

## April 4, 2025: Judicial Advocacy Update



### Court vacates FDA's laboratory developed test final rule

On March 31, the Eastern District of Texas granted laboratory plaintiffs' [motion for summary judgement](#) (PDF) and vacated the Food and Drug Administration's (FDA) final rule regulating laboratory developed tests (LDTs).

The rule, finalized in 2024, had affirmatively declared LDTs to be medical devices under the Food, Drug, and Cosmetic Act (FDCA) and required most LDTs to go through regulatory review. FDA had previously exercised enforcement discretion with respect to LDTs, exempting most LDTs from FDA review.

The lawsuit represents one of the first legal challenges to FDA rulemaking after *Loper Bright v. Raimondo*, which the court cited several times. The ruling in *Loper Bright* ended the principle of *Chevron* deference, which required courts to defer to the judgment of federal agencies on interpretation of the law. *Loper Bright* now allows courts to exercise their independent judgment on statutory interpretation. It is unclear whether the FDA will appeal the ruling given the change in Administration.

The AMA [raised concerns](#) (PDF) when FDA initially proposed these changes in 2023, as strict regulatory requirements for LDTs previously subject only to regulatory requirements of the Clinical Laboratory Improvement Amendments (CLIA) would limit access to critical testing services and increase costs and burdens to the laboratories developing the tests. Patients such as pediatric and rare disease patients could be severely impacted, as commercially available tests are frequently not available for these subgroups.

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