

## Federal Judge In Texas Strikes Down FDA's LDT Rule, Citing Loper Bright

By Maaisha Osman / March 31, 2025 at 7:16 PM

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A federal judge in Texas Monday (March 31) struck down FDA's rule classifying laboratory-developed tests (LDTs) as medical devices, citing *Loper Bright v. Raimondo* and siding with a molecular pathology group's argument that FDA lacks authority to regulate LDTs.

Judge Sean D. Jordan of the U.S. District Court for the Eastern District of Texas granted summary judgment in favor of the American Clinical Laboratory Association (ACLA), the Association for Molecular Pathology (AMP) and developer HealthTrackRX. The lobbying organizations have long opposed FDA's controversial LDT rule, as have many in Congress including Senate health committee Chair Bill Cassidy (R-LA). The first Trump administration had scrapped FDA's oversight of the tests and transferred the authority to CMS, but the Biden administration resurrected FDA's authority through rulemaking.

"AMP is extremely pleased with the court's clear and decisive ruling in our favor, and we hope this will finally end the FDA's attempts to exert an unwarranted overreach of authority of LDTs," AMP President Jane Gibson said in a statement Monday.

"This judgment is a significant victory for our members and for patients across the country," Gibson added. "The decision to vacate the FDA rule will avoid adding billions of dollars to healthcare costs and protect access to high-quality care for hundreds of millions of Americans."

**The court's decision heavily referenced the Supreme Court's ruling in *Loper Bright v. Raimondo***, which ended the principle of *Chevron* deference that obligated courts to defer to federal agencies' judgments if their interpretation of law was reasonable, even if judges didn't think it was the best interpretation.

The *Loper* decision underscored that courts must [independently interpret statutory texts](#) rather than deferring to agency interpretations when the language of the law is clear.

In *Loper Bright*, the Supreme Court affirmed that under the Administrative Procedure Act (APA), courts have a duty to exercise independent judgment on legal questions, rather than accepting an agency's interpretation simply because it is reasonable. The court emphasized that this principle is rooted in longstanding judicial practice dating back to *Marbury v. Madison*.

The *Loper Bright* ruling made it clear that when assessing the scope of an agency's authority, courts must look at the statutory text itself, and if the text is unambiguous, the inquiry ends there, Jordan wrote.

Jordan wrote that he applied the *Loper Bright* standard by scrutinizing FDA's claim to regulatory authority over LDTs under the Federal Food, Drug and Cosmetic Act (FDCA). The court concluded that FDA's rule exceeded the agency's statutory authority because the FDCA does not explicitly grant FDA the power to regulate LDTs as medical devices. Instead, the regulation of laboratory testing services falls under the Clinical Laboratory Improvement Amendments (CLIA), overseen by CMS.

The court's application of *Loper Bright* served as a key factor in its decision to vacate FDA's final rule, reinforcing that agencies' regulations can be more easily overturned by courts when not explicitly authorized by Congress in the post-*Chevron* era.

## **LDT developers celebrated the ruling.**

“The court’s ruling ensures that clinical laboratories can continue to focus on their primary mission -- offering innovative and reliable diagnostics that save and improve the lives of millions of patients every day,” ACLA President Susan Van Meter said in a statement Monday. “This is a victory that protects patient access to critically needed testing services and removes burdensome regulations that would have undermined the clinical laboratory system in this country.”

The decision specifically vacates FDA’s May 2024 final rule, which sought to classify LDTs as medical devices and subject them to increased regulatory scrutiny. The ruling remands the matter to HHS for further consideration.

The plaintiffs argued FDA overstepped its regulatory authority by attempting to classify LDTs as medical devices. “The FDA’s LDT rulemaking was burdensome, and the court rightly struck it down,” CAP President Donald Karcher said in a statement. “The regulation failed to target FDA oversight and threatened patient access to countless numbers of safe LDTs by saddling laboratories with unnecessary requirements. The CAP and its members are relieved that the court agreed with our arguments.”

On Feb. 21, the Department of Justice and FDA [mounted a strong defense](#) of the agency’s authority to regulate lab-developed tests (LDTs) during a federal court hearing, with the Trump administration maintaining support for the rule.

But an industry expert speculated the federal government didn’t reverse its stance because the new administration, which took office in January, didn’t have enough time to determine and articulate its policy under new Department of Justice leadership. -- *Maaisha Osman* ([mosman@iwppnews.com](mailto:mosman@iwppnews.com))

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