Congress of the United States
Washington, DC 20510

July 23, 2020

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

Dear Secretary Azar,

We write to thank you for your continued efforts to accelerate the development of vaccines, therapeutics, and diagnostics for SARS-CoV-2. However, on the heels of the largest government contract awarded to date to develop a vaccine, we remain concerned about transparency and oversight around Operation Warp Speed (OWS).

OWS was launched on May 15 by the Administration as a private-public partnership with the goal to deliver "300 million doses of a safe, effective vaccine by January 2021." Since its launch, the Department of Health and Human Services (HHS) has announced over $6.6 billion in support to pharmaceutical companies such as Johnson & Johnson, Emergent BioSolutions, Moderna, AstraZeneca, and Novavax to expedite the development of a vaccine. However, the Administration has failed to lay out how these candidates have been selected to receive federal support nor made public the names of all the companies being funded under OWS.

Even the candidates selected seem unclear on the full details of the project. In an interview, Novavax's president and chief executive, Stanley C. Erck, said he was unsure where the money was coming from for their $1.6 billion contract to expedite 100 million doses of a vaccine by the beginning of next year.

Of particular concern is the vaccine technologies that are based on experimental techniques and by companies that have never brought these types of products to market. Moderna Therapeutics, the company with a COVID-19 vaccine frontrunner, has never had a FDA-approved product before. Top scientific experts on the National Institutes of Health's (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) committee have also stated that they were not consulted during the selection process of these candidates nor asked to vet their products. Every American has a stake in this work and it is vital that both Congress and the public understand the rationale behind the Administration's pursuit of this approach and the scientific reasoning guiding the decisions.

We are, therefore, writing to request that you answer the following questions:

1. How were the currently selected vaccine candidates chosen to participate in OWS?
2. What are the parameters of the scientific review undertaken by NIH to vet these candidates prior to selection?
3. How many candidates have been under review?
4. How many candidates will be chosen in total to participate in the program?
5. How is the federal government determining funding level in these contracts?

6. How will OWS and HHS assist these candidates conduct clinical trials? What is the timeline for these clinical trials?
7. How will OWS collaborate with other global partners in the development of a vaccine?
8. How many investments have been made under OWS to invest in ancillary supplies such as syringes and vials?

Additionally, we are concerned about the affordability of any therapeutic and vaccine developed to fight COVID-19 under OWS and BARDA contracts. In Senate testimony, Biomedical Advanced Research and Development Authority (BARDA) Director Gary Disbrow stated that vaccines developed with the help of taxpayer funding will come at a reduced price to taxpayers. We are encouraged by this statement and ask for these efforts — and BARDA contracts — to be made public. We would also ask the Director:

1. How will HHS and BARDA ensure that taxpayers receive a reduced price? Will HHS negotiate? If so, what process will be used?
2. If HHS does not receive a discounted price, is the agency prepared to assert patent rights it retains on COVID-19 vaccines and therapeutics?
3. Are the BARDA contracts required to adhere to federal procurement regulations? Are they subject to Bayh-Dole provisions? What, if any, avenues does HHS have to pursue affordable therapeutics if drug companies set the price out of reach?

We specifically request that you prohibit exclusive licensing in OWS contracts for vaccines and drugs that receive federal funding to ensure the medicines are accessible to everyone and to reflect the investment of taxpayers. We would also ask that you require these companies to make their drugs available at a fair and affordable price; at the very minimum, the price paid in the U.S. should be no more than the prices charged in other peer OECD countries.

Every American understands the urgency to develop a vaccine to counter the devastating effects COVID-19 has had on this country, and to return our nation and the world to a more normal footing. But we must do so safely and transparently. We look forward to your response and working together on this issue.

Sincerely,

PETER WELCH
Member of Congress

KATIE PORTER
Member of Congress

GILBERT R. CISNEROS, JR.
Member of Congress

MIKE DOYLE
Member of Congress

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