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