

Congress of the United States
Washington, DC 20515

December 18, 2020

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar,

As the COVID-19 pandemic continues to ravage our nation, we write seeking information associated with the supply chain and planned distribution of vaccines. We are pleased that two vaccines are now being, or about to be distributed throughout the country, and several vaccine candidates are in advanced clinical trials and the data released publicly thus far suggests a high level of efficacy. While the speed at which these vaccines were studied and developed is unprecedented, we remain concerned regarding supply chain constraints.¹ We are also troubled by the lack of transparency exhibited by this administration with respect to the planning for nationwide vaccine distribution, which we fear will result in unnecessary problems and delays.

In November, a Government Accountability Office (GAO) report detailed challenges scaling up production of COVID-19 vaccines, including limited manufacturing capacity, potential disruptions to manufacturing supply chains, and gaps in available workforce.² However, the administration did not agree nor disagree with GAO's findings, nor has it expressed any concern to Congress for proper oversight or potential assistance in this area.

Public confidence in a vaccine is of the utmost importance right now, but the administration is not providing sufficiently clear communication with the public, state and local governments, the incoming administration, or Congress. Evidence is clear that without Non-Pharmaceutical Interventions (NPIs), such as wearing a mask, frequent hand washing, and social distancing, even a vaccine that is 90 percent effective will be ineffective at fully stopping viral spread.³ Coupled with the administration's decision not to aggressively communicate the need for NPIs along with clear vaccine information, we are concerned regarding the administration providing insufficient support for state and local governments.⁴ The administration's lack of support for state and local health departments will undoubtedly slow the rate of vaccination and make it difficult to vaccinate vulnerable and hard to reach populations.

In a recent report regarding vaccine distribution challenges, twelve states said that they still await further information from the CDC and other federal partners on various aspects of distribution strategy. Seven states raised concerns about funding and resources that the federal government will contribute to state vaccination efforts. Other challenges states mentioned include limited state and local resource and workforce capacity, logistical issues associated with vaccine

distribution and storage, a lack of public confidence in vaccine efficacy and safety, and uncertainty about how to reach all target populations.⁵ Despite these well-known obstacles, states have started reporting incoming vaccine allocations will be half of expected totals, while manufacturers report ready-to-ship vaccine stockpiles sit in warehouses without adequate distribution instructions and coordination.⁶ As well, press reports indicate that the administration has failed to share adequate information with President-elect Biden's transition team on vaccine production and distribution.⁷ Anything but an entirely smooth and cohesive transition will undoubtedly result in unnecessary delays.

Additionally, reporting has identified that the Trump administration had the option to purchase additional doses of one vaccine last summer but declined.⁸ The United States has reserved roughly 800 million doses from six manufacturers including an initial 100 million each from Pfizer and Moderna, whose manufacturing capacities are already stretched thin due to agreements to provide the vaccine globally.⁹ OWS has remained incredibly opaque regarding its projections for how fast it can fully vaccinate the public and which manufacturers those projections depend on. Without transparency for Congress, the states, and President-Elect Biden's transition staff, the American people are left in the dark regarding vaccine safety and access.

Please answer the following questions by January 1, 2020:

1. Please detail the administration's response to state reports of lower-than-expected allocations, the current state of vaccine stockpiles, and what steps the administration is taking to remedy the situation. As well, please detail any and all distribution or logistical challenges considered for all vaccine candidates and how the administration is addressing each one. Please include any documentation or communication from states, localities, and tribal entities outlining any distribution or logistical challenges.
2. What specific supply chain assumptions and metrics is OWS relying on to determine vaccination campaign timelines? Specifically, which vaccine candidates are included in these metrics? How has OWS accounted for potential delays due to supply chain constraints?
3. Please detail how OWS has worked with Pfizer, Moderna, other vaccine manufacturers and suppliers to accelerate production timetables and expeditiously procure the necessary raw materials for all vaccine candidates.
4. Why does the administration believe invocation of the Defense Production Act for vaccine manufacturing is not necessary to address the current supply chain challenges?
5. Please detail efforts the administration has undertaken to strongly communicate the necessity of NPIs along with vaccine information to the public.
6. How is the current administration working with the incoming Biden administration to ensure seamless procurement, distribution and delivery regarding vaccine distribution? Does the administration have plans to work with local, state, and federally elected officials regarding vaccine distribution and administration?
7. Please detail the administration's plan to ensure equity in vaccine distribution. Please detail which experts and organizations were consulted to develop this plan?
8. In November, states were informed they would receive a certain number of doses of a vaccine once an Emergency Use Authorization (EUA) was granted. To everyone's

surprise and disappointment, in December, that number decreased dramatically for many states. What changed in the few weeks between announcements to reduce the number of vaccine doses expected? Please describe the formula being utilized for the number of vaccines states will receive.

9. Please include a breakdown of federal funding, by department or program, to each state for the purpose of vaccine distribution and administration.

We remain concerned regarding the lack of transparency from the administration during this process. It is vital that a mass vaccination campaign provide clear metrics for its timeline, be transparent about potential delays, and give clear and concise direction and communication to the American people if it expects to be successful. We look forward to your response by January 1, 2020.

Sincerely,



Bill Pascrell, Jr.
Member of Congress



Bradley S. Schneider
Member of Congress



Donald S. Beyer Jr.
Member of Congress



John B. Larson
Member of Congress



Brendan F. Boyle
Member of Congress



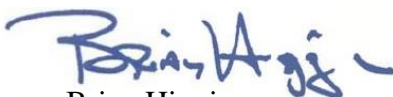
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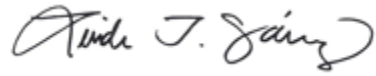
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Linda T. Sánchez
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Ron Kind
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¹ Supply-Chain Obstacles Led to Last Month's Cut to Pfizer's Covid-19 Vaccine-Rollout Target:

https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787?reflink=desktopwebshare_permalink

² Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations: <https://www.gao.gov/assets/720/710691.pdf>

³ Clinical Outcomes Of A COVID-19 Vaccine: Implementation Over Efficacy:

<https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.02054>

⁴ Missing From State Plans to Distribute the Coronavirus Vaccine: Money to Do It:

<https://www.nytimes.com/2020/11/14/health/covid-vaccine-distribution-plans.html>

⁵ Supporting an Equitable Distribution of Covid-19 Vaccines: <https://www.nga.org/wp-content/uploads/2020/12/Supporting-an-Equitable-Distribution-of-COVID-19-Vaccine.pdf>

⁶ Pfizer Says No Vaccine Shipments Have Been Delayed: <https://www.bloomberg.com/news/articles/2020-12-17/pfizer-says-no-vaccine-shipments-have-been-delayed>

⁷ Operation Warp Speed Head Says He's Been Instructed Not To Share Vaccine Information With Biden Team:

<https://www.forbes.com/sites/jemimamcevoy/2020/11/22/operation-warp-speed-head-says-hes-been-instructed-not-to-share-vaccine-information-with-biden-team/?sh=58c6f0733d33>

⁸ Trump administration officials passed when Pfizer offered months ago to sell the U.S. more vaccine doses:

<https://www.nytimes.com/2020/12/07/us/trump-covid-vaccine-pfizer.html>

⁹ Supply-Chain Obstacles Led to Last Month's Cut to Pfizer's Covid-19 Vaccine-Rollout Target:

https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787?reflink=desktopwebshare_permalink