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. How is the work of the National Academies of Sciences, Engineering, and Medicine's (National Academies) Committee on Equitable Allocation of Vaccine for the Novel Coronavirus different than the traditional role in vaccine allocation by the Advisory Committee on Immunization Practices (ACIP)?

    a. **RESPONSE:**
    The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) requested this study from the National Academies of Sciences, Engineering, and Medicine in order to provide independent, expert advice to supplement analyses and inform the decisions by the federal government and state, tribal, local, and territorial (STLT) authorities as COVID-19 vaccination plans and guidelines are created. The study conducted by the National Academies is an independent, nongovernmental study. Given that the COVID-19 pandemic is such an important, complex, and unprecedented issue, it makes sense that the federal government would seek advice from a broad array of expert sources in order to decide how to best move forward. The National Academies has a proven track record of providing trusted advice in similar situations, such as public health emergencies and disasters like Ebola and Hurricane Katrina.

    Meanwhile, ACIP is a well-respected and highly effective federal government advisory committee with expertise and experience in advising CDC on vaccination practice and policy. ACIP's scope of work will also continue beyond that of the National Academies report since our study committee has completed its work. Importantly, ACIP will have the ability to adjust its priority groups and plans for allocation and distribution—drawing from the National Academies report and other resources—as more information about the availability of COVID-19 vaccine emerges.

2. How is the National Academies's Committee on Equitable Allocation of Vaccine for the Novel Coronavirus working with ACIP to ensure there is clear guidance on vaccine allocation once a vaccine is available?

a. **RESPONSE:**
While the National Academies conducted its study independently, we remained in contact with ACIP throughout the study process. Current ACIP chair, Dr. Jose Romero, presented to our study committee at our first public meeting in July 2020 to discuss the role of ACIP in vaccine policy. A number of committee members and National Academies staff attended the public ACIP meetings in July, August, and September 2020 as well. In coordination with CDC staff, Dr. Romero also attended the briefing we provided to CDC upon the report's release in October 2020. We stand ready to answer any questions that ACIP and CDC may have as they continue to consider COVID-19 vaccine allocation.

The Honorable Diana DeGette (D-CO):

1. If any member of the Administration authorizes or approves the use of a coronavirus disease 2019 (COVID-19) vaccine prior to or over the objection of the U.S. Food and Drug Administration, 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?

a. RESPONSE:
Our report addresses this issue in the chapter titled *Achieving Acceptance of COVID-19 Vaccine* (Chapter 7). Among the unique challenges to COVID-19 vaccine acceptance in the United States are evolving concerns about the politicization of the vaccine development and approval process. To counter potential political interference and assuage concerns about the safety and speed of vaccine development, FDA has developed recommendations for the performance of any approved COVID-19 vaccine and committed to the use of an independent advisory committee to decide about licensure of candidate vaccines.

While the scenario posed in the question is not explicitly addressed in the report, given concerns over the FDA process and the lack of confidence in broader failures to contain COVID-19, it is my personal belief that such action would erode public confidence in COVID-19 vaccine, which is already of concern based on recent polls.

The Honorable Brett Guthrie (R-KY):

1. Given that the vaccine supply schedule for H1N1 projected by manufacturers was much faster than what could actually be achieved, even for the initial supply target populations, how do you think ACIP and the Centers for Disease Control and Prevention (CDC) can reduce the possibility of unrealistic projections of the COVID-19 vaccine supply schedule?

a. **RESPONSE:**
This question falls outside the scope of the study and is better suited to be answered by ACIP, CDC, Operation Warp Speed, and other federal partners. However, we acknowledge throughout the report that the number of vaccine doses to be initially made available remains a key unknown affecting vaccine allocation and could be

lower than anticipated. As a result of this unknown as well as other unknowns, we also stress the importance of risk communication in COVID-19 vaccination planning.

2. The discussion draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine notes a major success from the H1N1 pandemic was the use of public-private partnerships to allocate and distribute the vaccine. What steps would you advise the CDC to take to ensure these types of partnerships are maximized so the COVID-19 vaccine can be distributed timely?

   a. **RESPONSE:**
   The federal government's Operation Warp Speed is a public–private partnership leveraging relationships with pharmaceutical companies, manufacturers, and distributors to support the development and distribution of COVID-19 vaccine (e.g., McKesson will support distribution plans). In the final report released on October 1, we also recommend the importance of leveraging and expanding the use of existing systems, structures, and partnerships across all levels of government to support coordination and ensure equitable allocation of COVID-19 vaccine, which could include existing public–private partnership mechanisms in place across jurisdictions. Specifically, we recommend:

   RECOMMENDATION 2. Leverage and expand the use of existing systems, structures, and partnerships across all levels of government and provide the necessary resources to ensure equitable allocation, distribution, and administration of COVID-19 vaccine.

   The U.S. Department of Health and Human Services should commit to leveraging and expanding the use of existing systems, structures, and partnerships across all levels of government and provide the resources necessary to ensure equitable allocation, distribution, and administration of COVID-19 vaccine. Equitable allocation must be supported by equitable distribution and administration. Specific action steps to implement this recommendation are as follows:

   - Provide resources (including resources for staff) to state, tribal, local, and territorial (STLT) authorities and their implementation partners and adequately fund indirect assets (e.g., needles, syringes, personal protective equipment for vaccinators, resources for ultra-cold chain management, and so forth) necessary for effective vaccine allocation, distribution, and administration.
   - To ensure identification and delivery of COVID-19 vaccine to priority population groups, develop the capacity and systems to collect and integrate the necessary data (digital and other) from public health and private providers of care to facilitate the identification and monitoring of people with preexisting conditions and other high-risk characteristics.
   - Establish a robust and comprehensive surveillance system to monitor, detect, and respond to identified problems, gaps, inequities, and barriers. Monitoring should encompass equitable vaccine allocation and distribution, vaccine delivery, adverse events following immunization, promotion and communication, and uptake and coverage.

- Ensure that a rigorous COVID-19 vaccine safety monitoring program, built on existing systems, is in place, with an emphasis on rapid reporting and timely and transparent assessment of adverse events to determine whether events are associated with receipt of vaccine or occurring by chance.

3. In addition to the extensive efforts to support development of vaccines and therapeutics themselves, the Administration has made efforts to secure ancillary supplies needed to administer vaccines—such as glass vials, needles, syringes, and alcohol pads. With the concern of medical supply chain shortages throughout this pandemic, how much emphasis was placed on ancillary supplies when creating the framework for distribution?

   a. **RESPONSE:**
   Our report addresses this issue in the chapter titled *Administering and Implementing an Effective and Equitable National COVID-19 Vaccination Program* (Chapter 5). Recommendation 2 calls for HHS to provide resources to state, tribal, local, and territorial authorities and their implementation partners, including funding for indirect assets such as needles, syringes, and other ancillary supplies necessary for successful vaccine distribution and administration.