October 26, 2015

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

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

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

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

Dear Chairman Alexander, Ranking Member Murray, Chairman Upton, and Ranking Member Pallone:

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. We stand united in support of modernizing the oversight framework for high complexity clinical laboratory developed testing services and procedures primarily through reform of the Clinical Laboratory Improvement Amendments (CLIA). We agree that congressional action is needed to ensure that high complexity laboratory developed testing services and procedures are accurate, precise, clinically relevant, and monitored for continued quality performance largely through CLIA enhancements. The foregoing proposed modernization of the CLIA oversight structure is premised upon use of the clinical commons to perform oversight functions. To the extent tests fall outside of the clinical commons, there should be a limited, well-defined role for the Food and Drug Administration.

Laboratory developed testing services and procedures help to support medical decision making and continue to be central to the protection of public health. We urge Congress to pursue modernization of the CLIA oversight framework targeted on high complexity laboratory developed testing services and that would establish standards for clinical validity and strengthen established standards related to: (1) quality control; (2) quality assurance; (3) personnel standards; and (4) regular proficiency testing. Expanding the existing CLIA oversight framework for high complexity laboratory testing services will assure patient safety and provide a stronger structure to prevent laboratory errors while at the same time preserve patient access to care. Specifically, in light of the extraordinary progress in diagnostic medicine, including large-scale genetic sequencing and the application of information technology, the existing CLIA requirements should be enhanced to ensure the quality of high complexity testing services and procedures based on risk.

Updating CLIA requirements will achieve a flexible system that fosters innovation and promotes emerging medical knowledge. It is also the most streamlined and cost-effective approach (for the federal government and the health care system) and the least disruptive and burdensome approach (for the laboratory community and the patients they serve) to addressing clinical and analytical validity, transparency, and other concerns expressed by interested stakeholders. Modernizing CLIA oversight will support laboratory advances in clinical care, including infectious disease detection and treatment,

newborn screening, and precision medicine in oncology, as clinically validated discovery and innovation continues to develop rapidly.

Imposing an entirely new regulatory regime on health care providers, the health care system, and patients will deplete limited resources needed to strengthen existing requirements and inevitably constrict access to essential testing services as many public health, community, and academic laboratories would find switching to a new regime cost-prohibitive. In addition, approaches that do not account for the particular needs of the public health laboratories and the network of sentinel laboratories, which provide detection on the frontline of clinical care, endanger communities, regions, and ultimately the health of the nation. Equally concerning, a new regime would unnecessarily constrict the number of new tests providers are able to develop and offer patients, directly impacting access to breakthrough treatments and medical innovation. In short, legislative and regulatory proposals 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 appreciate your leadership and efforts to evaluate and modernize the oversight of laboratories where clinical testing services and procedures are performed. We understand the complexities of this issue and look forward to working with the Committees to ensure that appropriately tailored reforms are implemented so that patients continue to have access to medically necessary laboratory testing procedures and future advancements in testing and patient care are not stifled.

Sincerely,

American Medical Association
American Association of Bioanalysts
American College of Medical Genetics and Genomics
Association for Molecular Pathology
American Society for Clinical Pathology
Bioreference Laboratory
Infectious Diseases Society of America
National Independent Laboratory Association