November 22, 2024

The Honorable Patty Murray
Chair
Senate Appropriations Committee
S-128, The Capitol
Washington, DC 20510

The Honorable Susan Collins
Ranking Member
Senate Appropriations Committee
S-128, The Capitol
Washington, DC 20510

The Honorable Tom Cole
Chair
House Appropriations Committee
H-307, The Capitol
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member
House Appropriations Committee
1036 Longworth House Office Building
Washington, DC 20515

Subject: Laboratory developed tests regulation and the future of patient care

Dear Chair Murray, Ranking Member Collins, Chair Cole, and Ranking Member DeLauro:

The undersigned organizations, who represent a diverse and broad community of patient advocates, laboratory professionals, public health laboratories, clinical laboratories, and more from throughout the United States, are writing to express our strong support for appropriations report language addressing the U.S. Food and Drug Administration's (FDA) final rule on laboratory-developed tests (LDTs). This rule marks a significant shift in how LDTs are regulated, with far-reaching impacts on patients, healthcare providers, and laboratories. We commend the House Appropriations Committee for directing the FDA to pause its implementation of this rule and to collaborate with Congress on modernizing the regulatory approach for LDTs. We urge you to retain this language throughout the FY 2025 appropriations process.

LDTs are vital tools developed and utilized by hospitals, academic institutions, public health, and clinical laboratories to diagnose, monitor, and treat conditions, including cancers, rare diseases, inherited disorders, and infectious diseases. They enable laboratory professionals to assess disease risk, tailor treatment plans, predict drug responses, and provide prognoses. Currently, there are hundreds of thousands of LDTs available for clinical care that successfully guide the decisions of healthcare providers and patients because there are robust federal, state, and third-party mechanisms to ensure their quality. While LDTs are an essential part of the care that laboratory professionals provide to patients and are deeply ingrained in medicine guiding many health care decisions, they differ drastically from boxed and shipped, commercially-sold medical devices, like imaging machines, implantables, and surgical equipment, making the FDA's use of the medical device regulations inappropriate for this field.

The FDA's new rule presents serious concerns for patient care and innovation. According to FDA estimates, over 90% of affected laboratories are small businesses, with average annual receipts of roughly $4 million—comparable to the cost of a single premarket review submission. This financial burden could force laboratories to prioritize economic viability over patient care, undermining the ability to quickly adapt testing methods to the latest scientific advances. This is not the future we envision for a field so crucial to medical care, disease screening, and response to infectious disease outbreaks.

We stand united in urging Congress to develop a tailored, common-sense approach to regulating laboratories and their testing services. Years of discussion and substantial efforts have been devoted to this issue, aiming for a balanced solution. While our organizations may have varying perspectives, we share a deep concern that the FDA's rule is not the right path forward as it threatens the stability of the laboratory sector and its workforce. Therefore, we strongly urge you to protect the language instructing the FDA to pause its regulatory efforts and to allow Congress, in collaboration with the laboratory community, to craft a modernized framework that fosters innovation and supports patient care.

Sincerely,

Academic Coalition for Effective Laboratory Tests
Academy of Clinical Laboratory Physicians and Scientists
Accu Reference Medical Laboratory
Adela, Inc.
Advanced Genetics Laboratory
Akron Children's Hospital
America's Blood Centers
American College of Medical Genetics and Genomics
American Red Cross
American Society for Clinical Pathology
American Society of Hematology
Appalachian Labs of WV
Arbelos Genomics
ARUP Laboratories
Association for Academic Pathology
Association for Diagnostics & Laboratory Medicine
Association for Molecular Pathology
Association for the Advancement of Blood and Biotherapies (AABB)
Baylor College of Medicine
Biomeck
Boston Consulting
Cedars-Sinai
Children's National Hospital
Choice Pain and Rehabilitation Laboratory
Choice Vending, LLC.
City of Hope
Clinical Immunology Laboratory
Clinical Immunology Society (CIS)
Complete Diagnostic Laboratories, LLC
Concord Life Sciences
Copper State Lab Services
Damajha Systems
DASH Lab Services
Emplify Health Inc.
Flow Health Laboratories LLC
Gemelli Biotech Corp

Genome Medical, Inc
Genomind, Inc
Golden Health Consulting LLC
Greenwood Genetic Center
Helix, Inc.
Hyperdrive Bio
IMMYLabs
Immune Deficiency Foundation
IVD Logix LLC
Kaiser Permanente
Kindlabs llc
KSL Diagnostics Inc.
Lab Voice Media
Leukodystrophy Newborn Screening Action Network
Lifetime Sciences
Lighthouse Lab Services
Lights Right Laboratories
MCDXI Medical Diagnostics, Inc.
MD Labs Clinical Toxicology and Pharmacogenetics
Medical University of South Carolina
Meridian Diagnostics
Minomic Inc
MLD Foundation
Molecupath Consultants, LLC
MSACL
nuCARE Medical Solutions, Inc
Phoenix Laboratory Consulting
Previse
Principle Health System
Project Santa Fe Foundation- Lab 2.0
Promus Diagnostics LLC
Reya Laboratories
RGEN Inc.
Seattle Children's Hospital
Shadowbox, Inc.
Survivors Cancer Action Network
Telos PGX
Tharalink Technologies, Inc.
Three Rivers Diagnostics
TranSoar
Triangle Molecular Toxicology LLC
TriCore Reference Laboratories
Turnkey Clinical Laboratory Consulting
UMASS Memorial Health
University of Rochester
Wake Diagnostics Inc
Weill Cornell Medicine
Z2 Scientific LLC