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To Be (a device) Or Not To Be. That's The Legal Question

by Brian Bossetta

Now that the US FDA has published its final rule regulating lab developed tests, litigation challenging the rule and the FDA's authority to enact it is sure to follow. And the central argument will likely focus on whether the tests are defined as medical devices, which the agency regulates without question.

Is a laboratory-developed test a medical device?

The answer is simple: Yes. No. Well, maybe. It depends on who you ask. But more important, perhaps, is why does it matter?

Since the US Food and Drug Administration published its final rule last month assuming regulatory authority over lab-developed tests, or LDTs, opponents have been quick to reiterate one of their chief complaints: government overreach.

By acting unilaterally to establish the regulatory perimeters for LDTs, critics argue, the FDA stepped out of bounds and into the lane that is the domain of Congress.

Sen. Bill Cassidy, R-LA, summed up this view, which is popular on his side of the aisle, in a statement his office sent to *Medtech Insight*. The senator did not grant our request for an interview.

"The FDA does not have the authority to unilaterally increase its regulatory jurisdiction. During the pandemic, we saw how too much government interference and red tape delays lifesaving care to Americans," said Cassidy, who is also a physician. "Congress needs to take action to clarify the regulatory structure for diagnostic tests."

But clearly, the FDA disagrees.

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In its final rule, the agency phases out its general enforcement discretion of LDTs over four years, placing them under the same regulatory purview as other in vitro diagnostics (IVDs). Essentially, the final rule classifies LDTs as medical devices.

But are LDTs medical devices?

No, they are not, according to Susan Van Meter, president of the American Clinical Laboratory Association (ACLA), who has been clear in her opposition to the rule. LDTs, she told *Medtech Insight*, are not medical devices, but "professional services that leverage a variety of tools to derive a test result for a patient."

Van Meter also agrees with Cassidy in that the agency has exceeded its authority.

"Congress has never granted the agency authority to regulate laboratory developed testing services offered by laboratory professionals," she said, adding that regulating LDTs will hurt patients and stifle innovation.

And she's not alone.

In a 2015 white paper, legal scholars Paul Clement and Laurence Tribe cite the Federal Food Drug and Cosmetic (FD&C) act, which gives the FDA its regulatory authority. Clement and Tribe were writing as counsel to the ACLA.

"Congress gave FDA the authority to regulate medical devices, and laboratory-developed testing services are not devices," writes Clement and Tribe. "Moreover, FDA's effort to expand its jurisdiction will directly interfere with the practice of medicine, and will disrupt the ability of doctors to obtain the laboratory tests they need to provide the best possible care to their patients."

It's Official: FDA Drops Final Rule On LDTs

By Brian Bossetta

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They further argue that the agency's attempt to address LDTs as though they were medical devices "is an impermissible effort to force a square peg into a round hole."

The proper regulatory regime for items manufactured for sale, including medical devices, is in their view not a suitable approach for tests that labs administer as a service for individual physicians.

"To the contrary," they write, "laboratory testing services and medical devices raise completely different regulatory issues."

Case closed.

Or is it?

After much anticipation, the US FDA is set to publish its controversial final rule for regulating laboratory developed tests, which places the tests under the same regulatory purview as other in vitro diagnostics. While the agency opted to include an exemption for LDTs already on the market, it did not provide an exemption for tests developed in academic medical centers.

Read the full article here

Section 201(h)

The FD&C Act, which Clement and Tribe reference, defines a medical device in section 201(h) as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease…."

So, does this mean LDTs are, in fact, medical devices?

It's an open question, according to Sara Klock, an attorney with Holland & Knight and member of the firm's public policy and regulation group, who spoke to *Medtech Insight* about what the landscape of LDT litigation might look like.

"There are strong regulatory arguments from the FDA's perspective that they have the authority. I think they've always thought that an LDT was a medical device and now they're just acting on that authority," Klock said, "but I can also see that there may be other arguments that it is not a medical device."

But if it's established that the FDA regulates other diagnostics as medical devices — and if LDTs are diagnostics — then what's the issue?

As Klock explained, much of it has to do with the scope of the definition.

"Before all of this, an LDT was defined as an in vitro diagnostic that was performed at a single lab," she said. "So, in theory, an in vitro diagnostic test that was performed in multiple labs didn't meet the definition of an LDT. It was a narrowly crafted exclusion."

> *"If you just look at the plain language of how a medical device is defined, it arguably includes LDTs. There's nothing in there that differentiates between a medical device that is manufactured from a device manufacturer or in a single laboratory." — Kyle Faget*

The FDA also contends it needs to regulate LDTs to help ensure they are safe and reliable because they have become more complex over time — and because patients with often life-threatening diseases rely on their results.

This assertion, in Klock's view, could make for a compelling legal argument.

"The FDA's argument is that because LDT technology has changed and become more sophisticated it's suddenly putting patients at higher risk and therefore the agency has to respond. I don't know if that's true, I'm not a technical expert, but assuming their rationale is correct and that's actually happening, that makes sense," Klock said, likening the agency's thinking to the risk-based approach it has taken to regulating software.

However, if the FDA cannot substantiate this claim, Klock added, then it becomes a tougher sell.

She also noted there are more LDTs on the market today than there were two decades ago.

Nothing New

Though the FDA's final rule is new, the agency's position that it has regulatory authority over LDTs is not.

Kyle Faget, a partner at the law firm Foley & Lardner who co-chairs the firm's health care practice group, told *Medtech Insight* the FDA has held the view for decades that it could regulate LDTs based on what constitutes a device as defined in section 201(h).

"If you just look at the plain language of how a medical device is defined, it arguably includes

LDTs. There's nothing in there that differentiates between a medical device that is manufactured from a device manufacturer or in a single laboratory," Faget said. "I think it's going to be an uphill battle to argue that FDA doesn't have jurisdiction."

Faget also noted that prior to the final rule the agency was exercising enforcement discretion of LDTs, which, she added, could be an argument against the FDA's assertion it's within its regulatory lane.

"Because it's been the FDA's pattern and practice not to enforce in this space and exercise enforcement discretion, you could query whether the FDA really thought it was within its jurisdiction," she said, adding, however, "I don't think that's a winning argument."

Another potential argument, in Faget's view, is based on interstate commerce.

"When FDA decided to exercise enforcement discretion of LDTs, it was because they were single labs usually used on a very small local population. So, you could make an argument that these LDTs were not entering interstate commerce," she said. "But it's hard to make that argument now because so many of these LDTs are driving samples from all across the country."

Faget said she also disagrees with the line of legal reasoning Clement and Tribe take in their white paper, specifically their argument that LDTs are the practice of medicine and not the sale of medical devices in interstate commerce.

"LDTs are being used and sold in interstate commerce," she said. "They are a device requiring a prescription, which does not mean that they constitute the practice of medicine per se. Many devices require a prescription for use."

Faget also commented on ACLA's view that LDTs are not medical devices, but professional services and therefore outside of the FDA's regulatory scope.

When asked if one could make the argument that any diagnostic or medical treatment is a service, she said yes, "which is why I don't totally align with the argument being made."

Regardless, unless lawmakers finally get around to passing the VALID Act — which creates a comprehensive regulatory framework for LDTs — and which they failed to do at the end of 2022 setting the FDA down the rulemaking path, the final rule will likely do nothing to change the decades long debate over LDT regulation except move its venue from the Hill to the courts.

But when it does, the central argument, in Klock's estimation, will not change. It will remain whether LDTs fall under the FD&C's definition of a medical device.

“That’s basically the crux of it,” she said.