

June 7, 2024

The Honorable Rand Paul  
U.S. Senate  
295 Russell Senate Office Building  
Washington, DC 20510

The Honorable Brad Finstad  
U.S. House of Representatives  
1605 Longworth House Office Building  
Washington, DC 20515

The Honorable Dan Crenshaw  
U.S. House of Representatives  
248 Cannon House Office Building  
Washington, DC 20515

Dear Senator Paul, Representative Finstad, and Representative Crenshaw:

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 in support of your resolution initiating the Congressional Review Act as it pertains to the FDA's Proposed Rule, Docket No. FDA-2023-N-2177, Medical Devices: Laboratory Developed Tests.

Laboratory developed tests (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.

The final rule is a dramatic shift in how LDTs are regulated in the United States. It will disrupt the access patients have to clinical testing as laboratories narrow their test offerings or close due to the financial burden the rule places on them. Additionally, the new premarket review requirements will 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, Congress needs to only 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<sup>1</sup> to avoid widespread diagnostic shortages.<sup>2</sup> 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.<sup>3</sup> The new regulatory regime also led to unintended consequences such as the inability of laboratories to collaborate and share informatics pipelines.<sup>4</sup> In fact, the significant implementation challenges continue to persist nearly seven years since its enactment, so much so, that earlier this year, the IVDR compliance dates were further delayed to 2027.<sup>5</sup>

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 significant increase in regulatory costs required to provide clinical laboratory services will decimate the laboratory community all to the detriment of patient care.

Most laboratories without high revenues will be unable to shoulder the costs associated with compliance with the medical device regulations. For instance, FDA estimates<sup>6</sup> that the cost of a single premarket approval (PMA) or 510(k) de novo market authorization submission is \$4.3 million and \$527,000, respectively. Yet, 92% of laboratories impacted by the rule are small businesses who on average only have an annual revenue of \$4 million. Thus, the cost of compliance to make a new test available to patients is far beyond the financial capabilities of small businesses throughout the United States, forcing them to make difficult financial, not medical-based, decisions to stop offering tests or close their laboratories altogether. As the economy continues to rebound from the pandemic, this

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<sup>1</sup> <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>

<sup>2</sup> <https://www.medtechdive.com/news/eu-finalizes-rollout-ivdr/616392/>

<sup>3</sup> <https://www.medicpt.com/2022/02/07/eu-to-delay-portions-of-the-ivdr-rollout/>

<sup>4</sup> <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>

<sup>5</sup> <https://www.medtechdive.com/news/european-commission-proposes-delays-ivdr/705414/>

<sup>6</sup> <https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/laboratory-developed-tests-regulatory-impact-analysis-final-rule>

rule has the potential to harm this critical sector of the health care system in the United States.

Many members of Congress have expressed major concerns about the impact of the FDA rule. There is also bipartisan support for a legislative solution of some sort. However, allowing the rule to move forward while Congress works on a legislative solution will still lead to disruption in clinical test offerings and patient access to these services. Clinical testing laboratories are already weighing decisions about whether to bring on new tests because of the FDA rule. Given the short timeframe for implementation, laboratories must start making long-term decisions given the excessive costs and burdens associated with the medical device regulatory process. Thus, it is necessary that Congress use its authority to prevent implementation of this harmful rule while continuing to pursue a legislative solution.

This resolution will ensure that the final rule does not disrupt localized care, delay test turnaround times, increase healthcare costs, and stall innovation. For these reasons, we support the Resolution and encourage Congress to act swiftly for its passage.

Sincerely,

Academic Coalition for Effective Laboratory Developed Tests

Adela, Inc.

Akron Children's Hospital

American Academy of Allergy, Asthma & Immunology

American College of Medical Genetics and Genomics

American Pharmacogenomics Association

American Society for Clinical Pathology

American Society for Investigative Pathology

Arbelos Genomics

Association for Diagnostics and Laboratory Medicine

Association for Molecular Pathology

Association for Pathology Informatics

Baylor College of Medicine

BioReference Health, LLC

BioSTAT Laboratory

BNB Diagnostics

Clinical Immunology Society

Coalition for Innovative Laboratory Testing

Complete Diagnostics Laboratories  
Copper State Lab Services  
CRL  
Damajha Systems  
DECODE Health and Wellness, LLC  
Friedreich's Ataxia Research Alliance (FARA)  
Galaxy Diagnostics, Inc.  
Gene by Gene, LDT  
20/20 GeneSystems  
Genome Medical  
Genomind, Inc  
Glioblastoma Foundation  
Golden Health Consulting  
Greenwood Genetic Center, Inc.  
IMMYLabs  
IVD Logix LLC  
Kohif PharmaGenix  
Lab Genomics LLC  
Laboratory Access and Benefits Coalition  
Leukodystrophy Newborn Screening Action Network  
MCDXI Medical Diagnostics, Inc.  
Medgeneius Inc  
MLD Foundation  
Moffitt Cancer Center  
MSACL  
National Society of Genetic Counselors  
NorthShore/Endeavor Health  
nuCARE Medical Solutions, Inc  
Pearsanta, Inc.  
Peregrine WORx  
PlexusDx  
PPSF  
Premier Medical Management, LLC  
Previs  
Protean BioDiagnostics  
Rx-consultant, llc  
Sanford Health  
Spratt Financial

Survivor's Cancer Action Network  
Telos PGX  
The Doctor Lab  
The University of Vermont Health Network  
Theralink Technologies  
Transoar  
TriCore Reference Laboratories  
UGenome  
UK HealthCare  
University of Arkansas for Medical Sciences  
University of Iowa Health Care  
University of Rochester Medical Center  
University of South Alabama, Mobile, Alabama  
UW Health