work, it wouldn't have been feasible to further accelerate the review.

I think that people who work at the FDA, and this gets back to a question you were asking me earlier, in general, are there because they're highly motivated to make a difference for public health. And they -- they see their work as being very, very important. And so when they're told by leadership that the work is critical, then they -- they go the extra mile.

Q And so fair to say that when you and Dr. Gruber were in charge of this BLA review, you understood that the staff was working -- was prioritizing this over other things, and that they were working longer and kind of harder --

A Well, they were already working very hard.

Q Right.

A And after we were relieved of responsibility for this, my sense is perhaps they were working even harder. But I don't have direct knowledge of differences in the number of hours each individual worked.

Q Okay. All right. So when I asked you earlier, you know, what was it that

made it possible for OVRR to review -- do this review process in more than 8 months, the first thing you said was basically you prioritized it with staffing and people just kind of dropping maybe some other matters and focusing hard on this. Is that --

A Correct. That's correct, yes.

Q Okay. Were there any other issues that were kind of unique to COVID or this circumstance that helped this review go faster?

A I think expertise, right, because we had been living COVID for the last, well, by then, year and a half or so, or more, the experience that everybody had with COVID, as I said, the understanding they had of this particular clinical trial, and they would've gained some facility with the specific databases in which data was presented. These are all things that -- that certainly helped, having that experience, having the people. And some of that experience comes from the EUA; some of it also comes simply from being involved in other COVID-related reviews over a very short period of time.

Q Is it true that in kind of your typical BLA review process where it's prioritized and you have 8 months, you may not have had an EUA before that? Is that something that usually comes hand in hand?

A You would never have had an EUA before that, because the EUA is something that is unique to an emergency situation. So that requires an emergency declaration, it requires a life-threatening illness, and it, of course, then changes the standard under which the product is reviewed and ultimately authorized.

So the Office of Vaccines, before that time it had only one EUA and that was for a different schedule of an anthrax vaccine, so that was on a completely different scale. So the -- the sequence that occurred here was unlike any sequence that had ever occurred in the office.

Q In the entire history of the FDA?

A Well, in the history of the office for sure.

Q Okay. By the OVRR?

A Where there was this EUA product which then turned into a BLA with obviously a lot of data.

Q Because -- and I think you've already said this. Forgive me for just keeping asking the same thing, but because the EUA process, even though it was a different standard, involved data that you could later analyze in the BLA review process, is it fair to say that the FDA was able to move more quickly because they had already seen some of the data in the EUA process?

A So it's fair to say that that helped the FDA move more quickly, but I don't want to downgrade your impression of how much more complicated it is to review the BLA, because the BLA is reviewed to a very different standard. And in this particular case, when the EUAs were authorized, there was clinical data, but it encompassed relatively short follow-up on these people.

And by the time that the BLAs came in -- or the BLA came, the duration of follow-up was much longer and the total amount of data to be reviewed was much, much greater. And of course, in the meantime, there also was information about myocarditis that needed to be considered and much deeper dives into all of the individual components of a BLA review and approval to come up with the necessary conclusions that the statutory criteria were met.

Q Okay. And you already described the difference between the EUA and the BLA standard, but I don't know if you were asked this before: When Pfizer is submitting its own data for the EUA like initially, are they continue -- like is it a rolling process where they continue to submit data?

So like their product is out there under the EUA and then people are using it and

then I assume there's data being generated, and then the BLA process is distinct and it's a different standard and everything. But are they continuously submitting data to the FDA, like from that initial period, or is there -- is there a distinction between like when you accept data under the BLA process, and when you accept data under the EUA process?

A Right. So for BLA to be reviewed by the FDA it needs to be a self-contained document that has everything in it that is needed in order to support the license. And so that came from Pfizer in two pieces, some of it on May 6th, I think. Right? Or the 5th. I get that mixed up. The 6th, and the other on May 18th. And so, that submission between those days needed to include everything that was going to be reviewed as part of the BLA.

So the original EUA came in and was approved -- was authorized in December, and, of course, there was additional data that became available after that. Some of that came in in chunks to support EUA authorizations in certain pediatric age groups, and some of that came in as safety reports. But it all came in in a formal way. It's not that there is a pipeline between Pfizer and the FDA where data is constantly being streamed that the FDA has to look at in real time.

Q Okay. But still, the EUA process, because the FDA had looked at some data in the EUA process, in some ways it made it easier or faster for the FDA to look at some of that data in the BLA process?

A I think to -- so -- very often, the ways in which the databases are organized can be a little bit different from one application to another, and so these are things that would've stayed constant and so would've facilitated reviewing additional data from the same study.

Q Okay.

A So -- but at the same time, the volume of data that needed to be looked at

for the BLA greatly exceeded that, that needed to be looked at for the EUA. So the review of data for the EUA probably didn't appreciably help, but it was really the experience of having been through the data as it was organized for the EUA, in my opinion, that likely made the bigger difference.

Q Okay. Thank you for that.

I don't think you've mentioned this as a factor in terms of the speed with which the FDA was able to do the BLA review, but let me ask you: Do you think that -- I mean, obviously you're waiting on Pfizer or whoever, the sponsor, you know, the company, to give you information so that you can complete your review, right?

A Yes.

Q So some of the timing probably is dependent on how responsive they are to your requests. Is that fair to say?

A Absolutely.

Q And how was Pfizer's responsiveness to the FDA's request? How would you characterize it?

A Overall, I would say it was good. My impression is that after the -- after Dr. Marks took over that it was even faster.

Q Do you have any opinion about why, or do you know?

A I don't know. My -- it would be reasonable to suggest, though, that -- it would be reasonable to imagine that they knew, or were told that FDA was trying to complete the review rapidly, and was hoping that they would cooperate by providing rapid answers to questions.

Q Okay. Because it's fair to say, like this BLA process, it involves the FDA and the company, and there needs to be --

A Absolutely, yes.

Q -- some cooperation between the two --

A Correct.

Q -- right?

A Correct, yes.

Q And I take it that when you or Dr. Gruber or anybody in your position is trying to come up with a timeline under this priority review or any other, you have to build in some uncertainty because you don't know how responsive the company is going to be. Is that fair?

A No, that's exactly right, and that's what I was trying to say earlier. In coming up with the September 15th deadline, or ADD, that didn't mean that we were sure that it would take until September 15th, but we thought that was a date by which we could reasonably promise the review would be done, based on reasonable assumptions about how long it would take Pfizer to respond to questions, and how long it would take our teams to complete their reviews.

Q Right. And you made some effort in your position at FDA to get your people to move faster by doing staffing changes and prioritization, but you don't know what Pfizer was doing on their end, if they were dedicating more people to these responses or anything like that?

A That's correct, I don't know that.

Q Okay. I'm going to totally switch gears. We can set that subject aside for a second. I have a question that's kind of vexing me in some ways about boosters. And tell me if I'm wrong about this, but initially, when Pfizer's boosters were being, I guess, reviewed under the EUA, was all of -- were the boosters geared toward the alpha variant, or were they -- were the boosters supposed to be like evolving as the variants were changing?

A So there was a lot of thought into that, but the boosters as they were originally conceived in the fall of 2021 were exactly the same vaccine as the vaccine that we started off with in December of 2020.

Q Was that alpha?

A No, it was actually before that.

Q Oh.

A It's what's called the variant --

Q Oh, right.

A -- the Wuhan strain. Although, actually, I think it -- there might have been even a couple of modifications from that. But it really -- the vaccines that were made available in December of 2020 were based on the virus that was sequenced much earlier that year in January of 2020. And then the boosters that were made available in the fall, in September of 2021, were that exact same strain also based on the viral sequence from early 2020.

Q At that point, when those boosters were being considered by the FDA, were other variants of the virus already circulating in, like, the United States?

A Yes, by that time we'd been through the alpha variant, the beta variant, and that was a time for the delta variant. There was a gamma variant also that did not find its way substantially to the U.S. And then you probably remember that not long after that we ended up with -- well, there were actually, if you go through the Greek alphabet, there were other variants, but the one that caught everybody's attention later that fall was the only Omicron variant. And the virus that we have even now is derived from or related to those Omicron variants that appeared at that time.

Q So how, if at all, did the change in the different variants that were introduced affect the FDA's review process when it came to -- and how you looked at the

data? Like, did you have a consideration for like, say, data that was lagging and that might have been involving one variant versus another?

A It was a difficult question. And one of the companies, and I don't recall which one, and it may not even have been one of the mRNA companies, but at least one did some studies, for example, with a vaccine that was directed against the beta variant, and compared the immune responses in people using that kind of a vaccine versus the -- versus the original vaccine when used as a booster.

And a beta variant booster actually didn't appear to do substantially better than the original vaccine. And, of course, to switch the vaccine strain, or to switch the vaccine sequence would've been a much more complicated thing that one wouldn't do unless there were strong evidence that that would make a big difference.

Q Did considerations of these different strains, did that, in any way, affect your analysis when you looked at data about, say, waning immunity, for example, or the need for boosters in any particular population?

A So there were two factors in play when one was thinking about waning numeral immunity, which is antibodies. One of them is that if the virus is changing, the antibody that neutralizes the virus might not neutralize a changed virus as much as it neutralized the original virus. And then, of course, there's also the question of, if you got the vaccine a long time ago, you get some peak antibody level but then that may decline over time.

And so, with both of those factors that raised the question of both having some decline in antibody titers, and then those antibodies not being as effective against a new variant was a concern that the antibodies might no longer give the same kind of protection that they were giving before. The good news is that the vaccines were also inducing cell-mediated immunity, just as the natural infection induces both. And the

cell-mediated immunity did not wane as rapidly, and also the cell-mediated immunity was not as susceptible to changes in the viral sequence.

So the cell-mediated immunity that would back then, for instance, that protected against the original -- original strain as it infected the U.S., was still effective in protecting against the variants as they evolved. And so, the -- even when the antibodies started waning, the cell-mediated immunity provided people with strong protection against severe infection.

Q Regardless of the variant?

A Regardless of the variant, yes. And that's the immunological or scientific explanation for the data that I showed in The Lancet article, which showed that even though protection against mild disease appear to be lower in some of these studies, the protection against severe disease held up.

Q And when people get the vaccine today, are they getting one that's tailored toward a particular variant, or does it remain constant?

A So there have been different vaccines, and I'm not sure which vaccine is available is this very day. There is a bivalent booster, which was part Omicron and part original strain, and the rationale for giving that bivalent booster, and that came out last year, roughly in the fall, was to have a viral strain that would protect both if the virus went back to an earlier strain, so was -- or that would provide an immune response that would cover both an earlier strain if the virus turned the clock backwards and evolved in a new strain from something that we'd already seen, but then also, would better cover some of the Omicron strains that were becoming apparent last fall.

And so that vaccine had both of those viruses in it. The evaluation of that vaccine covered what was done just by antibody titer. So there still wasn't any clear evidence that immunity protection against severe disease was waning substantially, but the hope

was that by increasing the antibody titer, that might reduce the incidents of mild disease.

Unfortunately, studies that were done since then suggested that that booster did provide some protection against mild disease, but it was fairly short-lived. And -- and that because people already had pretty good protection against severe disease, there wasn't good evidence that it made a big difference against severe disease.

Now, last fall, that was a vaccine that we heard from various public health authorities was absolutely essential, or there would be tens of millions of cases and perhaps millions of hospitalizations, I don't remember the exact numbers, but then, a very small proportion of the population took that bivalent vaccine last fall as a booster.

And so, you could say that's bad news, but the good news is that the dire predictions did not come to pass. And so, it seems as though, although many people didn't take it, not taking it didn't harm many of the people who didn't take it. But it was available for the elderly and the immunocompromised, and people who otherwise might have been more likely to succumb to more severe disease.

And so, there was a lot of discussion earlier this year to try to figure out what the vaccine should look like this fall given that there was a sense that -- and this was discussed at various Advisory Committee meetings -- that it would be difficult to change the vaccine more than once a year. And so ultimately, the vaccine strain was selected in June, also of an Omicron sub-variant now, and that was set forward to be the vaccine that would be made available this fall.

The last I heard, it will be available sometime September. It's now September, and so I don't know if it's available yet or will just be available soon. But that's a vaccine that I think one could expect, based on past experience, will provide some relatively short-term protection against mild infection; and in people who need it, they provide some boosting against more severe infection, but at the same time may also be optional

for many people.

The -- of course, the other thing that has happened in the meantime is that there have been many, many cases of COVID in the U.S., and many people who are vaccinated, as well as many people who are not vaccinated, have also gotten COVID. So it's very unusual to find somebody, for instance, who's only had a couple doses of the original vaccine and never had a mild case of COVID.

And so overall, in the population, except among the most vulnerable people, there is a much higher level of immunity against the virus than we've -- than we've ever had. Although, if you measure that immunity by antibodies as the virus changes, it doesn't look as good. But if you measure it by cell-mediated responses, it still looks pretty good.

Q Can you say something, just stepping out, about the nature of COVID in terms of how quickly this was evolving and how much challenge there was to respond to this situation as it evolved so quickly, I mean, in relation to other, you know, flu or other matters that came before the FDA when there was a vaccine available?

A Sure. The evolution of COVID was unprecedented. And I remind myself that this evolution perhaps shouldn't have been such a surprise, because however this virus found its way into humans, it probably evolved very quickly and changed a lot in order to gain the ability to be transmitted quickly among humans. And so, even the early strains of COVID probably were based on a lot of evolution from animal precursors. And so the fact that it evolved quickly before it found its way into humans could reasonably have suggested that it was going to continue to evolve after it found its way into humans.

Q When you say it's unprecedented, do you mean specifically like the rapid evolution, or do you mean something more?

A Well, unprecedented for a virus that causes this much -- this big a public health problem. So, for instance, flu tends to be fairly stable. The flu vaccine has four

strains in it, and in any given year two of them might be changed usually on average from the previous year. And sometimes three are changed, but all four are almost never changed.

And so, the flu virus, although it changes, doesn't change nearly as fast. Coronaviruses are different viruses though, and coronaviruses can also cause common colds and other diseases where it's -- there's good evidence that the virus is also evolving rapidly.

So what made the rapid evolution of coronavirus so difficult was the fact that it was evolving greater infectivity as it was increasing its ability to infect humans while staying pretty pathogenic, and able to cause serious disease in the most vulnerable people, and early in the pandemic in a high proportion of people who weren't vaccinated.

Q Would you say -- is it fair to say that, you know, from the FDA's standpoint in making approvals so that people can have these vaccines available, that this COVID pandemic and this process that you had to go through to review the vaccines, was unprecedented from the agency's perspective?

A Yes, I will certainly wholeheartedly endorse that idea. What I would say is that the most unprecedented was what we had to do in 2020; next in unprecedented was what we had to do in 2021, and the situation is getting better with time as we understand more. But at the same time, the whole story caused -- necessitated a substantial disruption in the way that FDA did business in order to be able to respond.

Q And are you able to learn something looking back, just because in retrospect there are lessons to be learned by seeing what happened, that you couldn't have necessarily responded to in the moment just because it wasn't all clear?

A So, of course, the difficulty in the moment is there are many, many different experts, all of whom are saying different things, and it becomes very difficult to figure out

who's going to turn out to be right. And so, in retrospect, you can figure out who was right at least, although maybe it doesn't matter who was right because at least then you know what actually happened.

And so to me, one of the -- the key lessons from COVID is the extreme importance of paying attention to confidence in vaccines and confidence in public health agencies, because once that starts getting undermined it's a very slippery slope that can create problems not only for the pandemic but for other things.

But, you know, we've learned other things as well. There are international efforts now to figure out how to predict the next pandemic, to make sure that vaccines against additional strains of unusual viruses are available or have at least -- have had development initiated, so that there will be opportunities perhaps to come up with vaccines even more rapidly in a future pandemic.

And so, by seeing what worked here and what may not have worked as well, and to also apply the best current science, which has evolved even through COVID and even since, the hope is that the world is going to be much better prepared for a future pandemic.

Q Is that specifically about mRNA technology that you've learned, or are you talking about more broad issues than that?

A Much more broadly. So mRNA technology is -- obviously was very important for the response to COVID, because it allowed a rapid design of vaccines that turned out to be very effective, especially against severe disease. And it was fortunate that technology was ripe at the time COVID came around. It was ripe, and yet largely unproven, and so now it's been proven, at least in this context. But that doesn't mean that mRNA technology is going to save us in the next pandemic, because the next virus might be different, and to control it might require a different kind of immunity than the

kind that mRNA vaccines are able to induce, or there may be other complexities associated with getting the kind of protective immune response that we need. So I don't think that anybody can be complacent now that we have the mRNA and imagine that that's going to be the solution to all future pandemics.

[redacted] Okay. I think we're actually at the end of our hour. We can go off the record.

[redacted] Off the record.

[3:22 p.m.]

[redacted] We can go back on the record.

BY [redacted]:

Q Now, Dr. Krause, I apologize for kind of jumping around a little bit. I feel like some of this stuff can be pretty dense for us. So I think there might be a few reiterations or some clarifications or what seems to be similar questions. Hopefully not so much.

But going back to what we marked earlier as exhibit 2 and 3 -- 2 being the email with the timeline and 3 being the email with the memo -- now, I know exhibit 3 came on that Thursday, July 15th, and the timeline was Friday, July 16th. So I kind of introduced those in a little bit of reverse order on accident. But I wanted to get some clarification about a couple things in these emails.

Going back to exhibit 3, with the memo, in the email on page 346, at the very bottom, it's marked 346, Dr. Gruber wrote: "Phil and I further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know, we are targeting September 15 as the ADD." Which we discussed was the action due date. "It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW."

What does DVRPA and DVP stand for?

A Those are two divisions that are part of the Office of Vaccines.

Q Okay.

A So DVP is the Division of Viral Products, and that's a division that conducts vaccine-related research, but also contributes a lot of expertise to review of assays and manufacturing processes.

And DVRPA is the Division of Vaccines and Related Products Applications -- we

called it DVRPA -- and that division comprised two elements. So there were actually two deputy directors who ran that division.

One of them was Dr. Doran Fink, who was in charge of the medical officers in that division who were responsible generally for conducting clinical reviews.

And the other side was run by Dr. Loris McVittie, and that side was responsible for regulatory project management and for communications with sponsors.

So many of these people were highly educated Ph.D.s who needed to be able to understand all of the elements of an ongoing review and then be able to communicate with the companies about that, while then also making sure that all the projects were on track and that all the reviews were meeting their milestones, and everything that was between a milestone, to make sure that we were doing everything that we were supposed to be doing.

Q So did these two divisions report up to you, including --

A That's correct. They reported up to the Office of Vaccines.

Q So Doran Fink technically was a subordinate of yours and Dr. Gruber's?

A Correct.

Q Okay. And before Dr. Gruber drafted this email, on July 15th of 2021, I remember earlier in your testimony you had discussed the due date had been -- you all had been asked to move the due date up from October to September. Is that correct? Was that --

A And we had agreed to that.

Q Okay.

A And then this is the response to a request to move it up further from September 15th.

Q Okay. And who asked for you all to move it up both times?

A Both times it was Dr. Marks.

Q And do you know, to your knowledge, did the White House ask the FDA to move the due date up at all around this time?

A I have no knowledge of any communications between the White House and the FDA.

Q Would you, in normal circumstances, pre-COVID and then during COVID, ever have any direct communication with anyone in the White House regarding any of your work at the FDA?

A Normally not. Occasionally -- I remember one time I was invited to the White House -- I don't remember if this was related to ebola or Zika -- for some National Security Council subcommittee meeting. It takes a long time to get into the White House, I will say that. But not routinely.

Q Now, if corners were ever cut in the BLA approval process, would you or Dr. Gruber be, like, personally responsible for anything going wrong, like -- and I say personally responsible, meaning, like, for the sake of your job or, like, your department?

A Obviously, in the Federal employment, everybody is reporting to a supervisor, and there's an annual rating scheme, and there's a personnel system. So as far as job security goes, there are systems in place for dealing with employees who are problematic either due to their conduct or their performance.

And, luckily, I don't have so much experience with those systems. But I think, obviously, if something were to go wrong --

Q Would it reflect poorly on your work if cutting any of the corners for the BLA approval process, like, in your opinion?

A So that's such a hypothetical question I can't even answer it, because neither Dr. Gruber nor I would go along with cutting corners. If somehow we were asked to cut

corners, we would object.

And if something were to go wrong as a result of something we did, I don't think either of us would have worried about the personnel consequences. But if we felt responsible for something, we would have certainly felt terrible.

Q That's perfectly fine, and that's exactly what I was essentially getting at.

And "JW" in this email, that refers to Commissioner Janet Woodcock, correct?

A Acting Commissioner Janet Woodcock.

Q Yes.

A Yes.

Q And did you personally draft the memo attached, or was that a mixed effort between you and Dr. Gruber? Or who all was involved in that?

A I don't recall the number of people who were involved in that. I contributed some sections, but I don't remember what I contributed. And I know that Dr. Gruber, being a very careful person, also ran this by other people within the office to make sure that they found this to be as persuasive as they could.

Q And it would be other people within your specific OVRR group, or would it have been other divisions?

A So I don't recall whether or not this was sent, for instance, to Mary Malarkey or to Steve Anderson at this stage or not. I see that it was cc'd here to Celia Witten, who was the center deputy director and directly reporting to Peter.

And I don't remember who else would have participated in this, but surely this was more than just Marion and me.

Marion would have drafted -- well, did draft the first version.

Q Was it common for you all to compile a memo like this to discuss any type of BLA to send up to the director of CBER or the acting commissioner? Was this, like, a

typical thing for you all to do?

A So my recollection at the time is that Dr. Gruber felt under substantial pressure from Dr. Marks and so felt that it was important to document her reasoning in writing.

Normally, there might have been a much shorter discussion that wouldn't have required this level of detail.

BY [redacted]:

Q How did you come to that understanding?

A I don't recall. Almost certainly, though, because I was talking with Dr. Gruber every day, that this came about in the context of a conversation with her about discussions she had had with Dr. Marks that I was not a part of.

Q To the best of your recollection, what were some of the things Dr. Gruber conveyed to you about this pressure she felt from Dr. Marks?

A Just that Dr. Marks was intransigent that the action due date, that the ADD should be moved up, and that he was insistent that September 15th wasn't fast enough.

Q So as a practical matter, he said there will be no date beyond September 15th, as far as you know from your discussions with Dr. Gruber?

A I'm not sure I'm understanding the question.

So he was pushing for a day earlier than September 15th, and we had already agreed that this BLA, barring some unusual event, could likely be completed by September 15th.

Q Okay.

A So remember that we started with a plan of mid-October, and then he requested -- he agreed to that first but then requested September 15th, and then after that, came back and requested an earlier date. And it was that, upon the request for a

date earlier than September 15th, that we felt that we couldn't, in good faith, promise that.

Q Right. I guess my question was -- in some ways it's irrelevant -- was that if he was insisting on a day prior to September 15th, then the notion that you would need more time than September 15th would have been out of the question for Dr. Marks?

A Oh, if we'd said we wanted more time, for sure, he would not have gone along with that.

Q Okay.

[redacted] Did he provide any research or, like, a supportive reason as to why he wanted it to be moved up each time, or was it just, "We need this done sooner"?

Dr. Krause. I don't recall. What I remember best are things that were documented in Dr. Gruber's email to him and to Dr. Woodcock after the meeting we had on July 19th. I actually don't have a copy of the email, but I was able to find a FOIA'd copy online.

Mr. Thomas Krause. Can we just make it an exhibit?

[redacted] Yeah, of course.

Mr. Thomas Krause. I'm giving him latitude on the deliberative process because there is so much in these emails already.

[redacted] Absolutely.

[Krause Exhibit No. 5.
Was marked for identification.]

BY [redacted]:

Q I will enter this into the record as exhibit 5.

And not to disrupt your answer, if whatever you were saying, if this helps you to --

A Sure. Well, the specific concerns expressed in this memo are the ones that I

recall being brought up at the time, namely, that there were rising COVID cases in the U.S. and globally due to the delta variant, which is sort of towards the end of the second paragraph; the opinion that absent a license, States couldn't require mandatory vaccination, and that people hesitant to get an EUA-authorized vaccine would be more inclined to get immunized when the product was fully licensed.

So those were the three arguments in favor of going faster that had been put forward by -- in that meeting -- by him and Dr. Woodcock; and, in other meetings, in different orders, I recall having heard those but can't specify a meeting or a time.

Q Did Dr. Woodcock or Dr. Marks state that the goal was to require mandatory vaccination?

A Well, the, as stated in the email, the discussion was about State mandates, and of course there already had been some mandates announced by the Biden administration. There was a so-called vaccinate-or-test rule that they had put in place at some point earlier in August, as I recall.

And so there was no doubt, in my recollection, that Dr. Marks and Dr. Woodcock saw the licensure of the vaccine as a prerequisite to mandates.

Obviously, it's not up to the FDA to mandate vaccines, and so I don't know beyond what is written in this email exactly which mandates they were thinking of.

Q And going back a little bit -- I know we jumped ahead a little on talking about this email, but it lapses in with this exhibit 3 in the memo.

In the next section of your memo, it was titled -- it's in the middle of page 347 -- the next section, that's titled, "The BLA merits a complete and thorough review," it says: "OVRR's reviews of vaccine BLAs, unlike those of regulators in other countries, do not rely on summary tables that are generated by the developer. OVRR views it as essential that review of the safety and efficacy data not only includes an evaluation of the data analysis

conducted by the applicant, but also includes CBER's own analysis of the datasets submitted by Pfizer. This has been OVRR's standard for all other BLAs, and while time-consuming, OVRR believes that confidence in COVID vaccines would not be served by starting to cut corners on this review."

Is it fair to say that the FDA's usual practice is to evaluate and analyze BLAs separate and apart from any analysis provided by a pharmaceutical company like Pfizer?

A Yes. For BLAs, FDA looks at the analyses provided by the companies, but often does some of their own analyses, and in addition to that, confirms the analyses by going down to the individual source data and making sure that the individual source data supports the analyses that are presented.

Q And how long does that dataset analysis usually take?

A Depends on the size of the dataset, and it depends on -- and I don't know how big this dataset was in megabytes. But for a trial of, in this case, 43,500 people, that had been going on for, at this point, about a year, I believe that would have been a lot of data and would have taken a lot of effort.

Q And can you explain how the FDA's own analysis of a developer's data affects the confidence in the vaccine, in your opinion?

A Well, because the FDA states that they perform their own analyses, this way the public knows that the decisions that are made by the FDA are completely supported by the data and that the FDA isn't relying on assertions that are made by the developer.

Q And at the end of page --

A So it creates confidence in the objectivity of the review because assertions made by the developer might -- might -- be compromised by bias.

Q Of course.

And at the very end of page 1 of this memo, in the section that's titled, "As

compared with other BLAs, the proposed completion date of September 15 would be unprecedented," in that last section, the term "rolling" BLA was used. And I know my colleagues, they had mentioned before, in their last hour, I think they had asked you about the rolling BLA, but would you mind repeating or re-explaining?

A Sure. It's funny how I have to keep referring back to this diagram to remember the dates. But you can see above May in this picture in exhibit 2, there's "May 6: BLA Submission," called "Roll 1," and "May 18" BLA Submission," which is called "Roll 2."

And so for vaccines that can be reviewed under priority review, and the FDA will sometimes agree to start reviewing parts of the data before the entire BLA is in, it's a normal requirement for the entire BLA to show up at once.

But sometimes sponsors have some sections of the BLA ready before others. And if there's a desire to be efficient about the review process, sometimes it can be reasonable for the FDA to start reviewing some sections before all the other sections are there.

Sometimes that can also create some inefficiencies because a question might arise in a section and then that may raise a question that could be answered with reference to another section, and if that section isn't there, that actually may make the FDA's review less efficient.

But nonetheless with these two rolls -- and I don't remember how they were divided up -- what this just means is that the FDA received the data for this BLA in two tranches. But when there's a rolling review, the action due date is always calculated off of the date in which the BLA is considered to be complete by the sponsor. And so the action due date was calculated off of May 18th, even though some of the data had come in by May 6th.

Q Okay. And then going back to exhibit 3 in the memo on page 2, in the section titled, "This is possible only with deprioritization of other reviews, including some related to COVID, and reassignment of work to other experienced medical officers," it says: "We have de- prioritized certain COVID-vaccine related submissions (including some from Pfizer), e.g., amendments pertaining to protocols and studies in pregnant women and immunocompromised subjects, until such time that the BLA review is completed."

Does this mean that the BLA review was prioritized over the review of studies related to individuals with underlying conditions receiving their first dose of the COVID vaccine? I just want to get clarification.

A I don't know if it was prior to -- probably not prior to getting their first dose. More likely boosting.

And also I can't say that these were results of studies. They might also have been planned studies. So what's written here is ambiguous enough, and I don't remember exactly what is being referred to, to know precisely what these studies were.

But it does mean that the reviewers, who would otherwise potentially provide more rapid responses on those two topics, were pulled into the review of this BLA.

Q Who determined the order of priority for the reviews?

A This was -- well, the way that the system worked, this would have been determined within the office. But if something important needed to be deprioritized, the center director would have been informed in order to make sure that the center director was aware that that was happening.

Q In the last sentence of that paragraph, it reads: "In addition, if the trajectory of the pandemic/emergence of variant of concerns (i.e., delta variant) necessitates the review of EUA amendments for booster doses for the currently U.S. EUA authorized COVID-19 vaccines, from a public health perspective, these reviews will need to take

priority over completing the BLA review by September 15, 2021."

What is the difference between the review of the EUA amendments for the booster doses versus the BLA review you were already being asked to perform? I think you started to touch on that, but just to get clarification.

A Sure. So this BLA review was to provide full licensure for the two-dose series, the initial two-dose series of the Pfizer Comirnaty vaccine. And so this would take a vaccine that was authorized under emergency use authorization and available to people and change it to a vaccine that was licensed, but it would not change fundamentally the availability of the vaccine.

And so what I believe Dr. Gruber is saying here is that if there are new things that might change the availability of specific vaccines, then that might be more important than a review that won't change what vaccine is actually available to people.

Q Okay. And then the next section discusses how additional support from outside OVRR would not speed up the review process. Could you briefly summarize why?

A The difficulty is that these reviews, in order to be done efficiently, required reviewers who are very experienced with doing these kinds of reviews, and to do them efficiently also required the very reviewers who had already been involved in the Pfizer review.

And let's not forget, by the time this memo was written, the review had already been ongoing for a couple of months. So if one were to take somebody who is completely green and put them on that, the people who were busy doing the work would then have to take some time off to bring other people up to speed.

And so there certainly are times when you can train people, but right in the middle of a review that is viewed as urgent is not the best time to take the reviewers who need to do that and have them do the training.

And by the time that training was completed, the review itself might also have been done.

Q That makes sense.

And Dr. Marks had then, it looks like either that day or the next day, he had mentioned he forwarded your email -- or Dr. Gruber's email -- to Deirdre Hussey. And --

A Yeah. I don't have that here.

Q Oh, okay.

A Do you have it?

Q Oh, I think it's on page 351.

A Oh, it's farther. Okay, good.

Q Yeah, I'm sorry.

A That's fine.

Q At the very end.

And he wrote that Dr. Gruber declined additional resources from him to expedite the Pfizer BLA review.

Is her reasoning consistent with what was outlined in the memo, and did you agree with her?

A Yes. Yes, I did.

So Deirdre Hussey, just to answer the unanswered question, was the chief -- or the director of our Office of Management. And so she would have been in charge of HR issues.

So my interpretation of this email is that Dr. Marks is trying to document Dr. Gruber's intransigence with somebody who might be in a position to create a human resources consequence for her.

Q Did this concern you?

A I didn't see it. I only saw the --

Q Seeing it now, does this concern you?

A Yes, of course it does. Dr. Gruber was a highly dedicated Federal employee who gave her career to the Office of Vaccines, who put in countless extra hours, did everything she could to make vaccines available to the public that they could have complete confidence in.

And while it seems that Dr. Marks had a relatively minor disagreement with her about his request for a timeline, which I think he'd requested just a few days before but which she could not possibly provide without also involving other people, to send this to somebody in HR is pretty outrageous.

On the other hand, that is not the most outrageous thing that happened.

Q What was the most outrageous thing that happened, in your opinion?

A Well, I mean, from an HR -- from a human relations perspective, removing Dr. Gruber and myself from the review of a BLA that he regarded to be critical and important, when we were the two people in the office who knew the most about it, seems to be counterproductive.

Q Now, jumping to that, and this is where we can get back into exhibit 5, which is that email recounting your July 19th meeting with Acting Commissioner Woodcock and Dr. Marks. And I believe the chief of staff, Julia Tierney, was there as well. Is that right?

A That's correct.

Of course this was an online meeting --

Q It was an online --

A -- so none of us were in the same room.

Q Right. And how long did that meeting last?

A According to my recollection, probably a half hour or so.

Q And in this July 21 -- I'm sorry -- July 21st, 2021, email Dr. Gruber had drafted, she wrote that during the meeting she made reference to the memo that we just discussed, that was sent to Dr. Marks on July 15th, and it delineated OVRR's rationale for why the review timeline and target action date, September 15th, 2021, for this BLA cannot be compressed further.

We discussed before that Dr. Marks was obviously in favor in trying to compress this timeline. Do you know if there was anyone else that was trying to compress this timeline?

A Well, based on the opinions expressed during that meeting, it appeared that Dr. Woodcock also wanted the timeline to be compressed.

Q Did she explain why?

A Well, both of them together expressed the concern about the Delta variant, the need to have a licensed vaccine in order to be able to support mandates, and the idea that a licensed vaccine might engender more confidence than an EUA-authorized vaccine among the vaccine-hesitant.

[redacted] Now, you just said the need to support mandates. In your view, was that need part of why you all were being pressured to meet this deadline, or this assumed date?

Dr. Krause. Given that they brought it up, it's hard to imagine that that was not a component of this pressure.

BY [redacted]:

Q And she went on to write in the email that the memo to Dr. Marks stated that "the review requires a thorough evaluation and FDA's own analysis of the safety, effectiveness and manufacturing information submitted to support licensure of this vaccine. This has been OVRR's standard for all other BLAs, and while time-consuming,

OVRR believes that public confidence in COVID-19 vaccines would not be served by rushing our review and evaluation of the submitted data."

And I know earlier -- it was either the last hour or two hours ago -- you discussed your opinion that the FDA did ultimately provide a thorough review of the Pfizer BLA. But was this review done before or after you were relieved from working on this BLA?

A Well, the review had been initiated before Dr. Gruber and I were relieved from supervising the BLA.

I'll point out, I actually continued to try to contribute to the review even though normally, when Dr. Gruber would leave, I would have been the one who would have taken her place. But I still did my best to contribute to the review while it was ongoing even though I was not leading it.

Q And you had mentioned that normally you would be the one to be in charge or step in her shoes if she was gone, and I know that she had been away for a period of time on annual leave.

Do you know what the decision was to not have you be the acting director and why Dr. Marks was the one that became the acting director?

A I'm very puzzled by that. And what I can tell you is that, if you look very closely at the FOI emails, there may be some hints in there. And I can tell you which ones I think might have some hints, but I can't speak for any direct knowledge, only that some of these emails have some suggestions in them.

BY [redacted]:

Q Well, please provide --

A And I don't have any of the emails in front of me, and I don't know if you have them all either, from Judicial Watch. But --

Q From your recollection is fine.

A Sure. Well, there was a reference from the -- let me just see. One of the those words was in here. There's the timeline and -- 3, 4 -- what did I do with No. 2? Maybe it's in here.

Yeah, so there's a hint here in an email on Friday -- the first email in No. 2, which of course I wasn't on but I saw when I looked at the Judicial Watch emails -- and it says: "Please see the attached. Marion finally provided this timeline. I can already see a number of potential efficiencies. Perhaps we can discuss over the weekend briefly in preparation for Monday?"

Now, there were other emails that were sent on either Thursday or Friday between Dr. Marks and Dr. Woodcock that -- and there's one, I think, from Dr. Woodcock to Dr. Marks, suggesting that they would need to do certain things after he took over. So it seemed clear that that previous week there was already a plan for Dr. Marks to take over the review.

So aside from that, I don't have any basis for knowledge of what the reasoning for that might be. In general, I've learned that usually these things are not personal, and so at the time it occurred to me that there were aspects of the review that he might want to control.

Q Is that your --

A That he didn't think -- that was my opinion based on the situation, yes.

Q Do you have any other opinions on the situation?

Mr. Thomas Krause. Want to go outside?

Dr. Krause. Yeah, okay, we'll go outside.

[redacted] Off the record.

[Discussion off the record.]

[redacted] We'll go back on the record.

Dr. Krause. I think we've covered it. If you go back and look through the Judicial Watch emails, there are a number of emails that address the planning of Dr. Marks to take over.

[redacted] In your opinion, would you have been more prepared to lead the team on the Pfizer BLA in Dr. Gruber's absence and even after had she not retired?

Mr. Thomas Krause. More than what?

[redacted] I'm sorry.

Dr. Krause. More prepared than what?

BY [redacted]:

Q To lead the team on the Pfizer BLA, as opposed to Dr. Marks, in Dr. Gruber's absence and then subsequent retirement.

A So there I have no doubt that I was fully prepared to step in and lead the team to a successful conclusion of the review.

Q And then, going back to exhibit 5, in response to Dr. Woodcock -- I'm sorry -- in response to Dr. Gruber's email, Dr. Woodcock writes back thanking her for summarizing the meeting and noting that, "With respect to the specific timeline for completion that you propose, I do not have enough information to venture an opinion."

Based on the previous memo that you both drafted with a team of folks and the updated timeline, and your discussion at the meeting, does her response in this email track with what she said in the meeting?

A Well, you're asking me a question that a semanticist might be able to better answer. But I will give you my opinion that she had just decided to relieve Marion and myself from direction of this BLA, it would appear, solely over the question of whether this was the right timeline or not.

And based on the emails I was referring to between her and Dr. Marks, it

appeared that this was -- she was -- had thought this was the right thing to do for some number of days.

And so it's hard to imagine that she did not feel that she had enough information to venture an opinion, or maybe she felt that she had enough information to make a decision but not enough information to venture an opinion.

Q And also, in recapping the meeting in Dr. Gruber's email, like we had already discussed, she had said that absent a license States cannot require mandatory vaccination and that people hesitant to get an EUA-authorized vaccine would be more inclined to get immunized when the product is licensed. And that was recapping what Dr. Marks and Dr. Woodcock had said.

Do you recall if Dr. Marks or Dr. Woodcock expressed this belief about States requiring mandatory vaccines coming from outside of the FDA?

A So the decisions about mandating vaccines, whether for the Federal Government or for the States, did not -- were not made by the FDA. And the FDA normally separates itself substantially from decisions about how vaccines are used because of the need to retain confidence in the FDA's objectivity.

And so the FDA, the way the system is set up, performs objective reviews of the data to determine whether the product should be authorized or licensed and to make sure that the claims that the developer might want to make about this vaccine are supported by the data.

But the risk, if the FDA starts getting involved in deployment decisions, is that it will appear as though there's a bias there, because if the FDA says, for instance, these people should get that vaccine, these people shouldn't, it should be mandated for these and not those, or whatever, and then what if something goes wrong, then the FDA can't anymore be perceived as an objective arbiter of what to do next.

Maybe the vaccine needs to be recalled, but if the FDA said everyone should take it, maybe the FDA will be reluctant to make that decision.

And so this is how, when I was at the FDA, I learned was the evolution of the system where the recommendations for how vaccines be used were generally made by the Advisory Committee for Immunization Practices of the CDC and the decisions about what vaccines to authorize and license were made completely independent of any use decisions by the FDA.

So a statement that this is necessary for -- in order to mandate vaccines would suggest that that statement is coming from outside of the FDA because it's not part of the FDA's usual function.

And in giving you that proviso, I'll add an opinion here. And of course mandating vaccines, just as it was not in Dr. Woodcock's or Dr. Marks' purview, it also was not in mine, but my own opinion at the time was that that was not a sensible reason for speeding up a review. And really I had two main rationales for that.

One of them was the concern -- and this was evident just from reading the newspaper around that time -- that if vaccines were mandated, whether at the State level or the Federal level, that many people would resist that, because many people would be against being forced to get vaccinated for whatever reason.

And what I thought would likely happen was that that resistance to mandates could then turn into resistance to the vaccines themselves and that mandates themselves might paradoxically increase vaccine hesitancy. And one might be able to force some people to get vaccines, but then that might cause other people to be very reluctant to get vaccines.

And of course if there's a mandate and you also are hoping that you're going to convince people that the vaccine works well, then they might reasonably ask: Well, if

you're so confident that this is a good and safe vaccine, why do you have to mandate it? Why can't you trust me to make that decision myself.

And so I actually thought that moving towards mandates also undermined the very stated purpose of increasing confidence in the vaccine.

I will add one other thing, and that is, from a public health perspective -- so I guess actually I'm up to three reasons -- from a public health perspective, for a mandate to make the most sense, it has to be for a vaccine which will interrupt transmission of the virus, because one of the main ideas behind a mandate is that you're trying to protect additional people.

So if by insisting that you get vaccinated I can protect many other people, then maybe that's a societal good that comes out of the mandate.

But at the time that we at least reached the end of the BLA review, but around that time, there was increasing data that the vaccine wasn't actually substantially reducing transmission from people who were infected.

And so it was, while it was still protecting people against severe disease, its impact on transmission was much, much weaker.

So the public health case for mandates, I thought, was weak and -- but I was as concerned about the risk that mandates could actually paradoxically reduce confidence in the public health authorities and reduce confidence in the vaccines.

[redacted] And did you share this considered opinion with anyone in your office?

Dr. Krause. I did discuss this with Dr. Gruber. I don't know whether she shared it with Dr. Marks.

You know, these discussions were happening very rapidly under a lot of pressure, and by the time the meeting with Dr. Woodcock occurred, which was just one business

day after the timeline was sent and Dr. Gruber and I had a brief meeting with Dr. Marks to explain why we thought the action due date couldn't be sped up faster than September 15th, but there the issue of did we agree with the reasoning didn't really come up.

But by the time we were in the meeting with Dr. Woodcock, we'd both been relieved of responsibility, and so it didn't seem as though that was a time when anybody was going to listen to us.

BY [redacted]:

Q When did you -- when were you relieved of responsibility? You said it was before the July 19th meeting?

A Well, at the July 19th meeting, Dr. Gruber was told that Dr. Marks was in charge, and I was told that I would not be in charge when Dr. Gruber left.

Q So that you were both informed of that on July 19th at that meeting?

A That's correct, yes.

Q And then, going back to what you mentioned about the mandates, that being part of the discussion in that meeting, had there been any other discussion at the FDA or even just within your OVRR, to your knowledge, about the concern that there needed to be a license in order for these States to mandate the vaccine, like, or was this the first time that this was discussed?

A I don't recall. It seemed like this argument was coming out sort of most forcefully right around this time. It's possible that it was mentioned earlier, but I don't recall that.

Q And I briefly want to switch gears, going to -- going back to our discussion about your departure from the FDA. And I know that we discussed Dr. Gruber had been on leave, and I believe she was gone for, like, a month, and then she returned.

When did you decide to leave the FDA? Was it after this July 19th meeting? When did you make your decision to depart?

A I made my decision to depart as I heard that Dr. Gruber was departing.

Q And why is that?

A The -- well, the -- I had probably -- well, I had stayed at the FDA longer than I had originally intended to. I did not perceive that I would finish my career at the FDA, and I always wanted to do something else. And of course the question always is, then, well, when to do that, as one also gets older, right?

And so when the COVID pandemic came around and when I had the opportunity to have, I think, a very substantial influence in favor of public health, there was no question that the FDA was the right place for me to be and to stay.

I admit that the events in July and August surrounding the BLA and the booster vaccines made me concerned, without direct knowledge of any specific outside interference, because I didn't know of any communications from the outside, but it appeared as though major decisions that normally would have been within the purview of the office were now being made outside of the office, whether at the center director's level or even elsewhere.

And certainly, if one were to read the press at the time, many people interpreted some of these actions as representing political interference, especially around the booster issue.

[redacted] Is that how you interpreted it?

Dr. Krause. So, as I said before, the President announced that everyone in the country would be boosted, and he made this announcement on September 18th -- on August 18th -- and he said that they would be boosted by September 20th.

Also on August 18th, three leaders of public health agencies said, including the

acting commissioner of the FDA, said that boosters would be available for everybody by September 20th. So it was at that time there was some data on boosting in-house on the Pfizer vaccine and there was no application in-house from Moderna at that time.

And so it was clear that people outside of the FDA were creating an expectation around boosters. And of course they said, well, this is all subject to FDA approval. But the acting commissioner had also signed on to this, and this was the same acting commissioner who had just relieved Dr. Gruber and me of duty when we suggested that we might not be able to meet an aggressive timeline that was favored by other people.

And so, given that evidence, it was very difficult to imagine that there was -- that the Office of Vaccines would have the same level of autonomy going forward as it had had in the past.

[redacted] And the intrusion upon that autonomy was coming from where, in your opinion?

Dr. Krause. Well, in the case of the booster --

Mr. Thomas Krause. You don't need to speculate. Go ahead.

Dr. Krause. Well, in the case of the boosters, there were announcements simultaneously from the President and three public agency heads, right, Tony Fauci, Rochelle Walensky, and Janet Woodcock was the acting commissioner of the FDA. And so from someplace that impinged upon those levels, it appeared as though that this pressure was coming.

BY [redacted]:

Q Okay. To follow up, during one of our colleagues in the minority's questioning sessions, I believe there was an allusion to potential political pressure during the administration in office in 2020.

Given what you've just testified to, is it fair to say that, in your opinion, you've

witnessed political pressure in the vaccine and/or booster process from the Biden administration?

A I can say that I witnessed political pressure from outside the FDA likely, but I cannot point to any direct evidence of where that pressure came from. Everything else is a conjecture based on the evidence.

But there is no smoking gun of somebody who had -- where there's some evidence of a single person outside the FDA directly applying such pressure.

Q And I think you very carefully just testified, you didn't base that on direct evidence, but it sounds like you're saying based on the circumstantial evidence there was the political pressure from the administration -- the Biden administration.

A There was, again, circumstantial evidence that suggested to me that staying at the FDA didn't make any sense, and it was because of -- well, it was because I was planning to leave anyway, in part, and partly because of that circumstantial evidence.

It appeared to many in the press that this pressure came from the White House. I don't know exactly how that would have worked, and so I'm reluctant to say that I know that it came from the White House, but there is certainly some -- there is -- a reasonable person might think that was a possibility.

Q Fair enough.

[redacted] And in that same vein, I actually want to touch on briefly -- I don't know how much time, I think we are running low on time -- but I want to briefly touch -- cool -- I will enter this article into the record as exhibit 6.

[Krause Exhibit No. 6.

Was marked for identification.]

[redacted] And I won't ask a ton about it. But this might be a little bit about what you were referencing as things you were reading in the news regarding things that the

FDA was trying to accomplish.

And I know at the time that this article -- and this is a New York Times article published August 27th, 2021, and it said that "Biden Floats Faster Access to Booster Shots Amid Spread of Variant." You were still at the agency at this time.

Had you announced at this point, to your recollection, that you were going to be resigning?

Dr. Krause. No. I made that announcement on the first business day of September.

[redacted] Okay. Did this announcement about the boosters -- I know you started to touch on it -- but this announcement coming from the White House, where President Biden had said, after his meeting with the Prime Minister of Israel, he had said, "We were going to start mid-September, but we're considering the advice that you've given that we should start earlier. The question raised is should it be shorter than eight months? Should it be as little as five months? That's being discussed."

And when he says, "That's being discussed," is that something normally that the FDA would be discussing and making that type of determination?

Dr. Krause. So, yes, the FDA would normally be responsible for approving or authorizing an indication defining the population of people who would be eligible for boosters.

And so in the initial comments I think the suggestion was that people who had had their second dose of vaccine 8 months or more ago might have had sufficient waiting that they might benefit from a booster, at least as was being described by the people who were in favor of boosters.

And the comment raised by Mr. Biden was: Should that interval between the second dose of vaccine and the first booster be as short as 5 months?

In my view, that's a comment that is pretty damaging to public confidence in the original vaccine series because what you're saying is, initially, well, we think it at least lasts 8 months, but now we're not even sure it lasts 5 months.

And so it's really saying that the White House doesn't have confidence that the original vaccine series will protect people.

Now, I'm willing to accept that this may have been a completely unintentional comment and Mr. Biden may not have thought about the impact of such a comment on vaccine confidence or vaccine hesitancy or on people's willingness to accept the vaccine in the first place.

But of course that's a good reason to consult with vaccine experts before making these kinds of comments, because I'm sure that wouldn't have been his intent.

[redacted] We'll go off the record.

[redacted] We'll go off the record so Dr. Krause can consult with his counsel.

[Discussion off the record.]

[4:23 p.m.]

[redacted] We'll go back on the record. We probably only need just a few more minutes.

Dr. Krause. Can I just back up and make a correction of a statement that I made before where I may have been a little bit too glib in paraphrasing Mr. Biden as saying on August 18th about -- I might have said something like everybody will be eligible for boosters by September 20th.

And, of course, that wouldn't have been everybody. As you pointed out here, that would be people who have had their second dose of vaccine at some period of time before.

But he was talking about a fairly universal booster campaign. And so I would just like to make sure that I am not misunderstood as to have thought that he literally intended for everybody to get a booster by -- or have a booster available by September 20th.

[redacted] Thank you for clarifying that.

BY [redacted]:

Q Yeah, thank you very much.

And I think just in regards to two more additional questions that I have.

Other than you and Dr. Gruber, did anyone else on your team in OVRR decide to leave the FDA as well after or around this timeframe in September, October, November 2021?

A In those months, I think it was just the two of us. Since then, Dr. Fink has left the FDA, but it was not at exactly that time in terms of senior people in the office.

Q Do you know what Dr. Marks' reaction was regarding your resignation?

A I don't have a clear picture of that. He was certainly cordial, and he held a

retirement ceremony at which both Dr. Gruber and I were honored and received Distinguished Career Service Awards, and people were -- had an opportunity to give speeches. And so that was his visible reaction.

Q Awesome. Now, a little quick switching gears.

Did you do any work on Ivermectin?

A None.

Q None. Okay. That was in a different center then or a different --

A That's correct. Ivermectin would have been in the Center for Drugs, and we were in the Center for Biologics.

Q Who would have been the director, deputy director around this time, in 2021, that worked on that?

A That's a great question. There's an office of antivirals, and the director of that office is John Farley, I think, unless he's moved.

I don't know whether Ivermectin would have received a review through that office or through an antiparasitic drugs office, though, because that's the major indication for Ivermectin, and I don't know who's in charge of antiparasitics.

Q Okay. Well, I just didn't know if you did any work on that, so that's all I need. And then I think my colleague has a question, and then I'm --

[redacted] If I could just conference with my colleague for one second.

[redacted] We'll go off the record for a moment.

[Discussion off the record.]

[redacted] We'll go back on the record.

[redacted] Back on the record. I have one last question for you, Dr. Krause, and my colleague, [redacted], will ask a question.

You had indicated previously that at some point you were ready to step down and

do something different. Is it fair to say -- from the FDA. Is it fair to say that you made the decision to leave when you did because of Dr. Marks' sort of interference in the work that you were doing at the FDA?

Dr. Krause. So there are two ways in which I would slightly quibble with your statement.

So I wouldn't personalize this to Dr. Marks. I think that there was enough evidence of outside interference, without it being completely clear where it came from, that it made me uncertain that I would be able to do my job effectively as I thought it needed to be done.

And I suspect if this had not happened and there had been no pandemic, I would have left long before this. And so while, of course, the pandemic was a lot of work, and it was very important, and it was exhilarating to be involved in that work and to know how important it was to so many people, perhaps by contrast that also made the sudden change in how it was that the work of the office was being managed, it turned it into a more obvious difference.

And so I don't know if that's a fair answer to your question. So I wouldn't say it's just because of Dr. Marks. I would say that the situation, given the pandemic, made me more likely to leave at that time.

BY [redacted]:

Q Yeah. Thanks for your endurance. I'll be quick here.

If I understood you correctly in the first hour, it seemed that you indicated that you were kind of aware of this phenomenon of groupthink, and you would actively stoke debate in your team to bring out minority opinion. Is that right?

A Absolutely, yes.

Q And it seems like that contrasted with what Dr. Marks did with you guys in

removing you and Dr. Gruber. Is that right?

A I have wondered, if he was convinced that he had a solution for how to speed up the review, why he wouldn't have just told us what that solution was and we could have implemented it. There was certainly nobody who -- in the Office of Vaccines -- who was resistant to brilliant management suggestions.

Q Right. Right. So you were relieved along with Dr. Gruber because you had a minority opinion and Dr. Marks sought consensus?

A Well, I'm not sure how we define the word -- I'm not sure that "consensus" is the word that --

Mr. Thomas Krause. What do you mean by "minority opinion"?

[redacted] Well, it seems like you had a different perspective on what a reasonable timeline was, and rather than engage with you on the logic for your perspective on the timeline, you were just removed from the conversation.

Dr. Krause. I think that's fair. Of course, he might say that he attempted to engage and we came back to him and told him why we didn't think we could promise better.

But you're right, then he took over and did not officially change the ADD either. He just worked until the job was done, which is, of course, what I would have done in that position as well.

[redacted] Right.

Dr. Krause. But there's no doubt that he and I have contrasting management styles.

Mr. Thomas Krause. Do you want to address whether yours was a minority view of the timeline?

Dr. Krause. Well, again, I guess the question is, minority compared to what?

Certainly, his desire for a more rapid timeline was held by himself and Dr. Woodcock. It may well be that -- it seemed like, when you look at the number of office directors who were also contributing to Dr. Gruber's assessment of what the most appropriate timeline to promise would be, is his actually was the minority opinion.

[redacted] Understood.

Just one final question on this. To me, this appears that the graph in the Lancet article, it appears to me that the data very much supported your conclusion. I think you had said earlier that to look at this data would force you to this inescapable conclusion that the booster was not necessary.

Dr. Krause. That was my conclusion. And of course this paper, you didn't reproduce it because it's hard to find online, but there's also an appendix which lists all of the individual studies that were reviewed and what the individual results in those individual studies were.

And there are about 100 of them that were available at this time that met the criteria for this analysis of having -- of presenting credible analyses that would allow one to both look at efficacy in -- efficacy against severe disease and efficacy against symptomatic disease.

[redacted] Right. And in spite of the strength of the data that you presented, it was overwhelmed by another force, and that was what exactly, just the political pressure?

Dr. Krause. Well, so based on what I was reading at the time, the White House COVID task force was a strong believer in the Israeli data, and they were afraid that Israeli would be a harbinger for what would happen here, and so it would be a harbinger, and that we would soon find in the U.S. that there would be reduced efficacy even against severe disease.

I don't know how they came to that conclusion, because on looking at the Israeli data I did not find it to be persuasive, and I suspect other people with experience in epidemiology could have looked at that and come to the same conclusion.

But there certainly were scientists out there who I think may have been operating -- and I don't know if this was in the White House -- but who may have been operating as much out of fear as out of logic, and they were afraid of the Delta variant and were afraid that something might happen and wanted perhaps to be seen as doing something.

[redacted] And fear is not science?

Dr. Krause. Are you sure?

[redacted] I'm asking.

[redacted] That's all.

[redacted] All right. We can go off the record. Thank you.

[Discussion off the record.]

[redacted] Okay. We can go back on the record, please.

All right. I'm going to introduce for the record exhibit 7, and this is the actual FDA approval letter dated August 23th, 2021, for the BLA.

[Krause Exhibit No. 7.

Was marked for identification.]

Dr. Krause. Thank you.

BY [redacted]:

Q Have you seen this before?

A I have, yes.

Q Okay. And can you just turn to the very last page? And there's two names on it that were the approving officials for this BLA review. Can you tell us who they were?

A Sure. Mary Malarkey and Marion Gruber.

Q Okay. So a couple of -- and Marion Gruber is Dr. Gruber that we've been talking about throughout this TI, right?

A Yes.

Q So can you explain -- as you might be aware, Dr. Gruber came before this committee as a witness and was asked a series of questions about this approval process just as you were, and she testified that she approved and signed the approval letter. Does that surprise you, that she testified to that effect?

A No.

Q Okay. So you knew that she actually did participate in this process, the BLA review and approval?

A Yes, of course. I was there, yes.

Q Okay. So when you say that she was removed by Dr. Marks, can you explain what that means in light of the fact that she actually signed the approval letter?

A Yeah. I'm not exactly sure how that came to be, because Dr. Marks was supervising the approval process from the time he took over until the end. But in the end, Dr. Gruber signed as the director of the Office of Vaccine Research and Review. But she was not supervising the review process up until August 23rd.

Q While she was on leave?

A Well, she was on leave until early August, perhaps August --

Q August 7th, correct, or do you know?

A You know better than I then.

Q Well --

A Somewhere around there. That's consistent.

But just as I did, I think she attempted to help as much as she could to make sure

that the review was complete and thorough.

And, indeed, she reviewed many, if not all of the documents in the approval file. I reviewed many of these documents also and had a few comments on them. I made recommendations for how the benefit-risk analyses could be improved, and those recommendations were accepted.

And so she and I were both involved in doing everything we could to make this process as robust as possible.

Q Okay. So fair to say that you both participated in the approval process, but you were not the supervisor at that stage?

A That's correct, yes.

Q Okay. And your input was considered by the people who were supervising?

A Absolutely, yes.

Q Okay. Was there anything at the end of the day, when you came to be aware that this approval was granted by the FDA, that concerned you about the conclusions that are inherent in that approval?

A No. I completely agreed that the product met the standard for approval and that it was appropriate to approve the BLA.

Q Despite the compressed timeline that had you concerned at some points?

A So the compressed timeline had us concerned not because -- so what we were concerned about wasn't that -- wasn't the compressed timeline, per se. What we were concerned about was we were being asked to promise that the review would be completed on a certain date that we were not sure was a promise that we would be able to keep.

Q And ultimately Dr. Marks never promised that the FDA would complete the approval process on August 23rd. Is that right?

A I don't know what he promised external to the FDA. There are some emails that suggest that he had had a notional approval date of August 20th.

And there are some emails in the Judicial Watch tranche, which I'm sorry I can't provide you with, but if you are willing to dig through many, many pages -- or maybe it isn't even Judicial Watch, it's another one -- you could find those that imply that he was aiming initially for the 20th, but then it appeared that he wasn't -- that the team was not going to be able to meet that. The 20th was a Friday, and so it was ultimately approved the following Monday.

Q Okay. But he never moved the -- what was it again, the date is called the ADD?

A That's correct. So what he said was that the review was proceeding without an ADD. It was proceeding with the goal of completing it as quickly as possible. This is my recollection of what he said, and I was at many of those meetings.

Q Okay.

A I don't remember which meeting he said that at.

So what he did then obviously was operating under a somewhat different set of rules than the one that he was requesting that the office operate under. He requested that the office provide a certain date by which it would be finished as opposed to simply proceeding until it was done and hoping to get it done as rapidly as possible.

Q But ultimately exactly what happened was it got done as fast as possible without a required date, right?

A Yes. Yes.

Q And you have no concerns about the process itself as it was completed by the 23rd of August?

A So as I mentioned earlier, the one concern that I do have is that, while this

was within the range of activities that the FDA could -- within the range of appropriate process for the FDA, I think that confidence in the approval in the FDA would have been enhanced if there had been an Advisory Committee meeting. But that would have taken longer, probably, even than September 15th, to put that together and do that, because an Advisory Committee meeting for a BLA is very complicated.

So while I -- and I did not think, as I mentioned earlier, that the Advisory Committee was required in order to provide key advice to the FDA, which is one reason for calling the Advisory Committee, but I did think that overall confidence in the decision and public confidence in what the FDA was doing could have been increased if there was an Advisory Committee.

Q But you, yourself, when you were in charge of the supervision, along with Dr. Gruber, accepted that September 15th was a reasonable date, right? That was one of your recommendations?

A Well, Dr. Marks originally was the one who said that he wanted it to be September 15th instead of mid-October, but we ultimately agreed with that.

And, again, that's a suboptimal situation where you don't have the Advisory Committee. But if your goal is to approve quickly, then you have to sacrifice the Advisory Committee. The Advisory Committee was a nice-to-have but not a need-to-have.

Q And I'm just asking because you agreed to that September 15th. Under the circumstances, the extraordinary circumstances of this pandemic and the priority review, that was not something you disagreed with at that point when you and Dr. Gruber said September 15th is reasonable?

A At that point, we -- that's correct. We would have -- well, we did agree to an action due date of September 15th.

Q And it actually became problematic later than that, in your view, because

they were trying to push the date earlier than September 15th. That's when it became more of a concern for you?

A I'm not sure I can agree exactly with your characterization of "concern," right? What we said was that we couldn't promise an ADD before September 15th based on what the people who needed to do this work and the accounting were telling us, and the accounting that we needed to do for the interactions with Pfizer.

And so we were concerned that if there were an ADD before September 15th that that might create problems. Dr. Marks proceeded, and he also did not have an ADD before September 15th.

Q Exactly.

A And so --

Q So it didn't change?

A That didn't change.

Q Right.

A So I did not fundamentally have any concerns with the idea of saying let's proceed as quickly as we can. If the goal is to do it quickly, then that's a reasonable thing to do.

But if you asked me were there ways in which this process could have been better, right, I think you asked did I have any concerns about the process, although I don't remember exactly what the question was --

Q Well, I was asking you to kind of describe how your concerns kind of evolved with these different decision points.

A Right. So -- right.

So once the decision is made that this needs to be done by September 15th, then there cannot be an Advisory Committee meeting anyway; and yet, this approval would

have engendered more confidence if there had been an Advisory Committee meeting.

And so the question then is just, was the added transparency, which could have been accomplished with an Advisory Committee meeting, worth the amount of time it would have taken to do that?

Q And in your opinion, at least as of the time that you signed on to the September 15th goal, you decided what in terms of that balance, that it was not --

A Well --

Q -- outweighing the benefit of going ahead on this --

A So it's difficult, because when you're in a hierarchical organization like the FDA and your supervisor is saying it's very important to me that this get done by a certain day, then one has to, of course, weigh the potential advantages of getting it done by that certain day and what the cost of that is in terms of transparency.

Q And is that what you did when you and Dr. Gruber said September 15th is one possibility here?

A Well, again, Dr. Marks was the one who suggested September 15th.

Q But you agreed, correct?

A And we agreed to do that, that is correct.

Q Okay. And by agreeing that, you had decided, at least with respect to this Advisory Committee, that on balance you were willing professionally to let that go?

A Yes. On the other hand, one could argue that if one understood completely -- and of course, by the time that he said September 15th we didn't know that -- one could argue that if the consequence of this approval would be mandates, or if the consequence of this approval would be other things, then the importance of public confidence in that decision would be increased.

And so at the time that we agreed to September 15th we had no knowledge that

there was a plan or that there was a likelihood that this decision would then be used to justify downstream decisions that might actually require an even higher level of public confidence in the decision.

And so that calculus, at the time we agreed to change the action due date to September 15th, was different from the calculus once we understood all of the rationale for speeding things up even further.

Q Sure. Because at the time, like, none of those things existed, and you were trying to make a decision at the moment in time when it was presented to you?

A That's correct, yes.

Q Okay. I'm going to talk a little bit about public perception, because you've mentioned that that is kind of an overarching concern, is, like, how the public views the FDA and whether they could trust the decisions that are being made.

And you have -- I'm going to ask some questions about exhibit 6, which is this New York Times article that quotes President Biden.

Do you have that article in front of you?

A I'll find it here.

Q Okay. I can give you another copy.

A No. All right. Sounds good. Six.

Q Yep. Okay. So in the very first line, you see it says: "President Biden suggested on Friday that the government could offer coronavirus vaccine booster shots to most vaccinated adults sooner than eight months after a second shot, underscoring the administration's concerns about the spread of the Delta variant."

And it's interesting, I mean, they say he suggested on Friday. Is there anywhere in this article, or to your knowledge are you aware of any statements that Mr. Biden made with respect to this booster shot that are stronger than a suggestion as they're

characterized in this New York Times article?

A I do not have articles that -- actually, let me just look at something here. I don't think I have something that suggests that -- I don't have a copy of what he said on August 18th. But what he said on August 18th I recall as being more definitive than a suggestion.

Q Okay.

A But I could be -- but I can't -- I don't have a copy of that. And so it is possible that my memory is incorrect on that.

[Krause Exhibit No. 8.
Was marked for identification.]

BY [redacted]:

Q I'm going to go back to that in a minute. But for right now, I'm going to introduce for the record exhibit 8, which is a tweet from former President Donald Trump. And I have copies for you guys.

A Fantastic.

Q It's short so you can just look at it real quick.

A It's a tweet, right? 140 characters.

Q Very brief, yep. Right to the point.

Okay. So this tweet, as you'll see, is dated October 6th, 2020, 9:09 p.m., and it's from President Trump while he was in office. And the tweet reads, quote: "New FDA rules make it more difficult for them to speed up vaccines for approval before Election Day. Just another political hit job!" And then he tags @SteveFDA, so directly meaning to communicate to the FDA.

Now, earlier in the hour when you were asked about Mr. Biden's statements you hesitated to say that there's any direct evidence that the White House was trying to

influence the process, but you said maybe circumstantially you could argue that.

Well, what about this? Like, would you consider this some direct evidence that the occupant who was the President at the time, the occupant of the White House, made this statement directly to the FDA, would you consider that direct evidence of a political effort to influence the FDA?

A It certainly looks like it's direct evidence of such. Of course, it's -- and it's certainly a complaint. It's not completely clear what it is that he wants the FDA to do as a result of this.

Q Well, it seems to say -- he's complaining about FDA rules that make it, quote, "more difficult for them to speed up vaccines for approval before Election Day," unquote.

Would it be of concern to you if political operatives or actually the President of the United States wanted to speed up vaccines for approval before election day? I mean, is election day a consideration for the FDA when they make approval decisions?

A No, of course not. Election day is not a consideration.

Q So would that be a concern?

A And so it -- this does look like direct interference in the FDA's work.

Q I mean, it's pretty clear on its face, right? Like, election day is the concern for the President, right?

A Yes.

Q He says so.

A Yes, that is correct.

Q And this is a direct communication from the President himself to the FDA, right?

A Well, to Dr. Hahn, I assume, yes.

Q Right. I mean, his -- that's who's tagged there, right?

A Right, yes.

Q Okay. I think, just for the record, the one I read I labeled as exhibit 9. So let me introduce both of these. I have exhibit 8, which is the August 22nd --

[redacted] No, exhibit 8 is the October one.

[redacted] Oh, that's --

[redacted] Exhibit 9 is this --

[Krause Exhibit No. 9.

Was marked for identification.]

BY [redacted]:

Q Okay. The one I read is exhibit 8, sorry.

And then I'm going to introduce exhibit 9, which is another tweet from Donald Trump on August 22nd. So this is actually an earlier tweet but a later exhibit number. I'll give that to you. Again, it's brief.

Okay. So the tweet says, quote: "The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd. Must focus on speed, and saving lives!" And, again, tagging @SteveFDA.

Did I read that correctly?

A You did, yes.

Q Okay. And this was August 22nd, one day before the approval. Is that -- or this is, sorry, one year and one day before the final approval.

A Yeah, I think this may have been in very close proximity to the authorization of convalescent plasma that I described earlier.

Q Okay. So how close, in your recollection, was this tweet to that authorization?

A Within a day or two, I think.

Q Hmm. And do you find that timing suspicious or at least potentially damaging to the view of the public of the FDA?

A Yes.

Q Why is that?

A Well, because if FDA is perceived to be making decisions as a result of this kind of a statement then that can damage the credibility of the agency.

Q Do you think that this tweet could have had any influence on the FDA officials who did approve that therapeutic that you testified earlier you didn't think was effective or based on science?

A The convalescent plasma?

Q Yes.

A So I don't know all the ways in which communication occurs between higher levels of government and government agencies. I would be surprised if this was the only -- if, in fact, there was political interference there, I would be surprised if this was the only thing that happened. This might be -- if there were political interference, this might be the only readily available or openly available evidence of that. But -- so I don't know. But --

Q You mean, like, if there were a FOIA request, there might be emails out there that show more communications between White House officials and FDA officials?

A That I don't know. But if -- I've certainly read in various articles that people were suspicious of the authorization of convalescent plasma around this time. And so if, in fact, that authorization had something to do with this tweet, then there might sort of be other documentation of that.

Q Okay. But @SteveFDA, do you have an opinion about who that is, or do you

have knowledge of who that might be?

A Well, just as I said in the previous one, it's likely Stephen Hahn, who at the time was the commissioner of FDA.

Q Okay. And what would his role have been with respect to any of the approvals of convalescent plasma, for example?

A Probably very little, because those decisions were made within the centers. So I think Dr. Marks may have been the one who signed off on the authorization of convalescent plasma.

Whether -- but it's clear that -- well, not clear. It seems as though the President is trying to apply pressure on the commissioner so that the commissioner will apply pressure on other people who would make this decision, and I don't know how the commissioner responded.

And I also don't know whether the President making a statement of what he wanted that happen might have also influenced other people besides the commissioner. Obviously anybody can read a tweet.

Q Right. It could have influenced Dr. Marks in this instance potentially? He was in the same position that he was later?

A So you would have to ask him. I've probably already speculated too much. That's beyond what I'm willing to say.

Q Do you know if he was in the same position --

A Yes, he was. He was the center director.

Q Okay. And so his role in the approval of convalescent plasma, was it the same as his role in the approval of these other vaccines and things we've discussed?

A So I'm not completely sure how his role in the approval of convalescent plasma was defined. But he played a pivotal role in that approval.

Normally convalescent plasma would have also been signed off on by -- well, the review would have occurred within an office, and then an emergency use authorization would have been issued by the FDA's Office of Chief Scientist.

And so I don't know whether he -- I don't know the degree to which his signature is on various documents related to that authorization, but he certainly was a strong proponent for it within FDA.

Q So you wouldn't have had any role with respect to the approval of therapeutics like convalescent plasma. Is that right?

A It is true that I did not have any role, but when I heard that this was imminent -- and I don't remember if it was this week or the previous week -- I did actually send an email to Dr. Marks asking him if he was sure that this was the right thing to do, because it seemed like the evidence was very weak.

Q Did he respond to you?

A I don't recall.

Q Okay. Do you know if the person -- there must be a person who's in the equivalent of your position that would have been the expert underneath Dr. Marks, right, with respect to the convalescent plasma therapy?

Mr. Thomas Krause. We might be getting into deliberative process on -- we don't have the emails.

BY [redacted]:

Q I'm not asking about the deliberation. I'm just saying, is there a person?

A So the answer is the convalescent plasma would have been covered by the Office of Blood. Dr. Nicole Verdun at that time was the office director. She's actually now the director of the -- they've changed the name, the replacement for OTAT, the gene therapy and cell therapy office, Office of Therapeutic Products, I think it's called.

Q Would it be fair to say that, to the extent that you have concerns about any outside pressure from the White House or from anywhere else that's making the FDA -- influencing the FDA's decisions in a political manner, those concerns that you have, would they be the same concerns in the process, like, of approving convalescent plasma when there was no data that it was effective and when there's evidence of direct influence politically from the President of the United States?

A So I would have those concerns there as well, yes.

Q And does it surprise you that there was never a congressional investigation with respect to that decision, the approval of convalescent plasma ignoring science and in light of political influence?

A I know very little about how Congress works and what are the bases for congressional investigations. But I do understand that -- well, and so I know that at various times since then different parties have been in control of the House and the Senate. Either branch could launch investigations, I guess, but I don't know how the branches prioritize the investigations that that they would perform.

Q Sure. But in an ideal world, from the perspective of somebody who cares about how the FDA is perceived and how much trust people have in that regulatory process, would you like to see Congress interested in political influence over decisions like this in a nonpartisan way?

Like, say, if the FDA is being influenced unfairly by political pressure, would you like to say that that Congress is going to be just as interested if that political influence comes from a Republican President as if it comes from a Democratic President?

A Of course, I would hope that. But, honestly, it's very easy to look backwards and see problems. And so, to me, the critical question is, how can one devise systems going forward to reduce the likelihood that in a subsequent pandemic or a subsequent

emergency especially that the temptation for political pressure is reduced?

And that involves making sure that the Federal organizations are strong enough that they can do their job, and if they're not doing their job, it will become apparent that they're not doing their job.

And so this gets back to the suggestion that I made earlier, that regardless of whether or not specific interference occurs, it's clear that in many of these cases there is good reason for a public perception that there at least have been attempts at interference.

And so the question is, how can one -- how can we devise a stronger system, a stronger -- stronger Federal agencies such that that is less likely to happen?

And it's difficult when you look at the EUA standard, which of course was the standard for convalescent plasma and was the standard for boosters as well.

And so finding a way to make the work of the Federal agencies more transparent so that people can understand the basis on which these decisions are made, and how it is, especially that an EUA, which is such a remarkable mechanism for making products available and only can be used during an emergency, to create a situation where, as I said before, the public, physicians, other public health agencies, everybody can really understand what the evaluation that went into an EUA is and how it is that that might differ from, at least from the FDA perspective, full licensure of that product, I think would help, because that might then reduce these kinds of temptations and would then also reduce public perceptions, which then could be easily addressed by careful communication about what it is that the agencies actually did.

Q My colleague is going to ask you a couple questions.

A Sure.

BY [redacted]:

Q Thank you.

I just have a couple questions.

So in the previous hour you had stated something to the effect of scientists working under fear rather than logic. I just wanted to clarify, the fear that you had spoke of is related to the pandemic and all the kind of health consequences that would come with that specifically?

A Yes. I don't remember how much of that I said. But to me, I thought that some of the decisions were driven by fear of the evolution of the pandemic. So that was in the context of worry about what would happen with the Delta or a subsequent variant, where, although there wasn't any good evidence that vaccine protection against severe disease caused by the Delta variant was fading, nonetheless, some people may have worried that it would.

And yet the question is, how does one -- how can one make decisions based on science and data versus conjecture or in some cases fear? But the fear I was referring to was fear for the outcome in terms of public health.

Q And not political fear?

A Exactly, yes.

Q Okay. And then I just have a question, referring back to the September 17th meeting in 2021, in the Advisory Committee.

A Yes.

Q You had mentioned that FDA members do not vote during those meetings?

A Correct.

Q Would you -- do you happen to know why that is?

A It's a general rule that it's an outside Advisory Committee that is intended to provide objective advice from outside experts. If FDA employees were to vote, then FDA

employees might then drown out the voice of those outside experts.

It's an Advisory Committee, and so the purpose is to bring together people who know a lot and have thought a lot about the issues and to present data to them, some of which they might not have seen before, but to get their reaction to it as an independent check on what the FDA is doing.

And so while the FDA can play some role in what data are presented, and the FDA normally presents its evaluation of the data that the sponsor might present, it's very important for the integrity of an advisory process that the people we're advising not be the advisees, if that makes sense.

So these are outside advisers, and the FDA is not bound to accept their advice. But of course if a well-constituted Advisory Committee makes a recommendation to do something -- or not to do something -- and the FDA rejects that advice, people ask a lot of questions why.

And so there is -- the FDA had better have good answers for why they would reject the advice of people who represent the scientific and medical community at large; also includes patient representatives and representatives of the public. And so there is very broad expertise on the committee.

But, I don't know, I hope that answered the question. So it would really fly in the face of an advisory process for the FDA to vote on what its own advisers are telling them they recommend should be done.

Q That makes sense. Thank you.

[redacted] I don't have any other questions. We can go off the record.

[Discussion off the record.]

[redacted] Back on the record.

BY [redacted]:

Q Dr. Krause, our colleagues from the minority showed you what's been marked as exhibit 8 and 9. These are two tweets from President Trump when he was in office, correct?

A That is correct.

Q And President Trump was known for, among other things, tweeting publicly, correct?

A Correct.

Q And, as far as you know, these two tweets -- which were public for the world to see, correct?

A Correct, yes. That's my understanding of Twitter, although I admit my understanding is incomplete.

Q Fair enough. So this is transparent, what he's saying, this complaint, as you called it?

A It is transparent, yes.

Q It's open for everyone to see it, correct?

A Correct.

Q Okay. But the pressure, the political pressure or external pressure, as you perceived it, was done internally, privately, not for the world to see. Fair to say?

A Well, a mix perhaps. Obviously, the pressure that was created for the boosters was also publicly based on the announcement made that boosters will be available and the -- a statement made by Doctors Fauci, Walensky, and Woodcock that they would move to make boosters available by September 20th.

And so that was public as well. And so that also created a kind of a pressure on the FDA, especially when their own acting commissioner was saying this is what was going to happen, subject to the approval of the FDA, which I also control and can make sure

that -- right, then we will make this happen, is perhaps an imprudent way to communicate, because it creates for the people of the FDA the impression that an outcome is foreordained, and for the public it creates an impression that this outcome is foreordained.

Q But as far as you know, Dr. Marks didn't tweet his internal discussions with you publicly?

A About?

Q The September 15th deadline and/or advancing that even earlier.

A Oh, so you're mixing the -- well, right now I was talking about the announcement about the boosters.

Q Correct.

A And the September 15th deadline was related to the approval of the Comirnaty vaccine.

Q No, I'm just -- I'm referencing that in which you did speak of feeling some pressure, and your understanding is Dr. Marks, others, there was an external pressure. That was internal discussions, correct?

A That's correct, yes.

Q And as far as you know, Dr. Marks did not tweet his views on that deadline or any other day publicly, correct?

A That's correct. There was no tweet or public announcement that, to my knowledge, that mandates or an approved vaccine would -- well, I mean, there was actually the CNN article that Dr. Gruber referred to that said that they thought that the vaccine would be approved by -- in 2 months from July 16th. And so that somehow found its way out.

Q Right.

A But I can't -- so I think it's very difficult to line the situations up, though. I take your point.

[redacted] Thank you.

[redacted] I have another question, then.

[redacted] Off the record and back on the record.

BY [redacted]:

Q Okay.

So Dr. Marks was -- what's his position? What's his title?

A Director of the Center for Biologics Evaluation and Research.

Q Okay. He doesn't work for the White House?

A No.

Q No. And he worked during the Trump administration and the Biden administration, right?

A Correct. Yes.

Q And he was in the same position to approve the convalescent plasma therapy that was not supported by the evidence as he was when he encouraged the rapid BLA approval process for COVID, right?

A He was in the same position during both of those episodes, yes.

Q Okay. And so his -- whatever pressure he might have put on you or other people in similar positions within the FDA, the theory is that if there's political pressure it's coming from the outside, going to him, and then being kind of dispersed onto the people in your position. Is that what you understand is being said here?

A Well, so some of the circumstantial evidence about political pressure comes from public statements that have been made by people, right?

Q Right.

A And so -- and some of this comes from private statements that are in these emails. And so --

Q These are statements from Dr. Marks in the emails? Is that what you're referring to?

A Well, for instance, if one thinks, for instance, about the question of mandates, that was in the email that summarized the discussion with Dr. Woodcock and Dr. Marks, and so that was in an email obviously.

Q Okay.

A And yet, one could -- a reasonable person would think that a concern over mandates would not be something that would be within the purview of a center director or even a commissioner at the FDA. And so that must have -- may have come from the outside, without knowing where from the outside that came.

Q Right. So the speculation is that there's outside pressure above them in the political world, right, that is influencing their decisions or the pressure that they then put on the FDA employees?

A Well, I think it would be irresponsible for them to put pressure based on their own opinion about mandates given that that has nothing to do with their jobs.

Q Okay. I guess my point is this. Dr. Marks was in the same position under President Trump as he was under President Biden, right?

A Correct.

Q Okay. So whatever political pressure was coming from either party, if Dr. Marks is now being accused of private pressure or something to that effect, it was coming from Trump when he was in the position of approving convalescent plasma and it was allegedly coming from Biden when he was in the position of the BLA for the COVID vaccine approval, right?

A Well, as I stated, I don't know where the outside pressure, for instance in favor of mandates, would have come from in the context of the BLA approval. It may have come from many different places.

Q But if Dr. Marks was inappropriately influenced in that instance, clearly the

implication is that it's coming from the administration that's in power at that time, right?

Mr. Thomas Krause. Her premise is if he was inappropriately influenced --

BY [redacted]:

Q If he was. I'm not saying he was. I'm saying -- that's what we keep talking about here, right, a suggestion?

A If he was inappropriately influenced, yes, or from the acting commissioner, I suppose.

Q Okay. But the same thing is true when he is in the position in 2020 and there's the suggestion that he may have approved convalescent plasma without evidence or inappropriately or in response to political pressure, he would have done that in response to the administration that was in power, right, that was exerting the pressure, if he did it?

A So -- yes. So I don't know if he did that.

Q Right. But if he did, right?

A And so, yes, I've seen that asserted. So, yes.

[redacted] Okay. That's the only question I had. We can go off the record. Thank you so much.

[Discussion off the record.]

Mr. Thomas Krause. Can I say something on the record still? I'd just like to renew my request for a copy of the transcript or even access to the video in the event that this proceeding is publicly disclosed in some manner outside the subcommittee.

And I just want to state that Mr. Krause -- Dr. Krause -- has come here as a scientist. He has been completely nonpartisan. I think he's provided great testimony of significant importance to the public, which should not be used in a partisan manner. And to the extent that it is, we would like to be able to have access to his testimony so as to

be able to rebut or to put it in the broader context with which he's come here today on a completely voluntary basis.

And you said you'd take that request to the chairman, and I'm just reiterating here, we're willing to sign any kind of NDA that would be appropriately tailored to allow us to make limited use but to place whatever gets out to the public into the proper context.

[redacted] Thank you, Mr. Krause.

As previously indicated earlier, prior to the interview, all requests are subject to the chairman's discretion. And we're happy to take those requests to the chairman. We make no such representations here; that's the chairman's call.

But our standing policy is, as you know, the transcripts are committee property and we do not make them available, but we do make them available for you and your client to review, as long as you need, to go over the transcript. And ultimately, if there's issues that you have with any of the transcription, you are free to make those and submit those to the committee.

That's standing policy. And your requests are on the record and will be submitted to the chairman for a decision.

Mr. Thomas Krause. Okay. Appreciate that.

One question, though. Will parts of this potentially go into a report that's made public? Is that part of the conclusion of an investigation like this?

[redacted] These questions are ultimately subject to the chairman. Nothing has been decided at this point.

Mr. Thomas Krause. Thank you very much.

[redacted] Off the record.

[Whereupon, at 5:23 p.m., the interview was concluded.]

Certificate of Deponent/Interviewee

I have read the foregoing ____ pages, which contain the correct transcript of the answers made by me to the questions therein recorded.

_____

Witness Name

_____

Date

COMMITTEE ON THE JUDICIARY,

U.S. HOUSE OF REPRESENTATIVES,

WASHINGTON, D.C.

INTERVIEW OF: PETER MARKS

Monday, April 15, 2024

Washington, D.C.

The interview in the above matter was held in room 2237 Rayburn House Office Building, commencing at 9:58 a.m.

Present: Representatives Jordan, and Massie.

Appearances:

For the COMMITTEE ON THE JUDICIARY:

[redacted], PROFESSIONAL STAFF MEMBER

[redacted], FTC DETAILEE

[redacted], SENIOR PROFESSIONAL STAFF MEMBER

[redacted], PROFESSIONAL STAFF MEMBER

[redacted], DIGITAL ASSISTANT

[redacted], CHIEF COUNSEL FOR OVERSIGHT

[redacted], SENIOR SPECIAL COUNSEL

[redacted], MINORITY CHIEF OVERSIGHT COUNSEL

[redacted], MINORITY OVERSIGHT COUNSEL

[redacted], MINORITY PROFESSIONAL STAFF MEMBER

For FEDERAL DEPARTMENT OF AGRICULTURE:

PERRIN COOKE, SENIOR COUNSEL, HEALTH AND HUMAN SERVICES

MANSAI RAVEENDRAN, SENIOR ADVISOR, OVERSIGHT, FEDERAL DEPARTMENT OF AGRICULTURE

[redacted] On the record. This is a transcribed interview of Dr. Peter Marks. Chairman Massie has requested this interview as part of the committee's investigation of the FDA's COVID-19 Vaccine approvals.

And would the witness please state your name for the record.

Dr. Marks. It's Peter Marks.

[redacted] And I'd ask the court reporter to please swear in the witness.

[redacted] Let's go off the record.

[Discussion off record.]

[redacted] This is the transcribed interview of Dr. Peter Marks. Chairman Massie has requested this interview as part of the committee's investigation of the FDA's COVID-19 Vaccine approvals.

On behalf of the committee, I want to thank you for appearing here today to answer our questions. The chairman also appreciates your willingness to appear voluntarily.

My name is [redacted], and I'm the Senior Special Counsel for the Committee on the Judiciary. I'll now have everyone else from the committee who is here at the table to introduce themselves.

[redacted] with Chairman Jordan's staff.

Mr. Massie. Congressman Massie.

[redacted], Ranking Member Nadler's staff.

[redacted], Ranking Member Nadler's staff.

[redacted], Ranking Member Nadler's staff.

[redacted], Chairman Jordan's staff.

[redacted], Chairman Jordan's staff.

[redacted], Chairman Jordan's staff.

[redacted] Dr. Marks, we have agency counsel with us today. Agency counsel's first duty is to represent the FDA and not you personally. So I just want to make sure you understood that and that you're comfortable with that.

Dr. Marks. I do.

[redacted] Would counsel introduce yourselves for the record.

Mr. Cooke. Perrin Cooke, Senior Counsel at HHS.

Ms. Raveendran. Manasi Raveendran, FDA.

[redacted] I'd like to now go over a few ground rules and guidelines that we will follow during today's interview. Our questioning will proceed in rounds. The majority will ask questions for the first one hour, and then the minority will have an opportunity to ask questions for an equal period of time, if they choose. We will alternate back and forth until there are no more questions and the interview is over.

Typically, we take a short break at the end of each hour, but that will -- but if you would like to take a break apart from that, please just let us know.

As you can see, there is an official court reporter here taking down everything we say to make a written record, so we ask that you give verbal responses to all questions.

Do you understand that?

Dr. Marks. I do.

[redacted] So that the court reporter can take down a clear record, we will do our best to limit the number of people directing questions at you during any given hour to just those people on the staff whose turn it is. Please try to speak clearly so the court reporter can understand and so that the folks down at the end of the table can hear you.

It is important that we don't talk over one another or interrupt each other if we can help it, and that goes for everybody present at today's hearing.

We encourage witnesses who appear before the committee to freely consult with their counsel if they choose. It is my understanding that you are appearing today with counsel, correct?

Dr. Marks. It is.

[redacted] Okay. Thank you. We want you to answer our questions in the most complete and truthful manner as possible, so we will take our time. If you have any questions or if you do not understand one of our questions, let us know.

Our questions will cover a wide range of topics, so if you need clarification at any point, just please say so. If you honestly don't know the answer to a question, do not remember it, it is best not to guess. Please give us your best recollection, and it is okay to tell us if you learned information from someone else. Just indicate how you came to know the information.

If there are things that you don't know or can't remember or just -- just say so, and please inform us who, to the best of your knowledge, might be able to provide a more complete answer to those questions.

Is that clear.

Dr. Marks. It is.

[redacted] You should also understand that, although this interview is not under oath, that by law you are required to answer the questions from Congress truthfully.

Do you understand that?

Dr. Marks. I do.

[redacted] This also applies to questions posed by congressional staff in the interview.

Do you understand that?

Dr. Marks. I do.

[redacted] Witnesses that knowingly provide false testimony should be -- could be subject to criminal prosecution or perjury or for making false statements under 18 U.S.C. Section 1001.

Do you understand that?

Dr. Marks. I do.

[redacted] Okay. Is there any reason you are unable to provide truthful testimony today?

Dr. Marks. There is no reason.

[redacted] Finally, I'd like to make a note that the content of what we discuss here today is confidential. We ask that you not speak about what we discuss in this interview to anyone -- to any outside individuals to preserve the integrity of our investigation.

For the same reason, the marked exhibits that we will use today will remain with the court reporter so that they can go in the official transcript, and any copies of those exhibits will be returned to us when we wrap up.

All right. Is there anything else that my colleagues from the minority would want to add?

[redacted] We just thank the witness for taking time out of your schedule to appear today.

Dr. Marks. Thanks.

[redacted] The clock now reads 10:03, and we will start our questions. Okay. Number 1. Marking exhibit 1.

[Marks Exhibit No. 1.
was marked for identification.]

EXAMINATION

BY [redacted]:

Q Dr. Marks, I've handed you a document we've labeled exhibit 1. And this is -- appears to be your -- a bio of you from the FDA website, along with background on you receiving an award with the Partnership for Public Service.

Do you see that?

A I do.

Q Okay. And what I'd like to do is get some background on you. So let's start with, what is your current role at the FDA?

A I'm director of the Center for Biologics Evaluation and Research.

Q And what does that entail?

A So as director of the Center for Biologics Evaluation and Research, we -- I oversee the offices that review applications and conduct regulatory research in the areas of vaccines, live biotherapeutic products, blood products, cell tissue and gene therapies.

Q And how long have you held that position?

A Since April of 2016.

Q Okay. And how long have you been at the FDA?

A Since January of 2012.

Q What position did you -- positions did you hold between January 2012 and 2016?

A I was the deputy center director prior to becoming the director.

Q Okay. And prior, what was -- just in general, what was your background before coming to the FDA?

A I am trained as a hematologist oncologist, and I worked both in academic medicine and industry.

Q When you say academic medicine, what does that mean?

A Academic medicine means I spent six years immediately prior to coming to FDA as director of adult leukemia services at Yale University School of Medicine and Yale New Haven Hospital. Prior to that, I was in industry.

Q And when you say industry, what -- what companies?

A I worked for pharmaceutical companies Novartis, and then prior to that, Genzyme, and prior to that, I was also back in academic medicine.

Q Okay. So is it fair to say you started in academic medicine, went to industry, and then back to academic medicine?

A That's correct.

Q And then on to the FDA. Is that correct?

A That's correct.

Q Okay. On your bio, the first page, it says an example of these activities that you do include reviewing and providing advice during product development.

Do you see that?

A Yes, I do.

Q And can you describe what that -- that entails?

A So oftentimes we have people who bring us products early in the developmental process who want advice on the regulatory pathway forward. They could be anything from the best path forward for clinical trials to the best path forward to making a product, the best way of getting the nonclinical information to support the study of the product in humans.

So we provide that advice, and then we also conduct regulatory review of the applications once people submit both investigational drug applications to us, biologics license applications, and any other application.

Q So on the first piece there, just break that down so I understand it. Are you -- is it someone maybe from industry or research saying you'd like to do a test on -- to develop a vaccine, and you kind of give them guidance to say here's a compilation that you might want to test on?

A So a company might say we would like to develop a vaccine for infectious disease X. They might propose a certain population, a certain size trial.

We would discuss with them the size of the trial program that they would need to do to initially show that the vaccine had enough promise to take it forward into additional stages of development.

So vaccine development usually proceeds in orderly stages -- in non-pandemic times -- through -- traditionally through three stages of development. Stage one, which is to show that the vaccine is safe and that can produce some kind of immune response.

Phase 2 to show that in the larger population of individuals that it seems to produce a sufficiently robust immune response, and it's sufficiently safe to be studied in a large number of people.

And then phase 3 in which it's studied and usually in a large randomized controlled trial. That means people are a flip of a coin decided whether they get the vaccine or some other treatment, could be just a placebo.

And those clinical trial programs usually involve 10- or 20,000 people who are treated with the vaccine.

Q Okay. So starting with that -- that first level, when you're evaluating that first initial set of people in the size -- the sample size that you're looking at, what are the -- what are the factors as far as when you -- when you look at a vaccine? Is it the disease state or is it the crisis points, or what are the other public health factors that you're looking at?

A Usually to figure out how many -- and can you just explain -- in the first -- for phase 1, 2?

Q Phase 1. And correct me if I'm wrong, but I heard you kind of define -- define in phase -- three phases. The first is kind of like the initial, does it work and is it going to hurt someone or the effectiveness of it and safety. And then when it looks like it passes that threshold, goes to phase 2. Is that right?

A Right.

Q And it passes that threshold, it goes on to phase 3, right?

A Right. That's correct. And so usually that first phase is usually 100 for a vaccine. It might be 100 people. Could be 50 people to 100 people. It depends -- again, it's -- it depends on the infectious disease. It depends on the situation. It depends on whether there's a similar vaccine previously.

And that is mainly to just see that you have something that is reasonably safe and that you can produce an immune response.

Q In your position, do you hear of activities going on where someone says, oh, here's a disease state, let's work on trying to develop a vaccine for that, which can take, I understand, several years. Is that -- that accurate?

A That's correct.

Q Okay. And do you hear of it coming along so that you might be given a heads-up and say, hey, in a year we might want to go to phase 1?

A That happens very often.

Q Okay. And where do you hear that from? Is it from academia, industry?

A We hear it from meetings that we routinely attend, including vaccine -- you know, scientific meetings.

Q Uh-huh.

A We hear it from meetings with the sponsors that we have as part of routine meetings that we hold with various companies, and we hear it from investigators who sometimes come to meet with us.

Q Okay. And so can you describe for the committee what scientific meetings you're kind of talking about and the nature of them?

A So there are meetings -- there are Congresses where scientists who develop vaccines get together; could be anywhere from hundreds to thousands of people who get together and share products that are in development. Sometimes data about products that are fully developed to tell what's in the development pipeline and to try to identify current and future needs for vaccines.

Q And in your experience, were you doing all of this through your entire career when you were with academia and industry? Were you always on the developing side or the evaluation side or analogous to supervising side?

A So when I -- in academic medicine, I worked mainly in the laboratory initially and caring for patients, and then I moved on when I worked for industry to work on drug development, some biologics development.

I also did a fair amount of evaluation as part of what's called business deals and licensing. I didn't do the deals or the licensing, but I did the evaluation, the medical evaluation, of those products. Mostly for drugs and biologics and occasionally for therapeutic vaccines, which are different from preventative vaccines. They're like cancer vaccines.

And then when I went back to academic medicine, I was mainly involved in caring for patients and doing clinical trials. And then when I came to FDA, I continued, obviously, to do even more of evaluating products that were in the process of development.

Q So kind of going back to that first phase when your -- the application is now coming in -- back up. I don't know if we established that.

But does your investigation when you're kind of advising on the size of the sample that needs to be tested for phase 1, is that -- is there an application that triggers your involvement?

A So it can happen via a number of different ways. Usually what certainly triggers a discussion of the size of a phase 1 clinical trial is when we receive an Investigational New Drug application, because that is what you need in the United States to introduce an unapproved drug into any type of human. And so people submit that.

Now, sometimes people do come into the agency before -- because we have a variety of programs, such as pre-IND meetings and pre-pre-IND meetings, where people can have discussions about sizes of trials before we actually receive a formal Investigational New Drug application.

Q I see. And so you have these trials kind of before the application, and then when the NDA comes in, then you start the trial process. Is that right?

A So an Investigational New Drug application is generally submitted. The -- our regulations say that once an Investigational New Drug application is submitted, we have 30 days to act on that. And at the end of that 30 days, if a sponsor doesn't hear from us, they can proceed with their investigation.

In practice, however, sponsors always hear from us either that they have the okay to proceed or they don't have the okay to proceed, in which case they're placed on clinical hold because there is some deficiency in the application.

Q Okay. And if they get placed on that clinical hold, is there dialogue? Do they kind of go back and -- to the starting board?

A Excellent question. And we sometimes hear from lawyers about this, too.

Yeah. What happens is if a sponsor is placed on clinical hold, there is an interactive dialogue that ensues. Usually we tell the sponsor why they've been -- we're obligated to tell them why they've been placed on clinical hold, and then usually meetings are arranged.

In fact, per our standard operating procedures, usually within 30 days, a -- what's called a type A or kind of a most urgent type of meeting is arranged, and we have a discussion of what has occurred and how to resolve that.

Q And so I guess two threads here. The first one is, when you say we, this is kind of getting into the staff that you work with.

How are you organized as far as evaluating that?

A So our center has -- my office, which is an immediate office, has a group of individuals who work with me in certain specialty areas related to the center, such as medical countermeasures or overall policy, that's run out of my immediate office. And then there are eight different offices which then do various either direct product review or support of product review.

The three key ones are the Office of Vaccines Research and Review, which is relevant for vaccines. The Office of Therapeutic Products, which handles blood products that are blood derivatives, and cell tissue and gene therapies, and the Office of Blood Research and Review, which handles blood components and devices that are used to test the blood or make certain blood products.

Q And under -- under your overall division, how many people work in the group?

A We have about 1300 full-time equivalents.

Q And then in each subdivision?

A It's -- I can only tell you approximate numbers. But it's probably about 250 in

the Office of Vaccines, about 300 to 350 in the Office of Therapeutic Products, and about 125 in the Office of Blood.

Now, I just didn't come up to 1300. So the rest come from offices that are involved in biostatistics and pharmacovigilance. An Office of Compliance and Biologics Quality, they're the people who make sure that the inspections are done and the products meet quality standards. There's an Office of Communications and Outreach and Development to interface with the public and manufacturers; an Office of Regulatory Operations, which makes sure that all of the different components of things that we need to do regulatorily happen; that, essentially, the documentation is appropriate and correct.

And then there is an Office of Management, which, essentially, handles human resources and -- general human resources management and administrative issues for the center.

Q And when you say that -- that Department of Human Resources is just -- is just for your center?

A Is just for our center. They are subservient to a larger human resources at the agency.

Q At the FDA. How many centers like yours exist at FDA?

A So there are three medical product centers. The Center for Biologics, the Center for Drugs, and Center for Devices and Radiologic Health.

Q Okay.

A There are others for other things.

Q Okay. So back to the phase 1 and moving on to phase 2, when -- and this is me putting on my background in the FTC. Oftentimes, ownerships change from different phases because different companies need to -- they need to scale up or to expand their -- their scope for -- to do the studies that you require.

Do you have a way of working across multiple companies at once to -- to help shepherd a product through?

A So by our -- by our regulations, by what I believe is actually the laws that govern us, each application is essentially -- essentially, a trade secret. So we don't work across applications unless we're given permission to do so.

Q Okay.

A So although we can, obviously, take knowledge that we've gained in terms of experience with one product and apply it to another, we cannot apply information in one application directly to another. We can't -- we can't merge applications, if that's what you're asking.

Q That's sort of what I was asking, but you just kind of enlightened me to another -- another kind of question. If you're watching multiple applications moving along that might have interoperability, does the FDA have a role to say, you know, we could build a better product if you take this piece and this piece and put them together or they appear side by side? Are there other rules that -- that govern you on that?

A So we can make suggestions to sponsors based on what we see. But probably the most common time when we actually look at different products next to each other and might be -- feel compelled to inform someone of something is when we see safety signals with one product that's like another product, where we might ask a sponsor to look for a safety signal or something in their product because it might be like another product.

Q And what is a safety signal?

A A safety signal is a -- evidence that there could be an adverse effect that is directly related to administration of the product. It doesn't necessarily mean -- the fact that it's a signal does not necessarily mean that it is definitively associated with that

product. But as part of our job, which is to be very careful about the safety of medical products, we look first for signals and then look to confirm signals.

Q Okay. Before you mentioned when we talked briefly about scientific meetings and other ways that you gather information on products that are in development. Just trying to understand the community of FDA scientists and people that you interact with.

Do you often see the same people at these -- these meetings? Do you have relationships with them inside and outside of the agency?

A We -- so I can speak for myself. We have a large -- I told you, we have about 250 people in the Office of Vaccines. Many of those are experts in specific areas. They go to meetings with -- scientific meetings that have specific experts at them.

At least speaking for myself, I don't see the same individuals time and time again at meetings. I generally go, speak, might interact with people who have some questions, and then leave.

Q Do -- do your experts that work for you -- when you say experts, are they Ph.D. scientists?

A There are Ph.D. scientists and some M.D. scientists who are -- have -- some of them have tremendous expertise in a very specific area, like influenza or Coronaviruses or bacterial diseases.

Q And do you hire the people on -- specifically for those -- those expertises?

A So we -- yes. We look to have our -- a variety of different expertise -- areas of expertise covered by individuals who work at the center.

Q Back in 2012 when you were hired in, were you hired in for a specific expertise?

A I was hired as deputy center director, so I was hired for my general expertise

in the area of biologics.

Q And as a deputy, to me that sounds like it has some sort of managerial component to it to overseeing a bunch of -- several products. Is that accurate?

A My role as deputy to the person who is director at that time, Karen Midthun, was mainly to help shadow her and help make sure that areas had sufficient coverage when she wasn't available. And there were specific areas that we divided up in terms of I took a lead in managing and some where she was mainly responsible for managing.

Q And did Dr. Midthun, was she the person who hired you?

A Dr. Midthun was the previous director who hired me.

Q Did you -- did you need to be hired by the FDA commissioner or interviewed by a senior level?

A I was -- the most senior person I was interviewed by was Dr. Midthun.

Q Turning to the award bio, this was an award for the Samuel Heyman Service to American Medals.

Do you recall receiving an award?

A I was a finalist in this process.

Q And my understanding is that this is an award given to federal employees. Is that accurate?

A That's correct.

Q And one of the things -- you were receiving accolades because of your role on getting the COVID-19 vaccine up and going. Is that fair?

A That's fair.

Q Do you know how you came about to be nominated for this award?

A I believe it was by colleagues.

Q By colleagues at the FDA?

A My understanding is it was actually by a colleague at NIH, I believe.

Q Okay. So in HHS?

A In HHS.

Q And so that, actually, helps me dovetail into another area I wanted to explore when you just said NIH. I saw that you testified before a Senate subcommittee in March of 2021. And there were four folks there.

There was you, Dr. Fauci from NIH, David Kessler from the White House, and I might pronounce her name incorrectly, but --

A Rochelle Walensky.

Q -- Rochelle Walensky from CDC. To help the committee kind of understand how those four entities fit together -- and let me back up.

Under HHS, are there -- were there any other entities that were really at the forefront of the -- the COVID vaccine and -- and response?

A I think that's probably it.

Q Okay. And so what was -- what was FDA's role in the COVID response?

A FDA's role was to help define what a safe and effective COVID vaccine would look like, what the manufacturing requirements would be for that product.

It was then to help the manufacturers figure out an efficient development program that would most rapidly lead to a high-quality, safe, and effective vaccine that would be available to the American public under some -- one of our authorization mechanisms, whether that be Emergency Use Authorization or a Biologics License Application.

Q Let's unpack that a little bit. So as far as identifying the -- the components of what was necessary for a vaccine, what did that entail at FDA?

A So what that entailed was looking back at prior vaccines, since this --

although COVID was possibly the worst pandemic we've ever had in the United States, we've been through other issues where there have been epidemics and pandemics.

So we looked back at previous examples of vaccine development in similar situations, wanted to make sure that as we developed or helped put in place the criteria for development that it made sense in the context of what we expected of other vaccines. A natural example, for instance, was to look back at influenza vaccine where the safety and effectiveness of influenza vaccine has to be very good because of the number of people who are vaccinated.

And so we looked back at that and tried to develop parameters for what we would expect would be necessary as a bar for which we would want to see effectiveness. So as part of what we then did to help articulate this, so it was clear to everyone developing vaccines with a level playing field, we put out guidance.

Guidance is our tool where we can say, this is not how you must do something, but this is how you could do something and potentially get across the finish line. We suggested that in this case there be a certain level of effectiveness that we needed to see and that the vaccine had to be safe.

Q When you are doing this -- let me ask about the -- back up. We started hearing news of the outbreak in late 2019.

And do you start mobilizing when you hear of outbreaks like that on potential vaccine therapies?

A So we -- we generally start to mobilize pretty quickly after we hear about an outbreak. We started to mobilize about what would be necessary for SARS Coronavirus 2, the virus that causes COVID-19, sometime in mid to late January after there were clearly cases, potentially, occurring in the United States.

I can't tell you exactly when during January, but it was the January to February

time frame that we started to -- to move up.

Q And when you say you kind of identify all of those different components of how to -- how to attack the problem and you look back at the history, are you looking strictly at FDA protocols that were followed going back into the influenza, I'm guessing other things like SARS or Ebola, those other outbreaks, or are you -- on this particular case, were you looking beyond FDA and saying, you in academia, you in industry, how do we figure criteria out? How did you --

A I think the best the thing -- the best way I can describe it is we look at the totality of the available information that we have in the literature and in FDA's experience and in the combined experience of those in the agency, some of whom had both experience at the agency, in academic medicine, and some who also had industry experience.

Q And the folks that you pulled together inside the agency, do you -- inside your group of -- I think it was 250 scientists, do you -- do you lean on the ones that -- do you send out a mass email saying, hey, we have this new thing coming up, who wants to work on the project, or do you already know, I need to put together the A team or whatever team to do this?

A So the way this would work is, in the organization of the offices is each of the offices, including the Office of Vaccines Research and Review, have an individual who leads that office.

Q Uh-huh.

A That person would then be in the best position to assign staff who they would be -- know would be most familiar with these areas, and those individuals would start to provide that feedback.

Q And who is the head of -- is it OVRR at the time?

A That's correct. That's the abbreviation, and that's Marion Gruber.

Q And how many people worked in OVRR at the time?

A At this time, it was somewhere between 200 and 250. I don't know the exact number.

Q Okay. And those 200, 250 are all M.D.'s or Ph.D.'s or experienced scientists in --

A Some of them have other degrees, like master's, because some of those people are project managers, some of them are actually support staff. But the majority of these are people with M.D.'s or Ph.D.'s.

Some of them are laboratory scientists who primarily work in the laboratory and who may do some regulatory review. Others are individuals who primarily do regulatory review and do not work in a laboratory.

Q And if you recall, what was the range of experience within that group as far as evaluating the vaccine process, you know, from start to finish?

A So there were people who were very new to the process to people who had probably about 30 years of experience.

Q Okay. Okay. So back to asking the question, when the vaccine -- or not the vaccine. But the situation was identified in, I think you said, late January 2020. Is that --

A You know, I can't tell you -- obviously, there's -- it was -- during January of 2020 it became clear that something was going on, very clear. As that time progressed from January to February, it became clear that we were going to need to mobilize to potentially prepare for a threat.

Q And when you say it became clear, this is where I'm trying to link in where you -- the role of NIH and CDC and the White House and how you were working in different lanes, I guess.

Who was the -- what was the agency that was monitoring the development of the disease, the virus, as it was starting to spread?

A So at that point there was, as there were meetings that were being held by the -- which I probably should have said is another component involved -- because it's HHS -- was the assistant secretary for Preparedness and Response, their office was gathering meetings on this topic.

And they -- the assistant secretary for Preparedness and Response and their office at that time also had the BARDA, the Biomedical Advanced Research and Development Authority and then they held meetings to which NIH, CDC, and FDA would attend.

Q Okay. Who was the commissioner -- in January 2020, since we've kind of gone into that time frame, who was the commissioner at the FDA then?

A It was Stephen Hahn.

Q Okay. And who was the person at CDC?

A At that time?

Q Uh-huh.

A That was Dr. Redfield.

Q And that office -- I'm going to butcher it again, but the preparedness office --

A The Office of Preparedness and Response, that was Dr. Robert Kadlec.

Q Okay. And is that Office of Preparedness and Response under HHS?

A That is.

Q Okay. And so when -- just sticking to FDA -- I apologize for moving around.

But were you in frequent meetings with the commissioner, Mr. Hahn -- Dr. Hahn?

A Dr. Hahn, right. Reasonably frequent meetings.

Q Okay. And how would you learn that -- when you said it became obvious, was it preparedness was sending out alerts throughout HHS, or was it CDC, or how do you

get -- how do you share information so you can turn that into actionable items?

A There were meetings held with multiple agencies where information was shared about the spread of the virus into different countries.

Q And did you participate in those meetings?

A I did.

Q And were your counterparts of the head of other divisions at FDA in those meetings as well?

A You know, I can't recall. There were probably -- there may have been sometimes one other individual could have been from the commissioner's office at some of those meetings, but I can't recall for sure for each of them.

Q Okay. And then, as the pandemic developed or evolved, I should say, what was the role of CDC in -- as compared to your role in the FDA?

A So the CDC was -- again, you probably have to ask them so that they -- but at least from my understanding of CDC's role, it was more to gather statistics and to implement public health measures to try to help contain the pandemic, and then once vaccines were available, to help deploy those vaccines.

Q And when you say public health measures, are those the communication to tell the public, wash your hands, wear masks, those types of things?

A Yes, that would be correct.

Q Okay. And when you say statistics, they were the source for reporting on the frequency of the disease?

A Correct.

Q Okay. Did you coordinate with CDC -- would you have a role in coordinating with CDC on either of those?

A Not on -- not on statistics or the rollout, but we would have -- we did have a

role coordinating on something that happened after the vaccine rollout, which is, obviously, on safety reporting which we share with the CDC.

Q Okay. And is that something that you usually do when you roll out a vaccine?

A This is standard process for us. The FDA and CDC shares responsibility for vaccine safety reporting.

Q Okay. And then the role of NIH in -- remember when I started down this road, I said there were four of you testifying. And Dr. Fauci was at the NIH. What was their role?

A At least from my -- my perspective of what we interacted with them, they kept track of some of the -- they kept some -- the virus and the property of the virus over the course of the pandemic, as things moved on, they kept track of some of the variants. They developed some of the laboratory assays for assessing the virus, and, obviously, they did some of the basic work around the vaccine.

Q Did that -- did their work -- did you work closely with NIH?

A I can't -- I wouldn't describe it as closely. I was aware of what was going on. We had conversations occasionally, but we didn't -- it wasn't like we had a close relationship.

Q Did their -- and forgive me for sounding naive. But it sounds like if they're looking at the different assays and components of the virus and how it's evolving, does that information -- would that -- it sounds like it would logically feed into what you're looking at as to how a vaccine might interoperate with the virus.

Did you coordinate on that?

A It does. Yes, we did. And let me just correct something. I don't know whether you -- depends on how you describe close. If you describe that coordination as

close, yes, that's close.

Q Okay.

A But we didn't -- it's not like we directed their research or anything. We were there to -- we received information from them.

Q So did they -- not that they were directing you, but did their information inform your research?

A It certainly informed how we progressed in terms of understanding what needed to be covered, for instance, in terms of the vaccines.

Q Uh-huh. Were there opportunities for you to ask them questions as to the efficacy of their research, the nature of which they gathered their data, those types of things?

A Yes, there were.

Q Did you do those things?

A Our experts did, and I did as well at times.

Q And the experts you're talking about, again, maybe Marion Gruber's staff and those folks?

A That's correct.

Q Okay. And then what is the role of the White House -- when you testified, as I said, Dr. Kessler was -- was there.

Did he have a predecessor in the Trump administration during 2020 when you were doing this?

A The -- I don't know how the -- I don't know how things actually -- I can't explain to you how things, you know, match up.

The person that was doing the vaccine distribution during the Trump administration was General Gustave Perna. General Perna.

Q Perna. And was General Perna in the White House?

A No. General Perna was part of the HHS/DOD collaboration.

I actually -- to be honest, I don't know his relationship with the White House. I can't speak to it. But I do know that, at least in my understanding of his role in Warp Speed, it was part of the DOD/HHS collaboration.

Q Okay. And was there anyone in Dr. Kessler's role in the Trump administration, a similar counterpart that you were working with or -- I hate to reiterate what you're saying, but were you working with DOD instead?

A You know, before Dr. Kessler -- again, I could be -- there was a lot that happened during this period. So I -- the best I can recollect is before Dr. Kessler, for many of those same issues, we worked with -- we worked with General Perna.

Q Okay. And what were the types of issues that you worked with General Perna on?

A Mainly coordinating. He needed -- since he was dealing with distributing the vaccine, he needed to be aware when any vaccine approvals might be close to pending.

Q Okay. And why did he need that information?

A Because the idea was to be able to distribute the vaccine relatively rapidly, essentially, to mobilize, to get it out to be able to vaccinate people as quickly as possible during a time when we had rising number of hospitalizations and deaths due to COVID.

Q And is it fair to say that the goal was to get the vaccine out as soon as possible?

A That's a fair statement.

Q And it says back on your -- the bio piece -- background piece on your award, did you come up with the name Warp Speed?

A I came up with the name project Warp Speed.

Q And is it because you're a Star Trek fan?

A I watched -- I watched a fair amount of Star Trek when I was a kid. I'm a space fan.

Q Okay. And so when you're talking about working with General Perna and getting this out, were you advising as to who should get it first as far as maybe the age cohort or the --

Mr. Cooke. And let me just step in here. So to the extent that you're getting into the details of these internal deliberations, you know, particularly in this setting, we're not going to be able to get into that.

[redacted] Okay.

Dr. Marks. But I can --

Mr. Cooke. In general.

Dr. Marks. I can speak in general. That was something that was up to CDC, and we were mainly concerned with just having a safe, effective, high-quality vaccine.

BY [redacted]:

Q And without getting, I guess, into the specifics, the -- when you say safe and effective, that varies -- let me ask the question because you're the expert on this.

Does that vary based on maybe various factors, such as disease states or prior conditions or age or weight or other demographic factors?

A So for some vaccines, it might. For other vaccines, it doesn't necessarily. And, actually, that was something that was to be seen from the clinical trials that were done with the vaccine, the COVID vaccines.

Q Okay. And so, again, when you're informing General Perna, what was your -- what was the role? Would you be basically reporting on the data that you were finding and saying --

A My -- my major interaction with General Perna was just to make sure that he was aware of the general vicinity around when the vaccines might have been emergency use authorized so that he would be prepared to be able to distribute them rapidly.

Q And what would be the types of information that you were -- you would be sharing, as far as the type of information? Like, we expect it to be coming out on a -- in a month or two months?

A I think that was the general kind of -- again, the general timing of when the vaccine would be ready, much as we would inform any other sponsor, but perhaps trying to be a little more pinpoint as to a week or weeks.

Q Did you also do the thing besides just with the White House -- I'm sorry, the Department of Defense. Did you do the same with the states? Did you have calls with them to say this is where we are in the process?

A There were -- again, it gets a little hazy to me exactly when the state calls happened, but we were having calls. I was invited to participate sometimes in the calls with states, sometimes governors or lieutenant governors' calls during the Trump administration to just talk about what the vaccine would be like.

[redacted] Okay. I'm going to hold off. I know Mr. Massie has some questions, and we'll be revisit this.

Mr. Massie. Would you consider yourself one of the world's leading experts in vaccinology.

Dr. Marks. I don't think I would consider myself a world's leading expert.

Mr. Massie. Were you the top vaccine expert at CBER?

Dr. Marks. I would consider myself qualified to supervise the top vaccine expert, but I guess that's -- I don't know exactly how to answer that question.

Mr. Massie. Who would you say was your top vaccine expert at CBER or OVRR?

Dr. Marks. At the time when I was -- at this time, the 2020 time frame, it would have been Marion Gruber.

Mr. Massie. And who would be next in line to her in terms of expertise in vaccines?

Dr. Marks. There were several individuals who would have been quite capable and might have been more, depending on the different areas. Dr. -- there were individuals who might have been in other viral -- in charge of other viral disease areas who were -- who had 20 or 30 years' expertise in developing, for instance, influenza vaccines, who would have been quite expert.

Mr. Massie. What about Dr. Philip Krause, would you say he was an expert in vaccinology?

Dr. Marks. He was an expert in certain types of vaccines, correct.

Mr. Massie. Do you think you had more expertise than him?

Dr. Marks. Can you clarify what you're getting at?

Mr. Massie. In vaccine approval.

Dr. Marks. So he had certainly done more vaccine approvals than I had as the deputy director, been involved in more approvals.

Mr. Massie. Was he also on some WHO advisory capacity?

Dr. Marks. That's correct.

Mr. Massie. Tell us about your expertise in infectious diseases and vaccines in general.

Dr. Marks. So my expertise in infectious diseases dates back to the fact that, as a hematologist oncologist who cared for people with acute leukemia, much of what I did was manage infectious diseases, viral infections, bacterial infections, fungal infections.

And though I am board certified in internal medicine, hematology and medical

oncology, each of which requires some knowledge of infectious diseases, I'm not board certified in infectious diseases, nonetheless, over the course of a career and practice had gained a fair familiarity of infectious diseases and their management.

Mr. Massie. What have you published in peer-reviewed literature about vaccines?

Dr. Marks. In peer-reviewed literature, I've been a co-author on some safety publications for vaccines.

Mr. Massie. Would you say that you stay current with literature on vaccines and that during COVID you also kept up with what was published in prominent newspapers?

Dr. Marks. I would say I kept up with what was published in medical journals, and I was, obviously, reading the news media as well.

Mr. Massie. Besides on boosters, have you ever disagreed with OVRR experts that you mentioned, Marion Gruber and Philip Krause, on any review issues related to vaccines?

Dr. Marks. Possibly. I can't -- you know, I can't -- I can't speak to -- I'm sure we've had disagreements on certain aspects. We probably had certain disagreements on certain aspects, but they were resolved.

Mr. Massie. Did they persuade you or did you persuade them on those issues?

Dr. Marks. I can't recall.

Mr. Massie. Would it be fair to say that until the Pfizer approval and boosters came up, your only direct experience with vaccines was to ratify decisions that had already been made by experts at the office level?

Dr. Marks. I don't think that's a fair statement.

Mr. Massie. So can you describe what your direct experience on certifying vaccines was before the boosters?

Dr. Marks. So at FDA one application -- so we at FDA review medical product

applications, and medical product applications have more similarities to them, perhaps, across different areas than differences. They have information on quality, safety, and effectiveness.

And in my years of working in academics and particularly in industry, I've seen enough applications where there's -- whether they be for vaccines or other medical products such that I understood how to evaluate the data that came in on the quality of the vaccine, the manufacturing safety data which, whether it's for a vaccine that's a prophylactic vaccine or for another medical product, has to meet a certain standard, as well as effectiveness, which is based on statistics and other factors.

But it is -- generally, we do statistical analyses. So being able to understand these makes me somebody, I think, who can, even though maybe I wasn't an expert on a particular vaccine, was able to have expertise in being able to look at a vaccine application.

Mr. Massie. So that was from your role in private industry?

Dr. Marks. Correct.

Mr. Massie. But not -- you didn't have a direct role at OVRR?

Dr. Marks. So prior to this pandemic, I had been involved in vaccine development efforts peripherally, but -- for Zika, but also more involved in vaccine development efforts for Ebola virus.

So there were a number of vaccines that were developed during this time for which I was at multiple meetings of the review teams and those developing. I did not participate in the actual review of the -- of the submissions, the Biologics License Applications directly, but I was around enough of those meetings to understand and have a reasonable knowledge of vaccine development.

Mr. Massie. Would it be fair to say that your role there was to ratify decisions that

had been made by experts?

Dr. Marks. It was -- probably. That's a fair statement.

Mr. Massie. When it came time to make decisions on the COVID vaccines, whose expertise did you rely on?

Dr. Marks. I relied on those of the individuals in the Office of Vaccines and relied on my own experience at times.

Mr. Massie. So would that include Dr. Marion Gruber and Dr. Philip Krause?

Dr. Marks. Yes, it did.

Mr. Massie. And who else did you discuss those decisions with when you made decisions on COVID vaccines?

Dr. Marks. I would have, potentially, discussed them with individuals in my immediate office. My immediate office has several individuals who formerly worked in the Office of Vaccines who were in combination between them probably had more than 40 years of vaccine development experience. And so they also helped me understand the -- some of the nuances of these vaccines.

Mr. Massie. During the initial review of the EUA and beyond, how often did you discuss the ongoing review with Albert Bourla?

Dr. Marks. I did not.

Mr. Massie. Did he ever call you to discuss the review of the Pfizer vaccine?

Dr. Marks. He did not.

Mr. Massie. So there are no records of any conversations with you and Albert Bourla?

Dr. Marks. To be clear, I had one or two conversations with Albert Bourla very early on shortly after I conceived of project Warp Speed, and those were the last conversations I directly had with him.

Mr. Cooke. And, obviously, all of this is to the best of your recollection?

Dr. Marks. To the best of my recollection. Thank you.

Mr. Massie. The rest of my questions are pretty long, so I'll wait until the next hour. If you want --

BY [redacted]:

Q Okay. Well, I'll -- I'm going to pick up where we were kind of talking about.

A Okay.

Q Because -- trying to understand again -- we were trying to understand the different roles that were played. And you mentioned that General Pressler was working with you in the Trump administration, but then it was Dr. Kessler?

A Uh-huh.

Q And who was Dr. Kessler?

A Dr. Kessler is a former FDA commissioner who may have served other roles. I don't know what other roles he served in various administrations.

But he came to then be involved in the same function of helping to distribute the COVID-19 vaccines.

Q And he was also, we understand, working on the -- part of the Biden campaigns in 2020, their preparedness.

Did you speak with him during -- in the run-up at all?

A No, not to the best of my recollection.

Q And when you're talking about getting ready to get the vaccine out -- this is where I was going before was -- when I asked about the states -- were you talking to other entities about where -- where the FDA was as far as getting that vaccine ready to go?

[10:58 a.m.]

Dr. Marks. No, not to the best of my recollection. It was mainly with -- if it was for the EUA, it would have been coordinating with General Perna.

And then, as I say, occasionally -- and I -- honestly, I can't, to the best of my recollection, tell you about whether those calls with the States were pre-EUA or post-EUA. And I would tend to think they were probably post-EUA, as we were explaining the nature of the vaccines, because I know there were some calls that took place post-EUA. So they may have all been post-EUA.

BY [redacted]:

Q And when you say pre- or post-EUA, what is the defining -- what's the fulcrum there as far as what defines pre or post?

A So on December 8th -- sorry. Sorry. It's December 11th, 2020, we authorized -- we gave an Emergency Use Authorization for the Pfizer vaccine for individuals 16 years and older. And a week later, on the 18th of December 2020, we authorized the Moderna vaccine for individuals 18 and over.

Q Okay. And that was under the, you said, EUA?

A Emergency Use Authorization.

Q Okay. And how is that different than the BLA?

A So that's going to take a couple of minutes to explain. So a Biologics License Application --

Q Why don't we actually then save that for our --

A Okay.

Q -- next round as well. Because I don't want to lose sight of the different lanes that everyone was flowing in.

A Okay.

Q So you said Department of Defense was worried about getting the vaccine out, and that's what your communications were during the Trump administration.

A Correct.

Q And then, when Dr. Kessler came on board with the Biden administration, did you start working with them during the transition?

A We -- to the best of my recollection, most of -- there were not a ton of interactions there, and I didn't interact very much directly with Dr. Kessler.

Q Okay. Did he -- then he became, like, I saw the title of head of science for the White House when the Biden administration took over.

A Yeah, I unfortunately don't -- I can't speak to that because I don't actually even know.

Q So he testified at that Senate hearing. And what was his -- what was the White House's role, I guess, with CDC, FDA, and NIH?

A My understanding was that he had taken on the role of helping to make sure that the vaccine had -- was getting distributed, but I may be mistaken.

Q Okay. And who -- what role did Dr. Hahn, the commissioner, have before the administration changed on January 20th, 2020 -- 2021?

A Dr. Hahn supported -- was supportive of me and supportive of the endeavor to try to move forward vaccine development as quickly as possible. He was my -- I reported to Dr. Hahn, and he was supervising the overall process of development of the vaccines.

Mr. Massie. Can I ask? While we're talking about the various roles, I'd like to ask --

[redacted] Yeah.

Mr. Massie. -- a question about roles.

[redacted] Go ahead.

Mr. Massie. So how does the role of the CDC differ from the role of the FDA with respect to a vaccine? Like, what are their lanes and what are your lanes?

Dr. Marks. So we are responsible for ensuring that a product is made with safety -- I said with quality and that it is safe and effective.

Mr. Massie. Uh-huh.

Dr. Marks. CDC's roles are they have the Advisory Committee of Immunization Practices, which recommends what population the vaccine would potentially be used in. They share with FDA the responsibility for safety surveillance of a vaccine once it's authorized or approved. And they try to do -- their responsibility is more in the education about vaccines than -- I mean, we do some vaccine education, but they have a larger role in that.

Mr. Massie. So Congress appropriated a billion dollars to CDC to promote the vaccines. Is it the FDA's role to promote vaccines?

Dr. Marks. It's not our role to promote vaccines.

Mr. Massie. Did you ever promote the vaccines?

Dr. Marks. I guess -- can you define promote?

Mr. Massie. Let me -- let me ask. Why wouldn't it be your role to promote vaccines?

Dr. Marks. So it was --

Mr. Massie. Don't you know more about them than anybody else?

Dr. Marks. It was my role to -- I guess, if you call explaining the quality, safety, and effectiveness to physicians or to patient groups promotion, that's -- I was involved in that piece of this. So I recall, yes, to that extent, I was involved in their promotion.

Mr. Massie. Why is there a separate lane for CDC to promote the vaccine and for

the FDA to regulate the vaccine? Why wouldn't they just have that promotion function at the FDA?

Dr. Marks. In general, I think it's been separation of functions to help ensure the integrity of the vaccine approval process, that we are really mainly concerned that what comes out of the process of our valuation is something where all of the aspects of the Biologics Control Act of 1902 and its successor, the Public Health Service Act, in spirit and in practice are maintained, which is that the vaccines are very high quality, that they are safe and effective for their intended uses, and that that's not affected by other issues that -- except that at the end of the day it's a product that does what it's supposed to do.

Mr. Massie. Is it sometimes necessary to revoke authorization or approval for products like if based on ongoing safety data?

Dr. Marks. Yes, it is. Sometimes that occurs.

Mr. Massie. And is that the role of the FDA?

Dr. Marks. That's the role of the FDA.

Mr. Massie. Is there any conflict if the FDA's been promoting the vaccine and then they have to then revoke its authorization?

Dr. Marks. I think you might have answered your own question. There could be something of a matter of conflict there. I -- all I can speak to is to say that we -- I -- my goal in the COVID-19, after we authorized the vaccines, was to educate regarding the vaccines. And if you talk about promote, promote in the FDA world has a very specific meaning, which is to advertise. And my goal was never to advertise the vaccines. It was to provide individuals with the information that they needed to make their own decisions about whether they individually wanted to take them or not.

Mr. Massie. So recommendations to individuals, now you're saying not doctors?

Dr. Marks. Recommenda- -- to doctors so they could transmit to individuals. I

mean, and occasionally we did meet with patient organizations. But, again, it was to discuss the general nature of the vaccines.

Mr. Massie. All right. Our hour I think is up, so --

Mr. Neguse. We'll go off the record.

[Recess.]

[redacted] We can go back on the record.

EXAMINATION

BY [redacted]:

Q Thank you for being here, Dr. Marks.

I know we talked a bit about your professional background already, but I just want to get a little bit more into that. You have a bachelor's degree from Columbia University. Is that right?

A Correct.

Q And you have both an M.D. and a Ph.D. from New York University?

A Correct.

Q And then you were a practicing physician for some time. Is that right?

A That's correct.

Q Could you explain how your work in academic medicine is related or helped inform the work that you've done at FDA?

A So in academic medicine, I was both, for a time, a laboratory researcher and a clinician and then was a clinician and clinical researcher that was involved in the conduct of clinical trials, which is something that we at FDA regulate.

Q And did your time in academic medicine inform your expertise in infectious diseases and vaccines?

A It did. To the extent that, as a hematologist oncologist caring for leukemia

patients, I had to be well versed in the care and the treatment of individuals with infectious diseases, including bacterial, viral, and fungal diseases, as well as making sure that they were appropriately immunized to various infectious diseases.

I don't consider my -- I'm not board-certified in infectious diseases. But, again, internal medicine, board certification requires knowledge of infectious diseases. And hematology and medical oncology also does as well.

[redacted] Just to tease that out a little bit. So you said that you were required to have a good understanding of infectious diseases. Leukemia is a disease that weakens people's immune system, correct?

Dr. Marks. Correct.

[redacted] And so you would need to have a good understanding of those diseases because you're working with people with compromised immune systems. Is that right?

Dr. Marks. So people with acute myeloid leukemia, which was the basis of my practice at Yale, basically don't have an immune system generally. So they're completely susceptible to viral, fungal, and bacterial diseases. So most of the work is not actually giving them chemotherapy; it's preventing them from dying from infectious diseases.

[redacted] Thank you.

BY [redacted]:

Q And you've been a public health official at FDA now for over a decade. Is that right?

A Correct.

Q I know we looked at your biography related to an award you were nominated for. Have you won any awards for your work at FDA?

A Several.

Q Could you explain a couple of those?

A I've received awards from various professional societies for work in blood regulation, cell and gene therapy, and for the area of vaccines, including an award from the American Medical Association for public service.

Q In 2022, you became a member of the National Academy of Medicine. Is that right?

A That's correct.

Q Could you explain what the significance of becoming a member of that organization is?

A National Academy of Medicine is considered a prestigious professional society. About 100 physicians globally, 85 in the U.S., about 15 outside of the U.S., roughly, are elected each year. And membership is solely by election.

Q And I know you're here today because of your work during the COVID-19 pandemic, but you talked a little bit about overseeing work on other biologics products during your time at FDA. Is that right?

A Correct.

Q What were some of those other products you've overseen?

A Since I've been center director, we approved the first gene therapies in the United States. And so we've now approved a total of 18 cell-based or directly administered gene therapies in the United States. We've modernized a regulation of blood transfusion requirements in terms of donor requirements. And in vaccines we've dealt with multiple crises, including Zika, Ebola, and COVID-19.

Q Today we're talking about the Center for Biologics Evaluation and Research, and that's sometimes called CBER. Is that right?

A Uh-huh, that's correct.

Q Just to start off with the basic level, what's a biologic?

A A biologic is generally a product that is derived from -- it's derived for or comprised of a living organism. So biologics generally have come from or, today in the world of technology, are analogous to living substances.

Q And we've already talked a lot about vaccines, but could you just explain what is a vaccine?

A So, generally, a vaccine is a product that is given to elicit an active immune response in an individual to either a pathogen -- in the case of infectious diseases, that would be a bacteria, a virus, or a fungus, or in the case of cancer vaccines, which are therapeutic vaccines, it's to elicit an active immune response against a cancer cell.

Q Vaccines have sometimes been described as one of the most impactful public health interventions in reducing illness and death. Would you agree with that characterization?

A I would absolutely agree with that characterization.

Q Could you explain why?

A Vaccines have been responsible for saving millions of lives globally. We're here today, in part, because of them. Vaccines were responsible for eradicating smallpox from this globe. I take issue with anyone who says that smallpox just went away. It didn't. It's a very, very healthy virus, and it didn't just go away on its own. It went away because we vaccinated the world's population against smallpox. And smallpox killed a lot of people, and it prevented that.

We've reduced measles remarkably. Measles kills 90 to a hundred thousand people each year outside of the United States in places like Africa and certain parts of Asia. By having a well-vaccinated population here in the United States, we generally have prevented the worst consequences of measles, which include measles encephalitis and

measles pneumonitis, both of which kill one in a thousand kids in other countries and potentially here in the United States also if our rates of measles vaccination doesn't stay up.

So they -- I think those are among some of the things that they do, let alone our yearly influenzae vaccines, et cetera.

But the number of lives saved by vaccines, I think, is -- it's possibly that and understanding that your drinking water and sewage need to be in different locations are possibly among the most important advances in public health.

Q So is it fair to say that vaccines are important for both individual health and public health?

A That's correct.

Q Are vaccines safe?

A So one has to qualify that, right? We at FDA spend a lot of time looking at the safety and effectiveness of vaccines. So each vaccine is taken on its own and evaluated for its safety and effectiveness.

There are clearly unsafe vaccines, and those don't make it across the finish line to get approved. But our job is to look at all the data and to make sure that the data support the safety and effectiveness. And that's done by people who are both familiar with vaccines, as well as statisticians who look at numerical imbalances in adverse events, et cetera, to make sure that, even if a vaccine is efficacious, it's sufficiently safe.

I will offer that vac- -- for context, that vaccines are somewhat -- prophylactic vaccines are somewhat different from our other medical products, because if one has cancer and is getting chemotherapy, one is going to accept a certain amount of side effects in return for having that cancer killed.

In general, people who get -- are healthy and who get vaccines don't want to have

any side effects. And so the tolerance for adverse effects is very small.

So, in general, the calculus that we think about in approving vaccines is there has to be a very high margin of safety and very little uncertainty around the safety generally and that the efficacy has to be well-demonstrated.

Q When considering whether to approve a vaccine or other medical product, the FDA has to weigh the risks of that intervention against the benefits, as you were saying. Is that right?

A That's correct.

Q Could you explain that process for both vaccines or medical products more generally?

A Right. So we have -- actually, it's actually laid forth in guidance even. It's a risk, benefit, and uncertainty. So for every condition there's the nature of the underlying condition which sets the stage, and then we understand the potential benefits of a medical product in what it can bring. Every medical product has a certain rate of effectiveness, between zero and a hundred. And our goal is to understand what that is.

We then look at the risks associated, which are the adverse effects, and almost every medical product has some adverse effects. And we want to understand those effects in the context of the condition and in the context of any uncertainty regarding the benefits and the risks. We put all that together to make a determination of whether it is reasonable to put that product into use.

The same -- we use that same process, whether it's for a cancer drug, a headache drug, or a vaccine. There are differences, though, however, between those in terms of how much risk we'll accept and how much uncertainty we can accept in the different scenarios.

Q So would you say that every vaccine that the FDA has authorized or

approved for use in America is safe?

A It's safe according to the conditions of use. Some of the vaccines that we have authorized or approved have potentially serious side effects. But the overwhelming -- they are safe and effective for their intended use, and the potential adverse effects are disclosed because that's how we -- that's how we work through things.

By and large, most vaccines have very, very, very good safety profiles with very, very rare adverse events. There are some vaccines that have slightly higher side effects because they're designed to deal with potential pathogens that one might encounter in certain situations. What I'm thinking of is one that we might come back to later called ACAM2000, which is a smallpox vaccine that's sometimes given to the military because there's concern about biologic warfare in certain combat areas. And that particular vaccine has a higher incidence of myocarditis than we might like to see with other vaccines, but it's labeled for that so that people know what might happen.

Q And in that scenario, the potential benefits of the vaccine, meaning not getting the disease, still outweigh the potential risks?

A That's absolutely correct.

Q Turning specifically to the COVID-19 pandemic, in your opinion as a public health expert, did the benefits of the vaccines for COVID outweigh the potential risks?

A They absolutely did.

Q And in your opinion, did vaccines reduce the number of people that died from COVID-19?

A Right. So the vaccines -- let me just make sure I clarify. The vaccines that we authorized or approved, which were the mRNA vaccines, there was one viral-vectored vaccine that was authorized but never approved -- it was withdrawn -- and a

protein-based vaccine. And I would say that the mRNA vaccines and that a protein-based vaccine are safe and effective for their intended use, and we continue to strongly recommend their use to this day.

Q Did those vaccines reduce the number of people that died from COVID-19?

A Pretty certainly, yes.

Q And in your opinion, did those vaccines reduce the number of people that were hospitalized from COVID-19?

A Yes.

Q Do you agree that the COVID-19 vaccines are beneficial for society as a whole?

A So as -- from the FDA perspective, we are here to put forth vaccines for individuals. And it's -- but from the standpoint of putting it in context, the burden on society, when hundreds of thousands of people are hospitalized and thousands upon thousands of people die, is generally great.

So, yes, I guess, aside from any issue that sometimes come up -- comes up about whether these vaccines have reduced transmission of virus -- I might as well bring that up now -- the -- these vaccines, I believe, have been of benefit to society.

[redacted] Couple of quick follow-up questions. You said a couple of minutes ago that the smallpox vaccine for the military, that it was labeled with the risk of myocarditis. What does "labeled" mean.

Dr. Marks. It means that every medical product in the United States comes with something that tells you -- it tells -- there's usually two pieces. There's something that tells the provider all the information they need to know in terms of what the product is, what the data are that -- a summary of what the data are that suggests that the product works, as a summary of the risks associated with the product, and sometimes how to

minimize the risks of giving that product. And then we have something that's analogous in more lay language for the individuals, the people who get the vaccine.

[redacted] Okay. So is it fair to say that when FDA determines that a vaccine or another product, I guess, has a certain risk, such as myocarditis in the case of the smallpox vaccine, the FDA takes steps to make sure consumers are aware of that vaccine -- of that risk?

Dr. Marks. That's correct.

[redacted] Okay.

BY [redacted]:

Q I want to turn now to your work at CBER. You're the director of CBER currently, correct?

A Correct.

Q And the mission of CBER is to protect and enhance the public health through the regulation of biological and related products, including blood, vaccines, allergenics, tissue, and cellular and gene therapies. Is that right?

A That's correct.

Q And we talked a little bit about OVRR in the earlier hour. OVRR's mission is similar but specifically related to vaccines. Is that right?

A Correct.

Q Is it fair to say that both CBER and OVRR have a regulatory mission and a research mission?

A That's correct.

Q So that includes reviewing products for approval. Is that right?

A That's correct.

Q Developing policies and procedures, governing the review of those

products?

A Correct.

Q And also research related to the development of those products?

A That's correct.

Q And in your role as the director of CBER, you're a supervisor of these offices that are doing the review. That's right?

A That's correct.

Q You aren't necessarily taking part in the actual regulatory review processes?

A Not necessarily, but sometimes I take -- I have -- over the past year, sometimes I have taken part in the regulatory review process when necessary.

Q You mentioned that you'll attend meetings of the review team. Is that right?

A That's correct. Sometimes I may have, during the COVID pandemic, in order to assist with moving forward reviews, not just during COVID but even sometimes in other times, have been involved in actually reviewing material that's been submitted in the files.

Q So your experience isn't limited to just overseeing. You also have done some review work and have done some project management work. Is that fair?

A So let me make it specific. For the Emergency Use Authorization for the COVID-19 vaccines, for every emergency use authorized vaccine, I read through the entire Emergency Use Authorization submission, the request. I did not go through the line listings that were submitted, and I did not go through every last table figure and listing because those usually number in the hundreds. But for the hundred to 200-, 300-page submissions, I went through those.

Q And you're the ultimate supervisor for the teams that are going through the actual line items?

A That's correct.

[redacted] You used the term "supervisor" a couple of times, and I think in the first hour you said that you -- when you started as the deputy director, you divvied up management duties overseeing different sections. But I don't think we've actually established what it means to be the supervisor.

Can you talk through your responsibilities, what you would do on a day-to-day basis, how you would oversee these entities?

Dr. Marks. That's very -- thanks for the question, and that can help me actually separate out what the duties of the deputy were from the center director.

So as deputy center director, I did not have direct reports. I was not responsible for the performance evaluation; that is, giving a rating score to anyone under me.

For as the center director, I'm responsible for ensuring that each of the office directors is supervised on an ongoing basis, that they are proceeding with reviews in a manner that's consistent with our policies and procedures and our timelines. And I'm responsible for essentially holding them accountable to what they put forward as their goals for a given year.

[redacted] And how do you do that?

Dr. Marks. I do that through -- usually through weekly meeting with each of the office directors, through ongoing dialogue around particularly difficult submissions where we might have additional meetings. I will sometimes sit in on meetings of the teams if they're particularly difficult areas, and that happens whether it's blood, vaccines, or cell and gene therapies. And I also get, occasionally, reports on a semiannual basis from the office directors of what they've done as accomplishments.

[redacted] Thank you.

BY [redacted]:

Q Turning to the coronavirus pandemic, we talked a little bit about your response at the beginning of 2020. But I want to start from the beginning and try to work through chronologically.

Do you recall when you first learned about the emerging novel coronavirus?

A It was sometime in early to mid-January when I think one of the -- it came up in passing as 70 cases had been identified in China, and that was the first I had heard of it at that time.

Q What was your reaction when you first learned about it?

A A little bit of concern, but to be perfectly honest, since we see a lot of emerging threats, it was a watch but not panic yet.

Q As director of CBER, did you take particular steps in response to the news about the emerging coronavirus in that early 2020 timeframe?

A By the time we had gotten to mid to late February, we certainly did. By that time, we were starting to mobilize, to prepare to think about how we might have to help with vaccine development.

Certainly, by I can't say exactly when, but certainly during February, it was becoming increasingly clear that this was going to potentially become a global pandemic.

Q What do you mean by you were preparing to mobilize? What does that look like?

A That means starting to develop the guidance for what we would expect from a vaccine, providing potential manufacturers with what guidance we could about what we would want to see for the nonclinical evidence that would be necessary to take a vaccine into humans, and essentially understanding what the development pathways would look like towards a either emergency use authorized or to an approved vaccine.

Q Did your team begin meeting with manufacturers to discuss these guidelines

that you're talking about?

A They did. And I can't say whether that was in, you know, February and March, but it was sometime in that period of time.

Q The FDA issued its first guidance to industry about COVID vaccines in June 2020. Does that sound right?

A Actually, it's -- it's possible it was a little earlier, but it's around that timing.

Q And is it around this time that you were also working on Operation Warp Speed?

A So I worked for Operation Warp Speed for a period of time, from when it was conceived to sometime in May when, after giving it some thought and realizing that one couldn't have conflicting roles, I decided to just continue on at FDA rather than leaving FDA to work on Operation Warp Speed.

Q Could you explain what Operation Warp Speed was?

A So Operation Warp Speed was conceived of as a way of trying to accelerate vaccine development. The original -- what led to Operation Warp Speed was, first, the knowledge that the manufacturers had originally targeted spring of 2022 for when they might have a vaccine available. Predictions from the Centers for Disease Control said that if we went that long without a vaccine, we could see over 3 million deaths in the United States and -- in the first year alone. And so there felt like some urgency to see what we could do to reduce the time.

Project Warp Speed, which is the name I gave it, when we started to develop it in mid to late March, was a -- mainly a regulatory process. At the request of the commissioner at the time, I discussed the idea with the assistant secretary for preparedness and response, who liked the idea. That idea was subsequently further discussed with a larger team of individuals. And around April 10th to 14th, the project

was articulated on paper and subsequently was brought forth to the Secretary, and the Secretary then endorsed it.

Q And you said it was originally the commissioner at the time talked to you about it. Is that right?

A So the commissioner encouraged me to take -- I presented Project Warp Speed to our commissioner. The commissioner felt that it had merit, and it was mainly about trying to speed up the regulatory aspects of this. But in conversations with -- further conversations, it took on a larger -- a larger meaning to try to work with the companies to help speed things up as well. And some of this was the contribution of the assistant secretary in terms of thinking of how we might work to move things forward.

Q Who was the FDA commissioner at the time?

A It was Stephen Hahn.

Q And Stephen Hahn was appointed by President Trump. Is that right?

A That's correct.

Q So would you agree, based on your work, that in 2020, the United States Government placed a high priority on developing a COVID vaccine as quickly as possible?

A Yes.

Q And the decision was made that COVID-19 vaccines would be eligible for consideration under an Emergency Use Authorization. Is that right?

A That's correct. The -- that's correct.

Q We've been calling the Emergency Use Authorization an EUA. Is that right?

A That's correct.

Q What is that process?

A So an Emergency Use Authorization, it's an authority that was given to us by Congress after the terrorist attacks of 9/11, which is -- allows us to have tremendous

flexibility in our making available medical countermeasures that could potentially have a role when a threat comes, either biological, chemical, or radionuclear.

And so we have a lot of -- we have a lot of latitude in what we can do with these because the standard is that the -- not our normal standard. Our normal standard is that a product has to have demonstrated safety and effectiveness. So the approval standard is an effectiveness standard. Here, it's that the product may be effective and essentially that the potential benefits, the known and potential benefits outweigh the known and potential risks.

And so it's a way that we can make products available to people through a process that does not require informed consent. It has a -- we inform people through a patient information sheet, but it may -- allows us to make a product that would normally not be available without an approval available.

Q What do you mean that it does not require informed consent?

A So, normally, if one receives a product in the United States that is not approved by the -- in the most common circumstance in the United States, when one receives a product that has not received either Biologics License Application or does not have a New Drug Application and has been approved, one is receiving that under an Investigational New Drug Application. Under an Investigational New Drug Application to receive a medical product, one has to be participating generally in a clinical trial of some sort or receiving it on as part of an Expanded Access Program.

Either way, the individual receiving the product or their -- or their -- hang on for one second for me. It's either the individual receiving the product or their custodian, legal guardian would have to sign an informed consent. That informed consent describes what the product is or what the procedure is, the potential benefits, the potential risks and alternatives to treatment, as well as whether there's any compensation involved for

that product.

Q So under an EUA, instead of signing that form, instead, the patient receives an information sheet. Is that right?

A That's correct.

Q But not requiring informed consent doesn't mean that the patient doesn't receive information about the product, right?

A No, that's correct. And I -- and the reason why I believe that was put in place is because as somebody -- this is something I do consider myself an expert on.

In obtaining informed consent from patients, which I've done essentially hundreds of times, potentially thousands of times from cancer patients, is a lengthy process that requires a conversation between a physician and a patient or a licensed provider and a patient in which the various issues surrounding treatment are discussed. It's not very suitable for an emergency situation when one needs to roll out a product relatively rapidly in a setting where these kinds of doctor-patient relationships can't take place on an extended basis and someone can sign an informed consent.

[redacted] Can you describe the information sheet in a little more detail? What type of information's contained in that?

Dr. Marks. So the information sheet looks very much like what a best practices for an informed consent would look like. It talks about what the product is. It talks about the potential benefits, the potential risks. And it also has the alternatives and the -- by what is required, it also discusses where you would contact if you had an adverse event or felt you've been harmed by the vaccine.

BY [redacted]:

Q What circumstances allowed the FDA to consider approving these vaccines under an Emergency Use Authorization or authorizing these vaccines?

A So there were two declarations. The Secretary of HHS had issued a section 319 declaration. So we were in the middle of a public health emergency. And then there was also a section 564 declaration, which allows the FDA to make products available -- medical products available under Emergency Use Authorization. So both of those were in effect at the time.

Q Did the FDA apply the same standards to authorizing COVID vaccines under emergency use as it usually applies to reviewing products for Emergency Use Authorization?

A So there's -- it's -- I guess, there was only one vaccine that had been -- this was a very new area for us in medical products because there had only been one vaccine previously which had had very limited use under Emergency Use Authorization. And so this was somewhat new territory.

But I should provide you context that, because we were very concerned from the outset, vaccine hesitancy is not something new in 2023, 2024. We knew that it existed very much in 2020 and 2019 and before. In fact, one of my initial roles at the center was to deal with a lot of the issues in the area of vaccine hesitancy. So we knew very much that we needed to make sure that when the vaccines came through this process, people felt confident in them.

The Emergency Use Authorization differed from the Biologics License Application in this particular case by the fact that we only -- you know, we had the same size clinical trial which was required as a normal Biologics License Application. We did allow the manufacturers to submit a shorter time of safety followup, which was a meeting of 2 months of safety followup. That was articulated in, I believe, in an October 2020 guidance that was an Emergency Use Authorization that was put out there.

And then that -- that combined. So the other differences with BLA had to do with

the fact that we did not require the same number of manufacturing conformance slots that we did -- we would for a normal Biologics License Application.

But, otherwise, many of the same aspects were -- were met, and we tried to be very thoughtful about the duration of safety followup in that a meeting of 2 months of followup captures about 95 percent of the adverse events that will be found with vaccines. That was based on historical data that was in the literature.

[redacted] I'll introduce that October guidance that you mentioned as exhibit 2.

[Marks Exhibit No. 2.
was marked for identification.]

BY [redacted]:

Q So this is the October 2022 -- or sorry -- October 2020 guidance for EUA for COVID vaccines.

Before I talk more about this, the standard for an EUA is that the known and potential benefits of a product must outweigh the known and potential risks. Is that right?

A That's correct.

Q Was that standard applied in the case of the COVID-19 EUAs in 2020?

A Yes, it was.

Q So you mentioned a couple of different things that are contained in this guidance already. I want to start with section V, which is on page 5.

This section is entitled, "Recommendations Regarding Information and Data to be Included in a Request for an EUA for a COVID-19 Vaccine." Do you see that?

A Yes, I do.

Q So in this section, there is a lot of information laid out that must be included

in an EUA request. Is that right?

A Yes, there is.

Q So that includes regulatory information.

A Correct.

Q Chemistry, manufacturing, and controls information.

A Correct.

Q Safety and effectiveness information.

A Correct.

Q Okay. So the regulatory information on page 5, in section A2, it says that a request for an Emergency Use Authorization should include, "Available safety and effectiveness information for the product." Is that right?

A Correct.

Q And then looking at A3, it says that the request should include, "A discussion of risks and benefits, including available information concerning the threat posed by SARS-CoV-2 and how that threat would be addressed by the product under the proposed use under the EUA." Is that right?

A Correct.

Q Why is that important for it -- for the request to include a discussion of risks and benefits?

A Because that's the framework for all of our medical product review, including under Emergency Use Authorization. So as I may have mentioned before, we assess medical products based on risk, benefits, and uncertainty. And the same general procedure was used for the Emergency Use Authorization. It's just there is a different standard for making the conclusion that it could be deployed.

Q This paragraph also mentions meeting the prespecified success criteria for

the study's primary efficacy end point. It's like in the middle of the paragraph.

A Yeah.

Q See that?

A Got it, yes.

Q What were the primary -- or, first of all, what does that mean, meeting the study's primary efficacy end point?

A So when we conduct studies that are generally these types of large effectiveness studies, one sets out before -- before one goes and conducts the study, one determines what your criteria of success will be and one writes them down so one can't change the things at the end, you know, and do something sneaky. So the idea here is that someone wrote down at the beginning what they were trying to achieve.

We at FDA, in the April or June, it's -- it may have been revised, so I may have two different dates in my head. But in the earlier guidance on COVID-19 vaccines from 2020, spring of 2020, we did note that we wanted to see 50 percent effectiveness with a lower bound than 95 percent confidence interval of 30 percent.

So that meant is that there had to be reasonably -- reasonably good chance that there was clear effectiveness of the vaccine. And we did not want to have a vaccine that was deployed that had what we would consider insufficient effectiveness so that people would lose confidence in getting vaccinated.

Q And when we're talking about the COVID-19 vaccines, was that -- what was that efficacy end point? Was it preventing hospitalization? Preventing death?

A So in the setting of a trial that needed to be conducted quickly, it was simply preventing COVID-19 illness, symptomatic COVID-19, and that was defined in the protocol as certain things like fever, cough, shortness of breath.

Q Did the FDA require that manufacturers submit all of the information here in

their request before authorizing a vaccine for emergency use?

A Yes.

Q Turning to section B of that, part B, Chemistry, Manufacturing, and Controls, could you explain, generally, what does that mean? What is the FDA looking for?

A Right. So biologic products, even more so than small molecule drug products, the process in how they're produced is absolutely critical. And so chemistry, manufacturing, controls in this case is a detailed description of the process by which the product is made, where the product is made. And because these products are often made in one place and then brought to another to be put into vials and put into their final formulation, it will describe those facilities as well.

And then the controls aspect is what is done to test the product to make sure it is what it says it is and that it has the -- the labeled potency or the labeled characteristics and what's in the vial actually match.

Q Why is that kind of information important for the FDA to review for Emergency Use Authorization?

A Because it's absolutely critical that if we deploy a medical countermeasure, that it is -- it is what it says it is, and that if it was a vaccine against COVID-19 that had a certain effectiveness, that it performed in that manner.

Q In the case of the COVID-19 vaccines that had an EUA in 2020, was that information reviewed?

A It was.

Q Then turning to section C that's on page 9, this section is about safety and effectiveness information.

So there's, again, a lot of information that the FDA suggests that companies or sponsors include in their EUA request. Some of that includes information from phase 1,

2, and 3 trials.

You talked about phase 1, 2, and 3 studies in the earlier hour. But could you explain sort of what this guidance says that sponsors should be doing for these trials?

A Yeah. So, you know, in this particular case for COVID-19, we allowed manufacturers to move directly from one type of trial into another. Normally, there's phase 1, one looks at -- one does the trial, then stops and looks at the data, and then does phase 2 after essentially authoring another trial, and then stops and looks and decides whether they're going to do a phase 3 trial.

In this case, in order to keep the process moving, in some cases a phase 1, 2, 3 trial was done where there were just brief pauses after each section of the trial to keep it moving as rapidly as possible. That is a known way of trying to expedite trial conduct, and it's used not just in vaccines but also in a rare disease drug development.

[redacted] What's your response to people who would say that this kind of expedited trial process means that the FDA was now cutting corners with concerns to safety?

Dr. Marks. Yeah. There were no corners cut with respect to safety or effectiveness or quality of these vaccines. And that is just -- it's demonstrated by the fact that, on average, when we approve a vaccine, about -- this is for a full approval. Our average vaccine approval has involved a clinical trial program with 22,000 people receiving a vaccine, for instance, for the Pfizer COVID-19 vaccine or the Moderna COVID-19 vaccine.

For the Pfizer, about 22,000 people, so close to that same number, on average, had received the vaccine before we gave it an Emergency Use Authorization.

There is no way around the fact that the safety followup was shorter than we normally do. Normally, we like at least 6 months, if not a year, of safety followup. But as

I said, we know that 95 percent of the adverse events were seen within the first 2 months. And in a period where you're having many people dying of an infectious disease, generally, it made it very clear that the benefits of the vaccine would potentially outweigh any risks that we could see.

BY [redacted]:

Q When a manufacturer submitted an EUA request for the COVID-19 vaccines, did the FDA require that the vaccine be tested to ensure it was safe?

A If -- all of the vaccines that were submitted underwent -- they went clinical testing, as well as in most cases nonclinical testing. I shouldn't say in most cases. They went through clinical testing and nonclinical testing to ensure that they were safe and effective.

Q Could you explain the difference between clinical and nonclinical testing?

A So nonclinical testing is the testing that's done on a vaccine in animals to show that it might have efficacy or to show that it doesn't have certain toxicity. Nonclinical studies can include things like reproductive toxicology and biodistribution, for instance, of a -- of a vaccine. Additionally, then clinical testing is actually testing in humans.

Q Did the FDA review this information when issuing a authorization for the emergency use for the COVID-19 vaccines in 2020?

A We did.

Q So is it fair to say that, during the EUA review process for the COVID-19 vaccines, the FDA reviewed safety, efficacy, and manufacturing data?

A That's correct.

Q Turning to page 11 of the October 2020 guidance, there is a heading that says, "Considerations for Continuing Clinical Trials Following Issuance of an EUA for a

COVID-19 Vaccine." Do you see that?

A Yes.

Q Can you explain generally what these considerations were?

A So there was a lot of discussion when the initial effectiveness data became available for the COVID-19 vaccines of whether a blinded clinical trial; that is, because the way -- when the trial was conducted, it was unblinded. The individuals who participated in it did not know what they had received. So they might have received placebo or they might have received the active vaccine.

And the question was, after the unblinding, should they be told so they could potentially get vaccinated or should they just continue on so we would get more effectiveness data in a blinded manner?

Ultimately, after this guidance was issued and based on input from our advisory committee members, we ultimately allowed people to be told, if they wanted to, what vaccine they had received because it was felt to be unethical at this point, given the high effectiveness of the vaccine in preventing symptomatic disease, to withhold the vaccine.

Q Was it important that the clinical trials continued even after the issuance of an EUA?

A It was.

Q Could you explain why?

A We were very interested to make sure we understood continued accrual of efficacy data but, very importantly, continued accrual of safety data which allowed us to understand if there were any safety concerns in the population that had been treated. We gen- -- as I said, we generally like 6 to 12 months of safety followup for our vaccines.

Q And in the case of these vaccines, did the clinical trials continue?

A They did.

Q Finally, this next section, section VII, reads, "Consideration of an EUA for a COVID-19 Vaccine By an FDA Advisory Committee." The first sentence says that the, "FDA expects to convene an open session of FDA's VRBPAC prior to the issuance of any EUA for a COVID-19 vaccine."

VRBPAC refers to the Vaccines and Related Biological Products Advisory Committee. Is that right?

A That's correct.

Q Could you explain why this consideration was important?

A So it was felt that public confidence in vaccines was something that was very important. Additionally, this was a relatively unfamiliar process to the public. So we felt it was important for the public to be able to see what was going into the Emergency Use Authorization, so they were discussed.

The data were presented in terms of safety and effectiveness by the manufacturers and by FDA. They were discussed by a committee of experts in -- many of whom had significant expertise in coronaviruses, and it was a relatively expert group of individuals based on their resumes.

Q Generally, what is the job or the role of the VRBPAC?

A It's to make a recommendation to the FDA whether or not to approve a vaccine or, in some cases, to discuss a particular aspect of a vaccine.

Q And who sits on the VRBPAC?

A VRBPAC is comprised generally of experts in vaccinology, immunologists, and generally a statistician or two, as well as an industry representative that's nonvoting and a patient representative who is voting.

Q Did the VRBPAC meet to consider the EUA requests before the vaccines were granted Emergency Use Authorization?

A For each of the initial Emergency Use Authorizations, for the Pfizer vaccine, for the Moderna vaccine, and for the Janssen vaccine, and for Novavax vaccine, we had VRBPAC meetings.

Q And going through each of those, for the Pfizer vaccine, the VRBPAC met on December 10th, 2020. Does that sound right?

A It sounds about right.

Q Do you recall what the VRBPAC concluded regarding the Pfizer vaccine?

A The conclusion was that it was safe and effective for the intended use under Emergency Use Authorization; in other words, that it had met the standard of -- it appeared to offer benefit and that the potential benefits outweighed the potential risks.

Q And then the next day, the FDA issued the EUA.

A That's correct.

Q And then, a week later, you mentioned, that the Moderna vaccine, EUA came out -- the day before that, the VRBPAC met to discuss the Moderna EUA. Is that right?

A That's correct.

Q And do you remember what the VRBPAC concluded about the Moderna EUA?

A The same as it did for the Pfizer, that it was -- it was -- it met the criteria for EUA and that the potential benefits outweighed the potential risks.

Q So for both the Pfizer and Moderna vaccines in 2020, is it true that the FDA did not issue an Emergency Use Authorization until career scientists had conducted a thorough evaluation of those vaccines?

A That's correct.

Q And it was not issued until after the VRBPAC considered and voted in favor

of that EUA request?

A That's correct.

Q What, generally, allowed FDA to authorize these COVID vaccines for emergency use more quickly than it has authorized some other products in the past?

A So as part of the Emergency Use Authorization process, one of the things we put in place -- and this was, I think, part of what was laid out as part of Operation Warp Speed -- was the idea that the manufacturers would have an ongoing dialogue with FDA during this development process. That did not mean that we were in bed with the manufacturers. It meant that we were having ongoing regulatory dialogue where they would bring problems to us and that we would work through them on an ongoing basis.

Sometimes they were manufacturing challenges that needed to be overcome. Sometimes they were considerations on clinical trial design. And we also then received information on a rolling basis for the Emergency Use Authorization.

So when the -- when -- so some of this information was coming in on an ongoing basis, particularly in the manufacturing realm. And then when the clinical data was submitted, we were prepared for it because we kind of knew what we were going to be receiving because we knew the study design. And so that allowed us to move relatively rapidly through the review of the material. We also had a very large team that had been assembled to do this.

[12:06 p.m.]

BY [redacted]:

Q And then you mentioned the work of Operation Warp Speed.

How -- or did your work at Operation Warp Speed inform your work through the rest of the pandemic at FDA?

A So one of the concepts of Operation Warp Speed was that teams of people working together when motivated by a leader that can actually outperform what any individual can possibly do in order to accomplish something much more rapidly or that might seem otherwise impossible.

And with good motivation and good management, I think the group at FDA, much to its tribute, that the rank and file managed to make it through a tremendous amount of information without cutting any corners in order to get these products emergency use authorized in a timely manner.

Q Did you have confidence that the COVID-19 vaccines were safe, effective, and high-quality when the EUAs were issued in late 2020.

A Yes.

BY [redacted]:

Q Switching subjects, I just want to return to a line that was discussed in the prior hour.

You were asked about whether FDA promotes vaccines. Do you recall that conversation?

A Yes, I do.

Q You said that it's not FDA's role to promote vaccines, but you said you did engage with doctors, for example, to explain the quality, safety, and effectiveness, so if somebody considers that promoting, then -- then that would be promoting. I want to

tease that out a little bit.

What is your understanding of what the word "promoting" means?

A So as somebody who worked for a pharmaceutical company, promotion has a very specific meaning. Promotion means commercial advertising to try to use emotion and all of the traditional ways of selling to get someone to use a product. It's not meant necessarily for anyone to know all of the details of the product. It's mainly so that they would want to use a product.

I think most of us have probably watched TV in the past ten years, and you've probably seen promotional advertising, which I think embodies that. When they're -- as they're quickly telling you about how the product can kill you or maim you or et cetera, there are nice butterflies flying around and distracting you from that, but making you feel emotionally towards the product.

That is not what my job was. Okay? So if we're talking about that as promotion, that is an absolute no. On the other hand, my job after the authorization was to make sure people were informed, providers were informed of this, and we did so via various webinars to the American Medical Association and other medical societies.

I was occasionally asked by patient advocacy groups to answer questions by groups of individuals about the vaccines. I did that as part of a public service during a pandemic because I was somebody who knew about them. But it was not something that I -- I was -- I can say quite the opposite, and I don't have to -- I don't have to say any more than you can go to any one of the -- go to the web right now and watch me on one of those. It's recorded.

And at the end of the day, what I would always say is, look, my job here is to give you the information that you need to make a decision about whether you want to take the vaccine. And I -- I -- to the best of my recollection, I've never on a webinar ever said,

you should take the vaccine.

Q Right. So it's fair to say that your role was to explain the risks and benefits to doctors and, ultimately, to consumers, correct?

A That's correct.

Q So that they could make an informed decision. Fair to say?

A That's correct.

Q Okay. And so you were never involved in, for example, selling the vaccine?

A Absolutely correct.

Q Okay. And that's not the FDA's role in any circumstances?

A Absolutely not.

[redacted] Okay. Thank you.

[redacted] We can go off the record.

[Recess.]

[redacted] Let's go back on the record.

Mr. Massie. I'd like to follow up on some questions they had. So can you describe the role of VRBPAC in the EUAs?

Dr. Marks. So the Vaccine and Related Biologic Products Advisory Committee, their role was to look at the data summaries that were provided to them, to review the data, make sure it seemed to them that the safety and the effectiveness met the general standards of the EUA process, the Emergency Use Authorization process, as was presented to them -- the standard was presented to them.

That tends to be how Pfizer committees work. We present the standard that we're looking for, the data, and they then discuss the data and discuss whether or not it met the standard.

Mr. Massie. So they're an outside review board? They're not part of the FDA, or

they're comprised of people from the outside?

Dr. Marks. They're special government employees who are vetted for conflict of interest who are outside of FDA, and occasionally, there are people from other government agencies, like CDC or NIH that sit on the VRBPAC.

Mr. Massie. Would you say they help instill confidence in the process by having them involved?

Dr. Marks. I think it does, yes.

Mr. Massie. Did you skip that step in the BLA -- in the Biological License Application? Did VRBPAC review your suggestion and recommend to approve it for the license before the license was issued?

Dr. Marks. So we did not take the -- the Biologic License Application for the vaccines, we did not go back to VRBPAC because they had reviewed all of the effectiveness data as part of the Emergency Use Application.

They had also discussed the major safety concerns that emerged, such as the -- during the period of separate VRBPAC meetings. So that it was not felt that going back to VRBPAC to have a discussion on safety and effectiveness again was necessary because the question was asked and answered. They had determined the vaccine to be effective, and there was not any substantial major differences that they hadn't discussed.

So we didn't feel that it had to go back to a VRBPAC before the actual license application.

Mr. Massie. Do you typically go to VRBPAC before issuing the license?

Dr. Marks. Not for every vaccine.

Mr. Massie. Do you feel like it could have instilled some confidence or more confidence in the license application process had you used the outside board like you did for the EUA?

Dr. Marks. I can't speculate. But I can tell you that we were extremely -- at that point we were -- had our hands full, and each additional thing that we had to do meant we weren't doing something else. So we had to triage what would have the most impact.

But I really can't speculate as to what -- what the difference might have been.

Mr. Massie. So it also saved time in the process?

Dr. Marks. It -- it did save some time because we did not have to present it to the -- to the VRBPAC, yes.

Mr. Massie. I want to talk again about something we were talking about before, which is the role of CDC versus the FDA.

And is it -- is it true that you -- at the FDA you vet what can be said on the package inserts or the materials that the manufacturers put out about efficacy and safety? Do you decide -- as part of the application for an EUA or BLA, do they also tell you what they're going to print and then you approve that?

Dr. Marks. So, ultimately, for an Emergency Use Authorization, the manufacturer can propose what goes on the label, the Emergency Use Authorization, either the provider information sheet or the recipient information sheet, the patient information sheet; we will review it, make recommendations, send it back to them, and there's usually a back and forth.

But, ultimately, for an Emergency Use Authorization, FDA can decide what needs to be in that -- that patient information sheet or provider information sheet based on what we feel the data show.

Mr. Massie. Is it the same for a BLA?

Dr. Marks. For the BLA, we generally go back and forth and back and forth until we have agreement. There's a little bit less of a -- in the case of the -- of the EUA, it's very easy for us to say stop at a certain point, and we can decide what sits on the Emergency

Use Authorization. Usually for a Biologics License Application, we try to come to agreement with the company and -- without saying, this is the way it's going to be.

Mr. Massie. Did any of them ever ask to put on their insert for the EUA or the BLA a statement that the vaccine would prevent the spread or prevent infection?

Mr. Cooke. I'm sorry. Just to be clear, we're talking specifically about the COVID vaccine?

Mr. Massie. COVID vaccine -- sorry -- yes.

Dr. Marks. To the best of my knowledge, not.

Mr. Massie. And did you ever approve language for the manufacturers to say that it would prevent spread -- that the COVID-19 vaccine -- either the EUA process or the BLA process, did you ever approve for them to say it could prevent spread?

Dr. Marks. To prevent spread? To the best of my recollection, we never -- we never approved anything like that for the label because they didn't have data to support that. It's possible -- yeah, that's -- that's -- that's the best I can -- to the best of my recollection.

Mr. Massie. Did you vet data at the FDA -- as part of your official role at CBER and overseeing OVRR, did you vet data for the purposes of showing that it prevents spread?

Dr. Marks. To vet data from the manufacturers or from -- I'm just trying to get your question.

Mr. Massie. Did you ever confirm in your official capacity, like you -- like you would for vaccine claims, that this vaccine -- the COVID-19 vaccine prevented spread?

Dr. Marks. So over the course of time from real-world evidence that was collected, we became aware of data that suggested that it reduced spread, but not that it -- prevent means -- a lot of people, when you say prevent, it can mean a lot of different things to people. Prevent may mean it never will happen.

Mr. Massie. Right.

Dr. Marks. But in this case, the original versions of the vaccine appeared to reduce the risk of spread by about 40 to 50 percent, and that came from real-world evidence. That is not from studies conducted by the manufacturer.

Mr. Massie. So let's use the word reduce. I'm sorry I used the word prevent.

Did you ever vet that data in a role at the FDA like you would when you're vetting other claims?

Dr. Marks. It was never -- no. It was not submitted to the manufacturer -- by the manufacturer to -- for that kind of vetting.

Mr. Massie. And when the -- but if the FDA had made that claim, are you concerned, you know, if an FDA official made that claim, that people would think that the FDA had vetted it, that claim?

Dr. Marks. So there -- I guess it would be the way that it would be described. If one cites the fact that real-world evidence suggests that the spread was reduced by, you know, 40 percent, that's different than saying that the FDA has received evidence for a given vaccine and for that specific vaccine that would label it for a reduction risk of 40 percent.

In other words, one is general -- one is general scientific knowledge that people were aware of, and I'm -- I'm not aware of -- I mean, I'm not aware of us -- again, to the best of my recollection, we didn't repeat that figure extensively for, you know, the purposes of anything other than just making -- making known what was in the scientific literature.

Mr. Massie. So let me -- I asked you some questions at the end of the last hour, and I want to get a clarification.

Were you making recommendations directed at individuals or just to public health

agencies?

Dr. Marks. We were making recommendations to public -- to public health agencies and providing information to doctors.

Mr. Massie. So you never directly addressed your comments to parents of children?

Dr. Marks. So it's possible I may have been asked by a patient advocacy group to speak to parents' groups at some point during the pandemic to answer questions about the vaccine, but I -- to the best of my recollection, that could have happened on occasion, but it was not something I routinely did.

Mr. Massie. Would that be your role, to make recommendations to individuals about whether they should get the vaccine or not?

Dr. Marks. No, I don't make -- I don't make recommendations to individuals.

But my role is to actual answer questions about the vaccine so that people can make decisions themselves.

Mr. Massie. Can you talk about what kind of -- we started to talk about this before -- what -- why there is the separation between the CDC and the FDA and why they make recommendations about whether you should get the vaccine and why the FDA would typically just vet or approve or regulate the claims made by manufacturers and what -- what could happen if the FDA becomes a promoter of -- of a product and then the product then has to be recalled?

Dr. Marks. So I can't -- I can only say what we did. We were not promoting products. We were approving products that were quality, safe, and effective for their intended use. And then CDC's job is to help deploy them for the benefit of public health.

It's during the pandemic as part of one of my other duties as assigned was to sometimes take -- to help educate doctors through webinars, to sometimes meet with

patient advocacy organizations to answer questions. But it was not in any way, shape, or form to give individual advice to -- to patients to take the vaccine.

Mr. Massie. So the manufacturers, if they advertise their vaccines in their EUA, they're supposed to say that they're EUA. Is that correct?

Dr. Marks. To the best of my knowledge, that's correct.

Mr. Massie. Did you ever see any -- during the EUA period, did you ever see any of the vaccine manufacturers promoting their vaccines without that EUA disclaimer?

Dr. Marks. Not to my knowledge.

Mr. Massie. Did anybody ever contact you about companies violating this prohibition on doing promotion or ads without disclosing that it was EUA?

Dr. Marks. Not that I can recall. But I -- there was so many emails that came in during that time that -- with many, many different accusations against many different companies that anything is possible, but not to the best of my recollection.

Mr. Massie. Is the FDA exempted from disclosing that it's an EUA when they make -- I think it's the promotional material must clearly and conspicuously state that the product has not been approved or licensed by the FDA.

Is there an exemption to the language for FDA promotional material?

Dr. Marks. We don't have promotional material. We simply have patient information sheets and provider information sheets, which at the very top of any of them, I think you can pull down from the web, say, you know, this is for an Emergency Use Authorization. So where it's always -- and it would say that you're being offered this vaccine as part of an -- an Emergency Use Authorization. So it's pretty clear that these are emergency use authorized vaccines.

Mr. Massie. Are pharmaceutical companies allowed to do direct-to-consumer marketing of products that are not approved?

Dr. Marks. So if a product is not approved at all, they're not allowed to do that.

Mr. Massie. Did you ever do anything to prevent Pfizer or BioNTech from doing that?

Dr. Marks. So I'm -- you know, I'm not the one to speak to the legal issues of what can be done under an EUA in terms of promotion. It was a product that was -- that was authorized under Emergency Use Authorization, and my area of expertise is not what could be or couldn't be promoted. And so I can't speak to it with any authority.

Mr. Massie. And you weren't contacted to -- about any of these claims that were being made by companies that manufactured the vaccine? You weren't asked to intervene?

Mr. Cooke. Sorry, can I just ask. You mean, you -- Dr. Marks individually?

Mr. Massie. Yeah. Yeah. You mentioned there's a compliance division under you. Is that correct?

Dr. Marks. That's correct.

Mr. Massie. Was your compliance division ever contacted -- were you ever made aware that they were promoting them without the EUA disclaimer?

Dr. Marks. It's -- you know, again, it's possible that we -- we received so many various, sundry complaints about the vaccines that it's possible that we received a complaint, but I can't recall specifically.

Mr. Massie. I would like to show some videos now, if we could. These are -- let's see. And we can discuss them in any order, but I think these are from the FDA website. They'll be the one minute -- you did a -- you did a series of promotional -- well, I'll let you characterize them. But you did -- 41 videos, I believe, of one-minute each, roughly, talking about the vaccine.

Dr. Marks. Uh-huh.

Mr. Massie. And let's see. Which one is this?

[redacted] December 21st.

Mr. Massie. This is No. 21? Let me -- before you hit play --

[redacted] It's dated December 21st.

Mr. Massie. Oh, okay. Do we know which of the 41 it is? It's okay. Go ahead and play it.

[Video played.]

Mr. Massie. Okay. Can you pause that.

Mr. Cooke. If I may. So is this being entered as an exhibit? Is there a date on this?

Mr. Massie. It will be in the transcript. We can enter it as an exhibit if you want.

[redacted] Yeah, we can do that.

Mr. Massie. It's on the FDA's website.

Mr. Cooke. Okay. So this is a -- just so I'm clear, so this is a video on the FDA's website. It's a YouTube video, it appears.

And what's the date of it, so we have that?

[redacted] Do you have that, Prisila?

[redacted] December 21st, development --

Mr. Cooke. And it looks like it's titled, "Why should I get a COVID-19 booster? Just a minute with Dr. Peter Marks." Okay.

[redacted] I think, for the record, can you include the URL?

[redacted] The URL?

[redacted] That would be -- just to save the court reporter.

[redacted] With agreement, we will send the URL for the record rather than read it off.

[Marks Exhibit No. 3.

was marked for identification.]

Mr. Massie. Would you agree this is directed at individuals and not doctors? You're advising individuals to take the booster?

Dr. Marks. I would -- would say that individuals could con- -- it was for individuals to consider whether they would take a booster, yes.

Mr. Massie. Isn't this typically the role of the CDC?

Dr. Marks. You know, during the public health emergency, we took -- we basically worked together and in some cases did things to try to help people understand what the vaccines had the potential for.

Mr. Massie. But you said earlier in your testimony, my job here is to give the information you need to decide whether to take the vaccine.

Wouldn't it be more correct to say that your job is to determine whether the claims made by the manufacturer are accurate so that --

Dr. Marks. That's correct.

Mr. Massie. Is there -- in this video, you mentioned that it could reduce spread of the virus.

Had the FDA ever vetted that claim in any official process?

Dr. Marks. We had not officially -- we had -- that was the -- our best assessment of the scientific evidence available to us. So if you say, did we view it in terms of a submission, we did not have it in terms of submission, but it was viewed as the best available scientific evidence.

Mr. Massie. Did any manufacturer make that claim?

Dr. Marks. Not to my knowledge.

Mr. Massie. So now at the FDA, you were making claims about a product that not

only weren't vetted, but the manufacturer didn't even claim, and as you earlier stated, there was no trial data for?

Dr. Marks. It was the best of the available evidence that is to reduce the spread of COVID-19. And to this date, if you look at the scientific evidence across a range of literature -- and I know part of what we're going to have to talk about today is the fact that there is a lot of different literature out there.

This was the consensus, that getting vaccinated would help reduce the spread of COVID-19.

Mr. Massie. Today won't be a comprehensive review of the literature or the claims. My questions are focused on the FDA's role.

And here the FDA's role -- correct me if I'm wrong -- is to verify claims or debunk claims of manufacturers, not to make claims that the manufacturer itself aren't even making, is it?

Dr. Marks. The FDA's role in this case during a public health emergency when thousands of people -- this is not the usual -- I mean, I -- so around this time we had probably about a thousand people dying each day of COVID-19.

It was determined in another study that -- that boosters actually have -- the deployment of these boosters significantly reduced the numbers of deaths. The idea being that getting people to take boosters to help reduce deaths during a public health emergency, we collaborated together with our other public health agencies. And, yes, is it possible that we might have crossed over into some of what CDC might normally do? It's possible.

But this is not -- you know, this is what we were doing to try to help inform people about what they could do to help protect themselves against the threat that was causing tremendous number of deaths and hospitalization at this time in the country.

Mr. Massie. So Congress gave a billion dollars to CDC to reduce vaccine hesitancy and promote the vaccine because that's their role.

Did Congress ever direct the FDA to change its role as a regulator to become a recommender?

Dr. Marks. Not to my knowledge.

Mr. Massie. Let's look at another video here. And before we -- before we do, let me say that earlier you mentioned that some of these ads that the pharmaceutical manufacturers put out there are meant to have an emotional aspect to them.

Whose idea was it to make this cartoonish and to play the -- the music with it?

Dr. Marks. That would have been the FDA communications department.

Mr. Massie. And did you agree with that? That that was a -- this is an appropriate -- it's the kind of style to transmit information?

Dr. Marks. I didn't think much one way or the other that -- I thought that, you know, that the comm- -- the communications people, I deferred to them on what they thought might work best.

Mr. Massie. But can you see how this may be subject to the same criticism that you provided over the pharmaceutical manufacturers' ads?

Dr. Marks. I could see that. But I do think -- and I have to go on the record to say that I don't see how you would want to increase the number of deaths by reducing the amount of vaccination.

This is a vaccine that FDA determined to be high-quality, safe, and effective. And we are known after our approvals to put out press releases, and traditionally we do put out press releases that could be considered encouraging of the products that we have approved. That's because after we approve them, we feel confident that they are safe and effective of high quality.

Now, I -- I grant you that this during a pandemic was -- I see how you can -- I see how they can be, perhaps, you know, looked at in a different way. But the goal here was to try to help inform people, and some of them were better -- as we look at more, I think some of them, you'll see, were perhaps better quality than others.

Mr. Massie. I watched all 41. I think I deserve a medal.

So -- but can you see how the confidence -- like, right now we have a pandemic of vaccine confidence. There are mothers who aren't getting the standard vaccines for their children because of the -- they saw things that happened during COVID with the vaccine, claims that were maybe -- maybe there was a grain of salt, but they were taken too far.

And I would argue that it's the FDA's role, it seems to me -- it's the FDA's role to determine what can -- you know, what can be said about -- you have standards, what can be said about a product and what can't be said about the product, so that if something turns out not to be true, you've at least gone through a process.

And there doesn't seem to be a process that this went through, and you said you don't see how -- you mentioned there were people dying every day. There were also people who were being told that the vaccine -- if you got the vaccine, you didn't need to wear a mask and that you could then go on about your life because they didn't -- they didn't say reduce spread. They said prevented spread in some cases, but those weren't the FDA.

Your organization is the FDA, and I think your job -- and I'll let you comment on this -- is to vet those claims, not to make claims that aren't vetted.

Dr. Marks. So we -- when we make a statement, we -- it's to the best of our available knowledge of the scientific evidence, and that's what went into making these videos. The best of our available scientific knowledge.

Mr. Massie. It Pfizer and Moderna had worked to the best of your scientific

knowledge and produced that same video, would they be in violation of the law?

Dr. Marks. It would depend on what they had submitted to us for data that would underlie their claims.

Mr. Massie. As you said, they didn't submit any data to you supporting the claim that it reduced or prevented spread. So they would not be authorized to make that same --

Dr. Marks. That's correct.

Mr. Massie. And why do we do that? Why do we let them only promote things that you -- you have vetted?

Dr. Marks. Of course, because those are claims that they're making and, potentially, have commercial interest. And note that I said could produce, could produce -- I didn't say it will. I said could, I believe. And that's -- was what the state of the art was at that time.

Mr. Massie. But you regulate the state of the art, and at the FDA don't you -- isn't it your job not to extrapolate what benefits might be, but to verify the claims of the manufacturers?

Dr. Marks. That's correct. But we also keep knowledge of what's going on in a field with real-world evidence and look at a time during a pandemic of what was happening in real time to make conclusions of what was going on in the field.

So there's some things that were specific to the Pfizer vaccine, some things specific to the Moderna vaccine, some specific to the Novavax vaccine. But then there was also information of general knowledge that we would keep track of during this time.

Mr. Massie. And that seems to me to be the role of the CDC if the purpose is to make recommendations about, you know, vaccine policy and not the role of the FDA.

Dr. Marks. So our goal here was to help -- again, to help in the endeavor to help

people understand the information about the potential benefits of vaccination.

Mr. Massie. Can we watch some more of the other ones.

[redacted] Which?

Mr. Massie. Just another one.

[redacted] There was one from 2022, I believe.

BY [redacted]:

Q But before you do, can I just ask this -- two things. One, you didn't have a disclaimer at the end that said you should go see your doctor and ask if a vaccine is right for you. And is there a reason why that was omitted?

A In many of them, there were that -- you'll see -- if we go through them all, you'll see that many of them, that was said.

Q Okay.

A But that's -- that's correct.

Q Was there a change that you implemented to say how we have to say this?

A No. I -- why it was in some of the one-minutes and -- and not in others, I don't know for sure.

Q Did you -- did you edit them?

A I did edit them, although others edited them as well.

Q And then before he goes to the next one, you said that you based the claim on reducing the spread on the best available knowledge?

A Yes.

Q What was -- what was the --

A Published scientific literature suggesting that we can go to now and pull off the various studies that had shown around this time that there was potentially a certain percentage reduction in spread.

Q Did you publish something that said -- because, as I recall, there was a variety of claims and some that you gave more credibility than clearly others.

And did you ever publish anything that said we believe these claims but not these claims?

A We didn't publish anything.

Q Okay. Did anyone in the CDC or NIH or --

A I can't answer that. I just don't know.

[redacted] Okay.

Mr. Massie. Did -- in one of these videos, did you make claims about the effect on fertility of those who received the vaccine?

Dr. Marks. We -- there was one that was probably done to say that, to the best of our knowledge, there was no effect on fertility.

Mr. Massie. Did you know that some people -- one of the common things that they reported was that women missed their periods or had irregular periods after receiving the vaccine?

Dr. Marks. We have found and since -- if you look at various literature that there were menstrual irregularities. Some women did miss their period, but on average there was a one-day delay or a one-day lack in timing at least in some of the studies that have come out.

So it was not -- in terms of fertility, though, I think there's -- you know, you're talking about ability to have children versus menstrual cycle. They're two different things.

Mr. Massie. But you would agree that if you have an irregular menstrual cycle or don't have one, that you're not fertile at that moment?

Dr. Marks. I'm not -- you know something, you're in an area I can't speak to in expertise. This is gynecology and obstetrics, and it's possible for women to even have

children sometimes when they haven't had -- you know, they may have missed -- thought they missed a period, and they can become pregnant.

I'm not an expert in this area, and I can't say more because I'm not -- I just am not qualified to.

Mr. Massie. That would be an appropriate thing to say in a video if you were asked about fertility instead of -- at the time that you made the video, I believe people had reported that they were missing periods or had irregular periods. And then there were -- did -- there weren't -- I mean, you mentioned in the video that there was lack of data, and then -- or that data didn't exist to show that it affected fertility.

Dr. Marks. So let me make it perfectly clear for the record. The people who were asking the most about this were often minority communities or communities of -- particular religious communities, such as the Hasidic Jewish community. They were not asking about whether their menstrual period was going to be late or not.

They wanted to -- they were countering a misinformation campaign or asking about a misinformation campaign that spread widely over the internet saying that the vaccines made people infertile, period, unable to have children. So this video was made in order to help dispel this -- this misinformation that was spread about the vaccines.

Mr. Massie. Is that the role of the FDA as a regulator or of the CDC?

Dr. Marks. In the case of the pandemic, it was a role that we shared.

Mr. Massie. Who changed your role at the FDA?

Dr. Marks. I can't say -- speak to that. But this was fully endorsed by the commissioner of FDA to be doing this.

Mr. Massie. Which -- which commissioner was that?

Dr. Marks. At the time, this would have been acting Commissioner Woodcock.

Mr. Massie. So she directed you to -- or at least approved or didn't object when

you took it upon yourself to make part of your mission to recommend vaccines and to make claims about a vaccine that even the manufacturers weren't making?

Mr. Cooke. I'm sorry. Just to be clear, are you asking about a particular direction or instruction, in which case --

Mr. Massie. I'm wondering if Janet Woodcock -- what was her involvement in the shifting of the mission?

Dr. Marks. So this was not a shifting of the mission. This was continuation of the mission as established during the Trump administration to ensure that we had the highest percentage uptake of vaccines to save the maximum number of lives. That was the intent of Operation Warp Speed.

That was the intent of Secretary Azar, General Perna, all of those involved in the Trump administration who then subsequently was transferred over to the Biden administration, and we didn't -- we were doing the same things here, trying to ensure that we saved the maximum number of lives through the vaccines.

Mr. Massie. But we -- I mean, we've --

Dr. Marks. Talking as public health agencies together.

Mr. Massie. Right. Congress created these organization -- these -- these branches, these divisions and -- for different purposes. And right now the problem we have is vaccine hesitancy, and I believe that's because the FDA got out of its lane and started doing things it normally doesn't do.

We agree that this wasn't -- this wasn't something you would have done before COVID?

Dr. Marks. This was a pandemic that was unseen in a hundred years, and so we were trying to do what we could to save as many American lives as we possibly could.

Mr. Massie. Do you have the advertisement from Pfizer? Let's watch that.

[redacted] We'll put the URL in the record.

[Marks Exhibit No. 4.
was marked for identification.]

[Video played.]

Mr. Massie. So what we see at the end of that video is the Pfizer logo, and they're promoting a booster there. And I believe that the regulations and the laws require, when the -- when the manufacturer promotes a product that's an EUA, that they have to put that disclaimer there?

Dr. Marks. When was I -- I honestly, without knowing when that actually was posted, I can't tell you whether it was a period when they had an approved booster or that it was an EUA booster.

Mr. Massie. The EUA -- I'm sorry. The boosters have been operating under an EUA for most of the time. When was the first BLA that was given for a booster?

Dr. Marks. It would have -- well, this would have been this past year.

Mr. Massie. So she's mentioning Omicron there, which -- so the time period for this --

Dr. Marks. Was probably before.

Mr. Massie. -- was during an EUA.

So wouldn't this be illegal? Shouldn't your department have -- your compliance department --

Dr. Marks. I can't -- so, again, I can't -- probably there should have been something with EUA, but I'm not the one -- I don't have the expertise from the legal department to speak to that.

Mr. Massie. Do the compliance -- is there a compliance group --

Dr. Marks. There is a compliance group that -- that would have that knowledge.

Mr. Massie. And do they work in your umbrella?

Dr. Marks. There is a compliance group that works under me, as one -- as well as one that works centrally.

Mr. Massie. And to your -- best of your recollection, there's -- nobody communicated to you that the manufacturers were advertising their EUA products without a disclaimer?

Dr. Marks. You know, I'm going to have to just say, to the best of my recollection, it's possible that there was -- that we were informed. I just can't recall.

Mr. Massie. Is there a reason you wouldn't have responded to -- to an ad like this without the EUA disclaimer?

Dr. Marks. Again, I -- if we would have received a complaint about this, we would have investigated; that I can say.

Mr. Massie. I want to ask -- I want to switch gears now and talk about the BLA, unless you have something Gus. I'm ready to go.

Okay. At the time the Pfizer BLA was submitted, what data was missing that needed to be reviewed by the FDA in order to show that Comirnaty met the criteria for BLA as opposed to EUA?

Dr. Marks. So what -- so you're saying -- just can you repeat the question?

Mr. Massie. When Pfizer submitted their application, what data was missing that you didn't already have from the EUA?

Dr. Marks. So when the BLA came in, they submitted updated effectiveness data, updated safety data, and ultimately some additional manufacturing information on additional lots and things that were necessary to complete out the BLA.

Mr. Massie. What's -- what's your typical role -- or, sorry. What's the center's director's typical role in review of BLAs?

Dr. Marks. Generally, as an oversight function.

Mr. Massie. How did your involvement in the Pfizer BLA review differ from your typical role?

Dr. Marks. I became quite involved in it at a given point.

Mr. Massie. How often does the director get that involved?

Dr. Marks. It does happen on occasion in -- not just in vaccines, but in other areas as well.

Mr. Massie. Has there ever been a situation where you felt it was necessary to relieve the office leadership of responsibility for a review?

Dr. Marks. No.

Mr. Massie. Did you relieve Marion Gruber of her responsibility for the review?

Dr. Marks. So I was asked to take over the review of the BLA by Dr. Woodcock at the time when Dr. Gruber had -- after she had decided to go on leave.

Mr. Massie. Did she have a deputy or an assistant work for her?

Dr. Marks. Yes. She had Dr. Philip Krause.

Mr. Massie. Would you say he has more experience in -- or how would you characterize his experience?

Dr. Marks. Dr. Krause is a laboratory researcher who also did BLA reviews and helped in these with Dr. Gruber, and he was potentially -- what he might have had in terms of experience with vaccines, he did not have in terms of familiarity with the Emergency Use Authorization that I had from having worked with it through the entire process.

He also did not have the skills as a leader and manager to move through this process rapidly with a group of people, and there are plenty of -- there was a knowledge at the time that we needed to move efficiently through the BLA review because people

wanted a licensed vaccine, a licensed vaccine of safety, quality, and effectiveness that, like any other, in order to get vaccinated.

Mr. Massie. Since they already had the EUA, what was the push for the BLA? Since the vaccine was eligible, everybody was able to get the vaccine, why was it so important to get the BLA?

Dr. Marks. On a daily basis, I would get many emails from people around the country who felt that the Emergency Use Authorization was something that was very foreign to them, but that if something was a licensed product by the FDA, they would be comfortable receiving it.

So they urged me to try to get the BLA approved as quickly as possible.

[redacted] Were these from just regular citizens or doctors?

Dr. Marks. These were from citizens.

[redacted] How many are we talking about, thousands?

Dr. Marks. Many, many. I guess hundreds. I can't say more than that, perhaps.

Mr. Massie. If you can find it, I would like to introduce as an exhibit the email where Marion Gruber characterized a meeting, either telephonic meeting or in-person meeting, with you and Janet Woodcock where -- and while they're looking for that, she said in her email that -- well, I'll let you look at it.

Mr. Cooke. I'm sorry. Why don't we get it in the record, so we can take a look at it.

Mr. Massie. Which exhibit is this?

[redacted] That would be No. 5.

[Marks Exhibit No. 5.
was marked for identification.]

Mr. Massie. Do you remember receiving this email?

Dr. Marks. I do.

Mr. Massie. And I'd like to draw your attention to the third from last sentence in the second paragraph, and I'll read it. She said, "You expressed concern about rising COVID cases in the U.S. and globally largely caused by the Delta variant and stated your opinion that, absent a license, states cannot require mandatory vaccination." The sentence goes on.

And that people hesitant to get an EUA authorized vaccine would be more inclined to get immunized when the product is licensed.

So you stated to us here today that second motivator for getting the license, which was to reduce hesitancy, but did -- was it Janet Woodcock or was it you who told Dr. Gruber --

Dr. Marks. I can't speak to -- I don't know. And I don't recall that I would have ever said this, but I can't recall, and I can't speak to who said it.

Mr. Massie. Were you present when this was said?

Dr. Marks. Again, I can't recall it being said. It was something that had -- look, the issue of potential for vaccine mandates is something that may have been discussed over the course of time even from early on in -- during the pandemic. But I can't recall who would have introduced this to this conversation.

Mr. Massie. So is it true that the BLA was required for many of the mandates to proceed?

Dr. Marks. It's my understanding that that's the case.

Mr. Massie. And you were aware of that at the time? It's not some new revelation?

Dr. Marks. No. That was not a new revelation.

Mr. Massie. Okay. And you didn't dispute this -- that part of this email when Dr.

Gruber sent it, did you?

Dr. Marks. No, I did not.

Mr. Massie. So it was generally known that the BLA would be needed for vaccination, and Dr. Gruber claims that this was expressed to her that part of the reason that things needed to be speeded up for this BLA was for vaccine mandates?

Dr. Marks. All I can say is that this is Dr. Gruber's email. I didn't take issue with an email at this point in time, and I can't speak to what her -- you know, what her state of mind was or anything else that went into composing this, and I can't speak to who said that regarding this.

I can tell you that I'm on the record multiple times noting that I don't feel -- to me, the most important thing that we can do is provide people with information so that they can make choices and that I am not a -- someone that believes that vaccine mandates are what should get us over the edge of getting vaccinated but, rather, good information.

Mr. Massie. Did you support or oppose vaccine mandates?

Dr. Marks. As FDA, we don't have a role in vaccine mandates. And personally, as I said, I -- every time when asked this question -- that, I think, we can go to the video for at some point -- I always responded by saying, it's my hope. And I think I replied this on an American Medical Association webinar, that it's my feeling that we need to provide the information so people can make their own choices. It's not FDA's place to make vaccine mandates. That's the states and others.

Mr. Massie. But it was your understanding that, without a BLA, the vaccine mandates could not proceed?

Dr. Marks. That is correct.

Mr. Massie. And you agree that you received this email from Dr. Gruber that said that -- where she says that she was told, and she is -- this email is about -- the subject is

summary of a meeting dated July 19th, 2021, 8:30 a.m.

Were you in that meeting either by telephone or in person?

Dr. Marks. I would have been.

Mr. Massie. So -- and you don't dispute that she was told at the time that there would have to be a BLA for the vaccine mandate to occur?

Dr. Marks. I can't speak to that because I don't recall that part of the conversation.

Mr. Massie. Did you have any conversations with the Department of Defense, the Secretary of Defense or the White House about the timing of mandates?

Dr. Marks. No.

Mr. Massie. Did you ever provide a specific date to the office leadership -- that would be Marion Gruber -- or to the review team by which you thought the review should be finished -- the BLA review should be finished?

Dr. Marks. So I did at a certain point, when Dr. Gruber provided me with a date that she thought it was possible by, I did my own analysis of the various steps in the process and provided an approximate date.

I guess I would turn the question around for myself, which is that, why are we talking about a specific date in the middle of a pandemic when at this point in time a thousand people -- right now around this point in time, July 19th, 2021, never mind the 41 of those things, I know by date about when -- in July we were losing about 750 to a thousand people per day. By August it was close to a thousand or more, and by September it was about 1250 to 1500 people.

So at this point in time, we had a lot of people whose lives were being lost to COVID. Anything that we could do to make people feel more confident in getting vaccinated because about 80 percent to 85 percent of the deaths were still occurring in

the unvaccinated at this point was something that we wanted to do.

So the goal here was to try to maximally move up the time of when we could get to an approval without worrying so much about a specific date, which was aspirational, and more getting the work done in a manner consistent with what a very motivated team can do when they need to do something.

Getting back to -- not to digress, but getting back to that love of Star Trek and the space program, people during some of the space disasters think Apollo 13 were able to do remarkable things as teams, and they would not have accomplished them individually.

What this was bringing forward was could we do things more expediently to get to an end point without sacrificing quality, safety, and effectiveness. Because you don't bring the astronauts home alive, you haven't succeeded. And here, if we didn't do that, we haven't succeeded.

Mr. Jordan. Who set the date?

Dr. Marks. Who set the date of September 15th?

Mr. Jordan. Was that you?

Dr. Marks. No. That would have been Marion Gruber.

Mr. Massie. And why was it so urgent to shave two weeks off of that?

Dr. Marks. It was simply a matter of -- it was -- at this point in time was the number of deaths increasing at this rate. The sooner we could get a Biologics License Application, the idea that more people would potentially get vaccinated and reduce the number of deaths, that was felt to be pretty important.

Mr. Massie. Dr. Gruber thought it was inappropriate for -- let me back up.

You have stated here today it's not the role of the FDA to do mandates. And Dr. Gruber stated that she didn't say that it wasn't her role to do mandates, but she stated that it shouldn't be a consideration when the scientists decide whether this vaccine is safe

and effective and appropriate for licensing that they shouldn't have to -- in the back of their mind or from their boss be told that we need to -- we need your approval because we want to mandate this or somebody else wants to mandate this.

Would you agree with her?

Dr. Marks. I would agree with her.

Mr. Massie. And you don't dispute that she was told either by you or -- or Janet Woodcock that this was a consideration?

Dr. Marks. All I can say is that she noted it here. It was a known fact at FDA that when you had a licensed vaccine, it could be mandated by outside organizations -- outside external to FDA. But our motivation here was the fact that thousands of people were dying, and there were -- there was evidence that by having an approved vaccine, more people would get vaccinated.

Mr. Massie. So what was Janet Woodcock's role in this?

Dr. Marks. She was acting commissioner at the time.

Mr. Massie. In the role in the BLA, how did you involve her in the decisions and why did you involve her?

Dr. Marks. So Dr. -- Dr. Woodcock made it clear to me that this was a very important priority for the agency, just as her predecessors had, and that this was, if not the most, one of the most important priorities. And so I kept her well-informed of the process of what was going on.

Mr. Massie. Did she discuss with you the White House's interest in speeding up approval of the vaccine?

Dr. Marks. She did not.

[1:12 p.m.]

Mr. Massie. So let me go over the timeline here.

First you asked the office, your office, for a date and you agreed it to. Then you said it needed to be faster.

Why did you change your mind?

Dr. Marks. Because I looked -- so I -- I asked Dr. Gruber for a date, and then the date seemed somewhat arbitrary. Having worked with development programs many years in industry and in FDA, I asked her if she could show me the data that supported that conclusion on -- that it would be September 15th. And so that's when, when looking at the data that she provided to me, that took a while to get, that it did not appear that we needed that much time.

Mr. Massie. But you kept pressing her for a date and then accepted the date and then you wanted a shorter date.

Isn't it true that you eventually came up with a flexible approach after she was no longer on the program, removed from the program, and Peter Marks -- or sorry -- Philip Krause, didn't you come up with a flexible approach?

Dr. Marks. We still had a target date, which I believe was August 20th, that we used that as essentially an aspirational date.

Mr. Massie. Did you -- why didn't you trust Dr. Gruber and Dr. Krause for the date that -- on the date that they gave you?

Dr. Marks. For the same reason that you wouldn't trust me about something critical. You'd ask me to show you the data that went into something that's a multistep process.

So I asked her to show me the data, and I went through the steps that she had outlined. I used people in my immediate office who were familiar with this process as

well to look at those with me. We realized that there were efficiencies to be had. Some involved getting more people involved in the review process because that is something that we have as -- that we do as supervisors and, in doing so, realized that we could speed up the process.

Mr. Massie. After Comirnaty was approved, did the product that was marketed and made available in the United States meet all the criteria for an approved product?

Dr. Marks. It did.

Mr. Massie. And what are those criteria?

Dr. Marks. That it met the standards for safety, effectiveness, and quality that we expect from the -- from our products.

Mr. Massie. So to ensure quality, is it the case that when you approve something for a license, you also approve the manufacturing facility?

Dr. Marks. That's correct.

Mr. Massie. Was all of -- were all of the doses that were current -- you know, in the stockpiles at the time, were they manufactured in licensed facilities?

Dr. Marks. So there were emergency use authorize doses labeled as emergency use authorize products that were made in facilities that were -- that were authorized for emergency use. And then there were -- there was BLA product, Biologics License Application product, which had to be produced in facilities that we had inspected.

Mr. Massie. So there's a difference between the -- I mean, there was some claim in the public that there was no difference between the EUA product and the BLA product. But according to you, at the FDA, a BLA product, the manufacturing facility has to be approved.

And why is that? Isn't that to guarantee quality?

Dr. Marks. It's to guarantee quality. But, again, for all intents and purposes, given

the way we had been looking over the -- I mean, in law they were -- they -- one was a BLA product, one was an EUA product. In practice, given the way we had been inspecting these facilities and overseeing these facilities, there were -- they were very, very similar in nature.

Mr. Massie. So you just took a shortcut by saying that the EUA is the same as the licensed vaccine, even though we haven't licensed the manufacturing facilities.

Dr. Marks. No, that's not true, because we -- for the BLA product that had the label Comirnaty on it, it said that this was licensed product, and we inspected those facilities. And product that went into Comirnaty had to be produced in the facilities that we had fully inspected --

Mr. Massie. Let me ask --

Dr. Marks. -- for the license application.

Mr. Massie. So there -- but there was a difference -- there is a difference between an EUA product that's manufactured in a unlicensed facility versus a BLA product that's licensed in a licensed facility because there's a heightened level of control over the facility.

Dr. Marks. It's --

Mr. Massie. If it weren't true, you wouldn't --

Dr. Marks. That's right.

Mr. Massie. There would be an extra step.

Dr. Marks. That's right. It's an extra step to inspect and make sure that the facility meets our -- meets all of our appropriate --

Mr. Massie. So -- but are you aware that people who -- the mandate was predicated on a BLA, but people who were forced to take the vaccine were forced to take an EUA product. Are you aware of that?

Dr. Marks. Yeah, and that's because the products were substantially the same. They were -- the inspections that had been conducted on these products were very similar, and it is kind of a strange -- I acknowledge it's a little bit of a strange construct at the time where we had a BLA product and an EUA product next to one another that were highly, highly similar in terms of what had gone into them. And at a certain point we only had -- you know, we had BLA product that was being produced at a small number of doses and mostly EUA product that met all the standards.

Mr. Massie. So were you aware that a large amount of EUA product had already been manufactured and purchased by U.S. Government, and if demands shifted to approved product, there would be no market or use for the EUA product?

Dr. Marks. I'm not -- I'm not aware of that, because I believe that the -- there was a period where EUA product was produced in a manner consistent with the BLA and was used as BLA product.

Mr. Massie. Were you aware that Pfizer was later found to be misrepresenting a vaccine manufactured in unapproved facilities as an approved vaccine?

Dr. Marks. I'm not aware of that.

Mr. Massie. So that's --

Mr. Cooke. We're at an hour here.

Mr. Massie. Okay.

[redacted] Twenty more seconds.

Mr. Massie. All right. Well, we can -- let me just finish that thought. This was an allegation that was vetted in a hearing with Senator Ron Johnson. That's why I brought it up.

Dr. Marks. I can't speak to doctor -- to Mr. Johnson's claims here. I just -- I can't. Okay.

Mr. Massie. Okay. Thank you.

[Recess.]

[redacted] We can go back on the record.

BY [redacted]:

Q Dr. Marks, I want to revisit some of the stuff that we talked about in the earlier hour first. We were talking about the video that you were in that was talking about the evidence of COVID reducing -- or the COVID vaccine potentially reducing transmission, and you said that that information was viewed as the best available scientific evidence at the time. Could you just explain what that means?

A So during the pandemic, we had to deal with the fact that this was a new virus that we had not experienced before. And so we were always reevaluating information as it came in, knowing full well that sometimes we would have to adjust, that, you know, science evolves. Our thinking would evolve as new information came in during the pandemic. And indeed we did have to change our stance on certain things because, in the weight of the evidence, that's how it had to work as new data came in.

Q And what data did you have or did you review that led you to believe that the best available scientific evidence was that the vaccines may also help reduce transmission?

A There were studies from -- done in populations of individuals using the Pfizer vaccine and using the other vaccines, not just the vaccines we have approved in the United States, that suggested that the vaccines might reduce transmission anywhere from 40 to 50 percent, at least with the initial variants of COVID that were circulating.

Q We took a look at that video during the break. And what you said was, because getting a booster is likely to help decrease the overall spread of COVID-19, it may also help your friends and neighbors as well.

Does that sound about right, from what you recall?

A That sounds about right.

Q In that statement, do you say that COVID-19 is -- definitively reduces the -- or the vaccine definitively reduces the spread of COVID-19?

A No, I did not.

Q In fact, you said it's likely to decrease the overall spread. Is that right?

A That's correct.

Q And you said it may help your friends and family as well.

A Correct.

Q How much time approximately do you think you spent on videos like this?

A A very small amount of time. They were generally done as very quick things in between doing other things.

Q And did you see these videos as part of your overall education role?

A I did. And I should specifically say that none of these videos are saying you should get a Pfizer or a Moderna or a Novavax or a specific manufacturer's vaccine. It's talking about the public health benefit of getting vaccinated, which I'd like to believe is really indisputable.

Q Was there a specific office that you worked with to help produce these videos?

A They were led out of the Office of External Affairs and Office of Media Affairs at FDA.

Q And so to the best of your knowledge, those offices are funded by the FDA's budget. Is that right?

A To the best of my knowledge, they are.

Q And that budget is appropriated to the FDA by Congress.

A That's correct.

Q FDA's overall mission is to protect public health, and that includes providing accurate science-based health information to the public. Is that right?

A That's correct.

Q Did you see these videos as part of FDA's mission?

A I did. Actually, I saw these as part of our larger mission, which was the direction as part of a larger agency, the Department of Health and Human Services. We are a component of that larger Health and Human Services agency. And we're often faulted for not adequately liaisoning with our other public health agencies, the Centers for Disease Control and Prevention and the National Institutes of Health.

So it was actually, I think, an important part of what we did to work closely with our colleagues at these other public health agencies which shared our mission to reduce the number of deaths, disability, and suffering from COVID-19.

Q In the earlier hour, you were asked when FDA's role changed to this more communications-focused role. Do you think that the role changed?

A It never did. Our role never changed.

Q Do you believe that this was part of FDA's mission during the Trump administration?

A It was.

Q Do you believe that this has been a part of FDA's mission for as long as you've worked there?

A It has been.

Q You mentioned that FDA was not advocating a specific brand or manufacturer of vaccine. Why do you think that distinction is important?

A Because as a public health agency, there are certain things that are

foundational that we do, that we can speak about, that at least the weight of scientific evidence globally suggests is the truth. So I think the weight of scientific evidence globally is that vaccination against COVID-19 helps reduce death, hospitalization in this setting. So this was a public health measure that we -- we put forward as part of what we did, in collaboration with our sister agencies.

And, no, it wasn't our primary job. And as I can tell you, if I would have spent 5 percent or less of my time on this -- that's probably actually generous, 5 percent; probably less -- it was to try to answer people's questions about the products that we authorized or approved so that they could make a decision on their own about whether to use them or not.

Q You were also asked some questions about medical advertising done by manufacturers. How does that differ from the public health messaging that FDA was doing?

A So I can't speak to any -- without seeing it, again, I can't speak to any given. But, generally, a manufacturer is speaking to their particular product and wanting to direct your attention to their specific product rather than as a public service announcement that, you know, vaccination could be helpful.

And I think those videos were framed as questions to me that I was simply responding to. And we can argue all day about the cutesiness of them, and I don't particularly like the cutesy of them. I blush every time my kids -- my adult kids shown me one. And they haven't shown them to me for a long time, so yeah.

Q Medical -- or manufacturers, when they make advertisements for their products, have a commercial interest in those products. Is that right?

A That's correct.

Q The FDA does not have a commercial interest in these products.

A No, we do not.

Q You were also asked about how the FDA regulates the ads that the manufacturers are making about their products.

Your -- CBER has the Advertising and Promotional Labeling Branch as part of the center, correct?

A Yes, that's correct.

Q And that --

A It goes by the abbreviation APLB because I can't remember all of the words. But, yes, it's APLB.

Q That's helpful. Thanks.

So APLB reviews complaints about promotional materials that are under CBER's purview. Is that right?

A That's correct.

Q And anyone within or outside FDA may submit a complaint to APLB?

A Yes, they may.

Q That includes people sitting in the room today.

A That's correct.

And I -- if I receive a complaint to myself, I generally don't do anything with it personally. I actually forward it directly to APLB and they acknowledge it and then handle it from that point forward.

Q Are you familiar with their processes of how they handle those complaints?

A Just generally, which is they generally try to obey -- they respond to the complainant, noting that they received -- they don't make a determination at that point. They then do investigation to see whether there's merit or not to the complaints.

Q And are you familiar with the process where, if they do find merit to the

complaint, they can send a letter to the manufacturer?

A I am very familiar with that piece of it.

Q They being the APLB --

A APLB.

Q -- organization.

A Right. So APLB can -- yes.

Q And what does that letter entail?

A So there are a variety of things that they can do. They can send, essentially -- it's essentially a series of steps of, essentially, warnings. One would be simply it has come to our attention, which is just a letter that says, hey, it's come to our attention that you have this on the web. Please take it down. It's doesn't comport with our regulations.

That's often the first step. If that doesn't, they can escalate to sending either an untitled letter which basically says, we're telling you to take this down, or the next step we'll do is go to Department of Justice and ask them to potentially make you take this down.

And a warning letter is similar to an untitled letter, except it comes after -- generally, after an inspection that we've conducted to document the findings.

[redacted] So with respect to this, with the Pfizer commercial that was played in the earlier hour, you said that, to the best of your knowledge, nobody in the public submitted a complaint?

Dr. Marks. It's -- what I said was I just can't be -- we had so much email about so many different things, it's possible that someone submitted a complaint and I just wouldn't have kept it in my mind.

[redacted] Understood. But my point is that, if somebody did submit a complaint,

APLB would have investigated it.

Dr. Marks. That's correct.

[redacted] Okay.

BY [redacted]:

Q We talked about Dr. Woodcock's role in setting the priority, or you mentioned that it was a priority for her, the vaccine approval process, just as it had been for her predecessors, I believe is what you said.

Could you explain what you meant by that?

A So I think that it didn't -- I mean, one of the things that I think we pride ourselves at FDA about, whether or not -- regardless of the political affiliation of whoever is in power, is that we care about public health. And I think either during the prior Trump administration and during the Biden administration, there was one abiding goal, which was to save as many lives, to reduce as much suffering with hospitalization, and to the extent that we could help society get back, you know, to normal through having vaccines, to help with that, but mainly helping reduce deaths and hospitalization.

And I think that was a very strong commitment. During the Trump administration, the commissioner, Stephen Hahn, supported us moving as quickly as we could. And it was continued on into the Biden administration with Dr. Woodcock as acting, where she offered to provide what resources we needed to -- to help move forward the review of these vaccines. And because Dr. Woodcock was as good a manager as she was, she asked me to justify some of my statements to her with facts that could back them up.

Q So you're saying that the prioritization of the COVID vaccination approval wasn't a new thing during the Biden administration. It had preceded that.

A Moving as rapidly as we could from an Emergency Use Authorization to a Biologics License Application was anticipated in the guidance that you showed me earlier

and which talked about how to proceed towards a Biologics License Application. So, no, there was -- it was understood that there was urgency throughout this period.

Q Turning specifically to the Comirnaty BLA review process. Am I pronouncing Comirnaty --

A That's correct.

Q That was the Pfizer-BioNTech COVID-19 vaccine?

A Correct.

Q Comirnaty was the brand name of that.

A Correct.

Q And you're familiar with the BLA review process for that vaccine?

A Very much so.

Q Do you recall how it began?

A The BLA review process started by submission. Actually, at the time, you have to wind it all the way back because that BLA started to be submitted with the Emergency Use Authorization materials, and then there was an official submission of the BLA, which in this particular case is somewhat artificial.

It's unlike most of the other BLAs we usually get, because normally we don't have -- it's like we watched all the previews, every last preview we could get ahold of, and we knew the entire plot. And then on a given date, we received the Biologics License Application, knowing the plot. And then we started the review process to go through the tables, listings, figures, and the line listings with a very good knowledge of what was there and looking at the differences in what was submitted. And that was what was put underway.

And the actual submission, there's actually a formal submission date that triggers the Prescription Drug User Fee Act, what our goal date would be. This was a priority

review. Standard priority reviews, after filing acceptance, have a 6-month review clock.

Q We talked about this a little bit in the earlier hour, but why did Pfizer submit a BLA if the vaccine was already being distributed under EUA?

A First of all, I think it was well understood that we had to convert. We made it clear in guidance that we wanted these to be converted over to Biologics License Applications as quickly as possible for multiple reasons, including the fact that most people are more familiar with licensed products and feel more comfortable getting a product that has the imprimatur of FDA approved on it than an Emergency Use Authorization.

Q And, generally, what steps does FDA take when reviewing a vaccine BLA?

A So there are many different components. But to just try to highlight them briefly, there's looking over all of the nonclinical information which has come in that supports all the toxicology, preclinical efficacy of the product. There's looking over the quality information on how it's manufactured. There's looking over all of the facilities that are involved with its manufacture. Those also have to be inspected, whether they're involved in actually making the drug substance, which is the vaccine itself, or the drug product, which is the finished vial of the product.

And, obviously, we have to look over all of the safety and effectiveness information, plus any information that might come from other sources about the vaccine that could be relevant.

So we -- although we are obligated to look at what is in the submission, we will also look at any available evidence, because in terms of safety information, it's all relevant. And so all of that goes into this -- this process.

Q Talking specifically about the facility information that we discussed a bit in the previous hour, you were asked about the differences between the EUA facilities and

the BLA facilities. And the EUA facilities were referred to as unlicensed facilities.

Would you agree that those facilities had not been reviewed, or had those facilities also been reviewed?

A So there's a lot of deliberative material that I can't speak about because we were speaking about with our Office of Chief Counsel.

But to summarize it in a way that I can tell you, there -- a lot of this is the kind of stuff that is like arguing over the head of a pin, because these facilities were fully inspected. And inspected, they just were not inspected, in some cases, as BLA facilities under the license.

So they were -- not trying to pull a fast one, but the -- you couldn't tell -- there was no difference in the quality of the vaccine, except it is true, and there's no getting around it, that once we inspect for a BLA, that is a BLA-licensed product and you should not be producing a BLA-licensed product in a facility that has not been approved. Nonetheless, in this public health emergency, they were indistinguishable.

Q What do you mean by fully inspected the facilities?

A So when we go out and inspect a facility, it means we send anywhere from two to five people out to the facility. They spend anywhere from 2 days to 10 days at the facility. They look at all of the different processes. They look at the controls. They look at the records. And they make sure that the product is being made as it's supposed to be according to the specifications.

They also look for objectionable conditions. They don't look kindly to mice running around the -- or ants or cockroaches running around the floor of manufacturing. Don't laugh. It's happened. And they also don't look kindly to finding nuts or bolts or other things in final vials. That's also happened. So those are the kinds of things that they look for.

Q And that kind of inspection and review was done during the Emergency Use Authorization process?

A We did a -- so it was done -- it was done as we progressed through the Emergency Use Authorization process.

I think, to be clear, we learned a lot during the Emergency Use Authorization process. I think I should say that, early on in the process, we did not inspect quite as much as we probably should have. Later on, as we moved through towards the authorization of the vaccines, we increased our stringency of inspection. Based on -- you know, you learn from your -- you learn from your errors.

Q When the vaccines were first authorized in late 2020, had the FDA done review of the manufacturing and chemical information?

A Yes, we did. And, in fact -- yes, and we had inspected -- we had looked over the inspectional records for all of facilities producing the vaccine, if not having visited some of them.

Q And so when the vaccines were authorized in late 2020, in the first -- in the first instance, were you confident that they were created in a way that was -- would ensure that they were high quality?

A Yes.

Q Turning back to the Comirnaty BLA. You mentioned that even more facility inspections were done during that process. Is that right?

A That's correct.

Q And that a lot of the data that you were looking at for the Comirnaty BLA was similar to the EUA data and you were focusing on additional differences.

A Correct, for safety because there was -- we went from having safety data for 2 months, on average, the median -- sorry, not really average -- median of 2 months to

having safety data for at least 6 months. And it was a larger safety database because what happened was many individuals who had not received the vaccine originally had received the vaccine. So instead of having safety information on 22-, 23,000 individuals, we had safety information then on about 40,000 individuals. So it was a larger safety dataset.

Q We talked a bit in the earlier hour about the action due date that had been set for September 15th. Do you recall?

A Yeah, I do.

Q Could you explain for the record what an action due date is?

A An action due date is actually -- so an action due date is a prescription drug user fee activated period which is, depending on whether it's a standard review or priority review, it's actually 12 months or 8 months after the initial filing. But you subtract off 2 months in terms of the review time because there's a 2-month acceptance timeline, generally, that was not used for this particular vaccine.

So after submission, it's 6 months. The action due date would have been 6 months after acceptance of the filing, and that's just calculated by our systems.

The new action due date of -- ADD of -- is -- has quotes around it, essentially, because that was not an official date. It was a date that was selected.

Q So it was an internal working deadline.

A That's correct.

Q But it wasn't --

A It was an aspirational date.

Q And you mentioned that Dr. Gruber had brought you the September 15th date?

A Correct.

Q And then you asked if that date could be moved any earlier?

A So I asked her to justify what she showed me because I had to justify to Dr. Woodcock. It became readily apparent that Dr. Gruber had not deployed resources adequately to review the BLA. That was clear because at one point she only had one reviewer that was reviewing this, and then at most she had two reviewers reviewing this.

And I will be happy to say that I was mortified to find out that that was the case. That did undercut my confidence in Dr. Gruber tremendously, and it led me to ask for a justification in terms of a timeline about the various parts of the process because I felt that I was not prosecuting my job. Delegated authority comes from the HHS Secretary to the commissioner to me for these vaccine approvals. And I delegate to Dr. Gruber my -- and I delegate fully well and have confidence until that confidence is undermined.

At that point in time, when finding out that only one to two clinical reviewers were reviewing a file on which the lives of thousands of Americans were -- who were dying were riding on and millions of were counting on, I decided that I needed to see the data.

I also took it upon myself to look at the process myself using my best judgment as a manager, knowing what could be done. And independently of her putting together her timeline, and while I was waiting for her to put together a timeline, put together my own timeline and found that our timelines did not match and that probably about 3 weeks could be shaved from her timeline were we to move at full speed with additional resources which were readily obtainable from individuals in my office or that were offered to me through Dr. Woodcock.

Q So the small number of clinical reviewers on the team was concerning to you because of the severity of the pandemic at the time?

A At the time, we were losing -- we were starting to lose hundreds of people a

day, and the idea here was that we -- we had had discussions as a team that by having an approved BLA, we weren't sure how many more people would really get vaccinated, but we still knew that 80 to 85 percent of people who were dying of COVID were unvaccinated.

And we even would do back-of-the-envelope calculations to say that, even if only 5 million more people got vaccinated, because we had an approved BLA versus an EUA, we would save potentially hundreds to thousands of lives. So, yes, getting the BLA done sooner did have meaning for us.

Q Ultimately, the decision was made that you would oversee the BLA review process. Is that right?

A That's correct.

Q When was that decision made?

A That decision was made shortly after Dr. Gruber announced that she would be on leave for a period for personal reasons.

Q Was that decision made by anybody outside of FDA?

A To the best of my knowledge, not.

Q Ultimately, was the ADD moved to an earlier date?

A Ultimately, I suggested an earlier date, but we didn't call it an action due date. We suggested a goal date to try to get the work done.

Q Did Dr. Gruber and Dr. Krause work on the BLA review?

A Dr. Gruber certainly did.

Q And so you had a supervisory role, but Dr. Gruber still had a role in the process.

A Yes, she did. It's my understanding, if I recall correctly, that she actually was the signatory on the Biologics License Application.

Q The Comirnaty BLA was ultimately approved on August 23rd, 2021. Is that correct?

A That's correct.

Q So that was approximately 3 weeks sooner than the September 15th date.

A That's correct.

Q And that was about how much you thought you could shave off from the process. Is that right?

A It was.

Q Did the FDA conduct a thorough review of the Comirnaty BLA?

A Absolutely.

Q Did the FDA follow all of the necessary procedures in the review process?

A We did.

Q Was the review based on reliable evidence?

A It was.

Q Could you explain?

A We conducted the review based on our normal process of looking over line listings, tables figures and listings, doing the statistical analysis that needed to be done. And to be perfectly honest, like many things, perhaps, done even in other venues, things come together sometimes very rapidly at the last moment. And so I think that it is true that there might have been a lot of dust kicking up in the last week of the BLA review as we were settling down various things like postmarket followup and these kinds of things. That happens in all, just very common -- I shouldn't say all. That's an overstatement. It happens frequently in our rush towards the action due date of normal BLAs.

And in this case, as we were working through, we were doing a lot of different things to come to completion. But we didn't skip any steps. And I'm very confident as -- I

think anyone can go and look. There's 1.2 million pages of the Pfizer BLA and our reviews out there, plus now additional hundreds of thousands of pages that were produced in response to FOIA litigation.

This looks every bit like the review we've done on every other product. And I'm very happy to say that, you know, I went through all of the memos myself. I know Dr. Gruber made sure, and I have to commend her that we went through. People were working -- you know, the shop was working probably overall between different shifts 21 hours a day, 7 days a week to get the job done, again, because we all believed that it was going to be potentially helpful to get this out there sooner so that we would save -- you know, try to save more lives, reduce hospitalization.

Q You spoke to this a little bit, but could you just expand on what factors allowed the FDA to finish its review by August 23rd, if you didn't skip any steps?

A So one of the good things about having been in business and having been sent to some executive seminars now and then is you actually learn how to try to motivate people. And that is perhaps an expertise that Dr. Gruber and Dr. Krause not -- they were not expected to have that. But as a person in an executive role, leading an organization, it was, I believe, something expected of me.

And so we fundamentally changed how we were running things a bit, from running things as individuals doing parts of the work to a team working together to cover the work as quickly as possible with individuals helping out, when needed, and individuals feeling free, because they were encouraged by the team leader, to reach out whenever they were feeling overwhelmed.

We also changed how we were meeting. Instead of having intermittent meetings or not having the team meeting all together, we started having daily meetings of the team leads and weekly meetings of the entire team, which sometimes had -- I don't

know -- we might have had 80 or 100 or 120 people on a call from around our center, as well as sometimes from around the agency, of people involved in this.

And by motivating people, we were able to -- you know, people, when they feel motivated and appreciated, are able to do things together in a way that individuals simply can't. And so that was what was done. We would have a meeting. We occasionally, you know, once a week when we met with the whole team, we'd go through everything. Everyone was informed of what was going on. That actually made people in the trenches actually feel empowered. They often didn't get that feedback and didn't know that type of thing. So it got them motivated to work more.

And we actually talked about leadership in similar situations. And, yes, I showed some corny video from the space program that may have helped motivate people in terms of leadership moments. So I think that helped motivate people. It got the job done. And, again, it was with the interest of trying to -- the issue here was trying to have a vaccine that people would feel more comfortable getting so that they would take it and potentially save lives.

Q Some -- there was some questions in the earlier hour about the lack of a VRBPAC meeting before the approval of the Comirnaty BLA. Did you feel like a VRBPAC meeting was necessary for that at that point?

A This was discussed with our leadership team, and nobody felt that a VRBPAC was needed, because it was a question asked and answered. The data -- all the data that came in basically confirmed data that we had on hand. There may have been a new safety signal in the interval, myocarditis in kids. We had had a VRBPAC specifically on myocarditis in kids where we discussed the risk benefit.

So it didn't seem like having yet another VRBPAC meeting just to have people raise their hands was in the best interest. We had other issues at the time that we needed to

take to VRBPAC like at the time dealing with a potential need for boosters.

Q Is the VRBPAC required to meet on every vaccine-related biologics licensure application?

A No, and does it not.

Q For the original EUA, Emergency Use Authorization of the vaccines in late 2020, the guidance specifically mentioned that the VRBPAC would meet. Is that right?

A That's correct.

Q Was there a similar requirement for the BLA?

A No.

Q Did you feel like you had enough information, including from outside experts, to make a decision on the Comirnaty licensure application without another meeting of the VRBPAC?

A Absolutely.

Q What's your response to the suggestion that the licensure of Comirnaty without a positive recommendation from the VRBPAC means that the vaccine isn't safe?

A I have no -- no idea why anyone would suggest that, because we maintained our standard process and we made sure that all of the quality, safety, and effectiveness information was there.

The VRBPAC is an advisory body comprised of special government employees who look at a small portion of information for a brief period of time and make a recommendation. They're there to help, essentially, validate or refute FDA's thinking, but we don't need to use them and we don't use them for vaccines when the outcome is, essentially, a foregone conclusion.

I think we felt comfortable enough with the data in hand that there was no need to go to them.

Q In the earlier hour, you were asked some questions about how to explain to people, after the licensure was approved, that there might still be an EUA product that they're getting a vaccine with when -- and not the BLA product. Do you recall that?

A Yes, I do.

Q That was actually a conversation that you had about how to word the fact sheets. Is that right?

A That's correct.

Q And do you remember what the conclusion was?

A The conclusion is we put some language in the fact sheet that was quite -- that -- again, that involved -- this was for the -- that was involved with the fact sheets and in the labeling that was quite complicated, was developed with counsel to help us explain the fact that, at the time, a lot of vaccine had produced in vials that said EUA.

For many vaccines, one could relabel over that and take care of the problem. Unfortunately for this particular vaccine, which is kept at essentially very, very cold temperatures, minus 85 degrees centigrade, you couldn't relabel.

So you -- the choice was to have a tremendous amount of potentially useful vaccine go down the drain or to be able to use it as license product, and the decision was made that it could be used as licensed product.

Q And was there a significant difference between the EUA product and the BLA product?

A There was -- there was no -- again, it was a difference -- one can't deny it. It was a difference in that -- it was a difference on paper but not a difference in any kind of substance of the vaccine. And, frankly, I rolled up my sleeve for EUA vaccine, and I would still -- the vaccine was the same, basically.

Q I know there's been a lot of focus on the Comirnaty BLA review today. But to

clarify, CBER was working on a variety of other reviews concurrently, right?

A That's correct.

Q Did the Comirnaty BLA review have different standards than any of the comparable reviews from that time?

A No.

Q There was some discussion in the earlier hour about vaccine mandates. To be clear, the FDA Center for Biologics Evaluation and Research is not responsible for deciding how vaccines are going to be deployed. Is that right?

A That's correct.

Q The FDA is not responsible for imposing vaccine mandates?

A Absolutely not.

Q In your role at FDA, are you involved in whether States or private organizations choose to mandate vaccines?

A No.

Q Did you ask the Office of Vaccine Research and Review to move -- or to speed up the review process of the vaccine because you wanted the U.S. military to mandate the COVID vaccination?

A I did not.

Q Did you have any conversations with the Department of Defense about the Comirnaty BLA review and approval?

A Did not.

[redacted] We can go off the record.

[Recess.]

Mr. Massie. All right. We'll go back on the record.

Do you know who Maddie de Garay is?

Dr. Marks. I've heard the name.

Mr. Massie. Can you tell us in what context you heard her name?

Dr. Marks. As a child who potentially may have been or where there was an injury claim about participating in I think the -- I believe it's the Pfizer, one of the vaccine trials.

Mr. Massie. So can you describe what her condition is or what resulted after the vaccine?

Dr. Marks. The claim is that, after the vaccine, she developed some type of a functional disorder where she is unable to function.

Mr. Massie. And did Pfizer notify you of her condition when they did the study? It's a study of 1,131 children who received the shot, 12- to 15-year-olds in Cincinnati, and she is wheelchair-bound and reliant on a feeding tube.

Pfizer classified her injuries as functional abdominal pain in their EUA submission to you. But isn't it true that you later found out that she had other conditions?

Mr. Marks. It's my --

Mr. Cooke. "You" is FDA here?

Mr. Massie. Correct. Yes. Well, specifically Dr. Marks.

Mr. Cooke. Okay.

Dr. Marks. So it's my understanding that we became aware of issues with this individual, with Maddie de Garay. Our Office of Biostatistics and Epidemiology undertook an investigation of what appeared to happen in her case and tried to conclude any relationship to the vaccine.

Mr. Massie. Was it Pfizer that undertook the investigation or your department?

Dr. Marks. So data may have been provided to us by Pfizer. We may have asked Pfizer for additional information. I would have to rely on our Office of Pharmacovigilance on that.

Mr. Massie. So I've got an exhibit. I don't know what number we're up to.

[redacted] Six, I think.

Mr. Massie. Six.

We may want to characterize this as 6 and 7. We'll characterize these as 6 and 7.

[Marks Exhibit Nos. 6 and 7.
were marked for identification.]

Mr. Massie. The first is a chain of emails that include you and Janet Woodcock and Doran Fink and Pfizer.

Dr. Marks. Uh-huh.

Mr. Massie. And then the second is a summary of Maddie de Garay's medical condition.

Dr. Marks. Uh-huh.

Mr. Massie. So I'll give these. Both of those are in there.

Okay. Exhibit 6 and then 7. I'll show you where 7 begins. It's turned in landscape format.

Okay. Does anybody else need a copy?

I'll let you study that for a while.

Dr. Marks. No, it's okay. I actually don't -- it's fine. Okay.

Mr. Massie. Okay. We don't need to go through her complete medical summary, but she was, within hours of receiving the second dose, severely impacted. Pfizer characterized it as abdominal pain. And -- but as you can see from her medical summary here, it was much greater than abdominal pain, and it resulted in her not having control of her lower extremities. She's in a wheelchair and on a feeding tube.

Now, I'll turn your attention to exhibit 6, which is the email chain. And I believe -- let's see here.

Is there one more copy?

On the second page of the -- of that exhibit, we'll start there, a gentleman named Patrick de Garay, I believe that's the father, sent an email to Steve Kirsch, and where he says Maddie's struggling to hold her head up and can't stand on her own.

Dr. Marks. For context, can I just add that --

Mr. Massie. Yeah.

Dr. Marks. -- Steve Kirsch is a well-known individual who is very much against vaccination and he's been a large scale proponent of ivermectin during this pandemic, just for context.

Mr. Massie. Okay. That's fine.

Is there anything wrong with ivermectin?

Dr. Marks. I'm not going to -- I can't comment on that, but I'm just telling you that's what --

Mr. Massie. But you just did.

Dr. Marks. I'm sorry. It's something that has been studied in COVID-19, and the question is not in my domain. It's in the Center for Drugs.

Mr. Massie. Does the FDA have a position on ivermectin?

Dr. Marks. I don't, and you'd have to ask the Center for Drugs.

Mr. Massie. Is there a reason you brought up that Steve Kirsch is a proponent of ivermectin?

Dr. Marks. Because he has a website which I'm familiar with, because we obviously looked into this complaint quite thoroughly, because Dr. Woodcock, to her great credit, whenever we got one of these, was very anxious that we investigate these to the fullest.

Mr. Massie. Okay. So Steve Kirsch sends an email to Dr. Woodcock, says that, "I

forwarded you the last email you sent to the team."

I'm sorry.

"And, of course, FDA evaluates every serious adverse event related to a clinical trial and intensively if in a healthy population. Jan Woodcock."

Dr. Marks. Uh-huh.

Mr. Massie. So it looks like -- and I apologize, these emails are in reverse order because that's the way an email chain works.

You forwarded to Janet Woodcock an email from Doran Fink, where he said, "Dear Peter, Pfizer has provided the attached updated narrative on this study participant, which provides a more detailed account of her illness and diagnosis of a functional neurological disorder based on extensive specialist evaluation and consistent exam, labs, and imaging. This illness is considered not due to an organic process, and while temporarily associated with vaccination, it is difficult to explain a physiological causal association."

Dr. Marks. Uh-huh.

Mr. Massie. The email -- the information that he is providing comes straight from Pfizer. Pfizer told Doran, "Please attach to find" -- "Please find the updated narrative for this participant. Please note it's been downloaded from our system."

Did you just forward this to Janet Woodcock or did -- what Pfizer told you or did you do a study of Maddie de Garay within the FDA?

Dr. Marks. So we discussed this case with our Office of Biostatistics and Epidemiology. And these kinds of cases, when there was a severe -- apparent severe event, were thoroughly discussed. And, ultimately, I think in this case, Dr. Fink, who is an excellent infectious disease clinician, noted what was noted here, which seemed to be supported by the information provided by Pfizer.

And, again, I can't speak to this, but it's my recollection that our Office of

Biostatistics and Pharmacovigilance actually did look at -- tried to get additional information from various individuals around -- or various providers around this individual at their request.

[2:50 p.m.]

Mr. Massie. So there may be more information about Maddie de Garay that you all have uncovered?

Dr. Marks. Yes, but any information that I'm aware of actually tended to confirm what was noted in Dr. Fink's note here, which is that despite the fact that it's a terrible thing that this child has this disorder and it's really very, very sad to see, that according to all of the evaluation that was done in terms of functional imaging -- you know, basically function. People did imaging, structural imagining, she seems to have a functional neurologic disorder. And that means that a cause of it, either something in the brain or elsewhere, was not found.

Mr. Massie. So let me -- and that's according to Pfizer. I see no evidence -- I don't have any evidence that you guys did anything more than pass Pfizer's assessment of the situation to Janet Woodcock. But let me ask you this; if you're doing a vaccine study and somebody has a very severe reaction, is Pfizer obligated to tell you that?

Dr. Marks. Absolutely.

Mr. Massie. And did they tell you about her very severe reaction in the study of 1,113 children?

Dr. Marks. Let me go back here to the dating here. Obviously, we became aware of this. And I can only -- I can only say that we obviously became aware of it in some reasonable amount of time following this. It looks like the first dose was on 30 December, 2020. The second dose on 20 January, 2021, for a serious adverse event. Pfizer was required to report to us within 15 days. The date of the report is the first of February, 2021.

It would appear that they maintained their reporting requirements of a serious adverse event, now, and they note that it's a serious adverse event on page 3 of 8, where

it says, SAE. So SAE stands for serious adverse event. So they did report this.

Mr. Massie. They reported it as abdominal pain.

Dr. Marks. But as a serious adverse event.

Mr. Massie. Right. But abdominal pain is not being confined to a wheelchair and being fed through a tube, which is how they characterized it. It wasn't until 6 months later that this -- somebody finally made Maddie's condition -- well, finally got the FDA to acknowledge Maddie's condition.

Why wouldn't you be livid that Pfizer held from you -- I mean, this wasn't a giant study. This was 1,113 children, ages 12 to 15. And one child basically almost turned into a vegetable here, who prior to this is on TikTok videos dancing and singing. And all they told you was it was abdominal pain.

Dr. Marks. So they didn't just tell us it was abdominal pain. They told us a narrative description here that is very detailed about the subject.

So she had a variety of symptoms here. She was followed. She had spells observed in the hospital, less consistent with seizure given distractibility, variability of episodes and last postictal phase. They did a variety of tests, including a video thorasitic swallow study.

Again, I want to just reiterate, no one -- I mean, we obviously feel terribly for this child. But I do have to tell you that from the standpoint of causality, there's not causality demonstrated here between administration of the vaccine and what has been seen here. We don't have that.

Mr. Massie. Isn't it true that they're required to report all of the adverse events in a trial like this, that the company that's doing the trial, whether they think there's -- I mean, if somebody has a heart attack -- or that's unrelated, they still have to report that, right? Because they're being reported in the placebo group. These are people that have

issues?

Here, let me tell you why I'm concerned about this. They classified her adverse events in the EUA submission, not according to that medical summary that you see, as abdominal pain.

Dr. Marks. They may have classified it as that, but our statisticians and even I knew from the records that we had, that there was more complexity to that. And that's why we go through every -- when we go through things, we go through all of the information in our possession, which would have included this medical summary. And our reviewers would have noted here the variety of things. And you can see where Dr. Fink clearly had reviewed this, and the narrative was scanned on details initially.

Mr. Massie. Initially. That email's from June. This is 6 months after she suffered the injury that Dorian Fink reviewed this. Because it was characterized in the EUA application as abdominal pain.

Dr. Marks. Uh-huh. And that's what we go through. We go through and go back, and try to make sure that we understand all the adverse events that have occurred and whether there's a possible relationship to the vaccine.

And sometimes, things can happen. When you vaccinate 200 million people, some people are actually going to have a stroke the next day. They were going to have that stroke the next day whether or not they got vaccinated, but they just happened to have the stroke the next day.

Some people are going to die the next day and they happened to get the vaccine the day before. We know that. And so we try to correct for that.

Again, I have to say, everyone feels terrible -- in our center, when we see stuff like this with Maddie de Garay and others, our hearts go out to the families. But on the other hand, we can't -- you can't from this single episode say that this was definitely related to

the vaccine. We have to look at the totality of the evidence, and we don't see -- so obviously seeing this, we -- our antenna goes up. We go through. Our statisticians go through our databases, is there other things like it, was there another Maddie de Garay like event.

And they used actually advanced language processing. So even if Pfizer would have just said abdominal pain, they would be able to go through and say, oh, was there -- and they would have called it functional disorder, perhaps, or stroke or other things. So they would have looked for other cases like this. And we didn't find them, nor have we found them in surveillance of millions of kids since then in this same way.

Mr. Massie. Let me be clear, what you're telling me is that you have reviewed -- the FDA reviewed all of this at the time when it happened because this is -- that's contrary to what I have been told. I've been told that Pfizer characterized this as abdominal pain, and it went into the study. The study was completed with this characterized as abdominal pain. And as you said, if somebody has a stroke, you have to say it's a stroke, you can't say it's abdominal pain, whether there's causal relationship to the vaccine or not.

Given what you know now, do you believe that the characterization of abdominal pain was accurate given that medical summary you see in front of you?

Dr. Marks. I can't speak to how a provider characterized this. But I can correct the fact that this may have been -- because of the way it -- it was reported according to the way it should have been as a serious adverse event, and it may have not been -- it's true. It may not have been fully reviewed until Dr. Fink and his team looked over all the serious adverse events in this way.

Although, I just have to look back here at your original email. So it may have been that at the time, we would not have necessarily flagged this until we were doing the BLA

review because of the way it was characterized.

But again, they -- it's not uncommon that a sponsor -- they rely on the investigators here to tell them what something is. They sometimes will have things that are -- the sponsor might take issue with the way the investigator characterized it. And I don't know, was abdominal pain what Pfizer characterized it at?

Mr. Massie. Yes. And that's what it said in the EUA. Knowing what you know now, because I know I'm showing you these medical records now, but we know that you saw these in June of 2021.

Dr. Marks. Uh-huh.

Mr. Massie. So you saw these almost 3 years ago. So I'm not asking you to look at something you've never seen before.

What I'm asking is; was there characterization of Maddie's condition? I'm not asking if it was causal. I'm asking was the characterization of her condition as abdominal pain accurate?

Dr. Marks. The best I could say is in terms of taking the entire case overall, it was less than fully accurate. It was a part of her symptoms, but it's not -- in terms of what we would determine at the end of the day, which is that this represented a functional neurologic disorder, it's not fully accurate.

Mr. Massie. Were you livid when you found out that they reported that a girl who was confined to a wheelchair and being fed through a tube had abdominal pain, and that they had characterized that for the purposes of getting an EUA from you.

Dr. Marks. Again --

Mr. Massie. What was your reaction?

Dr. Marks. So the reaction is that people have adverse events that may or may not be related to a vaccine. Whenever we see something like this, our antenna go up and

we look for other events that could be similar. But this was a very -- her history is -- I mean, as a physician it's very complicated looking through her history here, which seems to have a -- what ultimately was called a functional neurologic disorder. It's very hard to make associations to a vaccine when you have that. Unlike, we can make -- you know, if there is specific diagnoses that we were able to make associations closely with the vaccines.

Mr. Massie. Can we remove any inference or -- that it's causal? They are obligated to report things to you accurately, correct, whether they're causal or not.

Dr. Marks. That's correct.

Mr. Massie. And this is a girl who within hours of taking the second dose was confined to a wheelchair, couldn't walk, and eat for -- receives her nutrition through a feeding tube. And they mischaracterized, as you said, they weren't completely accurate here. And you found out about this 6 months later.

What was your reaction when you found out that there had been -- this wasn't a giant trial. This was 1,113 children -- 31. What was your reaction when you found out that Pfizer hadn't been completely accurate with the characterization of her condition? Not whether it was caused by the vaccine or not.

Mr. Cooke. I'm sorry. The question is what was your reaction when you found out something that maybe you have only found -- if it's even true you --

Dr. Marks. The best I can say is that my goal when I found out about this and when it was brought to my attention also by Dr. Woodcock and by others was to try to understand whether there was a relationship of this to the vaccine. I think that was the most important thing, and any kind of punitive action or something on Pfizer for misreporting -- we like to think that they were hopefully doing their best here. And this particular case is quite complicated.

So, I mean, I -- I honestly, you know -- I honestly don't know -- they -- someone may have tried to do their best here. I'm not saying if they did the right thing, but you know, I don't -- it does not smell to me of somebody, you know, really trying to hoodwink us. It's just probably not as well described as it could have been.

Again -- and I just have to reiterate to you, this is -- it's a terrible thing to have a child in this situation, okay? And there's nothing more that I wish for the de Garays that something -- they can find some solution to this.

But I can't -- based on the information we have, we can't definitively connect the vaccine with what happened to her.

Mr. Massie. Were the members of VRBPAC aware of Maddie's injuries, not as characterized by Pfizer as abdominal pain, but the full extent of her injuries that she had a feeding tube and could not walk? Was VRBPAC aware of her injuries when they were discussing and voting on authorizations and approvals for the COVID-19 vaccines?

Dr. Marks. Not to best of my knowledge.

Mr. Massie. Should they have been.

Dr. Marks. Not necessarily. You know, to be honest, there was no reason to hold this back. On the other hand, this is not a clear association with the vaccine. And now, just by way of context, we did find things that had clear and compelling association with vaccines.

For instance, thrombosis thrombocytopenia syndrome was clearly associated with the Janssen vaccine. We do have a clear association of other things like anaphylaxis and myocarditis with the MRA vaccines.

So it's not that we can't make associations or that we don't make associations, it's that we have to have a sufficient level of evidence to make that association. And that level of evidence here was not met.

Mr. Massie. Let me be clear, I am a member the general public, and I don't really understand these things as well as you do. I mean, this is your job.

But the one thing I do understand that I think you are avoiding is that you are required to report -- the Pfizer, they're required to report the full extent of her injuries and not to downplay them or dismiss them.

In this case, it appears that they did downplay or dismiss them, regardless of any association to the vaccine.

Dr. Marks. But as medical professional, even if they called this abdominal pain, the fact that our reviewers then when they -- because it was a serious adverse event. Every serious adverse event in a trial was going to get looked at by a reviewer.

And the reviewer would have read here about what happened. And there's actually a very -- I mean there is an extensive narrative here that includes all of the different studies that were done that she had severe abdominal and flank pain.

They did a variety of studies. She had more abdominal studies. She had numbness progressing to inability to walk. It's here, so they did not at least from what I can say -- yes, could they have re-characterized it as functional neurologic disorder or something? I guess they could have, but they --

Mr. Massie. If she's in the trial, and she ends up not able to walk, regardless of whether the vaccine caused it or not, isn't it the obligation of Pfizer to report that in their EUA application?

Dr. Marks. They reported that -- they reported -- they provided us with the serious adverse event report.

Mr. Massie. It was characterized as abdominal pain. Do you believe that was a mischaracterization?

Dr. Marks. We're getting into a medical issue here of whether I believe this child

had a functional neurologic disorder or not. I'm not a neurologist. I'm not a child neurologist. A functional neurologic disorder is a disorder that is usually made by someone with a specialty in an area that I'm not one of.

A, I'm not a pediatrician. B, I'm not a child psychologist. They obviously made this diagnosis after looking for a variety of organic causes. So again, I feel terribly for this child.

But we are getting -- I really do believe -- I feel very, very badly for this child, but we looked at many other children, both in this trial and since that time by our surveillance methods in essentially millions of children and we haven't seen -- we're not seeing multiple children like Maddie.

Mr. Massie. Was the ACIP aware of Maddie's injuries when they were discussing voting on recommendations for COVID-19 vaccines?

Dr. Marks. I can't speak to that. I don't know.

Mr. Massie. And did you say whether or not VRBPAC was aware?

Dr. Marks. I don't know. To the best of my knowledge, not, but I don't know for sure.

Mr. Massie. And you agree that when they characterized what you see right there for the purposes of EUA as abdominal pain, they were not revealing the full extent of what they were obligated to report?

Dr. Marks. They were obligated to report a serious adverse event, which they reported in a timely manner. The serious adverse event was reported within 15 days. They called it abdominal pain. We might disagree with that, but because it was labeled as a serious adverse event, our reviewers would go through this and make their own determination.

We don't leave it to the companies to tell us, you know, what the determination

of serious adverse event is. We make our own determination based on that.

Mr. Massie. Okay. You're telling me that your folks reviewed that?

Dr. Marks. But it wasn't -- I'm acknowledging it was wasn't in realtime. It probably was later as they were reviewing the biologics license application.

Mr. Massie. Was it possibly after the EUA was submitted?

Dr. Marks. It is possible it was.

Mr. Massie. So what happened is, an EUA was released -- what I'm having a hard time understanding is why you're not upset with Pfizer.

I'm not saying this is your fault. Why are you not upset that Pfizer misrepresented her condition when they applied for and received the EUA? And that it was only months later that somebody was able to get this to Janet Woodcock's attention and then it became to your attention --

It wasn't -- if you look at this chain of emails, it doesn't say, oh, yes we know about her, we studied that. This is like novel to everybody here. In fact, their first instinct is not access their own files, but to ask Pfizer what happened.

This is in June. This happened to her in January. So their first instinct was to say what -- Pfizer, what happened here. If they had the information that's in front of you now -- if you had that at the FDA, they wouldn't have had to ask Pfizer for it. That's what Pfizer produced after previously characterizing it as abdominal pain.

Dr. Marks. All I can say is that I -- it's not my job to be angry with Pfizer. Pfizer provided the information. Yes, I'm -- it would have been nicer had they labeled it something else at the top, but it's something that we investigated.

And I'm not sure that -- in fact, I'm relatively certain that it wouldn't have changed the outcome of the Emergency Use Authorization because there's not a clear association between her functional disorder and the vaccine.

Mr. Massie. What would be the -- your reaction -- how would you characterize your reaction when you found out that Pfizer hadn't accurately reported her condition to you on their application for EUA?

Mr. Cooke. I think you asked that one.

Mr. Massie. No. He's not answered it.

Dr. Marks. So I'm -- honestly, the way our reviewers are trained is the way that I'm trained, which is I don't really care what they characterized it at. They could say that it was headache, abdominal pain, nosebleed. What I'm going to do is take this out, this medical summary.

And it doesn't matter whether it said abdominal pain at the beginning. I'm going to read through the entire narrative and make a judgment as a medical reviewer, as I think Dr. Fink did, of what's going on.

So the most important thing they did was they characterized it as a serious adverse event. That already says that they at least did part of -- I'm not disagreeing with you again that you could have characterized it -- so let's get this clear.

They could have characterized it better, perhaps, than abdominal pain, and could have perhaps said functional neurologic disorder. But it wouldn't have changed what we would have done with it.

I think we still would have during the EUA process would have looked through -- and looked through the relatively lengthy narrative and tried to understand this.

I, to refresh my -- just as my recollection comes back, one of our biostatistics physicians actually looked into this case pretty extensively to try to see if we could get any additional information because there was a lot of concern about, you know, what was going on with this girl.

So I think nobody is downplaying on our end what happened here. I just can say

that it's not uncommon, and I think you could ask others from FDA, that we get something as a serious adverse event that's labeled in one way, that we ultimately re-characterize as something else. That's why we review these files.

Mr. Massie. Did you review this one before the EUA was issued?

Dr. Marks. You know what, I would have to -- let me go back to -- I want to speak appropriately here. And I should note -- I'm sorry. My apologies. In the original message here, it's noted in an email from Donna Boyce to Doran Fink on June 29, 2021 at 9:49 a.m., that the case was presented to the ACIP working group.

That's the group of the ACIP team that was intimately familiar with the COVID-19 vaccines and many other recommending bodies. "We are collating the SAEs for FDA follow-up and will send to you shortly. In the meantime, Dr. Alejandra Gurtman spoke with Dr. Frank who is the principal investigator at Cincinnati Children's today, and confirmed that this case is not related to the vaccine and that the participant has had extensive workup with consultations."

And I'd have to actually -- I honestly, right now, I can't remember the date that we took the EUA action on the Pfizer pediatric, but I believe this is after the time. But I'd have to confirm that.

Mr. Massie. Okay. I'm going to move onto another subject here. I've got Exhibit 8.

[Marks Exhibit No. 8.
was marked for identification.]

Mr. Massie. Let me just clarify something here. We watched a video of Pfizer with Martha Stewart sharpening a sword and cutting the top of a pineapple off, and talking about how people should get the booster. And at the time, the booster was not licensed.

At the end, the Pfizer logo shows up. So it wasn't a PSA from some third party. This was Pfizer, a Pfizer advertisement. You stated that -- I believe, I don't want to mischaracterize. I'll give you another chance -- if your group had known about this, you would have done something?

Dr. Marks. What I would have done would have been -- I would have referred this to our advertising group to deal with -- if this was brought to my attention as a concern, I would have referred it to our advertising group because they in consultation with chief counsel would be figuring out whether it was appropriate or not. That's not area of expertise.

Mr. Massie. Do you know who Lisa Stockbridge is?

Dr. Marks. I do.

Mr. Massie. What's her role?

Dr. Marks. She's the head of our division of advertising and promotional labeling.

Mr. Massie. Exhibit 8 is a letter to Lisa Stockbridge, among other things, alerting her. I'll give this to you.

Dr. Marks. Okay

Mr. Massie. Okay. So the letter is a notification to Lisa Stockbridge who is a branch chief below you?

Dr. Marks. She would be somebody -- she's a branch chief who would report to the head of the office of biologics, compliance, and quality.

Mr. Massie. Okay. And then that person reports to you?

Dr. Marks. That's correct.

Mr. Massie. Okay. So it looks as though she was notified on April 13 of 2023, that these -- this ad and some other ads violated certain federal statutes.

And the letter mentions the Martha Stewart ad, the Sesame Street promotion,

and then numerous other Pfizer and Moderna advertisements of an EUA product, legendary voice featuring John legend, protected on tour featuring Charley Pooth, world keeps changing, college basketball, updated boosters, COVID-19 booster shots, and more.

So those are Pfizer ads, and then Moderna ran ads, get boosted this fall, what are booster shots, make it yours.

Do you know if there was any response to this letter?

Dr. Marks. I'm sorry, I don't.

Mr. Massie. Should there have been, given your understanding of the department that worked for you and what they're enforcing?

Dr. Marks. There should have been a response at least acknowledging the concerns and trying to address the concerns that were noted.

Mr. Massie. Do you --

Dr. Marks. That's our standard practice.

Mr. Massie. Is it true that they are required to put an EUA disclaimer on any ad?

Dr. Marks. You know what, I'd have to consult with counsel on that, with our chief counsel's office. I'm not an expert in that area. I'm just not an expert on where the line goes from public service announcements to a specific advertising in this area. I just can't -- I just don't know myself. Sorry.

Mr. Massie. So these were manufacturers promoting their own products, though. Is that a public service announcement or an ad?

Dr. Marks. No. If they're promoting their own product, then it's an ad. If you're promoting your Pfizer vaccine or your Moderna vaccine, that is clearly, I think one has to acknowledge that's an ad.

There is this issue if you are promoting getting a booster per se. I don't -- I'm not in a position to be able to speak to because I'm not an attorney that is familiar with this

advertising law in the area to be able to tell you where the -- you know, where the cut point is. And that's why we have experts like Lisa Stockbridge who deal this issue.

Mr. Massie. Seems to me if they're not violating the law, they're skirting it based on the ads that we've seen.

Dr. Marks. Look, I don't -- all I can say is I will acknowledge that that was -- the idea of a big samurai sword and a vaccine is a very bad taste ad. I will admit that. So whoever did that deserves a -- something for bad taste, but I just don't know about the legality of it.

Mr. Massie. Okay.

BY [redacted]:

Q I'm going to shift gears a little bit. Back to some of the stuff that you were asked in the previous hour. You talked a little bit about leadership and motivating folks, you remember that?

A Uh-huh.

Q And it was about the space program. Did you ever talk about a company called Morton Thiokol? Do you know who I am referring to when I say Morton Thiokol?

A I know what you're talking about. I know the company.

Q Do you know they're the makers of the O rings?

A That's correct. The ones where Richard Feynman showed by dropping one into a glass of ice water, they fractured.

Q Famously, someone was asked on that faithful day when the challenger exploded, made a business decision not a scientific decision, right?

A Uh-huh.

Q And you've heard that?

A Yes.

Q You ever share that as a motivating story to your teams?

A I would share that we have to do our job well. I didn't share that particular story. But I did share and did note that we had to do a very good job with our reviews so that people had trust in what we were doing.

Q Right. And you mentioned too, that at that point in 2021, getting the BLA out was important. And again, I don't want to mischaracterize, it was to I think lend confidence to the booster program. Is that accurate?

A No. I think at that point, having a BLA vaccine was so that -- at that point in time, I think if you look at the way the country was, there were many, many individuals -- and I forget exact percentage, but it was not an insignificant number of Americans who had not yet received a single COVID-19 vaccine.

People were waiting to see if these vaccines were going to be approved because they wanted something that was a licensed vaccine, an approved vaccine. And that's what was driving us then.

And in fact, there was a fair amount of, you know, back and forth about what the most important thing was at that time, getting people their first vaccine, or perhaps getting people who had been vaccinated an additional vaccine.

Q Right. And so that distinction between the EUA and the BLA, when you were talking before in the previous hour, why, if you can elaborate more, why did it matter to get that BLA out as opposed to doubling down on the EUA saying, we're not seeing adverse events, and let the CDC do its job and say no adverse effects here folks, better to get the vaccine if you've never been vaccinated?

A Really good point. We were trying with that. I think public health agencies, CDC, others were trying to do help with that, but we were hearing from numerous stakeholders, both individuals as well as in some case I believe, you know, stakeholder

groups that they wanted a licensed vaccine so that people would feel more comfortable than something that was felt to be experimental vaccine by some.

Q And well on the entities that that had the authority to mandate, as a parent with kids in college, I know they mandated vaccines. And no university is going to mandate something that's experimental or emergency. So getting that BLA for a mandate is important, states to the extent they can do it or employers who are putting their -- forcing their employees to get the vaccine.

Do they -- they needed that FDA informator to give it that confidence. Is that accurate?

A But that's not why -- I have to acknowledge that -- so there's necessary and, you know, I guess for those states it was something that was necessary perhaps to have a BLA. But what drove us to get to the BLA was the idea that we had something that people would feel confident in having more people vaccinated.

Q And so if you're aware of the data -- because mandates happen -- as you know, mandates happen a day or two after the approval. And do you have any data that would suggest that more people voluntarily got the vaccine as a result of the BLA versus those who are mandated? Was that ever collected?

A No. I can't speak to that. I'm not aware of it. I know what happened in terms of the number vaccines administered over the course of time, which did go up over the course of time. But I can't speak to what occurred because of what were any mandates.

Q So before I go down the next path, part of -- you know, this has been said, this is a once in a century vaccine -- not vaccine, a pandemic. And we say that because the last was a century ago. The next one could be 5 years from now.

But part of Congress's job doing oversight is to try to understand those nuances

there, understand how the public reacts and the confidence that they have to have in their government institutions. Would you agree with that?

A I would agree.

Q Okay. So in reviewing what you just explained, that we came up with the -- America came up with an emergency vaccine, and we had to pivot on that BLA, knowing that there's a legal component and also a public confidence component.

What would be the questions that they should be asking to suss that out, whether or not, you know, were we rushing to the BLA because it was only 3 weeks off, you shaved 3 weeks off of that, versus other steps that could have been taken to feel confident in the vaccine?

Mr. Cooke. Just so the record's clear, you're asking what question should Congress be asking?

[redacted] No. I'll ask him.

BY [redacted]:

Q What questions as someone who -- you're still in leadership at FDA, and we're moving beyond. But things -- as you do a self assessment at FDA, what were the things that?

A So I would do the following; I would ask, what would happen to an oversight committee looking at me when I had to sit in front of them and tell them for a BLA occurring with tens of thousands of Americans dying in a month, that I only had two reviewers, one or two clinical reviewers on that, I would say that's mortifying. And I would say, Dr. Marks, what did you do to remedy that deficiency?

So I implemented a plan, which consisted of multiple steps where we put together a team, which instead of having this is mine and this is yours, which is how the vaccine approval was working at this time, to this is ours. And so we sped up that course. And

now you could say, well what did that 3 weeks buy us? I don't think the 3 weeks -- getting it done 3 weeks later, would we have gotten more confidence? I don't think so.

And I think we at least got to a place where we had a licensed vaccine that people could potentially take at a time when the COVID cases were really rising.

In August of 20 -- I would ask you to look at the daily COVID cases and hospitalizations in August. So this was a way to try to help people have something that they could feel confident in.

And you know, I can just tell you in the spirit of being under oath, that it was not going through our heads that this was something that was going to -- we were doing this so that it could be mandated. We were doing this so that people would have a vaccine that they could feel confident in.

Q Right. And so -- but now we're going back and looking through, going through all the emails and records, and knowing that we all know there were mixed messages going around, some of them out of government's control and some of them, you know, that were made -- come across as inconsistent from one administration to the next or even within the same administration.

And that's kind of what I -- I understand your point that if oversight's looking at you, and saying Dr. Marks what did you do, when you learned that you only had two people working on this, well you took action. And that's what you just testified to?

A And it wasn't just two -- it was two clinical reviewers. There were many more people working on it, but there were two clinical reviewers -- one to two clinical reviewers.

Q Okay. So there were many people working on it, but only two clinical reviewers.

A Right.

Q And you would assign more clinical reviewers to it. That's what you want us to know that that's the action you took. But what are the other pieces, though that clearly what you're saying is that by getting that BLA out there was important because it drove a message of confidence in the vaccine?

A Look, we as -- could we have done things better as a whole of government response? Of course we could have. We could have spoke with a more unified voice about the importance of vaccinations, giving people the choice about vaccinations, giving them the facts and explaining to them the importance of vaccines. We could have had better consistent public health messaging overall.

Unfortunately, I can control what I can control in my world, which was to provide people with a vaccine that was of high quality, safe and effective, that was ultimately given an approval in a way that I feel we can hold our heads high on was as good as any other approval that we've made. And I think we did that. And I think if it helped get some people vaccinated and helped prevent some deaths from COVID, I don't have the data to say how many people were saved.

Q Okay.

[redacted] Did you have --

Mr. Massie. We're looking for a video, if we can find it. I'm looking for a video from a press conference from Joe Biden talking about the boosters being available. I'll reference that later. I won't reference now until we can find it.

Did you play a role in writing or editing the August 18 press release indicating that boosters would be made available by the week September 20, 2021?

Dr. Marks. Not that I can recall.

Mr. Massie. When do you think such a specific date was chosen?

Dr. Marks. I actually have no idea because it's -- I just can't speak to it. I don't

why.

Mr. Massie. At the time of the press release, had any manufacturer yet submitted an application to the FDA for a booster dose?

Dr. Marks. You're getting -- this is a while ago. It's possible at that point they might not have.

Mr. Massie. Wondering if the manufacturers thought they had enough data to support a booster dose why wouldn't they have submitted their applications by the time of that announcement?

Dr. Marks. Again, I can't speak to that.

Mr. Massie. Did you then play a role in soliciting applications from any of the manufacturers to support a booster dose?

Dr. Marks. We did invite Pfizer, Moderna to submit information about a booster -- about that they had about booster doses.

Mr. Massie. Was that after the press release?

Dr. Marks. Honestly, I can't -- I can't -- at that point, we were having ongoing dialogue about information that was coming in through studies that were going on in Israel and studies that were going on with boosters from Pfizer and Moderna. So I can't say exactly when it would have been with this press release?

Mr. Massie. Do you believe it was wise to preannounce the plan to make booster doses available on a specific date before applications had been submitted?

Dr. Marks. I can't speak to that decision from anyone else. I'm sorry.

Mr. Massie. Where do you think that decision was made?

Dr. Marks. I honestly don't know. I can assure you this, it was certainly -- did not come from me.

[redacted] Would it have come from the FDA?

Dr. Marks. I can't speak to whether it came from another part of the FDA. I can just speak to the fact it would not have come from me.

Mr. Massie. Would you have preannounced a plan to make booster doses available on a specific date before applications had been submitted, reviews had been conducted, and advisory committee discussions had taken place?

Dr. Marks. No. As a matter of policy, I probably would not have done that. In fact, I can say not probably, I would not have done that.

Mr. Massie. And why would that be problematic?

Dr. Marks. Because until you actually see the data, you can't promise anything.

Mr. Massie. So do you believe that Janet Woodcock's involvement in the President's announcement that booster vaccines would be available implied FDA endorsement of that plan?

Dr. Marks. I can't speak to -- I'm not aware of the events you're speaking about and I just can't speak to it.

Mr. Massie. Have you found --

[redacted] I believe I found it.

Mr. Massie. Okay. Can we play this? And what exhibit would this be?

[redacted] Exhibit 9.

[Marks Exhibit No. 9.
was marked for identification.]

Dr. Marks. I should just preface this that during this time, our office -- so I might not have been as up on current events because we were very busy with BLA approvals and trying to look at other data.

Mr. Massie. This may not be it. Does it include President Biden?

[redacted] Yes.

Mr. Massie. Oh, okay.

[Video played.]

Mr. Massie. Does Biden appear on this?

[redacted] Yeah.

Mr. Massie. Can you jump to that?

That's all right. I don't need to show anymore.

Dr. Marks. Sir, I'll acknowledge to you that I am aware that President Biden I think repeated that date later in that video because that's what I heard about. I did not see this. This is the first that I'm seeing this that you have shown me to the best of my knowledge. Okay. I don't recall it, but I am aware that the President, President Biden may have said something about that same date.

Mr. Massie. Did they get the cart in front of the horse? How could they know they could start all this on September 20 if you hadn't even received the application from the manufacturers for EUA booster.

Dr. Marks. To the best of my -- to the best of what I can say from my perspective, we were in the process of evaluating the data, and I did not have -- aside from noting that we had these data pending, aside from having looked over the data, which I think I would acknowledge at the time looked somewhat promising from the data we had from the Israeli studies. We did not have it in hand at the time nor did we have a VRBPAC. So I just can't speak more to it. All I can say is from my perspective, this was not something that I put forward.

Mr. Massie. Do you think preannouncing that plan led to reduced confidence in government decisionmaking, like the fact that VRBPAC and ACIP weren't part of that, nor you?

Dr. Marks. I can't speak -- I honestly can't speak to that. But again, it's not -- this

was not my decision to make.

Mr. Massie. Were you surprised when you saw that they were announcing September 20 for the rollout?

Dr. Marks. To be honest, I was surprised.

Mr. Massie. Okay. Thank you.

Mr. Trainor. Off the record.

[Recess.]

[redacted] Back on the record.

BY [redacted]:

Q I want to start by talking about the case of Maddie de Garay that we discussed at the beginning of the last hour. First, you were asked about -- multiple times about Pfizer's characterization about this severe adverse event as abdominal pain. Do you recall that?

A Yes, I do.

Q Do you remember how Pfizer originally categorized this severe adverse event?

A No, I do not.

Q I want to turn to page -- the one that's bates stamped 136 in Exhibit 6. Sorry, the email chains.

A Uh-huh.

Q And just to summarize, it looks like -- just summarize what's happening so far Steve Kirsch sent something to Dr. Woodcock, Dr. Woodcock forwarded it over to you, you sent it to your team, and then Dr. Fink sends a request to Pfizer to ask for more information. Is that a fair summary of what's happened up until page 136?

A Yes.

Q So in Dr. Fink's email to Pfizer about the request for information, Dr. Fink says --oh, on June 24, 2021, at 8:23 a.m.

Do you see that email?

A Got it.

Q It's in the middle. Yup. He says, "We received the below information," and then, "we have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE, meaning severe adverse event, that could potentially fit the description is for the participant with unique subject ID, C4591001100710071620 described as follows.

Before I read the description, does that indicate to you that Pfizer had reported this event with the submission of the EUA?

A Well, it would say that this is -- this was submitted at the time of the EUA. It was part of the EUA filing.

Q And Dr. Massie asked why -- sorry. Mr. Massie asked why FDA didn't search their own data first. Does this indicate to you that your staff did search their own data first?

A I would seem like that did, and they were trying to find what was described in our database.

Q And so, what they found was one specific severe adverse event that Pfizer described. And Pfizer described "the SAE, severe adverse event, of neuralgia, was reported in one female participant, 12 years of age, who had three emergency room visits beginning one day after the second dose.

She reported concurrent nonserious AEs, adverse events, of as vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive workup, including serial, physical, and laboratory

examinations and was diagnosed with functional abdominal pain.

She was referred to psychologically and physical therapy after which her symptoms were reported as gradually improving?"

Did I read that right?

A You did.

Q So looking at that description, is it your understanding that Pfizer reported the case of Maddie de Garay as only abdominal pain?

A No. They reported -- they may have -- you have to put one word when you submit these to characterize them at the top, and they put abdominal pain. But as you read through, there's a lot of complexity and nuance to this.

Q The first sentence says the SAE if neuralgia. What is neuralgia?

A Neuralgia could be some type of neurologic pain or neurologic inflammation.

Q And that's neurologic means referring to nerves?

A Nerves.

Q And then there's many other symptoms Pfizer reported?

A Correct.

Q So based on your understanding, before issuing Emergency Use Authorization for the Pfizer vaccine in adolescents, did reviewers look at the specific SAE?

A They probably did look through this as noted here in this description.

Q Looking at -- you pointed this out on page 135 of the emails, the one that's bates stamped 135.

A Yup.

Q A Pfizer employee responds on June 29, 2021 at 9:49 a.m. Do you see that email?

A Yes.

Q She says, "You are correct, that this is a participant with the participant ID. This is a case from this specific study and it was reported in the EUA with the narrative it was also presented to the ACIP working group and many other recommending bodies? Did I read that right?

A You did.

Q And the ACIP working group was the CDC group that was coming up with pediatric recommendations?

A That's correct.

Q And this confirms that the case was originally reported in the EUA application?

A That's correct.

Q Looking at the medical record, on page 2 of 8 in the bottom -- the bottom middle, there's -- it's a big block of text, but there's a reference to April 9, 2021, that the diagnosis was updated to generalized functional neurologic disorder on April 9, 2021. Do you see that?

A Yup.

Q So is it possible that when Pfizer originally reported the data in the EUA, it wasn't yet an updated diagnosis?

A It's possible.

Q So do you have any reason to believe that Pfizer incorrectly reported the data to you?

A You know, these re-characterizations occur very -- this happens in normal BLA times. And especially when there was a lot going on, it's a re-characterization. But what I've tried to state and I'll state again is, it doesn't matter if you call it "Joe" at the top, we're going to read the entire narrative and come to a conclusion. So no matter

what -- when it's a serious adverse event, we read through the entire narrative and come to our own conclusion.

And that's why it's not uncommon for sponsors to sometimes publish data and they say that there are 6 percent serious adverse events and then when we issue our license, they'll be 10 or 15 percent because we would reclassify things. So again, horrible outcome. Don't wish this for a child, but I don't -- again, I'm not able to fault them. I don't see evidence of deception.

[3:50 p.m.]

BY [redacted]:

Q And you mentioned that you review all of the data that the sponsor provides, no matter how they classify it. This report includes data from multiple medical visits, it includes multiple medical tests, descriptions of symptoms, descriptions of medication. Is that fair?

A That's correct.

Q It includes at least 46 different patient test results. Do you see that?

A Yes.

Q So your team reviewed that information, not just Pfizer's characterization. Is that fair?

A That's correct.

Q And then looking at page 134 of the emails --

A And I should say that it's -- actually, one of the challenges here is that when this was pointed out to us later on, it's very likely that a primary reviewer went through this as part of the normal review process of the EUA. They would have looked through this.

And I know how horrible it is, and I know -- and I acknowledge to Mr. Kirsch and to her family that this is a terrible thing, but the diagnosis, after all, is functional neurologic disorder, which is very hard to say is related to the vaccine.

And so the reviewer may not have flagged this any further. And so when it came back up later on, perhaps that's why we went back -- and so I'm not -- what I'm just trying to say is, I don't feel like this is something that was missed during an initial review, despite the fact that I wasn't exactly sure last time we were speaking exactly when this was. But you've helped clarify my recollection.

Q And I want to return to the discussion of causality.

But before that, can we -- can you turn to page 134 of the emails?

A Yes.

Q There's an email that Dr. Fink sends to you and Dr. Gruber on June 30th, 2021, at 1:38 p.m. Do you see that one? It's in the middle.

A Yes. I see it now.

Q So Dr. Fink says that Pfizer has provided the attached narrative, but then explains that that narrative provides a more detailed account of her illness and diagnosis of a functional neurologic disorder based on extensive specialist evaluation and consistent exam, labs, and imaging. This illness is considered not due to an organic process, and while temporally associated with vaccination, it is difficult to explain a physiologically causal association.

Did I read that right?

A That's correct.

Q Could you explain what "not due to an organic process" means?

A So not due to anything that a physician could find either structurally -- anatomically, structurally in the body. So not a known condition caused by disease, infectious disease, or other disease generally.

When we say something is a functional disorder, it's because we don't understand it. And it could be from either -- a nonorganic cause, which is basically to say a psychiatric disorder.

Q Is it your understanding that Dr. Fink came to the conclusion that this was considered not due to an organic process based on his own review of this narrative?

A So I suspect -- again, I can only speak to myself now. I can't speak to Dr. Fink's judgment. But I can say that, going through the data in front, you -- if you look at

the laboratory data, the laboratory data looks very much normal.

The report on pages 1 through 3, essentially, have repeated studies that were done that did not show that anatomical imaging showed something. So I think -- I would at least be in agreement with his characterization. I can't speak to how he came to his conclusion. I can speak to how I could see I could come to the same conclusion.

Q Based on the information in front of you, does it look like Dr. Fink is repeating something that Pfizer has told him or that he is summarizing this data?

A Dr. Fink is one of the more independent and incredibly competent medical officers that we have ever had in our center, and I think you'll find that out from -- if you ask Dr. Gruber, Dr. Krause, or anyone else to know him.

And he certainly, I think, would not have taken anyone's word. He would have evaluated this himself.

Q So in the earlier hour, you were asked whether your team did more than just pass on Pfizer's analysis.

Would you agree that your team did more than that and did their own independent analysis?

A They did. And as I noted, I believe that in addition to everything else here, that our internal records would reflect that we also looked into this, had our statisticians look, and epidemiologists look into this on more than one occasion, based on incoming from individuals.

Q Turning to the causality piece that we were discussing, earlier you said that you needed to have a sufficient level of evidence to make an association between a vaccine and an adverse event.

Could you explain a little bit more what that means, a sufficient level of evidence to make an association?

A So in the middle of a pandemic, when you're vaccinating many, many, many, many people, if you look on any given day in the United States, if you vaccinate a sufficient number of 85-year-olds, the next day, someone is going to die. And that's just the fact that -- that's just the nature. If you -- if you -- you know, there's a certain death rate in a million 85-year-olds that that's going to happen.

And so, you can't just look at isolated events. They have to have some connection. And so, we generally have windows of occurrence within the vaccination.

For many vaccines, we look within the first 7 days, or the first 21-day window of when a vaccine is administered to see whether a vaccine event has occurred compared -- and sometimes we'll use self-control. We'll look and see whether, if we look the previous 21 days, has that event occurred before somebody received the vaccine?

And so, in this case, we would look to see, are there others who would have had similar events?

Now, when an event is this far out of the ordinary, they get flagged generally, and we would try to see if we had others like it occurring. That's what happened when we had a collection initially of four and then six events with the Janssen COVID-19 vaccine where these episodes of thrombosis -- these are blood clots occurring with a blood clotting element called the platelets being very low, which is a very weird thing to have happen. When those were happening, it was pattern recognition.

So that happened within days -- in fact, most of this happened within 7 days of vaccination to -- where it was very clear that it was a very unusual adverse event. There was nothing else, when we looked at the cases, to report that there was some other drug that could have caused it. There's another drug that could. There's a drug called heparin that could have caused something like it. That wasn't on board.

So that led us very quickly to realize that that was causality in just four to six cases.

And soon after that, we had data from across -- in Europe with another vaccine, AstraZeneca, which confirmed out that they were also seeing something similar with that vaccine.

So that's how we would normally make a -- an association in that way. And we did that, obviously, for anaphylaxis and myocarditis, and it's the same way we look for other safety signals.

Q And you mentioned your center has biostatistics experts who helped do this analysis?

A Right.

Q And in this case, you didn't find a causal relationship?

A There was no -- so no causal relationship was assessed here, and there were no other similar cases that we could -- we could bring forward as, like, a case series to say that there was something else that could -- could link these things.

[redacted] To put this in a layperson's terms, if you're thinking of functional neurologic syndrome, for example, if there was a pattern, you would expect other children to have been diagnosed with the same condition within, you know, a certain time period after receiving the vaccine. Is that fair?

Dr. Marks. Correct. And now that we've -- and I understand that we're talking about this EUA period. But nothing changed with the vaccine except perhaps strain updates over the course of time. And now we've vaccinated millions of kids.

We're doing safety surveillance in conjunction with the CDC, and in none of the CDC experience, nor in ours, are we seeing other individuals who are having a similar diagnosis. That's not to say that there couldn't be a single -- it may be that there's another one, but not that has been reported in proximity to the vaccine.

So I -- we're left with this as -- it's like what happens to us in medicine sometimes.

It's tantalizing hints. If I were to see another person with Maddie de Garay's syndrome, we'd have to look harder to see whether there's something that we're not understanding here.

But much as we want to make parents feel like we're believing them, much as I care about this child, we can't lie and say that this is vaccine-related to make it a vaccine-related injury, when there's not evidence that there's vaccine -- and unfortunately, there is -- the way we as humans work, we like to make causality sometimes when there's no causality.

And I don't know that there's causality here, and we have to -- we have to have a certain level of evidence that there is causality. And so, sometimes these things sit on our desk, and they're there so that we know that if we saw something else like it, we'd flag it again.

That does happen in the world of vaccines where occasionally for rare rheumatologic disorders, we see something very strange, we don't see it again for a year or two, we see it again. And then, Oh, we'll go look further for it.

It's just at this point, you know, aside from feeling deeply -- you know, deep empathy for the parents, you know, I can't blame the vaccine.

BY [redacted]:

Q I want to move on to a discussion of the booster vaccines from fall of 2021. Before we talk too much about that, could you just explain what a booster shot is.

A So a booster shot is -- we usually use the term booster as -- to describe an additional dose of a vaccine that's used to restore immunity that may have waned over time because our immune systems, when not constantly challenged with a pathogen, tends to have waning of the immune response.

Some vaccines, to be honest, produce very, very, very good immune responses

such that you don't have to give boosters. You get the vaccine once, and you're protected pretty much for life, such as the live measles vaccine. Others do dwindle with time, either because of our ability to make good antibodies to them or because the viruses themselves change over time, like influenza.

Q Why might a booster shot be beneficial?

A So if one is losing immunity to a particular pathogen -- and in this particular case it was mainly -- we knew that antibodies were very important, particularly for older individuals, those over 50 years old, to help prevent a death or hospitalization from COVID-19, we went ahead -- you would potentially give a booster to try to restore waning immunity. Because at a certain point, antibody levels get low enough that they no longer protect against hospitalization or death.

And over the course of the summer -- and it became apparent starting in June and then over the summer months that it's just something that happened because we were -- you know, you just noticed that the -- we were following in real time the antibody levels to the vaccines. They were clearly going down over time. That was a concern.

Cases were potentially coming up, and at least one jurisdiction, Israel, decided to give an additional dose of the vaccine, a booster. And by midsummer, was reporting that their number of cases had come down dramatically, particularly in people over 50 years old, and especially in people over 60 years old who had received an additional dose.

Q And just briefly, could you explain what antibodies do, what role they play?

A So antibodies -- there are two components of the immune system that help us fight off viruses. One are the cellular portion of the immune system, which helps us generate antibodies, too, but also is able to help us have memory against viruses, and sometimes to fight off viruses themselves.

Antibodies are made by another type of immune cell, and they bind to viruses and

cause other cells of the immune system to either attack them, or they themselves can help clear the viruses in parts of the body.

Q Why might different groups of people have different risk benefit analysis related to booster shots?

A Because there were some people -- older people tend to lose their immune responses more rapidly. That's just because as we get older, we don't make as much of a robust immune response to begin with.

Additionally, it's pretty clear that the group at most risk of dying from COVID-19 for whom you could show that a booster would make a difference, an additional dose, were people, certainly, over 60 or 65 years old and those who had certain other comorbidities, diabetes or obesity and diabetes, or other disorders.

Q In the previous hour there was some discussion of COVID booster shots related to the Comirnaty -- yeah, the Comirnaty BLA review process.

The Comirnaty BLA that FDA approved in August 2021 was only for a two-dose series, not for any booster doses, right?

A That's correct.

Q So the Comirnaty BLA approval process was unrelated to the discussion of the vaccine beyond the two doses?

A That's correct.

Q And, in fact, the booster doses that were eventually given later in the fall of 2021 were authorized under -- for emergency use, not a BLA, right?

A That's correct.

Q So it's fair to say that the Comirnaty BLA review process was separate and unique from the discussion of booster shots?

A It was.

Q Can you explain the review process for booster shots?

A So for booster shots, because it was done under Emergency Use Authorization, we received -- received data from Pfizer -- so this is one where, in the interest of public health, we were speaking to our colleagues in Israel. They provided us with data via Pfizer, which was subsequently submitted by Pfizer.

And we had additional data from both manufacturers on the ability of the vaccines to restore or produce an additional immune response. Those data were taken. We, ultimately, had a VRBPAC meeting, at which we had presentations, including someone from the Ministry of Health that in Israel presented their data.

There was quite a lively discussion, and ultimately, a decision was made that we should recommend the Pfizer booster at that particular advisory committee for specific populations.

Q And what were those specific populations?

A They were -- they were individuals 65 years and older, and those over 50 years with specific medical concerns.

Q Was there also discussion at that VRBPAC meeting about people with high risk of occupational exposure to COVID-19?

A There was.

Q And what was the discussion?

A There was a -- I have to say, I'd have to go back to the -- to the minutes to refresh my recollection on all of the discussion at that time because there was a lot of back-and-forth and concern about whether people with occupational exposure should also be able to get a booster at the time.

Ultimately, I think when we -- when we moved further on and had additional data, we tried to simplify this so it wasn't as -- as complicated as it was during the initial rollout

of the boosters.

Q And we've discussed earlier today that the standard for an EUA is different than the standard for a BLA, right?

A That's correct.

Q So the VRBPAC voted that the -- for the specific population, elderly people, people with preexisting conditions, that the potential benefits outweighed -- the known and potential benefits outweighed the known and potential risks. Is that right?

A That's correct.

Q And the FDA amended the Emergency Use Authorization for the Pfizer vaccine in September of 2021 to allow for those boosters for specific populations?

A That's correct.

Q And similarly, the next month in October, the VRBPAC met about the Moderna vaccine boosters?

A That's correct.

Q And they came to a similar conclusion?

A They did. And we cleaned up the language for both of the vaccine and both of the boosters to make it somewhat simplified.

Q Do you remember exactly what the high-risk populations were?

A You know, I'd have to -- I'd have to look back at the authorization. But it was -- it was -- still, it was clearly still above 65 and 50 and up because of comorbidities. And I can't speak to the language we used. I think we used some language to try to make sure the high-risk populations could also receive a booster as well.

Q And FDA amended Moderna's vaccine EUA to allow for boosters in high-risk populations in October of 2021. Is that right?

A That's correct.

Q Are you confident that the potential benefits of both the Pfizer and Moderna boosters for high-risk populations outweigh the potential risks when those EUAs were authorized?

A Absolutely.

Q Did the FDA conduct a thorough review before issuing those EUAs?

A We did.

Q Did the FDA skip any necessary steps in those review processes?

A No, we did not.

Q Was the review based on reliable evidence and using reliable methods?

A It was. And I need to add that it was borne out by the fact that publications from, of all places, the World Health Organization in Europe, basically credits the rolling out of those boosters with saving about half the lives from COVID, at least in Europe.

And it's clear that after those boosters were rolled out in the United States, we had the crest and subsequent decline in the number of cases. So, you know, I think that that would tend to validate that a reasonable judgment had been used.

Q In the fall of 2021, do you think that there was clear scientific consensus about the efficacy of booster shots?

A No.

Q Why?

A Because there was -- can you repeat the date again?

Q In the fall -- like, early fall of 2021.

A There was -- there was -- there were different individuals who had different ideas about whether boosters would help the situation. There were also individuals who felt strongly, perhaps, that until everyone had received their initial vaccination series, that we should not give out second -- you know, a second round of booster shots. And there

was that feeling, potentially, globally, that the United States, we shouldn't do this until more of the global population had been vaccinated.

Q So there were both efficacy concerns and resource management concerns, would you say?

A I would say that's probably a fair statement.

Q There's also -- there were a lot of challenges and confounding variables that could arise when studying COVID in the middle of the pandemic. Is that fair?

A That's a very fair statement.

Q Why can it be difficult to have clear, unified data about the pandemic in the middle of it?

A Because things were constantly changing, and many of the conditions were changing. Vaccine uptake was changing. The virus was evolving in front of our eyes, and it wasn't really until the summer of 2021 when we really understood that the virus could evolve as rapidly as it could.

I mean, we knew it seemed to be able to evolve, but it became really clear that it was -- we were dealing with something that was a greater foe than we had originally conceived. Exactly when that occurred, I'd have to look back at notes to tell you when it was clear to us, but sometime over the course of spring to summer 2021, it became very clear.

Q Even if everybody is looking at the same data, could different public health officials look at that data but come to different conclusions when they do their risk benefit analysis?

A It's possible.

Q Why isn't there always, like, a clear, correct answer?

A Because there's benefit, risk, and uncertainty, and sometimes when different

people look at something, they will feel like a higher degree of certainty is necessary. Some will accept a lower degree of certainty.

In some cases people may find fault with certain aspects of the data, how it was collected, the populations, et cetera. So there may be many different reasons that people can come to different interpretations. And we respect those differences. I do at FDA, and I think my colleagues do as well. It's important to respect scientific differences.

Q Turning back to in the previous hour, the August 18, 2021, statement by the President and other public health officials, the statement said that subject to FDA approval, booster shots for all Americans would begin the week of September 20th. Is that right?

A Yes.

Q That didn't happen, right?

A No, it did not.

Q Booster shots for all Americans did not begin the week of September 20th?

A No, it did not.

Q Instead, the FDA issued a more limited authorization?

A That's correct. I might direct your attention to the fact that I might have been busy during the period of August 18th, 19th, 20th with a certain other activity that also kept me busy that weekend, including making the text tables from our submission 508 -- Section 508 compliance, that is, ADA compliance. So those were things that we all chipped in to do that weekend. So there was a lot keeping us busy during that time.

Q And you're referring to the Comirnaty BLA?

A To the Comirnaty BLA. So I wasn't particularly paying as much attention to what was said by other individuals.

Q The FDA amended the EUA -- the Pfizer and Moderna EUAs to expand

booster eligibility to all adults on November 19, 2021. Does that sound right?

A That sounds about correct.

Q Did you work on the review of the EUAs for expanded booster eligibility?

A Yes, I did.

Q Are you confident that the potential benefits -- the known and potential benefits of the booster shots for all eligible adults outweighed the known and potential risks on November 19, 2021, when that EUA was issued?

A I am.

Q Was the review for the EUA for expanded booster shots thorough?

A It was.

Q Did the FDA skip any necessary steps in that review process?

A We did not.

Q Was the review based on reliable evidence and using reliable methods?

A It was.

Q And the EUA was ultimately issued because the results of the review indicated that the potential benefits outweighed the potential risks?

A That's correct.

[redacted] We can go off the record.

[Discussion off the record.]

[redacted] Let's go back on the record.

Mr. Massie. Let's see. Did you ever tell Janet Woodcock that you thought that Marion Gruber could no longer be impartial or unbiased in the context of the boosters' project program approval?

Mr. Cooke. So --

Dr. Marks. I can't -- I can't speak -- you know what, I can't speak to memory of

that.

I can speak to the fact that, you know, she was co-author of a publication with -- with Dr. Krause that was contrary to FDA policy. That -- that I can speak to, that I did, obviously, bring that to Dr. Woodcock's attention.

Mr. Massie. What was the FDA policy that she -- do you believe she was violating?

Dr. Marks. So usually when I -- even if I would write something about a vaccine that had to do with FDA policy, it goes through a clearance process which includes, at least in our center, coming up to my immediate office, it gets reviewed by our policy group, and, if necessary, our policy group will flag it for review by our attorneys, because it could be potentially taken as being specific agency policy.

In this case, it was a publication where, even though a disclaimer was present, that the viewpoints were the individual author's. The lead author was from the World Health Organization, and it argued against boosters, the deployment of boosters.

Mr. Massie. So are you also -- as an employee of the FDA, are you also subject to those same requirements?

Dr. Marks. In general, yes.

Mr. Massie. Did you go through that to get those videos made, the "41 Minutes with Marks"?

Dr. Marks. So those were -- those were made by the -- through the commissioner's office. So those -- the text of that was cleared through the Office of General Counsel and through the, I guess, Deputy Commissioner for -- for Policy and Legislation. So that's how that would have worked. That was above my level.

Mr. Massie. So it was a different process, but it was cleared?

Dr. Marks. That's correct.

Mr. Massie. And who determines -- do those people work for you, or are they

above you, that determine that policy?

Dr. Marks. They are in the commissioner's office, so they would be above me.

Mr. Massie. So then it was the policy of the FDA to, for instance, say that this would stop -- sorry -- this would reduce spread of the virus, that the vaccine would? For instance, the claims that you made in those Minutes with Marks?

Dr. Marks. I don't think you can characterize it as that. I think it was a response to a question, and it was "could" or "might," and that was the best scientific judgment at the time.

Mr. Massie. So I want to focus on neurological issues. You had some meetings with individuals who believed that they were vaccine-injured, and do you recall a meeting or any meetings with Brianne Dressen?

Dr. Marks. Certainly. At least two, if not three.

Mr. Massie. Okay. What were the topics of those meetings?

Dr. Marks. The topics were a number of individuals. She claimed to have been injured by an investigational vaccine, and others claimed to be injured by other vaccines in terms of neurologic symptoms.

Mr. Massie. Do you recall in those meetings saying that in order for the FDA to make a public statement about vaccine injury, you'd have to find a signal in one of your databases?

Dr. Marks. It's very possible that I would have said that, or one of my colleagues could have said that, or both.

Mr. Massie. Do you recall meeting with Brianne Dressen and a vaccine-injured physician on March 3rd, 2022, where you indicated you were hoping to get a study -- a neurologic advance started because to that point, quote, "We don't have a signal," unquote?

Dr. Marks. I do.

Mr. Massie. Do you recall during that same meeting saying that you were looking into neuropathy and small fiber neuropathy specifically, and were hoping to get a background rate for them, but that active surveillance for small fiber neuropathy had been done, and we'd be happy to share the incident data after doing the analysis?

Dr. Marks. I can only say that that sounds about correct. I can't say for sure, but it sounds about correct.

Mr. Massie. Do you recall meeting with Brianne Dressen and that same vaccine-injured physician on May 25th, 2022, and stating, "No one was denying there are reports of neuropathy following COVID-19 vaccines, but they just weren't seeing a safety signal"?

Dr. Marks. I do recall that.

Mr. Massie. During your prior meeting on March 3rd, 2022, you and Dr. Nair committed to doing a manual review of VAERS to look for small fiber neuropathy, but during the May 25th, 2022, meeting, you still hadn't done that. Is that correct?

Dr. Marks. To the best -- again, I can only speak to that if you have something that's documenting that, that may be the case, but we -- we had been looking at the issue, and it may have taken us a while to get to it.

Mr. Massie. You indicated that Lori McNeill would get back to Dr. Schaefer and Ms. Dressen about whether you had done a manual review of VAERS reports involving small fiber neuropathy.

Did that -- did that ever happen? Did they get back to you?

Dr. Marks. I can't speak to whether Ms. O'Neill got back to them, but I know that the review was conducted.

Mr. Massie. On overall vaccine safety, did FDA conduct any empirical Bayesian

data mining related to COVID-19 vaccines?

Dr. Marks. We did.

Mr. Massie. What did it show?

Dr. Marks. That's a very large question. We looked for the most important part of our safety surveillance that actually showed signals came from looking at specific safety events. And, again, to the best of my recollection, I'm not aware of what the Bayesian -- I just cannot recall what the Bayesian analysis showed.

Mr. Massie. Do you remember how the results compared to CDC's proportional reporting ratio analysis?

Dr. Marks. Again, I can't speak to that. I'm just -- again, we generally looked at about 15 to 20 adverse events in our best -- a system of Sentinel, which is a very large database system, to ascertain whether something was occurring more commonly in vaccinated individuals than in nonvaccinated individuals, or in vaccinated individuals after they were vaccinated compared to before vaccination. Those are different types of studies.

And aside from signals of myocarditis and anaphylaxis, I'm not aware of any other signals.

Mr. Massie. Are you aware -- are you aware that the FDA has refused to make public anything related to its empirical Bayesian data mining?

Dr. Marks. I'm not aware of that.

Mr. Massie. Are you or the attorneys aware that FDA's been sued by multiple parties in an attempt to obtain that data and make it public?

Dr. Marks. I'm aware that we may have been sued, but I don't know the details of all of the lawsuits pending.

Mr. Massie. Why wouldn't FDA turn that data over to the American public?

Dr. Marks. It's possible that there is protected health information. I can't speak to it because I don't know what are in the datasets.

Mr. Massie. Okay. Switching gears, when you issue an EUA, is the threshold that the known and potential benefits may outweigh the known and potential risks?

Dr. Marks. It's that the known and potential benefits outweigh the known and potential risks.

Mr. Massie. Okay. And that varies according to age group, probably, the benefits and the risks?

Dr. Marks. It might, yes, correct.

Mr. Massie. And that's why you do it based on these categories?

Dr. Marks. That's correct.

Mr. Massie. What about -- does that ratio change if you have been formerly exposed to COVID and recovered?

Dr. Marks. It could. Although, to the best of our knowledge, at least at the time, people who had COVID could potentially benefit from a COVID vaccine after having had COVID.

Mr. Massie. Is that something you authorized Pfizer to say in their EUA for the first two doses?

Dr. Marks. The way the study was conducted was irrespective -- the way the people were dosed in this were irrespective of whether they had had COVID previously. So the label would have read -- would have been independent of whether someone had had COVID before, whether they could get vaccinated.

Mr. Massie. Do you know -- they could get vaccinated, but do you know if the -- sorry -- the Pfizer study for the EUA, if it showed any benefit for those who had prior infection?

Dr. Marks. I think what you're asking me -- let me just be clear -- is that, was there a benefit to getting vaccinated after one had had prior infection with COVID-19?

Mr. Massie. Did the -- did the Pfizer study test for that or demonstrate that?

Dr. Marks. Without looking back at the data, I can't speak to that. We certainly -- it certainly enumerated the number of individuals who were retrospectively diagnosed with COVID. But I'm not aware -- and again, I just can't speak to it -- whether there was an immunogenicity analysis conducted that could have helped speak to that.

Mr. Massie. So there were tens of thousands of people in the study, and it turns out they had about 1,300 that they found out during the study had evidence of prior infection. And as you might hope or expect, half of them in the placebo group, half of them in the treatment group. And each of those groups of 650, which became, like 600, because you have some people that fall out of it, you had one case in each of those groups.

And then the CDC went on to characterize in December of 2020 as you, the FDA, I'm sorry. When I say "you," sometimes I mean the FDA. The FDA put out a slide deck with sort of a top line review for public consumption of the Pfizer study, which is actually where I found out that there were 650, roughly, in each category.

But the top line review didn't show any benefit -- didn't show that there was enough data to provide that, but the CDC in an MMWR characterized that it was 92 percent efficacious, the vaccine was. Their characterization was in a mid-December MMWR, they said it was 92 percent efficacious for those who had had prior infection.

Dr. Marks. I can't speak to the CDC's characterization. That wasn't ours. So I just can't speak to it.

Mr. Massie. But you didn't see in the Pfizer study any evidence of --

Dr. Marks. I can't speak to that without actually going back to the data. It's been

a while.

Mr. Massie. Okay.

Dr. Marks. I'm sorry.

Mr. Massie. Go ahead, Gus, unless you have nothing.

[redacted] No. I do. I'm trying to -- I'll introduce -- I think this is exhibit 10.

[Marks Exhibit No. 10.
was marked for identification.]

BY [redacted]:

Q What I handed you was a series of emails that are all roughly about the same subject matter, by FDA, involving the, I guess, transition of the BLA review from Dr. Gruber to you.

Take a moment to kind of refresh your recollection around the -- but -- and before we go down too far in this, I do want to clarify one thing that you said in the earlier hour so that we can make sure I'm not misstating anything.

But the August 2021 approval was a BLA approval. Is that right?

A August 23, 2021, correct.

Q Okay. August 23, 2021. And that BLA, you said before, was essentially the same as the EUA vaccine that had already been on the -- out there, right?

A Much -- it wasn't the same, but much of the content had previously been submitted. Not all, but it was updated information on the data that had come in for the EUA.

Q And I believe in your announcement that you had said you could still use the EUA product, right? Don't get rid of that vaccine while we're getting the BLA out there. Is that correct?

A That's correct.

Q Okay. But then the booster that came out, you talked about in October '21 -- 2021, that was an EUA?

A That's correct.

Q And that was an EUA booster to boost which, the previous EUA, or was this the BLA?

A It could be used for -- it could be used to boost either vaccine.

Q Okay. And so in -- the characterization is there. You first have the EUA vaccine that is still kind of available after August 23rd, 2021, but now we have the BLA, and we talked about that being, you know, the imprimatur and given the ability to go mandate folks with that, and then you have the booster coming out right after.

Was there any dialogue -- and I'm not looking for deliberative things, but just dialogue about the potential appearance of inconsistency or why on the heels of two months after having the BLA that we have to have a booster on it right away?

A Because they weren't separate vaccines. The BLA was a continuation of the EUA vaccine. It was the same vaccine. It was just given the full authority and, hopefully, that made more people comfortable taking the BLA vaccine.

So that, hopefully, got more people to take their initial doses, but there was a cohort of individuals who had been dosed months and months before whose immunity was waning, and the idea was to allow them to have the opportunity to essentially tune up their immunity as it waned.

Q Okay. And in that tune-up, or that EUA in October for the booster, was part of the factoring -- factoring in that dose who had had COVID and survived, but maybe they hadn't been vaccinated, would that booster have helped the unvaccinated COVID survivor?

A The -- to the best of our knowledge, receiving a booster could help you

whether or not you had COVID or not. Now, there was some debate about how long one should wait between having COVID and getting a booster.

And I think at one point CDC was saying two or three months. It might have changed at times, but it was roughly that one should wait after having COVID to get a booster, just as we ultimately came to saying one should wait until a month or two after having COVID to get the initial vaccine series.

Q And that component of the guidance, is that something that was coming out of FDA on the timing of --

A That came out of CDC.

Q Okay. And does that -- does their data, however they informed it, inform your review of the vaccine as it would apply to people who had either been vaccinated or unvaccinated to get a booster?

A I'm just trying -- I'm just going to try to make sure I understand the question.

So did CDC's opinion about who should -- about whether a booster could help someone who was previously vaccinated, did that -- or previously unvaccinated who had COVID, did that affect --

Q Right. Let me back up a little bit to the American citizen who is receiving messages from their government, and they're receiving a message from everyone saying, you ought to get vaccinated, right? That was pretty consistent.

But then there's a message saying -- from FDA saying, we've just approved a BLA for -- so we have a fully licensed vaccine, and that is kind of the continuum from that EUA, right?

A Uh-huh.

Q And then -- coming out. So everyone says yes, we have this and now mandates are coming into place and we're getting more people vaccinated one way or

the other. And then there's a booster that comes out right after.

Meanwhile, you've got the CDC, and to a lot of people it's the same, HHS and the government, saying, Well, wait a minute, if you've got COVID, don't get the vaccine yet and -- do you follow me? There's multiple messages going on, and -- you said this before. When you were on your video and you didn't say on that particular one, go talk to your doctor.

Was there messaging to the doctors saying, okay, we have all of these different types of people, we need to be mindful of potential risks if they get vaccinated, if they're just coming off of COVID or other factors?

A So, first of all, there's no clear risk to getting a COVID vaccine after you've had COVID-19, and that actually was demonstrated in the 600 people in each arm. There was no safety -- adverse safety effects that were seen in that trial.

That was one of the reasons for not actually checking COVID upfront. First of all, it wasn't practical, but second of all, because, in practice, that was very helpful data to have moving forward. So there was not a safety concern there.

Q So by safety, getting sick again or getting symptoms again just as you're coming off of COVID, there was some cause for delay, and the explanation of what that was may not have been out of FDA, but it might have been CDC?

A Well, it was that you would have -- if you had just had COVID, you probably had reasonable levels of antibodies that would persist for a certain amount of time and might drop off. And, to wit, there were various studies -- at least two that I'm aware of -- that came out which seemed to show that even people who had COVID, if they were vaccinated a month or two later, ended up seeming to benefit in terms of increased protection from getting vaccinated.

Q Okay.

A Over just having had COVID alone. They're not easy studies to do, but --

Q Right.

A -- that's what was seen.

Q Okay. And so now I'm coming back to the messaging that's coming out from the government and the executive branch at some level.

Was there a central point, if you know, who was managing that as far as -- and go back to what I talked about earlier when you were testifying.

You had someone from the -- Dr. Kessler from the White House, and you and Dr. Fauci and Dr. --

A Walensky.

Q -- Walensky from the CDC. Different agencies, different experts, all scientists, all really smart people.

But the messaging needed to be coordinated, and that becomes mixed messaging that gets out there. And there's a lot of people who were saying, Oh, there's misinformation, or mal-information and those types of things. And then, you know, there was other things about social media taking control of what people were saying. That's not -- that's not what we're hearing about today, but there's that messaging.

I'm wondering where you fit into that, or if there was coordination on how to message that coming from higher in the executive branch?

A So we did our best to coordinate with CDC on safety surveillance, on actions that we were taking potentially regarding files that we had so that they were aware, because they needed to present those data to the ACIP, to the working group, and then to the larger ACIP. So that was my level of interaction.

There was a level above me, which was a doctor's group, which contained individuals who you might have seen on the video that I was not party to those

discussions. With rare occasion, I might have been invited to present something to that group, but I was not part of their deliberative process.

Q Were you -- not so much the deliberative process, but again, going back to the kind of the esprit de corps that you were largely responsible for with project Warp Speed where we're going all guns on getting everything out there, but the messaging has to be consistent and timely and all those things, were you getting any direction -- or were you aware that there was coordination on direction of messaging on the different events that were happening as we were fighting COVID?

A I was aware that we were trying to coordinate messaging. I was not involved in the coordination of the messaging.

Q Did you receive any directions on what was going on or, for example, we're going to speed this up to get the messaging out right now, or we need to slow it down?

A No, I didn't. That's not something that I was party to.

Q Okay.

Mr. Massie. I have an exhibit to clarify some things. What exhibit are we up to now?

[redacted] This should be 11.

Mr. Massie. 11. Okay.

[Marks Exhibit No. 11.
was marked for identification.]

Mr. Massie. In the email chain, there was an email from Doran Fink to Donna. That's what this is.

I think there's been some confusion about what was provided when to the FDA as part of a submission for the EUA and then what became known later, and I just wanted to pull this out of the email chain because I noticed it referred to an attachment, and so this

has the attachment that Dr. Fink is referring to.

After Pfizer got back to Dr. Fink and copied Gruber, Pfizer said, Oh, yeah, we told you about this, it's in the -- it was submitted to ACIP, or A-C-I-P. Dr. Fink replies, "Dear Donna, thanks for the update."

Just to be clear, the narrative provided with the EUA submission attached was pretty scant on details, and no additional details were available from Pfizer when we asked during the review. And so what -- what exactly Pfizer had told the FDA and the ACIP was that it was neuralgia vulva abscess and abdominal pain, gastritis, and constipation. But she had to be -- people had to help her go to the bathroom. It was -- you know, you could read this and think, Oh, she had a stomachache and it was all in her head. But the reality is, she ended up with a feeding tube and in a wheelchair.

So this is -- this is the concern that I wanted to get your reaction to that they -- it seems like they underreported this.

Dr. Marks. So I can't speak to what's in the -- I think I'd have to probably spend some time putting together all these different records to try to be able to give you an exact sequence of when we knew what when.

But I can with relative, I think, certainty, say that what we found out in the end would not have changed anything we did, because at the end of the day, she was diagnosed -- these various things that she had were wrapped up by somebody in the end and presented to, actually, a pretty large group of people and determined to be a functional disorder.

And so, again, I -- I can't -- I can't argue with the timing of here, and I don't know when, you know -- when the sequence is here. I do trust Dr. -- Dr. Fink. His -- if he said that it was thin, it was probably thin. And I suspect it probably was more like just --

Mr. Massie. I think that's what it is right there.

Dr. Marks. And then they -- and then a narrative may have been submitted -- the full narrative may have been submitted later on.

Just not in defense of Pfizer, not in defense of any sponsor, but sometimes when events are ongoing, this -- it may have been that they had the file open. I can't speak to that. But this is -- this is what can happen sometimes. Ultimately, thankfully, we did get the full narrative.

Mr. Massie. How many -- okay. I just wanted to introduce that and let you know what the narrative was at the time.

Dr. Marks. Uh-huh.

Mr. Massie. How many people in supervisory roles left the FDA after a regulatory disagreement with you?

Dr. Marks. In -- over the course of the years?

Mr. Massie. Since COVID.

Dr. Marks. Since COVID, three or four.

Mr. Massie. And you're including Dr. Gruber and Dr. Krause?

Dr. Marks. Well, I don't know what -- maybe I shouldn't characterize that, because both Drs. Gruber and Krause, they retired from the agency. And I think, as was very clear, I still consider Dr. Krause and Dr. Gruber, their contributions to the agency, very significant.

So I -- there's -- I mean, I do not view this disagreement as something that, you know, would have made them need to leave the agency. They -- Dr. Gruber came to me and had told me that she was very tired, having been through a long pandemic and wanted to do something different, and I thanked her for her service because she did a tremendous service to the country.

And Dr. Krause followed shortly or at some point thereafter.

Mr. Massie. As far as you know, were there any formal or informal communications from White House staff to FDA regarding the desired outcomes of the reviews of the vaccines?

Dr. Marks. Not to my knowledge.

Mr. Massie. Some people were -- on the outside -- I'll include myself, so that sample includes at least one -- thought that there was an appearance of political pressure on the FDA, and there were people on the inside who had that same concern.

What could you do at the FDA to reduce the appearance to people like myself or people who may be at the FDA of political influence on the process of science?

Dr. Marks. So we tried to have a very strict firewall with any communications between myself and anything outside of the agency. I did not -- I communicated with the commissioner. I might have appeared for the doctors' group when asked, but I did not have independent communications with anyone outside of FDA. And I think that was -- in both administrations, we tried to adhere to that, although we were perhaps less successful at some times than others.

Mr. Massie. Is there anything you would have done differently?

Dr. Marks. Regarding what?

Mr. Massie. The EUA, the interaction with the people who have contacted you, the BLA, the videos that you've made, any of the material we've covered today.

Dr. Marks. So I just would say that during both administrations, there was actually political pressure at times from the Trump administration to get the vaccine done rapidly. For instance, the commissioner and I were asked into Mark Meadows office at one point, at which time a significant amount of pressure was placed to accelerate when we took action.

By the way, it didn't matter because the decision had already been made, and

perhaps we might have accelerated things by 12 hours. That said, I -- you know, I view that with the same way I view other things, which I viewed that as Mr. Meadows doing his due diligence to try to help protect the population. I didn't view that as political pressure, per se.

The same way as through this entire period, I -- my primary importance was to make sure that we stayed true to the science of what it showed us to allow the American people to have the best possible vaccines that were supported by the available evidence.

Were the communications garbled at times through this pandemic? They certainly were. If I could go back, we would try to have more aligned communications. I think that is certainly something that we could have done much better on. I think, had we been aligned, and probably, we should have done something -- I should have done more during this hearing.

We should have all sat back in public health agencies and taken a deep breath, looked at the data and said, Okay. How do we combine to make a coherent message? What can we do that will help all of our population feel better with the vaccines that we've introduced?

So I think possibly because everyone was trying to rush so fast to try to do the right thing -- and we were not rushing the BLA approvals to pass where we could, nor were we rushing the EUAs, but I think we did sometimes, as we thought about the public health messaging, didn't take adequate time to consider what was necessary and what we were up against in terms of vaccine hesitancy, and some of those issues in the country.

[4:56 p.m.]

Mr. Massie. Well, what could be done to restore faith in the FDA or vaccine -- what could be done fix vaccine hesitancy, or to improve it that you could do at the FDA? I'm not talking about what somebody else could do.

Dr. Marks. So I think we have to make sure that our process is viewed as above and independent of political process. And I think anything that mixes the two, that's not a good thing. So that obviously has to be the case. We have to absolutely make it clear that we are following the science, public health, and that has to be very clear.

I also think we do actually have a role in helping to provide doctors with accurate information directly to practitioners so that they can help explain to their patients the nature of the vaccines, the benefits and risks of vaccines moving forward, because it is the doctor-patient relationship that I think will rebuild trust.

And when I say -- I shouldn't just say doctor. That's not being fair. It's the healthcare provider. It could be an advanced practice nurse or another healthcare provider.

But those are the individuals that I think we have to communicate with, because those are people who we do communicate with in our labels to help them understand, you know, the nature of the products that we're regulating. Ultimately, it is a discussion between individuals.

And from the feedback that I received during the pandemic, among the most important things that I learned was that the discussion between provider and patient was what helped more people take vaccines perhaps than anything else.

A good -- allowing a patient to ask as many questions -- or I shouldn't say patient, because they're not necessarily patients. They're just healthy individuals. Allowing a healthy individual to ask as many questions that they had in a doctor's office was what

helped us get over this.

The one issue that does come up is that that takes a lot of time, and so, I think probably it may mean we have to figure out ways to be most efficient in doing that moving forward.

And finally, I'd just say that it also helps if we could have consistent messaging, because I think there were divergent message from different places that were tougher.

BY [redacted]:

Q Just a quick follow-up on that is that one of the things we hear about is the revolving door of between former FDA folks and industry.

And it's well-known Scott Gottlieb, who was, I think, your supervisor, was then at Pfizer during this time and Scott has -- Dr. Gottlieb has been out there, speaking on things about natural immunity and promoting that.

Any thoughts on post-employment restrictions or the places that FDA people should go? Again --

A I'm going have to leave this to the attorneys for some of the more strict, because there are, obviously, restrictions in place with where people can go.

We -- you know, we do benefit at FDA from some back-and-forth with people coming from industry into the agency and perhaps also in people from the agency at an appropriate time, as specified by law, to go work for industry, because there is -- there is some important -- I mean, I wouldn't have known how to speed up, help speed up things in Operation Warp Speed, had I not had industry experience and known what was possible in manufacturing.

Q Right.

A So there is some benefit to this. And I think we do, at FDA, try to make sure that, you know, we don't monitor, to my knowledge, but we do make sure that people,

when they separate from the agency, are aware of the restrictions that are in place as they, you know, as they go to other companies.

Q Do you take steps to guard against the appearance of impropriety when you're approving drugs at the FDA?

A Well, I can say that, you know, I -- the best I can say, and I'm going look to you here to make sure it's okay to say this.

But, look, if somebody who just separated from the agency came before me with a matter that I knew they shouldn't --

Q Right.

A -- I would actually -- and it has happened once. I would call that person's counsel and explain to them that something doesn't or try to address the issue on an informal level so that it was addressed.

Mr. Massie. I'm done.

[redacted] Let's go off the record.

[redacted] We're good.

[Whereupon, at 5:01 p.m., the interview was concluded.]

Certificate of Deponent/Interviewee

I have read the foregoing ____ pages, which contain the correct transcript of the answers made by me to the questions therein recorded.

_____

Witness Name

_____

Date

Marks Errata

Page 2, Line 16: Replace "Federal Department of Agriculture" with "Food and Drug Administration"

Page 2, Line 19-20: Replace "Federal Department of Agriculture" with "Food and Drug Administration"

Page 16, Line 18: Replace "Coronaviruses" with "coronaviruses"

Page 22, Line 7: Replace "assistant secretary" with "Assistant Secretary"

Page 22, Line 9: Replace "assistant secretary" with "Assistant Secretary"

Page 22, Line 11: Delete "to"

Page 22, Line 12: Replace "commissioner" with "Commissioner"

Page 22, Line 13: Replace "commissioner" with "Commissioner"

Page 23, Line 11: Replace "commissioner" with "Commissioner"

Page 24, Line 7: Replace "shares" with "share"

Page 31, Line 25: Replace "developing" with "developing the vaccines."

Page 33, Line 13: Replace "Pressler" with "Perna"

Page 33, Line 17: Replace "commissioner" with "Commissioner"

Page 36, Line 16: Replace "commissioner" with "Commissioner"

Page 38, Line 5: Replace "valuation" with "evaluation"

Page 38, Line 25: Replace "Recommenda" with "Recommend"

Page 42, Line 3: Replace "for" with "from"

Page 43, Line 22: Delete "vac-"

Page 51, Line 25: Replace "commissioner" with "Commissioner"

Page 51, Line 25: Replace "assistant secretary" with "Assistant Secretary"

Page 52, Line 1: Replace "preparedness and response" with "Preparedness and Response"

Page 52, Line 5: Replace "commissioner" with "Commissioner"

Page 53, Line 7: Delete "that the"

Page 53, Line 15: Replace "approval available" with "approval"

Page 55, Line 25: Replace "meeting" with "minimum"

Page 56, Line 5: Replace "slots" with "lots"

Page 56, Line 7: Replace "meeting" with "minimum"

Page 58, Line 18: Replace "than" with "of the"

Page 61, Line 11: Replace "went" with "went through"

Page 69, Line 14: Delete ", such as"

Page 69, Line 15: Delete "the --"

Page 71, Line 1: Replace "on" with "in"

Page 84, Line 21: Replace "countering" with "encountering"

Page 94, Line 22: Replace "commissioner" with "Commissioner"

Page 103, Line 14: Replace "any given." with "any given ad."

Page 103, Line 20: Replace "cutesy" with "cutesiness"

Page 103, Line 20: Replace "shown" to "show"

Page 123, Line 7: Replace "Jan" with "Janet"

Page 126, Line 16: Replace "video thorasitic" with "videoscopic"

Page 127, Line 10: Replace "scanned" with "scant"

Page 128, Line 4: Replace "Garay like" with "Garay-like"

Page 129, Line 5: Replace "at" with "as"

Page 134, Line 4: Replace "biologics license application" with "Biologics License Application"

Page 137, Line 9: Replace "not" with "not my"

Page 138, Line 4: Replace "legendary voice with John legend" with "'Legendary Voice' with John Legend"

Page 138, Line 4: Replace "protected on tour with Charley Pooth" with "'Protected on Tour' with Charlie Puth"

Page 139, Line 12: Replace "CIGARILLO" with "CHIARELLO"

Page 139, Line 23: Replace "challenger" with "Challenger"

Page 143, Line 8: Replace "20" with "2021"

Page 143, Line 12: Replace "were" with "were not"

Page 155, Line 10: Replace "to know" with "who knows"

Page 156, Line 10: Replace "self-control" with "a self-control"

Page 167, Line 20: Replace "'41 " with "41 '"

Page 168, Line 17: Replace "individuals. She" with "individuals she"

Page 170, Line 3: Replace "empirical" with "Empirical"

Page 170, Line 22: Replace "empirical" with "Empirical"

Page 170, Line 14: Replace "best" with "BEST"

Page 181, Line 16: Replace "commissioner" with "Commissioner"

Page 182, Line 1: Replace "commissioner" with "Commissioner"

Page 186, Line 12: Replace "doesn't" with "doesn't--"

From: Tierney, Julia
To: Marks, Peter
Cc: Walinsky, Sarah
Subject: RE: Catching up
Date: Monday, July 19, 2021 9:09:00 PM

Happy to chat. I spoke with Janet tonight and she is aware.

From: Marks, Peter [redacted]
Sent: Monday, July 19, 2021 6:18 PM
To: Tierney, Julia [redacted]
Cc: Walinsky, Sarah [redacted]
Subject: FW: Catching up

Dear Julie and Sarah

Thoughts welcome. May be easiest to touch bases by phone. Thanks.

Best Regards,

Peter

From: Marks, Peter
Sent: Monday, July 19, 2021 6:16 PM
To: Gruber, Marion [redacted]
Subject: RE: Catching up

Dear Marion,

Thanks for all of these questions, all of which are entirely reasonable. I have been giving them some thought and have some thoughts to share with you, for which I would welcome your feedback. Look forward to speaking in the morning.

Best Regards,

Peter

From: Gruber, Marion [redacted]
Sent: Monday, July 19, 2021 6:14 PM
To: Marks, Peter [redacted]
Subject: RE: Catching up

Dear Peter,

I informed DVRPA and DVP management that for the time that I will be (b) (6), JW assigned you direct oversight of the Pfizer Corminaty BLA and that Phil will be overseeing other regulatory files. DVRPA and DVP management requested, before they inform their staff, to get clarification on the process that will be followed, specifically:

- How will you be interacting with the review team, i.e., will you be present at all their meetings, will you be directly interacting with the Chair?
- JW mentioned she wants to be briefed on the review process, what would this look like?
- I typically get updates from DVP and DVRPA and also interact with OBE: How do you foresee such interaction?
- Will you be directly interacting with Theresa Finn and Karen Farizo regarding labeling, PerC and getting agreement on potential PMRs?
- Have OBE and OCBQ be informed?

As you can imagine, there is a great deal of Angst and uncertainty and I would appreciate if we can discuss the above in our meeting tomorrow. I need to provide reassurance to the team. Also, it is not clear to me whether I, and for that matter Phil, will be put back in charge

regarding this BLA once I return (b) (6) .
Thank you,
Marion

From: Marks, Peter [redacted]
Sent: Monday, July 19, 2021 11:32 AM
To: Gruber, Marion [redacted]
Subject: Catching up

Dear Marion,

Just wanted to follow up on this morning's meeting with Janet. I appreciate all of the work that you and OVRR have done here and want to try to connect tomorrow to make sure that a number of different issues that are pending. I am open from 7 to 7:30 or 8 to 9. Just let me know what might work for you. Also, thanks very much for attending the (b) (4) meeting this afternoon. Though I may spend more than the hour with them, I will let them know that some team members will need to leave after and hour. Thanks again for doing this.

Best Regards,
Peter

From: Sheehy, Janice
To: Tierney, Julia
Subject: RE: Meeting w CBER
Date: Friday, July 16, 2021 3:06:55 PM

Yes, will do, thanks. -j

From: Tierney, Julia [redacted]
Sent: Friday, July 16, 2021 3:06 PM
To: Sheehy, Janice [redacted]
Subject: RE: Meeting w CBER
Thanks. And assume meeting will not be forwardable. Thanks.

From: Sheehy, Janice [redacted]
Sent: Friday, July 16, 2021 3:05 PM
To: Tierney, Julia [redacted]
Subject: FW: Meeting w CBER
FYI

From: Marks, Peter [redacted]
Sent: Friday, July 16, 2021 3:04 PM
To: Sheehy, Janice [redacted]; [redacted]; Grantham, Gloria [redacted]
Cc: [redacted]; Copeland, Jakea [redacted]
Subject: RE: Meeting w CBER
Dear Janice,
Please just invite Marion Gruber and me.
Best Regards,
Peter

From: Sheehy, Janice [redacted]
Sent: Friday, July 16, 2021 3:02 PM
To: [redacted]; Grantham, Gloria [redacted]
Cc: Marks, Peter [redacted]; [redacted]; Copeland, Jakea [redacted]
Subject: RE: Meeting w CBER
Hi, just checking back in please for the names of the CBER folks to be included in Monday's 8:30am.
Thanks so much! -janice

From: [redacted]
Sent: Tuesday, July 13, 2021 7:45 AM
To: Sheehy, Janice [redacted]
Cc: Marks, Peter [redacted]; [redacted]
Subject: RE: Meeting w CBER
Good Morning Janice,
The best time for Dr. Marks would be:
Monday, July 19: 8:30-9:00am
Sincerely,
[redacted]

From: Sheehy, Janice [redacted]
Sent: Tuesday, July 13, 2021 7:13 AM
To: [redacted]
Cc: Marks, Peter [redacted]; [redacted]
Subject: FW: Meeting w CBER

Good morning, [redacted]!

Per Julie's email below, would you please let me know which date/time (30-minute block) works best for Dr. Marks:

Friday, July 16: 2:00-3:00pm, 4:00-5:00pm

Monday, July 19: 8:30-9:00am, 9:30-10:00am

I will wait to hear who Dr. Marks would like to have included on the calendar invite.

Thank you!

-janice

From: Tierney, Julia [redacted]
Sent: Monday, July 12, 2021 9:06 PM
To: Copeland, Jakea [redacted]; Sheehy, Janice [redacted]
Subject: Meeting w CBER

Can you please find 30 minutes on Friday 7/16 afternoon or Monday 7/19 morning for JW to meet w Peter Marks and others in CBER to discuss vaccine review? For now, let's just hold on JW, mine, and Peter's calendars and then Peter can tell us who he'd like to invite from his staff.

From: Marks, Peter
To: Woodcock, Janet; Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timeline
Date: Friday, July 16, 2021 11:20:48 AM
Attachments: image001.png

Dear Janet,
Thanks. In my mind, the issue is that for four weeks, aside from mandatory IND review and safety work and continuing work on one PDUFA goal vaccine, all available hands in the office of vaccines, epi and my immediate office should be working to get the Pfizer vaccine done. I am putting together a notional Gantt chart that I will refine.
I am committed to getting this done timely – we will make it happen.
(I have Warp Speed to live up to!)
Best Regards,
Peter

From: Woodcock, Janet [redacted]
Sent: Friday, July 16, 2021 11:10 AM
To: Tierney, Julia [redacted]
Cc: Marks, Peter [redacted]
Subject: RE: Pfizer COVID-19 vaccine BLA review timeline
Well they seem open to additional support on other vaccine efforts, and are already working with CDER office of computational science, which is a good thing. Peter you can find out more when you take over. jw

---

From: Tierney, Julia [redacted]
Sent: Friday, July 16, 2021 9:26 AM
To: Woodcock, Janet [redacted]
Cc: Marks, Peter [redacted]
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Just reupping

From: Marks, Peter [redacted]
Sent: Thursday, July 15, 2021 10:11 AM
To: Woodcock, Janet [redacted]
Cc: Tierney, Julia [redacted]
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Dear Janet,
Perhaps we can have a brief call tomorrow? I can fill you in on the conversation that I had with Marion and Phil subsequent to their sending me this document. I have asked them to provide me with a timeline of milestones, and they are meeting with the review team today to be able to do so tomorrow morning. That said, they are intransigent at this time on the Sept 15 date.
Thanks very much.
Best Regards,
Peter

From: Gruber, Marion [redacted]
Sent: Thursday, July 15, 2021 8:00 AM
To: Marks, Peter [redacted]; Witten, Celia (CBER) [redacted]

Cc: Krause, Philip [redacted]

Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,

Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.

Marion

Marion F. Gruber, Ph.D

Director

Office of Vaccines Research & Review

Center for Biologics Evaluation & Research

Food & Drug Administration, DHHS

[redacted]

Tel.: [redacted]

Email: [redacted]

From: Woodcock, Janet
To: Marks, Peter; Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timeline
Date: Thursday, July 15, 2021 10:12:49 AM
Attachments: image001.png

Sure we can set up some time. jw

From: Marks, Peter <[redacted]>
Sent: Thursday, July 15, 2021 10:11 AM
To: Woodcock, Janet <[redacted]>
Cc: Tierney, Julia <[redacted]>
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline

Dear Janet,

Perhaps we can have a brief call tomorrow? I can fill you in on the conversation that I had with Marion and Phil subsequent to their sending me this document. I have asked them to provide me with a timeline of milestones, and they are meeting with the review team today to be able to do so tomorrow morning. That said, they are intransigent at this time on the Sept 15 date.

Thanks very much.

Best Regards,

Peter

From: Gruber, Marion <[redacted]>
Sent: Thursday, July 15, 2021 8:00 AM
To: Marks, Peter <[redacted]>; Witten, Celia (CBER) <[redacted]>
Cc: Krause, Philip <[redacted]>
Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,

Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.

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Marion F. Gruber, Ph.D
Director
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
[redacted]
Tel.: [redacted]
Email: [redacted]

From: Woodcock, Janet
To: Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Date: Saturday, July 17, 2021 1:07:11 PM
Attachments: image001.png

Great, thanks. jw

From: Tierney, Julia <[redacted]>
Sent: Saturday, July 17, 2021 12:45 PM
To: Woodcock, Janet <[redacted]>; Marks, Peter <[redacted]>
Subject: Re: Pfizer COVID-19 vaccine BLA review timelines
Sent an invite for 2

From: Woodcock, Janet <[redacted]>
Sent: Saturday, July 17, 2021 12:01:37 PM
To: Marks, Peter <[redacted]>; Tierney, Julia <[redacted]>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Agree. Anytime before 5 is good. wj

From: Marks, Peter <[redacted]>
Sent: Saturday, July 17, 2021 11:56 AM
To: Woodcock, Janet <[redacted]>; Tierney, Julia <[redacted]>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Dear Janet,
Totally fine with whatever you want to do with this. Based on what Marion provided, I think that shaving three weeks off is truly possible. We just need to motivate the team around this cause – that is something I actually know how to do as a leader (a la the beginning of Warp Speed and my previous work in industry).
I could do this afternoon anytime after 2 PM. Also could probably make 1 pm tomorrow work.
Best Regards,
Peter

From: Woodcock, Janet <[redacted]>
Sent: Saturday, July 17, 2021 11:52 AM
To: Tierney, Julia <[redacted]>; Marks, Peter <[redacted]>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
This afternoon or tomorrow is good for me. Marion has asked to include Phil Krause in the meeting with me. jw

From: Tierney, Julia <[redacted]>
Sent: Friday, July 16, 2021 6:56 PM
To: Marks, Peter <[redacted]>; Woodcock, Janet <[redacted]>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Happy to put a call-in on over the weekend for us whenever works best for the two of you.

From: Marks, Peter <[redacted]>
Sent: Friday, July 16, 2021 6:08 PM
To: Woodcock, Janet <[redacted]>; Tierney, Julia <[redacted]>
Subject: FW: Pfizer COVID-19 vaccine BLA review timelines

Dear Janet and Julie,
Please see the attached. Marion finally provided this timeline. I can already see a number of potential efficiencies. Perhaps we can discuss over the weekend briefly in preparation for Monday?
Thanks.
Best Regards,
Peter

From: Gruber, Marion <[redacted]>
Sent: Friday, July 16, 2021 5:39 PM
To: Marks, Peter <[redacted]>
Cc: Malarkey, Mary <[redacted]>; Anderson, Steven <[redacted]>; Krause, Philip <[redacted]>
Subject: Pfizer COVID-19 vaccine BLA review timelines

Dear Peter,
As requested, see attached our projected timelines for completing currently ongoing reviews, tasks and responsibilities for the above BLA. Of note, the bar graphs reflect targeted completion dates, some of these pending timely sponsor response to information request which we have been and are sending as we review the info contained in the submission. The target ADD is September 15. Note that DBSQC DS and DP testing will not be completed at that time because of reagent shortage.
Marion
[I saw earlier today that CNN announced that this review will be completed within 2 months; thus, Sep 15, even though ambitious, is within this projected timeline.]

Marion F. Gruber, Ph.D
Director
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
[redacted]
Tel.: [redacted]
Email: [redacted]

From: Woodcock, Janet
To: Marks, Peter; Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Date: Saturday, July 17, 2021 12:01:39 PM
Attachments: image001.png

Agree. Anytime before 5 is good. wj

From: Marks, Peter <[redacted]>
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Best Regards,

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Marion F. Gruber, Ph.D

Director

Office of Vaccines Research & Review

Center for Biologics Evaluation & Research

Food & Drug Administration, DHHS

[redacted]

Tel.: [redacted]

Email: [redacted]

From: Woodcock, Janet
To: Marks, Peter; Tierney, Julia
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Date: Saturday, July 17, 2021 11:53:05 AM
Attachments: image001.png

Tomorrow 1 or 2 PM? jw

From: Marks, Peter <[redacted]>
Sent: Friday, July 16, 2021 7:19 PM
To: Tierney, Julia <[redacted]>; Woodcock, Janet <[redacted]>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines

Dear Julie,

Pretty much any time that can work for Janet could work for me this weekend.

Best Regards,

Peter

From: Tierney, Julia <[redacted]>
Sent: Friday, July 16, 2021 6:56 PM
To: Marks, Peter <[redacted]>; Woodcock, Janet <[redacted]>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines

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Marion F. Gruber, Ph.D
Director
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
[redacted]
Tel.: [redacted]
Email: [redacted]

From: Woodcock, Janet
To: Tierney, Julia; Marks, Peter
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
Date: Saturday, July 17, 2021 11:52:01 AM
Attachments: image001.png

This afternoon or tomorrow is good for me. Marion has asked to include Phil Krause in the meeting with me. jw

From: Tierney, Julia <[redacted]>
Sent: Friday, July 16, 2021 6:56 PM
To: Marks, Peter <[redacted]>; Woodcock, Janet <[redacted]>
Subject: RE: Pfizer COVID-19 vaccine BLA review timelines
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Cc: Malarkey, Mary <[redacted]>; Anderson, Steven <[redacted]>; Krause, Philip <[redacted]>
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Marion F. Gruber, Ph.D
Director
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
[redacted]

Tel.: [redacted]
Email: [redacted]

From:	Marks, Peter
To:	Woodcock, Janet
Cc:	Tierney, Julia
Subject:	FW: Pfizer COVID-19 vaccine BLA review timeline
Date:	Thursday, July 15, 2021 10:11:27 AM
Attachments:	image001.png Pfizer COVID-19 vaccine BLA review timeline.docx

Dear Janet,

Perhaps we can have a brief call tomorrow? I can fill you in on the conversation that I had with Marion and Phil subsequent to their sending me this document. I have asked them to provide me with a timeline of milestones, and they are meeting with the review team today to be able to do so tomorrow morning. That said, they are intransigent at this time on the Sept 15 date.

Thanks very much.

Best Regards,

Peter

From: Gruber, Marion <[redacted]>

Sent: Thursday, July 15, 2021 8:00 AM

To: Marks, Peter <[redacted]>; Witten, Celia (CBER) <[redacted]>

Cc: Krause, Philip <[redacted]>

Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,

Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.

Marion

Marion F. Gruber, Ph.D

Director

Office of Vaccines Research & Review

Center for Biologics Evaluation & Research

Food & Drug Administration, DHHS

[redacted]

Tel.: [redacted]

Email: [redacted]

Pfizer COVID-19 STN 125742.0 BLA target AD: 09/15/2021

OVRR's decision to expedite the planned completion of the Pfizer BLA review to September 15, 2021, was based on a careful consideration of the steps that need to take place. OVRR's logic is outlined below.

The Pfizer BLA is a complex BLA

Of note, the pivotal study supporting the BLA was conducted in over 40,000 subjects. To provide additional assurance of the safety and effectiveness of this product that is currently administered to millions of subjects in the US and globally, we requested 6 months safety follow-up to support the BLA as opposed to the 2 months safety follow-up that supported the EUA. The applicant has also submitted additional efficacy data on substantial numbers of cases in vaccine and control groups that were not available with the EUA request submission and data on post-authorization safety experience. These additional data are substantial and enable additional important analyses.

The BLA merits a complete and thorough review

OVRR's reviews of vaccine BLAs, unlike those of regulators in other countries, do not rely on summary tables that are generated by the developer. OVRR views it as essential that review of the safety and efficacy data not only includes an evaluation of the data analyses conducted by the applicant, but also includes CBER's own analysis of the datasets submitted by Pfizer. This has been OVRR's standard for all other BLAs, and while time-consuming, OVRR believes that confidence in COVID vaccines would not be served by starting to cut corners on this review.

While the efficacy data may appear simple to evaluate, longer term follow-up of placebo-controlled data provides essential information that may be of high relevance to discussions about boosting. Moreover, the safety data represent the only placebo-controlled data we have on the safety of this vaccine. These placebo-controlled data are likely to be free of biases that might occur in post-licensure observational studies, so it is imperative to carefully review the reported adverse events, including evaluation of the sponsor's attribution of these events (or lack thereof) to vaccination.

As compared with other BLAs, the proposed completion date of Sept 15 would be unprecedented

The Pfizer COVID-19 BLA received priority designation, allowing 8 months for CBER review and is a "rolling" BLA. Note that the final piece of the roll was received on May 18, 2021 at which point the review clock started. We are targeting September 15, 2021 as the date we will be taking regulatory action, which is less than 4 months from the date the last section of the BLA was submitted. Thus, we will be reviewing this very large and complex BLA in a 1/3 rd of the time typically allowed for a BLA standard application and in less than half the time allocated for a priority review application.

This is possible only with deprioritization of other reviews, including some related to COVID, and reassignment of work to other experienced medical officers.

At this time, while we have hired additional medical officers, we have a limited number of clinical reviewers with the specialized experience needed to assess complex preventive vaccine files requiring comprehensive review, such as those for COVID vaccines that have progressed to pursuing an EUA or BLA. Addressing the high volume of COVID-related work has necessitated deprioritizing some vaccine files.

In addition, we have de-prioritized certain COVID-vaccine related submissions (including some from Pfizer), e.g., amendments pertaining to protocols and studies in pregnant women and immunocompromised subjects, until such time that the BLA review is completed.

However, Pfizer requested advice on 4 booster protocols and advice on the safety data base to support use of the COVID-19 vaccine in pediatric populations 6 months – 12 years of age. These cannot be deprioritized and will need to be reviewed by staff and overseen by supervisors familiar with the Pfizer COVID vaccine IND ad EUA, concurrent with review activities for the Pfizer COVID-19 BLA.

While it was not possible to completely reassign other COVID-19 vaccine- related and non-COVID vaccine-related review work for the MOs assigned to the Pfizer BLA, workload adjustments have been made to allow them to focus nearly exclusively on review of this BLA.

In addition, if the trajectory of the pandemic/emergence of variant of concerns (i.e., delta variant) necessitates the review of EUA amendments for booster doses for the currently U.S. EUA authorized COVID-19 vaccines, from a public health perspective, these reviews will need to take priority over completing the BLA review by September 15, 2021.

Additional support from outside OVRR will not speed up the review

Review efforts for the Pfizer COVID-19 vaccine BLA in the various disciplines, including CMC, nonclinical, PV and facility is ongoing. Information requests have been sent to Pfizer as part of these reviews, and responses are pending. However, the rate-limiting step in regard to potentially accelerating the review timeline to earlier than September 15 is the clinical review, considering the complexity of the clinical safety and effectiveness data. The safety review encompasses a critical evaluation and interpretation of solicited and unsolicited safety data and SAES, and clinical AEs of interest including, but not limited to, the myocarditis signal that has been observed following the administration of the Pfizer COVID-19 vaccine under EUA. We are also performing subgroup analyses of safety and effectiveness data for race, ethnicity and subjects with underlying conditions. Completion of these reviews may require additional correspondence with the sponsor. We hope that reviewers will be able to complete their detailed review memos for the various review activities by the beginning of September as planned. After this has been finished, there are important additional review activities to be completed, including label

negotiations, supervisory review, SBRA preparation, etc. such that it would not be possible to issue the license until September 15.

The experienced MOs assigned to this file are working closely with the data analytics team in CDER-OCS and staff in CBER/OBE who are supporting their review efforts. The need for coordination of evaluation and consistency within the review would lead to diminishing returns if additional staff would be added to this effort. In addition, the reviews have already been initiated and sections of the review are being written as they are completed. Other sections depend on the reviews of the earlier sections, so those parts of the review cannot be completed until the earlier parts of the review have been done, and because they need to take the subtleties of the earlier parts into account, cannot as reliably be performed by medical officers who are new to the file. Thus, assigning additional MOs (even if experienced) to assist in review of the Pfizer COVID vaccine BLA, it is likely that the review effort would be will delayed rather than expedited the review effort as these reassigned individuals would need to familiarize themselves with the file.

Furthermore, reassignment of experienced medical officers to the Pfizer BLA would lead to a cascade of further reassignments and their own assignments will be delayed ultimately leading to an increase in back-log including critical ongoing review activities to support:

- Many anticipated several BLA submissions in in 3/4Q of 2021 including the BLAs for the (b) (4) (b) (4) and BLAs for (b) (4) (b) (4) all of which are likely to qualify for priority review designation
- The (b) (4) BLA,
- Several BLA supplements including an efficacy supplement for (b) (4) for the pediatric population,
- Efficacy supplements for (b) (4) and
- Booster protocols for the Pfizer, Moderna, and Janssen COVID EUAs.

In summary, it is not possible to further abbreviate the BLA review timeline for the Pfizer COVID-19 vaccine BLA, our target review date for this file remains September 15, 2021.

Additional support from outside OVRR, if effectively used, might reduce the need to deprioritize certain submissions.

Going forward, OVRR will continue to assign lower priority INDs (including COVID vaccines submitted by small entities and academic investigators) to less experienced staff. Some may need to be deprioritized in order to allow our most experienced reviewers to focus on the submissions that have the greatest public health importance.

In addition, to be able to cope with its heavy and steadily increasing regulatory workload, the following is suggested:

- Hiring or assigning review staff from other offices/centers to support review activities regarding lower priority non-COVID files (e.g., (b) (4)) so that staff familiar with the COVID -19 vaccine files can continue to focus their review activities on these submissions,
- For CBER to hire additional program analysts to perform data analytics to support MO review activities
- Extension of the J review contract by one year
- For CBER to provide adequate IT support to its staff. It has been our experience that staff who need their laptops refreshed are receiving sub-standard equipment, i.e., refurbished computers that present with multiple problems. As a consequence of this being an Agency-wide issue, ERIC is backed up and cannot provide timely support. This has caused delays in the completion of review assignments.

From: Marks, Peter
To: Hussey, Deirdre
Cc: Walinsky, Sarah
Subject: FW: Pfizer COVID-19 vaccine BLA review timeline
Date: Friday, July 16, 2021 9:48:15 AM
Attachments: image001.png
Pfizer COVID-19 vaccine BLA review timeline.docx
Review timeline.msg

Dear Deirdre,
I am copying this to you because I think that it is important to document that despite repeated verbal attempts, and as documented in the attached email, I have asked Marion for a timeline that would help justify the September 15 data that she provides for completion of the review.
To further expedite the Pfizer BLA review, during the past month I have also repeatedly offered Marion additional resources from the center and my immediate office, some of whom have deep experience in vaccines. However, she had declined, stating that this would not help.
When asked how many clinical reviewers are working on the file, Marion has told me that there are two, and I have questioned why more could not be placed on the file to assist, but she states that does not feel that this would help.
Yesterday, 7/15, with Celia on the line, I reminded Marion that I asked for a timeline of activities, and she said that she would speak to the review team the evening of 7/15 and get back to me. However, she also noted that she didn't believe that the timelines would change.
In my opinion, the recurrent recent deterioration during the current public health emergency necessitates that we fully mobilize all center resources in order to approve a BLA for a COVID-19 vaccine as rapidly as possible.
I am hoping that Marion will get back to me soon with a timeline that we can discuss.
Best Regards,
Peter

From: Gruber, Marion <[redacted]>
Sent: Thursday, July 15, 2021 8:00 AM
To: Marks, Peter <[redacted]>; Witten, Celia (CBER) <[redacted]>
Cc: Krause, Philip <[redacted]>
Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,
Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.
Marion

Marion F. Gruber, Ph.D
Director
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
[redacted]
Tel.: [redacted]

Email: [redacted]

From: Marks, Peter
To: Gruber, Marion
Cc: Walinsky, Sarah
Subject: Review timeline
Date: Thursday, July 8, 2021 12:51:00 PM

Dear Marion,

Thanks so much for the update on the timelines this morning. Regarding the Pfizer review timeline, by early next week would it be possible to get a high level listing of review activities sorted by week over the course of the next two and a half months. I need to be able to demonstrate to Janet that we are diligently pursuing the process, and this would be very helpful. The level of detail would not need to be very great – just key completion milestones such as "completion of clinical review," "completion of labeling negotiation," etc.

Best Regards,

Peter

From:	Marks, Peter
To:	Tierney, Julia
Subject:	FW: Pfizer COVID-19 vaccine BLA review timeline
Date:	Thursday, July 15, 2021 8:23:15 AM
Attachments:	image001.png Pfizer COVID-19 vaccine BLA review timeline.docx

Dear Julie,

Let's discuss this morning before I forward this to Janet later. Thanks.

Best Regards,

Peter

From: Gruber, Marion <[redacted]>

Sent: Thursday, July 15, 2021 8:00 AM

To: Marks, Peter <[redacted]>; Witten, Celia (CBER) <[redacted]>

Cc: Krause, Philip <[redacted]>

Subject: Pfizer COVID-19 vaccine BLA review timeline

Dear Peter,

Phil and I have further discussed with DVRPA and DVP management the review timeline for the above BLA. As you know we are targeting September 15 as the ADD. It will not be possible to move the ADD up further without cutting corners and lowering our review standards and that I would not be able to defend. We have described our rationale and logic in the attached memo. Feel free to share with JW.

Marion

Marion F. Gruber, Ph.D

Director

Office of Vaccines Research & Review

Center for Biologics Evaluation & Research

Food & Drug Administration, DHHS

[redacted]

Tel.: [redacted]

Email: [redacted]

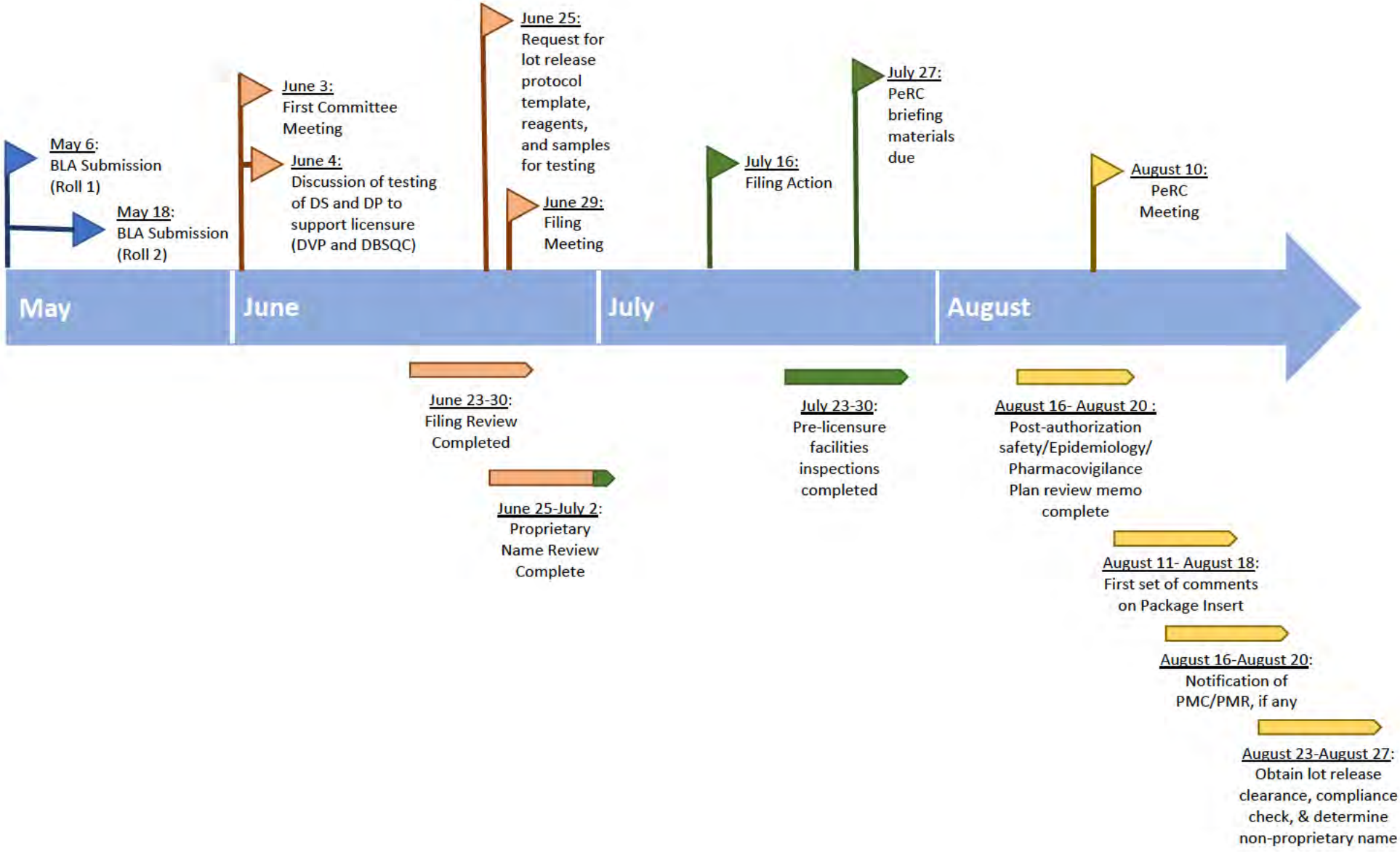
From: Marks, Peter
To: Woodcock, Janet; Tierney, Julia
Subject: FW: Pfizer COVID-19 vaccine BLA review timelines
Date: Friday, July 16, 2021 6:08:12 PM
Attachments: Updated Pfizer COVID Approval Timeline.pptx
image001.png

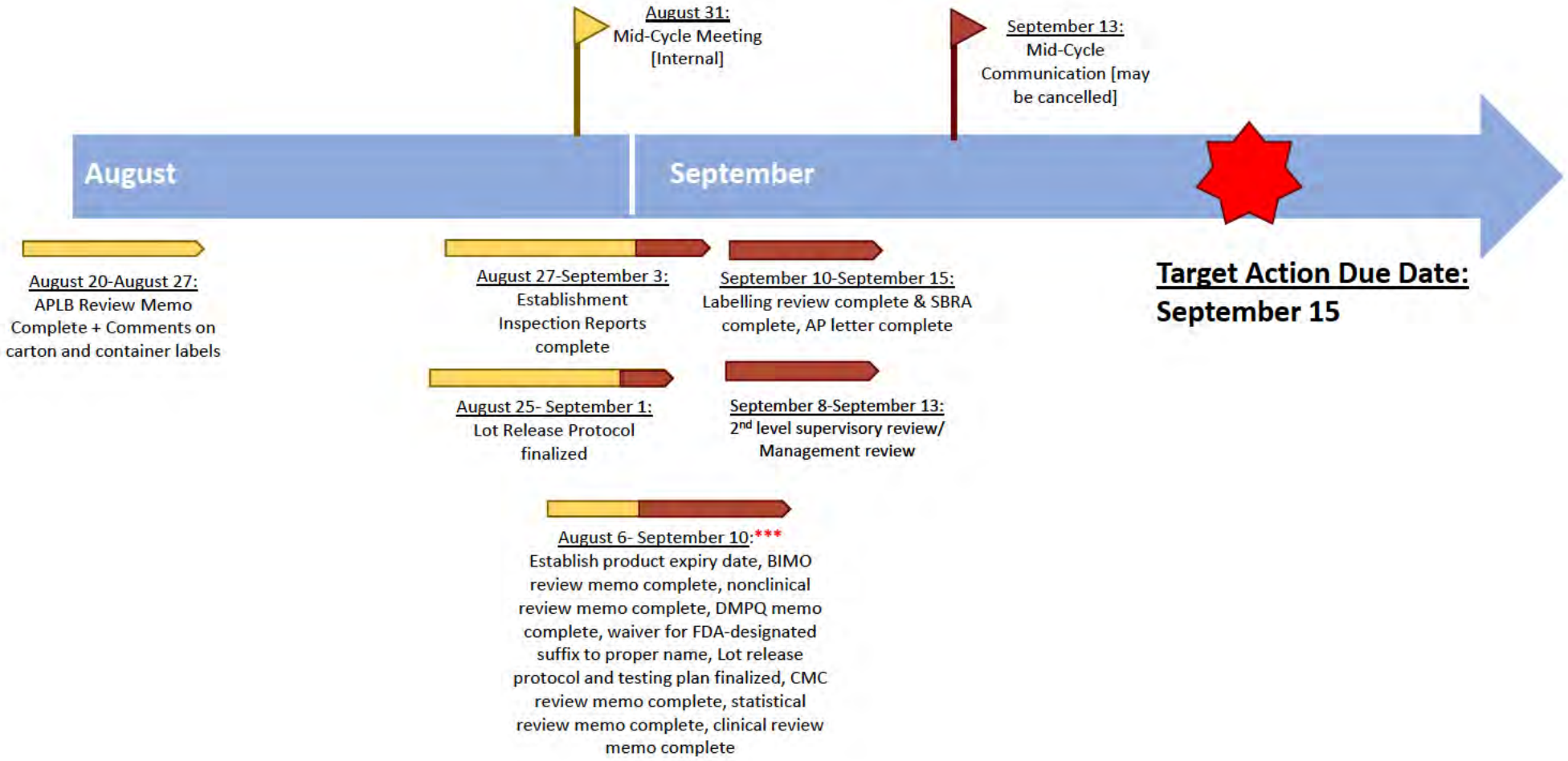
Dear Janet and Julie,
Please see the attached. Marion finally provided this timeline. I can already see a number of potential efficiencies. Perhaps we can discuss over the weekend briefly in preparation for Monday?
Thanks.
Best Regards,
Peter

From: Gruber, Marion <[redacted]>
Sent: Friday, July 16, 2021 5:39 PM
To: Marks, Peter <[redacted]>
Cc: Malarkey, Mary <[redacted]>; Anderson, Steven <[redacted]>; Krause, Philip <[redacted]>
Subject: Pfizer COVID-19 vaccine BLA review timelines

Dear Peter,
As requested, see attached our projected timelines for completing currently ongoing reviews, tasks and responsibilities for the above BLA. Of note, the bar graphs reflect targeted completion dates, some of these pending timely sponsor response to information request which we have been and are sending as we review the info contained in the submission. The target ADD is September 15. Note that DBSQC DS and DP testing will not be completed at that time because of reagent shortage.
Marion
[I saw earlier today that CNN announced that this review will be completed within 2 months; thus, Sep 15, even though ambitious, is within this projected timeline.]

Marion F. Gruber, Ph.D
Director
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
[redacted]
Tel.: [redacted]
Email: [redacted]





***Pending timely sponsor response to info requests

From: Sheehy, Janice
To: Tierney, Julia; Woodcock, Janet
Subject: RE: Vaccine Review
Date: Saturday, July 17, 2021 4:37:50 PM

Will do, thanks! -j

From: Tierney, Julia <[redacted]>
Sent: Saturday, July 17, 2021 2:28 PM
To: Sheehy, Janice <[redacted]>; Woodcock, Janet <[redacted]>
Subject: RE: Vaccine Review

Janice – I spoke with Janet, please extend the invitation to Phil Krause.
Thanks,
Julie

From: Sheehy, Janice <[redacted]>
Sent: Saturday, July 17, 2021 12:52 PM
To: Woodcock, Janet <[redacted]>
Cc: Tierney, Julia <[redacted]>
Subject: RE: Vaccine Review

Thank you, will do.

From: Woodcock, Janet <[redacted]>
Sent: Saturday, July 17, 2021 11:51 AM
To: Sheehy, Janice <[redacted]>
Subject: RE: Vaccine Review

Hold off on responding. jw

From: Sheehy, Janice <[redacted]>
Sent: Friday, July 16, 2021 6:58 PM
To: Woodcock, Janet <[redacted]>; Tierney, Julia <[redacted]>
Cc: Copeland, Jakea <[redacted]>
Subject: RE: Vaccine Review

Hi, please see Marion's email below. Thanks! -j

-----Original Appointment-----
From: Gruber, Marion <[redacted]>
Sent: Friday, July 16, 2021 6:45 PM
To: Sheehy, Janice; Olivarria, Frank; Goldie, Christina; Copeland, Jakea
Subject: Accepted: Vaccine Review
When: Monday, July 19, 2021 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Please see Zoom below

Dear Janet,
Thanks for the invitation. Would it be possible to extent this invitation to my deputy, Dr. Philip Krause ?
Marion

From: Sheehy, Janice
To: Tierney, Julia
Subject: RE: Vaccine Review
Date: Friday, July 16, 2021 7:08:38 PM

Ok thank you.

From: Tierney, Julia [redacted]>
Sent: Friday, July 16, 2021 7:00 PM
To: Sheehy, Janice <[redacted]>
Subject: RE: Vaccine Review
I'm going to defer to JW on this.

From: Sheehy, Janice <[redacted]>
Sent: Friday, July 16, 2021 6:58 PM
To: Woodcock, Janet <[redacted]>; Tierney, Julia <[redacted]>
Cc: Copeland, Jakea <[redacted]>
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Where: Please see Zoom below
Dear Janet,
Thanks for the invitation. Would it be possible to extent this invitation to my deputy, Dr. Philip Krause ?
Marion

Gruber, Marion

From: Gruber, Marion
Sent: Wednesday, July 21, 2021 11:59 AM
To: Marks, Peter; Woodcock, Janet
Cc: Tierney, Julia; Krause, Philip
Subject: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Janet and Peter,

The following summarizes my understanding of the July 19, 2021, 8:30 am meeting held between you, Phil Krause, Julie Tierney and myself to discuss the review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine. During this meeting, I made reference to the memo that Dr. Krause and I composed and sent to Dr. Marks on July 15, 2021, delineating OVRR's rationale for why the review timeline and target action due date, September 15, 2021, for this BLA cannot be compressed further. To recap, that memo stated that the review requires a thorough evaluation and FDA's own analysis of the safety, effectiveness and manufacturing information submitted to support licensure of this vaccine. This has been OVRR's standard for all other BLAs, and while time-consuming, OVRR believes that public confidence in COVID-19 vaccines would not be served by rushing our review and evaluation of the submitted data. In addition, Dr. Krause and I pointed out the very important regulatory issues that still need to be settled by the time we take action on this BLA—including the pediatric plan — which is becoming increasingly complex in light of increasing evidence of association of this vaccine and development of myocarditis (especially in young males, but also ages included in the BLA indication). This also impacts the finalization of post-marketing requirements and post-marketing commitments. In addition, there are pending information requests to the sponsor, and there will likely be additional information requests based on ongoing review of the data, and the timing of the sponsor response is beyond CBER control.

I reiterated during our meeting that OVRR is targeting September 15, 2021, as the date we will be taking regulatory action, which is less than 4 months from the date the last section of the BLA was submitted. Thus, we will be reviewing this complex BLA with a large amount of data, in a third of the time typically allowed for a BLA standard application and in less than half the time allocated for a priority review application. In response to your questions, I described OVRR's BLA review assignment processes. I emphasized that for this particular BLA, we assigned two experienced medical officers to this file who are working closely with the data analytics team in CDER-OCS and three statisticians from CBER/OBE who are supporting these review efforts. I did not emphasize this during our meeting, but you should also know that our typical review process includes frequent formal and informal communications with managers at all levels and other OVRR experts not directly assigned to the review team. I reiterated that adding staff to this review at this advanced stage would likely slow down the review due to the need to bring new people up to speed. You inquired whether we need additional help and also asked about the expertise of MOs assigned to this file noting that there would be staff in FDA, e.g., pediatric cardiologist that could assist in the review. You expressed concern about the rising COVID-cases in the US and globally, largely caused by the Delta variant and stated your opinion that, absent a license, states cannot require mandatory vaccination and that people hesitant to get an EUA authorized vaccine would be more inclined to get immunized when the product is licensed. You emphasized your interest in licensing this vaccine as soon as possible—a goal that we agree with. We too are concerned about the rising COVID-19 cases in the US, however, our concern is that a review that is hyper-accelerated beyond the already very rapid September 15 target date and as a consequence, may be less thorough than our typical review seems more likely to undermine confidence in the vaccine (and, indeed, in FDA's credibility) than to increase it.

You informed us of your decision that OVRR management and oversight of the BLA review will be delegated to Dr. Marks who will provide you with weekly updates on the review process and ensure that due diligence is exercised while I am away on annual leave. You also informed me that Dr. Krause will not be involved in the BLA oversight as he will be overseeing other regulatory and programmatic programs in OVRR. I expressed my disagreement with these decisions

because standard procedures are for the deputy Office Director to assume an Acting Role when the Office Director is out of the Office. I note that Dr. Krause is a recognized expert in vaccine regulation, development and very familiar with the scientific and clinical issues presented by this specific vaccine product and that the review team relies on his expertise and guidance.

I would also like to emphasize OVRR staff's dedication and experience in promoting public health by making safe and effective vaccines available for use in the United States. Since I believe we all agree in the importance both of a rapid decision and a thorough scientific and credible review, Dr. Krause and the OVRR staff will stand ready to assist in any way possible to achieve both of these goals. Please confirm that this summary reflects your recollection of this meeting. If it does not, I would appreciate your letting me know any specific areas where your recollection is different.

Thank you,
Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
[redacted]

Tel.: [redacted]
Email: [redacted]

FDA U.S. FOOD & DRUG ADMINISTRATION

Gruber, Marion

From: Woodcock, Janet
Sent: Wednesday, July 21, 2021 2:09 PM
To: Gruber, Marion
Cc: Krause, Philip; Marks, Peter; Tierney, Julia
Subject: Re: Your email on Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Marion,

Thank you so much for your email. I appreciate you taking the time to speak on Monday, and appreciate you summarizing our conversation.

To begin with, let me express my sincere thanks for your leadership and for the hard work of the Office of Vaccines over the past year and half. Your efforts have made a tremendous difference in combating this pandemic.

It's clear that we are all in agreement about the public need to license the vaccine as soon as possible. This is a once in a lifetime public health crisis and probably the most important application we will all be involved in. With this public health imperative in mind, as well as the intensifying problem of vaccine hesitancy, we all also agree about the importance of not only reviewing this BLA as efficiently as possible, but also ensuring that it is done thoroughly and in keeping with FDA's high standards that protect and promote the public health. With respect to the specific timeline for completion that you propose, I do not have enough information to venture an opinion. I have asked Peter to become familiar with the details of the various elements of the review process and to work with the team to identify potential efficiencies, which they can report back to me during status updates. I also reiterate my offer to provide any resources that the Agency has to assist in components of the review.

Finally, Marion, I offer you and your family my best wishes.

Janet

From: Sheehy, Janice
To: Tierney, Julia; Woodcock, Janet
Subject: RE: Vaccine Review
Date: Saturday, July 17, 2021 4:37:50 PM

Will do, thanks! -j

From: Tierney, Julia [redacted]
Sent: Saturday, July 17, 2021 2:28 PM
To: Sheehy, Janice [redacted]; Woodcock, Janet [redacted]
Subject: RE: Vaccine Review
Janice – I spoke with Janet, please extend the invitation to Phil Krause.
Thanks,
Julie

From: Sheehy, Janice [redacted]
Sent: Saturday, July 17, 2021 12:52 PM
To: Woodcock, Janet [redacted]
Cc: Tierney, Julia [redacted]
Subject: RE: Vaccine Review
Thank you, will do.

From: Woodcock, Janet [redacted]
Sent: Saturday, July 17, 2021 11:51 AM
To: Sheehy, Janice [redacted]
Subject: RE: Vaccine Review
Hold off on responding. jw

From: Sheehy, Janice [redacted]
Sent: Friday, July 16, 2021 6:58 PM
To: Woodcock, Janet [redacted]; Tierney, Julia [redacted]
Cc: Copeland, Jakea [redacted]
Subject: RE: Vaccine Review
Hi, please see Marion's email below. Thanks! -j
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Subject: Accepted: Vaccine Review
When: Monday, July 19, 2021 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Please see Zoom below
Dear Janet,
Thanks for the invitation. Would it be possible to extent this invitation to my deputy, Dr. Philip Krause ?
Marion

From: Sheehy, Janice
To: Tierney, Julia
Subject: RE: Vaccine Review
Date: Friday, July 16, 2021 7:08:38 PM

Ok thank you.

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Sent: Friday, July 16, 2021 7:00 PM
To: Sheehy, Janice [redacted]
Subject: RE: Vaccine Review

I'm going to defer to JW on this.

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Where: Please see Zoom below

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Marion

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 7/21/2021 12:10:03 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Julie,

I vote no. Thanks.

Best Regards,
Peter

From: Tierney, Julia [redacted]
Sent: Wednesday, July 21, 2021 12:07 PM
To: Woodcock, Janet [redacted]; Marks, Peter [redacted]
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

I'm attaching my summary of the meeting for your records. Please let me know if you would like me to circulate to Marion.

From: Gruber, Marion [redacted]
Sent: Wednesday, July 21, 2021 11:59 AM
To: Marks, Peter [redacted]; Woodcock, Janet [redacted]
Cc: Tierney, Julia [redacted]; Krause, Philip [redacted]
Subject: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

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Thank you,
Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel: [redacted]
Email: [redacted]

FDA U.S. FOOD & DRUG ADMINISTRATION

To: File

From: Julia Tierney, JD, Acting Chief of Staff

Date: July 21, 2021

Re: July 19, 2021 Meeting with CBER regarding Review of Biologics License Application for Pfizer/BioNTech COVID-19 Vaccine

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On July 19, 2021, Dr. Woodcock, Acting Commissioner of Food and Drugs, and I met with Dr. Peter Marks, Director, Center for Biologics Evaluation and Research (CBER), Dr. Marion Gruber, Director, Office of Vaccine Research and Review (OVRR) in CBER, and Dr. Philip Krause, Deputy Director, OVRR/CBER to discuss the process for review of the Biologics License Application (BLA) for the Pfizer/BioNTech COVID-19 Vaccine.

The meeting began with a discussion of the review process for BLAs in CBER in general and with respect to the Pfizer/BioNTech BLA. Dr. Woodcock asked questions about the structure and staffing of the BLA Review Committee, to which Dr. Gruber responded. Dr. Gruber stressed the complexity of the additional data generated after the EUA issuance that were submitted to the underlying IND, including safety data, and the need to have multiple experienced reviewers for disciplines such as medical officers and statisticians. Dr. Gruber referred to a memo she had provided to Dr. Marks regarding the anticipated timeframe to complete review of the BLA by September 15; Dr. Woodcock acknowledged that Dr. Marks had shared the memo. Dr. Gruber stated that she believed OVRR couldn't compress the review further. Dr. Woodcock asked question about any plans to leverage additional resources from other parts of the agency, such as consults from subject matter experts on CDER's computational science team or pediatric cardiologists in CDER and Commissioner's office. Dr. Gruber acknowledged that they had consulted with some staff in CDER, but not done so widely.

Dr. Krause reiterated many of Dr. Gruber's concerns, stressing that if the review is not thorough, it will further undermine vaccine confidence. He also described some of the additional data that had been submitted since issuance of the EUA, as well as other administrative steps that need to occur.

Dr. Woodcock thanked Dr. Gruber and Dr. Krause for their explanation of the issues associated with the BLA review and stressed the public health importance of this review, including the importance of performing a thorough review. She further stated that she is aware that Dr. Gruber has a [redacted] and will be out of the office for several weeks in July and August. Dr. Gruber acknowledged that she would be out of the office during this time and planned for Dr. Krause to be Acting Director of OVRR in her absence. Dr. Gruber raised that there may be political pressure at play.

Dr. Woodcock emphasized that she has not felt any political pressure, but feels the public health imperative associated with completing the review of the BLA and potentially have a licensed vaccine available. To this end, given the importance of this BLA, while Dr. Gruber is out of office, Dr. Woodcock explained, she is assigning Dr. Marks to lead on the Pfizer/BioNTech BLA, and Dr. Krause will be the Acting Director of OVRR and lead on all other files. Dr. Woodcock reiterated the public health need to complete this review. She will hold Dr. Marks accountable for completing the review as quickly as possible, while performing a thorough review that meets FDA's standards. Dr. Woodcock offered all of the resources of the Agency to get this done as timely as possible. Dr. Woodcock asked that Dr. Gruber transfer leadership of the BLA to Dr. Marks over the next week or two.

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 7/21/2021 2:25:03 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
CC: Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Your email on Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Marion,

I don't have much to add to Janet's response below, except to echo her gratitude for all of your work and to say that I remain absolutely committed to ensuring that we maintain our high quality standards in any work undertaken to further expedite the BLA review.

Thank you again.

Best Regards,
Peter

From: Woodcock, Janet [redacted]
Sent: Wednesday, July 21, 2021 2:09 PM
To: Gruber, Marion [redacted]
Cc: Krause, Philip [redacted] Marks, Peter [redacted] Tierney, Julia [redacted]
Subject: Re: Your email on Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Marion,

Thank you so much for your email. I appreciate you taking the time to speak on Monday, and appreciate you summarizing our conversation.

To begin with, let me express my sincere thanks for your leadership and for the hard work of the Office of Vaccines over the past year and half. Your efforts have made a tremendous difference in combating this pandemic.

It's clear that we are all in agreement about the public need to license the vaccine as soon as possible. This is a once in a lifetime public health crisis and probably the most important application we will all be involved in. With this public health imperative in mind, as well as the intensifying problem of vaccine hesitancy, we all also agree about the importance of not only reviewing this BLA as efficiently as possible, but also ensuring that it is done thoroughly and in keeping with FDA's high standards that protect and promote the public health. With respect to the specific timeline for completion that you propose, I do not have enough information to venture an opinion. I have asked Peter to become familiar with the details of the various elements of the review process and to work with the team to identify potential efficiencies, which they can report back to me during status updates. I also reiterate my offer to provide any resources that the Agency has to assist in components of the review.

Finally, Marion, I offer you and your family my best wishes.

Janet

From: Sly, Elizabeth
To: Sly, Elizabeth
Subject: FW: Request for as meeting
Date: Tuesday, March 7, 2023 5:46:37 PM
Attachments: image001.png

From: Gruber, Marion [redacted]
Sent: Friday, August 13, 2021 6:29 PM
To: Marks, Peter [redacted]
Subject: RE: Request for as meeting

Dear Peter,
Next Thursday at noon works! see you then.
Marion

From: Marks, Peter [redacted]
Sent: Friday, August 13, 2021 3:41 PM
To: Gruber, Marion [redacted]
Subject: RE: Request for as meeting

Dear Marion,

No problem. I was planning on being at FDA starting late morning on Thursday. Could noon on Thursday work for you?

In the meantime, I hope that [redacted]

Your team in vaccines is amazing.

Best Regards,
Peter

From: Gruber, Marion [redacted]
Sent: Friday, August 13, 2021 2:21 PM
To: Marks, Peter [redacted]
Subject: Request for as meeting

Dear Peter,
Are you planning to be at the WO campus next week? I would like to talk to you and I would prefer an in-person meeting if at all possible.
Please let me know and I will schedule around your availability.
Thanks,
Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: [redacted]
Email: [redacted]

From: Sly, Elizabeth
To: Sly, Elizabeth
Subject: FW: Retirements
Date: Tuesday, March 7, 2023 5:47:11 PM

From: Krause, Philip [redacted]
Sent: Monday, August 30, 2021 7:40 AM
To: Marks, Peter [redacted]
Cc: Gruber, Marion [redacted]
Subject: Retirements

Hi Peter,

Marion mentioned over the weekend that she told you about her plans. I wanted to urgently provide you with information that I suspect will be useful for you going forward. I would have preferred to see you in person for this— but I also don't want to cause unnecessary delays as you make plans for the Office.

I am in a very similar position to Marion. [redacted] the public health crisis and the opportunity to make a big difference [redacted] — and I am very proud to have been part of the amazing work that OVRR has done. However, we've now accomplished some of the more complex public health and regulatory goals and I am [redacted] I have been planning to [redacted]

So I am writing to let you know formally that I will also retire as of [redacted] I know that this will be a tough time for the Office, and am ready to help with the transition in any way possible.

I'm dealing with [redacted] but would be happy to talk about the situation after that if you would like to.

Best regards,
Phil

From: Brand, Anstice M. (CDC/OD/CDCWO)
To: Morelli, Jeff (CDC/DDID/NCEZID/DFWED); Oliver, Angela (CDC/DDID/NCEZID/OD); Serna, Christina (CDC/OD/CDCWO)
Cc: Brand, Anstice M. (CDC/OD/CDCWO)
Subject: Notes from Massie call with Dr. Schuchat.
Date: Wednesday, January 20, 2021 3:15:20 PM

Massie: I contacted Anstice and Dr. Cohn and was given the impression that you would fix the language but it is still on the website. Getting anecdotal information that this misinformation is being propogated and young people who have had infection are getting the vaccine. I know this is not correct. There is a messaging aspect, but there is also a science aspect. The folks who want to do the messaging are pressuring the people doing the science not to correct the document. The CDC can do whatever messaging they want, but they cannot propagate false information. I am really disappointed this has gone on a month without getting fixed – if it is the CDC's position to cover this up – then I will make this public.

AS: Thank you for explaining the issues and concerns. There is no desire to cover this up – this was an honest mistake. There are two tables. As you note correctly, there is not sufficient information to say that

I apologize for the delay. The information that is written for the public as opposed to what is in the detailed ACIP review of the data. There is nowhere in the public facing plain language information that includes that language. Logistically having to screen people doesn't make sense in a large scale vaccination effort. What you are getting at in a supply constrained environment is everyone's concern and this statement could lead to confusion. There is an ability to get an erratum out there. It is just a matter of competing priorities. We are also in the midst of convening post marketing trials. Even in the previous large study, potentially in post marketing study, there might be enough information to be able to talk about effectiveness in subgroups. Really apologize about the confusion.

TM: Going forward – will there be an errata issued?

AS: Our MMWR as a medical professional journal. The editor will decide whether it is published as an errata. Whatever they do when you click on it, it will show what the correction was. I take your concern seriously. We regularly update clinical guidance – most people don't go to these specific statements. Really what is used by Drs. and Nurses and pharmacists is the clinical guidance is what do you do in these specific instances – this guidance is being updated to include information about this issue. Scientifically, there is a lot of interest into whether people who have had prior infection are at risk for the new variant. Raising concerns that whatever immunity you have from prior infection you might be at additional risk. Existing information is that reinfection risk has been low, not non-existent, but new variant might mean something else. So two courses – one might be a correction or errata whatever the editor decides is appropriate, and then updated clinical guidance. Since initial vx was available, there have been differences in states – trying to get it to work more smoothly including that those at greatest risk are getting the vaccine.

TM: What is the timeline – I have waited over a month.

AS: I don't have dates – but will follow up.

TM: I will call you tomorrow.

AS: You are saying this is getting picked up – can you tell me where – because that would be helpful.

TM: Don't know if it is possible to fix all of this information – there is a you tube video where Dr. Cohn interviewed two or three other doctors. There are a few slide shows.

AS: I don't have access to unpublished data so need to look at that.

TM: Have been subsequent comments. The science here – it doesn't make sense to debate the knowable. If we could acknowledge this and just move on. The trial did not show efficacy.

AS: Yes, it was not powered to do that.

TM: So to say that it did is just wrong. It was suggested to me it was just wordsmithing, but in fact you cannot. …"" It's not like – it would be analogous to find out the vx trial doesn't do anything for AA, but then you say it was 92% efficacious for all races, even though there was no evidence. It's just not right to put evidence of prior infection in that sentence. It was meant to say something scientific. I would like to see how this is going to be fixed. This information is sitting on the CDC website. One of my friends is governor Ron Desantis. I will let him know this is sitting on the CDC website incorrectly. There will be debates about whether this vaccine will be mandatory or not. It needs to be fixed. The longer we go without fixing this the more it gets propagated.

AS: One thing I would like to ask is that you not propagate this yourself. If you find other areas where you find the language please let us know. I think you can probably appreciate that we want people to get vaccinated, so there wasn't a requirement for ruling out prior infection, but we weren't trying to push people to do this.

TM: That depends on the timing, if this had been fixed a month ago this would have been off my radar. We are in this period of time when vx are limited. I know people who know they have had COVID before and have had a positive PCR and they are getting the vaccine. I also know people who have missed their opportunity. I don't want to wait two more weeks for that.

AS: I will look into the timing. The reality is they aren't overnight.

TM: I understand there are two regimes – public policy and there is science. The science cannot follow the public policy.

AB: We will follow up.

Highly Sensitive/Recipients Only

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Sat, 23 Jan 2021 04:26:17 +0000
To: [redacted]
Subject: RE: CDC COVID Vaccine recommendations

Congressman Massie, as promised, I am sending the following link to our updated clinical guidance on COVID vaccine. As we discussed, (among other changes) the guidance updates language on vaccination of people with a history of SARS-CoV-2 infection to say, "...**while vaccine supply remains limited**, persons with recent documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired, recognizing that the risk of reinfection, and therefore the need for vaccination, may increase with time following initial infection."

Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine | CDC

I hope you have a nice weekend,

Anstice

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Thursday, January 21, 2021 4:31 PM
To: [redacted]
Subject: RE: CDC COVID Vaccine recommendations

Congressman Massie, here is a link to the MMWR with the change. And following is an excerpt. Note that in the online version the change is highlighted and at the top there is a note about the upcoming erratum.

Here is the note on the erratum:

Weekly / December 18, 2020 / 69(50);1922-1924

On December 13, 2020, this report was posted online as an MMWR *Early Release.*

***Please note:** This report has been corrected. An erratum will published.*

Here is the excerpted paragraph (I included the whole paragraph so you can see the highlight):

The body of evidence for the Pfizer-BioNTech COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase II/III clinical trial that enrolled >43,000 participants (median age = 52 years, range = 16–91 years) (*5,6*). Interim findings from this clinical trial, using data from participants with a median of 2 months of follow-up, indicate that the Pfizer-BioNTech COVID-19 vaccine was 95.0% effective (95% confidence interval = 90.3%–97.6%) in preventing symptomatic laboratory-confirmed COVID-19 in

persons without evidence of previous SARS-CoV-2 infection. start highlightConsistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection. Although numbers of observed hospitalizations and deaths were low, the available data were consistent with reduced risk for these severe outcomes among vaccinated persons compared with that among placebo recipients. Among vaccine recipients, reactogenicity symptoms, defined as solicited local injection site or systemic reactions during the 7 days after vaccination, were frequent and mostly mild to moderate. Systemic adverse reactions were more commonly reported after the second dose than after the first dose and were generally more frequent and severe in persons aged 18–55 years than in those aged >55 years. Systemic adverse reactions had a median onset of 1–2 days after vaccine receipt and resolved in a median of 1 day. Severe local and systemic adverse reactions (grade ≥3, defined as interfering with daily activity) occurred more commonly in vaccine recipients than in placebo recipients. Among vaccine recipients, 8.8% reported any grade ≥3 reaction; the most common symptoms were fatigue (4.2%), headache (2.4%), muscle pain (1.8%), chills (1.7%), and injection site pain (1.4%). Generally, grade ≥3 reactions were more commonly reported after the second dose than after the first dose and were less prevalent in older than in younger participants. Serious adverse events were observed in a similar proportion of vaccine (0.6%) and placebo (0.5%) recipients and encompassed medical events occurring at a frequency similar to that within the general population (6). No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, underlying medical conditions, or previous SARS-CoV-2 infection. A detailed summary of safety data, including information on reactogenicity, is available at https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/reactogenicity.html.

Thanks!

Anstice

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Thursday, January 21, 2021 1:33 PM
To: [redacted]
Subject: RE: CDC COVID Vaccine recommendations

Congressman, I wanted to give you an update on the erratum for the MMWR.

We will be issuing an erratum to the December 18 MMWR. We plan to post the actual correction online this afternoon at 4pm. The erratum will be published in the MMWR that comes out at 1pm on 1/28 (it is technically the 1/29 issue). I will share the updated post as soon as I have it.

Thanks again for your careful consideration of these issues,

Anstice

Anstice Brand Kenefick
Acting Director
CDC Washington Office
[redacted]
www.cdc.gov/washington

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Wednesday, January 20, 2021 10:47 AM
To: [redacted]
Subject: CDC COVID Vaccine recommendations

Good morning Congressman Massie, would you be available for a call with our Deputy Director, Dr. Anne Schuchat this afternoon at either 2 or 2:30pm?

Thanks so much,

Anstice

Anstice Brand Kenefick
Acting Director
CDC Washington Office
[redacted]
www.cdc.gov/washington

From: Schuchat, Anne MD (CDC/OD)
Sent: Wed, 20 Jan 2021 14:24:12 +0000
To: Berger, Sherri (CDC/OCOO/OD);Brand, Anstice M. (CDC/OD/CDCWO)
Subject: RE: Rep. Massie

Anstice – later today am happy to have a call w you and after I get a little more up to speed could speak w Rep. Massie directly. Trying to understand what his motivation for concern is which is difficult to see in the summary.

From: Berger, Sherri (CDC/OCOO/OD) [redacted]
Sent: Wednesday, January 20, 2021 8:46 AM
To: Brand, Anstice M. (CDC/OD/CDCWO) [redacted] Schuchat, Anne MD (CDC/OD) [redacted]
Subject: RE: Rep. Massie

+Anne, I will speak to you after our 9AM

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Wednesday, January 20, 2021 8:45 AM
To: Berger, Sherri (CDC/OCOO/OD) [redacted]
Subject: FW: Rep. Massie

Per our discussion.

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Tuesday, January 19, 2021 5:01 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted] Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted] Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

Just hung up with Rep. Massie. He reiterated his concern that the sentence isn't accurate and said his concern is that the MMWR states that the Pfizer vaccine has consistent 92% efficacy across several groups including in people with prior SARS-CoV-2 infection and he says the data does not support that claim. I told him (after basically saying the following) I would have to get back to him on specifics about the data and why we don't think it is technically inaccurate.

- Most important to get to your concern first – we expect to publish additional guidance this week that continues to promote the option for people who have had prior COVID infection to defer vaccination in the context of limited supply.
- We want people to get vaccinated and in the context of sufficient supply encourage people with prior infection to get vaccinated.

- Re: The sentence in the December 18 MMWR – we are evaluating from a public health perspective whether the benefit of changing the language outweighs the potential it will cause additional confusion.
- We view the language as a secondary point and doesn't directly inform whether a person should We don't believe the language is inaccurate, but could have been more clearly worded.
- In addition we are not hearing from States or others that they are confused on this point.

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Tuesday, January 19, 2021 3:49 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD[redacted]
Cc: Serna, Christina (CDC/OD/CDCWO)[redacted]; Protzel Berman, Pamela (ATSDR/OPPE)[redacted]; Oliver, Angela (CDC/DDID/NCEZID/OD)[redacted]; Morelli, Jeff (CDC/DDID/NCEZID/DFWED)[redacted]
Subject: RE: Rep. Massie

Here is the language from both the MMWRs:

From the December 18 MMWR (which was a December 13 early release):
"Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection."
We agreed with him on our call that this would have been more clearly stated: "Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with or without evidence of previous SARS-CoV-2 infection."

From the January 1st MMWR (which was a December 18 early release):
"High efficacy (≥86%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions."

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Tuesday, January 19, 2021 2:53 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD)[redacted]
Cc: Serna, Christina (CDC/OD/CDCWO)[redacted]; Protzel Berman, Pamela (ATSDR/OPPE)[redacted]; Oliver, Angela (CDC/DDID/NCEZID/OD)[redacted]; Morelli, Jeff (CDC/DDID/NCEZID/DFWED)[redacted]
Subject: RE: Rep. Massie

I just talked with him. He is concerned as he is stating this was an error (misrepresents the data) and he believes it is resulting in people with prior infection being misled into getting the vaccine ahead of people who need it more. I think I need to walk through the language in both MMWRs and get back to him with an update. It seems to me like the underlying issue is (and I said this on my call with him) it doesn't matter whether or not someone has had infection already, we still recommend they get the vaccine. The point of the sentence in the MMWR was to say that there was no difference in efficacy of vaccine between people who had already had COVID infection and those who had not. Right?

If you prefer I do that with someone else, I understand – but thought it might be helpful if we could talk quickly since you have the background. Attaching my notes for all as a refresher.

Thanks!

Anstice

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Sent: Tuesday, January 19, 2021 2:29 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted]; Protzel Berman, Pamela (ATSDR/OPPE) [redacted]; Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted]; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massey

Hi Anstice,
There was not an erratum made to the one he mentioned (it technically was not an error, but was confusing language), but it was clarified in the updated MMWR the next week and in all places on our website.

Thanks,
Amanda

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Tuesday, January 19, 2021 2:25 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted]; Protzel Berman, Pamela (ATSDR/OPPE) [redacted]; Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted]; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: Rep. Massey

Hi Amanda, hope you are well. I just heard that Rep. Massey is calling again – I don't know about what yet, but wondered if we ever issued a correction from the MMWR we discussed with him.

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Sent: Mon, 1 Feb 2021 17:27:53 +0000
To: Nordlund, Kristen (CDC/DDID/NCIRD/OD);Cohn, Amanda (CDC/DDID/NCIRD/OD);Brand, Anstice M. (CDC/OD/CDCWO)
Subject: FW: Request for Comment - Report Correction

Passing this along. Let me know how you would like me to handle this.

Sara

From: Zack Stieber [redacted]
Sent: Monday, February 1, 2021 12:24 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Subject: Request for Comment - Report Correction

Hi Sara,

Good day, hope you're well.

A correction was issued for the Dec. 13 MMWR report you co-authored. It appeared to clarify that no efficacy was found among patients who had already been infected with COVID-19. However, it also says that "Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection."

What secondary analysis is this referring to? Please provide a link. Why wasn't a link included in the correction? Rep. Massie told me that you and other authors are "culpable for spreading misinformation that could negatively affect the distribution of the vaccine." Do you have a response?

Thanks,
Zack Stieber
The Epoch Times
[redacted]

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD)
Sent: Mon, 1 Feb 2021 17:40:02 +0000
To: Brand, Anstice M. (CDC/OD/CDCWO);Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD);Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: RE: Request for Comment - Report Correction

Thanks Anstice. We have a response that I'm going to run up for clearance.

Thanks,
Kristen

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Monday, February 1, 2021 12:39 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]; Nordlund, Kristen (CDC/DDID/NCIRD/OD) [redacted] Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Subject: RE: Request for Comment - Report Correction

Kristen, I would recommend looping in Dr. Schuchat and Sherri Berger. Dr. Schuchat also spoke with Rep. Massie and may want to provide input on the response.

Thanks,

Anstice

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Monday, February 1, 2021 12:28 PM
To: Nordlund, Kristen (CDC/DDID/NCIRD/OD) [redacted] Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]; Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Subject: FW: Request for Comment - Report Correction

Passing this along. Let me know how you would like me to handle this.

Sara

From: Zack Stieber [redacted]
Sent: Monday, February 1, 2021 12:24 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Subject: Request for Comment - Report Correction

Hi Sara,

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that "Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection."

What secondary analysis is this referring to? Please provide a link. Why wasn't a link included in the correction? Rep. Massie told me that you and other authors are "culpable for spreading misinformation that could negatively affect the distribution of the vaccine." Do you have a response?

Thanks,
Zack Stieber
The Epoch Times
[redacted]

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Tue, 19 Jan 2021 20:47:11 +0000
To: Brand, Anstice M. (CDC/OD/CDCWO);Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Cc: Serna, Christina (CDC/OD/CDCWO);Protzel Berman, Pamela (ATSDR/OPPE);Oliver, Angela (CDC/DDID/NCEZID/OD);Morelli, Jeff (CDC/DDID/NCEZID/DFWED)
Subject: RE: Rep. Massie

I'm on another call now but should be done in a few minutes, does 4 pm work?

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Tuesday, January 19, 2021 3:45 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted] Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted] Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

That would be great. Can you talk now?

From: Cohn, Amanda (CDC/DDID/NCIRD/OD [redacted]
Sent: Tuesday, January 19, 2021 3:43 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) [redacted] Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted] Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

Anstice- Rep Massie actually called Sara Oliver on her cell, so we probably need to connect on this issue, we are not changing the language as it is not as well stated as it was prior but it is not an error. I don't know what next steps are but should we all connect?

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Tuesday, January 19, 2021 2:53 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted]; Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted] Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

I just talked with him. He is concerned as he is stating this was an error (misrepresents the data) and he believes it is resulting in people with prior infection being misled into getting the vaccine ahead of people who need it more. I think I need to walk through the language in both MMWRs and get back to him with an update. It seems to me like the underlying issue is (and I said this on my call with him) it

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Wed, 16 Dec 2020 22:04:59 +0000
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Subject: RE: Call from Rep. Massie (R-KY)

Perfect!

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Wednesday, December 16, 2020 4:46 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Subject: RE: Call from Rep. Massie (R-KY)

We pulled this from the FDA VRBPAC briefing document, attached. Data are limited but it isn't a typo.

Data are supported by the following statements:
Page 24:
For participants with and without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively (Table 7). The posterior probability was >99.99% for the true VE being greater than 30%. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%, indicating that the true VE is at least 89.9% with a 97.5% probability given the available data.

Page 28: FDA Interpretation of the data; Pfizer VRBPAC meeting
Only 3% of participants had evidence of prior infection at study enrollment, and additional analyses showed that very few COVID-19 cases occurred in these participants over the course of the entire study (9 in the placebo group and 10 in the BNT162b2 group, only 1 of which occurred 7 days or more after completion of the vaccination regimen – data not shown). The placebo group attack rate from enrollment to the November 14, 2020, data cut-off date was 1.3% both for participants without evidence of prior infection at enrollment (259 cases in 19,818 participants) and for participants with evidence of prior infection at enrollment (9 cases in 670 participants). While limited, these data do suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

Page 46: FDA Interpretation of the data; Pfizer VRBPAC meeting
Efficacy findings were also consistent across various subgroups, including racial and ethnic minorities, participants aged 65 years and older, and those with one or more of the following conditions: obesity, diabetes, hypertension, and chronic cardiopulmonary diseases. While limited, available data suggest that individuals with previous SARS-CoV-2 infection can be at risk of COVID-19 (i.e., re-infection) and may benefit from vaccination.

Helpful?
Sara

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Sent: Wednesday, December 16, 2020 4:30 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Subject: FW: Call from Rep. Massie (R-KY)

Can you help with this question below? I am so sorry…

From: Swartwood, Candice (CDC/DDID/NCIRD/OD) [redacted]
Sent: Wednesday, December 16, 2020 4:29 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Subject: RE: Call from Rep. Massie (R-KY)

Thanks. I will let you know if this moves forward. And note – he is asking if there is a typo in the MMWR (see highlighted part). I posted the link below.

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950e2-H.pdf?ACSTrackingID=USCDC_921-DM44546&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2069%2C%20December%2013%2C%202020&deliveryName=USCDC_921-DM44546

From: Cohn, Amanda (CDC/DDID/NCIRD/OD [redacted]
Sent: Wednesday, December 16, 2020 4:24 PM
To: Swartwood, Candice (CDC/DDID/NCIRD/OD) [redacted]
Cc: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted] CDC IMS 2019 NCOV Response VTF Policy [redacted]
Subject: RE: Call from Rep. Massie (R-KY)

Hi Candice- I can be free after 5:30 pm est. Let me know if that works

---

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Wednesday, December 16, 2020 1:48 PM
To: Serna, Christina (CDC/OD/CDCWO) [redacted]
Cc: Wortman, Eric (CDC/OD/CDCWO) [redacted]
Subject: Call from Rep. Massie (R-KY)

Just spoke with Congressman Massie (R-KY). He is asking if there is a typo in our MMWR from 12/13. Specifically he is concerned about the sentence: "Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection."

He doesn't believe there is enough evidence to make the statement about people with evidence of previous infection. He quoted from the VRBPAC slides:

- 1303 were enrolled in the trial with evidence of prior infection.
- 633 in vx group and 670 in placebo group.
- After first shot 10 subjects in vx group had COVID symptoms and 9 in placebo group.
- After second shot still 526 in vx group who had prior positive indicaction and one of those got covid.
- 576 with evidence of prior infection and one of those got COVID> Only 2 sample points one person in each.
- Probably cut and pasted from other sentence?

Slide deck from FDA Susan Wallersheim – Dec. 10th 60 + slides, page 25 and 30 – slide deck called Vx and related biological products Advisory Committee meetings. FDA review of efficacy and safety of Pfizer vx EUA request. Got it from CDC. Think it could be typo. It doesn't seem to be supported by the data. Important because we don't want people who have already had infection rushing to get the vaccine because we don't have evidence. Somewhere on CDC website it says people can wait three months post infection to get the vx.

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Sent: Tue, 19 Jan 2021 22:16:55 +0000
To: Brand, Anstice M. (CDC/OD/CDCWO);Cohn, Amanda (CDC/DDID/NCIRD/OD)
Cc: Serna, Christina (CDC/OD/CDCWO);Protzel Berman, Pamela (ATSDR/OPPE);Oliver, Angela (CDC/DDID/NCEZID/OD);Morelli, Jeff (CDC/DDID/NCEZID/DFWED)
Subject: RE: Rep. Massie

Just as an FYI: Rep Massie also called a contractor who works with ACIP, who is the 8th author on the MMWR (Doug Campos-Outcalt). I said not to engage, and that we were working on it through other channels. But just wanted you guys to be aware that the outreach is extending to other authors (and beyond the direct CDC authors).

Sara

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Tuesday, January 19, 2021 5:01 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

Just hung up with Rep. Massie. He reiterated his concern that the sentence isn't accurate and said his concern is that the MMWR states that the Pfizer vaccine has consistent 92% efficacy across several groups including in people with prior SARS-CoV-2 infection and he says the data does not support that claim. I told him (after basically saying the following) I would have to get back to him on specifics about the data and why we don't think it is technically inaccurate.

- Most important to get to your concern first – we expect to publish additional guidance this week that continues to promote the option for people who have had prior COVID infection to defer vaccination in the context of limited supply.
- We want people to get vaccinated and in the context of sufficient supply encourage people with prior infection to get vaccinated.
- Re: The sentence in the December 18 MMWR – we are evaluating from a public health perspective whether the benefit of changing the language outweighs the potential it will cause additional confusion.
- We view the language as a secondary point and doesn't directly inform whether a person should We don't believe the language is inaccurate, but could have been more clearly worded.
- In addition we are not hearing from States or others that they are confused on this point.

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To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE)

[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

Here is the language from both the MMWRs:

From the December 18 MMWR (which was a December 13 early release):
"Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection."
We agreed with him on our call that this would have been more clearly stated: "Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with or without evidence of previous SARS-CoV-2 infection."

From the January 1st MMWR (which was a December 18 early release):
"High efficacy (≥86%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions."

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Tuesday, January 19, 2021 2:53 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

I just talked with him. He is concerned as he is stating this was an error (misrepresents the data) and he believes it is resulting in people with prior infection being misled into getting the vaccine ahead of people who need it more. I think I need to walk through the language in both MMWRs and get back to him with an update. It seems to me like the underlying issue is (and I said this on my call with him) it doesn't matter whether or not someone has had infection already, we still recommend they get the vaccine. The point of the sentence in the MMWR was to say that there was no difference in efficacy of vaccine between people who had already had COVID infection and those who had not. Right?

If you prefer I do that with someone else, I understand – but thought it might be helpful if we could talk quickly since you have the background. Attaching my notes for all as a refresher.

Thanks!

Anstice

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Sent: Tuesday, January 19, 2021 2:29 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff

(CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massey

Hi Anstice,
There was not an erratum made to the one he mentioned (it technically was not an error, but was confusing language), but it was clarified in the updated MMWR the next week and in all places on our website.

Thanks,
Amanda

From: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Sent: Tuesday, January 19, 2021 2:25 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: Rep. Massey

Hi Amanda, hope you are well. I just heard that Rep. Massey is calling again – I don't know about what yet, but wondered if we ever issued a correction from the MMWR we discussed with him.

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD)
Sent: Mon, 1 Feb 2021 19:26:37 +0000
To: Brand, Anstice M. (CDC/OD/CDCWO)
Cc: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD);Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: RE: Request for Comment - Report Correction
Attachments: Full Measure Response 2 (002).docx

Anstice,

Attached is our response.

Thanks,
Kristen

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Monday, February 1, 2021 12:41 PM
To: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[redacted]>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted] Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Subject: RE: Request for Comment - Report Correction

Thanks Kristen, can you share?

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[redacted]>
Sent: Monday, February 1, 2021 12:40 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Subject: RE: Request for Comment - Report Correction

Thanks Anstice. We have a response that I'm going to run up for clearance.

Thanks,
Kristen

From: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Sent: Monday, February 1, 2021 12:39 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>; Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[redacted]>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Subject: RE: Request for Comment - Report Correction

Kristen, I would recommend looping in Dr. Schuchat and Sherri Berger. Dr. Schuchat also spoke with Rep. Massie and may want to provide input on the response.

Thanks,

Anstice

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Monday, February 1, 2021 12:28 PM
To: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[redacted]>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>; Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Subject: FW: Request for Comment - Report Correction

Passing this along. Let me know how you would like me to handle this.

Sara

From: Zack Stieber <[redacted]>
Sent: Monday, February 1, 2021 12:24 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>
Subject: Request for Comment - Report Correction

Hi Sara,

Good day, hope you're well.

A correction was issued for the Dec. 13 MMWR report you co-authored. It appeared to clarify that no efficacy was found among patients who had already been infected with COVID-19. However, it also says that "Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection."

What secondary analysis is this referring to? Please provide a link. Why wasn't a link included in the correction? Rep. Massie told me that you and other authors are "culpable for spreading misinformation that could negatively affect the distribution of the vaccine." Do you have a response?

Thanks,
Zack Stieber
The Epoch Times
[redacted]

In the Pfizer clinical trial, the attack rate of COVID-19 was the same for participants with or without prior infection. There were not enough participants who had previous disease based off antibody testing to determine if the vaccine works or not (persons with known previous disease were excluded from the study. Given that the vaccine is 94% effective when you look at both groups together, the data suggest the vaccine works well in both groups. The data also suggests that people who had COVID-19 before can still be at risk of reinfection and could benefit from vaccination. The clinical trials show the vaccine is safe for people who have had COVID-19 before.

Due to the severe health risks associated with COVID-19 and the fact that reinfection is possible, CDC recommends getting vaccinated regardless of whether you already had COVID-19 infection. Experts do not yet know how long someone is protected from getting sick again after recovering from COVID-19. However, because the risk of reinfection is low in the months after initial COVID-19 infection, while vaccine supply remains limited, people who have recent infection may choose to temporarily delay vaccination. Additionally, CDC's implementation phased implementation guidance provides on sub-prioritization considerations that indicate that when supply is limited vaccine should be prioritized to persons who do not have a history of documented acute SARS-CoV-2 infection in the preceding 90 days (https://www.cdc.gov/vaccines/covid-19/phased-implementation.html).

Our current understanding of COVID-19 suggests that the risk of reinfection is low in the months after initial infection but may increase over time. We won't know how long immunity produced by vaccination lasts until we have more data on how well the vaccines work. Anyone getting vaccinated after having COVID-19 vaccine should follow jurisdictional recommendations for who is eligible to get vaccinated. Please visit your state's website to see what phase of vaccination they are in.

From: Oliver, Angela (CDC/DDID/NCEZID/OD)
Sent: Tue, 19 Jan 2021 22:35:17 +0000
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD);Brand, Anstice M. (CDC/OD/CDCWO);Cohn, Amanda (CDC/DDID/NCIRD/OD)
Cc: Serna, Christina (CDC/OD/CDCWO);Protzel Berman, Pamela (ATSDR/OPPE);Morelli, Jeff (CDC/DDID/NCEZID/DFWED)
Subject: RE: Rep. Massie

Thanks for letting us know, Sara. Sorry this keeps happening. Jeff and I chatted with Anstice briefly and we think we'll need to do another call with the Representative to walk him through the data again. Amanda, would you be willing to jump on the phone with him again?

Angela Oliver, JD
Lead | Policy Unit
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
[redacted]

https://www.cdc.gov/COVID19

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Tuesday, January 19, 2021 5:17 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) [redacted] Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
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- Most important to get to your concern first – we expect to publish additional guidance this week that continues to promote the option for people who have had prior COVID infection to defer vaccination in the context of limited supply.
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(CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

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If you prefer I do that with someone else, I understand – but thought it might be helpful if we could talk quickly since you have the background. Attaching my notes for all as a refresher.

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Anstice

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Subject: RE: Rep. Massey

Hi Anstice,
There was not an erratum made to the one he mentioned (it technically was not an error, but was confusing language), but it was clarified in the updated MMWR the next week and in all places on our website.

Thanks,
Amanda

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Subject: Rep. Massey

Hi Amanda, hope you are well. I just heard that Rep. Massey is calling again – I don't know about what yet, but wondered if we ever issued a correction from the MMWR we discussed with him.

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Wed, 20 Jan 2021 14:00:22 +0000
To: Brand, Anstice M. (CDC/OD/CDCWO);Oliver, Angela (CDC/DDID/NCEZID/OD);Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Cc: Serna, Christina (CDC/OD/CDCWO);Protzel Berman, Pamela (ATSDR/OPPE);Morelli, Jeff (CDC/DDID/NCEZID/DFWED)
Subject: RE: Rep. Massie

It sounds like we can go ahead and move forward with the Erratum, can we just let him know that it is in process?

Thanks,
Amanda

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Tuesday, January 19, 2021 6:15 PM
To: Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted] Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted] Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

Yes, apologies for the multiple back and forth on this. I couldn't answer his detailed questions about the data in the Pfizer study and evidence to support the sentence in the MMWR that is the source of his concern. Amanda, is it possible to call him with me? We would need to make a plan in advance.

From: Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted]
Sent: Tuesday, January 19, 2021 5:35 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]; Brand, Anstice M. (CDC/OD/CDCWO) [redacted]; Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
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COVID-19 Response
Centers for Disease Control and Prevention (CDC)
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https://www.cdc.gov/COVID19

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Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

Just as an FYI: Rep Massie also called a contractor who works with ACIP, who is the 8th author on the MMWR (Doug Campos-Outcalt). I said not to engage, and that we were working on it through other channels. But just wanted you guys to be aware that the outreach is extending to other authors (and beyond the direct CDC authors).

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Sent: Tuesday, January 19, 2021 5:01 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>
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Subject: RE: Rep. Massie

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[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
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From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Sent: Wed, 20 Jan 2021 14:03:36 +0000
To: Cohn, Amanda (CDC/DDID/NCIRD/OD);Brand, Anstice M. (CDC/OD/CDCWO);Oliver, Angela (CDC/DDID/NCEZID/OD)
Cc: Serna, Christina (CDC/OD/CDCWO);Protzel Berman, Pamela (ATSDR/OPPE);Morelli, Jeff (CDC/DDID/NCEZID/DFWED)
Subject: RE: Rep. Massie

I will work with MMWR to get the erratum taken care of.

However, Anstice: if he calls you again to discuss the data, below is what is in the FDA VRPAC briefing document to support what is stated in the MMWR (and our policy of offering vaccine to individuals with prior infection). But hopefully the erratum will help with the calls.

Sara

Pfizer MMWR, VE among those with and without prior infection.
Data from the FDA VRBPAC Briefing document:

Page 24:
For participants with and without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively (Table 7).

Page 28:
Only 3% of participants had evidence of prior infection at study enrollment, and additional analyses showed that very few COVID-19 cases occurred in these participants over the course of the entire study (9 in the placebo group and 10 in the BNT162b2 group, only 1 of which occurred 7 days or more after completion of the vaccination regimen – data not shown). The placebo group attack rate from enrollment to the November 14, 2020, data cut-off date was 1.3% both for participants without evidence of prior infection at enrollment (259 cases in 19,818 participants) and for participants with evidence of prior infection at enrollment (9 cases in 670 participants). While limited, these data do suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

Page 46:
Efficacy findings were also consistent across various subgroups, including racial and ethnic minorities, participants aged 65 years and older, and those with one or more of the following conditions: obesity, diabetes, hypertension, and chronic cardiopulmonary diseases. While limited, available data suggest that individuals with previous SARS-CoV-2 infection can be at risk of COVID-19 (i.e., re-infection) and may benefit from vaccination.

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Sent: Wednesday, January 20, 2021 9:00 AM
To: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted] Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE)

[redacted] Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

It sounds like we can go ahead and move forward with the Erratum, can we just let him know that it is in process?

Thanks,
Amanda

From: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Sent: Tuesday, January 19, 2021 6:15 PM
To: Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

Yes, apologies for the multiple back and forth on this. I couldn't answer his detailed questions about the data in the Pfizer study and evidence to support the sentence in the MMWR that is the source of his concern. Amanda, is it possible to call him with me? We would need to make a plan in advance.

From: Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>
Sent: Tuesday, January 19, 2021 5:35 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>; Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

Thanks for letting us know, Sara. Sorry this keeps happening. Jeff and I chatted with Anstice briefly and we think we'll need to do another call with the Representative to walk him through the data again. Amanda, would you be willing to jump on the phone with him again?

Angela Oliver, JD
Lead | Policy Unit
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
[redacted]

https://www.cdc.gov/COVID19

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Tuesday, January 19, 2021 5:17 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff

(CDC/DDID/NCEZID/DFWED) [redacted]
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Subject: Rep. Massey

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From: Tatem, Anne (HHS/OS/ASL)
Sent: Wed, 20 Jan 2021 22:18:27 +0000
To: Brand, Anstice M. (CDC/OD/CDCWO)
Cc: Serna, Christina (CDC/OD/CDCWO)
Subject: Re: Call with Rep. Massie

Thanks for the heads up. Let me know if you need anything from me.

Sent from my iPhone

On Jan 20, 2021, at 3:54 PM, Brand, Anstice M. (CDC/OD/CDCWO) [redacted] wrote:

Anne, FYI...a month ago Dr. Amanda Cohn and I had a call with Rep. Thomas Massie of Kentucky re: a concern about language in an MMWR from December 13 that was inaccurate. We thought possibly it was just inartfully worded but was not entirely inaccurate. He called again yesterday and is raising concerns about the issue (including on twitter). After further consideration we have decided the sentence is inaccurate and we will issue some sort of correction (not sure what form). I wanted to let you know in case you hear anything more about it. I believe I was in touch with Sarah A at the time, but wanted you to be aware this issue is continuing. Dr. Schuchat spoke with Rep. Massie today. We are working on identifying how the statement will be corrected for the record. Let me know if you have any additional questions.

Anstice

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Wed, 20 Jan 2021 15:09:02 +0000
To: Schuchat, Anne MD (CDC/OD);Berger, Sherri (CDC/OCOO/OD)
Subject: RE: Rep. Massie

He told me his major concern is that the language as written is inaccurate (data in the MMWR does not support the statement that the vaccine is ≥92% effective in people with evidence of prior infection) and will lead to people with prior infection getting the vaccine while there is still limited supply instead of people who need it who have no immunity.

I heard from Amanda Cohn and Sara Elizabeth Oliver (in DVD and an author on the MMWR) they are discussing an erratum with Charlotte Kent. They also shared the following data from the FDA VRBPAC briefing document (see below in highlight). This language actually seems to support the statement in the MMWR – and suggest that while in-artfully worded, is technically accurate. I could call him back and convey this, but a) want to make sure that you are OK with the idea of an erratum, and b) also would be good to have someone who can get into the data in a more granular way than I feel comfortable doing. If you have time, it would be a nice way to show how seriously we take issues of scientific integrity.

A

Pfizer MMWR, VE among those with and without prior infection.
Data from the FDA VRBPAC Briefing document:

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From: Schuchat, Anne MD (CDC/OD) [redacted]
Sent: Wednesday, January 20, 2021 9:24 AM
To: Berger, Sherri (CDC/OCOO/OD) [redacted] Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Subject: RE: Rep. Massie

Anstice – later today am happy to have a call w you and after I get a little more up to speed could speak w Rep. Massie directly. Trying to understand what his motivation for concern is which is difficult to see in the summary.

From: Berger, Sherri (CDC/OCOO/OD) <[redacted]>
Sent: Wednesday, January 20, 2021 8:46 AM
To: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>; Schuchat, Anne MD (CDC/OD) <[redacted]>
Subject: RE: Rep. Massie

+Anne, I will speak to you after our 9AM

From: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Sent: Wednesday, January 20, 2021 8:45 AM
To: Berger, Sherri (CDC/OCOO/OD) <[redacted]>
Subject: FW: Rep. Massie

Per our discussion.

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Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
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From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Tue, 19 Jan 2021 20:09:51 +0000
To: Wortman, Eric (CDC/OD/CDCWO)
Subject: FW: Rep. Massie
Attachments: Call with Rep. Massie re: Question on MMWR Dec. 13 ACIP recommendation publication.

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Tuesday, January 19, 2021 2:53 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted] Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <zrc6@cdc.gov>
Subject: RE: Rep. Massie

I just talked with him. He is concerned as he is stating this was an error (misrepresents the data) and he believes it is resulting in people with prior infection being misled into getting the vaccine ahead of people who need it more. I think I need to walk through the language in both MMWRs and get back to him with an update. It seems to me like the underlying issue is (and I said this on my call with him) it doesn't matter whether or not someone has had infection already, we still recommend they get the vaccine. The point of the sentence in the MMWR was to say that there was no difference in efficacy of vaccine between people who had already had COVID infection and those who had not. Right?

If you prefer I do that with someone else, I understand – but thought it might be helpful if we could talk quickly since you have the background. Attaching my notes for all as a refresher.

Thanks!

Anstice

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Sent: Tuesday, January 19, 2021 2:29 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massey

Hi Anstice,
There was not an erratum made to the one he mentioned (it technically was not an error, but was confusing language), but it was clarified in the updated MMWR the next week and in all places on our website.

Thanks,

Amanda

From: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Sent: Tuesday, January 19, 2021 2:25 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: Rep. Massey

Hi Amanda, hope you are well. I just heard that Rep. Massey is calling again – I don't know about what yet, but wondered if we ever issued a correction from the MMWR we discussed with him.

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Thu, 17 Dec 2020 00:06:13 +0000
To: Oliver, Angela (CDC/DDID/NCEZID/OD);Protzel Berman, Pamela (ATSDR/OPPE)
Cc: Serna, Christina (CDC/OD/CDCWO)
Subject: Call with Rep. Massie re: Question on MMWR Dec. 13 ACIP recommendation publication.

Participants:

- Rep. Thomas Massie (R-KY)
- Dr. Amanda Cohn
- Anstice Brand

Follow up: Amanda will discuss possible erratum with MMWR editors and ensure it is corrected in the next publication which will have likely similar language. .

Discussion about Rep. Massie's question about the following sentence in the MMWR:
"Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection."

TM: Should say those "with and without and without evidence of previous SARS-CoV-2 infection." Similar number of participants in both categories.

AC: Trying to say – you don't need to test your antibodies before vx. It doesn't matter if you had prior infection. Word got taken out and no one picked up on it. Way answered – people who have had disease – suggesting people wait. But if you don't know whether you had it don't wait. Will soon have more data on people with prior infection. Our recommendations for vx in general are that people can. Evidence for safety is similar. We don't usually have limited doses.

TM: Wasn't designed for this – but I found interesting that it seemed there were higher rates of infection in those who had already had infection. It seems off that in the 50 overall cases in vx group – wait – 50 after first shot, 9 after second shot in the vaccine group who got covid. First group – in 50 who had COVID that got first shot 10 of 50 are people who had prior infection. 20%. What are the odds of that. Might just be people who are exposed to it more.

AC: Possibility – will do talk to company. Pre-tested – excluded those with active disease. People can go in and out of positivity – why they want to look at this longer term. Will be looking in post authorizations as well.

TM: How will you fix the sentence?

AC: We will talk to the MMWR staff tomorrow about the best way to do this – can publish an erratum or can fix it online. Usually fix online. Have another publication coming on Sunday for Moderna. It will be a similar statement.

TM: Hope I was helpful.

From: Morelli, Jeff (CDC/DDID/NCEZID/DFWED)
Sent: Wed, 20 Jan 2021 16:03:32 +0000
To: Brand, Anstice M. (CDC/OD/CDCWO)
Subject: RE: Rep. Massie

Good luck! It'll be interesting to hear how it goes. Enjoy watching the inauguration!

Jeff Morelli
Government Affairs and Policy Team | Policy Unit
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
[redacted]

https://www.cdc.gov/COVID19

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Wednesday, January 20, 2021 10:44 AM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>; Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted] Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted] Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

I spoke with Dr. Schuchat about this this morning. She and I will call Mr. Massie and hopefully this issue will be done. Thanks so much to everyone for all the work on this!

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Wednesday, January 20, 2021 9:04 AM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>; Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

I will work with MMWR to get the erratum taken care of.

However, Anstice: if he calls you again to discuss the data, below is what is in the FDA VRPAC briefing document to support what is stated in the MMWR (and our policy of offering vaccine to individuals with prior infection). But hopefully the erratum will help with the calls.

Sara

Pfizer MMWR, VE among those with and without prior infection.

Data from the FDA VRBPAC Briefing document:

Page 24:

For participants with and without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively (Table 7).

Page 28:

Only 3% of participants had evidence of prior infection at study enrollment, and additional analyses showed that very few COVID-19 cases occurred in these participants over the course of the entire study (9 in the placebo group and 10 in the BNT162b2 group, only 1 of which occurred 7 days or more after completion of the vaccination regimen – data not shown). The placebo group attack rate from enrollment to the November 14, 2020, data cut-off date was 1.3% both for participants without evidence of prior infection at enrollment (259 cases in 19,818 participants) and for participants with evidence of prior infection at enrollment (9 cases in 670 participants). While limited, these data do suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

Page 46:

Efficacy findings were also consistent across various subgroups, including racial and ethnic minorities, participants aged 65 years and older, and those with one or more of the following conditions: obesity, diabetes, hypertension, and chronic cardiopulmonary diseases. While limited, available data suggest that individuals with previous SARS-CoV-2 infection can be at risk of COVID-19 (i.e., re-infection) and may benefit from vaccination.

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Sent: Wednesday, January 20, 2021 9:00 AM
To: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

It sounds like we can go ahead and move forward with the Erratum, can we just let him know that it is in process?

Thanks,
Amanda

From: Brand, Anstice M. (CDC/OD/CDCWO) <[redacted]>
Sent: Tuesday, January 19, 2021 6:15 PM
To: Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

Yes, apologies for the multiple back and forth on this. I couldn't answer his detailed questions about the data in the Pfizer study and evidence to support the sentence in the MMWR that is the source of his concern. Amanda, is it possible to call him with me? We would need to make a plan in advance.

From: Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted]
Sent: Tuesday, January 19, 2021 5:35 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]; Brand, Anstice M. (CDC/OD/CDCWO) [redacted]; Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted]; Protzel Berman, Pamela (ATSDR/OPPE) [redacted]; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

Thanks for letting us know, Sara. Sorry this keeps happening. Jeff and I chatted with Anstice briefly and we think we'll need to do another call with the Representative to walk him through the data again. Amanda, would you be willing to jump on the phone with him again?

Angela Oliver, JD
Lead | Policy Unit
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
[redacted]

https://www.cdc.gov/COVID19

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Sent: Tuesday, January 19, 2021 5:17 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]; Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted]; Protzel Berman, Pamela (ATSDR/OPPE) [redacted]; Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted]; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

Just as an FYI: Rep Massie also called a contractor who works with ACIP, who is the 8th author on the MMWR (Doug Campos-Outcalt). I said not to engage, and that we were working on it through other channels. But just wanted you guys to be aware that the outreach is extending to other authors (and beyond the direct CDC authors).

Sara

From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Tuesday, January 19, 2021 5:01 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted] Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) [redacted]; Protzel Berman, Pamela (ATSDR/OPPE) [redacted] Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted]; Morelli, Jeff

(CDC/DDID/NCEZID/DFWED) [redacted]
Subject: RE: Rep. Massie

Just hung up with Rep. Massie. He reiterated his concern that the sentence isn't accurate and said his concern is that the MMWR states that the Pfizer vaccine has consistent 92% efficacy across several groups including in people with prior SARS-CoV-2 infection and he says the data does not support that claim. I told him (after basically saying the following) I would have to get back to him on specifics about the data and why we don't think it is technically inaccurate.

- Most important to get to your concern first – we expect to publish additional guidance this week that continues to promote the option for people who have had prior COVID infection to defer vaccination in the context of limited supply.
- We want people to get vaccinated and in the context of sufficient supply encourage people with prior infection to get vaccinated.
- Re: The sentence in the December 18 MMWR – we are evaluating from a public health perspective whether the benefit of changing the language outweighs the potential it will cause additional confusion.
- We view the language as a secondary point and doesn't directly inform whether a person should We don't believe the language is inaccurate, but could have been more clearly worded.
- In addition we are not hearing from States or others that they are confused on this point.

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Tuesday, January 19, 2021 3:49 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]
Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) [redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

Here is the language from both the MMWRs:

From the December 18 MMWR (which was a December 13 early release):
"Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection."
We agreed with him on our call that this would have been more clearly stated: "Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with or without evidence of previous SARS-CoV-2 infection."

From the January 1st MMWR (which was a December 18 early release):
"High efficacy (≥86%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions."

From: Brand, Anstice M. (CDC/OD/CDCWO)
Sent: Tuesday, January 19, 2021 2:53 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[redacted]>

Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: RE: Rep. Massie

I just talked with him. He is concerned as he is stating this was an error (misrepresents the data) and he believes it is resulting in people with prior infection being misled into getting the vaccine ahead of people who need it more. I think I need to walk through the language in both MMWRs and get back to him with an update. It seems to me like the underlying issue is (and I said this on my call with him) it doesn't matter whether or not someone has had infection already, we still recommend they get the vaccine. The point of the sentence in the MMWR was to say that there was no difference in efficacy of vaccine between people who had already had COVID infection and those who had not. Right?

If you prefer I do that with someone else, I understand – but thought it might be helpful if we could talk quickly since you have the background. Attaching my notes for all as a refresher.

Thanks!

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Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
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Cc: Serna, Christina (CDC/OD/CDCWO) <[redacted]>; Protzel Berman, Pamela (ATSDR/OPPE) <[redacted]>; Oliver, Angela (CDC/DDID/NCEZID/OD) <[redacted]>; Morelli, Jeff (CDC/DDID/NCEZID/DFWED) <[redacted]>
Subject: Rep. Massey

Hi Amanda, hope you are well. I just heard that Rep. Massey is calling again – I don't know about what yet, but wondered if we ever issued a correction from the MMWR we discussed with him.

From: Folkers, Greg (NIH/NIAID) [E]
Sent: Mon, 15 Mar 2021 23:03:18 +0000
To: Undisclosed recipients:
Subject: JAMA: Immunogenicity of a Single Dose of SARS-CoV-2 Messenger RNA Vaccine in Solid Organ Transplant Recipients

March 15, 2021

Immunogenicity of a Single Dose of SARS-CoV-2 Messenger RNA Vaccine in Solid Organ Transplant Recipients

Brian J. Boyarsky, MD[1]; William A. Werbel, MD[2]; Robin K. Avery, MD[2]; et al Aaron A. R. Tobian, MD, PhD[3]; Allan B. Massie, PhD[1]; Dorry L. Segev, MD, PhD[1]; Jacqueline M. Garonzik-Wang, MD, PhD[1]
Author Affiliations Article Information
JAMA. Published online March 15, 2021. doi:10.1001/jama.2021.4385

Immunocompromised individuals have been excluded from studies of SARS-CoV-2 messenger RNA (mRNA) vaccines. In such patients, the immune response to vaccination may be blunted. To better understand the immunogenicity of mRNA vaccines in immunocompromised individuals, we quantified the humoral response to the first dose in solid organ transplant recipients.

Methods

Transplant recipients across the US were recruited though social media to participate in this prospective cohort and those who underwent SARS-CoV-2 vaccination between December 16, 2020, and February 5, 2021, were included. The study was approved by the Johns Hopkins University institutional review board and participants provided informed consent electronically. Participants underwent either at-home blood sampling with the TAPII blood collection device (Seventh Sense Biosystems) or standard venipuncture. The TAPII samples were tested using an enzyme immunoassay (EUROIMMUN) that tests for antibodies to the S1 domain of the SARS-CoV-2 spike protein.[1] The venipuncture samples were tested using the anti–SARS-CoV-2 S enzyme immunoassay (Roche Elecsys) that tests for antibodies against the receptor-binding domain of the SARS-CoV-2 spike protein. Both tests are semiquantitative, correspond to mRNA vaccine antigens, and are consistently correlated with neutralizing immunity.[2-4] The sensitivity and specificity of the enzyme immunoassays are excellent for detection of the antispike humoral response to SARS-CoV-2 infection (sensitivity of 87.1% and specificity of 98.9% for EUROIMMUN[3] and sensitivity of 84.0% and specificity of 100% for Roche Elecsys[4]) and are analogous to the antispike antibody assays used during immunogenicity assessments in mRNA vaccine clinical trials.

We assessed the proportion of patients who developed a positive antibody response with exact binomial 95% CIs. We evaluated the associations among demographic and clinical characteristics, vaccine type, and positive antibody response using modified Poisson regression with a robust variance estimator. A sensitivity analysis of vaccine type limited to those tested 14 to 21 days after vaccination was performed. All tests were 2-sided with an α level of .05. Analyses were performed using Stata version 16.1 (StataCorp).

Results

There were 436 transplant recipients included in the study (Table). None had a prior polymerase chain reaction–confirmed diagnosis of COVID-19. The median age was 55.9 years (interquartile range [IQR], 41.3-67.4 years), 61% were women, and 89% were White transplant recipients; 52% received the BNT162b2 vaccine (Pfizer-BioNTech) and 48% received the mRNA-1273 vaccine (Moderna). The median time since transplant was 6.2 years (IQR, 2.7-12.7 years). The maintenance immunosuppression regimen included tacrolimus (83%), corticosteroids (54%), mycophenolate (66%), azathioprine (9%), sirolimus (4%), and everolimus (2%). At a median of 20 days (IQR, 17-24 days) after the first dose of vaccine, antibody (anti-S1 or anti–receptor-binding domain) was detectable in 76 of 436 participants (17%; 95% CI, 14%-21%).

Transplant recipients receiving anti–metabolite maintenance immunosuppression therapy were less likely to develop an antibody response than those not receiving such immunosuppression therapy (37% vs 63%, respectively; adjusted incidence rate ratio [IRR], 0.22 [95% CI, 0.15-0.34], $P < .001$; Table). Older transplant recipients were less likely to develop an antibody response (adjusted IRR, 0.83 [95% CI, 0.73-0.93] per 10 years, $P = .002$). Those who received mRNA-1273 were more likely to develop an antibody response than those receiving BNT162b2 (69% vs 31%, respectively; adjusted IRR, 2.15 [95% CI, 1.29-3.57], $P = .003$). This association was similar in a sensitivity analysis limited to those tested 14 to 21 days after vaccination (n = 245; adjusted IRR, 2.29 [95% CI, 1.32-3.94], $P = .003$).

Discussion

In this study of immunogenicity of the first dose of the mRNA SARS-CoV-2 vaccine among solid organ transplant recipients, the majority of participants did not mount appreciable antispike antibody responses. However, younger participants, those not receiving anti–metabolite maintenance immunosuppression, and those who received mRNA-1273 were more likely to develop antibody responses. These results contrast with the robust early immunogenicity observed in mRNA vaccine trials, including 100% antispike seroconversion by day 15 following vaccination with mRNA-1273[5] and by day 21 following vaccination with BNT162b2.[6]

Limitations include a convenience sample that may lack generalizability, lack of serial measurements after vaccination, and lack of a concurrent control group without immunosuppression. In addition, these data represent the humoral response to the first dose of a 2-dose series.

These findings of poor antispike antibody responses in organ transplant recipients after the first dose of mRNA vaccines suggest that such patients may remain at higher early risk for COVID-19 despite vaccination. Deeper immunophenotyping of transplant recipients after vaccination, including characterization of memory B-cell and T-cell responses, will be important in determining vaccination strategies as well as immunologic responses after the second dose.

Section Editor: Jody W. Zylke, MD, Deputy Editor.

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Article Information

Accepted for Publication: March 8, 2021.

Published Online: March 15, 2021. doi:10.1001/jama.2021.4385

Corresponding Author: Dorry L. Segev, MD, PhD, Department of Surgery, Johns Hopkins University Medical Institutions, 2000 E Monument St, Baltimore, MD 21205 (dorry@jhmi.edu).

Author Contributions: Drs Segev and Garonzik-Wang had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Boyarsky, Werbel, Avery, Massie, Segev, Garonzik-Wang.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Boyarsky, Massie, Segev.

Administrative, technical, or material support: Boyarsky, Tobian, Segev, Garonzik-Wang.

Supervision: Massie, Segev, Garonzik-Wang.

Conflict of Interest Disclosures: Dr Avery reported receiving grant support from Aicuris, Astellas, Chimerix, Merck, Oxford Immunotec, Qiagen, and Takeda/Shire. Dr Segev reported serving as a consultant and receiving honoraria for speaking from Sanofi, Novartis, CSL Behring, Jazz Pharmaceuticals, Veloxis, Mallincrodt, and Thermo Fisher Scientific. No other disclosures were reported.

Funding/Support: This work was supported by the Ben-Dov family; grants F32DK124941 (awarded to Dr Boyarsky), K01DK101677 (Dr Massie), and K23DK115908 (Dr Garonzik-Wang) from the National Institute of Diabetes and Digestive and Kidney Diseases; grant gSAN-201C0WW (Dr Werbel) from the Transplantation and Immunology Research Network of the American Society of Transplantation; and grant K24AI144954 (Dr Segev) from the National Institute of Allergy and Infectious Diseases.

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The analyses described are the responsibility of the authors and do not necessarily reflect the views or policies of the US Department of Health and Human Services. The mention of trade names, commercial products, or organizations does not imply endorsement by the US government.

Additional Contributions: We acknowledge the following individuals for their assistance with this study, none of whom was compensated for his or her contributions: Oliver B. Laeyendecker, PhD, Yukari C. Manabe, MD, Christine M. Durand, MD, Caoilfhionn M. Connolly, MD, and Julie J. Paik, MD, MHS (all 5 for analysis and affiliated with the Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland); William A. Clarke, PhD, and Patrizio P. Caturegli, MD, MPH (both for analysis and affiliated with the Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland); Aaron M. Milstone, MD, MHS (data collection and analysis), and Ani Voskertchian, MPH (data collection) (both affiliated with the Department of Pediatrics, Johns Hopkins University School of Medicine, Baltimore, Maryland); and Sunjae Bae, MD, PhD (analysis), Michael T. Ou, BS (data collection and writing/editing assistance), and Richard Wang, BA, Aura T. Teles, BS, Ross S. Greenberg, BA, Jake A. Ruddy, BS, Leyla R. Herbst, BA, Michelle R. Krach, MS, Michael D. Irving, BA, Kayleigh M. Herrick-Reynolds, MD, Mackenzie A. Eagleson, MD, Andrew M. Hallett, MD, and Victoria A. Bendersky, MD (11 for data collection) (all 13 affiliated with the Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland).

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1.
Boyarsky BJ, Ou MT, Werbel WA, et al. Early development and durability of SARS-CoV-2 antibodies among solid organ transplant recipients: a pilot study. *Transplantation*. Published online January 19, 2021. doi:10.1097/tp.0000000000003637PubMedGoogle Scholar

2.
Klein SL, Pekosz A, Park HS, et al. Sex, age, and hospitalization drive antibody responses in a COVID-19 convalescent plasma donor population. *J Clin Invest*. 2020;130(11):6141-6150. doi:10.1172/JCI142004PubMedGoogle ScholarCrossref

3.
Patel EU, Bloch EM, Clarke W, et al. Comparative performance of five commercially available serologic assays to detect antibodies to SARS-CoV-2 and identify individuals with high neutralizing titers. *J Clin Microbiol*. 2021;59(2):e02257-20. doi:10.1128/JCM.02257-20PubMedGoogle Scholar

4.
Higgins V, Fabros A, Kulasingam V. Quantitative measurement of anti-SARS-CoV-2 antibodies: analytical and clinical evaluation. *J Clin Microbiol*. 2021;JCM.03149-20. doi:10.1128/JCM.03149-20PubMedGoogle Scholar

5.

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6.

Walsh EE, Frenck RW Jr, Falsey AR, et al. Safety and immunogenicity of two RNA-based Covid-19 vaccine candidates. *N Engl J Med*. 2020;383(25):2439-2450. doi:10.1056/NEJMoa2027906PubMedGoogle ScholarCrossref

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Sent: Wed, 16 Dec 2020 21:50:26 +0000
To: Gargano, Julia Marie W. (CDC/DDID/NCIRD/DVD);Wallace, Megan (CDC/DDID/NCIRD/DVD);Curran, Kathryn (CDC/DDID/NCHHSTP/DHPSE)
Subject: FW: Call from Rep. Massie (R-KY)
Attachments: VRBPAC-12.10.20-Meeting-Briefing-Document-FDA.pdf

Just a heads-up. Congressman giving pushback on our MMWR. Below is the question and my response. We might walk it back a little in the Moderna MMWR? Just passing it along. Don't think there's anything else specifically we need to do…

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Sent: Wednesday, December 16, 2020 4:46 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Subject: RE: Call from Rep. Massie (R-KY)

We pulled this from the FDA VRBPAC briefing document, attached. Data are limited but it isn't a typo.

Data are supported by the following statements:
Page 24:
For participants with and without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively (Table 7). The posterior probability was >99.99% for the true VE being greater than 30%. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%, indicating that the true VE is at least 89.9% with a 97.5% probability given the available data.

Page 28: FDA Interpretation of the data; Pfizer VRBPAC meeting
Only 3% of participants had evidence of prior infection at study enrollment, and additional analyses showed that very few COVID-19 cases occurred in these participants over the course of the entire study (9 in the placebo group and 10 in the BNT162b2 group, only 1 of which occurred 7 days or more after completion of the vaccination regimen – data not shown). The placebo group attack rate from enrollment to the November 14, 2020, data cut-off date was 1.3% both for participants without evidence of prior infection at enrollment (259 cases in 19,818 participants) and for participants with evidence of prior infection at enrollment (9 cases in 670 participants). While limited, these data do suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

Page 46: FDA Interpretation of the data; Pfizer VRBPAC meeting
Efficacy findings were also consistent across various subgroups, including racial and ethnic minorities, participants aged 65 years and older, and those with one or more of the following conditions: obesity, diabetes, hypertension, and chronic cardiopulmonary diseases. While

limited, available data suggest that individuals with previous SARS-CoV-2 infection can be at risk of COVID-19 (i.e., re-infection) and may benefit from vaccination.

Helpful?
Sara

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Sent: Wednesday, December 16, 2020 4:30 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) [redacted]
Subject: FW: Call from Rep. Massie (R-KY)

Can you help with this question below? I am so sorry…

From: Swartwood, Candice (CDC/DDID/NCIRD/OD) [redacted]
Sent: Wednesday, December 16, 2020 4:29 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Subject: RE: Call from Rep. Massie (R-KY)

Thanks. I will let you know if this moves forward. And note – he is asking if there is a typo in the MMWR (see highlighted part). I posted the link below.

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950e2-H.pdf?ACSTrackingID=USCDC_921-DM44546&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2069%2C%20December%2013%2C%202020&deliveryName=USCDC_921-DM44546

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [redacted]
Sent: Wednesday, December 16, 2020 4:24 PM
To: Swartwood, Candice (CDC/DDID/NCIRD/OD) [redacted]
Cc: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [redacted]; Protzel Berman, Pamela (ATSDR/OPPE) [redacted]; CDC IMS 2019 NCOV Response VTF Policy [redacted]
Subject: RE: Call from Rep. Massie (R-KY)

Hi Candice- I can be free after 5:30 pm est. Let me know if that works

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From: Brand, Anstice M. (CDC/OD/CDCWO) [redacted]
Sent: Wednesday, December 16, 2020 1:48 PM
To: Serna, Christina (CDC/OD/CDCWO) [redacted]
Cc: Wortman, Eric (CDC/OD/CDCWO) [redacted]
Subject: Call from Rep. Massie (R-KY)

Just spoke with Congressman Massie (R-KY). He is asking if there is a typo in our MMWR from 12/13. Specifically he is concerned about the sentence: "Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions as well as among participants with evidence of previous SARS-CoV-2 infection."

He doesn't believe there is enough evidence to make the statement about people with evidence of previous infection. He quoted from the VRBPAC slides:

- 1303 were enrolled in the trial with evidence of prior infection.
- 633 in vx group and 670 in placebo group.
- After first shot 10 subjects in vx group had COVID symptoms and 9 in placebo group.
- After second shot still 526 in vx group who had prior positive indicaction and one of those got covid.
- 576 with evidence of prior infection and one of those got COVID> Only 2 sample points one person in each.
- Probably cut and pasted from other sentence?

Slide deck from FDA Susan Wallersheim – Dec. 10th 60 + slides, page 25 and 30 – slide deck called Vx and related biological products Advisory Committee meetings. FDA review of efficacy and safety of Pfizer vx EUA request. Got it from CDC. Think it could be typo. It doesn't seem to be supported by the data. Important because we don't want people who have already had infection rushing to get the vaccine because we don't have evidence. Somewhere on CDC website it says people can wait three months post infection to get the vx.

SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

AUG 24 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members

To defend this Nation, we need a healthy and ready force. After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people.

Mandatory vaccinations are familiar to all of our Service members, and mission-critical inoculation is almost as old as the U.S. military itself. Our administration of safe, effective COVID-19 vaccines has produced admirable results to date, and I know the Department of Defense will come together to finish the job, with urgency, professionalism, and compassion.

I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19.

Service members are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine. Those with previous COVID-19 infection are not considered fully vaccinated.

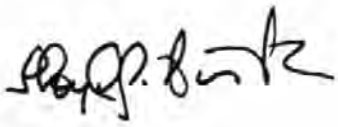
Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance. Service members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated. Service members who are actively participating in COVID-19 clinical trials are exempted from mandatory vaccination against COVID-19 until the trial is complete in order to avoid invalidating such clinical trial results.

Mandatory vaccination requirements will be implemented consistent with DoD Instruction 6205.02, "DoD Immunization Program," July 23, 2019. The Military Departments should use existing policies and procedures to manage mandatory vaccination of Service members to the extent practicable. Mandatory vaccination of Service members will be subject to any identified contraindications and any administrative or other exemptions established in Military Department policy. The Military Departments may promulgate appropriate guidance to carry out the requirements set out above. The Under Secretary of Defense for Personnel and

Readiness may provide additional guidance to implement and comply with FDA requirements or Centers for Disease Control and Prevention recommendations.

The Secretaries of the Military Departments should impose ambitious timelines for implementation. Military Departments will report regularly on vaccination completion using established systems for other mandatory vaccine reporting.

Our vaccination of the Force will save lives. Thank you for your focus on this critical mission.



AUGUST 09, 2021

Statement by President Joe Biden on COVID-19 Vaccines for Service Members

I strongly support Secretary Austin's message to the Force today on the Department of Defense's plan to add the COVID-19 vaccine to the list of required vaccinations for our service members not later than mid-September. Secretary Austin and I share an unshakable commitment to making sure our troops have every tool they need to do their jobs as safely as possible. These vaccines will save lives. Period. They are safe. They are effective. Over 350 million shots have been given in the United States alone. Being vaccinated will enable our service members to stay healthy, to better protect their families, and to ensure that our force is ready to operate anywhere in the world. We cannot let up in the fight against COVID-19, especially with the Delta variant spreading rapidly through unvaccinated populations. We are still on a wartime footing, and every American who is eligible should take immediate steps to get vaccinated right away. I am proud that our military women and men will continue to help lead the charge in the fight against this pandemic, as they so often do, by setting the example of keeping their fellow Americans safe.

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