

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

August 5, 2020

The Honorable Deborah L. Birx, M.D.
Coronavirus Task Force Coordinator
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Dr. Birx and Secretary Azar:

On July 21, 2020, the Committee held an oversight hearing on the efforts underway to develop a safe and effective vaccine against the coronavirus disease of 2019 (COVID-19). Congress has provided billions of dollars to support the unprecedented pursuit of a COVID-19 vaccine and we applaud the progress that has been made to date through public-private partnerships. We continue to root for collective success in finding a COVID-19 vaccine that is both safe and effective, that will be a crucial tool in helping restore the nation's health and economy.

As the pursuit for a safe and effective COVID-19 vaccine proceeds, however, we are concerned that the Trump Administration has yet to finalize and release a national COVID-19 vaccine plan. Alarming, in the absence of a comprehensive plan, the Administration appears to be making decisions without the critical input of public health partners or consideration for the existing infrastructure the nation has long relied upon for the allocation, distribution, and tracking of vaccines. While the Administration has awarded billions of dollars for the development and manufacturing of COVID-19 vaccines, Congress, key public health stakeholders, and the American people have yet to be informed about how the Administration intends to ensure the equitable distribution of a vaccine once it is available.

On May 21, 2020, we wrote to the Trump Administration's White House Coronavirus Task Force regarding the urgent need for a comprehensive national COVID-19 vaccine plan that extends beyond research and development—including manufacturing, distribution, education, and patient cost considerations.¹ In our letter, we requested critical information about the

¹ Letter from Rep. Frank Pallone, Jr., Chairman, House Committee on Energy and Commerce, Rep. Diana DeGette, Chair, Subcommittee on Oversight and Investigations, to Deborah Birx, White House Coronavirus Task Force Coordinator (May 22, 2020).

Administration's vaccine planning efforts and sought a copy of the plan itself.² More than two months later, we have yet to receive a response. According to testimony from senior Administration officials before this Committee on June 23, and before the Senate Committee on Appropriations on July 2, such a plan is still under development more than six months into the COVID-19 pandemic.³

Despite the lack of a comprehensive plan, the White House and the Operation Warp Speed (OWS) initiative appear to be advancing decisions that will impact future COVID-19 vaccine distribution efforts. In an interview on May 14, 2020, President Trump indicated that the U.S. military would be mobilized to distribute a COVID-19 vaccine once it was available.⁴ More recently, reportedly at the initial request from Dr. Francis Collins, Director of the National Institutes of Health—followed later by a formal request from Dr. Collins and Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention (CDC)—the National Academies of Sciences, Engineering, and Medicine (NASEM) convened a new committee to develop “a framework for equitable allocation of vaccine for the novel coronavirus.”⁵

While we value the input of NASEM, these ongoing efforts do not appear to fully incorporate CDC, the Advisory Committee on Immunization Practices (ACIP), and state, territorial, tribal, and local health departments, all of which have played critical roles in planning and implementing existing vaccine programs and prior outbreak responses. The nation's current immunization system, for example, relies on ACIP, which is convened by CDC, comprised of medical and public health experts, and charged with developing recommendations on the use of vaccines in the United States.⁶ According to ACIP Chairman Dr. José Romero, however, the Administration has yet to provide clarity as to ACIP's role or any assurance that the prioritization

² *Id.*

³ House Committee on Energy and Commerce, *Hearing on Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (June 23, 2020); Senate Committee on Appropriations, *Hearing on Review of Operation Warp Speed: Researching, Manufacturing, & Distributing a Safe & Effective Coronavirus Vaccine*, 116th Cong. (July 2, 2020).

⁴ *Trump says he would mobilize military to distribute coronavirus vaccine when it's ready*, CBS News (May 15, 2020).

⁵ *Confusion spreads over system to determine priority access to Covid-19 vaccines*, STAT News (July 22, 2020); National Academies of Sciences, Engineering, and Medicine, *A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus*, (accessed July 28, 2020) (www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus#sectionCommittee).

⁶ Centers for Disease Control and Prevention, *Advisory Committee on Immunization Practices (ACIP) General Committee-Related Information* (accessed July 28, 2020) (www.cdc.gov/vaccines/acip/committee/index.html).

guidelines it develops will contribute to the national COVID-19 vaccine plan.⁷ And, in a presentation to ACIP on OWS, Administration officials reportedly asked ACIP members to bear with the “lack of ability to provide a lot of specifics about what we're doing.”⁸

Additionally, as of July 22, 2020, Claire Hannan, the Executive Director of the Association of Immunization Managers (AIM)—a 21-year-old-organization representing the leadership of CDC-funded programs across 64 states and territories working together to improve immunization coverage in the United States—had not heard from OWS.⁹ In addition to her concerns regarding “how distribution will be carried out” and “the lack of planning with state and local public health agencies,” she stated that AIM members had “received no assurance that existing vaccine allocation, distribution, and tracking systems will be used.”¹⁰

The Administration’s apparent lack of engagement with these key stakeholders is deeply troubling. Experts agree that CDC and public health partners will be vital to the successful execution of a future COVID-19 vaccine program. In a recent report, for instance, Johns Hopkins University researchers spoke to the importance of these public health partners’ roles in the distribution of vaccines in prior pandemics.¹¹ The researchers also noted that the U.S. Department of Defense (DOD) appears to be taking over CDC’s role with respect to the distribution of COVID-19 vaccines, cautioning that this may undermine public confidence in any eventual COVID-19 vaccine.¹² If true, in addition to threatening public trust in a future COVID-19 vaccine, distribution efforts by DOD may also risk duplicating or undermining existing public health partners and infrastructure with longstanding experience in supporting the distribution, allocation, and tracking of vaccines.

Finally, some vaccine company executives have also emphasized the importance of partnering with these public health experts to ensure equitable distribution of a future COVID-19 vaccine. In testimony before the Committee, for example, Dr. Julie Gerberding, Executive Vice

⁷ *Confusion spreads over system to determine priority access to Covid-19 vaccines*, STAT News (July 22, 2020).

⁸ *Even once a vaccine gets approved, big hurdles remain for distribution*, CNN (July 23, 2020).

⁹ *Confusion spreads over system to determine priority access to Covid-19 vaccines*, STAT News (July 22, 2020).

¹⁰ *Id.*

¹¹ Schoch-Spana, Monica, Emily Brunson et al, *The Public’s Role in COVID-19 Vaccination: Planning Recommendations Informed by Design Thinking and the Social, Behavioral, and Communication Sciences*, Johns Hopkins University (July 2020).

¹² *Id.*

President and Chief Patient Officer of Merck—and a former CDC Director—stated, “we cannot possibly do this without the CDC and the frontline of our state and local health departments.”¹³

Public health leaders and the existing immunization infrastructure will be vital to the development and implementation of a national COVID-19 vaccine plan. Unfortunately, the Administration’s apparent failure to engage these stakeholders, its continued secrecy surrounding OWS, and its ad hoc announcements in lieu of a comprehensive national plan perpetuates confusion and further threatens public trust in a future COVID-19 vaccine.

Given the concerns above, we reiterate our request for a staff briefing on the full scope of OWS and responses to our May 21 letter, as well as responses to the following by August 19, 2020.

1. When will the Administration publicly release its national COVID-19 vaccine plan?
2. Will the Administration include public health experts and partners, including CDC career staff, and state, territorial, tribal, and local health officials, including state immunization program leadership, in the development of its COVID-19 vaccine plan? If so, when?
3. What will be DOD’s role with regard to the distribution of a future COVID-19 vaccine? Will DOD coordinate with CDC and state, territorial, tribal, and local health officials to utilize existing immunization program distribution centers and processes?
4. What is the role of the newly charged NASEM committee and its relationship with ACIP and their respective guidance recommendations for populations to prioritize for future COVID-19 vaccination?

Thank you for your attention to this matter. If you have any questions, and to schedule the requested briefing, please contact Jesseca Boyer and Kevin Barstow of the Majority staff at (202) 225-2927.

Sincerely,



Frank Pallone, Jr.
Chairman



Diana DeGette
Chair
Subcommittee on Oversight
and Investigations

¹³ House Committee on Energy and Commerce, *Hearing on Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine*, 116th Cong. (July 21, 2020).