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Could SCOTUS Chevron Reversal Reverse FDA's Final Rule On LDTs?

by Brian Bossetta

In June, the US Supreme Court reversed the *Chevron* doctrine, a long-standing precedent requiring courts to defer to regulatory agencies when statutory language was ambiguous. But will that decision prevent the FDA's final rule on laboratory developed tests from taking effect? A legal expert weighs in.

In a June 6-3 verdict along ideological lines, the US Supreme Court ruled in *Loper Bright Enterprises et al. v. Raimondo et al.*, that what had become known as the *Chevron* doctrine gave agencies too much regulatory discretion by deferring to their interpretation of statutes when the language was murky. (Also see "*Supreme Court Strikes Down Chevron. What's Next?*" - Medtech Insight, 28 Jun, 2024.)

Chevron was established in 1984 when the Supreme Court handed down a landmark decision giving US agencies the final say in gray areas concerning regulatory matters.

In that case, *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, the justices ruled unanimously that courts must defer to regulators when statutory language was ambiguous. In its opinion, penned by Justice John Paul Stevens, the Court determined that Congress had empowered government agencies — in this case, the Environmental Protection Agency — to make policy decisions.

That ruling established a two-step process courts had to follow: one, enforce a statute when the statutory language is clear and, two, defer to an agency's interpretation of the statue when it is not.

For 40 years, the *Chevron* precedent has proved central in administrative law by allowing federal agencies to interpret and implement complex and technical regulations without constant judicial

interference.

Writing for the conservative majority in the *Loper Bright* decision, Justice Samuel Alito opined that agencies cannot rely on broad and vague statutory language to justify expansive regulatory actions.

"The courts must not abdicate their responsibility to interpret the law," Alito wrote. "Agencies must demonstrate that their interpretations are grounded in the statutory text and are not an overreach of their authority."

Alito's opinion speaks directly to one of the chief criticisms of the decision by the Food and Drug Administration to unilaterally phase out enforcement discretion of laboratory developed tests and regulate them as medical devices: government overreach.

Republican lawmakers, such as Bill Cassidy, R-LA, and others on his side of the aisle, have said it's the job of Congress to determine what the FDA, or any other agency, can regulate, not the agency itself.

The central argument concerning LDTs is whether the tests are medical devices, over which Congress has given FDA the authority to regulate without question.

> ***"I don't think there's much to argue that there was ambiguity, and the FDA abused some kind of interpretation to make this decision. I think this falls within the definition of a medical device." — Michael Werner***

But while some agree with the FDA that LDTs are medical devices, others argue they are not, casting a pall of ambiguity over the debate, which is where the *Chevron* decision potentially comes in.

So now, if regulators must, as Alito outlined in his opinion, demonstrate their interpretations are grounded in statutory text and not outside the scope of their purview, could the definitive answer to whether LDTs are medical devices be decided by the courts and not the FDA?

Michael Werner, a public policy and regulatory attorney with the DC firm Holland & Knight, is skeptical.

A Device Defined

Even though *Chevron* might have given more legal cover for the FDA to determine that LDTs are medical devices, Werner told *Medtech Insight* he does not see a court stepping in and telling the FDA it was wrong.

Werner said he bases that view on the legal definition of a device under the Federal Food Drug and Cosmetic (FD&C) Act, which states, in part, that a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, which is…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease…."

"It's just hard for me to see that a court could say to the FDA, this is what the law says a device is and you regulate devices, but you can't determine if something falls within the statute," he said, "or that it's ambiguous or an overreach of your authority."

Others have argued, however, that LDTs are unlike other in vitro diagnostics the FDA already regulates because they were initially defined as tests performed in single labs, not in multiple ones.

And some, such as Susan Van Meter, president of the American Clinical Laboratory Association (ACLA), who has been a vocal opponent of the FDA's final rule, argues LDTs are not medical devices but rather professional services that leverage a variety of tools to derive a test result for a patient.

Like Cassidy, Van Meter has contended that Congress never granted the FDA the authority to regulate laboratory developed testing services offered by laboratory professionals.

In May, the ACLA filed a lawsuit in the US District Court for the Eastern District of Texas against the FDA to stop enactment of the final rule.

> ***"The decision will also likely provide greater opportunities to challenge unfavorable regulations or decisions in the courts." — Michael Abernathy et al.***

While Werner disagrees with ACLA's view and believes the FDA's action is supported by the law's definition of a medical device, he doesn't rule out that a legal challenge could be successful,

especially if it goes before a judge with antipathy toward the agency.

Still, he remains confident the FDA is on solid ground in its position that LDTs are devices.

“I don't think there's much to argue that there was ambiguity, and the FDA abused some kind of interpretation to make this decision,” he said.

Chevron Impact

But in a *LawFlash* posted by the law firm Morgan Lewis, several attorneys argue the *Loper Bright* decision and the Court striking down *Chevron* would have significant impacts on all regulated industries, including the life sciences industry and the FDA.

“The decision will also likely provide greater opportunities to challenge unfavorable regulations or decisions in the courts, whether broadly unfavorable to industry or to particular companies facing specific circumstances, including FDA enforcement actions and inspectional findings,” writes Michael Abernathy et al.

The coauthors reference the ACLA’s suit stating the Supreme Court’s decision to overrule *Chevron* will likely work in ACLA’s favor, raising the question of the future of the FDA’s new LDT framework, “although success is not guaranteed.”

What is guaranteed, though, is the crux of any litigation will hinge on whether LDTs fall within the definition of a medical device. (Also see "*To Be (a device) Or Not To Be. That’s The Legal Question*" - Medtech Insight, 8 May, 2024.)

But regardless of the outcome of the ACLA’s suit, or any others that might arise, Werner believes Congress is going to have to craft statutes with more clarity.

“Agencies are going to want that. Stakeholders are going to want that, so we're not guessing what an agency thinks, or what some court is going to think. We want it to be very clear in the statute,” Werner said, adding agencies are also going to be more careful going forward to make sure they can justify their decisions based on what is spelled out in statute.

“I'm not saying they didn't do that before, but now, in theory, somebody could come in later and look over their shoulder and say they didn't have the authority to do that,” he said.