

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

**MEMORANDUM**

**April 24, 2020**

**To: Democratic Members of the Subcommittee on Economic and Consumer Policy**

**Fr: Subcommittee Staff**

**Re: Preliminary Findings of the Subcommittee's Coronavirus Antibody Testing Investigation**

**PRELIMINARY FINDINGS**

- White House plans to reopen economy are flawed by their dependence on coronavirus antibody tests, which face unanswered scientific questions of utility and accuracy.
- The Food and Drug Administration (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.

The Subcommittee appreciates the immense challenges facing HHS, FDA, CDC, and other health agencies in the midst of the coronavirus pandemic. But, when it comes to serological testing, more should be done to help protect the American people from suspect companies seeking to take advantage of the crisis.

## **I. WHITE HOUSE PLANS TO REOPEN ECONOMY ARE FLAWED BY THEIR DEPENDENCE ON CORONAVIRUS ANTIBODY TESTS, WHICH FACE UNANSWERED SCIENTIFIC QUESTIONS OF UTILITY AND ACCURACY**

White House plans to reopen the economy are dependent on the availability, validity, and widespread use of antibody tests to determine who can rejoin the workforce. The White House Coronavirus Task Force is considering issuing “immunity certificates” to those individuals whose blood testing reveals that they have antibodies to the virus.<sup>1</sup> That finding would allow them to return to work and travel freely.<sup>2</sup>

During a briefing with Subcommittee staff on April 17, 2020, officials from HHS admitted that the epidemiological basis for using antibody tests for this purpose has not been established. HHS said that it is “not ready to say that antibody response is equal to protection,” and they “need that connection” before any “immunity certificates” can be issued based on antibody tests.<sup>3</sup>

Officials from FDA and CDC agreed that “immunity certificates” are not yet feasible. FDA said “we still don’t have the answers” on an amount of antibody that confers immunity or how long the antibody response lasts.

Those opinions from top public health officials are supported by scientific consensus. The National Academies of Sciences, Engineering, and Medicine recently concluded that, “in the case of SARS-CoV-2, it is not known whether the presence of antibodies indicates protection from illness” and asserted that “[w]ell-controlled longitudinal studies are critically needed as they can determine the relationship between different types of SARS-CoV-2-specific antibodies and the likelihood of an individual becoming re-infected.”<sup>4</sup>

HHS stated that the White House’s Office of Science and Technology Policy was involved in “policy” related to “immunity certificates,” but as of the morning of the April 17 briefing, the White House had not yet consulted with HHS’s serology test team on policy recommendations.

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<sup>1</sup> *Fauci: Coronavirus Immunity Cards for Americans are ‘Being Discussed’*, Politico (Apr. 10, 2020) (online at [www.politico.com/news/2020/04/10/fauci-coronavirus-immunity-cards-for-americans-are-being-discussed-178784](http://www.politico.com/news/2020/04/10/fauci-coronavirus-immunity-cards-for-americans-are-being-discussed-178784)).

<sup>2</sup> *The Health 202: Immunity Certificates Could Help People Return to Work. But Huge Questions Remain*, Washington Post (Apr. 14, 2020) (online at [www.washingtonpost.com/news/powerpost/paloma/the-health-202/2020/04/14/the-health-202-immunity-certificates-could-help-people-return-to-work-but-huge-questions-remain/5e94d3d7602ff10d49ae3bb6/](http://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2020/04/14/the-health-202-immunity-certificates-could-help-people-return-to-work-but-huge-questions-remain/5e94d3d7602ff10d49ae3bb6/)).

<sup>3</sup> 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 Majority and Minority Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Apr. 17, 2020).

<sup>4</sup> National Academies of Sciences, Engineering, and Medicine, *Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic* (Apr. 8, 2020) (online at <http://nap.edu/25775>).

That has not prevented President Trump from declaring that antibody tests are “very exciting” because they will “support our efforts to get Americans back to work by showing us who might have developed the wonderful, beautiful immunity.”<sup>5</sup>

## **II. FDA DID NOT REVIEW CORONAVIRUS ANTIBODY TEST KITS BEFORE THEY WENT ON THE MARKET, AND A LACK OF ENFORCEMENT BY FDA HAS ALLOWED MANUFACTURERS TO MAKE FRAUDULENT CLAIMS ABOUT THE EFFICACY OF THEIR TESTING KITS**

In the April 17 briefing, FDA reported that it has not reviewed the validity of the vast majority of coronavirus antibody tests that are currently on the market. Its current policy and lack of enforcement effectively allow fraudulent claims to be made about the efficacy of testing kits.

On March 16, 2020, FDA issued a policy for laboratories and manufacturers on marketing diagnostics for the novel coronavirus. According to FDA, “This guidance describes policies intended to help rapidly expand testing capacity by facilitating the development and use of SARS-CoV-2 diagnostic tests during the public health emergency.”<sup>6</sup>

However, FDA’s policy, which it stated was intended to “make it easier” for tests to go to market, has allowed serological antibody tests without any substantive review. On April 18, 2020, the day after the briefing, FDA issued a statement justifying its policy as one that “provided regulatory flexibility for serological tests in an effort to provide laboratories and health care providers with early access to these tests.”<sup>7</sup>

There are two general types of tests for the novel coronavirus, SARS-CoV-2, which causes the disease COVID-19: (1) molecular tests, which check for viral genetic material to determine whether one has the disease; and (2) serological tests, which check for antibodies that could theoretically indicate an immune response to a disease.<sup>8</sup>

Molecular tests are the most accurate way to test for a current and active coronavirus infection and determine whether someone presents a transmission risk to others. They work by testing for the presence of viral RNA in a patient.<sup>9</sup> Polymerase chain reaction (PCR) testing is “the gold standard for diagnosing an infectious agent” and is currently the most common test for

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<sup>5</sup> *President Trump with Coronavirus Task Force Briefing*, C-SPAN (Apr. 17, 2020) (online at [www.c-span.org/video/?471279-1/president-trump-coronavirus-task-force-briefing](http://www.c-span.org/video/?471279-1/president-trump-coronavirus-task-force-briefing)).

<sup>6</sup> Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency: Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (Mar. 16, 2020) (online at [www.fda.gov/media/135659/download](http://www.fda.gov/media/135659/download)).

<sup>7</sup> Food and Drug Administration, *Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts* (Apr. 18, 2020) (online at [www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts](http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts)).

<sup>8</sup> National Academies of Sciences, Engineering, and Medicine, *Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic* (Apr. 8, 2020) (online at <http://nap.edu/25775>).

<sup>9</sup> *Id.*

clinical diagnosis for SAR-CoV-2.<sup>10</sup> Labs and manufacturers are required to submit a request to FDA for an Emergency Use Authorization (EUA) within 15 business days of offering molecular testing products or services.<sup>11</sup>

Serological tests identify antibodies in the blood. The body generates antibodies as part of its immune response to fight the virus, and antibody tests “measure whether an individual has been previously exposed to the agent.” Currently available serological tests identify one of two different types of antibodies that the body produces at different times during its response to a viral infection: IgM antibodies, which appear earlier in the infection, and IgG antibodies, which appear later and may last long after the infection.<sup>12</sup>

According to an FDA-approved fact sheet for one serological test for COVID-19 antibodies:

When IgM antibodies are present, they can indicate that a patient has an active or recent infection with SARS-CoV-2. IgG antibodies develop later following infection, and generally do not begin to appear until 7 – 10 days after infection. When IgG antibodies are present it, often indicates a past infection but does not exclude recently infected patients who are still contagious, especially if detected with IgM antibodies. **It is unknown how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.**<sup>13</sup>

There are two general types of serological tests on the market today: (1) laboratory-performed tests, which rely on healthcare providers to collect samples and send them to central labs, typically with “high throughput” capacity capable of performing hundreds of tests at a time; and (2) “rapid” tests, which can be performed in minutes with a few drops of blood taken at the point of care at a healthcare provider, or potentially in the home. Some “lateral flow assay” varieties of rapid tests contain a strip of reactive paper that changes color when antibodies are present, showing a set of lines to indicate results—similar to a home pregnancy test.<sup>14</sup>

Unlike for molecular testing, FDA does not require a laboratory or manufacturer to submit an EUA request to FDA for serological tests. Under Section IV.D of FDA’s March 16, 2020, policy, so-called “Pathway D,” a manufacturer may distribute serological test kits, and laboratories may perform serological testing, “where the test has been validated, notification is

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<sup>10</sup> *Fast, Portable Tests Come Online to Curb Coronavirus Pandemic*, Nature (Apr. 17, 2020) (online at [www.nature.com/articles/d41587-020-00010-2](http://www.nature.com/articles/d41587-020-00010-2)).

<sup>11</sup> Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency: Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (Mar. 16, 2020) (online at [www.fda.gov/media/135659/download](http://www.fda.gov/media/135659/download)).

<sup>12</sup> National Academies of Sciences, Engineering, and Medicine, *Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic* (Apr. 8, 2020) (online at <http://nap.edu/25775>).

<sup>13</sup> *Fact Sheet for Healthcare Providers: DPP COVID-19 IgM/IgG System—Chembio Diagnostic Systems, Inc.* (Apr. 14, 2020) (online at [www.fda.gov/media/136962/download](http://www.fda.gov/media/136962/download)) (emphasis added).

<sup>14</sup> *Understanding the Role of Antibody Testing in Battling the Spread of COVID-19*, ARUP Laboratories (Apr. 13, 2020) (online at [www.aruplab.com/news/4-13-2020/Antibody-Testing-COVID-19](http://www.aruplab.com/news/4-13-2020/Antibody-Testing-COVID-19)).

provided to FDA, and information” regarding the lack of FDA review and limitations of serological testing results is provided to patients with their test results.<sup>15</sup>

During the April 17 briefing, FDA acknowledged that it did not validate any of the 101 manufactured test kits that have entered the market through Pathway D. FDA admitted that it did not receive validation data from manufacturers, which it could have used to assess whether the tests work, how accurate they are, or whether there is a risk of false positives from other common infections. Instead, FDA asked manufacturers to state that their tests were validated, while requesting no proof. FDA also admitted that it did not request copies of any packaging, marketing, or instructions for use—or any documents whatsoever—which would have allowed it to ensure that tests were being properly marketed and complied with FDA policy, such as the requirement that results are accompanied by reliable and accurate information about the tests and their limitations.

FDA had publicly described the Pathway D confirmation process as “a few exchanges to understand that everything is being addressed according to the guidance.”<sup>16</sup> FDA has taken manufacturers at their word without question or independent verification.<sup>17</sup> FDA does not know the accuracy of Pathway D tests that are currently on the market.

FDA has acknowledged that the number of tests on the market through Pathway D is “huge.”<sup>18</sup> During the April 17 briefing, FDA stated it has “no insight into how many” tests have been distributed in the United States under Pathway D.

Public health professionals have asserted that tests of “frankly dubious quality” have been distributed throughout the United States to physicians, pharmacies, and other healthcare providers.<sup>19</sup>

There are reports of inaccurate point-of-care serological tests on the market. The United Kingdom paid \$20 million for two million Chinese test kits which proved to be unusable because

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<sup>15</sup> Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency: Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (Mar. 16, 2020) (online at [www.fda.gov/media/135659/download](http://www.fda.gov/media/135659/download)).

<sup>16</sup> Food and Drug Administration, *Virtual Town Hall Series: Immediately in Effect Guidance on Coronavirus (COVID-19 Diagnostic Tests* (Apr. 8, 2020) (online at [www.fda.gov/media/136833/download](http://www.fda.gov/media/136833/download)).

<sup>17</sup> *Dozens of Coronavirus Antibody Tests on the Market Were Never Vetted by the FDA, Leading to Accuracy Concerns*, Washington Post (Apr. 19, 2020) (online at [www.washingtonpost.com/health/2020/04/19/fda-antibody-tests-coronavirus-review/](http://www.washingtonpost.com/health/2020/04/19/fda-antibody-tests-coronavirus-review/)).

<sup>18</sup> Food and Drug Administration, *Virtual Town Hall Series: Immediately in Effect Guidance on Coronavirus (COVID-19 Diagnostic Tests* (Apr. 8, 2020) (online at [www.fda.gov/media/136833/download](http://www.fda.gov/media/136833/download)).

<sup>19</sup> *Antibody Test, Seen as Key to Reopening Country, Does Not Yet Deliver*, New York Times (Apr. 19, 2020) (online at [www.nytimes.com/2020/04/19/us/coronavirus-antibody-tests.html](http://www.nytimes.com/2020/04/19/us/coronavirus-antibody-tests.html)).

they were found to be inaccurate.<sup>20</sup> In Laredo, Texas, an emergency room purchased 20,000 tests from China for \$500,000, found them impossible to validate, and could not use them.<sup>21</sup>

### **III. FDA IS UNABLE TO VALIDATE THE ACCURACY OF ANTIBODY TESTS ON THE MARKET, AND COMPANIES ARE IGNORING REQUESTS FROM HHS TO VOLUNTARILY SUBMIT TESTS FOR VALIDATION**

FDA is not yet able to assess the reliability of any serological antibody tests on the market. During the April 17 briefing, FDA stated that it had asked laboratories and developers to voluntarily share their validation assessments of other manufacturers' tests, but FDA had not yet received any information in response to this request.

HHS is trying to validate the tests. HHS has convened an interagency group to validate the tests, 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.<sup>22</sup>

During the April 17 briefing, HHS explained that this program is voluntary, and any manufacturer can submit copies of its test kit to be validated by the group. HHS is not requiring manufacturers to submit tests, and it has no plans to attempt to validate tests that it does not receive on a voluntary basis.

HHS stated that the group had received only seven of the more than 100 tests marketed through Pathway D. Two weeks into the program, HHS stated that it had not yet validated any test. HHS stated that it expects preliminary results by the end of April.

FDA stated that it will “go back and revisit” the policy—and Pathway D—after receiving some of these validation results and may consider requiring EUA submissions for all serology tests. During this delay, FDA and the American public would have no knowledge of whether any Pathway D serology tests work. As of April 21, 2020, FDA had authorized only four serology tests under an EUA, and zero “rapid” tests that can be performed by healthcare workers at the point of care or in the home.<sup>23</sup>

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<sup>20</sup> *U.K. Paid \$20 Million for New Coronavirus Tests. They Didn't Work.*, New York Times (Apr. 16, 2020) (online at [www.nytimes.com/2020/04/16/world/europe/coronavirus-antibody-test-uk.html](http://www.nytimes.com/2020/04/16/world/europe/coronavirus-antibody-test-uk.html)).

<sup>21</sup> *He Spent \$500,000 to Buy Coronavirus Tests. Health Officials Say They're Unreliable.*, ProPublica (Apr. 10, 2020) (online at [www.propublica.org/article/he-spent--500-000-to-buy-coronavirus-tests-health-officials-say-theyre-unreliable](http://www.propublica.org/article/he-spent--500-000-to-buy-coronavirus-tests-health-officials-say-theyre-unreliable)).

<sup>22</sup> Centers for Disease Control and Prevention, *Coronavirus Disease 2019: Serology Testing* (online at [www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html](http://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html)) (accessed Apr. 19, 2020).

<sup>23</sup> Food and Drug Administration, *Emergency Use Authorizations* (online at [www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations](http://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)) (accessed Apr. 21, 2020).

#### **IV. FDA AND CDC HAVE NOT SET STANDARDS AND GUIDELINES FOR SEROLOGY TESTS, DEPARTING FROM PRACTICES GOVERNING MOLECULAR TESTS**

FDA has issued no public guidance on what it is looking for from serology tests. In contrast, FDA published guidance for molecular tests over a month ago, including templates for EUA applications.<sup>24</sup>

More than a month after issuing the Pathway D guidance for serology tests, FDA still has not released an EUA template for serological antibody tests. During the April 17 briefing, FDA confirmed that it had not published an EUA template, though it planned to release one in the near future. FDA stated that serological tests with 90 percent sensitivity—the rate of correctly identifying true positives—should not be used as the sole basis for determining infection, and such tests should be supplemented with another test indicating a different coronavirus antigen.

For healthcare providers and patients, there is similarly little guidance on serology tests. At the April 17 briefing, CDC said it has no plans to issue guidelines for physicians or patients on who should receive a serology test and how the results should be interpreted and used to determine a course of treatment or action. After the briefing, FDA sent a letter to healthcare providers with the recommendation, “Continue to use serological (antibody) tests, as appropriate, and be aware of their limitations.”<sup>25</sup>

#### **V. FDA HAS FAILED TO POLICE THE TEST MARKET, HAS TAKEN NO PUBLIC ENFORCEMENT ACTION, AND HAS NOT CONVEYED ANY CLEAR POLICY ON SEROLOGICAL TESTS, BUT HAS ISSUED A SERIES OF UNCLEAR “CLARIFICATIONS”**

FDA has not taken the appropriate enforcement action to rid the market of fraudulent tests that falsely claim to be FDA-approved, are illegally marketed for at-home use, or falsely claim to be effective.

During the April 17 briefing, FDA said it has “not taken enforcement action yet.” Though FDA was able to correct some fraudulent marketing practices informally by emailing the companies, it has not sent any formal warning letters or taken any other public action against any company offering diagnostic tests or testing services.

FDA also admitted that the same team reviewing EUA applications is also tasked with monitoring the market and taking corrective action. It may be difficult for one team to

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<sup>24</sup> Food and Drug Administration, *Accelerated Emergency Use Authorization (EUA) Template for SARS-CoV-2 That Causes Coronavirus Disease (COVID-19) Molecular Testing of Respiratory Specimens in CLIA Certified High-Complexity Laboratories* (Mar. 7, 2020) (online at [www.fda.gov/media/135658/download](http://www.fda.gov/media/135658/download)); Food and Drug Administration, *EUA Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 That Causes Coronavirus Disease 2019 (COVID-19)* (Mar. 12, 2020) (online at [www.fda.gov/media/135900/download](http://www.fda.gov/media/135900/download)).

<sup>25</sup> Food and Drug Administration, *Important Information on the Use of Serological (Antibody) Tests for COVID-19—Letter to Health Care Providers* (Apr. 17, 2020) (online at [www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers](http://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers)).

effectively conduct both jobs, meaning that additional enforcement resources should be directed to this issue.

FDA has had to issue a number of corrections, clarifications, and warnings regarding its March 16 policy, following reports that testing companies were making unsubstantiated claims about the accuracy and validity of their products and were marketing them for home use.

FDA has had to issue a series of clarifications to the statement in its March 16 policy that it “does not apply to at home testing.”<sup>26</sup> Shortly after the policy was announced, a number of testing companies stated that their tests allowed patients to collect samples at home and send them to labs for testing. In response, on March 20, FDA issued a statement that it had not yet authorized at-home sample collection.<sup>27</sup>

Following inquiries of whether at-home sample collection includes supervision of a healthcare provider via telemedicine, FDA clarified that it “has not authorized any COVID-19 test for at-home testing, including self-collection of a specimen with or without the use of telemedicine.”<sup>28</sup> FDA confirmed during the April 17 briefing that any at-home testing, including through use of telemedicine, would have to be authorized by an EUA expressly spelling out the collection method.

On April 21, 2020, FDA authorized the first coronavirus test with at-home sample collection and warned test developers “that this is not a general authorization for at-home collection of patient samples using other collection swabs, media, or tests, or for tests fully conducted at home.”<sup>29</sup>

Nearly a month after issuing guidance allowing serology tests to go to market, FDA issued a clarifying statement on April 7 that firms using Pathway D may not claim “that their serological tests are FDA approved or authorized.” However, FDA was unable to clarify the claims that testing companies can make. FDA warned about serology tests “falsely claiming that they can diagnose COVID-19.”<sup>30</sup> But because FDA does not review or even ask for marketing, packaging, or instructional materials from manufacturers, it can enforce these restrictions only after tests are already put on the market.

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<sup>26</sup> Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency* (Mar. 16, 2020) (online at [www.fda.gov/media/135659/download](http://www.fda.gov/media/135659/download)).

<sup>27</sup> Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits* (Mar. 20, 2020) (online at [www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits](http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits)).

<sup>28</sup> Food and Drug Administration, *FAQs on Diagnostic Testing for SARS-CoV-2* (Mar. 21, 2020) (online at [www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2](http://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2)).

<sup>29</sup> Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Authorizes First Test for Patient At-Home Sample Collection* (Apr. 21, 2020) (online at [www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-patient-home-sample-collection](http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-patient-home-sample-collection)).

<sup>30</sup> Food and Drug Administration, *Coronavirus (COVID-19) Update: Serological Tests* (Apr. 7, 2020) (online at [www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests](http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests)).



FDA recently had to clarify that only a limited set of sophisticated laboratories could perform any serological tests brought to market through Pathway D. FDA’s March 16 policy on Pathway D states that serology tests are “less complex than molecular tests” and the “policy is limited to such testing in laboratories or by healthcare workers at the point-of-care.”<sup>31</sup> Contrary to this language, FDA later took the position that tests through Pathway D could not be performed by healthcare workers at the point of care, even if the tests are designed for a point-of-care setting. Instead, FDA asserted that Pathway D, unless an EUA authorized other settings for testing, only allows testing to be performed at laboratories certified by the Centers for Medicare and Medicaid (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) for high-complexity testing.

When asked about this issue at a town hall on April 8, FDA said that “it’s a challenging question and a challenging answer” and that even though “it was not our intention to limit the use of these rapid serology tests that are otherwise designed to be used in a point-of-care setting,” separate CMS regulations prohibited the tests from being performed outside of a CLIA-certified high-complexity lab.<sup>32</sup>

During the April 17 briefing, FDA admitted that it was not until the week of April 10, three weeks after the Pathway D policy was published, that the agency required tests designed for point-of-care to be performed only “under the auspices of a laboratory that has a high-complexity CLIA certificate.” As a result, test manufacturers, following the suggestion in Pathway D, marketed and distributed tests for use by “healthcare workers at the point-of-care”—into the hands of providers without the “high-complexity” technology to validate the tests and ensure their accuracy.

FDA has publicly threatened that it would “take appropriate action against firms making false claims or marketing tests that are not accurate and reliable.”<sup>33</sup> But this is a hollow threat. FDA does not require any documentation to be submitted by companies bringing their tests to market through Pathway D. FDA will be unable to take enforcement action against companies that are making false claims about the accuracy or reliability of their products.

## **VI. NUMEROUS COMPANIES APPEAR TO BE MARKETING FRAUDULENT TESTS**

The Subcommittee has identified numerous companies that appear to be violating FDA policies regarding diagnostic testing.

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<sup>31</sup> Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency: Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (Mar. 16, 2020) (online at [www.fda.gov/media/135659/download](http://www.fda.gov/media/135659/download)).

<sup>32</sup> Food and Drug Administration, *Virtual Town Hall Series: Immediately in Effect Guidance on Coronavirus (COVID-19 Diagnostic Tests* (Apr. 8, 2020) (online at [www.fda.gov/media/136833/download](http://www.fda.gov/media/136833/download)).

<sup>33</sup> Food and Drug Administration, *Coronavirus (COVID-19) Update: Serological Tests* (Apr. 7, 2020) (online at [www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests](http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests)).

On March 24, 2020, the Subcommittee sent letters to three companies that had offered at-home testing in violation of FDA policy.<sup>34</sup> Each of those companies has now verified that they are not currently offering home test kits, refunded any money they had collected, and destroyed any biological samples consumers provided.

On March 30, 2020, the Subcommittee sent a letter to Wellness Matrix Group, which had offered for sale directly to consumers an at-home serological antibody test.<sup>35</sup> The Securities and Exchange Commission then suspended public trading of the company's stock.<sup>36</sup>

On April 22, 2020, the Subcommittee sent letters to Vault Health and RUCDR Infinite Biologics for Vault Health's marketing of a testing program in which a patient collects a saliva sample at home during a telehealth appointment. This is not expressly authorized by the FDA's EUA for RUCDR's saliva-based test, which states that sample collection should be performed "in a healthcare setting under the supervision of a trained healthcare provider."<sup>37</sup> During the April 17 briefing, FDA confirmed that telehealth sample collection would require explicit approval in an EUA.

On April 23, 2020, the Subcommittee sent a letter to ARCpoint Labs, which appears to be violating FDA policy by offering point-of-care tests outside of the purview of certified high-complexity labs and appears to have been circulating erroneous information about the meaning of antibody test results.<sup>38</sup>

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<sup>34</sup> Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, *Press Release: Oversight Subcommittee Seeks Info from Companies Selling Unauthorized At-Home Coronavirus Test Kits* (Mar. 25, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-seeks-info-from-companies-selling-unauthorized-at-home>).

<sup>35</sup> Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, to Barry Migliorini, Wellness Matrix Group, Inc. (Mar. 30, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-03-30%20RK%20and%20KP%20to%20Wellness%20Matrix%20Group%20re%20Rapid%20Tests.pdf>).

<sup>36</sup> Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, *Press Release: Economic and Consumer Policy Subcommittee Leads SEC to Suspend Trading of Wellness Matrix Group Stock* (Apr. 9, 2020) (online at <https://oversight.house.gov/news/press-releases/economic-and-consumer-policy-subcommittee-investigation-leads-sec-to-suspend>).

<sup>37</sup> Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, to Jason Feldman, Vault Health Inc. (Apr. 22, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-22.RK%20to%20Vault%20Health%20re%20At-Home%20Diagnostic.pdf>); Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, to Dr. Jay A. Tischfield, RUCDR Infinite Biologics (Apr. 22 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-22.RK%20to%20RUCDR%20re%20RUCDR%20Infinite%20Biologics%E2%80%99s%20Testing.pdf>).

<sup>38</sup> Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, to John Constantine, ARCpoint Labs Franchise Group, LLC (Apr. 23, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-23.RK%20to%20ArcPoint%20Labs%20re%20Serological%20Antibody%20Tests.pdf>).