Health Law & Business News

Biden’s FDA Needs Course Corrections to Increase Covid-19 Testing

By Jeffrey N. Gibbs and Gail H. Javitt

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The FDA under President Joe Biden has the opportunity to improve the availability of Covid-19 testing. Hyman, Phelps & McNamara P.C. attorneys say the FDA can start by eliminating needless hurdles in the regulatory approval process, providing greater clarity, and applying criteria consistently.

From the start of the Covid-19 pandemic, access to accurate, reliable testing was identified as a critical element of an effective public health response.

Testing of all types—PCR, antigen, and antibody—in all settings—labs, at the point of care, and in non-medical settings—is needed to diagnose symptomatic and asymptomatic individuals, enable early identification and quarantine of individuals, determine the development of Covid-19 antibodies, assess disease prevalence, and ultimately, help ameliorate the pandemic.

Although vaccines are now being distributed, testing remains critical. Yet, the Food and Drug Administration, which has the lead role in determining what tests are available in the U.S., has continually moved the testing goalposts, making the regulatory pathway unpredictable and unnecessarily limiting access to tests.

By amending the FDA’s course, the Biden administration has an opportunity to improve America’s ability to meet our Covid-19 testing needs.

Changing and Conflicting Guidance

Within a matter of two months from the onset of Covid-19, the FDA’s requirements for serology (antibody) tests dramatically changed. From initially allowing the marketing and sales of antibody tests without Emergency Use Authorization to then abruptly reversing course in May, the FDA created two pathways for sales Covid-19 antibody tests, neither of which functioned appropriately.

The first allows tests appropriate for high-complexity settings to be sold following notification of EUA filing —for which there is no market. The second requires that tests appropriate for point-of-care use obtain an EUA from the FDA to sell. Then, the FDA made the critical internal decision to "deprioritize" serology tests, i.e., not review, without any public announcement.

The FDA's guidance for EUA of Covid-19 serology point-of-care testing has also wavered. Initially it seemed that serology tests could be sold to and used outside of lab settings in, for example, doctors' offices or pharmacies—consistent with the administration's goal of broad testing access.

However, subsequent FDA interpretations required additional clinical trials and a new EUA for point-of-care use. This switch has not only confused companies in the authorization process, but it eliminated the ability of these tests to be used in settings most suited for simple, rapid tests.

It also completely undermined the utility of Medicare's concurrent announcement of reimbursement for these tests in pharmacies since the FDA's policy largely blocked pharmacies from offering those tests.

Disastrous for Companies

As the FDA has continued to shift regulatory goalposts, their changes have not always been followed with clear, timely communications, hampering companies seeking EUAs. To help meet the dire need for tests, companies made significant investment to expeditiously validate their tests according to the FDA's initial recommendations. A subsequent FAQ document released by the FDA containing different requirements resulted in a tremendous waste of resources and loss of access to testing.

Some of those early applications have sat with the FDA for months, with no explanation to applicants. This same pattern has occurred repeatedly throughout the pandemic, with the FDA applying new standards for diagnostics well after companies submit applications. As applications continue to languish, the FDA's requirements continue to evolve. This dooms companies that worked in good faith to meet FDA requirements in effect at the time of submission.

Worse Yet for the American Public

Appropriately, the FDA has implemented changes to testing regulatory requirements as the agency learns more about the tests and Covid-19. But abruptly making changes that apply retroactively also imposes costs and creates confusion. These changes have had a direct adverse impact on the availability of all testing types in the U.S.

Even though testing is integral to schools seeking to safely resume in-person instruction and the health and safety of employees returning to work, the FDA has granted only EUAs for 69 antibody and just 14 antigen tests as of Feb. 11—a miniscule fraction of the total EUA submissions filed. Meanwhile, the demand for convenient testing continues to far out-pace authorized supply.

At the same time, the FDA has stopped reviewing submissions for hundreds of other non-Covid assays, including for breakthrough devices. This unpublicized decision will impose significant long-term costs on America's health.

Course Corrections Necessary

The FDA has faced a daunting task, having received thousands of EUA submissions since March 2020—the equivalent of several years of work. It's physically impossible for the FDA, with current staffing levels and the surge of submissions, to review EUA submissions in a timely manner. The reality is that some submissions will never be reviewed, and some deserving products will never receive authorization.

However, even without increased staffing, the FDA surely has capacity to review submissions for adherence to their specific, concise templates and engage in better, clearer communications with companies.

As FDA regulatory practitioners who have watched multiple companies struggle to bring new Covid-19 tests to market, it's obvious current policies are not fully meeting America's needs. While the FDA has reviewed numerous submissions, held countless calls, and began to fill the Covid-testing void starting from scratch, regulation of Covid-19 tests can be improved. The authorization of vaccines does not obviate this need.

With a new administration, we can course correct and take steps to increase the availability of all Covid-19 test types—starting with eliminating needless hurdles in the regulatory approval process, providing greater clarity, applying criteria consistently, communicating better with applicants, and authorizing more "CLIA waived" point-of-care serology tests, which can be performed outside of a certified laboratory.

Until these processes are more streamlined, the U.S. will continue to be at least one step behind the virus, even with a vaccine.

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