

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

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

The Honorable Christopher Miller
Acting Secretary
U.S. Department of Defense
1000 Defense Pentagon
Washington, D.C. 20301

Dear Secretary Azar and Acting Secretary Miller:

The promising developments in vaccine candidates bring us one step closer to curtailing what has become uncontrolled spread of COVID-19. Widespread availability of COVID-19 vaccines will be critical to overcoming this pandemic, but the distribution of these vaccines presents a herculean logistical challenge that must be met with seamless federal and state coordination and planning. This is a task that requires a whole of government response. I write to ensure our nation is prepared to engage in the largest vaccine campaign in U.S. history to safely, effectively, and equitably distribute millions of COVID-19 vaccines to Americans, when authorized for emergency use by the Food and Drug Administration (FDA). With over a quarter of a million American lives already lost from this virus, we cannot afford avoidable missteps or unnecessary delay.

The COVID-19 pandemic has exacerbated many vulnerabilities in our nation's medical supply chain. While the federal government has made significant investments to expand domestic manufacturing capacity and supply of needles, syringes, and glass vials, concerns remain regarding the availability of critical ancillary supplies needed to safely distribute and administer COVID-19 vaccines, such as personal protective equipment (PPE). Last month, the Government Accountability Office (GAO) identified limited manufacturing capacity and potential disruptions in supply chains as challenges to the distribution of COVID-19 vaccines.¹ Recent supply chain disruptions will reportedly impact expected worldwide vaccine shipments from one developer by half – from 100 million doses to 50 million by the end of this year.² According to one report, HHS has indicated these disruptions should not impact expected U.S. supply this month.³ Although Operation Warp Speed has emphasized the need for visibility into both vaccines and ancillary supplies, this information must be consistently shared with states and

¹ Government Accountability Office, *COVID-19: Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations* (GAO-21-207) (Nov. 2020).

² *Pfizer Slashed Its Original Covid-19 Vaccine Rollout Target After Supply-Chain Obstacles*, New York Times (Dec. 3, 2020) (<https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787>).

³ *Marks: Quick vaccine authorization possible after ad comms*, Politico Prescription Pulse (Dec. 4, 2020) (<https://www.politico.com/prescriptionpulse/>).

public health departments to improve coordination, garner trust, and set expectations.⁴ We learned early in the pandemic that transparency is essential for coordinated and successful supply distribution, and the same principles apply to the nation's vaccination efforts.

Our states also face significant challenges in this effort, including the complex logistics of vaccine delivery and public hesitancy surrounding COVID-19 vaccines. Of the three vaccine candidates that have released preliminary or full data as of this letter, one vaccine must be stored on dry ice at ultra-cold temperatures with strict handling instructions, while another must be kept frozen.⁵ Further, none of the vaccines are interchangeable, making traceability – knowing which individual received what vaccine – of critical importance.⁶ In addition, political pressure on scientific agencies like the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) have shaken public confidence in the federal government's response efforts, including vaccinations.⁷ Clear and consistent communication and public engagement will be essential for a successful vaccination campaign. To build public trust and actively combat misinformation and disinformation about COVID-19 vaccines, this Administration must provide transparent and nonpartisan information to the American people.

Another concern is the impending costs of this effort. Without sufficient federal funding, states' ability to rollout their vaccine distribution plans will be restricted. Although the *CARES Act* and the *Coronavirus Preparedness and Response Supplemental Appropriations Act* made funding available for the development and purchase of COVID-19 vaccines, additional funding is critically needed. Reports indicate that states need anywhere from \$6 billion to \$8.4 billion for vaccine distribution.⁸ Concerns remain that without sufficient funding, states will be hamstrung in effectively implementing their vaccine distribution campaigns, regardless of even the most meticulous planning efforts.

I ask that your agencies do everything possible to ensure a seamless transition focused on safe, effective, and equitable vaccine distribution preparedness. To ensure the swift and safe distribution of eventual COVID-19 vaccines, I request responses to the following questions as soon as possible, but no later than December 14, 2020.

⁴ *In Warp Speed Effort, Knowing Where Vaccines Are Is Key to Distribution Strategy*, U.S. Department of Defense (Oct. 28, 2020) (<https://www.defense.gov/Explore/News/Article/Article/2395789/in-warp-speed-effort-knowing-where-vaccines-are-is-key-to-distribution-strategy/>). The Department of Defense (DOD) has identified four tenets for vaccine distribution: visibility and control; uptake; traceability; and coverage.

⁵ *The challenges Pfizer faces distributing its Covid-19 vaccine to the masses*, CNBC (Nov. 25, 2020) (<https://www.cnbc.com/2020/11/25/challenges-pfizer-faces-distributing-covid-19-vaccine-to-the-masses.html>).

⁶ *Operation Warp Speed Refines Vaccine Delivery Plan*, U.S. Department of Defense (Nov. 23, 2020) (<https://www.defense.gov/Explore/News/Article/Article/2423700/operation-warp-speed-refines-vaccine-delivery-plan/>).

⁷ *More Americans Now Willing to Get COVID-19 Vaccine*, Gallup (Nov. 17, 2020) (<https://news.gallup.com/poll/325208/americans-willing-covid-vaccine.aspx>).

⁸ *Missing From State Plans to Distribute the Coronavirus Vaccine: Money to Do It*, New York Times (Nov. 14, 2020) (<https://www.nytimes.com/2020/11/14/health/covid-vaccine-distribution-plans.html>).

1. To ensure sufficient uptake, any vaccine must be trusted by the public.
 - a. What specific steps has the Administration taken to increase public confidence in a vaccine, including specific public education campaigns and resources?
 - b. What support, if any, has the Administration provided to states and other jurisdictions in the development of such campaigns and community engagement efforts? How is the Administration working to build trust in communities of color that have been disproportionately affected by this virus?
2. How will the Administration ensure transparency and equity in its vaccine distribution and allocation process?
 - a. What specific factor(s) is the Administration using to determine vaccine allocation to jurisdictions?
 - b. How, if at all, does the Administration anticipate this allocation criteria will change as vaccine availability increases? Does the Administration plan to ship vaccines outside the U.S.?
 - c. How does the Administration define a hot spot and what methodology is used to make this determination? Will hot spots play a role in allocating vaccines to states? If so, why?
3. How is the Administration working to actively combat misinformation and disinformation surrounding vaccines and secure the COVID-19 vaccine infrastructure from potential cyberattacks?
4. Given the country's continued shortages of vital PPE, what measures are your agencies taking to ensure a sufficient amount of PPE is available for health care workers to safely treat the rising number of COVID-19 patients and administer eventual COVID-19 vaccines?
 - a. According to a recent GAO report, states have reported concerns about having enough supplies needed to administer vaccines, such as needles. In addition to the federal government's previous investments in expanding manufacturing capacity for vaccine supplies, please describe HHS's plan to mitigate shortages.
 - b. How will the federal government ensure coordination of vaccine shipments with the appropriate ancillary supply kits?
5. How are Operation Warp Speed, the Department of Defense (DOD), CDC, and any other relevant agencies working with the incoming Biden Administration to ensure they are prepared to oversee widespread vaccine distribution?
 - a. What support is needed from Congress to ensure a unified transition between Administrations?
6. Please explain in detail how the federal government plans to continue supporting state public health departments in executing their vaccine distribution plans once FDA issues emergency use authorization(s).

- a. Will the federal government's support change as states move through the phased priority groups?
7. A successful vaccine distribution campaign will require a number of effective, up-to-date information technology systems, both existing and newly developed, to track vaccine distribution, administration, and other information. While data systems appear to be in place at both the state and federal levels, their seamless and secure operation is critical.
 - a. Please explain any shortfalls and anticipated challenges with current technology systems that will be used in vaccine distribution, the status of each system (existing or in development), and what steps have been taken to ensure each system is working as intended.
 - b. The CDC has stated that each state should have an immunization information system that is up to date and capable of storing and submitting certain information to the CDC. What steps has the Administration taken, if any, to support states and other jurisdictions in the development, update, and maintenance of these systems?
 8. How is the FDA ensuring that vaccine manufacturing facilities (including packaging and ancillary supply facilities) are in compliance with Current Good Manufacturing Practice (CGMPs) regulations and that the vaccines and supplies manufactured at those sites are safe?
 9. Please provide an accounting of any funds being used to support vaccine distribution, including accounting, monies expended, obligated, and any unobligated funds that could be used to support states' vaccine distribution efforts.

Thank you for your prompt attention to this matter. If you have any questions about this request, please contact Senator Peters' staff at (202) 224-2627.

Sincerely,



Gary C. Peters
Ranking Member

cc: Dr. Robert R. Redfield, Director, Centers for Disease Control and Prevention
Dr. Stephen M. Hahn, Commissioner, Food and Drug Administration
Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response
Gen. Gustave Perna, Chief Operating Officer, Operation Warp Speed
Dr. Moncef Slaoui, Chief Advisor, Operation Warp Speed