Missteps To Avoid In Marketing COVID-19 Antibody Tests

By **Anna-Liisa Mullis, Alissa Gardenswartz and Erin Eiselein** (May 11, 2020)

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As the United States looks to reopen its economy and get Americans back to work, many have called for widespread COVID-19 antibody testing to determine who may previously have been exposed to the virus. In an effort to speed up this process, the U.S. Food and Drug Administration had until recently allowed private industry test developers to bypass the traditional FDA development and approval process and offer antibody tests so long as the developers make certain representations to the FDA and the public.

The FDA's apparent disinclination to regulate the onslaught of unapproved yet available antibody tests enabled antibody test developers to engage in outright fraud. This culminated in state attorneys general — including Colorado's — stepping up to stop the test developers' fraudulent marketing practices and the FDA ultimately reversing course.

Background

Antibody tests are designed to check for antibodies in an individual's blood that the immune system makes in response to exposure to a virus, but they do not test for active COVID-19 infection. At least in theory, individuals with antibodies may have some level of immunity to COVID-19, although it is at present unknown whether and to what extent a person with prior exposure or infection is protected in the event of reexposure.

In an effort to disabuse misleading information around the efficacy of the antibody test, the World Health Organization issued a scientific brief expressly stating that there is no evidence that those with COVID-19 antibodies will not succumb to a second infection.[1]

In order to speed antibody tests to market, the FDA issued a policy permitting antibody test manufacturers to market tests that had not been reviewed by the FDA. Specifically, on March 16, the FDA released its Policy for Diagnostic Tests for Coronavirus Disease-19 during the Public Health Emergency. In the policy, the FDA stated that it "does not intend to object" to antibody tests sold by commercial developers where the developer validates the test, notifies the FDA that the test is being provided, and includes certain information in test reports, including that the test has not been reviewed by the FDA.

As of the most recent information available on the FDA's website, 170 commercial manufacturers had notified the FDA that they had validated and were offering antibody tests in accordance with the FDA's policy. The vast majority of tests are listed on the FDA's website as "Not FDA Authorized," meaning the FDA has not reviewed the test developer's validation or issued an emergency use authorization, or EUA, for the test.

The FDA's website further clarifies that the test developers may not be pursuing EUAs from the FDA for their tests at all. Thus, the FDA has not reviewed or verified the efficacy of the vast majority of antibody tests prior to those tests coming to market — the FDA is instead

depending on the developers to affirm that the tests are valid.

Indeed, in an April 17 briefing to Congress, the FDA acknowledged that it had not validated any of the antibody test kits that were by that time being sold under the auspices of the policy and that it had not requested proof of validation or validation data from developers.[2] The FDA also acknowledged that it did not know how many tests had been sold under the policy.

Although FDA Commissioner Stephen M. Hahn has assured the public that the FDA will be taking appropriate action against companies marketing tests that pose risks to patient health, to date, the FDA has issued only a handful of cease-and-desist letters and hasn't taken any enforcement action in nearly two months.[3]

Enforcement by State Attorneys General

Perhaps unsurprisingly, the elimination of the FDA's development and approval process, coupled with minimal enforcement efforts, has opened the door to unscrupulous activity. Some individuals have made fraudulent claims about tests, including that such tests are FDA-approved. Others may be peddling tests of dubious quality or accuracy.[4]

As they have done in other areas, state attorneys general are filling the void left by lack of federal oversight in COVID-19 antibody testing.

In recent years, state attorneys general have demonstrated an unwillingness to take a backseat on a number of issues where federal agencies have reduced enforcement efforts, particularly related to consumer protection. State attorneys general are now using their consumer protection authority to address private test developers' abuses of the FDA's willingness to allow tests to go to market without approval.

For example, the Nebraska attorney general has threatened to issue warning letters to anyone overstating the effectiveness of their COVID-19 antibody test,[5] and both the Texas and Illinois attorneys general have been called upon to address concerns about antibody testing.[6]

On May 1, Colorado Attorney General Phil Weiser announced he has gone a step further and issued cease-and-desist letters to companies allegedly making false claims in connection with COVID-19 antibody tests.[7] The letters state that, according to the office's investigation, these companies have misrepresented that their tests have been FDA-approved or received emergency use authorization, misrepresented likelihood of COVID-19 immunity, failed to make other FDA-required disclosures and, in the case of one company, made false statements concerning the costs to or the profits made in providing the tests.

However, it is worth noting that, while false and misleading statements are never protected under the Colorado Consumer Protection Act, the act also provides that it does not apply to conduct that complies with an order, rule or statute administered by a federal agency.[8] Accordingly, the fact that a company is marketing an antibody test without FDA approval would not be actionable under the act as long as the marketing contains the requisite disclosures and no false or misleading representations.

The FDA Reacts to Criticism for Lack of Oversight

Companies currently distributing, providing or facilitating antibody tests should be vigilant in monitoring the evolving guidance on these tests, which is continuing to change weekly, if

not daily.

Indeed, after the increase in state attorneys general activity described above, as well as the April 28 letter from the Congressional Committee on Oversight and Reform's Subcommittee on Economic and Consumer Policy to the FDA commissioner raising serious doubts about the validity of the antibody tests and admonishing the FDA for "abdicating" its responsibility to "protect the public health" and "trusting private industry to regulate itself," the FDA changed course on May 4.[9]

The FDA issued an updated policy stating that it does not intend to object to a commercial manufacturer's development and distribution of serology tests for a "reasonable period of time" where the test has been validated and while the manufacturer prepares an EUA request.[10] The FDA also required commercial manufacturers that had previously released tests under the prior version of the policy 10 business days in which to prepare an EUA submission for tests whose performance had supposedly already been validated by the developer.

The FDA also released two voluntary EUA templates for antibody tests — one for commercial manufacturers and one for Clinical Laboratory Improvement Amendments, or CLIA, certified high-complexity labs that decide to seek FDA authorization.[11] The FDA intends to publicly share the names of any developers that are currently marketing tests under the prior policy and that fail to submit an EUA to the FDA within 10 business days.

However, the new policy has little to say on enforcement actions the FDA intends to take against developers distributing tests of poor quality or making misleading statements about tests:

> If FDA becomes aware of questions or concerns about a test after notification, such as poor performance or misleading statements about the test, FDA will communicate those concerns to the manufacturer and provide the manufacturer an opportunity to address the questions or concerns. If the concerns cannot be or have not been addressed in a timely manner, and the manufacturer has already distributed the test, FDA would expect the manufacturer to suspend distribution of the test. FDA also intends to remove the test from the website listing of notifications and may take additional actions as appropriate.

Put another way, the policy states the FDA's continued expectation that the private developers will essentially self-regulate and will themselves adequately address any concerns and poor test performance or fraudulent marketing.

The policy does not specify any actions the FDA will take if the developer fails to address concerns. Nor does the policy specify any actions the FDA intends to take to rectify any harm that may have already come to consumers from fraudulent or poor-quality tests. Thus, state attorneys general will likely continue to be the primary authorities policing antibody testing concerns.

Guidance for Marketing Antibody Tests

Even in this dynamic environment, certain advertising principles stand firm. Most importantly, false or misleading advertising statements are not permissible under federal or state law — and certainly will not be tolerated when such statements pose a public health risk.

Companies marketing these tests need to be careful about how they describe them, and should additionally include required disclosures regarding the limitations of these tests. In addition to making false or misleading statements being problematic, omitting material information about a product, i.e., information that would impact a consumer's purchasing decision, can also violate state and federal consumer protection laws.

For example, stating that an antibody test is FDA-approved when it is not is a clear example of false advertising. Likewise, in light of the WHO's admonition that antibody tests do not assess a person's ability to avoid a second infection, claims that an antibody test will determine or guaranty immunity from COVID-19 are false statements that can have dire public health consequences. However, failing to disclose that tests are not FDA-approved, or that antibody testing cannot provide definitive information on whether a consumer is immune from infection, can also create the misleading impression to consumers that the tests are approved and provide conclusive results on future immunity.

Accordingly, companies need to screen their marketing for misleading statements as well as for required disclosures such that there is no argument that a reasonable consumer could not understand the benefits and limitations of an antibody test. Additionally, regular tracking of key issues relating to antibody tests, such as daily monitoring of the FDA's website, will enable a company to quickly assess whether its current marketing statements remain true and accurate.

Because there are public health implications for misinformation about antibody testing, state attorneys general will be closely monitoring marketing of antibody testing for even the slightest misstep.

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[1] https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19

[2] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Staff%20Report%20on%20Preliminary%20Findings%20of%20the%20Subcommittee%E2%80%99s%20Coronavirus%20Antibody%20Testing%20Investigation.pdf

[3] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits

[4] https://www.reuters.com/article/us-health-coronavirus-tests-specialrepor/special-report-fdas-lax-rules-on-coronavirus-blood-tests-open-us-market-to-dubious-vendors-idUSKBN22C3IG

[5] https://www.omaha.com/livewellnebraska/health/businesses-pushing-antibody-tests-for-covid-19-may-hear-from-nebraska-attorney-general/article_fa097f7d-1521-5a59-91af-1bc4706d3660.html

[6] https://www.kvue.com/article/news/health/coronavirus/austin-public-health-leader-warns-against-buying-covid-19-antibody-test/269-8716020e-389a-41e7-85a9-8532e704429e; https://www.dailyherald.com/news/20200430/covid-19-antibody-testing-met-with-scrutiny-in-suburbs-illinois

[7] https://coag.gov/press-releases/5-1-20/

[8] C.R.S. § 6-1-106

[9] https://www.politico.com/f/?id=00000171-c33b-d9e7-a3f1-cb7fbdfa0000

[10] https://www.fda.gov/media/135659/download

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