U.S. FOOD & DRUG ADMINISTRATION

October 15, 2024

The Honorable Brad Wenstrup
Chairman
Select Subcommittee on the Coronavirus Pandemic
Committee on Oversight and Accountability
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Wenstrup:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the February 15, 2024, hearing before the Select Subcommittee on the Coronavirus Pandemic, Committee on Oversight and Accountability entitled "Assessing America's Vaccine Safety Systems, Part 1." This letter is a response for the record to questions posed by the subcommittee.

Sincerely,

Erin O'Quinn
Associate Commissioner for
Legislative Affairs

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

U.S. Food & Drug Administration
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Questions for the Record
Select Subcommittee on the Coronavirus Pandemic
Committee on Oversight and Accountability
U.S. House of Representatives
"Assessing America's Vaccine Safety Systems, Part 1"
February 15, 2024

Questions for Dr. Peter Marks
Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

Rep. Debbie Lesko

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

The Vaccine Adverse Event Reporting System (VAERS) receives unconfirmed reports of possible adverse events following the use of a vaccine licensed or authorized in the United States. These reports are received and entered into VAERS and used to monitor the occurrence of both known and unknown adverse events. As part of the Food and Drug Administration (FDA)'s and Centers for Disease Control and Prevention (CDC)'s multi-system approach to safety monitoring, VAERS is designed to rapidly detect signals of unusual or unexpected patterns of adverse events. FDA and CDC continuously monitor and analyze VAERS COVID-19 vaccine data (including collection of follow-up medical information in certain cases) for possible safety concerns related to COVID-19 vaccines. As part of this monitoring, FDA staff have conducted screening of incoming serious VAERS reports involving COVID-19 vaccines and continuously monitor VAERS data from incoming reports, including serious and non-serious reports, involving COVID-19 vaccines. The VAERS Program staff have routinely collected follow-up information on all serious reports for COVID-19 vaccines. For signals identified in VAERS, physicians from FDA and CDC screen relevant individual reports, including medical record review. If the VAERS data suggest a possible link between an adverse event and vaccination, the relationship may be further studied in a controlled fashion through other vaccine safety monitoring systems, such as the Vaccine Safety Datalink.

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

As described above, VAERS receives unconfirmed reports of possible adverse events following the use of a vaccine, and FDA and CDC continuously screen and analyze VAERS data for possible safety concerns related to vaccination.

Rep. Michael Cloud

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

In addition to the Government-wide conflict of interest laws and the Standards of Ethical Conduct for Employees of the Executive Branch, FDA employees are subject to a stringent ethics requirement that generally prohibits the holding or acquisition of any financial interest in "significantly regulated organizations."[1] Dr. Marks does not own individual stocks in the companies named above.

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?

For questions related to the PREP Act and the Countermeasures Injury Compensation Program, FDA defers to the Health Resources and Services Administration.

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**

FDA provides information about post-Government employment restrictions on its public-facing website.[2] FDA has implemented a standard process of advising each departing employee on the applicable post-Government employment restrictions once the employee has notified FDA of his or her termination of employment. As part of this process, departing employees are routinely advised that they may continue to seek ethics guidance from FDA's Office of Ethics and Integrity (OEI) regarding the post-Government employment restrictions even after they leave FDA.[3] As a general matter, FDA employees are subject to the Government-wide post-employment statute, 18 U.S.C. 207, which prohibits certain communications to or appearances before the Government, made on behalf of their new employer or anyone else, with the intent to influence certain governmental action. Additionally, OEI advises departing employees or others seeking non-Federal employment on the applicable ethics restrictions, which may require the

[1] http://www.fda.gov/about-fda/ethics/prohibited-financial-interests-fda-employees
[2] http://www.fda.gov/about-fda/ethics/post-employment-restrictions
[3] https://www.fda.gov/about-fda/ethics/ethics-and-integrity-contacts

employee to recuse from personally and substantially participating in particular matters that involve or affect the financial interest of the prospective employer. Under the Stop Trading on Congressional Knowledge (STOCK) Act of 2012, FDA employees that are required to file a public financial disclosure report must notify FDA if they negotiate for, or reach an agreement of, future employment or compensation with a non-federal entity within three (3) business days after the start of the negotiation or agreement.

Rep. Mariannette 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?

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) reviews available data and made recommendations on the selection of influenza viruses for the composition of influenza vaccines for the 2024-2025 U.S. influenza season. As of February 15, 2024, FDA had announced that VRBPAC would meet to discuss and make recommendations on the selection of strain(s) to be included in the 2024-2025 Formula for COVID-19 Vaccines. Dependent on the available data, and following any potential recommendations for the 2024-2025 Formula, and subject to appropriate regulatory actions, manufacturers will be able to make updated COVID-19 vaccines available in advance of the 2024-2025 respiratory virus season.

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

FDA announced plans to convene the VRBPAC meeting earlier this year to discuss and make recommendations on the selection of strain(s) to be included in the 2024-2025 Formula for COVID-19 Vaccines.

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

FDA has identified an anticipated process to assess the composition of the COVID-19 vaccines and the effectiveness of the vaccines to prevent COVID-19 as the SARS-CoV-2 virus evolves. We reiterated this process at the January 26, 2023, meeting of VRBPAC. During this meeting, we stated that we expect this process would occur at least yearly, targeting May/early June, but that the committee could be convened ad hoc if the virus evolves to be more pathogenic and impact public health.[4] The process is one that balances anticipating virus evolution and having effective COVID-19 vaccines for the United States, while also considering the manufacturing timelines for various types of COVID-19 vaccines.

We are committed to facilitating the timely availability of safe and effective COVID-19 vaccines for the United States. Our engagement and interactions with COVID-19 vaccine manufacturers continue. As noted above, dependent on the available data, and following any potential recommendations for the 2024–2025 Formula, and subject to appropriate regulatory actions, manufacturers will be able to make updated COVID-19 vaccines available in advance of the 2024-2025 respiratory virus season.

[4] https://www.fda.gov/media/164807/download, page 21.