Published on *The National Law Review* https://natlawreview.com

District Court Strikes Down FDA's LDT Rule, Opens the Door for Challenges to FDA's Regulation of Other "Services" as Medical Devices

Article By:

Keith Bradley

Jack Deschauer

Sam Ballingrud

On Monday, March 31, a court in the Eastern District of Texas found unlawful and vacated the Food and Drug Administration's 2024 Rule regulating as "devices" under the Food, Drug, and Cosmetic Act ("FDCA"), certain laboratory-developed test ("LDTs") used to diagnose, monitor, or determine treatment for diseases and conditions. The decision, *American Clinical Laboratory Assoc. v. FDA*, No. 4:24-CV-479-SDJ, 2025 WL 964238 (E.D. Tex. Mar. 31, 2025), marks another application of the Supreme Court's recent *Loper Bright* decision rejecting the longstanding *Chevron* principle of deference to agency statutory interpretation. *Loper Bright* continues to fundamentally rework the legal framework for challenging agency actions.

LDTs are familiar products which underlie an enormous amount of modern medical care and range from the prosaic to the profound. Anyone who has ever had bloodwork done during an annual checkup has been a part of this well-known process: a doctor orders a specimen to be taken—here, blood—which is drawn from the patient and sent off to a laboratory for analysis to report quantitative measurements such as blood type which are in turn reported to the ordering physician to inform patient care. Other LDTs are much more specialized; Human Leukocyte Antigen ("HLA") tests are necessary components of emergency, life-saving care which involves a rapid histocompatibility test as part of organ, stem cell, and tissue transplantation.

LDTs have long been regulated by the Center for Medicare and Medicaid Services under the 1967 Clinical Laboratories Improvement Act. CMS has issued extensive regulations to regulate LDTs under this authority, for example, regulating HLA testing by requiring use of the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System for laboratories performing such tests. 42 C.F.R. § 493.1278(b)(1). For years, FDA has claimed the authority to regulate LDTs but purported to exercise its discretion to decline to do so. *E.g.*, 62 Fed. Reg. 62,243, 62,249 (Nov. 21, 1997) (stating position but not invoking the authority). But in 2024, given the dramatic increase in quantity and importance of LDTs to modern medicine, FDA issued the Rule to phase out what it terms its prior "enforcement discretion" of non-regulation. This was, effectively, a

dramatic expansion of FDA's regulatory authority given how ubiquitous LDTs are; FDA estimated tens of billions of dollars of anticipated costs (and benefits).

Regulated parties swiftly challenged the new rule, arguing FDA lacked the legal authority to regulate LDTs. The Eastern District of Texas agreed. Grounding its analysis in *Loper Bright*, the Court began by noting that "abdication in favor of the agency is *least* appropriate" for matters concerning the scope of the agency's authority. In that way, the Court departed from the pre-*Loper Bright* principle—from a 2013 case, *City of Arlington v. FCC*—that such scope questions are *Chevron*-eligible as any other. Right from the outset, the Court made clear that the analysis was different in the *Loper Bright* era.

Proceeding from first principles, the Court held that LDTs are not "devices" under the FDCA and FDA's regulatory authority. Rather, the Court emphasized that LDTs are "medical service[s]" and that this was the "common sense" interpretation of the plain terms of the FDCA. An LDT, the Court said, is "far afield from such tangible products" covered by the term "device." After all, LDTs and FDCA "devices" had long been addressed by Congress and regulated by agencies are parallel but distinct objects. Decades of practice presupposing the distinct nature of the two could not be so easily overcome.

Loper Bright is doubtless a fundamental transformation of administrative law, but despite the Court's emphasis on the case, it is not clear what difference it made to the outcome here. Before *Loper Bright*, a court would only have deferred to the agency's interpretation if the statute was ambiguous and the interpretation reasonable; but the Court was at pains here to emphasize the clarity of the statute and the untenable nature of FDA's interpretation. Courts have never deferred to unreasonable readings of clear statutes, and indeed the Court here relied extensively on pre-*Loper Bright* caselaw in its analysis.

Further, analyzing whether *Loper Bright* was dispositive in the fine details may disguise the forest in the trees. The past few years have revealed a dramatic shift in the judiciary's approach to agency regulation and a reassertion of the judicial function to interpret the law. Respect is still due to the interpretation of coordinate branches of government—as the Supreme Court emphasized in its *Bondi v. VanDerStok* decision the week before—but *Loper Bright* has clearly ushered in a new era of rigor in reviewing agency decisions. FDA's failed attempt—subject to appeal—to regulate LDTs is merely the latest casualty.

Another important takeaway from District Court's decision in *American Clinical Laboratory Assoc.* is that it may inform FDA's interpretation of whether other products, that include service components, meet the definition of a medical device under the FDCA. Since at least 2005, FDA has issued several guidance documents governing how it intends to regulate software as a medical device, mobile medical apps, clinical decision support software and— most recently—artificial intelligence. FDA has made clear the first inquiry in determining whether these products and/or services are regulated by FDA is whether they meet the definition of a medical device under FDCA (section 201(h)). Query whether FDA now may (or must) reach a different conclusion than it has previously especially for products that are comprised exclusively of software versus hardware functions.

National Law Review, Volume XV, Number 101