Congress of the United States

Washington D. C. 20515

April 10, 2020

Stephen M. Hahn, M.D. Commissioner of Food and Drugs 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Dr. Hahn:

I am writing regarding the need of our nation to massively invest in large-scale production and rapid deployment of COVID-19 antibody, or serology, tests to help combat the future spread of the coronavirus as well as ensuring that adequate diagnostic tests continue to be available nationwide.

While we have received some positive models that indicate social distancing continues to mitigate the spread of coronavirus around the country, including in my home state of Colorado, I want to ensure that we continue to ramp up diagnostic testing for those who are suspected of being actively infected with COVID-19. Without that we will not be ready to tackle our next challenge – transitioning the American people back into society and reopening our country. With medical leaders telling us that a vaccine to COVID-19 is still months away, I am concerned that without an adequate strategic plan to transition beyond social distancing measures and shelter-in-place orders, we will put our nation's public and economic health at risk again.

To achieve this goal, I ask you and other senior federal medical professionals to urge the President to use authorities afforded to him, including the Defense Production Act, to increase production of FDA-approved serology tests, including all necessary equipment and supplies (e.g., reagents) which are critical to manufacturing these tests. This includes ensuring that when an FDA-approved antibody test is ready, that it can be immediately deployed on a nationwide scale. This comes as state and local leaders across the country continue to evaluate how best to keep their citizens safe, such as extending stay-at-home orders. We know that these tests will be essential to identifying people who have already acquired some immunity to COVID-19, and who can begin to return to normal life.

I also ask that you develop a national testing strategy, that includes consideration of both diagnostic and antibody testing. During the past two months we have learned that without a federal-coordinated response, local and state leaders are scrambling, often competing with one another to attain key testing supplies. This lackluster federal approach to diagnostic testing has been detrimental to public health workers and other frontline workers and those they continue to serve. This will be especially important as different states and regions continue to be at different points along the progression of the pandemic, and it is crucial a national testing strategy takes into account all relevant testing types and methodologies.

Further, as you know, the *Families First Coronavirus Response Act* included a provision that I authored that ensures free diagnostic testing for every American who needs to get one.

Additionally, the *Coronavirus Aid, Relief, and Economic Security (CARES) Act*, included \$1.5 billion in flexible funding to support CDC's continuing efforts to contain and combat the virus. It is imperative that a portion of these funds go to developing the tests that will allow someone who has established COVID-19 antibodies to return to the productive economy either by working or driving demand.

I thank you again and urge you to develop and deploy these tests as rapidly and widely as possible.

Your swift response is appreciated.

Sincerely,

Diana DeGette

Member of Congress

Cc:

The Honorable Mike Pence, Vice President of the United States

The Honorable Robert R. Redfield, Director of the Center for Disease Control

The Honorable Admiral Brett Giroir, M.D., Assistant Secretary for Health and Human Services