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December 9th, 2022

The Honorable Patty Murray,  
Chair  
Senate Committee on Health, Education,  
Labor and Pensions (HELP)  
U.S. Senate  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Richard Burr,  
Ranking Member  
Senate Committee on Health, Education,  
Labor and Pensions (HELP)  
U.S. Senate  
833 Hart Senate Office Building  
Washington, D.C. 20510

Dear Chair Murray and Ranking Member Burr,

The Pew Charitable Trusts is pleased to respond to the committee's request for feedback on your efforts to strengthen the Food and Drug Administration's oversight of laboratory developed tests (LDTs). Pew is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of health care.

We appreciate the committee's efforts to identify areas of consensus around the key policy and regulatory issues affecting the oversight of diagnostic testing. In general, we strongly support the committee's current approach and we urge Congress to quickly enact these measures into law as part of the broader omnibus appropriations legislation under development.

Thank you for your leadership to improve our public health infrastructure and medical preparedness and response programs. We appreciate the opportunity to inform this important process. Please contact Kyle Kinner ([kkinner@pewtrusts.org](mailto:kkinner@pewtrusts.org)) in our Government Relations practice for additional information or questions.

Sincerely,

Kathy Talkington,  
Director, Health Programs  
The Pew Charitable Trusts

## **RECOMMENDATIONS RELATED TO THE CURRENT DRAFT AGREEMENT**

The Pew Charitable Trusts is pleased to submit these comments on the current discussion draft to the Verifying Accurate Leading-edge IVCT Development (VALID) Act. We thank the committee, FDA and other stakeholders for the collaborative, years-long process that led to this draft, and we are optimistic that the most recent edits provide a tailored and risk-based approach that delivers the meaningful assurance of analytical and clinical validity for the indications for use of *in vitro* clinical tests.

### **Academic Medical Centers**

Pew supports the academic medical center provisions found in Section 587C(a)(7). They are sufficiently narrow to protect patient health and provide reasonable and necessary oversight for tests no matter where they are performed. We agree with the Association of Academic Medical Centers that tests “are often an integral component of innovative medical care” which is why it is so important that tests be safe and effective and accurately labeled.<sup>1</sup>

The proposed edits meet the stated needs of academic medical center (AMC) stakeholders, particularly in reference to their use of “clinically validated, well-proven, and carefully tailored diagnostic tests.” The revised bill requires that tests offered at AMCs meet the applicable standard, addressing the validated and well-proven issue, and are not offered elsewhere, ensuring that such testing is indeed carefully tailored and narrow in scope.

Further, AMC stakeholders have expressed concern about the unique needs of labs that more frequently integrate test development and administration into direct patient care. The edits to the discussion draft ensure that tests are exempt only when they are integrated into direct medical care for patients and used for patients receiving care or treatment at the same location as the lab. These narrow exemptions ensure that non-AMC labs cannot take advantage of exemptions, and that the stated needs of AMCs are met.

### **Regulatory Simplicity**

While some stakeholders have argued that the Clinical Laboratory Improvement Amendments (CLIA) already provide the same degree of oversight that VALID promises, even the Center for Medicare and Medicaid Services (CMS) agrees that is not the case.<sup>2</sup> There is a clear need for FDA to take on the carefully targeted functions outlined in VALID to fully ensure the safety and effectiveness of LDTs for patients and clinicians.

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<sup>1</sup> June 2<sup>nd</sup>, 2022, AAMC Letter to Senators Murray and Burr, at <https://www.aamc.org/media/61121/download?attachment>

<sup>2</sup> See, CMS CLIA Overview at [https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ldt-and-clia\\_faqs.pdf](https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ldt-and-clia_faqs.pdf). See also, 360Dx, Oct 06, 2022, “Lab Orgs Call for CLIA Modernization to Handle LDT Oversight, but CMS Appears to Oppose Idea,” at: <https://www.360dx.com/clinical-lab-management/lab-orgs-call-clia-modernization-handle-ldt-oversight-cms-appears-oppose>

Nonetheless, we understand that laboratories, hospitals and others may have an administrative burden associated with VALID. We agree with the edits to the bill that specifically require FDA to comply with the long-established least burdensome principles.

### **Resources**

We remain concerned about FDA's ability to implement the provisions of this bill without additional resources. Of concern is the implementation requirement in section 829(b)3D that would limit FDA's ability to spend user fees unless final regulations are published within three years of enactment of VALID. While we agree that swift promulgation of final guidances would provide a stable regulatory pathway, we are concerned that a three-year timeframe may not be within FDA's control and not appropriate for legislation. FDA is already providing numerous reports to Congress about its implementation which, along with the public nature of the guidance process, provides a significant amount of transparency into FDA's implementation process. We urge the Committee to remove these restrictions.