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FDA Stops Granting EUAs For Lab Developed Tests, Denying LDT Makers PREP Act Liability Protections

It's the latest salvo in the push-and-pull between the FDA and the HHS over LDTs

by Shawn M. Schmitt

The tug of war between the US HHS and the FDA over laboratory developed tests took a surprising turn on 7 October when the agency declared that it will no longer issue emergency use authorizations for LDTs. That means unapproved COVID-19 tests that come to market without an EUA won't be covered under the PREP Act, which protects makers of pandemic-fighting products from lawsuits.

The push-and-pull between the US Department of Health and Human Services and the Food and Drug Administration over laboratory developed tests took a surprising turn today when the agency declared that it will no longer grant emergency use authorizations (EUAs) for LDTs.

That means unapproved COVID-19 tests that come to market without an EUA won't be covered under the Public Readiness and Emergency Preparedness Act – or *PREP Act* – which protects makers of pandemic-fighting products from most related lawsuits.

The HHS *announced in August* that LDT makers no longer need to notify the FDA before sending their diagnostics to market. The HHS said at the time that the agency won't impose premarket review on LDTs absent the formal notice-and-comment rulemaking process. (Also see "*Legal Experts: HHS Policy Change Strips FDA Of Oversight For All LDTs*" - Medtech Insight, 26 Aug, 2020.)

> *"FDA is declining to review EUA requests for LDTs at this time." – Tim Stenzel*

Because of "the recent HHS announcement that FDA will not require premarket review of LDTs, to make the best use of our resources for the greatest public health benefit, FDA is declining to review EUA requests for LDTs at this time," said Tim Stenzel, director of the FDA's Office of In Vitro Diagnostics and Radiological Health.

"FDA continues to prioritize review of EUA requests for point-of-care tests, at-home collection kit tests, at-home tests, tests that reduce reliance on tests supplies, and of course those tests that are high throughput, widely distributed tests on widely available platforms," he said. "This approach, we believe, will provide greater potential to improve the national testing capacity and permit FDA to take appropriate steps to assure that authorized tests may be effective."

Stenzel's comments came on 7 October during the Food and Drug Law Institute's Annual Conference.

But it wasn't only the policy shift by the HHS that precipitated the FDA's move to block LDTs from the emergency use process, Stenzel said.

"We recognize that we're currently in a different phase of the pandemic with respect to tests than we were previously," he said. "Many COVID-19 tests are now authorized to be run in labs, so there is this huge testing capability already that's EUA-authorized."

The FDA has issued more than 250 EUAs to tests related to the novel coronavirus since the national public health emergency was announced in January.

During a separate *weekly FDA town hall* held earlier in the day, Stenzel claimed the move had nothing to do with denying LDT makers protection under the PREP Act – although that's what it effectively does.

Instead, he said, "this is an effort to prioritize FDA resources for the greatest public health benefit, considering the extent to which we can use our authorities under the Food, Drug, and Cosmetic Act."

Former FDA commissioner Scott Gottlieb warned in late August that the LDT policy shift by the HHS could lead to a "limbo" for COVID-19 tests with EUA status. (Also see "*Ex-FDA Commish*

Warns Of 'Limbo' For COVID-19 LDTs Granted Emergency Use Authorization" - Medtech Insight, 22 Aug, 2020.)

"FDA has worked with labs to advance countless testing innovations under FDA's emergency use authorization ... authority," Gottlieb *wrote on Twitter*. "Under this process FDA provides feedback to test makers. Countless labs say FDA counsel helped improve test quality."

Gottlieb, who was commissioner from 2017 to 2019, went on: "The process was mostly working. New tests were entering the market; innovation unfolding. Now all LDTs authorized under EUA could be in limbo. How can FDA grant EUA for something it has no authority to require? Liability protections that attach with EUAs may be inoperable."

But in an August *FAQ sheet*, the HHS says that won't happen. "All EUAs granted under the previous requirement are unaffected by this [LDT] policy announcement," the department wrote. (Also see "*FAQ Sheet From HHS Says FDA 'Rarely Enforced' Premarket Review Of LDTs*" - Medtech Insight, 29 Aug, 2020.)

The FDA's authority over LDTs has long been an open question. The Centers for Medicare and Medicaid Services regulates LDTs under Clinical Laboratory Improvement Amendments (CLIA) rules. But since 2014, some stakeholders have argued that LDTs have become too complex for CLIA regulation and should be FDA-reviewed.