COLORADO BIOSCIENCE ASSOCIATION

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July 24, 2020

The Honorable Michael Bennet
United States Senate
261 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
United States Senate
217 Russell Senate Office Building
Washington, DC 20510

The Honorable Larry Bucshon, MD
United States House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

Dear Senator Bennet, Senator Burr, Representative Bucshon, and Representative DeGette,

On behalf of the Colorado BioScience Association and our members, thank you for the opportunity to provide comments on the Verifying Accurate Leading-edge IVCT Development (VALID) Act.

Colorado BioScience Association (CBSA) represents over 720 life sciences organizations across Colorado that drive innovations, products, and services to improve and save lives. Our state is the center for life sciences in the Rocky Mountain Region, directly employing over 32,000 people and spinning out an average of 20 new life sciences companies each year. The industry is largely comprised of small, early-stage companies that play a crucial role in the development of new diagnostic testing and targeted treatments that are leading to improved patient outcomes and reduced health care costs.

CBSA applauds your leadership in working to enact comprehensive diagnostic regulatory reform. We believe a modern, risk-based framework will be critical to ensure a consistent and predictable pathway for all IVCT developers and to promote public health and diagnostic innovation. We recognize what a significant undertaking this has been over the course of many years to develop a framework that can keep up with the pace of innovation, and we appreciate your willingness to work with a variety of stakeholders to make meaningful improvements to the bill. We offer comments to convey important questions raised by our members and ensure there is consistency, transparency, and flexibility in any new regulatory framework.

Our comments address the following key areas:

1. Clarification of Key Terms
2. Consistent Application of a Risk-Based Approach
3. Meaningful and Sustainable Technology Certification Program
4. Harmonization of VALID Act Framework with Clinical Laboratory Improvement Amendments
5. Impact on Diagnostic Reimbursement

Clarification of Key Terms

We have provided comments for terms in the 'definitions' section to clarify their meaning and ensure that the appropriate oversight is applied for different test technologies, based on their level of risk and potential impact on public health.

> *First of a Kind (FoaK):* We recommend clarifying in the definition of FoaK whether the intended use and elements from (10) need to differ from one specific IVCT that is already legally available or if the intended use of one IVCT can be combined with elements from (10) of a different IVCT to therefore not be considered FoaK.
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> *Low-Risk:* The breadth of tests that would fall under low-risk is incredibly broad, as both high-risk tests with mitigating measures as well as tests that are low-risk without mitigating measures would all fall under the same classification. We recommend or propose a "middle class" for tests that would be high-risk in the absence of the mitigating measures, in order for the agency to be able to focus on these for guidance on mitigating measures and additional controls.

Consistent Application of a Risk-Based Approach

CBSA supports a risk-based approach to IVCT review that ensures accurate and high-quality testing, while continuing to foster innovation and preserve patient access. As currently written, the bill only defines two risk categories: high-risk and low-risk and affords FDA broad discretion about how to apply those categories. For a risk-based classification system to be meaningful, the risk levels must be adequately defined, and it must be clear how that system will be applied. We do not believe this is achieved through the legislation, and we are concerned it will force every developer to do a pre-submission to determine the appropriate pathway, leading to significant delays. We suggest applying a risk-based approach more consistently, so no category automatically requires review, but rather undergoes a risk-based evaluation to determine its review pathway. Additionally, while we appreciate the inclusion of a re-designation process for certain types of tests, we urge you to consider a more flexible approach that could take place as part of the developer's submission, rather than after the test is on the market.

Meaningful and Sustainable Technology Certification Program

CBSA supports the concept of technology certification as part of a new regulatory framework for diagnostics, and we see potential in a thoughtfully constructed pathway that can demonstrate high quality testing, while advancing a least burdensome approach for IVCT development. Our biggest priority in this area is ensuring that certain test types are not preemptively excluded from the technology certification program. We appreciate changes in the bill that allow certain excluded categories to be deemed eligible by the FDA through a re-designation process, but there are still many categories that are automatically excluded. Our hope is that the process to qualify certain test categories will prove to be nimble and over time, more tests will be made eligible.

Harmonization of VALID Act Framework with Clinical Laboratory Improvement Amendments

While we acknowledge provisions in the bill that seek to eliminate the potential for duplication of Clinical Laboratory Improvement Amendments (CLIA) requirements for any regulated IVCTs, we remain concerned about potential conflicts or redundancies, particularly for in vitro diagnostic manufacturers that also operate their own high-complexity CLIA lab. It is not clear through the legislation if such companies would need to satisfy different quality management system requirements for purchasing controls, acceptance activities, CAPAs, and records to comply with both CLIA and the VALID Act. We encourage you to consider how these quality management system requirements could be harmonized to more effectively eliminate redundancies for all IVCT developers who are also laboratory operators.

Impact on Diagnostic Reimbursement

CBSA appreciates the extensive work to reform the regulatory framework for diagnostics, however, we also recognize that some of the most pressing challenges for diagnostic developers relate to the reimbursement system, specifically in obtaining affirmative coverage, appropriate coding, and value-based payment for novel diagnostics. The limitations of the current reimbursement system impact investment in innovative diagnostics and ultimately impede patient access to new technologies. While we understand this legislation is focused on regulatory reforms, we would also welcome the opportunity to provide feedback on the reimbursement challenges diagnostic companies are facing and work with you to develop potential solutions.

In closing, CBSA appreciates the opportunity to provide comments on this important piece of legislation. We look forward to working with you and other stakeholders to advance diagnostic reform that will foster innovation and protect patient access to accurate, high-quality testing.

Sincerely,

Jennifer Jones Paton
President & CEO
Colorado BioScience Association

Emily Roberts
Vice President
Colorado BioScience Association