BRAD R. WENSTRUP, D.P.M.
CHAIRMAN

ONE HUNDRED EIGHTEENTH CONGRESS

RAUL RUIZ, M.D.
RANKING MEMBER

Congress of the United States
House of Representatives
SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143
Majority (202) 225–5074
Minority (202) 225–5051

February 29, 2024

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 (Select Subcommittee) is continuing its investigation into the COVID-19 vaccine approval and regulatory processes, including any attempts by outside entities to wrongly influence those processes. We first wrote to you on this issue on March 10, 2023, but recent testimony from Dr. Peter Marks indicates that further investigation remains necessary.[1]

During a Select Subcommittee hearing on February 15, 2024, Dr. Marks' testimony suggested that the review of Pfizer's Biologics License Application (BLA) may have been accelerated to enable government entities to more rapidly mandate COVID-19 vaccination:

Chairman Comer.	Do you recall any conversations regarding the need to approve the vaccines in order for it to then be mandated?
Dr. Marks.	There was an acknowledgment that an approval could allow vaccine mandates to occur… [2]

This testimony supports Dr. Marion Gruber's July 21, 2021 email to Dr. Marks and Dr. Janet Woodcock, where she stated, "[y]ou expressed your concern about the rising COVID-cases [sic] in the US and globally, largely caused by the Delta variant and stated your opinion that, absent a license, states cannot require mandatory vaccination…"[3]

[1] Letter from Brad Wenstrup, D.P.M., Chairman, Select Subcomm. on the Coronavirus Pandemic, to Robert M. Califf, M.D., Comm'r, Fed. Food & Drug Admin. (Mar. 10, 2023).
[2] *Assessing America's Vaccine Safety Systems, Part 1: Hearing before the Select Subcomm. on the Coronavirus Pandemic* 118th Cong. 2 (Feb. 15, 2024); (Statement of Dr. Daniel Jernigan, CDC).
[3] 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).

Further, Dr. Marks also provided a highly questionable explanation for Dr. Gruber's and Dr. Krause's concerns about accelerating the review of Pfizer's BLA:

Chairman Comer.	Do you recall why Dr. Gruber and Dr. Krause expressed concern about accelerating the approval of the vaccine?
Dr. Marks.	They were concerned about the workload.[4]

Dr. Marks' characterization of Dr. Gruber's and Dr. Krause's concerns seemingly contradicts documents reviewed by the Select Subcommittee, wherein they express specific concerns about regulatory issues that need to be settled related to a pediatric plan to study an increased risk of myocarditis and pericarditis in adolescents before the BLA could be approved.

The Select Subcommittee's March 10, 2023 letter included a request for transcribed interviews with Drs. Janet Woodcock, Peter Marks, Marion Gruber, and Phillip Krause, as well as more than 10 requests for documents and communications. Dr. Marks' recent testimony and the Select Subcommittee's review of particular documents require us to renew our previous requests. As an accommodation to the Administration, the Select Subcommittee has removed two of the interview requests and significantly scoped down the requests for documents.

Please provide the following documents and information as soon as possible but no later than March 14, 2024. If the Administration fails to satisfactorily meet this deadline, the Select Subcommittee will be forced to evaluate the use of the compulsory process.

1. All documents and communications, complete and unredacted, regarding a memo sent by Dr. Gruber on July 15, 2021, which described her rationale and logic for why it was not possible to further abbreviate the BLA review.

2. All documents and communications regarding a Zoom meeting attended by Dr. Gruber, Dr. Krause, Dr. Marks, Dr. Woodcock, and Julia Tierney on July 19, 2021, where they discussed review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine.

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

4. 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, particularly regarding a pediatric plan to study this association.

[4] *Id.*

5. All documents and communications, including with the CDC and EOP, regarding or referring to mandating COVID-19 vaccines, or the inability for states to require mandatory COVID-19 vaccination before the BLA for Comirnaty was approved.

6. All documents and communications regarding the appointment of Dr. Marks to take over the review of the Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine.

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

We also renew our request for the following individuals to sit for in person transcribed interviews on the requested dates. The Select Subcommittee reserves the right to conduct follow-up interviews or request testimony from other witnesses pertinent to our investigation as necessary.

1. Dr. Peter Marks: March 21, 2024
2. Dr. Janet Woodcock: April 4, 2024

The Select Subcommittee 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.[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, D.P.M.
Chairman

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

[5] H. Res. 5 §4(a)(2023).