



COLLEGE of AMERICAN PATHOLOGISTS

May 22, 2022

The Honorable Patty Murray
Chair
Health, Education, Labor, and
Pensions Committee
428 Dirksen SOB
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Health, Education, Labor, and
Pensions Committee
428 Dirksen SOB
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr:

The College of American Pathologists (CAP) appreciates the opportunity to respond to the discussion draft of the Verifying Accurate Leading-edge IVCT Development (VALID) Act, as included in the FDA Safety and Landmark Advancements (FDASLA) 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 CAP commends the hard work and dedication that you and your colleagues have devoted over the last four years to creating a comprehensive regulatory framework for the oversight of laboratory-developed tests (LDTs). Your bipartisan, bicameral approach to developing this legislation has been inclusive, open, and iterative allowing for ongoing input from a broad spectrum of stakeholders. The CAP also is pleased that the legislation provides for continuing stakeholder input, informally and formally in the rulemaking process, which as provided is a multi-year process.

The CAP would like to outline several aspects of the legislation that the CAP supports and identify areas where we believe the legislation and regulatory framework might be improved.

RISK CLASSIFICATION FRAMEWORK

The CAP has consistently advocated for a three-tiered, risk-based system to focus the FDA's resources on high-risk tests including LDTs, while leveraging existing structures, to improve and promote patient safety. The legislation "risk classification" framework is similar to the one recommended by the CAP and other groups.

High risk

The high-risk definition in this draft lines up closely to how the CAP would define a high-risk test and it does not include companion diagnostic (cross-referenced) tests. **The CAP supports this definition.**

Moderate risk

The CAP supports the reintroduction of a moderate-risk category and believes a three-tiered system, instead of the two-tiered system that was proposed in VALID 2021, provides more regulatory consistency and stability.

Low risk

The CAP definition of a low-risk test is similar to the legislative draft language. **The CAP can support the definition in the bill.**



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Mitigating measures

The CAP supports the use of mitigating measures that can be deployed to reclassify tests into appropriate categories while still protecting patient safety.

REGULATORY FRAMEWORK

Premarket review

Like the discussion draft, the CAP has pushed for a three-tiered approach with the FDA's oversight focused on high-risk tests, accreditors assisting with moderate risk tests, leveraging existing processes, and maintaining flexibility. **The CAP supports this provision.**

Exempted Categories

The CAP largely supports the exemptions described in the draft but would like the Committee to make two changes. First, the CAP asks that restrictions on the use of software for immediate or final interpretation be removed. Secondly, the CAP asks that the humanitarian exemption provision be amended so that the exemption is based on incidence rate, not number of tests performed.

Technology Certification

Since its introduction as precertification, the CAP developed general principles for Technology Certification that focus on avoiding duplication with CLIA and broader applicability. The CAP sees this as a potential pathway that is set up to reduce burden and use accreditors to decrease intrusions. We urge the Committee to ensure that the laboratories can use "accredited persons" to submit documentation for laboratories to the FDA.

Grandfathering

The CAP supports the grandfather provision in the discussion draft as it offers greater flexibility to laboratories by grandfathering LDTs currently in use while also providing patients with certainty and peace of mind that the FDA can intervene if necessary to review grandfathered tests currently in the market.

Test Design and Quality Requirements

The draft clarifies that FDA-regulated quality requirements are limited to only the design and manufacturing of IVCTs, and the Centers for Medicare and Medicaid Services (CMS) will continue to regulate laboratory operations under CLIA. **The CAP supports this provision.**

Accredited Person

The CAP supports the role of "Accredited Persons" outlined in the legislation. This draft broadens the role of accredited persons to perform inspections, premarket reviews, and technology certification reviews. We support this provision and urge the Committee to allow accreditors to submit documentation to the FDA for laboratories.

Collaborative Community

The CAP supports and appreciates additional opportunities for stakeholders to have input on risk classification and tests eligible for premarket review.



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Applicability

- **Duplication of CLIA: We strongly support** the inclusion of legislative language directing the FDA to avoid issuing or enforcing regulations that are duplicative of existing regulations or guidance under CLIA.
- **Scope of Practice: The CAP strongly supports** that the provision in the bill that specifically bars the FDA from infringing on the practice of medicine.

RESOURCES

User Fees

The CAP acknowledges and supports the process established by the legislation for stakeholders and the regulators to negotiate future user fees to support this program. While the legislation does not establish the user fees, the CAP believes that if user fees are set too high, it will limit the development of LDTs by clinical laboratories and impede innovation by laboratories which are financially stressed. The CAP encourages minimal user fees, particularly for low and moderate risk LDTs which are already in widespread use.

The CAP appreciates the opportunity to offer our input into the latest version of the VALID Act. The CAP believes the legislation continues to improve as a result of stakeholder input and we look forward to continuing the dialogue as this legislation moves forward. If you have any questions or concerns, please contact Michael Hurlbut, Assistant Director, Legislation and Political Action at mhurlbu@cap.org.

Sincerely,

Emily E. Volk MD, FCAP
President
College of American Pathologists