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

March 5, 2024

Peter Marks, M.D., PhD.
Director
Center for Biologics Evaluation and Research
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
[TRANSMITTED VIA EMAIL]

Dear Dr. Marks:

Enclosed are post-hearing questions that have been directed to you and submitted to the official record for the Select Subcommittee on the Coronavirus Pandemic hearing that was held on Thursday, February 15, 2024 titled "Assessing America's Vaccine Safety Systems, Part 1."

To ensure a complete hearing record, please return your written response to the Committee on or before Tuesday, March 19, 2024, including each question in full as well as the name of the member. Your response should be addressed to the Committee office at 2157 Rayburn House Office Building, Washington, D.C. 20515. Please also send an electronic version of your response by email to Marie Policastro, Clerk for the Select Subcommittee, at marie.policastro@mail.house.gov.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Committee on Oversight and Accountability staff at (202) 225-5074.

Sincerely,

Brad Wenstrup, D.P.M.
Chairman

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

Questions for George Reed Grimes, M.D., PhD.
Director
Center for Biologics Evaluation and Research
U.S. Food & Drug Administration

February 15, 2024: Select Subcommittee on the Coronavirus Pandemic hearing titled "Assessing America's Vaccine Safety Systems, Part 1"

Questions from Rep. Debbie Lesko

1. How many of the VAERS reports about the COVID vaccine have been fully investigated?

2. How many of the VAERS reports about the COVID vaccine have been confirmed?

Questions from Rep. Michael Cloud

1. Do you own individual stocks in any of the following companies?
   a. Pfizer
   b. Moderna
   c. BioNTech
   d. Novavax

2. Several of the COVID-19 vaccines have received full FDA approval and are no longer being used under emergency authorization. Is it standard practice for the countermeasures that have received such approval to continue receiving liability protection under the PREP Act and for injury claims regarding these countermeasures to be compensated via the Countermeasures Injury Compensation Program?

3. Have any FDA employees who participated in the approval process for any COVID-19 vaccine, including but not limited to evaluating the vaccines for emergency use authorization, left the FDA to work at any of the following companies within the last four years?
   a. Pfizer
   b. Moderna
   c. BioNTech
   d. Novavax

Questions from Rep. Miller-Meeks

Last year, updated Influenza and COVID vaccines were approved by FDA in July and September respectively. As a result, there was a five-week gap between both vaccines being available at the same time in pharmacies, clinics and doctor's offices. Data indicate that the COVID vaccine uptake rate was around 10% higher for those who also received the Influenza vaccine when both vaccines were available as compared with the first five-week period when only the Influenza vaccine was available.

1. What is FDA's current plan for Influenza and COVID vaccines approval for 2024?

2. What action could FDA take this year to reduce or eliminate the gap between Influenza and COVID vaccine approval dates?

3. What support, if any, does FDA need to achieve closer alignment of Influenza and COVID vaccines approval dates?