December 10, 2024

The Honorable Aaron Bean
U.S. House of Representatives
1239 Longworth House Office Building
Washington, DC 20515

The Honorable Pete Sessions
U.S. House of Representatives
2204 Rayburn House Office Building
Washington, DC 20515

Subject: Revocation of FDA's May 6, 2024 rule on LDTs

Dear Representatives Bean and Sessions:

The Association for Diagnostics & Laboratory Medicine (ADLM) supports your efforts as the Co-Chairs of the new House Delivering Outstanding Government Efficiency (DOGE) Caucus to reduce unnecessary government regulation and improve the delivery of public services. We want to bring to your attention a rule promulgated by the Food and Drug Administration (FDA) that creates a duplicative regulatory structure, is conservatively estimated to cost tens of billions of dollars, and would harm, rather than improve patient care—particularly for children and those living in rural areas.

On May 6th, the FDA issued a final rule (Docket No. FDA-2023-N-2177), which extends its oversight to laboratory developed tests (LDTs) that are already regulated by the Centers for Medicare and Medicaid services (CMS) under the longstanding CLIA regulations. This rule, if implemented, 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-elect 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 urge the House DOGE Caucus to seek the revocation 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 changes are needed.

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,

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