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The LDT Debate: Unpacking Public Responses to FDA’s Proposed Rule

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The U.S. Food and Drug Administration (FDA) recently released a proposed rule that would seek to regulate laboratory developed tests (LDTs) as medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA). This rule could reshape the landscape of LDTs and, as expected, has generated substantial attention and feedback from the public, with both supportive and negative comments flooding in. We previously provided a summary of the proposed rule and FDA’s lengthy justification for it here. In this blog post, we will examine some of the key arguments presented in the public comments submitted to Docket FDA-2023-N-2177, as well as public statements published by industry trade associations.

As of November 20, 2023, approximately 1,900 comments have been posted to the docket, and a significant majority of them oppose FDA’s proposed expansion of the device regulatory framework to cover LDTs.

Supportive Comments

Proponents of FDA’s proposed rule argue that increased oversight is necessary to protect patient safety and ensure the accuracy of diagnostic tests. They believe that a uniform regulatory framework will standardize LDT quality, enhance patient care safety, and prevent research-based methods with limited clinical performance studies and medical relevance from being accepted as diagnostic tests. Many of the comments submitted to date supporting the proposed rule have been anonymous; however, such supporters identify themselves as health care providers, individual patients and consumers, and advocacy groups, and in some cases, diagnostic industry employees.

Negative Comments

Critics argue that the regulatory burden could stifle innovation and limit the availability of certain tests, especially those tests needed to meet emerging public needs, with response to the COVID-19 pandemic often cited as a prime example. They express concerns that laboratories may struggle to comply with the extensive regulatory requirements, especially the premarket review process, and that patients might face delays in accessing critical diagnostic information. These critics include some health care providers, patients, clinical laboratories, diagnostic test developers, and certain industry associations. Further, some critics have argued that FDA does not have the statutory authority to regulate LDTs under its medical device authority and are continuing to push for a legislative resolution to the issue.

Statements from Members of Congress

The House Energy and Commerce Committee Chair Cathy McMorris Rodgers (R-WA) issued a statement arguing that the proposed rule, if enacted, would stifle innovation, and that Congress should be the one to craft LDT policy. Bill Cassidy (R-LA), the ranking member of the Senate Health, Education, Labor and Pensions (HELP) Committee, went further, stating that FDA does not have the authority to expand unilaterally its regulatory jurisdiction and called on Congress to assert itself and clarify FDA’s authority.

Taking a more neutral tone, U.S. Representatives Larry Bucshon (R-IN) and Diana DeGette (D-CO) released a statement agreeing with the need for greater oversight of LDTs, and hoping that the proposed rule will further educate Congress and the public about the need to oversee LDTs through legislation in Congress.

Response by Trade Associations

Several key industry associations, such as the National Independent Laboratory Association, the American Association of Bioanalysts and College of American Pathologists, along with many members of the laboratory community, have not submitted substantive comments to the FDA Docket, instead seeking a 60-day extension of the comment period. However, numerous associations have issued public statements taking aim at the proposed rule and FDA’s authority. Many laboratory associations, such as the American Clinical Laboratory Association, ARUP Laboratories, and Association for Diagnostics & Laboratory Medicine have released statements opposing unilateral FDA actions to regulate LDTs under the medical device authority and believe that FDA is overstepping its authority and that the proposed rule will impede clinical laboratories’ efforts to rapidly develop, validate and offer innovative LDTs for the advancement of patient care. On the other hand, consumer advocacy groups and non-laboratory groups have issued public statements in support of FDA’s proposed rule, and believe that it will lead to better and more reliable patient care.

Conclusion

If finalized and adopted, the proposed rule will have a major impact on the future of LDT regulation and use, with implications for both patient care and the diagnostic industry. We will continue to monitor comments submitted to FDA. Comments on the proposed rule must be submitted by December 4, 2023, and FDA stated during its webinar on the proposed rule that it does not intend to extend this deadline (see here at page 13). Thereafter, FDA will examine all the comments and may adopt some modifications to the rule, such as certain adequately justified exemptions for certain laboratory tests. By refusing to extend the comment period, the agency seems poised to issue a Final Rule in April 2024 or soon after, but it remains to be seen if Congress will attempt to derail the process.

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