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Challenges to LDT Final Rule Continue as Rule Goes into Effect

As discussed in our May 6, 2024, Client Alert, earlier this year FDA issued its Final Rule for the regulation of laboratory-developed tests (LDTs) that the FDA has historically treated with enforcement discretion. A week before the rule took effect on July 5, 2024, FDA released a Small Entity Compliance Guide signaling that despite criticism over the Final Rule and challenges filed in court, the Agency intends to continue regulating LDTs. The Guidance does not introduce new or different enforcement discretion policies from those discussed in the preamble to the Final Rule but is intended to provide a high-level summary of FDA's compliance expectations as the phase-out policy begins next year.

With the Final Rule now in effect, the industry has a year to prepare for the first phase of regulatory obligations. However, as predicted in our Client Alert, legal and congressional challenges are in full swing, making the LDT regulatory landscape far from certain.

ACLA Lawsuit

The clinical laboratory industry expressed opposition to the Proposed Rule and the Final Rule, questioning FDA's statutory authority to regulate LDTs as medical devices. Therefore, it was not surprising that soon after the LDT Final Rule was published, the American Clinical Laboratory Association (ACLA) filed a lawsuit against FDA, asserting that "FDA has exceeded its statutory authority and acted arbitrarily and capriciously in violation of the Administration Procedures Act."

ACLA alleges in the complaint that the statutory definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not extend to LDTs, which, ACLA argues, qualify as professional services. Nor, ACLA argues, has any new statutory authority been granted to FDA that would justify changing the regulatory framework that has existed for decades. It is worth noting that Congress failed to pass The VALID Act last Congress, which was intended to provide FDA clear statutory authority to regulate LDTs.

As the litigation moves forward, ACLA may seek a preliminary injunction to prohibit FDA from enforcing the rule, but it has not filed for one yet, presumably because the regulatory requirements will not take effect for another year. It is also unclear whether FDA will delay enforcing the Final Rule as the case moves through the courts.

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Chevron Overruled

In June, The Supreme Court voted 6-3 to overturn the decades-old *Chevron* doctrine in its decision in *Loper Bright Enterprises v. Raimondo,* No. 22-241 (June 28, 2024), together with *Relentless, Inc. v. Department of Commerce*, No-1219 (*"Loper Bright*"). Until this ruling, *Chevron* required courts to defer to a federal agency's interpretation, as reflected through rulemaking, of ambiguous statutes passed by Congress. *Chevron* created a two-step framework requiring courts first to determine whether Congress directly spoke to the question at issue, and if the answer was no, then courts were required to defer to and uphold the agency's interpretation unless it was determined not to be a reasonable construction of the statute. *Loper Bright* departed from this long-standing doctrine and held that judicial review of agency action under the Administrative Procedures Act does not require deference to an agency interpretation of the law simply because the statute is ambiguous. Rather, courts are permitted to exercise their independent judgment.

ACLA's lawsuit challenging FDA's authority may be one of the first FDA cases to be decided under *Loper Bright.* The Supreme Court's decision to overturn *Chevron* may very well work in ACLA's favor. Without the judicial deference the FDA would have enjoyed under *Chevron*, its LDT Final Rule may be at greater risk of being struck down.

House Appropriations Committee Asks FDA to Suspend Final Rule

On July 15, the House Appropriations Committee, through its Committee report, directed the FDA to suspend its efforts to implement the Final Rule and continue working with Congress to modernize the regulatory regime for LDTs.

Committee members backed the appropriations bill by a narrow 29-26 vote. As of this writing, the legislation is pending. It is unclear how FDA will respond to this expression of congressional intent. It is also unclear if Congress will adopt appropriations bills before adjournment this Fall.

Post Chevron Webinar Series

Polsinelli can help your company navigate the uncertainties surrounding the LDT Final Rule and assess the challenges and new opportunities post-*Chevron* across various industries. Please join Polsinelli for a series of one-hour discussions on the impact of the Supreme Court's decision on multiple aspects of health care, including resolving FDA disputes without the *Chevron* shield.

Register for one or all of the upcoming webinars.