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FDA Issues Final Rule on Regulation of Laboratory Developed Tests

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After many years of anticipation and various congressional and agency proposals, on May 6, the Food and Drug Administration (FDA) published its final rule titled "Medical Devices; Laboratory Developed Tests." The final rule lays out the framework for FDA's regulation of laboratory developed tests (LDTs) as in vitro diagnostic devices (IVDs) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This rule marks a significant shift in the regulation of LDTs, ending FDA's longstanding enforcement discretion policy for these tests.

Background

LDTs are IVDs intended for clinical use and designed, manufactured, and used within a single laboratory certified or accredited by the Clinical Laboratory Amendments Improvement Act (CLIA). FDA has consistently maintained that it has regulatory authority over LDTs. Historically, however, FDA has exercised enforcement discretion and not enforced medical device requirements on LDTs, including pre-market approval or 510(k) clearance where applicable, current good manufacturing practices, and establishment registration and device listing, among others. FDA and others have, for several years, expressed that the evolving LDT landscape has shifted the risk profile, with many modern LDTs relying on complex instrumentation, being used for high-risk indications, and being manufactured in high volumes. Given these changes, FDA determined that continued enforcement discretion for LDTs poses risks to patients and that a revised policy is needed.

Key Provisions of the Final Rule and Implications

The final rule modifies the existing definition of IVDs in FDA regulations to explicitly include products designed, manufactured, and performed in individual laboratories as medical devices under the FD&C Act. Additionally, FDA will be gradually eliminating the general enforcement discretion policy for LDTs across a span of four years. This phased implementation aims to provide adequate time for an orderly transition, but labs should evaluate their LDT portfolios and begin preparations now. Laboratories offering LDTs will need to assess the applicability of the enforcement discretion policies to their tests and plan to come into compliance with applicable FDA regulations based on the phaseout timeline. A proactive approach will mitigate risk and business disruption in this new regulatory environment.

The final rule also includes targeted enforcement discretion policies for certain categories of LDTs, including LDTs designed, manufactured, and performed within the Veterans Health Administration (VHA) and Department of Defense, LDTs approved by the New York State Department of Health, LDTs for unmet needs within an integrated health care system, currently marketed LDTs, and certain non-molecular antisera LDTs for rare red blood cell

antigens.

While the rule is intended to assure the safety and effectiveness of LDTs, some stakeholders have raised concerns about the impact on test access, pricing, and innovation. FDA, however, believes the rule strikes the right balance between protecting public health and other considerations, including access and innovation. FDA has committed to providing additional guidance. Legal challenges to the final rule are also anticipated. Laboratories should evaluate near-term implications and monitor for changes.

Conclusion

FDA's final rule on LDTs represents a major policy shift, ending longstanding enforcement discretion for LDTs. While providing continued flexibility for a fairly narrow class of LDTs, the final rule will require many laboratories to comply with FDA's significantly more rigorous medical device regulations. Laboratories manufacturing high-risk LDTs in particular will need to plan for the substantial costs and efforts involved with complying with FDA regulations. FDA estimates the rule will promote test quality, innovation incentives, and regulatory consistency between lab and non-lab manufacturers of IVDs. The true impact of these changes will become clear over time as laboratories adjust to the new regulations.

Brayden Turner, Research Specialist, also contributed to this article.

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