May 23rd, 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 2051

Dear Senators Murray and Burr:

We represent a broad group of public interest organizations that believe reforming the regulatory framework for clinical laboratory diagnostics—both laboratory-developed tests (LDTs) and in vitro diagnostics (IVDs)—is essential to protect patients and ensure access to innovative and high-quality diagnostic tests. We are grateful that the HELP Committee has continued to prioritize this issue and we appreciate how challenging it is to balance competing policy interests as complex as those addressed by the VALID Act.

After carefully reviewing the most recent discussion draft, we have serious concerns about the current version of the legislation that the HELP Committee has proposed for inclusion in the user fee reauthorization package. Though some changes in the draft are beneficial, certain provisions in the VALID discussion draft would likely impose a significant burden on FDA's ability to ensure that LDTs are safe and effective for their intended use if they are not structured appropriately.

Importantly, we also acknowledge that key sections of the bill of critical importance to FDA's public health mission remain in brackets pending final resolution by the Committee, and we are hopeful that you will consider the input from patient and public health groups represented here as you finalize the text. Though each of our respective institutions have their own priorities regarding specific changes they would like to see, we strongly urge you to prioritize changes in the following areas of the bill.

Risk categories

We applaud the addition of a moderate risk category, which if structured appropriately would help clarify how tests that are neither high-risk nor low-risk will be regulated under the new framework. However, we are concerned that the current risk definitions still need more careful refinement in order to ensure that all tests receive the appropriate level of premarket review. The high-risk category in particular is too narrowly defined, and would likely exclude many tests that would otherwise be considered high-risk under the current framework. It is essential that FDA be empowered to individually review any test that is used to inform critical health care decisions that might have life-altering consequences.

Grandfathering and Technology Certification

We recognize that, under any risk-based regulatory framework, many tests will not require premarket review before their use in clinical care. However, it is essential that any clinical test on the market be held to the applicable standard; that is, that it be analytically and clinically valid for its intended use, regardless of whether the test received premarket review or not. In the current version of VALID, it is unclear whether FDA would be able to apply this standard to either grandfathered tests or tests entering the market under a technology certification order. Given how many tests would fall into one of those two categories, we strongly urge you to clarify these provisions so that FDA has the clear, unambiguous authority it needs to ensure the validity and quality of all tests on the market, including grandfathered tests and tests approved for use under a technology certification order.

Post-market authorities

Similarly, FDA must have sufficient post-market authority to preserve patient safety, which ultimately means that regulators must have continuous insight into the performance of tests once they have reached the market, as well as the ability to request information from developers about the validity and quality of their tests. Moreover, when there is reason to believe that a test is not delivering accurate and reliable information to patients and their providers, FDA must also possess the ability to take action, whether that means putting additional safeguards in place to mitigate risks or requiring that the test be removed from the market. The current draft of VALID does not provide those clear-cut assurances and their absence presents a risk to public health and patient safety as a consequence.

Resources

Adequate funding is absolutely essential to ensure that FDA has the ability to deliver effective oversight and reassure patients and providers that LDTs are safe and effective. The current draft fails to provide FDA with the necessary resources to effectively implement the changes proposed in the legislation. Of particular concern is the lack of authorization for essential appropriated funding that FDA will need in the years immediately after enactment, before user fees can be collected, as well as the restrictive statutory limits on total user fees available to the agency in the future. Insufficient funding will handicap the agency's ability to quickly develop and promulgate the complex regulations and guidance documents required to stand up the new regulatory regime for IVCTs. If FDA is forced to implement the bill without these resources, the agency will be unable to meet the ambitious requirements that Congress specifies under the new law, undermining the ability of labs to bring safe, innovative new tests to market while leaving patients at risk of serious harm from faulty, high-risk diagnostics.

Our organizations represent the consumer and patient interests of millions of Americans from every corner of the country, and we have been united in working with your offices to craft a diagnostics reform bill that fixes the current broken system and insulates vulnerable patients from undue risk associated with diagnostics that never undergo independent review. Though we were very encouraged to see the Committee's bipartisan work to advance comprehensive diagnostics reform legislation in the medical device user fee reauthorization package, the

legislation as drafted needs additional work to fully meet the promise of a modern regulatory framework for LDTs. Patient safety and consumer confidence in LDTs urgently demands that we reform the current federal framework for diagnostic testing and pass the VALID Act in the strongest form possible.

We look forward to continuing to work with you to address the concerns the remaining barriers to the success of this important legislation and help achieve its passage in this Congress.

Sincerely,

Center for Science in the Public Interest

FORCE: Facing Our Risk of Cancer Empowered

Living Beyond Breast Cancer

LUNGevity Foundation

National Center for Health Research

The Pew Charitable Trusts

Public Interest Research Group

Triage Cancer