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Client Alert

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FDA's LDT Rule Struck Down by Court: FDA Has Lost the Battle, But Is the War Over?

A court has struck down the Food and Drug Administration's attempt to extend its regulatory authority to clinical laboratory testing services. On March 31, 2025, in the consolidated cases *American Clinical Laboratory Association (ACLA) v. FDA* and *Association for Molecular Pathology v. FDA,* the United States District Court for the Eastern District of Texas vacated FDA's final rule seeking to regulate laboratory developed tests as medical devices. The court held that FDA's attempt to regulate laboratory testing services as medical devices exceeds the Agency's statutory authority under the federal Food, Drug, and Cosmetic Act (FDCA).

In an opinion that closely tracked ACLA's arguments, the court concluded that "the text, structure, and history of the FDCA and [the Clinical Laboratory Improvement Amendments of 1988 (CLIA)] make clear that FDA lacks the authority to regulate laboratory-developed test services." *See* Slip Op. at 2. Key elements of the court's holding include:

- **Statutory Definition** – The FDCA defines the term "device" as including "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article." 21 U.S.C. § 321(h). The court observed that all of the "operative terms" in that definition "refer to tangible, physical products," *id.* at 30, and that an LDT, which involves a laboratory test process and methodology, "is far afield from such tangible products." *Id.* at 32. The court went on to state that:

> [J]ust as the use of mechanical tools, instruments, and equipment for a scientific "experiment" or "investigation" does not render the experiment or investigation itself an "apparatus" or "contrivance," the use of such products as part of a laboratory-developed test service does not transform this medical service into an apparatus or contrivance under the FDCA.

Id. According to the court, "devices" under the FDCA "are articles of commerce, not the kinds of services performed by doctors and laboratories." *Id.* at 28.

- **Structure** – The court also observed that FDA's claim that laboratory testing services are devices "sits uncomfortably with" other FDCA provisions. *Id.* at 39. "For example, the statute repeatedly and consistently refers to the making of devices as 'manufacturing'. . . . [T]he ordinary meaning of 'manufacture' is to 'make into a product suitable for use' or 'make from raw materials by hand or by machinery.' . . . Unlike physical products, professional services are not 'manufactured.'" *Id.* at 39-40.
- **History of the FDCA and CLIA** – The court concluded that "Congress considered the unique regulatory issues raised by clinical laboratories and the tests they develop and perform" and "addressed those issues through the comprehensive but distinct statutory regime of CLIA, not through the FDCA." *Id.* at 28. In reaching that conclusion, the court observed that:

> 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. Congress passed the FDCA in 1938, the Clinical Laboratories Improvement Act in 1967, the Medical Device Amendments in 1976, and the Clinical Laboratory Improvement Amendments in 1988. Despite this alternating sequence, Congress never indicated that there was any overlap between these regulatory schemes.

Id. at 9.

In reaching these conclusions, the court criticized FDA for taking the "implausible" and "untenable" position that "the entire [clinical laboratory] profession is operating unlawfully and can be subject to criminal and civil penalties at any time, with its only protection coming from a policy of enforcement discretion that FDA maintains it is free to revoke at any time." *Id.* at 46-47. And although FDA had asked the court to allow further briefing on remedial issues, the court rejected that request and set aside the rule in its entirety, based on the principle that "courts should generally 'nullify and revoke' illegal agency action." *Id.* at 50.

The immediate impact of the court's decision is that laboratories will not have to comply with FDA's five stages of phased-in regulation of LDTs (outlined in our Client Alert on the final LDT rule). The preamble to the final rule that spurred the litigation and that attempted to exert regulatory jurisdiction over laboratory testing services had set a timetable with deadlines spanning 2025 through 2027 to phase-in LDT pre-market and post-market regulatory requirements (e.g., medical device reporting, registration and listing, the Quality System Regulation, and premarket clearance or approval).

In the aftermath of this decision, one key question is whether this decision is the end of the decades-long struggle between those who believe that FDA should exert more oversight over LDTs and those who believe that additional FDA oversight is unauthorized by Congress and would slow or even prevent important innovations from emerging. We chronicled this long-running debate in our client alert on FDA's proposed LDT Rule in October 2023. To recap, FDA started the debate by intermittently suggesting between 1992 and 2014 that it had jurisdiction to regulate

professional laboratory testing services. The debate shifted to Congress when FDA conceded that it would not finalize a 2014 draft guidance that the Agency had issued seeking to assert jurisdiction over LDTs. At that point, Congress took up related legislation, including the VALID Act of 2020. After Congress failed to pass the VALID Act, FDA reclaimed the initiative, issuing a final rule asserting authority to regulate LDTs. ACLA challenged the rule shortly after it was issued in 2024. That litigation culminated in the recent decision striking down FDA's rule, making clear that clinical laboratory testing services are not "devices" under the FDCA, and holding that a laboratory performing such testing services is not a "device manufacturer."

Having watched this saga this play out for decades, we had previously predicted that any loss, on either side, would be appealed. But it now seems possible that the Department of Health and Human Services (HHS) might decide not to appeal.

In 2020, the then-General Counsel of HHS, Robert Charrow, issued a memorandum questioning FDA's jurisdiction over LDTs, and the administration issued a declaration stating that FDA would not exercise jurisdiction over COVID-19-related LDTs absent rulemaking. In light of the recent return of the Trump administration, it is possible that HHS may take a position similar to the 2020 memorandum and decide not to appeal and instead take the position that any significant change in the existing regulatory regime should be made by Congress. If HHS decides to file an appeal, a notice of appeal would be due May 30, 2025.
