COLLEGE of AMERICAN PATHOLOGISTS

December 14, 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

The Honorable Frank Pallone
Chair
Energy and Commerce Committee
2125 Rayburn HOB
Washington, DC 20515

The Honorable Cathy McMorris-Rodgers
Ranking Member
Energy and Commerce Committee
2322 Rayburn HOB
Washington, DC 20515

Dear Chairs Murray and Pallone, Ranking Members Burr and McMorris-Rodgers:

As you and the rest of Senate and House leadership consider a year-end omnibus funding package, the College of American Pathologists (CAP) has endorsed the Verifying Accurate Leading-edge IVCT Development (VALID) Act. The CAP commends the hard work and dedication that you and your colleagues have devoted over the last four-plus 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. We understand an exemption is under consideration. The CAP is concerned about any site-based exemption that would prevent the appropriate oversight of high-risk LDTs. There's no evidence LDTs are better performed in AMCs, for example, than elsewhere. The CAP appreciates that this proposed language is narrowly defined and if the language is included, we can continue to support this new proposed version of the VALID Act.

The VALID Act reflects many of the policy priorities advocated by the CAP since 2009. It establishes a reasonable and balanced regulatory framework that will ensure quality laboratory testing for patients and minimize the regulatory burden on laboratories while allowing for continued innovation in laboratory testing. To that end, the CAP supports VALID's three-tiered, risk-based system, which will focus the U.S. Food and Drug Administration's (FDA) resources on high-risk tests, including LDTs, while leveraging existing structures to improve and promote patient safety. The legislation's "risk classification" framework is like the one recommended by the CAP and other groups and we support the use of mitigating measures for the down-classification of risk.

We also support the regulatory framework established in the legislation. We strongly support the inclusion of guardrails that prevent encroachment into the Clinical Laboratory Improvement Amendments (CLIA) laboratory operations as well as infringement on the practice of medicine. The CAP appreciates the need for a premarket review process for the high-risk tests as defined in the legislation, and we appreciate the streamlined pathway that the technology certification provides for the development of new tests on existing technological platforms. The exempted categories laid out in the legislation, especially the grandfathering provision, are appropriate. We are supportive of provisions that clearly define test design and quality requirements. The ability to modify existing LDTs helps to reduce burden and will allow for expedited patient care. The CAP does recommend allowing accreditors to submit documentation to the FDA on behalf of laboratories.

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The legislation strikes an appropriate balance of stakeholder demands and provides five years to perfect the framework of the bill through the regulatory process. This will require continued engagement between the FDA and all stakeholders.

We are aware that you are hearing from groups opposed to this legislation and the committee has proposed some changes. The opposition argues that this oversight structure will negatively impact patient care, stifle innovation, or duplicate current law. The CAP disagrees with these assertions as provisions in the bill will create pathways to fast-track new tests and offer exemptions and mitigating measures to ease the burden on laboratories. The exemption the committee created for academic medical centers is narrowly defined and we believe that community-based hospitals that also meet the criteria should qualify. Finally, VALID has minimum duplication with other laws and provides expansive flexibility for innovation to continue in these areas. The CAP could not support legislation that set rigid parameters that would not allow advancement in laboratory medicine. Additionally, this legislation provides stability in the LDT regulatory landscape which will likely encourage innovation.

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. As such, the CAP offers its support the VALID Act. We hope to see the legislation included in an end of year package. 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

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