



February 21, 2025

The Honorable Brad Finstad
U.S. House of Representatives
2418 Rayburn House Office Building
Washington, DC 20515

Dear Representative Finstad:

The Association for Diagnostics & Laboratory Medicine (ADLM) endorses your legislation, the Freedom for Laboratory Innovation and Testing Act, which would prohibit the Food and Drug Administration (FDA) from using federal funds to implement its May 6, 2024 final rule regulating laboratory developed tests (LDTs). We believe this rule, if it takes effect, would duplicate existing federal standards and harm, rather than improve patient care -- particularly for children and those living in rural areas.

LDTs are currently overseen by the Centers for Medicare and Medicaid services (CMS) under the longstanding CLIA regulations. The FDA rule would regulate laboratories, including hospital laboratories, that develop LDTs as if they are medical device manufacturers, failing to recognize the difference between the two sectors - manufacturers develop and sell their devices to anyone, whereas laboratories only develop LDTs for their patients at the request of an ordering physician.

During President Trump's first term, the Department of Health and Human Services prevented the FDA from advancing this LDT policy. In fact, after his election in 2016, the agency revoked guidance to oversee LDTs stating it would leave the issue to Congress. When Congress refused to give the FDA explicit authority over LDTs in 2022, the agency claimed it already had such authority and fast-tracked a final rule to make sure it was promulgated before the 2024 election.

ADLM is concerned that if this rule is implemented it will:

- Hinder the development of new LDTs, which are critical to advancing care;
- Significantly increase the administrative and compliance costs associated with LDT testing, thus forcing laboratories to reduce or eliminate LDTs from their test menu; and
- Duplicate existing federal regulation that already governs the development and use of LDTs.

To this day, the FDA still has not demonstrated that there is a problem to fix - the data provided by the agency is limited and of questionable value. We strongly support your efforts to prevent the implementation of this rule, which lacks statutory authority, and preserve patient access to these vital tests. Congress should take the lead and explore this issue and determine whether any changes in LDT oversight are needed.

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We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org, or Evan Fortman, MPA, ADLM's Manager of Government Affairs at efortman@myadlm.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "Anthony A. Killeen".

Anthony A. Killeen, MD, MSc, PhD
President, ADLM