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Health Care ADVISORY ■

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# What Happens to EUAs for Diagnostic Tests After the COVID-19 Public Health Emergency Is Over?

Since the start of the coronavirus pandemic, the Food and Drug Administration (FDA) has issued almost 400 emergency use authorizations (EUAs) for molecular diagnostic tests, antibody tests, and antigen tests combined. As life returns to something approximating "normal," many are wondering what happens to tests offered pursuant to EUAs once the public health emergency is terminated.

## Background on Emergency Use Authorizations

Section 564A of the Federal Food, Drug, and Cosmetic Act permits the Secretary of Health and Human Services (HHS) to authorize the emergency use of an unapproved medical product after the HHS Secretary has made a declaration of an emergency or threat justifying authorization of emergency use. Then-HHS Secretary Alex Azar made such a declaration on February 4, 2020. It is important to recognize that this "emergency use" declaration is separate from a declaration of the existence of a public health emergency under Section 319 of the Public Health Service Act (PHSA), which Azar first made on January 31, 2020. A declaration allowing emergency use of unapproved medical products is not dependent on the existence or renewal of a public health emergency declared under the PHSA.

During an EUA declaration, the commissioner of the FDA, acting under authority delegated by the HHS Secretary, may issue an EUA for an unapproved medical product such as a clinical laboratory test if four statutory criteria have been met: an agent of some sort is capable of causing a serious or life-threatening disease or condition; the medical product may be effective to prevent, diagnose, or treat serious or life-threatening diseases or conditions caused by the agent; the known and potential benefits of the product outweigh the known and potential risks of the product; and there are no adequate, available, and approved alternatives to the medical product for diagnosing, preventing, or treating the disease or condition.

An EUA declaration terminates on the earlier of when (1) a determination by the HHS Secretary that the circumstances that precipitated the emergency use declaration no longer exist; or (2) only a single product has emergency authorization and the use or uses of the product have been approved by the FDA

through normal clearance or approval means. The Secretary is to provide advance notice of termination of a declaration, which should allow time for unused medical products and labeling and other information to be disposed of properly.

Separate from the EUA declaration and the public health emergency declaration, Azar issued a declaration under the Public Readiness and Emergency Preparedness (PREP) Act on March 10, 2020 (effective February 4, 2020). It provides for liability immunity against claims of loss caused by, arising out of, or resulting from the manufacture, distribution, administration, or use of certain medical countermeasures, including any diagnostic used to diagnose COVID-19. Liability immunity is available to "covered persons," which includes any person, corporation, or entity that is authorized to prescribe, administer, or dispense a covered countermeasure or that is authorized to perform an activity under an EUA. Such liability immunity under the PREP Act is in effect through the final day of the PREP Act declaration or October 1, 2024, whichever occurs first. Importantly, this liability immunity is not available to a laboratory for a COVID-19 diagnostic that is a laboratory-developed test (LDT) validated and performed under a Clinical Laboratory Improvement Amendments (CLIA) certificate of compliance or certificate of accreditation, if the LDT has not been granted an EUA.

During public health emergencies, the FDA typically has required even an LDT to have an EUA before it is offered because of the serious public health implications of faulty tests or inappropriate use. In normal circumstances, the FDA exercises what it characterizes as "enforcement discretion" and does not require pre-approval of LDTs, but its policy has been that during an "emergency use" declaration, LDTs need to be FDA approved.

## EUAs for Diagnostics to Detect SARS-CoV-2

The first test granted an EUA was an RT-PCR test developed by the Centers for Disease Control and Prevention (CDC). It was available for use in CDC laboratories and public health labs. Many of the labs had trouble validating the test, which turned out to be the result of a problem with one of the reagents included in the test kit. Finally, on February 29, 2020, the FDA issued a new policy to accelerate development of COVID-19 testing and broaden access to testing by allowing a CLIA-certified high-complexity laboratory to begin testing after having validated a test and having notified the FDA of the validation, with the expectation that an EUA submission would be submitted within 15 days of notifying the FDA. The guidance also allowed a state or territory to authorize a laboratory within its jurisdiction to develop and perform a COVID-19 test under state or territorial law. The FDA guidance opened the floodgates, and scores of laboratories started developing tests to detect SARS-CoV-2 or antibodies to the virus. As of May 2021, the FDA had issued almost 250 EUAs for molecular diagnostic tests, almost 80 EUAs for antibody tests, about 30 EUAs for molecular diagnostic tests performed as LDTs, and about 25 EUAs for antigen tests. While the Secretary's "emergency use" declaration that authorizes issuance of EUAs is separate from a declaration of a public health emergency under Section 319 of the PHSA, the FDA's policy guidance states that it is "intended to remain in effect only for the duration of the public health emergency … made by the HHS Secretary in accordance with section 319(a)(2) of the [PHSA]."

Several CLIA-certified and CLIA-accredited laboratories sought EUAs from the FDA for COVID-19 LDTs they had validated, in part to avail themselves of PREP Act liability protections triggered by the issuance of an EUA, and in part to maintain coverage and payment for their diagnostics under Division F of the Families First Coronavirus Response Act. An action by HHS in August 2020 set in motion a series of events that upended this approach by laboratories. On August 19, HHS announced that the FDA no longer would require premarket review of LDTs because, absent rulemaking, the FDA lacks the legal authority to require it. A Frequently Asked Questions document that came out soon thereafter said that a laboratory could submit a request for an EUA for a COVID-19 test to the FDA voluntarily, and it acknowledged that a laboratory may be motivated to do so in order to trigger PREP Act coverage. It also said that EUAs that already had been issued for LDTs would be unaffected by the policy. On October 7, 2020, the FDA announced in an updated FAQ that it no longer would review EUA requests for LDTs, explaining that it would prioritize other types of EUA submissions (e.g., home collection, point-of-care tests). Laboratories that had submitted EUA requests for LDTs were stuck in limbo and had their requests returned with a notice that they would not be reviewed.

In mid-November 2020, HHS directed the FDA to review all voluntarily submitted EUA requests for LDTs, including both new requests and those that were already in the process of being reviewed. Some EUA submissions for LDTs still did not get reviewed, however, leaving the laboratories performing them without PREP Act liability protections.

## What Happens When the EUA Declaration Expires?

An ever-growing percentage of U.S. residents are vaccinated against COVID-19, and clinical trials are well under way for use of vaccines even in children. Mask requirements, indoor capacity limits, and temperature checks soon may be relics of the past. We may be closer to the point at which the Secretary will declare that the circumstances that precipitated the emergency use declaration no longer exist.

What happens next to tests that received EUAs? The FDA addresses this question in its FAQs for medical devices with EUAs. It acknowledges that when an EUA is no longer in effect, a device may not be marketed legally unless it has received marketing authorization from the FDA. It encourages sponsors of EUA products to follow up with the appropriate premarket submission to the FDA (e.g., 510(k), de novo request, premarket authorization) while the public health emergency still is in effect so that the sponsor may continue to offer its product seamlessly when the emergency is over.

On March 21, 2021, the FDA granted marketing authorization under the de novo premarket review pathway to BioFire Diagnostics for its BioFire Respiratory Panel. It was the first SARS-CoV-2 diagnostic test that had been granted an EUA to be approved through normal channels. Acting FDA commissioner Janet Woodcock said that while it was the first, she does not expect it to be the last and that FDA reviewers look forward to working with developers of medical products to move their products through the FDA's traditional review pathways.

In recent months, the FDA has said it is working on guidance for transitioning diagnostics and other medical products from EUAs to conventional premarket authorization, but to date, such guidance has not been issued, and the agency still is issuing EUAs for rapid and at-home diagnostic products. Agency officials have

said that the EUA pathway would remain open even after there are COVID-19 tests that have received full market authorization, and they recommend that test developers get started on clinical studies for premarket authorization soon. But they also have said that an end to the emergency declaration is "a long way off."

A laboratory that has an EUA for a COVID-19 LDT certainly can seek FDA clearance or approval for the test, but it must consider the costs and benefits of that strategy. A laboratory that currently does not have in place a robust medical device compliance program that is suited to the FDA's postmarket requirements and expectations may find that the costs associated with developing and administering such a program, plus the costs of premarket authorization studies, outweigh the benefit of the FDA's imprimatur for the test. On the other hand, a laboratory that already offers other FDA-cleared or approved tests would bear the cost of conducting premarket authorization studies and of compiling the application, but the costs to integrate a newly cleared or approved COVID-19 test into an existing compliance program would be marginal. (Of course, a manufacturer that sells test kits used in laboratories must seek premarket authorization if it wants to continue marketing the kits.)

Laboratories should be thinking through their strategies for continuing to offer COVID-19 testing after the current emergency declaration has been terminated and whether that will involve seeking full FDA premarket authorization for their tests. Even with a return to "normal," some amount of the virus and its variants are likely to continue circulating for years to come in the United States, and some amount of COVID-19 testing will remain necessary.

Alston & Bird's multidisciplinary COVID-19 Response & Relief Team advises clients on the business and legal implications of the coronavirus, including the rollout of vaccines. You can view all our work on the coronavirus across industries and subscribe to our future webinars and advisories.

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Alston & Bird has launched the **Digital Transformation of Health Care**, a new initiative that advances our commitment to an industry approach to providing legal services in the health care space. Our health care and technology teams can assist with establishing or significantly growing telehealth capabilities and navigating the regulatory landscape.

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