LEGAL UPDATES

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# Federal Court Vacates FDA's Final Rule on Laboratory-Developed Tests

## Industries

Healthcare

Life Sciences

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**Key takeaways**

A federal court has vacated the Food and Drug Administration's (FDA) attempt to regulate laboratory-developed test (LDT) services as medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA).

The court ruled that the FDA's classification of LDTs as "devices" exceeds its statutory authority, emphasizing that LDTs are professional services, not tangible products.

Oversight of LDTs remains under the Clinical Laboratory Improvement Amendments (CLIA) framework, administered by the Centers for Medicare and Medicaid Services (CMS).

The FDA has 60 days to appeal the decision.

**Background**

On March 31, 2025, the Eastern District of Texas issued a decision in the case brought by the American Clinical Laboratory Association (ACLA) and the Association for Molecular Pathology (AMP), challenging the FDA's final rule issued in May 2024. The rule sought to change the regulation of LDTs by classifying LDT services as medical devices under the FDCA, subjecting them to FDA regulation.

LDTs are in-house diagnostic services performed by clinical laboratories to assist physicians in diagnosing and treating patients. Historically, these services have been regulated under CLIA (1988), which is administered by CMS, not the FDA. Over the years, LDTs have been used to fill in gaps where commercial tests are not available, allowing clinicians additional tools to treat

their patients. LDTs are frequently used in the digital health space as digital health companies often rely on LDTs to provide consumers with a more personalized approach to healthcare, including with innovative molecular diagnostics.

### Court's decision

The court ruled in favor of the plaintiffs, granting summary judgment and vacating the FDA's final rule. Key findings include:

1. **Exceeding statutory authority:** The court determined that the FDCA's definition of "device" applies to tangible, physical products, not professional services like LDTs.
2. **Congressional intent:** The court emphasized that Congress established a distinct regulatory framework under CLIA for laboratory services, entrusting CMS with oversight and never intending for the FDA to regulate LDTs as devices.
3. **Regulatory and practical inconsistencies:** The court found that the FDA's interpretation would create significant disruptions, including the potential criminalization of long-standing laboratory practices.

### Implications for the laboratory industry

The decision nullifies the FDA's final rule nationwide, preventing its implementation. This ruling removes the immediate threat of FDA oversight for LDTs and maintains the status quo under CLIA. However, the FDA retains the option to appeal the decision within 60 days.

### What this means to you

Laboratories and stakeholders in the diagnostic industry, including digital health companies, should monitor developments closely, particularly if the FDA decides to appeal. Organizations should also assess their compliance strategies under the existing CLIA framework while remaining informed about potential regulatory changes.

### Contact us

If you have questions relating to this decision or the CLIA framework, contact Kimberly Chew, Kathleen Snyder, or your Husch Blackwell attorney.