

June 21, 2018

The Honorable Greg Walden  
Chairman, House Committee on  
Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Lamar Alexander  
Chairman, Senate Committee on  
Health, Education, Labor and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510

The Honorable Frank Pallone  
Ranking Member, House Committee on  
Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Patty Murray  
Ranking Member, Senate Committee on  
Health, Education, Labor and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510

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Re: Diagnostic Accuracy and Innovation Act

Dear Representatives Walden and Pallone, and Senators Alexander and Murray:

The undersigned organizations represent a diverse and broad community of laboratories, physicians, and other professional health care providers involved in delivering medical care to millions of patients daily. As Congress considers legislation focused on oversight of clinical laboratory tests, we urge you to continue to engage with all stakeholder groups to develop consensus legislation that would modernize the oversight of laboratory developed testing procedures. The Diagnostic Accuracy and Innovation Act (DAIA) discussion draft's approach to regulating laboratory developed testing procedures is not appropriate as it consequently generates a new regulatory environment that would overburden and stifle clinical laboratories and medical professionals' ability to provide laboratory testing to patients. As drafted, DAIA would sharply curtail medical innovation, which is contradictory to the overwhelming bipartisan support for the 21<sup>st</sup> Century Cures Act to advance precision medicine. Precision medicine is dependent on precision diagnostics—the field of medicine that DAIA is likely to freeze in place.

Laboratory developed testing services and procedures represent an essential component in medical practice, including infectious disease detection and treatment, newborn screening, inherited disease testing, and precision medicine in oncology. We stand united in support of modernizing the oversight framework for high complexity clinical laboratory developed testing procedures but primarily through reform of the Clinical Laboratory Improvement Amendments (CLIA). We believe that modernization of CLIA requirements could better achieve a flexible system that fosters innovation and promotes emerging medical knowledge to enable healthcare professionals the ability to offer precise, accurate, and the most up-to-date tests to patients. It is also the most streamlined and cost-effective approach, for both the government and laboratories, and the least disruptive and burdensome approach to addressing clinical and analytical validity, transparency, and other concerns expressed by interested stakeholders. Modernizing CLIA oversight will support laboratory advances in clinical care as validated discovery and innovation continue to develop rapidly.

The creation of a new center at the Food and Drug Administration (FDA), as proposed in the DAIA discussion draft, to regulate laboratory developed testing procedures is not only unnecessary but also unrealistic given the current budgetary restraints on the agency. The proposed regulatory approach could reduce patient access to essential testing services as many community and academic clinical laboratories would find complying with a new FDA regime cost-prohibitive. This is especially true in an environment in which deep cuts to Medicare payment for clinical testing, due to the Protecting Access to Medicare Act of 2014, already threaten patient access to clinical testing services. In short, legislative and regulatory proposals such as DAIA that shoehorn clinical laboratories into an entirely new regulatory agency and set of requirements will interject tremendous instability and unpredictability that will harm access and innovation.

We are sensitive to the concerns expressed by manufacturers of the regulatory paradigm for in vitro diagnostic test kits (IVDs) as they relate to the length and unpredictable nature of the review processes at FDA. Many of our members rely on IVDs in their practice and we do support legislative and regulatory efforts at FDA that would streamline existing pathways for commercially manufactured tests, both to support the Administration's priority to reduce unnecessary regulatory burdens and to maintain innovation of IVDs currently on the market.

We appreciate your leadership and efforts to evaluate and modernize the oversight of laboratory developed testing procedures and the laboratories in which these clinical testing services and procedures are performed. All stakeholders on this issue have the same ultimate desired outcome: that laboratory developed testing procedures continue to be high quality, accurate, and precise as the science advances and changes while maintaining patient access to these vital procedures. Our organizations would like to offer our expertise as a resource on this issue, and we hope that moving forward, all stakeholders will have an equal place at the table for those conversations.

Sincerely,

American Association for Clinical Chemistry  
American College of Medical Genetics and Genomics  
American Medical Association  
American Society for Microbiology  
Association for Molecular Pathology  
Association of Pathology Chairs  
Association of Public Health Laboratories  
BioReference Laboratories  
Columbia University Irving Medical Center  
Emory University Woodruff Health Sciences Center  
Infectious Diseases Society of America  
Oregon Health & Science University  
Pan American Society of Clinical Virology  
Stanford University Department of Pathology  
University of Chicago Medical Center  
University of Washington School of Medicine  
Vanderbilt University Medical Center