

Congress of the United States

House of Representatives

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC

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Majority (202) 225-5074
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April 12, 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. We first wrote to you on this topic more than a year ago on March 10, 2023, and then followed-up with greater specificity on February 29, 2024.¹ The Select Subcommittee considers requests (1), (2), (6), and (7) to be closed, however requests numbered (3), (4), and (5) remain open.

As an accommodation to the FDA, we are willing to scope down the outstanding requests even further. Therefore, we reiterate our request for the following documents and information as soon as possible but no later than April 26, 2024. If the FDA 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, 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 Biologics License Application (BLA) for Comirnaty, COVID-19 mRNA vaccine.
2. 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.
3. 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.

Additionally, as discussed with your staff, we are willing to table the request for a transcribed interview with Dr. Peter Marks, reserving our right to request his testimony pending new

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); 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. (Feb. 29, 2024).

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information. Further, as discussed with your staff, we suggest the following dates for the transcribed interview of Dr. Janet Woodcock:

- May 6, 2024
- May 7, 2024
- May 8, 2024
- May 9, 2024
- May 10, 2024

Please confirm one of the above dates as soon as possible but no later than April 19, 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. 5.² 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

² H. Res. 5 §4(a)(2023).