



Better health through
laboratory medicine.

March 27, 2020

The Honorable Rand Paul
United States Senate
167 Russell Office Building
Washington, DC 20510

Dear Senator Paul,

The American Association for Clinical Chemistry (AACC) endorses S.3512, the Verified Innovative Testing in American Laboratories (VITAL) Act, which would codify current federal regulations that place oversight of laboratory developed tests (LDTs) under the Clinical Laboratory Improvement Amendments administered by the Centers for Medicare and Medicaid Services (CMS). In recent years, there have been legislative efforts to usurp CMS authority and create a duplicative regulatory structure for LDTs within the Food and Drug Administration (FDA).

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

AACC agrees that the increase in the number and complexity of LDTs may warrant a fresh assessment of the regulatory and professional oversight for these tests. Although we agree some adjustments may be necessary, we believe that the current CLIA oversight structure is adequate to address any concerns regarding LDTs and that a major change in policy is unwarranted.

There appears to be a misconception that because the FDA is using its “enforcement discretion” regarding LDTs that these tests are unregulated. This belief is inaccurate. Currently, all laboratories performing LDTs are regulated under CLIA. These testing facilities are categorized as high complexity laboratories, subject to stringent personnel, quality control and proficiency testing requirements as well as regular inspections.

The FDA regulatory structure is designed for medical device manufacturers, not clinical laboratories. Laboratories occasionally modify FDA-cleared or approved tests or develop new in-house tests to meet specific clinical needs. The results from these tests are used to diagnose and treat patients and are also regulated under CLIA. To add FDA requirements to clinical laboratories utilizing these tests will stifle innovation and hinder patient access to testing, as

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occurred recently when the FDA became involved in LDT oversight during the outset of the COVID-19 public health emergency. AACC believes that S.3512 will prevent such a re-occurrence in the future.

We look forward to working with you on this most important issue. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at dstine@aacc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Carmen Wiley", with a stylized flourish at the end.

Carmen L. Wiley, PhD, DABCC, FAACC
President, AACC