HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS: PATHWAY TO A VACCINE: ENSURING A SAFE AND EFFECTIVE VACCINE PEOPLE WILL TRUST

EXECUTIVE SUMMARY

The House Energy and Commerce (E&C) Subcommittee on Oversight and Investigations (O&I) convened a hearing to examine the safety and effectiveness of, access to, and the public's trust in prospective COVID-19 vaccines. Throughout the hearing, Democrats criticized the Trump administration's political interference at the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC), noting that the administration has contributed to public mistrust in COVID-19 vaccines. Meanwhile, Republicans blamed Democrats for causing the mistrust through their heightened scrutiny of the FDA. Republicans also criticized states (including California and New York) that have announced plans to conduct additional safety and efficacy reviews of FDA-approved COVID-19 vaccines. Overall, the witnesses expressed confidence that existing safeguards at the FDA, particularly its career scientists, will ensure that the agency will only approve a COVID-19 vaccine that is safe and effective. The discussion also touched on the importance of engaging communities of color in clinical trials and potential challenges with vaccine storage and handling. Lastly, E&C Subcommittee Chair Diana DeGette (D-CO) agreed to work with Rep. Buddy Carter (R-GA) on obtaining temporary "provider status" for pharmacists, which would allow pharmacists to be reimbursed for administering COVID-19 vaccines under Medicare.

OPENING STATEMENTS

O&I Subcommittee Chair Diana DeGette) (D-CO) noted assurances from pharmaceutical manufacturers, including their signed pledge, that "safety and science would not be sacrificed for speed" in their pursuit of COVID-19 vaccines. Chair DeGette called out the Trump administration for "politicizing science," which she noted, has contributed to a decline in public confidence in a COVID-19 vaccine. As noted in the committee memorandum, only 51 percent of American adults in September said "they would get a COVID-19 vaccine if one is available to them today," down from 72 percent in May. She suggested the following to help restore public confidence: (1) allow career scientists the time necessary to conduct robust reviews; and (2) allow the FDA to release its updated emergency use authorization (EUA) guidance, which has reportedly been blocked by administration officials.

O&I Subcommittee Ranking Member Brett Guthrie (R-KY) described safeguards currently in place at the FDA – including the Vaccines and Related Biological Products Advisory Committee, an independent expert panel that reviews and evaluates data concerning the safety, efficacy, and appropriate use of vaccines.

He noted that that FDA Commissioner Dr. Stephen Hahn said he would support career scientists. Ranking Member Guthrie also praised vaccine manufacturers, particularly those in Phase 3 clinical trials, for releasing their trial protocols. Though he did not specifically mention Democrats, Ranking Member Guthrie scolded "some who are trying to score political points" for criticizing the FDA, and therefore contributing to mistrust in the agency.

E&C Committee Chairman Frank Pallone, Jr. (D-NJ) highlighted provisions in the updated Heroes Act aimed at support COVID-19 vaccine development and distribution. They include $20 billion in grant authority to support vaccine and therapeutic development; $7 billion to improve and expand vaccine distribution and administration; and language authorizing grants to state and local public health departments to procure vaccines and enhance public health data systems.

E&C Committee Ranking Member Greg Walden (R-OR) criticized states, which he did not name but do include California and New York, for plans to conduct their own "unprecedented" review of FDA-licensed COVID-19 vaccines for safety and efficacy. He said this added review will contribute to public confusion and mistrust. Ranking Member Walden further remarked that states lack the expertise and legal authority to conduct such a review.

WITNESS TESTIMONY

Dr. Mark McClellan, Founding Director, Duke-Margolis Center for Health Policy, Duke University (testimony) praised FDA staff for their expertise and commitment to following proper procedures to ensure vaccine safety and efficacy and expressed confidence in COVID-19 vaccines that will be authorized under an EUA. He echoed concerns raised by Ranking Member Walden regarding states that plan to conduct their own reviews of COVID-19 vaccines. Dr. McClellan previously served as FDA Commissioner November 2002 to March 2004 and currently serves on the board of directors of Johnson & Johnson, which is developing a COVID-19 vaccine supported by Operation Warp Speed.

Dr. Ali S. Khan, Dean, College of Public Health, University of Nebraska Medical Center (testimony) discussed challenges to distributing and administering a COVID-19 vaccines. They include: (1) minimum orders of 100 doses, which may require states to repackage vaccines to serve smaller vaccination sites; and (2) coordination involving the delivery of two vaccine doses that must be administered 21 to 28 days apart. He recommended several solutions to improve vaccine uptake. They include: (1) avoiding the use of predictions in messaging; (2) using fact-based messaging; and (3) tailoring messages to their audiences, including diverse populations. Dr. Khan previously served as Assistant Surgeon General at the CDC.

Dr. Paul A. Offit, Director, Vaccine Education Center, Children's Hospital of Philadelphia (testimony) acknowledged that the Trump administration's pressure on the FDA to approve hydroxychloroquine and convalescent plasma through an EUA without clear evidence of safety or efficacy has contributed to concerns about COVID-19 vaccine approval. However, he expressed optimism that the approval process for COVID-19 vaccines will be different for several reasons. The conduct of phase 3 trials, which entail "large, prospective, placebo-controlled trials of about 30,000 people" will provide robust evidence on vaccine safety and efficacy, he explained. Dr. Offit currently serves on the Vaccines and Related Biological Products Advisory Committee.

Dr. Helene Gayle, Co-Chair, Committee on Equitable Allocation of Vaccine for the Novel Coronavirus, National Academies of Sciences, Engineering, and Medicine (NASEM) (testimony) discussed the work of NASEM's committee to develop an overarching framework for COVID-19 vaccine allocation. She noted that the committee will release its final report on October 2. A preliminary draft was released on September 1. Dr. Gayle said the final report will also address topics related to "implementation, risk communication, community engagement, vaccine hesitancy, and global considerations."

Dr. Ashish K. Jha, Dean, School of Public Health, Brown University (testimony) echoed Dr. Offit's comments regarding the contribution of the controversial EUAs for hydroxychloroquine and convalescent plasma to public mistrust. He called for increase transparency, including hearing from career scientists when an EUA is issued to ensure that science, not politics, is driving the process. Dr. Jha also called for (1) a strong communication plan that engages public health and community leaders; (2) a plan for fair vaccine distribution; and (3) the elimination of all financial barriers to getting the vaccine.

MEMBER DISCUSSION

FDA Approval Process and Public Trust

Both Democrats and Republicans asked the witnesses if they trust the FDA to only license or authorize (via EUA) a COVID-19 vaccine only if it is proven safe and effective. All witnesses (except for Dr. Gayle who did not get to answer the question due to time limits) expressed confidence in the current safeguards at the FDA. However, throughout the hearing, they acknowledged that the Trump administration's interference in decisions at the FDA (e.g., EUAs for hydroxychloroquine and convalescent plasma) has contributed to the public's mistrust in a prospective COVID-19 vaccine.

Dr. McClellan pointed to the recent Washington Post op-ed authored by seven former FDA commissioners, which states "Despite recent political actions, we continue to have confidence in the integrity and high-quality scientific work of FDA staff." In the article, they describe political interference by the Trump administration as "deeply troubling" and cite several examples, including HHS' announcement that all rules must be approved by the HHS Secretary.

Ranking Member Guthrie asked how similar vaccines authorized under an EUA would be similar to licensed vaccines. Dr. McClellan explained that vaccine safety standards are "very similar" between FDA licensure and EUA. He added that multiple layers of review, including by FDA career scientists, FDA's Vaccines and Related Biological Products Advisory Committee, and CDC's Advisory Committee on Immunization Practices (ACIP), will ensure the approved COVID-19 vaccine is safe and effective.

Rep. Yvette Clarke (D-NY) asked if a COVID-19 vaccine will be enough to "stamp out" this pandemic. Dr. Jha explained that "even under the most optimistic scenario," a COVID-19 vaccine will likely be about 70 percent effective, and possibly only 70 percent of the population will get the vaccine. He added that the vaccine will need to be implemented along with other multiple public health measures. As noted in the committee memorandum, "herd immunity" is typically achieved when 70 to 90 percent of the population develops immunity to a disease, which occurs through infection or vaccination.

Communities of Color

Rep. Joe Kennedy (D-MA) expressed concern that vaccine manufacturers are "struggling to recruit Black participants" for their clinical trials. Dr. Gayle recommended manufacturers conduct clinical trials in ways that are "accessible to communities most hard hit by the pandemic," which entails considering where the trials are done, which doctor's offices participate in clinical trials, and medical institutions that are engaged. Dr. Jha suggested engaging community leaders and religious leaders.

After pointing out **Rep. Raul Ruiz (D-CA)** that the NASEM committee's draft framework for COVID-19 allocation does not specifically name communities of color as a priority group, he asked what the committee considered. Dr. Gayle explained that the committee applied CDC's "social vulnerability index," which incorporates multiple factors (including socioeconomic status; race, ethnicity, and language; household composition; and housing and transportation) and has been used to allocate resources during public health emergencies. Rep. Ruiz called for evaluations to see if recommendations are followed.

COVID-19 Vaccine Distribution and Management

Rep. Ann Kuster (D-NH) asked how Congress can support COVID-19 vaccine distribution and management. Dr. Khan said strengthening the "four to five [data] systems that have to work together," including immunization registries, CDC's Vaccine Adverse Event Reporting System, among others.

Regarding existing infrastructure, Dr. Offit expressed concern that at least one of the COVID-19 vaccines will require ultra-cold shortage (i.e., minus 80 degrees Celsius), which may likely pose challenges (e.g., replenishing dry ice, which has not typically been used to store vaccines).

Pharmacists' Scope of Practice

Rep. Buddy Carter (R-GA) called for a "blanket policy" allowing all pharmacists to administer COVID-19 vaccines. He explained that his is currently working with the Centers for Medicare and Medicaid Services (CMS) to grant pharmacists, on a temporary basis, "provider status," which would facilitate reimbursement for administering a COVID-19 vaccine under Medicare. Chair DeGette said she would work with Rep. Carter on securing that regulation.