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June 8, 2022

The Honorable Patty Murray,
Chair
Committee on Health, Education,
Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr,
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
833 Hart Senate Office Building
Washington, DC 20510

Dear Senators Murray and Burr:

We applaud your efforts to reform the regulation of clinical testing through S. 4348, the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022. FDASLA's clinical testing provisions are [urgently needed](#) to protect Americans' health, because the clinical testing industry has evolved significantly since Congress first authorized FDA to regulate diagnostics in 1976. Despite their importance to modern medicine, labs are not required to demonstrate to regulators that the tests they develop or modify in-house are reliable, nor are they required to publicly report instances of patient harm resulting from inaccurate results—requirements that FDA applies to device companies that manufacture and sell diagnostic tests. Though many LDTs are highly accurate and clinically valid—and in some cases, perform even better than tests developed and sold by large commercial manufacturers—this lack of oversight poses preventable public health risks.

The reforms included in the legislation would put FDA in a better position to understand how all tests on the market are performing and whether patients are at risk for being subject to inaccurate results—which could lead to delayed or missed diagnosis, undertreatment or overtreatment. The legislation balances safety and innovation by mandating that FDA review and approve high-risk tests—products that pose serious or long-lasting implications if inaccurate—before they can be used on patients. The bill would also require developers—including labs—to register their tests with the agency and provide information on their performance, as well as report cases of harm due to faulty tests.

These crucial reforms are the product of years of collaboration led by the [Senate](#) and [House](#) sponsors of the Verifying Accurate Leading-edge IVCT Development (VALID) Act. This legislation has continued to become stronger through careful negotiation over the course of three sessions of Congress, and we are encouraged that VALID's pragmatic approach enjoys broad support among groups who don't always see eye-to-eye on regulatory issues, including patient and consumer advocates, nurses' and physicians' associations, health care providers, labs, medical device manufacturers, and nonprofit organizations that represent victims of cancer and other diseases. Still, the Committee should address two outstanding issues in FDASLA before advancing it to the full Senate.

First, as currently drafted, test importers would be left without appropriate oversight. As entities responsible for the introduction of tests onto the U.S. market, they should have to comply with

the same registration and reporting requirements as domestic test developers. In its current form, these importers would not need to list their tests with the FDA or report harm to patients from faulty results, and the agency could not mandate that the importers recall tests found to be unreliable or unsafe. U.S. businesses deserve a level playing field—and American patients and their health care providers must have confidence that tests are subject to robust FDA oversight no matter where they're made.

Second, the legislation's Humanitarian Test Exemption provides a low-burden path to market for tests intended for use in limited patient populations, but additional guardrails are needed to ensure that this exemption does not put public health at risk. The current criteria would allow infectious disease tests with a different risk-benefit profile to qualify for the exemption. Given how quickly a communicable disease can go from novel or rare to an outbreak that threatens millions, FDA should be able to ensure that tests for infectious diseases meet appropriate risk-based standards for validity and reliability.¹

The Pew Charitable Trusts is an independent, nonpartisan research and policy organization with a longstanding focus on the quality and safety of medical products, including research and policy analysis on issues related to the regulation of in vitro diagnostics (IVDs). We appreciate your leadership in advancing this complex but important legislation—VALID succeeds where other efforts have failed and represents a comprehensive reform effort, modernizing the regulation of these products under a uniform regulatory framework for all tests, making clear FDA's authority to protect patients from substandard tests and granting increased transparency.

We remain committed to providing support and assistance to the Committee as it navigates these issues and remain optimistic that they can be resolved in a way that provides for the appropriate oversight of these critical diagnostic tools. Should you have any questions, or if we can provide any assistance, please do not hesitate to contact Kyle Kinner at kkinner@pewtrusts.org or (202) 540-6597.

Sincerely,



Kathy Talkington
Director of Health Programs
Pew Charitable Trusts

¹ Please see our May 21st, 2022 [Technical Assistance Letter](#) addressing the Committee's most recent legislative discussion draft for more detailed information on these requests.