October 31, 2023

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Request for an extension to the comment deadline to the Rulemaking Docket No. FDA-2023-N-2177, Medical Devices: Laboratory Developed Tests

Dear Dr. Califf,

On behalf of the 89 undersigned organizations representing patient advocacy organizations, medical and professional societies, hospitals, health systems, clinical laboratories, and more, we respectfully request an extension to the deadline to submit comments to Rulemaking Docket No. FDA-2023-N-2177, Medical Devices: Laboratory Developed Tests. Specifically, we ask that the December 4th deadline be extended an additional 60 days to provide adequate time for stakeholders to assess the impact of the proposed rule on patient access to care, clinical practice, and innovation.

If finalized, the proposed rule would be a dramatic shift in how laboratory developed tests (LDTs) are regulated in the United States. This would not only potentially disrupt the current access patients have to clinical testing as laboratories narrow their test offerings or close due to the financial burden the rule places on them, but given the new premarket review requirements, the proposed rule could delay or prevent modifications and introductions of new tests that best reflect the latest scientific understanding and clinical practice guidelines.

These concerns are not hypothetical, rather, the agency needs only to look toward the European Union's implementation of the legislation enacted in 2017, In Vitro Diagnostic Medical Device Regulation (IVDR) for reference. By 2022, laboratories were required to be in full compliance with the regulation; however, the rollout has experienced multiple delays leading regulators to issue grace periods for classes of devices[1] to avoid widespread diagnostic shortages.[2] According to MedTech Europe, the European medical device industry association, had the compliance periods not been delayed, at least 22% of currently marketed diagnostics tests would not have been accessible during the transition.[3] The new regulatory regime also led

[1] https://www.360dx.com/policy-legislation/ivdr-rollout-brings-new-hurdles-clinical-labs-smaller-diagnostic-firms-europe#:~:text=With%20the%20increase%20in%20resources,tests%20for%20rare%20disease%20patients.
[2] https://www.medtechdive.com/news/eu-finalizes-rollout-ivdr/616392/
[3] https://www.medicept.com/2022/02/07/eu-to-delay-portions-of-the-ivdr-rollout/

to unintended consequences such as the inability of laboratories to collaborate and share informatics pipelines.[4]

Even within the proposed rule, through its requests for information, the Food and Drug Administration (FDA) acknowledges the negative impact the rule will have on different types of clinical laboratories, such as those in academic medical centers and small businesses, as well as on different patient populations including those in rural communities who may only have access to small, community-based laboratories. The potential of these consequences is significant and adequate time must be given to stakeholders to fully assess, research, and understand how the proposed rule will affect their constituencies. For this reason, we request an additional 60-day extension of the comment period (total comment period length of 120 days) and urge you to announce this extension expeditiously.

Sincerely,

Academy of Clinical Laboratory Physicians and Scientists
Adela
Akron Children's Hospital
American College of Medical Genetics and Genomics
American Society for Clinical Pathology
American Society of Hematology
Appalachian Labs of WV
Aptivedx
Arbelos Genomics
ARUP Laboratories
Association for Diagnostics and Laboratory Medicine
Association for Molecular Pathology
Association for Pathology Informatics
Association of Organ Procurement Organizations
Association of Pathology Chairs
Avant Diagnostics
Beutner Laboratories
Beutner Labs
BNB Diagnostics
Boston Children's
Cancer Advocacy Group of Louisiana
Cedars-Sinai
Children's Hospital Colorado
Children’s Hospital of Philadelphia
Children's National Hospital

[4] https://www.360dx.com/policy-legislation/ivdr-rollout-brings-new-hurdles-clinical-labs-smaller-diagnostic-firms-europe#:~:text=With%20the%20increase%20in%20resources,tests%20for%20rare%20disease%20patients.

Children’s Wisconsin
Cincinnati Children’s Hospital
Clinical Immunology Society
Coalition for Innovative Laboratory Testing
Cov19+ testing Laboratory
Damajha Systems
Deirdre Pierry CGMBS, MLS (ASCP), MB, SM
Diamond Medical Laboratories LLC
Exceltox Laboratories, LLC
FORCE: Facing Our Risk of Cancer Empowered
GeneCentric Therapeutics, Inc
Genomind, Inc.
Great Scott! Consulting
Guaranty Consultant Services
Helix
Immune Deficiency Foundation
Innoterix Labs
Invitae Corporation
IVD Logix LLC
Kaiser Permanente
KSL Diagnostics Inc
Laboratory Access and Benefits Coalition
Laboratory Nexus LLC
Leukodystrophy Newborn Screening Action Network
Lifetime Sciences
Lighthouse Lab services
MCDXI Medical Diagnostics, Inc.
Medical Group Management Association (MGMA)
Michigan Department of Health and Human Services
MolecularDiagnostics Inc.
MSACL
National Society of Genetic Counselors
Nationwide Children's Hospital
Nebraska Medicine
nuCARE Medical Solutions, Inc
Ochsner Health
Pan American Society for Clinical Virology
Parallel Profile
Patient Safety Impact
Phoenix Laboratory Consulting
Previse
Principle Health Systems
PTL Holdings
Purine Metabolic and Immunodeficiency Lab, Duke University

Seattle Childrens Hospital
Select Laboratory Partners
SilverStarDX LLC
Society for Pediatric Pathology
Survivor's Cancer Action Network
Teiko Bio
The Foundation for Casey’s Cure, Inc
Theralink Technologies, Inc
Three Rivers Diagnostics
TriCore Reference Laboratories
Ultimo Medical Consulting
Ultragenyx Pharmaceutical
University of North Carolina at Chapel Hill Department of Pathology and Laboratory Medicine
University of Rochester Medical Center
University of Texas Southwestern Medical Center
University of Wisconsin School of Medicine and Public Health
UVA Health
UW Health
Wisconsin State Laboratory of Hygiene