



September 19, 2016

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

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

Dear Chairman Alexander and Ranking Member Murray:

The American Association of Clinical Chemistry (AACC) appreciates your continued interest and active involvement in the ongoing policy debate involving the regulation of laboratory developed tests (LDTs). We have shared our views with committee staff in meetings over the past few years, and we remain committed to serving as a resource on this important issue.

AACC members work in a variety of healthcare institutions, including Vanderbilt University Medical Center and Sacred Heart Hospital in Spokane, where they are routinely called upon to develop timely, accurate, and reliable LDTs to treat patients. Quite often the test is needed because there is no existing commercial test that meets current clinical needs.

AACC realizes that this is a complex issue that involves many stakeholders with differing opinions and interests. As an organization that includes a variety of these interests within its membership, AACC offers a unique consensus developed from robust discussions among individuals with slightly differing views. I am attaching two policy statements that our Association developed on this issue that I hope may assist you in Tuesday's hearing, where you once more will grapple with this issue.

The first position statement discusses the impact of LDTs on the broader healthcare community and patient care <https://www.aacc.org/health-and-science-policy/advocacy/position-statements/2014/oversight-of-laboratory-developed-tests>, while the second document focuses on specific improvements to the regulations implementing the Clinical Laboratory Improvement Amendments (CLIA) <https://www.aacc.org/health-and-science-policy/advocacy/position-statements/2016/modernization-of-clia> that may address some of the concerns raised by various groups.

AACC looks forward to working with you on this issue. If you would like to learn more about AACC's positions, or if we can help in any other way as you sort through this complicated issue, please contact AACC Director of Government Affairs Vince Stine, PhD, at vstine@aacc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia M. Jones".

Patricia M. Jones, PhD, DABCC, FACB
President, AACC