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

October 16, 2020

Ashish Jha, M.D., M.P.H.
Dean
School of Public Health
Brown University
121 South Main Street, Box G-S121-3
Providence, RI 02912

Dear Dr. Jha:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, September 30, 2020, at the remote hearing entitled "Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust." 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 me and other 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 Friday, October 30, 2020. As previously noted, your responses to the questions in this letter, 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 have your staff 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
"Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust"

September 30, 2020

Ashish Jha, M.D., M.P.H., Dean
School of Public Health, Brown University

The Honorable Frank Pallone, Jr. (D-NJ):

1. Given your testimony that there have been a series of "failures and mishaps surrounding EUAs [Emergency Use Authorizations] for treatments," what red flags should Congress be aware of that might indicate the U.S. Food and Drug Administration (FDA) has been improperly pressured to prematurely authorize a coronavirus disease 2019 (COVID-19) vaccine? Are there guardrails in place to prevent that and, if so, what are they?

2. Please explain how FDA's decision to authorize a COVID-19 treatment should differ from its analysis of whether to authorize a COVID-19 vaccine, which, as you point out in your testimony, would be given to healthy people to prevent illness?

The Honorable Diana DeGette (D-CO):

1. If any member of the Administration authorizes or approves the use of a COVID-19 vaccine prior to or over the objection of FDA, or against the recommendations of the Vaccine and Related Biological Products Advisory Committee, what impact do you believe this action would have on the American people's confidence in the vaccine?

The Honorable Brett Guthrie (R-KY):

1. As large amounts of a vaccine become available, what checkpoints should the Centers for Disease Control and Prevention place on jurisdictions to ensure that they have the necessary resources before vaccine manufacturers ship vaccine doses to the states?

    a. What are some of the challenges that you think jurisdictions will face in transitioning to the next phase to accommodate an increased volume of vaccine doses?

    b. How should the federal government be preparing for, and helping to mitigate, those challenges?

c. How can providers use their influenza vaccine administration period to begin operationalizing their plans for COVID-19 vaccine-distribution data reporting and patient communication systems?