

**Congress of the United States**  
**Washington, DC 20515**

June 16, 2020

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

Dear Secretary Azar:

We write to express concern and request information about recent changes in leadership related to COVID-19 vaccine contracts managed by the Biomedical Advanced Research and Development Authority (BARDA) as part of the Trump Administration's Operation Warp Speed effort. Recently, it has come to our attention that the Administration has removed BARDA from project leadership in relation to several of the vaccine contracts, and replaced it with other agencies. Such reassignments undermine the mission and expertise of BARDA scientists and delay progress toward COVID-19 vaccine production and manufacturing. These disruptions threaten to prolong the COVID-19 pandemic, and put lives at risk. In order to avoid this unnecessary delay, we urge HHS to immediately reinstall BARDA employees as the project leads on COVID-19 vaccine contracts.

The development, production, and distribution of a safe and effective COVID-19 vaccine is of the utmost importance to public health and economic recovery. The Pandemic and All Hazards Preparedness Act (PAHPA) established BARDA as the focal point for the advanced research and development, acquisition, and manufacturing of medical countermeasures to protect Americans against threats to public health. In addition to BARDA's experience in providing technical assistance and core services ranging from a clinical research organization network to Centers for Innovation in Advanced Development and Manufacturing and a fill-finish manufacturing network, its track record of managing public-private partnerships that promote broad categories of countermeasures is unparalleled across the Federal government. It is the only entity at the Department of Health and Human Services (HHS) with the mission and capability to develop, manufacture and facilitate distribution of medical countermeasures during a public health emergency.

Congress has invested \$6.5 billion of supplemental appropriations in BARDA since March 2020 for the development, manufacturing, production, and purchase of medical countermeasures including diagnostics, therapeutics and vaccines against COVID-19. Since that time, BARDA has awarded five vaccine contracts in its COVID-19 medical countermeasures portfolio to AstraZeneca, ModernaTX, Inc., Merck and IAVI, Protein Sciences, and Janssen Research & Development, LLC. Given that it may be many months before a COVID-19 vaccine is available

for use, the Administration must employ an all-hands-on-deck approach by leveraging the strength and expertise of every department and agency to develop and manufacture a safe and effective vaccine as quickly as possible. To that end, it may be appropriate for other departments and agencies to provide administrative and contract support where and when it is needed. However, it was Congress' intent for BARDA to use its technical and scientific expertise in managing and leading federal efforts related to medical countermeasure advanced research and development against COVID-19 and we are troubled by this Administration's moves which undermine that intent.

To better understand how the federal government is currently working to rapidly develop, manufacture, and distribute a safe and effective COVID-19 vaccine, we request you respond to the following questions no later than June 26, 2020.

1. How is BARDA working with NIH, DoD and FDA on developing and manufacturing COVID-19 vaccines and other countermeasures? How is the individual expertise of each agency being leveraged in Operation Warp Speed (OWS)?
  - a. Please describe the structure and function of OWS, which agencies are represented in its leadership, and how award decisions are made. If BARDA is not represented in OWS leadership, please explain why.
2. Why were BARDA scientists removed from project lead positions related to the COVID-19 vaccine contracts, which were issued by BARDA? Please explain who was selected to replace them, why their expertise was determined to be more appropriate, and who made these decisions.
3. What resources, personnel, or other support is BARDA lacking that prevent it from leading the current COVID-19 vaccine contracts issued by BARDA? How does this impact its future award-making capabilities?
4. What responsibilities in connection with the five COVID-19 vaccine contracts have been assigned outside of BARDA and what was the basis for this decision?

We appreciate your attention to this inquiry and ask for a response to this letter by June 26, 2020.

Sincerely,



Rosa DeLauro  
Chair  
House Appropriations Committee  
Subcommittee on Labor, Health and  
Human Services, Education, and  
Related Agencies



Patty Murray  
Ranking Member  
Senate Appropriations Committee  
Subcommittee on Labor, Health and  
Human Services, Education, and  
Related Agencies