Congress of the United States

Washington, DC 20515

March 10, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Califf:

The Select Subcommittee on the Coronavirus Pandemic is investigating the COVID-19 vaccine approval and regulatory processes and any attempts by outside entities to wrongly influence those processes.

According to new internal U.S. Food and Drug Administration (FDA) communications, it appears the Biden Administration may have bypassed, wrongly compressed, and possibly compromised the longstanding process for awarding a full biologics approval to a vaccine. This effort may not have been to save lives, but concernedly to provide cover for implementing and enforcing vaccine mandates across the country.

On May 7, 2021, Pfizer and BioNTech (Pfizer) initiated a rolling submission of their Biologics License Application (BLA) for full FDA approval of their COVID-19 vaccine.[1] On July 16, 2021, the FDA granted priority review for Pfizer's BLA with a public goal for approval set for January 2022.[2] Priority review allows the FDA to take action within six months versus 10 months under standard review.[3] However, while the FDA publicly said its goal for approval was January 2022, its privately stated goal was September 15, 2021—four months earlier than the expedited goal and eight months earlier than standard review.[4] Further, according to Dr. Marion Gruber, the former Director of the FDA's Office of Vaccines Research and Review (OVRR), the Biden Administration wanted to cut more corners to approve the vaccine even faster. This fast-tracked approval is concerning.

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[1] Press Release, Pfizer and BioNTech Initiate Rolling Submission of Biologics License Application for U.S. FDA Approval of Their COVID 19 Vaccine, Pfizer (May 7, 2021).
[2] Press Release, U.S. FDA Grants Priority Review for the Biologics License Application for Pfizer-BioNTech COVID-19 Vaccine, Pfizer (July 16, 2021); *U.S. FDA sets January target to decide on approval of Pfizer's COVID-19 shot,* REUTERS (July 16, 2021).
[3] *Priority Review*, U.S. FOOD & DRUG ADMIN. (last accessed Jan. 25, 2023).
[4] E-Mail from Marion Gruber, Dir., Office of Vaccine Research & Review, U.S. Food & Drug Admin, to Peter Marks, et. al., Dir., Cent. For Biologics Evaluation & Research, U.S. Food & Drug Admin. (July 21, 2021) (on file with Subcomm. Staff).

Dr. Gruber expressed concerns with the condensed timeline for approval after a July 19, 2021 meeting between herself, Dr. Janet Woodcock, Dr. Peter Marks, Dr. Phillip Krause, and Ms. Julia Tierney.[5] In a July 21, 2021 email summarizing the meeting, she stated:

> …the review timeline and target action due date, September 15, 2021, for this BLA cannot be compressed further…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.[6]

Dr. Gruber continued:

> …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.[7]

Further, Dr. Gruber was also concerned that the fast-tracking of Pfizer's BLA could downplay concerns regarding myocarditis in young men and adolescents. Dr. Gruber wrote:

> 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 included in the BLA indication).[8]

Dr. Gruber stated that FDA officials were pushing for a quick approval in order to provide states and, eventually, the federal government, the ability to mandate these vaccines. She stated:

> You expressed your concern about the rising COVID-cases [sic] in the US and globally, largely caused by the Delta variant and stated

[5] *Id*; Dr. Marion Gruber, former Dir., Office of Vaccine Research and Review, U.S. Food & Drug Admin; Dr. Janet Woodcock, former Acting Commissioner, U.S. Food & Drug Admin.; Dr. Peter Marks, Dir., Cent. For Biologics Evaluation & Research, U.S. Food & Drug Admin.; Dr. Phillip Krause, former Deputy Dir., Office of Vaccine Research & Review, U.S. Food & Drug Admin.; and Ms. Julia Tierney, Chief of Staff, U.S. Food & Drug Admin.
[6] *Id.*
[7] *Id.*
[8] *Id.*

> your opinion that, absent a license, states cannot require mandatory vaccination…[9]

Finally, Dr. Gruber expressed her concern that the push from the Biden Administration to fast-track the vaccine approval would result in a less thorough review and damage the credibility of the FDA, stating:

> We too are concerned about the rising COVID-19 cases in the US, [sic] 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.[10]

This email points to evidence that the Biden Administration chose to sideline experts and fast track full approval of the COVID-19 vaccine, sacrificing thoroughness and veracity, to establish a precedent for vaccine mandates. This is unconscionable.

The Biden Administration's political interference in the impartial vaccine approval process is a recurring theme. Last Congress, Select Subcommittee Republicans wrote to the FDA requesting information about potential political interference with the FDA's booster shot approval process.[11] In that letter, we inquired into President Biden's announcement that booster doses of the COVID-19 vaccine would be available to Americans starting September 20, 2021, prior to the Centers for Disease Control and Prevention (CDC) or FDA concluding their independent reviews of the data.[12] It was reported at the time that, this political push by Biden's White House contributed to the decision of two top career scientists, Dr. Gruber and Dr. Krause to leave the FDA.[13] These scientists believed the Biden Administration was sidelining FDA and "what finally did it for them was the White House getting ahead of FDA on booster shots."[14]

This information in conjunction with these new communications shed light on the political influence the Biden Administration wielded over the vaccine approval process. To assist the Select Subcommittee in conducting legitimate oversight of the COVID-19 vaccine approval process we request the following documents and information as soon as possible but no later than March 24, 2023:

1. All documents and communications regarding a meeting to discuss review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine that occurred on July

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[9] *Id.*
[10] *Id.*
[11] Letter from Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform, & Hon. Steve Scalise, Ranking Member, Select Subcomm. on the Coronavirus Crisis, H. Comm. on Oversight & Reform, to Janet Woodcock, Acting Commissioner, U.S. Food & Drug Admin. (Sept. 14, 2021).
[12] Laurie McGinley, et. al., *Biden administration to offer vaccine booster shots beginning Sept. 20, require vaccinations for nursing home staff,* THE WASH. POST (Aug. 18, 2021).
[13] Caitlin Owens, *The bureaucracy pushes back on Biden's booster plan*, AXIOS (Sept. 1, 2021).
[14] *Id.*

19, 2021, including but not limited to a memorandum prepared by Drs. Marion Gruber and Phillip Krause from July 15, 2021.

2. All documents and communications, including with the CDC and the Executive Office of the President (EOP), regarding review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine.

3. All documents and communications, including with the CDC and EOP, regarding increased evidence of association of mRNA vaccines and the development of myocarditis or pericarditis.

4. All documents and communications, including with the CDC and EOP, regarding or referring to mandating vaccines.

5. All documents and communications regarding the departure of Drs. Marion Gruber or Phillip Krause from the FDA.

In addition to the above requests, we reiterate the pertinent and related requests from Oversight Committee Republican's January 19, 2022 letter to the FDA to be produced as soon as possible but no later than March 24, 2023. For your ready reference, those requests are:

1. All documents and communications related to President Biden's August 18, 2021, announcement that booster shots would be available for Americans beginning September 20, 2021.

2. All documents and communications relating to any effort by political appointees or White House personnel to review, revise, edit, delay, or prohibit publication of information related to booster shots.

3. All documents and communications relating to any adverse employment action taken or considered against any employee, official, or contractor of the federal government for actions taken in the course of their employment related to the science of Americans receiving booster shots.

4. All documents and communications between or among employees at the White House, FDA, and/or CDC referring or relating to the decision not to convene additional meetings of the Vaccines and Related Biological Products Advisory Committee after September 17, 2021.

5. All documents and communications between or among FDA employees and experts on the Vaccines and Related Biological Products Advisory Committee since September 17, 2021.

6. All documents and communications between any FDA employee and Dr. David Kessler at the White House.

We also request the following individuals sit for transcribed interviews. For former employees, we request the FDA facilitate the communications between those employees and the Select Subcommittee. Accordingly, Select Subcommittee staff will contact you to schedule transcribed interviews with the following individuals, reserving the right to conduct follow-up interviews or request testimony from other witnesses pertinent to our investigation.

1. Dr. Janet Woodcock, Principal Deputy Commissioner;
2. Dr. Peter Marks, Director, Center for Biologics Evaluation and Research;
3. Dr. Marion Gruber, former Director, Office of Vaccine Research and Review; and
4. Dr. Phillip Krause, former Deputy Director, office of Vaccine Research and Review.

The Select Subcommittee on the Coronavirus Pandemic is authorized to investigate "the development of vaccines and treatments, and the development and implementation of vaccination policies for Federal employees and members of the armed forces" under H. Res. 5. To schedule the interviews or ask any follow up or related questions please contact Committee staff at (202) 225-5074.

Thank you for your attention to this very important matter.

Sincerely,

Brad Wenstrup
Chairman
Select Subcommittee on the
Coronavirus Pandemic

Lisa McClain
Chairwoman
Subcommittee on Health Care and
Financial Services

Nicole Malliotakis
Member of Congress

Mariannette Miller-Meeks, M.D.
Member of Congress

John Joyce, M.D.
Member of Congress

Ronny Jackson, M.D.
Member of Congress

Michael Cloud
Member of Congress

Debbie Lesko
Member of Congress

Marjorie Taylor Greene
Member of Congress

Rich McCormick, M.D., M.B.A
Member of Congress

cc: The Honorable Raul Ruiz, Ranking Member
Select Subcommittee on the Coronavirus Pandemic

The Honorable Katie Porter, Ranking Member
Subcommittee on Health Care and Financial Services