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Post?Chevron Spotlight: Federal Court Nixes FDA Rule Reclassifying Laboratory Services as Medical Devices

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In another rebuke to federal regulatory overreach, the U.S. District Court for the Eastern District of Texas ("District Court") has vacated the Food and Drug Administration's ("FDA") 2024 final rule that sought to bring laboratory-developed test services ("LDTs") within the scope of the agency's medical device regulatory framework. The case, *American Clinical Laboratory Association et al. v. FDA*, Nos. 4:24 CV 479 and 4:24 CV 824, marks a watershed moment for clinical laboratories and diagnostic providers in a post-*Chevron* landscape and underscores the judiciary's growing willingness to police the limits of agency authority in the wake of *Loper Bright Enterprises v. Raimondo*.

The Regulatory Framework Governing LDTs

LDTs are diagnostic services developed, validated, and performed by professionals within a single clinical laboratory, often in response to individual physician orders. These services, which range from standard pathology tests to advanced genomic sequencing, have long been regulated under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), which are administered by the Centers for Medicare & Medicaid Services ("CMS"). CLIA's framework—developed after its predecessor law, the Clinical Laboratories Improvement Act of 1967—was designed to govern *services*, not products. It imposes requirements on laboratory staffing, quality control, methodology validation, and proficiency testing. Laboratories are certified under CLIA and must meet rigorous federal and accreditation-based standards.

By contrast, the Federal Food, Drug, and Cosmetic Act ("FDCA"), enacted in 1938 and amended in 1976 by the Medical Device Amendments ("MDA"), grants the FDA authority to regulate *products*—specifically, drugs, devices, foods, and cosmetics. The FDCA's definition of a "device" encompasses physical items such as instruments, machines, and reagents—not intangible services performed within clinical settings. Notably, Congress's enactment of CLIA in 1988, more than a decade after the MDA, reaffirmed this division of regulatory labor: the FDA governs devices while CMS governs services. Since then, Congress has repeatedly declined to legislate FDA oversight of LDTs, instead preserving CLIA as the operative statute governing the field.

The Final Rule: A Costly Expansion of Authority

The FDA's final rule, issued May 6, 2024, would have upended this regulatory equilibrium by reclassifying LDTs as medical devices. Specifically, the rule, as amended, sought to clarify that *in vitro* diagnostic products "are devices . . . including when the manufacturer of these products is a laboratory." In effect, the rule would have treated LDTs as manufactured devices, requiring laboratories to obtain premarket authorization for each test and to comply with the FDA's Quality System Regulation. This dramatic shift would have affected more than 79,000 existing tests and over 10,000 new tests annually. The FDA further estimated that compliance costs would have exceeded $1 billion per year, with total implementation costs ranging from $12.5 billion to $79 billion over twenty years, potentially forcing some LDTs off the market and suppressing future innovation.

Judicial Review in a Post-*Chevron* Era: *Loper Bright* Takes Center Stage

In response to the FDA's proposed expansion of its authority, a coalition of plaintiffs—including the American Clinical Laboratory Association, the Association for Molecular Pathology, HealthTrackRX, and a practicing clinical pathologist—filed suit in the Eastern District of Texas, arguing that the final rule exceeded the agency's statutory mandate and moved for summary judgment under the Administrative Procedure Act. On summary judgment, the Court's analysis turned on *Loper Bright*, whichoverturned *Chevron* deference and restored the task of interpreting statutes to the courts. Applying this new standard, the District Court declined to defer to the FDA's interpretation of the FDCA, instead undertaking its own statutory analysis.

In its analysis, the District Court found that the term "device" under the FDCA referred to tangible articles—not professional services. It emphasized that none of the listed terms in the FDCA's definition section ("instrument," "machine," "in vitro reagent," *etc.*) could be read to encompass laboratory services. The Court also rejected the FDA's argument that laboratories' use of devices during diagnostic testing somehow converted those services into devices subject to the FDA oversight. The District Court further held that Congress clearly intended to treat laboratory services separately from devices when it enacted CLIA in 1988, reaffirming a services-based regulatory regime administered by CMS.

Importantly, the District Court also noted that Congress had multiple opportunities to legislate FDA oversight of LDTs—and yet declined to do so. On the contrary, the District Court observed, the statutory framework governing LDTs has remained unchanged since 1988, and the FDA's rule was an impermissible attempt to rewrite that framework through regulation. As a result, the District Court granted summary judgment for the plaintiffs, vacated the final rule, and denied the FDA's cross-motion, concluding that remand without vacatur was inappropriate given the final rule's legal defects and the absence of any persuasive justification from the agency.

What's Next? Another Brick in the Post-*Chevron* Wall

This decision is the latest in a growing line of federal court rulings reining in agency authority in the wake of *Loper Bright*. As with recent invalidations of other federal agency rules across multiple courts, this decision reflects a reshaped judicial posture that demands clear congressional authorization before agencies can regulate new areas or expand their reach. Providers and regulated entities should, thus, take note: in this evolving legal landscape, agency interpretations of rules may no longer suffice. Courts are now scrutinizing regulatory assertions with fresh eyes and heightened textual rigor. For diagnostic labs and other stakeholders in particular, this ruling marks not only a reprieve, but also a call to vigilance as Congress and agencies revisit regulatory pathways for diagnostics and digital health.

Proskauer's Health Care Group is closely monitoring developments in this area, including whether the case is appealed to the Fifth Circuit. For more insights into this and related regulatory trends, subscribe to the Health Care Law Brief.

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