

June 23, 2020

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

The Honorable Mark Esper
Secretary
Department of Defense
1000 Defense Pentagon
Washington, DC 20301

Dr. Moncef Slaoui
Chief Advisor, Operation Warp Speed
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

General Gustave F. Perna
Commanding General
Army Materiel Command
4400 Martin Road
Redstone Arsenal, AL 35898

Secretary Azar, Secretary Esper, General Perna, and Dr. Slaoui,

Providing a safe and effective vaccine for COVID-19 is key to fully reopening American society and preventing future outbreaks of the coronavirus. While I commend the goal of Operation Warp Speed (OWS) to deliver 300 million doses of a vaccine by January 2021, I am concerned about a lack of transparency and accountability around the project. A COVID-19 vaccine is of intense interest to Congress and the American public, and confidence in the process and results will only be possible with transparency. So far, there is limited information and clarity around the division of responsibilities, contracting decisions, and safeguards in place to ensure Americans' health and safety are the first priority.

At a Senate Armed Services Committee hearing on June 18, 2020, I asked General Perna if he would commit to brief Congress and the public every two weeks on OWS. He said he would report as directed. The importance of full and open transparency as OWS leadership make decisions of significant consequence in the weeks and months ahead cannot be overstated. I am asking again that a member of OWS leadership provide biweekly briefings to Congress on the project. Regular briefings to Congress not only allow for transparency and oversight, but also empowers Congress to help with additional authorities and funding as needed. Regular, open communication is key to successfully deploying the whole of nation effort that OWS purports to represent. I suggest that the first such briefing occur the week of July 6 and request that OWS leadership be prepared to answer the following questions:

1. What is the division of responsibilities among OWS leadership, specifically between General Perna and Dr. Slaoui?
2. According to a fact sheet on HHS's website, OWS has been "selecting the most promising countermeasure candidates and providing coordinated government support" including the awarding of over \$2 billion to private pharmaceutical companies developing a vaccine candidate. Who selected those vaccine candidates and what criteria and metrics were used to determine their award?

3. The OWS fact sheet mentions “investments in manufacturing capabilities.” Please provide additional information on those investments, including whether they are financial, and whether they are occurring in the private sector or the federal government.
4. How is OWS preparing to efficiently distribute a vaccine to patients across the nation? In the instance where there is an initial limited supply, will there be prioritization for who receives doses and how will that determination be made? How will the 25 – 40 million uninsured Americans access the vaccine?
5. As a condition of receiving support from OWS, companies will provide the U.S. government an allocation of countermeasures developed. Is that condition only required for companies receiving financial support? How large of an allocation will companies be required to provide? How will the government decide to distribute its allocation? Are there any requirements or limitations placed upon the remainder of a company’s countermeasure supply (for example, cost limitations or requirements to distribute equitably)?
6. Will OWS use any Defense Production Act authorities including to establish prices and coordinate distribution of a vaccine?
7. The American people must be confident that a COVID-19 vaccine is safe and effective. Unfortunately, confidence in the Food and Drug Administration’s (FDA) independence has already been eroded during this pandemic, when the agency granted Emergency Use Authorization for hydroxychloroquine, seemingly under political pressure from the president. How will OWS leadership and FDA assure the American public that any approved vaccine is based on science and independent of political pressure?
8. OWS is a massive use of taxpayer dollars. How will Congress and the public be kept informed of the selection process for awards for vaccine research, development, manufacture, and distribution?
9. This is a global pandemic and we should engage with all possible partners. Please provide the rationale for intentionally excluding any nation in this effort, as General Perna indicated he would do during his nomination hearing.

I appreciate and share your commitment to delivering a safe and effective vaccine to the American people and hope you will proactively engage with me and my colleagues in Congress so we can assist in this endeavor. I look forward to learning more about OWS in the near future.

Sincerely,



Mazie K. Hirono
United States Senator