September 18, 2023

The Honorable Shalanda Young
Director
Office of Management and Budget
725 17th St, NW
Washington, DC 20503

Richard Revesz
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
1800 G Street, NW, 9th Floor
Washington, DC 20503

Dear Director Young and Administrator Revesz:

On behalf of the National Independent Laboratory Association (NILA)—a collective voice representing a diverse network of community, regional, and health system clinical laboratories committed to improving the operations of member laboratories, fostering innovation in diagnostic testing, and increasing patient access to essential clinical laboratory testing—we write to express our concerns and respectfully urge the White House to reconsider releasing the proposed rules allowing the Food and Drug Administration (FDA) to regulate Laboratory Developed Tests (LDTs).

LDTs are testing processes created, validated, and performed within a single CLIA-certified laboratory. LDTs are pivotal in addressing gaps left by commercially manufactured In Vitro Diagnostic (IVD) tests. Unlike IVDs, LDTs are developed, improved, and refined by experienced laboratory professionals who are equipped to respond rapidly to evolving medical needs and emerging threats, as demonstrated during the COVID-19 and Zika virus crises. LDTs, in their diverse applications, provide essential information that enhances patient care. These tests often involve detecting or quantifying substances within the human body, enabling precise diagnosis and treatment. The majority of LDTs offered by NILA-member laboratories perform these fundamental functions, posing low risks and falling under the purview of existing regulatory authorities like CLIA and state laws.

Clinical laboratory tests play an indispensable role in enabling health care providers to make informed treatment decisions for patients. The existing regulatory landscape, including the federal Clinical Laboratory Improvement Amendments (CLIA) and state regulations, mandates stringent standards for laboratories performing complex clinical testing. These regulations, coupled with professional society guidelines, certifications, and accreditations, ensure that patients receive reliable and accurate clinical laboratory testing services.

NILA firmly believes that extending blanket FDA regulation to LDTs as medical devices could have unintended consequences that undermine patient care and hinder innovation. Our concerns include:

1. **Restricted Access to Innovation**: Regulating LDTs as medical devices could inadvertently stifle laboratory innovation, limiting patient access to breakthrough technologies and advances in disease diagnosis and treatment, without adding significant safety benefits.

2. **Duplicative Requirements and Regulatory Delay**: Adding FDA oversight to all LDTs regardless of risk could result in unnecessary duplications and delays due to slower regulatory processes, impeding the swift adoption of innovative diagnostic technologies.

3. **Unsustainable Cost Burden**: The implementation of user fees for laboratories to access the FDA review process will be prohibitive for smaller regional and community clinical laboratories—significantly limiting patient access to these essential tests.

NILA strongly recommends a balanced approach to LDT regulation that avoids unnecessary duplication of existing safeguards, maintains patient access to innovative testing, and ensures clear, consistent, and transparent regulatory practices. We believe that Congress, by understanding the unique nature of LDTs and their role in patient care, can enact policies that promote innovation while protecting patient safety. We appreciate your consideration of our concerns, and we urge you to collaborate with stakeholders in the clinical laboratory community to strike a balance that benefits patients, health care providers, and the broader public health landscape.

Thank you for your attention to this critical matter. We look forward to collaborating with federal agencies and Congress on LDT policy. Please reach out to Erin Morton at emorton@dc-crd.com with any questions or feedback.

Sincerely yours,

Mark S. Birenbaum, Ph.D.
Executive Director
National Independent Laboratory Association