October 9, 2020

FDA Announces It Will No Longer Review EUA Requests for COVID-19 Laboratory Developed Tests

As Ropes & Gray previously reported, on August 19, 2020, the U.S. Department of Health and Human Services ("HHS") unexpectedly published a notice on its website stating that the U.S. Food and Drug Administration ("FDA") will not require premarket review of any laboratory developed tests ("LDTs"), absent notice-and-comment rulemaking. On October 7, 2020, FDA for the first time publicly addressed how this announcement will affect the agency's review activities for COVID-19 tests.

Change in FDA's EUA Review Priorities

In a new addition to its Frequently Asked Questions ("FAQs") website regarding SARS-CoV-2 testing, FDA explains that it will be "declining to review EUA requests for LDTs at this time." FDA states that the purpose of this change is to make the "best use of its resources for the greatest public health benefit" in light of the significant number of COVID-19 tests currently authorized to be run in laboratories, and because of "the recent HHS announcement that FDA will not require premarket review of LDTs." The statement also notes that "FDA continues to prioritize review of EUA requests for [point-of-care] tests, home collection tests, at-home tests, tests that reduce reliance on test supplies, and high-throughput, widely distributed tests."

Shortly after posting its new FAQ on October 7, FDA hosted a virtual town hall during which agency personnel addressed questions related to its decision to end review of EUA requests for LDTs. Key takeaways from that discussion include:

- FDA will not continue to review previously submitted EUAs for LDTs.
- Prior to announcing its new policy, FDA completed its reviews of LDT EUAs that were "close to the finish line."
- FDA will notify submitters of EUAs for LDTs in writing that their submissions will not be reviewed.[1]

Unanswered Questions for the Laboratory Industry

Not surprisingly, FDA's announcement and subsequent town hall comments leave a number of questions unanswered. We do not yet know exactly how FDA will define "LDTs," when considering which EUAs it will decline to review. More insight into this question may be obtained by looking at any EUAs that FDA may issue to laboratories in the coming weeks or months.

In addition, although FDA has explained that it will continue to prioritize "home collection tests," it has not made clear whether it will continue to review EUA requests for LDTs performed on specimens collected "at home." More likely,

[1] These comments are based on notes taken by Ropes & Gray during the virtual town hall. A formal transcript is likely to be issued within the next few weeks and will be available on FDA's website at this link: https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-coronavirus-covid-19-test-development-and-validation-10142020-10142020?utm_source=FDALinkedin.

FDA will review EUA requests for at-home specimen collection kits and devices that may be used with LDTs, but not any associated LDT assays. It also remains to be seen what position FDA will take with respect to use of legally marketed specimen collection kits that are intended for at-home collection, but not specifically indicated for use with COVID-19 diagnostic tests. Another question is whether FDA's desire to foster more "high-throughput, widely distributed tests" means the agency will entertain EUA requests for testing programs that rely on high throughput methodologies developed and performed in a laboratory, with widely distributed specimen collection kits. Finally, it is unclear whether FDA's focus on tests that reduce consumption of testing supplies means that the agency will review EUAs for LDTs that use novel supply-sparing methods.

Other unanswered questions include why FDA decided to change its EUA review policy now, and how long its refusal to review EUAs for LDTs will last. FDA claims this change was prompted both by the increased availability of authorized tests and by the HHS announcement barring it from requiring premarket review for LDTs. FDA appears to have decided to focus its limited resources on review of categories of tests that indisputably require its authorization to be legally marketed, and FDA may have a significant backlog of EUA requests for such tests. Perhaps FDA will reinstate its review of EUAs when it clears its backlog, or if there is a change in HHS policy, which presumably would occur only if the upcoming presidential election results in a change in administration. Congressional pressure, such as an October 7 letter from the House Committee on Energy and Commerce to HHS Secretary Alex Azar criticizing HHS's August announcement and the negative impact it could have on the quality and accuracy of LDTs, might also influence FDA's priorities going forward.

Regardless of what the future holds, for the time being this policy change means that laboratories that develop LDTs for COVID-19 will no longer be able to obtain the potential benefit of PREP Act immunity or to market their tests as authorized by FDA. When HHS made its August 2020 announcement that FDA would not require premarket review for any LDTs, it described as voluntary the decision whether to submit an EUA request to FDA for an LDT. HHS had explained that a laboratory might voluntarily request an EUA because "[a]n EUA triggers PREP Act coverage which immunizes laboratories from suits for loss related to the test." FDA's October 7 announcement removes that option for COVID-19 LDT developers, which may create a disincentive for laboratories to continue to develop COVID-19 diagnostics. Quite possibly, because HHS has announced that FDA can no longer require EUAs for COVID-19 LDTs, FDA intends to discourage additional LDTs from being developed while that policy remains in effect.

Ropes & Gray will continue to monitor developments in this area. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.