Congress of the United States
Washington, DC 20515

April 9, 2020

Dr. Stephen Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hahn,

We request information about the accuracy of COVID-19 diagnostic tests, as provided to the FDA regarding sensitivity (false negatives) and specificity (false positives). As the FDA and other experts have noted, accurate tests are critical to "flatten the curve" in order to phase out costly "social distancing" strategies. The accuracy of recently approved tests is of particular concern because the original CDC test kits, which arrived at public health labs in early February, were flawed, indicating coronavirus in samples which did not contain the virus. Despite clear evidence that the test was fatally flawed, the Administration continued to rely on that inaccurate test for 3 weeks. This troubling and unjustified delay contributed greatly to the spread of the novel coronavirus in February and March, when those who were infected were not accurately identified and quarantined.

FDA's ongoing emergency approval of new tests in an effort to fill the serious gap caused by the Administration's failure to provide adequate testing raises continued questions. Both a March 11 study in the Journal of the American Medical Association and the United Kingdom Centre on Evidence-Based Medicine have questioned the accuracy of COVID-19 tests. Because they lack confidence in test results, some physicians are still recommending the quarantine of patients with negative test results.

In its clearance of diagnostic tests under normal circumstances, we are aware that FDA requires information on false positives and false negatives. Examples include:

> FilmArray Respiratory Panel 2 Plus (RP2plus) which tests for other types of coronavirus
> https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170017.pdf
>
> Cologuard a screening test for colorectal cancer
> https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017B.pdf
>
> Cobas HPV test https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100020B.pdf

Because of the urgent need for accurate tests, the FDA announced on February 29 that COVID-19 tests could be used prior to FDA approval. Fortunately, FDA published a document entitled *Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency* https://www.fda.gov/media/135659/download that stipulates that "All clinical tests should be validated prior to use. In the context of a public health emergency, it is especially important that tests are validated as false results can have broad public health impact beyond that to the individual patient. FDA has provided recommendations regarding the minimum testing that should be performed to ensure analytical and clinical validity."

The guidance specifies that "Following completion of assay validation, laboratories should notify FDA (e.g., e-mail to CDRH-EUA-Templates@FDA.HHS.GOV) that their assay has been validated. ….As noted above, FDA recommends that laboratories submit a completed EUA [Emergency Use Authorization] request **within 15 business days of the initial communication to FDA that the assay has been successfully validated**."

We request an update on the current status of information provided to the FDA about the accuracy of the COVID-19 tests of which the FDA has been notified and whether or not each included a completed EUA. Please provide the following information:

1. A list of laboratories that have submitted accuracy information to the FDA in terms of sensitivity and specificity about their COVID-19 diagnostic tests.
2. All the information the FDA has received from laboratories regarding the specificity and sensitivity of COVID-19 tests that have been used to test patients in the U.S. since February 29. The accuracy of those tests should also be made publicly available so that physicians and patients can make informed decisions about which tests to use, when options are available.
3. All the information the FDA has received from non-laboratory sources regarding the specificity and sensitivity of COVID-19 tests, or any concerns regarding the accuracy of the tests.
4. A list of actions the FDA has taken in response to performance data submitted, as required by the EUA.
5. A list of laboratories that failed to meet the deadline of 15 business days noted above and any actions FDA has taken to obtain the required information.

While the FDA Policy Announcement was explicit regarding required information, the key to success over the pandemic will be both laboratory compliance through timely submission, and prompt FDA action pursuant to the Announcement regarding the "preliminary review to identify if there are any problems with the performance data" and resolving any such problems.

We appreciate your timely response and shared commitment to protecting the public's health and safety.

Sincerely,

Lloyd Doggett

Rosa DeLauro