

November 16, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human
Services
200 Independence Avenue, SW
Washington, D.C. 20201

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Secretary Azar and Dr. Redfield:

We write to express concern about the lack of details regarding the Centers for Disease Control and Prevention (CDC) and Health and Human Services' (HHS) plans for allocation, transportation, distribution, and storage of approved or authorized COVID-19 vaccines. We are especially concerned about the logistics of distributing and storing vaccines that require ultra-cold storage, particularly in rural and remote areas.

The CDC's interim COVID-19 Playbook, published on September 16, 2020, provided initial guidance to state, territorial,¹ and local public health programs and their partners for planning and operationalizing a vaccination response to COVID-19 within their jurisdictions. The Playbook also asked that states submit their distribution plans to the CDC within 30 days. According to the Playbook, it is expected that cold chain storage and handling requirements for COVID-19 vaccine products will range from refrigerated (2°C to 8°C) to frozen (-15 to -25°C) to ultra-cold (-60°C to -80°C). Yet, jurisdictions were advised not to purchase ultra-cold storage equipment at this time.²

The Playbook's lack of details prompted the National Governors Association (NGA) to send a list of additional questions to the agencies on October 18, 2020 covering a range of topics including funding for vaccine administration, allocation and supply chain, and communication and information requirements. Among the concerns raised by NGA is the need for more details on handling vaccines that should be stored at ultra-cold temperatures, including if states should purchase ultra-cold freezers and how the vaccines requiring ultra-cold storage can be redistributed. The NGA questions also cited a shortage of dry ice, which is currently being used to store vaccines during clinical trials, and asked about plans for redistribution of vaccines requiring ultra-cold storage. The answers received on November 5, 2020 noted that plans were still forthcoming regarding redistribution of vaccine, provided minimal details on ultra-cold storage requirements, and lacked critical details spelling out how the federal government will ensure states have the necessary equipment required for management of ultra-cold vaccines.

¹ *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*, (Sept. 16, 2020), defines this as the U.S.-affiliated Pacific Islands of American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

² *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*, (Sept. 16, 2020), available at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

While we understand that some logistical details may be unknowable at this time given that a vaccine has yet to be granted an Emergency Use Authorization (EUA), it is alarming that the federal government has not provided more detailed guidance or additional resources to help state, territorial, and local governments understand the most likely mechanisms for distribution or requirements and recommendations for maintaining the cold chain, funding projections, or critical risks that should be addressed.

This lack of guidance has severely hindered the ability of state, Tribal, territorial, and local public health officials to develop distribution plans and of individual clinics to prepare to accept, store, handle, and administer vaccines, and to share their comprehensive plans with CDC. Additionally, unknowns around cold chain storage issues add to the already difficult task of ensuring vaccination locations can schedule vaccine clinics to administer the doses quickly while also adhering to public health protocols like social distancing.

The time to get ahead of potential distribution issues and cold chain requirements is now. The federal government should be looking ahead to secure our supply chains and prepare to adequately transport and distribute whatever vaccine becomes available first. Communities around the country are still trying to compensate for the federal government's failure to secure adequate and sustainable supplies of personal protective equipment earlier this year³ and throughout the pandemic. That failure has had tragic results, and your agencies should be doing everything in your power to avoid such a fiasco with the distribution of a vaccine.

These concerns are not hypothetical. Several leading vaccine candidates are expected to require cold or ultra-cold storage. For example, without adequate cold chain refrigeration mechanisms, deployment of the Pfizer/BioNTech vaccine, which recently demonstrated a high level of efficacy in Phase 3 trials⁴, would be severely limited, impacting not only the ability to transport the vaccine, but clinics' ability to store and administer the vaccine to patients as well.

We understand that Pfizer has made an investment in the design of a reusable container to keep the vaccine ultra-cold for up to 10 days.⁵ While that will be helpful to ensure initial delivery, our concerns lie with what is being done to enable this cold chain to be maintained beyond that point so that shipments may be unpacked and moved in smaller lots. Neglecting to invest in additional ultra-cold transportation and storage capabilities would necessitate that an ultra-cold vaccine could only be used in certain settings with proper storage equipment, further exacerbating the disparity of the pandemic among poor, rural, and marginalized communities.⁶

Put another way, we know a vaccine is coming. We know cold storage and transport capacity are likely necessary. We know that there is insufficient capacity nationwide. Therefore, we need the

³ Testimony of Dr. Rick Bright, former Director of the Biomedical Advanced Research and Development Authority (BARDA) before the House Energy and Commerce Subcommittee on Health, May 14, 2020. Available at: <https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/200511%20Testimony%20of%20Dr.%20Rick%20BrightRevised.pdf>

⁴ *Press Release*. Nov. 9, 2020, available at <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against>

⁵ See Costas Paris and Jared S. Hopkins, *Pfizer Sets Up Its 'Biggest Ever' Vaccination Distribution Campaign*, The Wall Street Journal, Oct. 21, 2020, available at <https://www.wsj.com/articles/pfizer-sets-up-its-biggest-ever-vaccination-distribution-campaign-11603272614>

⁶ See Selena Simmons Duffin and Pien Huang, *Facing Many Unknowns, States Rush To Plan Distribution Of COVID-19 Vaccines*, NPR, Oct. 16, 2020 available at <https://www.npr.org/sections/health-shots/2020/10/16/924247360/facing-many-unknowns-states-rush-to-plan-distribution-of-covid-19-vaccines>

federal government to be planning ahead to ensure that our delivery networks, equipment procurement, supply chains, and other logistical capacities are secure and operational *before* the first vaccine is ready. Without such preparation, we can expect a tragic delay that may unnecessarily cost additional loss of life.

We urge the CDC and HHS to work with state, Tribal, territorial, and local stakeholders to identify gaps in ultra-cold storage capability, particularly in outlying and underserved communities, and then utilize all existing authorities to prevent shortages, including by coordinating with the Department of Defense (DoD) to leverage the Defense Production Act (DPA) to produce the supplies necessary to ensure ultra-cold storage capability. The federal government must use every tool at its disposal to guarantee the safe, timely, and effective delivery of a COVID-19 vaccine as soon as it is approved or authorized for use by the Food and Drug Administration.

To ensure stakeholders nationwide can be prepared to distribute, store, and administer ultra-cold vaccine(s), we request responses to the following:

- 1) Do state vaccination plans report on the number and location of health care providers that have ultra-cold storage capabilities?
 - a. If so, please characterize the types of provider locations that have ultra-cold storage capabilities, including the types of populations they serve (rural/urban, socioeconomic, and racial/ethnic demographic groups).
 - b. If not, do you plan to request this information in the future?
- 2) Do you anticipate adequate supplies of dry ice to be able to serve nationwide demand if a vaccine requiring ultra-cold storage is authorized?
 - a. If so, please explain your rationale.
 - b. If not, please describe the steps your agencies will take to ensure adequate supplies.
- 3) Besides dry ice, what additional supplies are needed and what protocols should be implemented to maintain the cold chain (and ultra-cold chain if required) and to properly handle cold or ultra-cold vaccines?
- 4) What are critical risks that state, Tribal, territorial, and local health departments should plan for in advance of vaccine distribution?
- 5) Reports indicate that CDC has advised health departments and providers to not purchase ultra-cold freezers, though many larger hospital systems and some state health departments have still chosen to invest in this equipment.⁷
 - a. Please detail any guidance your agencies have provided to health care providers and state, Tribal, territorial, and local health departments about the purchase of

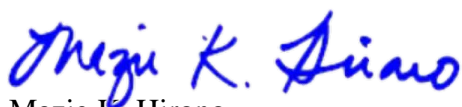
⁷ See Olivia Goldhill, *'We're being left behind': Rural hospitals can't afford ultra-cold freezers to store the leading Covid-19 vaccine*, STAT News, Nov. 11, 2020, available at <https://www.statnews.com/2020/11/11/rural-hospitals-cant-afford-freezers-to-store-pfizer-covid19-vaccine/>

ultra-cold freezers in preparation for vaccine distribution, particularly for storage and distribution in rural and underserved communities.

- b. Does CDC have confidence that rural and remote settings without access to freezers will be able to safely and efficiently distribute a vaccine that must be stored at ultra-cold temperatures?
 - c. Please detail the agency's thinking in providing these recommendations, and any contingency planning if settings experience constraints due to a lack of freezer equipment.
- 6) CDC has stated it is up to the states to coordinate the distribution of smaller dose packages for more rural communities.
- a. Does CDC have confidence that all states will have the appropriate expertise, resources, and capacity to ensure that this occurs effectively? If so, please provide that analysis.
 - b. Will CDC support this distribution including through resources, funding, and supplies if requested by a state, or if a state is determined to have inadequate capacity?
 - c. Has the CDC communicated with vaccine developers, including Pfizer, about making changes to the package size of vaccine allotments, including guidance on breaking up packages or providing additional cold-storage supplies, to better support distribution to rural communities?
- 7) In the beginning of the pandemic, due to the federal government's lack of leadership and guidance, states began procuring their own medical equipment, like ventilators, and Personal Protective Equipment (PPE), creating bidding wars between states and unnecessarily driving up the costs of these items. How will the administration use the DPA and/or other authorities to ensure all communities have access to the equipment required for cold and ultra-cold chain management, including for redistribution to rural and underserved communities?

We request a response addressing these concerns by no later than November 30, 2020, as well as a briefing by appropriate administration officials so that Members and staff can discuss cold chain and other distribution logistics. We look forward to your response.

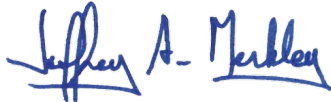
Sincerely,



Mazie K. Hirono
United States Senator



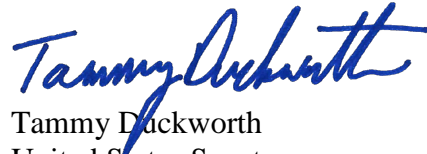
Cory A. Booker
United States Senator



Jeffrey A. Merkley
United States Senator



Tina Smith
United States Senator



Tammy Duckworth
United States Senator



Kristen Gillibrand
United States Senator



Chris Van Hollen
United States Senator



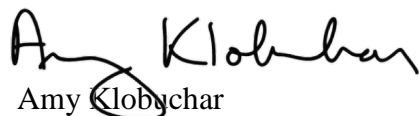
Sherrod Brown
United States Senator



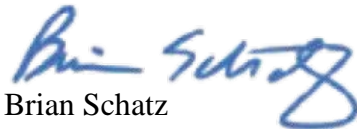
Elizabeth Warren
United States Senator



Tammy Baldwin
United States Senator



Amy Klobuchar
United States Senator



Brian Schatz
United States Senator

Cc: Acting Secretary of Defense, Christopher C. Miller