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What New FDA Policy Means For COVID Tests And Beyond

By **Stacy Amin and Bethany Hills** (December 14, 2021, 5:49 PM EST)

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For the diagnostics industry, the U.S. Department of Health and Human Services took one of the most anticipated — and hotly debated — actions in recent memory on Nov. 15, when it withdrew a controversial Trump administration policy that prohibited the U.S. Food and Drug Administration from requiring premarket review of laboratory-developed tests, including LDTs for COVID-19.

The policy HHS rescinded was an August 2020 web announcement that occurred alongside a cloud of reporting about infighting between HHS and the FDA over the policy.

Close observers noted that the FDA never publicly supported or acknowledged the August 2020 position, and speculation had been building for months about whether or when it would be rescinded.

In withdrawing the Trump administration policy, HHS Secretary Xavier Becerra noted in his statement that HHS "no longer has a policy on LDTs that is separate from FDA's longstanding approach in this area."

The "longstanding approach" references the FDA's stated position, which dates back to at least 1992, that LDTs are subject to the FDA's jurisdiction as medical devices, like any other in vitro diagnostic test.

Though the FDA has a long history of mostly not enforcing the premarket review requirements for LDTs, the agency has on occasion taken compliance action against certain tests, and has proposed and then pulled back on plans to more actively regulate LDTs.

And in the case of a public health emergency, the FDA had taken the position even before COVID-19 that premarket review was required to ensure that tests' design, validation and performance were appropriate for an infectious disease, where inaccurate results could exacerbate spread of the disease.

This enforcement approach by the FDA has widely been referred to as shifting sands, where the industry is not quite sure when the FDA might take a compliance action or when its policy of enforcement discretion might change. So the recent announcement by HHS has led to a host of questions about what going back to the past might mean for the future.

This article will address the most common questions we hear about the new policy and will try to make some predictions for 2022 and beyond.

How will COVID-19 tests be treated under this new policy?

Along with HHS' Nov. 15 rescission of the previous administration's web statement, the FDA issued new guidance withdrawing the policies it had issued in the early days of the pandemic that provided flexibility for certain LDTs and serology tests to market without an emergency use authorization, or EUA.

Those policies allowed tests to be marketed without an EUA if they provided notification to the FDA or worked through state regulators. There are now likely hundreds of these tests on the market, either offered through these flexible policies or through the August 2020 HHS web statement permitting the marketing of the tests without FDA review.

The FDA will now require an EUA to market these tests.

If an EUA request has not already been submitted, developers have 60 days from the date of the guidance to submit an EUA request.

The FDA has articulated clear and specific priorities for tests that it will review, including:

- Molecular and antigen diagnostic tests that can be used at the point of care or completely at home and are able to be used on symptomatic and nonsymptomatic individuals;

- Laboratory-based molecular diagnostic tests that are highly sensitive; high-throughput; intended for pooling, home specimen collection, screening or detection of multiple analytes; and from experienced developers, i.e., developers that have already received an EUA;

- Home specimen collection kits intended for use with laboratory-based molecular diagnostic tests; and

- Serology tests intended for quantitative measurement of antibody titers or qualitative detection of neutralizing antibodies.

For all of these categories of tests, the FDA only intends to review tests from developers who have indicated the ability to scale up manufacturing capacity to at least 500,000 per week within three months of authorization.

This testing capacity threshold was a surprise to the industry, and it is unclear how many LDTs will have the capacity to scale up to more than 500,000 tests per week.

At the same time, the FDA has emphasized in recent virtual town hall meetings that the agency is going to be as flexible as possible to maintain current access to testing.

For example, the FDA has said it wants to make this as easy as possible for developers with LDTs that are currently in use, and plans to work with labs to address any questions or concerns.

And the FDA emphasized that labs with novel tests that do not meet the capacity threshold should reach out to the FDA to discuss their tests, and noted that the guidance says developers can make an

argument to the agency as to why their tests should still be reviewed.

For the tests on the market that have been offered through one of the various HHS or FDA policies in place from the earlier days of COVID-19, if the FDA notifies a developer that it declines to issue an EUA, the developer has 15 calendar days from the date of notification to stop marketing the test or risk enforcement action from the FDA.

What does the new policy mean for other LDTs?

Predicting what will happen to COVID-19 tests is perhaps easier than predicting what will happen to the rest of the LDT market.

Because the HHS and FDA announcements did not come with a new policy for LDTs generally, what's old is new again, and LDTs are in the same position of uncertainty they experienced before the pandemic.

As noted above, FDA has generally had a policy of not requiring premarket review for LDTs — what the FDA calls "enforcement discretion."

Living in a perpetual state of enforcement discretion is not ideal for any regulated product, because the FDA could choose at any time to change its policy writ large or with respect to specific tests or categories.

This makes it hard for many labs to invest resources in developing tests, and we've seen during the last two years just how rapidly the industry can innovate to meet patient need.

Industry sentiment regarding the lack of certainty in an enforcement discretion policy is well founded.

The FDA's more recent history with LDTs over the last decade indicates a concern about the accuracy and safety of the tests in this growing market, and a willingness to take compliance action and potentially even enforcement action against LDTs that it believes pose a public health risk.

The FDA issued warning letters to tests in 2007, 2008, 2013 and 2019, and in 2016 sent a series of "it has come to our attention" letters to Zika virus tests that had not obtained EUAs.

The FDA signaled an intent to regulate LDTs in a 2010 public meeting and published draft guidance in 2014 that would have adopted regulatory oversight for certain LDTs given the growing market, increased complexity of tests and increased risks to patients. That guidance was never finalized and was walked back in January 2017 on the eve of former President Donald Trump taking office.

Labs do not have much guidance regarding what tests may or may not be an enforcement priority for the FDA and whether the FDA would issue some kind of guidance before beginning any compliance or enforcement actions.

Moreover, the FDA's experience regulating COVID-19 tests may encourage the agency to increase its oversight of LDTs.

This lack of clarity and certainty, combined with the shifting policies back and forth, have led to this will-they-won't-they mentality on regulation that feels like shifting sands to the industry.

What can LDTs expect in 2022 regarding litigation and legislation?

There seem to be two primary pathways for resolving the uncertainty over the future of LDT regulation — litigation or legislation — and both pathways have supporters.

Litigation is getting traction among some industry veterans in light of a memo purportedly leaked by the previous administration in support of the August 2020 web statement prohibiting the FDA from regulating LDTs.

The memo, as published in news outlets, argued that the FDA would need to undertake notice and comment rulemaking to require premarket review for any LDTs, including COVID-19 LDTs.

Some commentators and practitioners have argued that the memo gives potential litigators a basis to sue, because the FDA did not engage in notice and comment rulemaking before issuing its revised LDT guidance.

However, the likelihood of success in such a litigation seems slim due to standing issues. Any lawsuit based only on the revised guidance is likely to raise standing issues for plaintiffs because courts generally do not consider guidance to be final agency action.

The FDA has been sued numerous times in recent years over the issuance or withdrawal of compliance policy guidance, and courts have usually concluded that FDA guidance does not establish any rights or obligations, and thus does not constitute final agency action that can provide a basis for suit.

Potential plaintiffs' standing would be on stronger footing if they were the subject of an enforcement action by the FDA, through the U.S. Department of Justice, seeking to remove a test from the market.

But such an action seems unlikely in the near term. The FDA likely would need to determine that a particular test poses a significant risk to patient safety or public health to take an enforcement action.

And in such cases where there is a risk to patients, the deference the FDA receives from courts is at its highest.

Moreover, such an action would likely start with much lower level compliance communications and even a warning letter before ever resulting in an action from the DOJ that would provide a clear basis for suit.

That kind of compliance activity buildup could take months or years. And litigants have also had difficulty establishing standing to challenge warning letters or lower level compliance actions.

Legislation provides a more straightforward pathway to resolve the uncertainty over the FDA's regulation of LDTs.

A coalition of major industry players are supportive of a legislative solution, where previously some of those same players went to the mattresses to try to fight FDA efforts to regulate LDTs.

Most of these players are supportive of a risk-based framework for the regulation of LDTs that would ensure safety and efficacy of diagnostic testing while continuing to promote innovation.

Many have coalesced around the Verifying Accurate, Leading-Edge IVCT Development, or VALID, Act as the most likely candidate for a permanent legislative solution for diagnostics reform.

Even with broad industry support and a supportive agency, it would rarely be wise to predict legislative reform as a likely outcome for any intractable policy challenge.

However, 2022 is unique in that the Medical Device User Fee Amendments provide a must-pass legislative vehicle that diagnostics reform could be attached to.

This confluence of events may just provide the perfect timing for that rarest of accomplishments — a true bipartisan compromise that solves a serious policy problem.

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