Texas Federal District Court Vacates Final Rule Regulating Laboratory Developed Tests

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On March 31, 2025, a federal judge in the U.S. District Court for the Eastern District of Texas vacated a final rule from the Food and Drug Administration ("FDA"). This rule would have applied certain FDA regulations to laboratory-developed tests ("LDT"), which are services already regulated by the Centers for Medicare and Medicaid Services ("CMS") (the "Final Rule"). With this ruling and for the near future at least, the current CMS regulatory framework will continue to govern LDTs, without additional FDA requirements that would have gone into effect in May 2025 and later.

The court vacated the Final Rule[1] nationwide, rejecting the FDA's authority to regulate LDTs as medical "devices" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), which governs the FDA's regulation of devices. Instead, the court held that Congress enacted the Clinical Laboratory Amendments Act ("CLIA"), which establishes federal quality standards for laboratory testing, to provide for separate comprehensive regulation of laboratory services. The Administration has not announced whether it intends to appeal the district court's decision.

Background

In the Final Rule, the FDA attempted to extend certain requirements applicable to FDA-regulated goods to also cover laboratory-developed tests, which are CLIA-regulated services. The FDA regulates drugs and devices, including instruments and supplies that are used by laboratories. The quality and accuracy of the laboratory services themselves are regulated by CMS through CLIA. The FDA generally defined an LDT as an in vitro diagnostic test "that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under [CLIA] and meets the regulatory requirements under CLIA to perform high complexity testing."[2]

The FDA has consistently claimed authority to regulate LDTs but, until the Final Rule, it had stopped short of issuing specific regulations under a policy of "enforcement discretion" for low-complexity and low-risk tests. The FDA's view changed over time, particularly due to trends arising during the COVID-19 pandemic. According to the preamble of the Final Rule, LDTs were no longer perceived to be low risk, as they were increasingly being used for broader populations, relied on high-tech machinery and software, and had public health impacts that the FDA argued would require greater oversight.

PROFESSIONAL

ANDREW HAYES
Associate
Boston
Washington, D.C.

COLE M. HOYT
Associate
Los Angeles

BRIDGET A. GORDON
Partner
Los Angeles

PAUL L. GARCIA
Partner
Los Angeles
San Diego

MARTHA P. CRAMER
Associate
Washington, D.C.

CLAIRE ERNST
Director, Government Relations & Public Policy
Washington, D.C.

KELLY A. CARROLL
Partner
Washington, D.C.

The Final Rule would have required laboratories to meet certain standards similar to device manufacturers in order to offer homegrown tests. The FDA intended to impose these requirements by defining LDTs as "devices" in the Final Rule:

> "In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act or the "FDCA"), and may also be biological products subject to section 351 of the Public Health Service Act, including when the manufacturer of these products is a laboratory."

Unsurprisingly, the Final Rule faced significant opposition, in part, due to the burdens it threatened to place on laboratory services providers.

The Decision

Judge Sean D. Jordan of the Eastern District of Texas issued a memorandum opinion and order setting aside the Final Rule and vacating it in its entirety. Plaintiffs had challenged the Final Rule, contending that it violated the Administrative Procedure Act ("APA") by exceeding the agency's statutory jurisdiction. In response, the FDA argued that the rule was well within its authority because LDTs could be construed as "devices" subject to FDA regulation. The decision in favor of the Plaintiffs proceeded in three parts:

1. An exploration of the history of LDT services, the evolution of medical service regulation, and the FDA's historical oversight of medical devices.
2. An analysis of the plaintiffs' standing and a detailed examination of why the FDCA and CLIA clearly indicate that the FDA lacks the authority to regulate LDT services.
3. A determination of the appropriate remedy under the APA, guided by controlling circuit precedent.

The opinion emphasized that the FDCA generally applies to tangible products, while CLIA specifically addresses laboratory testing services. Judge Jordan described how CLIA and its regulations implicate a distinct body of scientific and technical expertise, training, experience, and judgment, differing from the expertise involved in regulating manufactured devices. Consistent with this distinction, the text and structure of CLIA and the FDCA support the notion that they regulate separate topics, including because "the sequence of legislative enactments underpinning FDCA and CLIA reflects that Congress viewed (1) ensuring medical-device safety and effectiveness, and (2) ensuring laboratory-testing accuracy, as distinct problems requiring different regulatory solutions."[3] Judge Jordan went on to highlight multiple failed attempts in Congress to alter the regulatory framework for LDT services, stressing that agencies cannot bypass the framework established by Congress.

The order also pointed out the extraordinary costs laboratories would face for premarket-approval applications and annual compliance, projected to nearly triple to $14 billion per year. The court noted the FDA's admission that these increased costs would lead to higher test prices and "reduce the amount of revenue a laboratory can invest in creating and/or modifying tests."[4]

The court agreed with the Plaintiffs' argument that the Final Rule violated the APA, and did not address the additional claim that the rule was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. The court nullified and revoked the Final Rule, remanding it to the FDA for "further consideration in light of this opinion."

The court's opinion relied heavily on the recent *Loper Bright* decision from the U.S. Supreme Court. This precedent is significant because it directs courts to use their own independent judgment when interpreting laws, rather than simply deferring to how a governmental agency reads its authority. [5] Consistent with *Loper Bright*, Judge Jordan engaged in detailed textual analysis of the meaning of the term "device" in the text of the FDCA, and related provisions of CLIA, to inform his decision.

Impact

With the Final Rule vacated, laboratories offering LDTs are not immediately obligated to comply with FDA medical device requirements that would have become effective May 2025 and later (*e.g.*, adverse event reporting, device registration, class-based listing, and labeling). This may come as a relief to many laboratories concerned with the burdens imposed by the Final Rule, although many laboratories have already incurred significant costs to plan for compliance prior to this ruling. While the LDT Rule has been vacated and will not go into effect under its prior timeline, the court's decision is not final until the time to appeal has expired or any appellate decisions have been issued. Practically speaking, that means affected stakeholders may reasonably elect to pause further efforts to comply with the Final Rule, while continuing to monitor efforts to appeal the decision and/or congressional action.

The court's decision is sweeping in its rejection of the FDA's attempt to regulate laboratory services. If the decision is not modified on appeal, it effectively reaffirms that CLIA provides the sole federal scheme that governs laboratory services. Of course, CMS could use existing authority under CLIA to maintain the current practice of confining LDTs to a single laboratory or impose additional regulations under its CLIA authority. How CMS might exercise this authority in the current regulatory environment remains uncertain, particularly given potential shifts in enforcement priorities.

As the Administration weighs whether to appeal the ruling, it may be premature to determine whether this decision will present obstacles for the FDA's regulation of other technologies that rely on similar interpretations of the agency's statutory authority.

Conclusion

This ruling reflects the continuing impact of *Loper Bright* in requiring courts to assess the legality of agency action by independently interpreting statutory authorities without deference to the agency's interpretation. Here, the FDA's long-held view of its own jurisdiction as including the authority to regulate LDTs received little-to-no deference from the court. Rather, applying its independent judgment as guided by *Loper Bright*, the court determined that the best reading of the plain text of the FDCA and CLIA indicates that a LDT is not a "device" subject to FDA regulation. The full impact of this ruling remains to be seen, and HLB will continue to track related developments.

[1] Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286 (May 6, 2024).

[2] Final Rule at 37,289 (citing 88 Fed. Reg. 68,006, 68,009).

[3] Opinion at 9.

[4] Opinion at 22.

[5] *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

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