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"

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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?

The two places where there have been substantial failures surrounding EUAs for treatments did not utilize randomized controlled trials to demonstrate efficacy, which are typically considered the gold standard amongst the research community. Rather, the EUA for hydroxychloroquine relied on a small, non-representative observational study, and that for convalescent plasma relied on observational data that lacked randomization. These two treatments did not have sufficient data to demonstrate efficacy and therefore, did not truly meet the bar for an EUA. Given that all vaccine candidates are studied using a randomized controlled trial design, issues regarding observational data should not be a concern. Nonetheless, it is critical that we follow the guidance of FDA scientists in determining whether a vaccine reaches safety and efficacy standards. These rigorous standards have been clearly outlined by the FDA, and include a requirement that the vaccine lowers the rate of COVID-19 in study subjects by 50% or more compared with those who received the placebo, as well as a two-month safety follow-up period after study subjects receive their final dose. As long as the FDA remains devoted to these standards and continues with scientifically rigorous trial design, we can avoid repeating the mistakes we made with hydroxychloroquine and convalescent plasma.

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?

Given that treatments are given to sick people, who without treatment might otherwise die or suffer severe consequences, there is an understandably lower bar of evidence employed for

issuing these EUAs. But vaccines are given to healthy people, so ensuring that they are safe is of particular importance, especially considering that these healthy individuals can be protected through other means such as social distancing, mask-wearing, and hand washing. Further, we must clearly demonstrate efficacy before a vaccine is authorized to avoid providing the general public with a false sense of security that will lead to a breakdown of other public health measures or undermine trust in vaccines. Therefore, the FDA's decision to authorize a COVID-19 vaccine should rely on substantially higher bars for both safety and efficacy compared with those for COVID-19 treatments.

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?

If political appointees overruled career scientists, it would greatly undermine the American people's confidence in the vaccine. Given the critical importance of widespread distribution and acceptance of a COVID-19 vaccine in order for it to be effective in combatting this virus, political meddling, such as this, would have disastrous consequences. Already, vaccine hesitancy is widespread and this type of political interference would only further the hesitations of the American people, leading some individuals to forego using the vaccine and consequently, undermining the benefits of the vaccine to the American population.

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?

The widespread distribution of a COVID-19 vaccine will pose some unique challenges to jurisdictions across the country, the first of which is establishing an adequate cold chain, which is necessary for the distribution of the majority of vaccine candidates. RNA-based vaccines, such as the Pfizer and Moderna candidates, require deep-freeze storage and therefore, cannot be stored in typical refrigeration systems in doctors' offices. Challenges in establishing these supply chains will uniquely impact more rural areas, as urban areas are generally better equipped at managing cold chains, which may result in the inequitable distribution of a COVID-19 vaccine. The second

unique challenge is that this vaccine will likely require two doses, which will only increase the complexities of distribution and introduce additional logistical hurdles. Of the seven Operation Warp Speed candidates, up to six may require multiple doses. Two-dose vaccine regimens require additional tracking and follow-up with patients to ensure that they receive the correct second dose at the appropriate time.

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

Investments in the infrastructure needed for an effective cold chain have substantially lagged behind investments made in the discovery and development of the vaccine itself. The federal government attests that it may implement a distribution approach consisting of distributed networks of federally managed cold chain sites to prevent specific jurisdictions from needing to procure additional equipment, but these plans have yet to be implemented. Given that vaccine distribution hinges upon the ability to adequately scale-up cold chains, it is imperative that the federal government invest in these systems and create a team of individuals who can oversee and ensure their implementation.

Further, the federal government is in the process of implementing a new vaccine tracking system to monitor COVID-19 vaccine administration called the Vaccine Management Administration System (VAMS). While this new system aims to alleviate some of the challenges inherent in multiple-dose vaccine regimens, it is unclear how this new system will integrate with existing Immunization Information Systems (IIS). There are many benefits to leveraging these existing tracking systems, such as familiarity amongst local providers and past experience with the administration of other vaccines. Rather than overhaul each state's current vaccine registry with a new one, the federal government should support states in modifying existing systems so that they have the capacity to successfully track and monitor the administration of a COVID-19 vaccine.

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?

While it is unclear when exactly VAMS will be released to local healthcare providers and how this new system will work alongside existing IIS, there are a few ways in which data reporting and patient communication systems can be improved in the meantime. Currently, there is wide variation across states' IIS, with different policies regarding data-sharing, provider participation, and patient consent. During the influenza vaccine administration period, providers should begin to identify the shortcoming of their particular IIS system and coordinate with public health officials to improve these systems. Further, data-sharing capabilities between states are lacking,

posing additional challenges to coordinating multiple-dose vaccine administration. In order to coordinate a national COVID-19 vaccine program, we need greater consistency and coordination across these systems. By identifying the shortcomings of existing systems and improving coordination between neighboring jurisdictions during the influenza administration period, we can hopefully avert these challenges when it comes time to administer a COVID-19 vaccine on the national scale.