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[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 to unintended consequences such as the inability of laboratories to collaborate and share informatics pipelines.[4] 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.[5]

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[6] 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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[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/

[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

[5] https://www.medtechdive.com/news/european-commission-proposes-delays-ivdr/705414/

[6] 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
Previse
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