September 9, 2014

The Honorable Joseph Pitts
Chairman
House Energy and Commerce Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Subcommittee on Health
U.S. House of Representatives
2415 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone:

On behalf of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), representing independent community and regional clinical laboratories, we thank you for holding today's hearing, "21st Century Cures: Examining the Regulation of Laboratory Developed Tests."

AAB administers one of the nation's largest full-service proficiency testing programs approved by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Centers for Medicaid and Medicare Service (CMS), and all state agencies to satisfy laboratory proficiency testing requirements. NILA's members are community-based laboratories that range in size from intra-state to multi-state regional community laboratories. In addition to providing diagnostic laboratory services relied on by physicians across the country every day, a number of AAB and NILA members are engaged in the development of laboratory tests that provide patients and their physicians access to safe and effective testing options.

Laboratory Developed Tests (LDTs) offer patients the potential to prevent disease, obtain early diagnoses, and receive the most accurate and best course of treatment from their health care provider. Any regulatory process to oversee LDTs must incorporate the promise these tests hold without stifling innovation, while simultaneously ensuring that patient safety remains paramount. Physicians must be able to rely on and trust the results provided from an LDT to make the best clinical decisions for patients.

As health care providers and as providers of federal and state approved proficiency testing, AAB and NILA strongly believe that LDT technology must be accurate, reliable and reproducible, and that the primary goal of regulatory oversight of LDTs should be to avoid potentially life-altering or life-threatening implications from an inaccurate or misleading test result.

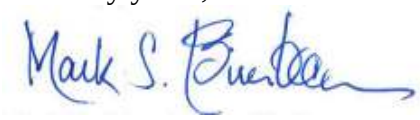
Since 1988, the clinical laboratory industry has been regulated through CLIA (P.L. 100-578) by CMS, an agency program that understands and has direct experience with laboratory testing. Additional oversight of laboratory testing is provided by the College of American Pathologists, the Joint Commission on Accreditation of Healthcare Organizations, and other accrediting organizations "deemed" by the government to provide such oversight.

The current CLIA regulatory framework was designed over 22 years ago. Dramatic changes in clinical laboratory testing have occurred since then and will continue to occur at a rapid pace. As a result, elements of CLIA's regulatory framework need to be updated and modernized to better address LDTs and emerging disciplines such as genomics, proteomics, and pharmacogenetics. We believe Congress should ensure that CLIA has the resources, technical expertise, and flexibility to provide, enforce, and maintain a 21st Century regulatory system for LDTs and other emerging disciplines.

AAB and NILA are committed to working with the Committee, the federal agencies, and the patient community to address these challenges. It is important that we collaborate to ensure that a fair and sustainable regulatory process is in place to assess the quality and safety of LDTs while allowing for continued innovation.

Thank you again for today's subcommittee hearing on this important issue. We applaud the Committee's focus and work on the 21st Century Cures Initiative. Clinical laboratories should be viewed as a central partner in advancing clinical care and reducing health care costs. We look forward to continuing to work with you. Should you have any questions, or require additional information, please contact Julie Scott Allen, our Washington representative, at (202) 230-5126 or julie.allen@dbr.com.

Sincerely yours,



Mark S. Birenbaum, Ph.D.
Administrator

cc: Committee Members