Congress of the United States
Washington, DC 20515

April 1, 2020

The Honorable Michael R. Pence
Vice President of the United States
The White House
Washington, DC 20500

Dear Vice President Pence,

As the country responds to the Coronavirus Disease 2019 (COVID-19), we would like to commend our health professionals responding to this pandemic and working diligently to treat and protect Americans. The Coronavirus Preparedness and Response Supplemental Appropriations Act passed by Congress and signed into law by the President represents a critical step in ensuring a coordinated and comprehensive response to COVID-19. As we consider additional supplemental appropriations as well as Fiscal Year 2021 funding for the Department of Health and Human Services (HHS), we stand ready to provide the resources that are needed to respond to this pandemic.

As the United States combats the rapid spread of COVID-19, we would like to draw your attention to the attached March 12, 2020 *Defense One* report on a company leveraging innovative, flexible, plant-based, technologies to rapidly respond to COVID-19. According to the article, the company "produced a COVID-19 vaccine in just 20 days" and "could produce as many as 10 million doses a month." This new technology was proven in 2012 in conjunction with an investment by the Department of Defense's Advanced Research Projects Agency[1]. Under the partnership, an H1N1 influenza vaccine was developed in under a month and the ability to rapidly scale up production to provide millions of doses validated. In 2018, we raised the prospect of leveraging successful taxpayer investments in pursuit of vaccine preparedness with HHS: "Has the Department considered pursuing successful capabilities already funded by other agencies to include DOD's Defense Advanced Research Projects Agency (DARPA)?"

Growing concern over influenza, Ebola and other pathogenic threats, led us to evaluate HHS' ability to respond to pandemics. While supportive of HHS' goal to develop a vaccine within 12 weeks of a pandemic declaration, we repeatedly expressed frustration that after years and billions spent on development, no HHS-backed entity has been able to meet the goal. Frustrated, we sought input from innovators, universities and the private sector and found instances of promising late-stage technologies that could not only offer rapid response to influenza but other pandemics like coronavirus. The value in pursuing these technologies was clear: rapid development combined with flexible, multi-modal facilities that reconfigure quickly to respond to new pandemic threats.

In April 2018 at the FY2019 House LHHS budget hearing, we asked, "What investments or approaches should our country be taking to better respond to potential outbreaks? HHS responded that "it is critical to continue to develop platform-based enabling technologies that would provide a flexible capability to respond to new or re-emerging threats" and we need "to develop new production strategies to allow for rapid response to seasonal and pandemic outbreaks, including the use of modern platform technologies rather than growth of the virus in eggs or cells. It's

[1] https://globalbiodefense.com/2012/07/28/darpa-program-hits-milestone-in-plant-based-vaccines-for-pandemics/

clear from this response that "platform-based," "flexible," "rapid response," "modern platform technologies" are key responding to outbreaks – something we noticed in this technology funded by the Department of Defense, as one example.

As a result of the threat posed by influenza and yet-unknown pathogens, and our limited capacity to respond to them, we included language in both the FY2019 and FY2020 HHS funding measures expressing our concern about our limited ability to rapidly respond to a pandemic and encouraged "ASPR and BARDA to support development of promising pre-clinical as well as development and acquisition of late-stage vaccine candidates that can meet the goal of producing a pandemic vaccine within 12 weeks of a declaration." In the FY2020 HHS funding measure, Congress again expressed concern about BARDA's approach to achieving the 12-week goal and the need to partner with multiple suppliers to ensure our nation is adequately prepared for future outbreaks. It is fair to continue this debate on the standard influenza vaccine through regular order. However, with time being of the essence in responding to coronavirus and critical investments on the line, now is the time to embrace novel technologies so we can tell the American public and the world we are exploring every option to solve this complex issue.

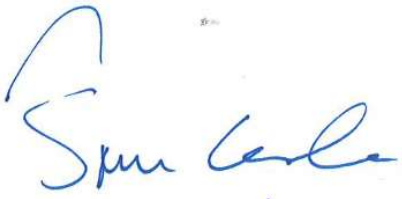
In H.R. 6074, Congress provided supplemental appropriations for development of necessary countermeasures and vaccines, which prioritize platform-based technologies with U.S. based manufacturing capabilities. Further, the bill states that such funds may be used to develop and demonstrate innovations and enhancements to manufacturing platforms and facilities to support these capabilities. This seems to be a clear sign that BARDA should be encouraged to explore novel production technologies that are flexible and well positioned to rapidly respond at this uncertain time.

There are innovative companies eager to collaborate with the U.S. Government to provide solutions. The time to act is now. We urge you to fund, partner and work with these entities to ensure treatments and vaccines are brought online as rapidly as possible.

We are grateful to the dedicated health professionals in our country fighting on the frontlines – in hospitals, laboratories, and research facilities – as they work to safeguard and treat Americans. Rest assured, we stand ready to do whatever it takes to ensure solutions and are provided as quickly as possible.

Sincerely,

Mike Simpson
Member of Congress



Tom Cole
Member of Congress

cc: Ambassador Deborah L. Birx, M.D
Coronavirus Response Coordinator

Stephen M. Hahn, M.D.
Commissioner, Food and Drug Administration

Dr. Robert Kadlec
Assistant Secretary for Preparedness and Response
Department of Health and Human Services

Rick Bright, PhD
Deputy Assistant Secretary for Preparedness and Response
Director for the Biomedical Advances Research and Development Authority
Department of Health and Human Services

Enclosure