

May 6, 2022

The Honorable Patty Murray
Chair, Senate Committee on Health, Education,
Labor and Pensions
154 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Frank Pallone
Chair, House Committee on Energy &
Commerce
2107 Rayburn HOB
Washington, DC 20515

The Honorable Richard Burr
Ranking Member, Senate Committee on Health,
Education, Labor and Pensions
217 Russell Senate Office Building
Washington, DC 20510

The Honorable Cathy McMorris Rogers
Ranking Member, House Committee on Energy
& Commerce
1035 Longworth House Office Building
Washington, DC 20515

Re: The Verifying Accurate Leading-edge IVCT Development Act of 2021

Dear Senators Murray and Burr and Representatives Pallone and McMorris Rogers:

The undersigned organizations represent a diverse and broad community of healthcare and public health professionals concerned with delivering high-quality care to patients throughout the United States. As Congress considers the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021, or any other legislation to change regulations for laboratory developed tests (LDTs), we urge you to allow sufficient time to evaluate such legislation independently, proceeding under regular order to allow for thorough consideration.

The VALID Act is a complex bill proposing dramatic modifications to current oversight mechanisms and thus has the potential to significantly impact many clinical testing laboratories, public health laboratories, healthcare providers, and patients throughout the United States. Careful consideration must be given to the entirety of the bill to avoid unintended consequences that may ultimately restrict innovation and harm patient access to clinical testing. A wide range of stakeholders, including supporters of the VALID Act, still have numerous and significant concerns, and discussions with sponsors and relevant committees are ongoing. Further, the COVID-19 pandemic has revealed important lessons about the regulation of laboratory testing and its effects on testing capacity within the United States that should be thoughtfully considered in the context of the VALID Act. To allow for thorough discussions and appropriate stakeholder engagement, it is important that this legislation go through regular order with its own hearing, mark-up, and scheduled votes.

Specifically, we ask that Congress consider legislation that would significantly alter the regulation of laboratory testing (such as the VALID Act) separately from the Medical Device User Fee Agreement (MDUFA) legislative process. Legislation to reauthorize MDUFA will reflect an agreement negotiated between the FDA and the medical device industry it fully regulates, entailing policy issues and considerations that have been discussed and debated before that agreement is even transmitted to Congress. These negotiations involve different stakeholders than those relevant to the reform of the regulatory oversight of LDTs; thus, it is inappropriate to associate the VALID Act with MDUFA. Further,

MDUFA reauthorization will proceed on an expedited basis because of both the FDA's agreement with medical device stakeholders and the necessity to reauthorize legislation before the current agreement expires at the end of the fiscal year.

More time and diverse stakeholder agreement is needed to undertake substantial reform of regulatory oversight of LDTs. For these reasons, the undersigned organizations ask that the VALID Act be considered under regular order, not attached to a must-pass vehicle, to allow for careful consideration and development of sound policy that is in the best interest of patients and public health.

Sincerely,

Academy of Clinical Laboratory Physicians and Scientists
American Association of Bioanalysts
American Association for Clinical Chemistry
American College of Medical Genetics and Genomics
American College of Obstetricians and Gynecologists
American Medical Association
American Society for Clinical Pathology
American Society of Hematology
American Society for Microbiology
American Society of Transplantation
American Society for Histocompatibility and Immunogenetics
Association for Molecular Pathology
Association of Pathology Chairs
Association of Public Health Laboratories
Clinical Immunology Society
Lyme Disease Association Inc.
Medical Group Management Association
National Independent Laboratory Association
National Society of Genetic Counselors
Pan American Society for Clinical Virology
Pediatric Endocrine Society
Society for Reproductive Investigation