December 12, 2023

Chair Bernie Sanders
Senate Committee on Health,
Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Ranking Member Bill Cassidy
Senate Committee on Health,
Education, Labor and Pensions
828 Hart Senate Office Building
Washington, DC 20510

Chair Cathy McMorris Rodgers
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Sanders, Ranking Member Cassidy, Chairwoman McMorris Rodgers, and Ranking Member Pallone:

The Food and Drug Administration (FDA) published a proposed rule on October 30, 2023, asserting that it had the authority to regulatory laboratory developed tests (LDTs). The agency took such action after Congress refused to give the agency responsibility for overseeing LDTs during the 117th session of Congress.

The Association for Diagnostics & Laboratory Medicine (ADLM) urges you to direct the FDA to withdraw this proposal and permit Congress to address this issue as part of CLIA modernization.

I am attaching ADLM's comments to the FDA, which provide greater details about our concerns with the agency's proposal and its impact on patient care. Among the key points made in the document are:

- Legitimate concerns have been raised about the FDA's the legal authority to regulate LDTs. This issue needs to be resolved before the proposed rule is permitted to advance.
- Congressional hearings are necessary to discuss LDTs, including their usefulness, how they are currently regulated, and what, if any, additional oversight is required.
- LDTs are currently regulated under the CLIA standards. Any modifications to LDT oversight should be made by Congress by updating the 1988 statute.
- The FDA's cost-benefit analysis makes wide-ranging claims on limited and faulty information, rendering it meaningless. Congress should direct an independent body to conduct an assessment on the 'true' costs of FDA oversight and its impact on patient care.
- The FDA proposed rule would limit patient access to care, particularly in marginalized and underserved communities, adversely affecting patient outcomes.

- The FDA still has not demonstrated that there is a problem to fix—the data they have offered is limited and of questionable value.
- Many areas of care are dependent on the use of LDTs, such as newborn screening (most pediatric tests are LDTs), toxicology screening for substance abuse (e.g., individuals using fentanyl), and molecular tests for diagnosing and treating cancer, among others.
- As the FDA has already acknowledged, they do not have the resources to meet their current responsibilities. LDT oversight is likely to result in tens of thousands of additional submissions.

ADLM is concerned that if the FDA is permitted to expand its authority to LDTs, patient care will suffer. We are committed to working with you to ensure that patients continue to have access to high-quality, accurate testing.

If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org.

Sincerely,

Octavia M. Peck Palmer, PhD, FADLM
President, ADLM