Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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April 28, 2020

The Honorable Dr. Stephen M. Hahn Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

The Subcommittee is writing about the failure of officials of your agency to respond to our outstanding requests for information in furtherance of our investigation into Food and Drug Administration (FDA) policies governing serological testing for coronavirus.

On April 17, 2020, FDA briefed Subcommittee staff on what the agency is doing with respect to serological testing.¹ During the briefing, FDA committed to providing follow-up answers to several questions that FDA could not answer during the call. Subcommittee staff memorialized those outstanding questions in an April 17, 2020, email to FDA.² On April 27, 2020, Subcommittee staff again requested the promised information in an email to FDA.³ To date, the Subcommittee has received no response.

With many plans to reopen the economy requiring the availability of consistently reliable serological testing, we need your answers now, while there is still time to fix shortfalls in FDA policy.

On April 24, 2020, the Subcommittee issued a staff report detailing preliminary findings of the Subcommittee's coronavirus antibody testing investigation.⁴ The Subcommittee made the following findings:

³ Email from Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Food and Drug Administration (Apr. 27, 2020).

¹ Briefing by Dr. Tammy Beckham, Director, Office of Infectious Disease and HIV/AIDS Policy, Department of Health and Human Services; Dr. Jeffrey Shuren, Director, Center for Devices and Radiological Health, Food and Drug Administration; and Dr. Gregory Armstrong, Director, Office of Advanced Molecular Detection, Centers for Disease Control and Prevention, to Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Apr. 17, 2020).

² Email from Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Food and Drug Administration (Apr. 17, 2020).

⁴ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Preliminary Findings of the Subcommittee's Coronavirus Antibody Testing Investigation* (Apr. 24, 2020) (online at

- White House plans to reopen economy are flawed by their dependence on coronavirus antibody tests, which face unanswered scientific questions of utility and accuracy.
- FDA did not review any coronavirus "rapid" antibody test kits before they went on the market, and a lack of enforcement by FDA has allowed manufacturers to make fraudulent claims about their efficacy.
- FDA is unable to validate the accuracy of antibody tests that are already on the market, and companies are ignoring requests from the Department of Health and Human Services (HHS) to voluntarily submit their tests for validation.
- FDA and the Centers for Disease Control and Prevention (CDC) have not put forth standards and guidelines for serological antibody tests, departing from practices governing molecular tests.
- FDA has failed to police the coronavirus serological antibody test market, has taken no public enforcement action against any company, and has not conveyed any clear policy on serological tests, but rather has issued a series of unclear "clarifications."
- Numerous companies appear to be marketing fraudulent tests.

When you were asked about the Subcommittee's staff report during the April 24 White House Coronavirus Task Force press briefing, you stated the following:

So, under our policy, we provided flexibility. What we've told manufacturers is that in order to market in the U.S., they have to validate their tests, **they have to tell us that they validated their test**, and then in the package insert they have to let people know—end users, labs, etc.—that those tests were not authorized by the FDA. We've authorized four, as I mentioned, more are in the pipeline. And **these tests that have come in without any information to us, but have been self-validated**, as I mentioned at the podium a couple days ago, we are working with the National Cancer Institute, as well as CDC, to perform our own validation of the tests that have been sent to us. So, we'll provide as much information as we possibly can. And there is transparency on our website about those tests, and also the tests that we have authorized.⁵

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP% 20Staff% 20Report% 20on% 20Prelimina ry% 20Findings% 20of% 20the% 20Subcommittee% E2% 80% 99s% 20Coronavirus% 20Antibody% 20Testing% 20Inves tigation.pdf).

⁵ The White House, *Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing* (Apr. 24, 2020) (online at www.youtube.com/watch?v=3EsVCWN-txU) (emphasis added).

Your statement did not refute any of the Subcommittee's findings. In fact, you admitted that FDA is relying on companies telling FDA "that they validated their test" and that you are permitting "tests that have come in without any information to us."⁶ It is FDA's job to protect the public health. Abdicating that responsibility and trusting private industry to regulate itself is unacceptable.

You also claimed that you are "working with the National Cancer Institute and well as CDC, to perform our own validation of the tests that have been sent to us." However, as the Subcommittee found in its report, this interagency serology test validation initiative—which includes FDA, CDC, the Biomedical Research and Development Authority, the National Institutes of Health, the Department of Defense, and the White House Office of Science and Technology Policy—had, as of April 17, received only seven of the more than 100 tests on the market and had validated none.

On April 24, 2020, researchers confirmed our concern that FDA's lax policies are permitting a flood of fraudulent tests onto the market. The research—conducted by the University of California, San Francisco; the University of California, Berkeley; and the Chan Zuckerberg Biohub—found that 11 of 14 serology tests that were analyzed did not deliver consistently reliable results.⁷

Today, the Subcommittee sent letters to four companies that manufacture or distribute tests that the University of California researchers found did not deliver consistently reliable results, seeking information about their interactions with FDA and data supporting claims about the accuracy of their tests: UCP Biosciences, BioMedomics, Epitope Diagnostics, and Premier Biotech.⁸

⁶ Id.

⁸ Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Nancy Chen, Chief Executive Officer, UCP Biosciences, Inc. (Apr. 28, 2020) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-28.RK% 20to% 20UCP% 20Biosciences% 20re% 20Serology% 20Tests.pdf); Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Dr. Frank Wang, Chief Executive Officer, BioMedomics, Inc. (Apr. 28, 2020) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-

28.RK%20to%20BioMedomics%20re%20Serology%20Tests%20FINAL.pdf); Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Dr. Ping Gao, Chief Executive Officer, Epitope Diagnostics, Inc. (Apr. 28, 2020) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-

28.RK% 20to% 20Epitope% 20re% 20Serology% 20Tests.pdf): Letter from Chairman Raia Krishnamoorthi.

Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Todd Bailey, Chief Executive Officer, Premier Biotech, Inc. (Apr. 28, 2020) (online at

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-

⁷ Coronavirus Antibody Tests: Can You Trust the Results?, New York Times (Apr. 24, 2020) (online at www.nytimes.com/2020/04/24/health/coronavirus-antibody-tests.html?smid=em-share); Dr. Jeffrey D. Whitman et al., *Test Performance Evaluation of SARS-CoV-2 Serological Assays*, Pre-Publication Manuscript (Apr. 24, 2020) (online at www.dropbox.com/s/cd1628cau09288a/SARS-CoV-2_Serology_Manuscript.pdf?dl=0).

^{28.}RK%20to%20Premier%20Biotech%20re%20Serology%20Tests.pdf).

I am encouraged by one thing that you said in the White House press briefing—that FDA will "provide as much information as we possibly can."⁹ Based on your assurance, please respond to the following questions by May 6, 2020:

- 1. How many serological tests are currently confirmed through Pathway D? Of those tests:
 - a. Who are the manufacturers?
 - b. What are the test models of the tests currently confirmed though Pathway D?
 - c. How many have had an EUA application submitted?
 - d. For how many has FDA received validation data?
 - e. For how many has the interagency serology test validation initiative received a submission for its voluntary validation program?
 - f. How many more have indicated they will send a test for validation to the interagency serology test validation initiative?
- 2. Has FDA removed Pathway D confirmations for any serology tests? If so, what are the names of the tests, and for what reasons were they removed?
- 3. During the briefing, you mentioned a case involving concerns that a diagnostic test had falsified data, which has since been removed from the marketplace. Who was the manufacturer, what was the test model, and when and how was it removed from the market?
- 4. To which serological test manufacturers have you sent warning letters or taken any other formal enforcement action?
- 5. Has FDA made any enforcement referrals to any other agencies? If so, how many referrals, to what agencies, and with what information?
- 6. What can manufacturers using Pathway D say about their status with FDA? They may not say they are "FDA approved" or "FDA authorized," but are they permitted to say they are marketed pursuant to FDA policy?
- 7. What is the U.S. manufacturing capacity for serology tests, and what is FDA doing to ensure that this capacity will meet future demand and that supply chains will be sufficient? Please include in your response projections of future need for serology testing.
- 8. What regulatory or enforcement actions, such as removing Pathway D marketing permissions or sending a public Warning Letter, do you plan to take in response

⁹ The White House, *Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing* (Apr. 24, 2020) (online at www.youtube.com/watch?v=3EsVCWN-txU) (emphasis added).

to the findings of the University of California researchers that certain commercially available serology tests were not consistently reliable?

- 9. Will you commit to revising FDA's policy on serological testing to:
 - a. Require serological test makers to apply to FDA for approval to market?
 - b. Submit validation data to FDA?
 - c. Use your enforcement tools on bad actors?
 - d. Pull ineffective serological tests from the market?
 - e. Ensure that only effective serological tests are allowed on the market?

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

Raja Krishnamoorthi Chairman Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member