



Better health through
laboratory medicine.

April 6, 2017

Congressman Larry Bucshon
U.S. House of Representatives
1005 Longworth House Office Bldg.
Washington, DC 20515

Congresswoman Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Bldg.
Washington, DC 20515

Re: Laboratory Developed Tests and The Diagnostic Accuracy and Innovation Act

Dear Representatives Bucshon and DeGette,

On behalf of the American Association for Clinical Chemistry (AACC), representing many of the nation's leading laboratory professionals and other diagnostic leaders, I thank you for the opportunity to comment on the recently released draft legislation entitled "The Diagnostic Accuracy and Innovation Act." AACC appreciates your efforts on this important issue as our society represents the clinical professionals who routinely perform LDTs in pursuit of the best possible patient care.

After careful review, AACC has concerns that this proposal may result in negative consequences for patients and the clinical healthcare teams and medical institutions that rely on accurate and timely laboratory results to make critical, immediate, and frequently lifesaving decisions in the course of patient care. AACC is concerned that without further refinement, the present legislative proposal outlined in the Diagnostic Accuracy and Innovation Act (DAIA) will:

- Foster an anti-competitive environment;
- Stifle test innovation; and
- Hinder patient care.

AACC has long supported federal oversight of LDTs. These tests are currently regulated by the Centers for Medicare and Medicaid Services (CMS) and its deemed private accrediting organizations under the Clinical Laboratory Improvement Amendments (CLIA). We are concerned that the proposed changes will be substantive and costly despite the lack of evidence that current processes are insufficient. Further, under the draft legislation, the FDA—which has no experience regulating laboratory practices—would supplant CMS as the federal agency overseeing laboratory developed tests. Based on AACC's recent review of the proposed draft LDT legislation, our organization submits for your consideration the following patient-focused policy recommendations:

Our overriding concern is that DAIA is based on the misguided assumption that LDTs are comparable to medical devices. Whereas the FDA clears and approves test kits to be used in a variety of medical settings by a diverse group of health care personnel, LDTs can only be developed and performed by high complexity CLIA laboratories under the direction of highly trained and experienced personnel. Although each is invaluable to patient care, LDTs and IVD medical devices are distinctly different tools in the healthcare process and as such they need to be discussed and regulated differently. AACC recommends that Congress utilize the existing CLIA regulatory framework to address concerns regarding LDT oversight rather than creating a new one. These established standards could be easily adapted, eliminating the need for new regulatory mechanisms. What follows is a limited list of suggested policy changes that could be accomplished through the existing regulatory model:

Notification and Listing of LDTs

The draft legislation would require that laboratories performing LDTs notify the FDA that they are performing such tests and provide a listing of the tests. CMS would be the more logical, readily available repository for this information and already has in place a mechanism for addressing the issue. All CLIA laboratories must submit a laboratory activity list to the agency that includes all the tests it performs, including LDTs, as well as the methodologies utilized.

The College of American Pathologists (CAP), a key private accrediting body, requires that laboratories provide a specific list of all LDTs they perform. Any additional information could be gathered under the current regulatory framework.

Validation of LDTs

AACC agrees that clinical laboratories using LDTs should demonstrate the analytical and clinical validity of the test prior to its use. Updates or modifications to the validation process should take place within the CLIA framework.

CLIA requires laboratories performing LDTs to document the analytical validity of the test. Most laboratories utilizing LDTs voluntarily obtain accreditation from more rigorous CLIA accrediting organizations, such as CAP and the Joint Commission, that require laboratories to also demonstrate the clinical validity of LDTs.

Classification and Prioritization of LDTs

Like you, AACC supports the use of a risk-based approach for stratifying LDTs and determining the appropriate level of oversight. We agree that modifications to an FDA cleared or approved test kit should not automatically result in additional regulatory oversight. Certain categories of tests, such as newborn screening and testing for unmet needs and public emergency testing, do not require greater regulatory scrutiny.

AACC supports a risk-based classification approach for determining the level of oversight for LDTs. This regulatory scheme should include three categories: high, moderate, and low risk. Moderate and low risk LDTs—which would represent the vast majority of such tests— should remain exclusively under CLIA.

Tests in the high-risk category—for example LDTs for which significant proprietary information limits the ability to independently verify the accuracy of the test, and direct-to-consumer tests for which the absence of professional consultation/interpretation could lead to serious patient harm—should be jointly regulated by FDA and CMS.

Reporting Testing Errors

Clinical laboratories work diligently to provide laboratory test results that meet the customer expectations the great majority of the time. When a laboratory identifies that a testing error has occurred, it should report that mistake to the appropriate oversight body.

According to a scheme in which high-risk tests are under dual regulation, adverse events involving these tests would be reported to the FDA and CMS. Errors involving low and moderate risk tests would remain under the current CLIA reporting structure, which requires laboratories to document and report the errors to CMS and the appropriate accrediting bodies, the organization's risk management department, and the physician.

Concerns with the Role of the FDA

The legislative proposal would grant the FDA powers to inspect laboratories and force them to meet new post-market reporting requirements that essentially redefine hospitals, commercial laboratories, and physician office laboratories performing LDTs as medical device manufacturers. DAIA would grant complete authority to the FDA for overseeing the development, introduction and validation of LDTs, including assessing the analytical validity of a test—a current responsibility of CMS. In addition, any modification of LDTs would need to be reported to the agency, in many cases subject to prior approval.

AACC is concerned that a new dual regulatory structure for laboratories performing LDTs as defined in the draft legislation will stifle test innovation, particularly developing areas of testing such as those used in precision medicine, and force many hospitals and rural testing facilities to stop performing LDTs, thus limiting patient access to testing.

Most importantly, clinical laboratories are not medical device manufacturers and cannot afford the additional regulatory and financial costs associated with this draft legislation. As proposed, the current legislative draft could result in an anti-competitive system that favors

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the few laboratories with sufficient resources to comply with FDA requirements that were developed for manufacturers, thereby creating a situation wherein testing costs could rise. Our interpretation of the draft bill is that it will eliminate the 510(k) clearance and pre-market approval processes for tests developed and marketed by in vitro diagnostic (IVD) manufacturers. This proposal would be a significant change from the current review process. While AACC agrees that Congress should perhaps explore reforms to this area, this manufacturing issue is entirely separate from the regulation of tests developed and performed in individual clinical laboratories. Any change in the IVD company submission process should be considered separately from LDT oversight.

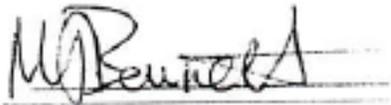
Summary

AACC believes the current regulatory structure can be modified to address concerns regarding LDTs, without introducing costly, burdensome dual oversight for which there is neither evidence of need nor proof of improvement over the current system. The vast majority of LDTs should remain under direct CMS oversight with a small number of high-risk tests jointly overseen by both CMS and FDA. We are concerned that the current draft legislation will greatly restrict the ability of clinical laboratories to develop and provide the tests needed to care for their patients, will diminish the number of laboratories with the resources to do so, and significantly hinder patient care and access to testing.

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 progressing laboratory science. Since 1948, AACC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation.

On behalf of AACC, I would like to thank you for the opportunity to provide comments to the subcommittee on this most important issue. If you have any questions, please do not hesitate to contact Vince Stine, PhD, Director of Government Affairs, at vstine@acc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Bennett". The signature is written in a cursive style and is positioned above a horizontal line.

Michael J. Bennett PhD, FRCPath, FACB, DABCC
President, AACC