

November 1, 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 Chair Sanders, Ranking Member Cassidy, Chair McMorris Rodgers, and Ranking Member Pallone:

On behalf of the undersigned organizations that represent a diverse and broad community of patient advocates, laboratory professionals, public health laboratories, and clinical laboratories from throughout the United States, we write to express our significant concerns with recently announced plans by the U.S. Food and Drug Administration (FDA) to impose existing medical device regulations on laboratory developed testing procedures (LDTs). LDTs are testing services that hospitals, academic, public health, and clinical laboratories develop and use in patient care. These services are not commercially manufactured and marketed, but rather are designed, developed, validated, performed, and interpreted by board-certified professionals in a single laboratory. LDTs are often created in response to unmet clinical needs and are instrumental for early and precise diagnosis or monitoring and guidance of patient treatment including hereditary disease testing, oncology, infectious disease, and more. As such, FDA regulating them as medical devices would be inappropriate and disruptive to patient care.

We stand united in support of modernizing the oversight framework for high complexity clinical LDTs but primarily through reform of the long-standing Clinical Laboratory Improvement Amendments (CLIA). We believe that the modernization of CLIA requirements could better achieve a sustainable system that fosters innovation and promotes emerging medical knowledge to enable healthcare professionals the ability to offer precise, accurate, and the most up-to-date tests to patients. It is also the most streamlined and cost-effective approach, for both the government and laboratories, and the least disruptive and burdensome approach to ensuring clinical and analytical validity, transparency, and addressing other concerns expressed by interested stakeholders. Modernizing CLIA oversight will support laboratory advances in clinical care as validated discovery and innovation continue to develop rapidly.

Therefore, we urge Congress to direct the FDA to pause rulemaking on LDTs and instead, renew bipartisan efforts to work with stakeholders to pass legislation that would establish a modernized approach within the existing regulatory framework under CLIA.

Sincerely,

Academy of Clinical Laboratory Physicians and Scientists  
American College of Medical Genetics and Genomics  
ARUP Laboratories  
Association for Diagnostics and Laboratory Medicine  
Association for Molecular Pathology  
Association for Pathology Informatics  
Association of Pathology Chairs  
Avant Diagnostics, Inc.  
Beutner labs  
Cancer Advocacy Group of Louisiana  
Cedars-Sinai  
Coalition for Innovative Laboratory Testing  
Damajha Systems  
Diamond Medical Laboratories LLC  
Elina Labs, LLC  
Entvantage Diagnostics, INC  
Gene by Gene  
GeneMatters, LLC (A Genome Medical Company)  
Genomind, Inc.  
Igentify INC  
Innoterix Labs  
Invitae Corporation  
IVD Logix LLC  
Kaiser Permanente  
KSL Diagnostics Inc.  
Laboratory Access and Benefits Coalition  
Laboratory Nexus LLC  
Leading Edge Laboratory Consultants  
Lifetime Sciences  
Lighthouse Lab Services  
Medical Group Management Association (MGMA)  
Meridian Diagnostics  
Michigan Department of Health and Human Services  
MSACL  
My geneTx  
National Society of Genetic Counselors  
Nationwide Children's Hospital  
Nebraska Medicine  
nuCARE Medical Solutions  
Pan American Society for Clinical Virology  
Phoenix Laboratory Consulting  
Principle Health Systems

Purine Metabolic and Immunodeficiency Lab, Duke University  
Society for Pediatric Pathology  
Survivor's Cancer Action Network  
Teiko Bio  
The Foundation for Casey's Cure  
Theralink Technologies, Inc  
TriCore Reference Laboratories  
University of Chicago Medical Center  
University of North Carolina at Chapel Hill Department of Pathology and Laboratory Medicine  
University of Rochester Medical Center  
University of Wisconsin School of Medicine and Public Health  
UW Health  
Wisconsin State Laboratory of Hygiene