

September 20, 2016



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

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

Dear Senators Alexander and Murray:

On behalf of the American Clinical Laboratory Association (ACLA), I am writing to applaud the Senate Committee on Health, Education, Labor and Pensions (HELP) for holding today's hearing, "Laboratory Testing in the Era of Precision Medicine." Clinical laboratories and the laboratory testing services they provide are critical to increasing the quality of care available to patients. Whether for genotyping cancer, preventing or treating chronic disease, keeping pace with infectious disease and innumerable other disease states, laboratory test services, including laboratory developed tests (LDTs) are vital tools to assist physicians and patients in making diagnosis and treatment decisions, as the Committee's hearing will no doubt demonstrate.

ACLA continues to be committed to working with the Senate HELP Committee, the House Energy & Commerce Committee, the Administration and other stakeholders on developing and enacting comprehensive reform of LDT oversight to ensure our nation's patients continue to have robust access to innovative and high quality clinical laboratory diagnostics. Robust innovation has occurred under the current statutory framework, primarily the Clinical Laboratory Improvement Amendments (CLIA). However, the statute predates the Human Genome Project and our current understanding of molecular and genetic medicine by decades. Accordingly, ACLA has long supported modernizing the regulatory framework that oversees LDTs while making sure we do not hamper continued innovation that has been a major catalyst for the Precision Medicine revolution.

To assist in developing comprehensive reform, ACLA supports the following key principles as necessary for any new, workable statutory framework:

1. LDTs are not Devices: LDTs are not medical devices and cannot be regulated, listed, or designated as such. Accordingly, any new framework to regulate LDTs or laboratories shall be implemented by a diagnostic-specific authority (such as a diagnostic-specific center within a designated agency) and not an authority otherwise charged with medical device regulation or other medical product regulation;
2. Grandfathering and Transition: LDTs introduced prior to enactment must be grandfathered from any premarket review or design control requirements, and laboratories must be granted a reasonable transition period after enactment to come into compliance with any new applicable requirements;
3. Preemption: Any new federal framework for LDT and laboratory oversight shall preempt state requirements addressing the same subject matter;

4. Evidence Standards: The standard for approval, clearance, or marketing of a test must be based on a rational assessment of the test's analytical validity and clinical validity and not be based on the medical device standard of "safe and effective". Also, clinical trials are presumed not to be required;
5. Modifications: Agency review of modifications to an already marketed test (including grandfathered tests) should be limited to only those modifications which have a meaningful clinical impact or significantly modify the test's intended use after validation and verification;
6. Labeling: Labeling requirements applicable to laboratories will be limited to reasonable requirements appropriate for laboratory protocols, for instance not requiring a label to be affixed to the physical elements of a test where those elements are not distributed to another facility or third party. Legitimate scientific or medical exchanges or discussions will not constitute labeling or constitute a change in intended use;
7. Rulemaking: Implementation of any new framework must be carried out in a transparent process that includes formal notice and public comment;
8. Fees: Any fees associated with the new framework must reasonably take into account the resources necessary to implement the framework in addition to the impact on the entities from which the fees will be assessed. Fees paid for oversight of laboratory operations shall be credited towards any additional fees assessed for oversight of test development;
9. Duplication: Statutory and regulatory provisions developed under the new framework shall be designed to avoid duplication of oversight of test development and laboratory operations so as to ensure continued robust patient access to high quality clinical laboratory services;
10. Innovation: Any new federal framework should drive patient access to cutting-edge, high quality, and accurate diagnostics through incentivizing the development of novel tests, taking into account the time and resources required for the research, development, and commercialization of diagnostics.

ACLA applauds the Senate HELP Committee for recognizing the critical role of clinical laboratories and the laboratory services they provide. With leadership by the Senate HELP Committee and the House Energy & Commerce Committee, ACLA believes the goal of a new framework is within reach and ACLA is ready to fully contribute to this effort.

Sincerely,



Alan Mertz
President