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FAQ Sheet From HHS Says FDA 'Rarely Enforced' Premarket Review Of LDTs

by Shawn M. Schmitt

The US HHS defends its recent decision to relieve the FDA from oversight of laboratory developed tests in a new FAQ sheet, saying the agency hardly ever enforced the premarket review of LDTs in the first place.

A new FAQ sheet from the US Department of Health and Human Services (HHS) defends its recent decision to remove Food and Drug Administration oversight of laboratory developed tests, saying the agency "rarely enforced" premarket review of LDTs in the first place.

"FDA will no longer require premarket review of tests developed by a laboratory for use solely within that lab (laboratory developed tests, or LDTs), due to a determination by the HHS Office of the General Counsel … that, absent rulemaking, the FDA lacks the legal authority to require it," the undated FAQ sheet says.

It goes on: "FDA has rarely enforced this premarket review requirement and in recent years, only began enforcing again when [HHS] secretary [Alex] Azar declared a public health emergency on January 31, 2020. This meant that laboratories wishing to quickly begin conducting COVID-19 tests now first had to receive FDA review – a requirement they had not been subjected to in years."

The HHS stripped the FDA of any authority over lab developed tests in a *five-sentence 19 August policy statement*. Three legal experts told *Medtech Insight* on 25 August that the statement indeed removed agency oversight of LDTs, with one lawyer calling the move "a broader directive wrapped in a COVID sandwich." (*See sidebar story.*)

Legal Experts: HHS Policy Change Strips FDA Of Oversight For All LDTs

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The HHS in its FAQ sheet confirmed that it made its decision "as part of an ongoing departmental review of our response to COVID-19," noting that it "will allow labs to more quickly develop and utilize tests" during future pandemics.

Three lawyers tell *Medtech Insight* that the recent move by the US HHS to revoke the FDA's authority to oversee laboratory developed tests extends to all LDTs, and not just those used to test for COVID-19.

Read the full article here

Meanwhile, former FDA commissioner Scott Gottlieb, who led the agency from 2017 to 2019, took to Twitter on 29 August to say that the FDA has, in fact, conducted "selective enforcement actions" related to LDTs.

"During my tenure at FDA, the agency continued to exercise enforcement discretion over most laboratory developed tests ... but we also took selective enforcement actions to protect public health," he wrote.

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Gottlieb pointed to an *April 2019 warning letter* the FDA's device center sent to Inova Genomics Laboratory as an example of the agency flexing its LDT enforcement muscle. (Also see "*Warning Letter Roundup & Recap – April 9, 2019*" - Medtech Insight, 9 Apr, 2019.)

"We took actions when FDA determined 'inaccurate test results could impact the decision-making of health care providers and patients in ways that are seriously detrimental to patient health' to 'address significant public health concerns,'" he wrote, quoting Inova's warning letter.

And in one of a series of 13 tweets on 22 August, Gottlieb predicted that a "plethora" of direct-to-consumer COVID-19 tests will come to market and be "processed in a central lab operating outside FDA oversight" because of the HHS policy shift. (Also see "*Ex-FDA Commish Warns Of 'Limbo' For COVID-19 LDTs Granted Emergency Use Authorization*" - Medtech Insight, 22 Aug, 2020.)

But in its FAQ sheet, the HHS says that won't happen: "Nothing will be flooding the market as a result of this change. LDTs, by definition, cannot be sold outside of the laboratory in which they were developed. There is no reason to believe that complying with law will have any effect on the quality of LDTs. Every COVID-19 test, including LDTs, are still regulated by the federal government."

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.

Bills to move LDT regulation to the FDA have been introduced in Congress multiple times in recent years, but have yet to pass. (Also see "*Lawmakers Issue Dx Reform Bill To Strike Regulatory Balance*" - Medtech Insight, 6 Mar, 2020.)