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

July 2, 2020

Robert Kadlec, M.D., MTM&H, M.S.
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Gary L. Disbrow, Ph.D.
Acting Director
Biomedical Advanced Research and Development Authority
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Assistant Secretary Kadlec and Acting Director Disbrow,

We write today to request information about the status of the development of COVID-19 vaccines and therapeutics supported by the federal government.[1,2] We recognize and appreciate the need for expediency during the ongoing pandemic to provide a vaccine that will allow Americans to return to some semblance of normalcy. However, such expediency must not abandon the core principles of safety, efficacy, and transparency that should be the cornerstones of our collective national efforts on development of COVID-19 vaccines, treatments, and diagnostics. Any decisions regarding the development of vaccines and therapeutics should be based on sound science only, not political pressure or favoritism. To that end, we request information about the Administration's work on advancing therapeutics and diagnostics for COVID-19.

We previously wrote to the Department of Health and Human Services Office of the Inspector General about the Food and Drug Administration's (FDA's) April 27, 2020 Emergency Use Authorization (EUA) for hydroxychloroquine and chloroquine and the role played by Dr. Rick Bright, who was removed from his position as Director of the Biomedical Advanced Research and Development Authority (BARDA). The EUA led to confusion about the drugs' efficacy in treating COVID-19. Subsequently, on June 15, 2020, the FDA withdrew their EUA for these two products, but real and irreversible harm was done because of the FDA's rushed rubber stamp approval. The United States is currently in possession of 60 million unused doses of hydroxychloroquine as a result and the damage to the FDA's reputation as the gold standard for drug approvals remains.

Since Dr. Bright's departure, BARDA's work appears to have changed significantly. On June 3, 2020, BARDA amended the Broad Agency Announcement (BAA), originally released on March 4, 2020, to suspend Areas of Interest that are integral to the development of therapeutics to prevent and to treat COVID-19.[3] Instead of working with partners to develop products to diagnose, treat, and prevent COVID-19, BARDA has decided to focus efforts mainly on vaccines and therapeutics

that do not treat the full range of the disease. BARDA's wholesale shift in strategy occurred without notice to its partners. The lack of transparency in the move, including shifting resources away from BARDA's core mission, is extremely shortsighted.

We request responses to the questions below no later than July 20, 2020 and would also request a Congressional briefing on these issues:

1. How much funding has been allocated to the development of new therapeutics that have shown evidence to improve symptoms in patients with COVID-19?
2. Why were Areas of Interest 9.3: Immunomodulators or therapeutics targeting lung repair; 9.5: Pre-exposure and Post-exposure Prophylaxis; and 11: Ventilators suspended in the amended June 3 BAA? Who made the decision to suspend those Areas of Interest?
3. How many companies were removed from BARDA's process or had contracts cancelled by BARDA after the amended June 3 BAA?
4. HHS made a statement that BARDA is "only leaving open areas of interest that are of highest priority" in order to "make the most of potential partners' time and effort."[4] Why did BARDA open Areas of Interest 1 through 6, which are unrelated to COVID-19, in the amended June 3 BAA?
5. How does BARDA's operation function with the President's "Operation Warp Speed" and the National Institutes of Health's Accelerating Covid-19 Therapeutic Interventions and Vaccines (ACTIV) project?
6. Has any funding been diverted from BARDA to "Operation Warp Speed"?

Thank you for your consideration of this critical issue. We look forward to hearing from you and working with you going forward on this important issue.

Sincerely,

Bill Pascrell, Jr.
Member of Congress

Robert Menendez
United State Senator

[1] Owermohle, S. (June 15, 2020). White house pressure for a vaccine raises risk the U.S. will approve one that doesn't work. Politico Retrieved from https://www.politico.com/news/2020/06/15/pressure-coronavirus-vaccine-risk-approval-316094

[2]Thomas, Katie. (Jun 19, 2020). Coronavirus attacks the lungs. A federal agency just halted funding for new lung treatments. The New York Times Retrieved from https://www.nytimes.com/2020/06/19/health/coronavirus-lung-treatment-funding.html

[3] Biomedical advanced research and development authority (BARDA) broad agency announcement (BAA) (2020). Retrieved from https://beta.sam.gov/opp/e33b08d0e9e04e6faf2f84d5e25c1970/view

[4] Ibid., Thomas