

July 20, 2022

The Honorable Frank Pallone, Jr.  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Cathy McMorris Rodgers  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Patty Murray  
Chair  
Committee on Health, Education,  
Labor and Pensions  
United States Senate  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Richard Burr  
Ranking Member  
Committee on Health, Education,  
Labor and Pensions  
United States Senate  
833 Hart Senate Office Building  
Washington, D.C. 20510

Dear Chairman Pallone, Chair Murray, and Ranking Members Rodgers and Burr:

We write on behalf of a diverse group of stakeholders, representing test manufacturers, laboratories, physicians, healthcare providers, patients, consumers, and public health groups, and we are united in a commitment to ensuring patients' access to accurate and reliable *in vitro* diagnostics. We appreciate your continuing efforts to deliver vital funding to the U.S. Food and Drug Administration (FDA), and we ask that as you reconcile differences between the user fee reauthorization legislation passed by the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions (HELP), you address an urgent public health issue by enacting the diagnostics reform provisions included in the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022 (S. 4348).

These provisions reflect years of continuous engagement and thoughtful collaboration among committee and congressional leaders and the stakeholder community. Our organizations deeply appreciate the careful balance the Senate HELP Committee struck in the diagnostics provisions it advanced to the markup on June 14<sup>th</sup>, referred to as the VALID Act of 2022. This approach not only enjoys broad support from the stakeholder community, it was approved by the Senate HELP Committee on a bipartisan basis and was largely developed under the leadership of Members from both sides of the aisle in both chambers of Congress.

As you are aware, the legislation addresses a longstanding issue that has been recognized by administrations of both parties. The current federal approach to oversight has fueled regulatory uncertainty that jeopardizes investment in the next generation of diagnostics that will provide for improved patient outcomes. As Congress finalizes a legislative package reauthorizing FDA's user fee programs, it can also seize this truly unique opportunity to advance a flexible, risk-based regulatory system for all *in vitro* clinical tests. We appreciate your continued support for meaningful diagnostics reform and we remain committed to working with you and the committees to advance these reforms into law this year.

Signed,

Abbott  
AdvaMedDx  
American Cancer Society Cancer Action Network (ACS-CAN)  
American Society of Clinical Oncology (ASCO)  
Arizona Bioindustry Association, Inc. (AZBio)  
Ascensia Diabetes Care  
BD (Beckton, Dickinson and Company)  
Beckman Coulter Diagnostics  
BioFlorida  
bioMérieux Inc.  
BioNebraska  
BioOhio  
Bio-Rad Laboratories  
Center for Science in the Public Interest  
Cepheid  
College of American Pathologists (CAP)  
Colorado BioScience Association  
Danaher Diagnostics  
Foundation Medicine  
Friends of Cancer Research  
Global Liver Institute  
GRAIL, LLC  
HealthCare Institute of New Jersey (HINJ)  
Hologic  
Indiana Health Industry Forum  
Indiana Medical Device Manufacturers Council  
LUNgevity  
Lymphoma Research Institute  
MassBio  
MedTech (New York)  
Michigan Biosciences Industry Association (MichBio)  
Muscular Dystrophy Association  
North Carolina Biosciences Organization (NCBIO)  
Ovarian Cancer Research Alliance (OCRA)  
PERSOWN, Inc.  
Pew Charitable Trusts  
QIAGEN  
QuidelOrtho Corporation  
Renalytix AI, Inc.  
Renegade Bio  
Roche Diagnostics  
Sekisui Diagnostics  
South Dakota Biotech  
Triage Cancer  
U.S. PIRG  
Werfen