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A Final Rule Bites the Dust, Part II: FDA Gives up on Regulating LDTs as Medical Devices

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As the song goes, the Food and Drug Administration's ("FDA's") 2024 Final Rule regulating laboratory-developed tests ("LDTs") as medical devices ("Final Rule"), is not merely dead—it's really most sincerely dead.

Perhaps not for good, but for the foreseeable future, at least.

The FDA has let the clock run out on the 60-day time period to appeal the March 31, 2025, decision by the U.S. District Court for the Eastern District of Texas concluding that: 1) the FDA overstepped its authority, and 2) the LDT Final Rule of May 6, 2024, was unlawful. As we explained at that time, the Final Rule would have required virtually all clinical laboratories offering their own LDTs to comply with FDA expectations for medical device manufacturers in phases over a four-year period—with the first compliance deadlines set for May 2025.

The March 2025 opinion by Judge Sean D. Jordan vacated the controversial Final Rule a little more than a month before the first implementation deadlines were to take effect, and remanded the issue back to the FDA.

Now, absent an appeal, it is not likely that the last remaining option to salvage the Final Rule—i.e., congressional action—will happen in the current political climate.

As we explained at the time of its release, the 2024 Final Rule followed more than a decade of uncertainty as to the course of action the agency would take with respect to LDTs. When it came, the Final Rule escaped potential rollback by a future presidential administration as a "midnight rule" under the Congressional Review Act—yet threw clinical labs into nearly a year o

As we anticipated, the Supreme Court's June 28, 2024, decision in *Loper Bright Enterprises v. Raimondo*—ending *Chevron* deference to agencies when interpreting ambiguous statutes—made it easier for entities to challenge both FDA authority and the validity of the agency's Final Rule. The

American Clinical Laboratory Association and the Association for Molecular Pathology filed suit in federal district court in Texas on May 29, 2024, and August 19, 2024, respectively.

But perhaps no one could have anticipated the extent to which the FDA itself has changed in the lifespan of the LDT Final Rule—with unprecedented staff cutbacks, changing policies and priorities, and a continued emphasis on deregulation at the federal level that is not likely to change until a future presidential administration rolls in. States, meanwhile, continue to regulate LDTs to some extent, and the FDA continues to have authority to regulate certain components of LDTs (such as reagents and collection devices), as well as in vitro diagnostics. While this particular chapter on LDTs has drawn to a close, we aren't going anywhere—and we will continue to advise our lab clients on state as well as remaining federal compliance considerations.

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