

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  
Previser  
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