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

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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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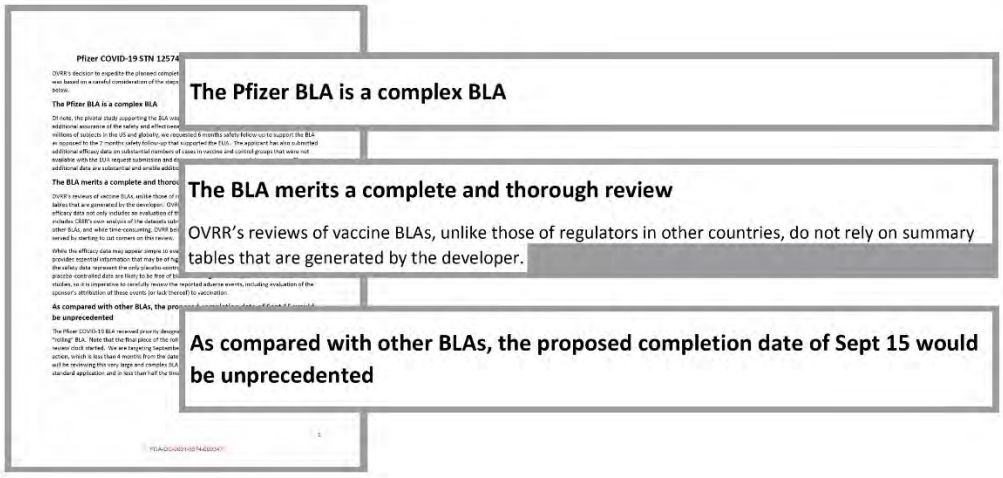
[87] *See* Kristen Abboud, *Marion Gruber, Changemaker*, International AIDS Vaccine Initiative (Nov. 9, 2023).
[88] *See id.*
[89] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 15:2–17.
[90] *See* Transcribed Interview of Philip Krause, *supra* note 73, at 12:2–13:8.
[91] *See id.*
[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]

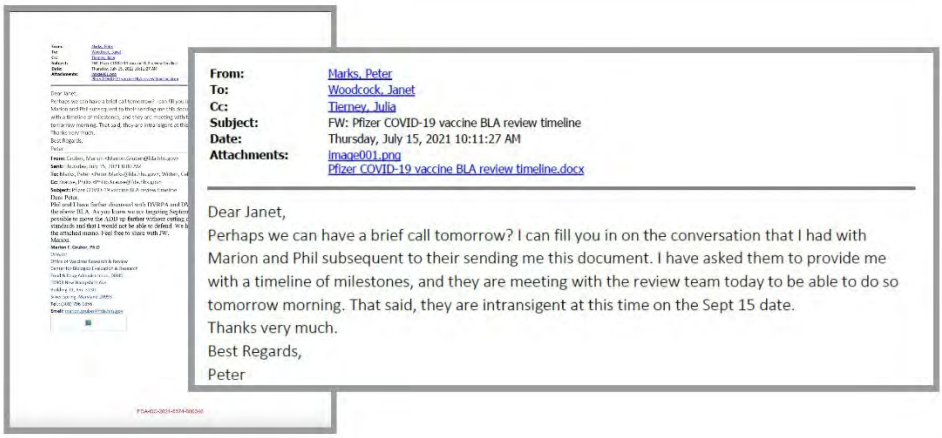
[101] *See id.* at 22:4–23:1.
[102] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 123:11–127:5.
[103] *See Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older*, Pfizer (Aug. 23, 2021).
[104] *See* Transcribed Interview of Philip 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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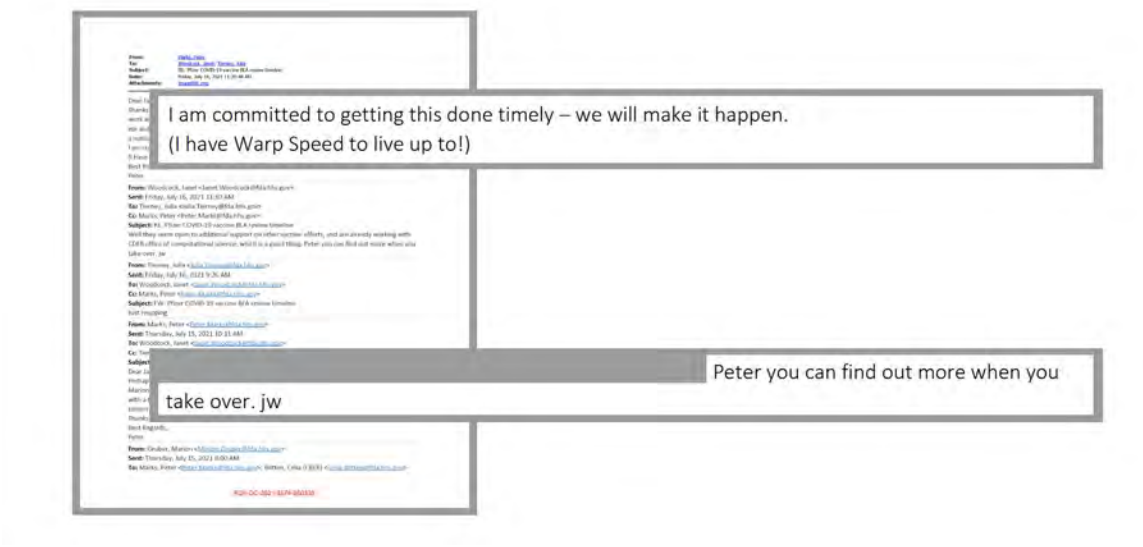
[116] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 101:21–102:8.
[117] *See id*. at 60:18–62:15.
[118] *See id*. at 67:7–12.
[119] *See* Transcribed Interview of Peter Marks, *supra* note 4, at 90:15–20.
[120] *See* FDA-OC02021-5574-000351.
[121] *See id.*
[122] *See* FDA-OC-2021-5574-000351; *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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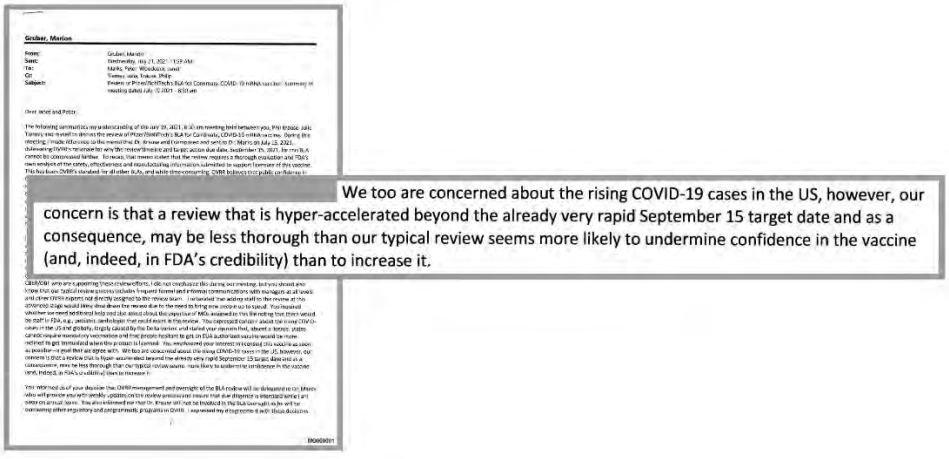
[123] FDA-OC02021-5574-000335.
[124] *Id.*
[125] *Id.*
[126] *Id.*
[127] *Id.* (cleaned up).
[128] *Id.*; *see also* MG000001–02; *see also* HJCVaccine00003–5 (reflecting FDA internal notes of the same meeting).
[129] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 68:16–69:14.
[130] *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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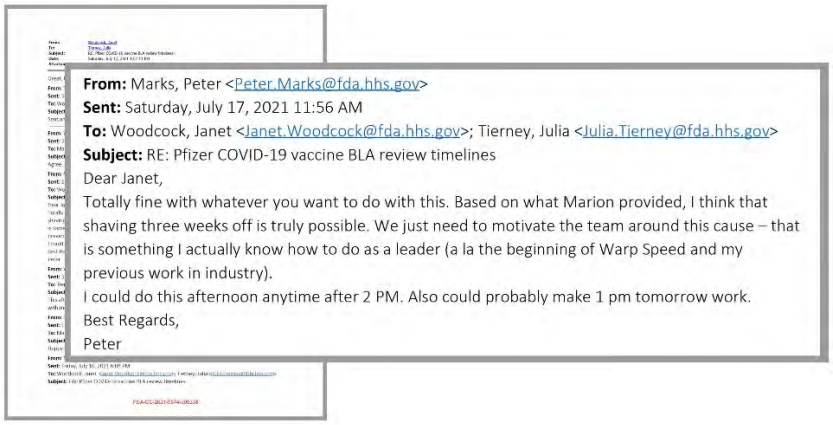
[135] *See* Transcribed Interview of Marion Gruber, *supra* note 15, at 65:4–66:21.
[136] *See id*. at 79:2–23; *see also* Philip R. Krause, MD, et al., *Considerations in Boosting COVID-19 Vaccine Immune Responses*, Lancet, vol. 398, no. 10308, 1377–80 (Oct. 9, 2021).
[137] *See id; see also* Transcribed 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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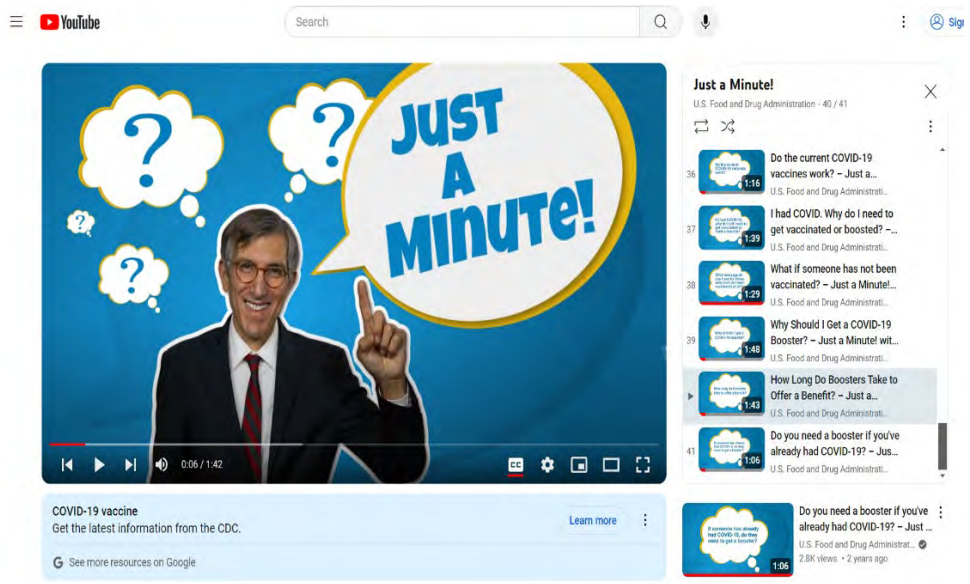
[158] *See* HJC_CDCMMWR000240.
[159] *See* HJC_CDCMMWR000239.
[160] *See* HJC_CDCMMWR000214.
[161] *See id.*
[162] *See id.*
[163] *See id.*
[164] *See* HJC_CDCMMWR000001-002.
[165] *Id.*
[166] *Id.*
[167] *See* HJC-CDCMMWR00000451.
[168] *See* INTERIM STAFF REP. ON THE CENSORSHIP-INDUSTRIAL COMPLEX: 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.

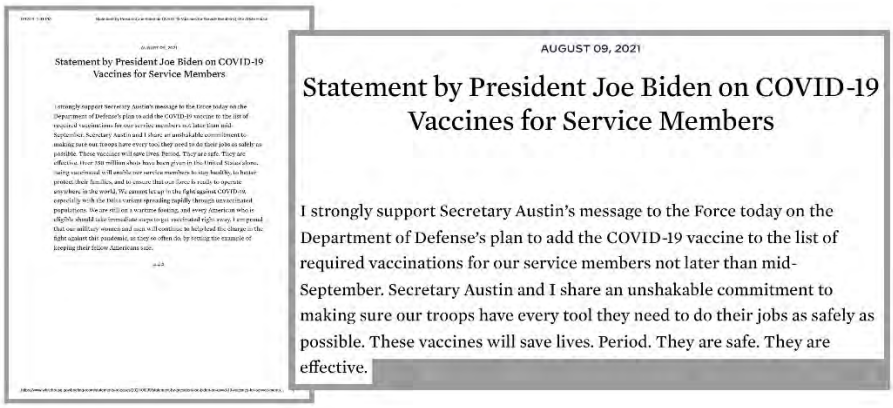
IV. THE RUSHED AND POLITICIZED PROCESS RESULTED IN REAL AND AVOIDABLE HARM TO AMERICANS.

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).

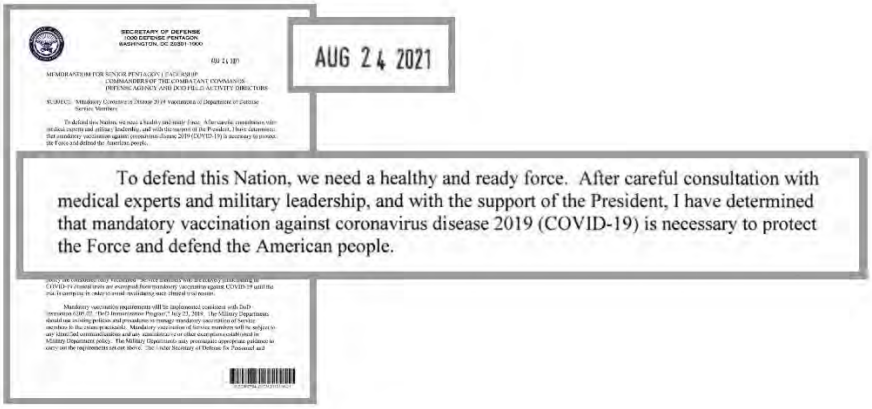


AUGUST 09, 2021

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]

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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

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