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.\(^1\) 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.

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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,

Brian Higgins
Member of Congress