American
Clinical Laboratory
Association

June 1, 2014

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Via Electronic Mail to: Cures@house.mail.gov

Re: Request for Information (RFI) Regarding the May 1, 2014 Energy and Commerce Committee White Paper, *21st Century Cures: A Call to Action*

Dear Chairman Upton and Representative DeGette:

The American Clinical Laboratory Association (ACLA) applauds the Energy and Commerce Committee for undertaking the 21st Century Cures initiative. ACLA shares the Committee's goal of facilitating and accelerating the pace of biomedical innovation to ensure the United States remains a world leader in health care and patients have access to more effective and higher quality care. Laboratory diagnostics are an essential component to providing the most effective and highest quality care and ACLA is eager to participate in the 21st Century Cures discussion.

ACLA is a not-for-profit association representing the nation's leading providers of clinical laboratory services, including national, regional and esoteric laboratories, as well as academic medical centers throughout the United States. ACLA member laboratories are centers of diagnostic innovation, and conduct billions of laboratory tests each year which empower patients and their physicians to diagnose and treat countless diseases and medical conditions.

From a clinical standpoint, clinical laboratory diagnostic services furnish patient-specific clinical information that guides more than 70% of all medical decisions made by health care providers. Clinical laboratory tests provide objective information on the functioning of the human body, so that patients can be diagnosed, treated, or monitored accurately, precisely and as quickly as possible. The information provided by these tests, which are performed on samples of a patient's tissues or fluids, provide the necessary data for physicians to make informed decisions and best direct patient care.

Over the last few decades, laboratory medicine has seen many exciting advances in the areas of cancer, infectious disease, rare disease, and numerous other health conditions, which are helping us to realize the goal of personalized medicine. These advances have fundamentally changed our understanding of the mechanisms of disease, enabling physicians to diagnose conditions more precisely, detect the onset of disease earlier, target patient treatments more effectively, monitor disease progression, and predict individual predisposition to disease due to genetic or molecular factors. Simply put, clinical laboratory services are providing more accurate diagnoses, quicker; allowing physicians and patients to choose the best treatment, first and sooner; and, in the process, increasing the quality of life, lowering costs, and saving lives.

America's clinical laboratories are complex health care operations staffed by highly skilled and specialized pathologists, geneticists, laboratorians and technicians operating in highly controlled environments. Patient specimen samples sent to labs require time-sensitive preservation, transport, and handling. Lab results, assessments, and interpretations need to be transmitted to physicians promptly and, recently due to new regulations, made accessible to patients in secure, HIPAA-compliant formats. Further, no single laboratory provides every known laboratory service; thus, labs partner and collaborate with each other both regionally and nationally so that *all* laboratory services are ultimately available for patients.

To accomplish these feats with high quality reliability, lab facilities, personnel, and the tests they provide are highly regulated under a three part framework consisting of federal regulations under the Clinical Laboratory Improvement Amendments (CLIA), state laws, and accreditation by deemed authorities such as the College of American Pathologists. This regulatory framework requires both extensive validation and oversight to ensure quality of diagnostic services, yet allows laboratories the flexibility to develop and validate lab tests quickly and, thus, more quickly adopt new scientific knowledge and rapidly respond to unmet public health needs.

Operating this way, laboratory medicine and innovation, as we know it, allowed laboratories in the 80's and 90's to find, characterize, and keep pace with the rapidly mutating HIV virus so that drugs could be designed, their effectiveness measured, and the disease transformed from a death sentence to a more manageable condition. Laboratory medicine and innovation has provided greater certainty to managing chronic health risks and conditions such as stroke, heart disease, and diabetes. Laboratory medicine and innovation *is* allowing for breast and other cancers to be differentiated at the genetic and molecular level into multiple disease subcategories and, thus, allow physicians and patients to eliminate ineffective, unnecessary, even harmful treatments, and select more targeted therapies to better affect patient outcomes.

Like other health care sectors, the clinical laboratory industry faces pressure from all sides, whether for lower prices and less robust insurance coverage of services or whether from calls for increased, even duplicative oversight and overly cumbersome standards for introducing innovative new technology and medical knowledge. Unlike other health care sectors, however, laboratory services do not "act on" the patient and, in fact, the laboratory will often not even encounter the patient in-person. Whereas a drug is absorbed, a pace-maker inserted, or even a surgeon operates on the patient, the lab analyzes and quantifies samples *removed from* the patient so that these other, more direct health care interventions can be weighed, assessed, and decided upon by the physician and patient.

Grounded in our long history of innovation and commitment to patient care, ACLA looks forward to partnering with the Energy and Commerce Committee and other stakeholders to highlight the critical role of clinical laboratory services in increasing health care value and advancing innovation. We are committed to working with you to ensure patients have access to ever higher quality health care.

Sincerely,

Alan Mertz
President, ACLA