COLLEGE of AMERICAN PATHOLOGISTS

August 23, 2021

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Richard Burr
217 Russell Senate office Building
Washington, DC 20510

The Honorable Larry Bucshon, M.D.
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Michael Bennett
261 Russell Senate Office Building
Washington, DC 20510

Dear Representatives Bucshon and DeGette, Senators Burr and Bennett:

The College of American Pathologists (CAP) appreciates the opportunity to provide some of our priorities for the latest version of the Verifying Accurate Leading-edge IVCT Development (VALID) Act. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The COVID-19 pandemic has highlighted the importance of diagnostic tests including how important they are to help track and trace the virus as well as identify those who need to be quarantined and treated. It also backs up the CAP belief that a regulatory approach for the oversight of LDTs should be flexible, build on the existing framework and institutional knowledge while limiting intrusions and compliance burdens on laboratories. We support an approach that leaves the Clinical Laboratory Improvement Amendments (CLIA) out of the picture and uses the existing regulatory structures instead of creating new processes that could be costly and burdensome to laboratories, especially those with limited resources.

The approach outlined by the 2021 VALID Act continues to move in a positive direction, making fewer changes, but overall, providing flexibility the CAP believes will help the oversight process run more smoothly. We believe that VALID should not contain modernization of CLIA. While some of the new changes may help, we still worry that the FDA will have trouble meeting the demands of VALID at its current funding levels and support.

We appreciate the changes that were made from the last year's legislation. Several concerns we outlined in previous comments were addressed in some way. Changes to the high-risk and low risk definitions that include lowering the standard from premarket review for humanitarian exemption, including mitigating measures and requiring regulations within the Technology Certification section, and finally, moving up some of the implementation dates were all positive developments in the CAP's opinion. We still believe there are additional ways to refine VALID to be streamlined, nimbler, and less burdensome.

The COVID-19 pandemic and various changes stemming from it put our system through a test that brought some stark realities into view. The emergency use authorization (EUA) process, which we agree needed to be triggered, when coupled with the delayed FDA reviews, allowed the use of several tests with performance problems or tests that were poorly validated. The sheer volume of diagnostic tests created pressure on the FDA, producing varying results, and confusion for developers, health care professionals, and patients. In a sense we were trading test availability for test quality.

Combined with supply chain difficulties, it was almost impossible to get testing supplies, such as reagents, that are needed to run the tests. This slowed down response times and

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allowed people to unknowingly spread the virus, compounding the strain on the health system. Dr. Shuren and Dr. Stenzel suggested in the New England Journal of Medicine (NEJM) that "it would be more effective to authorize a small number of well-designed, well-developed, and validated tests run on common high-throughput platforms, followed by a few point-of-care tests, all of which are manufactured in high quantities…" We agree that this change would create less confusion, would focus efforts, and would provide safer and more accurate tests starting at the onset of a pandemic.

Finally, establishing statutory jurisdiction of LDT oversight is necessary to stop inter-agency tug of wars in the middle of a pandemic. We worry that without proper funding and support, the FDA will not be able to meet this enormous task in front of it.

Below are the CAP's main priorities for VALID:

1. Operationalization

The CAP seeks policies that avoid duplication and reduce burden throughout the system. Leveraging existing frameworks and limiting intrusions will only help laboratories run more smoothly. We appreciate the continued inclusion of reporting elements and will continue to push for reductions in regulatory burdens on laboratories. In the 2020 draft the CAP was happy to see operational aspects of the program addressed, including the use of a comprehensive test information system, and third-party accreditors to conduct reviews, inspections, and some regulatory reporting. One specific change allows an accredited person to perform the registration and listing function.

The CAP strongly supports the current draft's concept of the practice of medicine. We believe that codifying the term at the federal level would be overreach and thus, unnecessary. We also support the bill's idea of laboratory operations. We urge that both provisions stay as they are as legislation progresses. These areas are ripe for certain stakeholders to target and modify, which could make it more difficult for the CAP to support VALID.

The COVID-19 pandemic illustrated the need for legislation that provides clarity and oversight in this space. The CAP believes that an agreed upon framework would help streamline validation and improve test accuracy overall.

2. Risk classification

The CAP appreciates the continued changes to the technology certification – in the 2020 legislation the eligible categories were broadened and again in this iteration, more changes will make it less burdensome. The ability to streamline a test's approval without additional submissions is a step in the right direction, and the addition of mitigating measures for first-of-a-kind and direct-to-consumer tests to qualify for tech cert will help streamline several tests that would never be subject to additional review in the first place. We are also happy to see that the secretary will issue regulations for public comment instead of guidance so stakeholders may help shape the outcome.

We are, however, concerned about the potential regulatory burden the technology certification could require. We will continue to assert that the existing framework within CLIA be leveraged, ensuring the FDA framework does not duplicate submissions or intrusive visits. The CAP would like to see only the highest risk tests go through a premarket review process, lowering the burden on pathologists and labs. The system must work for not only the FDA, but for the labs and stakeholders using this system.

An IVCT is not high-risk if it meets some of the standards laid out in the new draft, but also having the availability of confirmatory or adjunctive tests or certain relevant materials standards. We still have some questions about the premarket requirements for these tests and exactly how the process will work. Are they exempt for pre-market review? Is there a streamlined process? Are they eligible for third-party review or precertification? Furthermore, we need to really flesh out and clarify the FDA's standard that will determine if something is "well characterized."

We continue to believe that the two-tiered system introduced in VALID will make it extremely difficult and time-consuming for laboratories to determine the regulatory requirements, particularly for mitigated high-risk tests. The CAP has long advocated for a three-tiered approach. We are working to better understand the risk categories for more regulatory certainty, and we encourage more changes along the lines of what the sponsors did in this language that will reduce the burden of complying with this program.

3. Modifications

The CAP continues to be concerned about Congress moving forward with such a prescriptive list in legislation. VALID leverages the premarket review process for any tests that make modifications that impact any test group criteria, change test performance, safety, were omitted from the original application change protocol, or meet the mitigating factors. The list of criteria is more extensive than proposed by DAIA or the CAP. As a result, many changes may require a new premarket application. The CAP 2009 Policy stipulates that reporting would be required for any modification to a Moderate Risk LDT or Low Risk LDT that results in a change to the intended use and has a Meaningful Clinical Impact. Meaningful Clinical Impact means with respect to a modification of an LDT, the potential to result in a change to the patient's diagnosis or the therapy delivered to the patient.

The CAP policy envisions a process where the laboratory would notify the Secretary or third-party accreditor of any such modification. The Secretary or third-party accreditor would then determine if the change would be subject to the pre-market review process set forth above for Moderate Risk LDTs. While this example involves low and moderate risk LDTs, the process remains important. We want to ensure that the burden on laboratories is kept as low as possible. It is also important for Congress to be cognizant of the fact that this field is one that changes quickly – setting prescriptive lists in legislative language can prove to be inflexible and cumbersome as the system evolves.

The CAP appreciates the opportunity to provide our views and priorities on the VALID Act. Please contact Michael Hurlbut, CAP Assistant Director, Legislation and Political Action at mhurlbu@cap.org if you have any questions on these comments.

Sincerely,

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President

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