November 5, 2021

The Honorable Richard Burr
U.S. Senate
217 Russell Senate Office Building
Washington, DC 20510

The Honorable Michael Bennet
U.S. Senate
261 Russell Senate Office Building
Washington, DC 20510

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Dear Senators Burr and Bennet and Representatives DeGette and Bucshon,

The American Association for Clinical Chemistry (AACC) offers its initial comments on the *Verifying Accurate, Leading-edge IVCT Development (VALID) Act*, which would establish a new model for regulating in vitro diagnostic (IVD) test kits and laboratory developed tests (LDTs). While AACC supports your efforts to streamline and reform the medical device review process, we do not believe that LDTs belong in this legislative package.

Current Regulatory System

AACC agrees that increases in the number and complexity of LDTs may necessitate a review of the regulations governing these critically important clinical testing services. When Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, it established a mechanism for conducting such an assessment. Administered by the Centers for Medicare and Medicaid Services (CMS), CLIA provides a robust framework within which the agency oversees laboratory testing. CMS, with public input, created stringent federal standards that regulate laboratory testing, including LDTs. These standards include rigorous personnel, quality control and proficiency testing requirements; regular inspections; and required corrective actions, if necessary.

In addition, many of the testing facilities that perform LDTs actively participate in the New York State, Joint Commission, College of American Pathologists (CAP) or other oversight programs, where they must meet requirements even more stringent than CLIA. AACC is concerned that expanding oversight to include the Food and Drug Administration (FDA) will divert limited laboratory resources from the provision of care to new, duplicative administrative requirements. The additional costs associated with this bill may force many laboratories providing LDTs to discontinue this vital patient service.

It is important to note that the FDA regulatory structure is designed for medical device manufacturers, not clinical laboratories. Manufacturers develop IVD instruments and test kits to assist laboratories; laboratories create LDTs to help physicians when no comprehensive IVD product is available for a particular condition or purpose. The number of labs permitted to perform LDTs is limited to a relatively small number of highly equipped laboratories with well-trained personnel. The FDA estimates that roughly 11,000 (or approximately four percent) of laboratories are eligible to perform LDTs.

AACC supports modernizing both the IVD and LDT regulatory processes, but through distinct approaches that optimize the regulation of each. While VALID identifies many proposals that may improve the effectiveness and efficiency of the IVD review process, the same proposals would cause irreparable damage if applied to LDTs. AACC urges that any refinements to the regulation of LDTs be discussed and acted upon within the Clinical Laboratory Improvement Advisory Committee (CLIAC), which is the federal advisory body that guides CMS on changes to the CLIA standards.

There are several provisions within VALID that we believe could limit physician and patient access to state-of-the art LDTs:

Grandfathering of LDTs and Maintaining Innovative LDTs
One of the strengths of the current regulatory process is that it encourages healthcare providers to continually update and improve the LDTs they perform. We support the continuation of this practice as permitted under CLIA. VALID proposes to grandfather LDTs that are performed prior to a certain date from having to comply with premarket review requirements. While we appreciate the intent of the provision to permit continued access, we are concerned that if enacted, it may have unintended consequences, such as stifling innovation.

The clinical laboratory community has historically been quick to respond to changing clinical and service demands, such as meeting the need for more sensitive and specific tests and filling the gaps when FDA-cleared or approved commercial tests are unavailable. AACC is concerned that grandfathering may discourage labs from modifying their LDTs or introducing new and better testing services to replace grandfathered tests, since they would then be subject of additional oversight.

Technology Certification
VALID proposes a technology certification provision that would allow an individual, if they meet certain criteria, to introduce tests without going through the premarket review process. The wording of this section is confusing as it applies to clinical laboratories. This section seems to require a single individual (i.e., test developer) to apply for technology certification. It is unclear whether the "test developer" can be an individual, a laboratory or a manufacturer. Regardless of whether the intent of the bill is to focus on the individual or the entity, the technology certification process appears to be nearly as cumbersome and costly, from a clinical

laboratory perspective, as the existing 510(k) review process. Few, if any hospital laboratories, would be able to comply with this requirement.

Adverse Event Reporting

The FDA document states that test developers shall "establish and maintain" a reporting system that notifies the agency of adverse events quarterly. AACC does not believe the adverse event framework, which was developed for reporting problems involving medical devices, is appropriate for services provided by clinical laboratories. Results from LDTs do not generally result or contribute to the death or severe injury of a patient. During a January 2015 FDA Public Workshop on LDTs, the Mayo Clinic reported that over the previous five years it had conducted more than 2.5 million LDT-based tests without a single sentinel event (The Joint Commission defines a sentinel event as a safety event that results in death or permanent harm to the patient).

One reason for the overall safety of LDTs is that laboratories implement internal quality controls that detect many analytical and pre-analytical errors and prevent inaccurate results from being reported. The current CLIA regulatory framework also requires laboratories to identify, document and perform corrective measures for any laboratory errors, and this would include errors resulting in patient harm if they were to occur. This documentation is reviewed on a regular basis by a CLIA inspector or its accrediting bodies. The current CLIA process could be modified to recommend that when a laboratory identifies a testing error it should report that mistake to the appropriate oversight body. This does not require legislative action.

User Fees

The bill would create a new user fee program that can be applied to laboratories performing LDTs. Reimbursement for clinical laboratories is being cut dramatically under the Protecting Access to Medicare Act, while at the same time, testing facilities must pay registration and accreditation fees under CLIA, as well as incur the costs of on-site inspections and frequent proficiency testing to demonstrate performance. The regulatory requirements outlined in this measure, along with the additional costs, would assure that only a few laboratories would continue to offer LDTs. Unfortunately, this outcome would stifle innovation and harm patient care. While we support your efforts to reform the broader medical device review process, AACC believes that LDTs should remain under CLIA and that improvements should occur within the existing process established by Congress.

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.

On behalf of AACC, I would like to thank you for the opportunity to provide comments on this legislation. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

Stephen R. Master, MD, PhD
President, AACC