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Federal Court Vacates LDT Final Rule

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The U.S. District Court for the Eastern District of Texas vacated the Food and Drug Administration's (FDA) final rule on March 31, 2025, under which the FDA would have started regulating most laboratory-developed tests (LDTs) as medical devices on May 6, 2025.[1]

The judgment comes just weeks before the controversial May 6, 2024, final rule's (Final Rule) initial implementation date and remands the issue to the FDA for further consideration. The Final Rule would have required all clinical laboratories offering their own LDTs to come into compliance with the FDA's expectations for medical device manufacturers, in phases, over a four-year period.

In the consolidated cases *American Clinical Laboratory Association (ACLA) v. FDA* and *Association for Molecular Pathology v. FDA,* the plaintiffs challenged the Final Rule under the Administrative Procedure Act (APA). The court vacated the Final Rule on the basis that the FDA lacks the statutory authority to regulate LDTs because LDTs are not "devices" under the Food, Drug, and Cosmetic Act (FDCA).

Central to the court's ruling was its defining an LDT as a service offered by a single clinical laboratory:

A "laboratory-developed test" is a methodology or process by which a laboratory generates biochemical, genetic, molecular, or other forms of clinical information about a patient specimen for use by the treating physician. Each laboratory uses its own unique knowledge of the protocols, performance characteristics, and means of analysis to develop such methodologies and processes. Laboratory-developed tests are offered as services. Unlike a drug or device, which is a manufactured and packaged article of commerce with user instructions, a laboratory-developed test service is a proprietary methodology performed by only the developing laboratory. That service generates information from test results and transmits that information to the ordering physician. The testing service is not sold as a kit, and the protocol is not transferred in any manner to other laboratories, hospitals, or other facilities outside the developing laboratory entity. No physical product is sold, and no article of personal property is transferred such that title passes from one party to another.

The court reasoned that the FDA's authority to regulate "devices" extends to tangible, physical products that are commercially distributed, not professional services utilizing such products. The court found that LDTs should instead be regulated by CMS under authority granted by CLIA.

The vacated and remanded Final Rule now goes back to the FDA for further consideration. While it is possible that the FDA could appeal the decision, an appeal is unlikely under the current administration. The former Trump administration took the position in a June 2020 memorandum that the FDCA does not give the FDA the authority to regulate LDTs. The current Trump administration, purportedly acting on a generally pro-industry, deregulation platform, has made no indication that its position on the issue has changed. If the FDA decides to appeal the court's decision to the Fifth Circuit, a notice of appeal would be due May 30, 2025.

In the meantime, the immediate impact of the court's decision is that clinical laboratories will not have to comply with the FDA's five stages of phased-in regulation of LDTs. The court's ruling does not otherwise impact any other regulatory requirements under FDA or CLIA authorities. Clinical laboratories wishing to

develop and use LDTs for patient testing purposes will need to establish performance specifications for the tests consistent with CLIA requirements and obtain and complete any relevant state approvals. Because LDTs are considered CLIA high-complexity tests, the clinical laboratory must meet all applicable CLIA requirements for high-complexity testing.

For additional guidance on the current LDT oversight process and to stay informed about potential changes to the regulation of LDTs, please contact Alissa D. Fleming, Robert E. Mazer, Mary Grace Griffin, or any member of the Baker Donelson Health Law team.

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[1] Memorandum Opinion and Order, *American Clinical Laboratory Association et al. v. U.S. Food and Drug Administration*, No. 4:24-CV-479-SDJ (E.D. Tex. Mar. 31, 2025), *available at* https://www.acla.com/wp-content/uploads/2025/03/Memorandum-Opinion-and-Order.pdf.