

**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. 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 availability of a vaccine will not immediately or single-handedly return Americans to their pre-pandemic lives. While a crucial part of the overall strategy for overcoming the pandemic, the use of vaccines must be accompanied by continued physical distancing and public health measures like wearing masks in order to continue mitigating the spread of virus among individuals yet to be vaccinated. Anticipating a staged distribution and access plan for vaccines, it will take an all-of-the-above approach for many months to return to any semblance of normalcy.*

**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?

*It remains incredibly unlikely that a vaccine will be approved by the Administration against the expert judgment of career experts at FDA. The American public should have confidence in the well-established process and multiple safeguards in place for proper regulatory review and approval of vaccines – a process that FDA has publicly committed to fully maintaining.*

**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?

*One of the most critical considerations a DSMB makes when deciding whether to convene an open or closed session is the need to avoid sharing data that may introduce bias into the study. For example, DSMBs do not usually share data on study outcomes, since this may bias researchers and affect how the study is conducted or how the analyses are planned. However, certain aspects of the study can be discussed openly without biasing the conduct of the study: for example, information about accrual and dropout rates, how many patients were deemed eligible, and how quickly data was submitted. This information may help researchers conduct the study more efficiently and help the public better understand how the study is proceeding.*

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?

*Yes, the American public should have faith in not only the regulatory independence of the FDA but also the commitment of its career officials and scientific experts to adhering to well-established gold standards for regulatory review and approval of a vaccine. This is based in repeated public statements to this effect by leadership and staff at FDA during the course of the pandemic, as well as decades of FDA experience at the forefront of trusted medical product regulation.*

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 Douguilh 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?

*I agree that FDA both has rigorous standards for regulatory review and approval of vaccines, and that the agency has demonstrated its commitment to these standards through published guidance related to COVID-19 vaccines. These guidance documents demonstrate that FDA will be holding candidate vaccines to these standards within the regulatory flexibility that the agency has under statute.*

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?

*There are many well-established steps in the process for regulatory review and approval of a vaccine, including for any candidate vaccines that might be considered under an Emergency Use Authorization. First, and prior to a formal application from a manufacturer, is the analysis of independent Data and Safety Monitoring Boards (DSMBs) that help manufacturers assess the evidence being generated in clinical trials and whether or not to move forward with an FDA submission. At FDA, these steps include the typical standards for expert review and analysis by FDA’s career staff, public consultation with the independent experts that form the FDA’s Vaccine and Related Biologic Products Advisory Committee (VRBPAC), and a transparent process for reporting out the FDA’s ultimate decision. It would be very hard for political influence to overcome or override any individual step, whether the independent expert consultation with DSMBs and VRBPAC or the day-to-day adjudication of the evidence by FDA career staff. It is built to be a trusted, transparent process.*

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?

*As noted above, the EUA guidance documents have made it clear that FDA intends to adhere to the well-established regulatory review and approval standards and will not be lowering those standards for a vaccine EUA. It would be very hard to interfere with that process.*

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

*My opinion has not changed since the publication of the most recent guidance document. If anything, public-facing statements like that guidance document help to further ensure*

*that FDA is adhering to its long-held gold standards for regulatory review and approval, and is exercising appropriate judgement in meeting those standards.*