

**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

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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?

Although it’s hard to predict how the administration will act, I have become more and more confident over the past couple of months that the FDA and HHS will follow the advice of the committee regarding approval of vaccines through an EUA. But that’s just the first step. The ACIP, which is the principle recommending body in the US for vaccines, will also independently review the vaccine data and make a recommendation, as is always the case.

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?

It would be a good start. Historically, the first vaccine licensed for a particular disease is often not the last best, vaccine. But a vaccine with 50 percent efficacy would offer something in the fight against this disease. The influenza vaccine is also roughly 50 percent effective.

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?

I think Americans right now have a fragile confidence in vaccines and generally don’t trust the administration to get the science right. If the administration allowed use of a vaccine over the objections of academics and researchers who decried it, I think few people would choose to get it.

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?

Yes, it should boost confidence. But we have a long way to go to again build up trust from the American public in science-based federal agencies like the EPA, FDA, and CDC given recent events.

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?

I think that the fact that several states have expressed an interest in forming their own vaccine advisory committees is a terrible idea and will only sow seeds of confusion. But it's a sign of how little people think of the FDA right now. I believe that the CDC and FDA can turn this around by getting good information out there once all the data on these vaccines are available.