FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

ONE HUNDRED SIXTEENTH CONGRESS

# Congress of the United States

## House of Representatives

## COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

January 2, 2019

Dr. Peter Marks
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Marks:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, December 4, 2019, at the hearing entitled "Flu Season: U.S. Public Health Preparedness and Response." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Thursday, January 16, 2020. As previously noted, this transmittal letter and your responses, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your responses should be transmitted by email in the Word document provided with this letter to Benjamin Tabor with the Committee staff (benjamin.tabor@mail.house.gov). A paper copy of your responses is not required. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Mr. Tabor at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachment

cc: Hon. Greg Walden, Ranking Member, Committee on Energy and Commerce
Hon. Diana DeGette, Chair, Subcommittee on Oversight and Investigations
Hon. Brett Guthrie, Ranking Member, Subcommittee on Oversight and Investigations

**Committee on Energy and Commerce**
**Subcommittee on Oversight and Investigations**

**Hearing on**
**"Flu Season: U.S. Public Health Preparedness and Response"**

**December 4, 2019**

**Peter Marks, M.D., Ph.D.**
**Director, Center for Biologics Evolution and Research**
**U.S. Food and Drug Administration**

**The Honorable Brett Guthrie (R-KY)**

1. An Executive Order issued by President Trump on September 19, 2019 directs the U.S. Food and Drug Administration (FDA) as well as other agencies to accelerate the adoption of improved influenza vaccine technologies. What actions does FDA plan to take to implement FDA's responsibilities under the Executive Order? Please also include information about the timeline for these actions.

2. A few years ago, we had a flu season where there was a bad mismatch between the flu vaccine and a flu strain that had drifted. If FDA were confronted with vaccine mismatch again, what would FDA do differently than in the 2014-2015 flu mismatch season to respond to the mismatch?

3. Under what circumstances would it be appropriate to pursue a monovalent rescue vaccine to respond to a drifted influenza strain?

**The Honorable Jeff Duncan (R-SC)**

1. It appears that universal flu vaccines carry tremendous potential, as we do not need to modify the flu vaccine to a different strain each year. I also find it encouraging to hear there is tremendous progress with respect to universal flu vaccine development.

    a. How will the FDA treat regulatory approval of these novel vaccines?

    b. Is the FDA ready and prepared with an approach to consider these vaccine candidates for regulatory approval?