November 16, 2015

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

The Honorable Fred Upton
Chairman, 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

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

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

On behalf of the undersigned organizations and laboratory directors, we are writing to urge Congress to enact legislation to modernize the laws that enable oversight of clinical laboratory diagnostics, including laboratory developed test (LDTs) services and *in vitro* diagnostic (IVD) test kits. Both the Senate Committee on Health, Education, Labor and Pension (HELP) and the House Committee on Energy and Commerce (E&C) have demonstrated dedicated leadership on the critical issue of clinical laboratory diagnostics through extensive stakeholder engagement. We believe your leadership has created the opportunity to enact legislation to ensure our nation's patients continue to have robust access to innovative and high quality clinical laboratory diagnostics.

As you are aware, clinical laboratory diagnostics are a vital component of health care impacting the overwhelming majority of patients across the country. Every day, laboratory physicians and practitioners employ innovative diagnostic technologies, methods, and knowledge to deliver critical and life-saving clinical information to assist physicians and patients in diagnosing, assessing, preventing and treating diseases and conditions. The unlocking of the human genome has allowed diagnostic innovation to boom over the past two decades leading to precision medicine tests with higher accuracy, precision, and predictive ability.

These more specific and personalized diagnostics allow for earlier and in many cases preventive clinical interventions which ultimately reduce the cost of care, increase the patient's quality of care, and can save lives. Whether in the context of 21st Century Cures, Innovation for Healthier Americans, or the President's own Precision Medicine Initiative, the furtherance of innovation in clinical laboratory diagnostics is vital to our shared goals of bending the cost curve in health care and a healthier America.

These goals, however, are in danger as innovation is far outpacing federal regulations based on statutes that in the case of FDA are nearly four decades old, and in the case of CLIA are almost three decades old. These statutes were enacted at a time when the rapid advances in

personalized medicine, and critical importance of advanced diagnostic tests could not have been foreseen. The 2014 FDA draft guidance documents proposing to regulate LDTs as medical devices show the problematic limits of current oversight. The guidance proposals threaten both current access to, and the future development of, tests that impact the care of all Americans. We believe that allowing FDA to move forward with finalizing the draft guidance documents is the wrong approach and legislation is needed in lieu of the FDA guidance.

The ensuing conflict between innovation and access on one side and the need for oversight on the other has led to numerous proposals for reform over the past year. The proposals vary in approach and breadth, but collectively they prove that the underlying statutes are deeply in need of modernization through Congressional action.

We, the undersigned, believe that with your help and leadership, stakeholders can reach consensus on a modernized statutory framework to oversee clinical laboratory diagnostics that ensures patients have access to innovative and high quality diagnostic services. We urge you and the rest of your colleagues in Congress to advance reform legislation; we pledge to work with Congress and the Administration to achieve enactment.

Sincerely,

Organizations & Stakeholder Groups
American Clinical Laboratory Association
California Clinical Laboratory Association
Coalition for 21st Century Medicine

Laboratory Directors
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