

BRIAN HIGGINS  
26TH DISTRICT, NEW YORK

COMMITTEE ON WAYS AND MEANS  
VICE RANKING MEMBER  
SUBCOMMITTEE ON HEALTH  
SUBCOMMITTEE ON SOCIAL SECURITY

COMMITTEE ON THE BUDGET

CO-CHAIR, CANCER CAUCUS  
CO-CHAIR, NORTHERN BORDER CAUCUS  
CO-CHAIR, REVITALIZING OLDER CITIES  
TASK FORCE

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515-3226

2459 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515  
(202) 225-3306  
(202) 226-0347 (FAX)

726 EXCHANGE STREET  
SUITE 601  
BUFFALO, NY 14210  
(716) 852-3501  
(716) 852-3929 (FAX)

800 MAIN STREET  
SUITE 3C  
NIAGARA FALLS, NY 14301  
(716) 282-1274  
(716) 282-2479 (FAX)  
higgins.house.gov

March 10, 2020

The Honorable Stephen Hahn  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Dear Commissioner Hahn:

I write today to urge the Food and Drug Administration (FDA) to validate and approve the use of high-throughput technologies to test for coronavirus disease (COVID-19) in New York laboratories as rapidly as possible.

As you know, COVID-19 poses a significant public health threat both in the United States and around the world. As of today, 148 cases of the disease have been confirmed in New York State.<sup>1</sup> But our ability to test for COVID-19 remains restricted, and we are unable to know the true number of cases in New York State and elsewhere. As a result, our ability to respond to and contain the spread of the virus has been severely limited. When individuals cannot get tested in a timely manner, they risk not only delaying treatment for themselves, but also can inadvertently infect others. This places the health and safety of the public, especially elderly and immunocompromised populations, in danger.

New York State has been granted Emergency Use Authorization (EUA) by FDA to allow certain labs to begin manual testing of samples for COVID-19. However, labs using manual testing are only typically able to process fewer than 100 samples per day. This capacity is completely insufficient to meet the need for COVID-19 testing in New York State. Labs in New York State have not yet been granted the ability to perform high-throughput (also known as “automated”) testing of samples for COVID-19, a process that would greatly expand the capacity of each lab to test thousands of samples per day. In my district, Roswell Park Comprehensive Cancer Center houses one such lab that is seeking to perform high-throughput testing in order to help identify infected persons and contain the spread of this disease.

---

<sup>1</sup> Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). Online at:  
<https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>.

I urge FDA to work with New York State in order to authorize high-throughput testing of samples for COVID-19 as soon as possible. Thank you for your attention to this critical public health issue.

Sincerely,

A handwritten signature in blue ink that reads "Brian Higgins". The signature is written in a cursive style with a horizontal line underneath it.

Brian Higgins  
Member of Congress