

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

Paul Offit, M.D.  
Director  
Vaccine Education Center  
Children's Hospital of Philadelphia  
45 West 23rd Street  
Avalon, NJ 08202

Dear Dr. Offit:

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](mailto: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.

Dr. Paul Offit  
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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,

A handwritten signature in blue ink that reads "Frank Pallone, Jr." in a cursive style.

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**

**Paul Offit, M.D., Director  
Vaccine Education Center, Children’s Hospital of Philadelphia**

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

1. As a member of the Vaccine and Related Biological Products Advisory Committee (VRBPAC), are you confident that the U.S. Food and Drug Administration (FDA) will follow VRBPAC’s recommendations regarding potential coronavirus disease 2019 (COVID-19) vaccines? Are you confident that the President and U.S. Health and Human Services Secretary Alex Azar will adhere to VRBPAC’s recommendations?
2. As a vaccine development expert, what would be the benefit of a COVID-19 vaccine that is only 50 percent effective? How drastically would that improve our effort to combat this virus?

**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 VRBPAC, 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. FDA has scheduled a meeting of its VRBPAC on October 22, at which the committee will discuss the general development of COVID-19 vaccines publicly. While this meeting is not intended to discuss any particular vaccine candidates, the FDA has said the agency is also prepared to rapidly schedule additional meetings of this Committee upon submission of any Biologics License Applications or requests for an Emergency Use Authorization to further ensure transparency. Should that process further boost public confidence in the legitimacy and scientific basis of the FDA’s decision on COVID-19 vaccines? Why or why not?
2. Some state officials are expressing skepticism about federal reviews of potential COVID-19 vaccines, indicating that their states plan to conduct their own independent review of the clinical trial data before distributing a vaccine, despite an approval or authorization from the FDA. Do you believe that such a review by the states would be necessary? What resources

and expertise would a state need to have to conduct a review of clinical trial data at the same level as the FDA?

- a. How would such second-guessing of the FDA impact the confidence that the American people have in the FDA and any future vaccines that are approved by the FDA?
- b. If states went in such a direction, do you think this would make the problem of vaccine confidence even worse?