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

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Majority (202) 225-2927
Minority (202) 225-3641

October 16, 2020

Mark McClellan, M.D., Ph.D.
Founding Director
Duke-Margolis Center for Health Policy
Duke University
100 Fuqua Drive, Box 90120
Durham, NC 27708

Dear Dr. McClellan:

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

Mark McClellan, M.D., Ph.D., Founding Director
Duke-Margolis Center for Health Policy, Duke University

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

1. Your testimony states that, "Vaccines will not provide a short-term silver bullet under any plausible circumstances. Even as we begin to use vaccines, we will still need the other proven steps that work—masks, distancing, avoiding large groups especially indoors, and personal hygiene like hand washing and sanitizing." What should the public expect over the next few months and coming year even if a vaccine becomes widely available? To what extent will a vaccine enable a return to pre-pandemic life?

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 the U.S. Food and Drug Administration (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. Data Safety and Monitoring Boards (DSMB) meet in both open and closed sessions. Following the open session, the DSMBs convene a closed session to review emerging trial data. How does the industry balance both clinical trial transparency and participant confidentiality and proprietary information?

2. At a full Committee hearing in June, FDA Commissioner Hahn said, "I can assure you that we will retain our regulatory independence. We will use the science and data that come to us, and we will use our high standards to assess the safety and efficacy of a vaccine. We have world-class experts who will continue to maintain that." Similarly, Commissioner Hahn said, "[w]hat I can promise the American people, we will work with companies. We will work with Operation Warp Speed to provide the assistance, so the right studies are done with the right information. But we will independently look at those data and we will make a decision in the best interest of the American people with respect to safety and efficacy. We will use science and data to do that." Commissioner Hahn made a similar commitment at a

September 23, 2020 hearing before the Senate Committee on Health, Education, Labor and Pensions. Should the American people believe Commissioner Hahn when he says that the FDA will retain its regulatory independence? Why or why not?

3. At a July hearing before the Oversight and Investigations Subcommittee, Dr. Julie Gerberding of Merck stated: "And, in fact, we're quite relieved that the FDA insisted upon applying the same high standards of safety and efficacy, even under these emergency conditions, that they would apply to any of the vaccines that we've prosecuted in the past." She later added: "I think the way to think about this, really, is to understand that the FDA is not loosening any standards, so business as usual. Whatever portfolios or dossiers that we bring to the FDA have to meet these rigorous standards." At the same hearing, Dr. Macaya Douoguih of Johnson & Johnson stated: "We also agree that the standards are appropriate, and perhaps even more stringent than some of the criteria we've had for some of our other products." Do you agree with these statements about the rigor of FDA's guidance? Why or why not?

4. In a recent opinion piece in The Wall Street Journal that you co-authored with former FDA Commissioner Scott Gottlieb, you wrote, "[w]e also reject the idea that the FDA's professional staff can be cowed by outside influences." You also said, "[p]olitical appointees shouldn't intrude in these endeavors, though the FDA's thorough and transparent process doesn't lend itself to meddling. Any deviation would be quickly apparent. That should reassure those worried about furtive influences." Can you please elaborate on these comments and why you believe the American people can trust the FDA to do the right thing?

5. In a recent opinion piece in The Wall Street Journal that you co-authored with former FDA Commissioner Scott Gottlieb, you wrote, "[t]here is concern that an [Emergency Use Authorization] EUA is a lower bar than the FDA's rigorous standard for safety and effectiveness. Or that the EUA decision could be subject to political influence similar to some clumsy, recent intrusions into reports issued by the [CDC]. We reject the claim that a vaccine EUA inherently falls short of FDA's gold standard review, or that the process will be hijacked." Can you please explain why you believe that?

    a. Has your opinion changed in light of the EUA guidance that FDA released on October 6, 2020? Why or why not?