



Summary of Court Decision Nullifying FDA Regs for LDTs

By Michael Hawrylchak, Esq.

After the FDA's publication of its Final Rule asserting authority over laboratory-developed tests ("LDTs") by characterizing them as "devices" regulated by the Food, Drug, and Cosmetic Act ("FDCA"), two legal challenges to the rule's validity were brought by the American Clinical Laboratory Association ("ACLA") and the Association for Molecular Pathology ("AMP"), which were ultimately consolidated before Judge Jordan in the United States District Court for the Eastern District of Texas. The parties cross-moved for summary judgment.

Erin Morton, AAB/NILA's Washington Representative, assembled a coalition of five professional associations led by AAB/NILA, and Mike Hawrylchak, AAB/NILA's attorney, prepared an amicus brief on behalf of this coalition in support of ACLA and AMP. This amicus brief focused on two key points: the implausibility of FDA's position that the entire laboratory industry has been operating in flagrant violation of federal law for decades; and the serious negative consequences that FDA's Final Rule would have for the entire laboratory industry and the delivery of healthcare more broadly.

On March 31, 2025, the Texas District Court issued its decision in the consolidated cases. In a thorough and well-written opinion, the court granted summary judgment in favor of ACLA and AMP, holding the FDA's LDT rule invalid and ordering it vacated.

The court began by reviewing the history of the enactment of the FDCA and the Clinical Laboratory Improvement Act of 1967 ("CLIA") and subsequent amendments to each. The court noted the contrast between the language of the FDCA, which is directed at tangible physical objects, and CLIA, which expressly regulates the provision of services. The court also noted that Congress, in enacting and later amending CLIA, showed no awareness of any overlap in coverage with the FDCA and expressly stated an intent to establish a single unified regulatory mechanism.

The court next reviewed the history of the FDA's assertion of authority over LDTs. The court noted that the earliest statements relied on by FDA failed to establish a historical pedigree for its current position. Moreover, later efforts by FDA to assert control over LDTs were rebuffed by Congress.

The court concluded its historical review by discussing the LDT Final Rule, noting FDA's acknowledgement that it will impose enormous costs on the healthcare industry and



FDA's extensive reliance on enforcement discretion to mitigate the Final Rule's adverse impacts, topics that were the subject of the AAB/NILA amicus brief.

After briefly confirming ACLA and AMP's standing to challenge the LDT Final Rule, the court began its analysis of the rule's validity under the FDCA. The court first examined the statutory text, noting that the FDCA's definition of "device" repeatedly uses words (e.g., instrument, apparatus, machine, contrivance) that ordinarily refer only to tangible, physical products, not services. FDA's argument that some of these terms, like contrivance, could be broad enough to encompass intangible processes relied on unusual senses of the terms in question and glosses that are not found in the statute itself. The court also noted that FDA's expansive definition of device requires an untenable definition of the word "manufacture." Finally, the Court noted, adopting a hypothetical first posed by ACLA, that the FDA's position, taken seriously, implies that almost any aspect of the practice of medicine would be a "device" subject to the FDA's authority.

The court went on to bolster its statutory interpretation by considering the broader statutory context. First, the language in the definition of device, taken as a whole, confirms that it refers to a tangible, physical product. Second, various other provisions of the FDCA make sense only in the context of a physical product, including provisions relating to shipping, repair, labeling, and packaging of devices. Third, the legislative context of the FDCA gives no indication that Congress intended to regulate anything other than tangible products, and CLIA's history does not suggest that Congress believed FDA had overlapping authority.

Having concluded that the statute itself did not support FDA's interpretation, the court went on to consider the practical implications of the Final Rule. Echoing an argument that was heavily emphasized in the AAB/NILA amicus brief, the court was troubled by FDA's position that tens of thousands of professionals have for decades been operating in direct and open violation of federal law carrying substantial criminal penalties. The court held, however, that it need not rely on the rule of lenity to avoid this outcome because the FDA's interpretation was unambiguously wrong. The court emphasized, however, that the practical "fallout" from the FDA's interpretation underscored the implausibility of its position.

The court concluded its decision by considering the appropriate remedy. The court noted that under binding Fifth Circuit precedent, vacatur (nullification) is the default remedy for an invalid agency rule. Although a narrow exception exists where vacatur would be disruptive and the agency might be able to salvage its regulations, the court noted that



FDA had not remotely satisfied these criteria, and, in fact, had acknowledged that its Final Rule would impose enormous costs on the healthcare system. The court also noted that it would be impractical, if not impossible, to tailor relief only to the parties in the case, as opposed to all laboratories.

The court therefore granted summary judgment in favor of ACLA and AMP, and vacated the Final Rule.