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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

July 13, 2020

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

Since the beginning of the coronavirus disease of 2019 (COVID-19) outbreak in the United States, public health experts have consistently called for increased access to reliable diagnostic testing to improve treatment, surveillance, contact tracing, and containment efforts. While many diagnostic tests have been authorized to come onto the market under an Emergency Use Authorization (EUA), questions remain about the Food and Drug Administration's (FDA) oversight of these tests and their reliability. As we continue to take the necessary steps to improve access to testing, it is imperative that Americans and their health care providers have the utmost confidence in diagnostic tests. We write to you today to inquire about FDA's work to determine the accuracy and sensitivity of these tests.

On February 29, 2020, one month after the Department of Health and Human Services Secretary Alex Azar declared the outbreak of COVID-19 a Public Health Emergency, FDA issued guidance on how the agency will evaluate EUA requests for molecular diagnostic tests used to detect the presence of the SARS-CoV-2019 virus, which causes COVID-19, in the body. Since that time, FDA has issued more than 170 EUAs for in vitro diagnostic testing products.[1] Although this has improved overall testing capacity—progress we must build on—we do not know enough about the reliability of most of these tests. While most diagnostic tests might typically undergo large patient studies prior to approval to determine accuracy, those authorized under an EUA are required to undergo a much smaller clinical testing sample. Under the most recent FDA guidance, commercial test developers of new diagnostic tests for COVID-19 are only required to test 30 positive and 30 negative samples while determining their product's

[1] U.S. Food and Drug Administration, *Emergency Use Authorization* (June 23, 2020) (www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev).

accuracy.[2] Other developers have been granted an EUA under FDA's previous guidance, which required the even lower standard of only testing five positive and five negative samples.[3]

While no diagnostic test will ever be 100 percent accurate, these lower standards for determining reliability in diagnostic tests could affect our understanding of COVID-19's spread within a community and across the United States. As outbreaks continue to arise, patients, health care providers, and public health officials must be able to quickly test and trace the path of the disease. Some community settings and workplaces have also indicated that they are using, or plan to use, rapid point-of-care diagnostic tests to aid in decision-making as they take steps to reopen. Knowing the accuracy of these tests is critical in order to make these decisions safely.

These concerns recently touched the highest levels of government, when one study found that the Abbott ID NOW test, which the White House uses to test all visitors to the Oval Office, could have a false-negative rate as high as 48 percent.[4] FDA announced on May 14 that it had received 15 adverse event reports about the Abbott ID NOW device, and that Abbott had agreed to conduct post-market studies on the test.[5] Since then, it has been reported that FDA has received 106 adverse event reports about the ID NOW device.[6] This is just one of many tests on the market under an EUA. FDA has said that it has requested multiple test developers to conduct post-market studies, and Americans deserve to know more about these requests, the results of the ensuing studies, and any adverse event reports received by FDA.[7]

Similar concerns have been raised about serological tests, which are used to determine the presence of antibodies to the coronavirus. While we do not yet know the degree to which antibodies protect against COVID-19 infection, serological testing data can be used by epidemiologists and other public health officials for surveillance and to understand paths of transmission, allowing for improved preparedness and response. Citing the relative simplicity of

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[2] U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency* (May 11, 2020).

[3] *Id.*

[4] *Coronavirus Testing Used by White House Could Miss Infections*, New York Times (May 13, 2020).

[5] U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Informs Public about Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test* (May 14, 2020) (www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point).

[6] *As Problems Grow with Abbott's Fast COVID Test, FDA Standards are Under Fire*, Kaiser Health News (June 22, 2020).

[7] *Accuracy Still Unknown for Many Coronavirus Tests Rushed Out*, Associated Press (June 13, 2020).

serological tests, FDA said in a March guidance document that it would allow some serological tests to be used without first receiving an EUA, under certain conditions.[8] As a result, a flood of unauthorized tests, which were later found to provide unreliable results, soon inundated the market.[9] While FDA has since revised its guidance on serological tests, requiring developers to request an EUA, dozens of unreliable and unauthorized tests remain on the market.[10] While we are pleased that FDA is finally evaluating these tests under its May 4 revised guidance and is also publicly listing tests that should no longer be distributed, we believe FDA should do more to protect the safety and health of the American people.

We were pleased that at our Committee's recent hearing you pledged to continue monitoring diagnostic tests authorized by an EUA and to be transparent about FDA's oversight actions. To aid in our understanding of FDA's actions to date and the reliability of tests currently on the market, we ask that you respond to the following questions no later than July 27, 2020:

1. Please describe the post-market actions FDA is taking to evaluate the reliability of COVID-19 in vitro diagnostic tests, including serology tests.

2. Please identify which commercial test developers FDA has requested provide additional data or conduct post-marketing studies of tests authorized by an EUA. In each case, please describe the agency's rationale for such request.

3. Please describe any issues FDA has become aware of in reviewing EUA submissions, as well as any adverse event reports FDA has received for COVID-19 tests authorized under an EUA, and the actions FDA has taken in response to these issues or reports. In your response, please identify:

    a. The COVID-19 tests and developers associated with issues identified by FDA during the EUA review process and a summary of such issues.

    b. The COVID-19 tests and developers about which an adverse event has been reported and a description of the adverse event(s).

    c. Any follow-up request or action FDA has taken in response to issues associated with an EUA submission or the adverse event report(s).

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[8] U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency* (Mar. 16, 2020).

[9] *Coronavirus Antibody Tests: Can you Trust the Results?*, New York Times (Apr. 24, 2020).

[10] Jacquie Lee and Alex Ruoff, *FDA Pressured to Move Faster to Vet Coronavirus Antibody Tests*, Bloomberg Law (June 9, 2020).

4. Please describe the EUA status of serology tests that remain on the market. In your response, please include:

    a. The number of serological tests that FDA was notified were on the market prior to May 4 that had submitted an EUA request. Please list those tests and their developers.

    b. Of the serology tests that FDA was notified were on the market prior to May 4, the number of tests that have had their EUA request denied. Please list those tests and their developers.

    c. Of the serology tests that FDA was notified were on the market prior to May 4, the number of tests that have not been granted an EUA, but remain on the market. Please list those tests and their developers.

    d. The number of EUA requests that have been submitted for serology tests that were not on the market prior to May 4, and when those EUA requests were submitted. Please include how many of these EUAs have been granted.

5. Please describe the authorities or tools FDA may use to enforce compliance with the agency's emergency use authorities for diagnostic tests. Please also describe the actions FDA is taking or intends to take in the following examples. Please include in your response the authorities or mechanisms (i.e., revocation of EUAs, warning letters, civil monetary penalties, criminal penalties, etc.) FDA may use to effectuate its policy.

    a. Example 1: A test developer with a test authorized by an EUA fails to respond to FDA requests for additional information or post-marketing studies.

    b. Example 2: FDA determines, after receiving additional data, that a test authorized by an EUA delivers insufficiently accurate results.

    c. Example 3: A serology test remains on the market after failing to submit an EUA request after the May 4 guidance.

    d. Example 4: A serology test remains on the market after having an EUA request denied.

Thank you for your attention to this important matter. If you have questions about this request, please contact Stephen Holland of the Majority staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Anna G. Eshoo
Chairwoman
Subcommittee on Health

Diana DeGette
Chair
Subcommittee on Oversight
and Investigations