MEDTECH INSIGHT
CITELINE COMMERCIAL

26 Aug 2020 | **Analysis**

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

Last week's policy statement from HHS is "a broader directive wrapped in a COVID sandwich," one attorney says

by Shawn M. Schmitt

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.

A week-old policy statement from the US Department of Health and Human Services that stripped the Food and Drug Administration of its oversight of laboratory developed tests indeed applies to all LDTs and not just those for COVID-19, legal experts tell *Medtech Insight*.

While the HHS announcement refers to the coronavirus pandemic three times, the core policy declaration – the FDA "will not require premarket review of laboratory developed tests absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances" – covers all LDTs.

"Based on a reasonable reading of [the policy statement], it's a broader directive wrapped in a COVID sandwich," said Nathan Brown, a partner in the Washington, DC, office of the law firm Akin Gump.

And Scott Danzis, a partner in the Washington, DC, office of the law firm Covington & Burling, agrees. "By the terms of the policy that was issued, it is not restricted to COVID-19 LDTs. It is broader than that. Moreover, we've had recent discussions with senior HHS officials who have confirmed that the intent of this policy statement is broad. It is not intended to be only applicable to COVID-19 diagnostics."

Some in industry were left scratching their heads after reading *the bare-bone, five-sentence, out-*

of-left-field 19 August statement, trying to determine whether it applied only to COVID-19 tests. On 22 August, former FDA commissioner Scott Gottlieb weighed in, writing on Twitter that the policy, as he reads it, extends to all LDTs. (Also see "*Ex-FDA Commish Warns Of 'Limbo' For COVID-19 LDTs Granted Emergency Use Authorization*" - Medtech Insight, 22 Aug, 2020.)

Meanwhile, the HHS has clouded matters by not publicly addressing the policy or offering any type of transparency around it. The department, which oversees the FDA, has ignored repeated requests for comment by *Medtech Insight*.

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Danzis surmises that the HHS was concerned that the FDA's requirement that COVID-19 LDTs be put through the agency's emergency use authorization (EUA) process was slowing test development, leading to the policy change.

A February FDA guidance document gave labs certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) the go-ahead to deploy validated COVID-19 tests without prior approval. But the document instructed labs to confirm to the FDA via email that the assay had been validated, and to complete an EUA request within 15 days. (Also see "*COVID-19: FDA Eases Approval Policy By Allowing LDT Use Under 'Immediately In Effect' Guidance*" - Medtech Insight, 1 Mar, 2020.)

"That caused, I think, an HHS evaluation of how FDA has gone about overseeing LDTs, and that led to the policy statement saying that, 'If FDA wishes to go forward with regulation of LDTs, at minimum it has to use notice-and-comment rulemaking rather than less formal means of making announcements about LDT regulation,'" Danzis said.

The policy "is absolutely related to COVID in the sense that, that's what caused the evaluation, but I think the conclusion of that evaluation was broader than just COVID-19 diagnostics," he added.

Kyle Sampson, a partner in the Washington, DC, office of the law firm King & Spalding, said there's little doubt that the policy statement applies to all LDTs. After all, he said, the title of the statement – "Rescission of Guidances and Other Informal Issuances Concerning Premarket

Review of Laboratory Developed Tests" – makes no mention of it being a policy that's exclusively for COVID-19 tests.

But why would the HHS make such a policy move now, in the middle of a pandemic?

"One way to look at it is, a pandemic is a terrible thing to waste," Sampson said. "So if your position is, 'We want less regulation of LDTs, we think innovation is served by having less regulation and we're not really concerned about the risks of imprecise or unreliable tests getting out there in the market,' then it would be an opportunity to clip FDA's wings, to kind of cabin FDA's authority and say, 'You can only regulate LDTs if you go through this onerous regulatory process.'"

An 'Enduring' Policy Change?

Nevertheless, Sampson questions the "endurance" of the policy statement.

"It's a naked statement. It's not even signed by [HHS] secretary [Alex] Azar or the deputy secretary, or anyone else. No one's name is attached to it. It doesn't cite any statutory authority. There's not even an accompanying press release," he said. "I find that fascinating."

Sampson went on: "I'm not sure what would prevent a President Biden HHS from issuing a statement on Jan. 21, 2021, that says, 'LDTs are medical devices under the Food, Drug and Cosmetic Act,' essentially rendering this current policy statement void," Sampson said. "I don't see anything that would prevent a future administration from doing that."

> *"Many in the laboratory community have long asserted that FDA lacks authority … to regulate LDTs at all." – Scott Danzis*

But for now, the FDA must follow the policy set down by the Trump administration HHS.

"FDA is a component of HHS, and if HHS put out this statement, then FDA is obliged to comply with it," Sampson said. "Now, what does that mean? That means that if any test developer went to market with its LDT, that FDA really couldn't come in and say, 'Hey, you don't have clearance for that.' I think the HHS policy statement has rendered FDA toothless as far as coming in and taking some enforcement action."

In its policy statement, the HHS says labs can still submit EUAs or other premarket applications

to the FDA on a voluntary basis.

The HHS also warned that LDTs distributed without FDA notification or clearance aren't covered under the Public Readiness and Emergency Preparedness Act – or *PREP Act* – which protects makers of pandemic-fighting products from most related lawsuits.

"So, under the HHS policy, test developers can now go to market without getting FDA approval. But of course they sort of go to market at-risk, because if their test has some false positives or false negatives, or is imprecise or unreliable, then they do have that liability hanging over them. They don't have any of that liability protection under the PREP Act," Sampson said.

"So, how practical is that, really? That's why I think most of our clients are still going to want to work with FDA and get emergency use authorization, or clearance or approval, just so they get that liability protection."

Policy Shift Could Push Legislation

The FDA's authority over LDTs has long been an open question.

The Centers for Medicare and Medicaid Services regulates LDTs under 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.)

"Many in the laboratory community have long asserted that FDA lacks authority under the Food, Drug and Cosmetic Act to regulate LDTs at all," attorney Danzis said.

"This policy statement from HHS, I don't think, takes a specific position on that underlying authority, but I think what it's saying is, if indeed there is going to be LDT regulation, FDA has to go through a more formal notice-and-comment rulemaking process," he said. "There's a reason why the administrative procedure provides for notice-and-comment rulemaking, because it provides for public input and accountability in a way that other less-formal pronouncements do not.

"To that extent, I think there's some value to this policy."

And Danzis believes that – regardless of the outcome of the upcoming US presidential election, regardless of whichever administration is in place come January – the HHS statement puts pressure on lawmakers to finally develop comprehensive legislation for the diagnostics.

"There is more than one bill that has been introduced in Congress. The one that's gotten the

most attention is the VALID Act. I think this policy statement may put more attention and focus on that legislative effort," he said.

The Verifying Accurate, Leading-edge IVCT Development (VALID) Act was drafted by Congress *in late 2018*, but time ran out that year before legislators could give the proposed law its full attention. The act – which focuses on proposed FDA requirements for premarket review, priority review, pre-certification, third-party review, and postmarket surveillance of diagnostics – was reintroduced in Congress earlier this year, but there's been little movement on it since. (Also see "*US Lawmaker Demands Briefing From HHS Chief On LDT Loophole*" - Medtech Insight, 21 Aug, 2020.)