



May 22, 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  
428 Dirksen Senate Office Building  
Washington, DC 20510

**Re: Comments on Food and Drug Administration Safety and Landmark Advancements Act of 2022 (FDASLA)**

Dear Senators Murray and Burr:

On behalf of the American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, thank you for the opportunity to provide feedback on Food and Drug Administration Safety and Landmark Advancements Act of 2022 (FDASLA), which reauthorizes the user fee programs as well as creates new oversight paradigms for cosmetics, dietary supplements, and *in vitro* clinical tests. The user fee program has provided critical resources for FDA to review drug and device applications, as well as to develop regulatory science and policy. We are wholly supportive of reauthorizing the user fee programs, but we do have specific comments and questions related to Subtitle C, the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022, which creates a new oversight framework for *in vitro* clinical tests. In addition, as the process for reauthorizing the user fee programs continues, we urge you to take bold steps to improve the diversity of enrollment in clinical trials as part of this year's Prescription Drug User Fee Act (PDUFA) reauthorization.

**Subtitle C: The Verifying Accurate Leading-edge IVCT Development (VALID) Act**

Cancer patients rely on accurate and clinically valid diagnostic tests to optimize their treatment options, and ACS CAN has long called for harmonizing and modernizing the regulatory framework. ACS CAN's overarching goal for diagnostic reform legislation is to ensure that patients have confidence in the results of diagnostic tests, which have become increasingly

critical in the management of cancer. Currently, diagnostic tests undergo widely different levels of oversight depending on whether they are submitted to the FDA for review or are offered as laboratory developed tests (LDTs). This difference opens the door to the possibility that test results may vary depending on where the test is conducted, potentially leading to incorrect treatment decisions and patient harm if a test result is not valid. Cancer patients and their physicians should be able to trust the information produced by a diagnostic test regardless of where that test is conducted. The VALID Act conceptually proposes to create harmonized oversight for all diagnostics with tiered requirements tied to the risk posed by a given diagnostic test. We have focused our comments below on areas of the legislation that are of the most importance to our organization.

### **Bracketing**

The draft legislation includes a significant portion of the text in brackets, implying that such text may or may not be included in the final draft. Overall, we evaluated the legislation with the assumption that bracketed text would be included. If not included, the framework and the assessment of its impact would be significantly altered. Below we call out several specific examples where removal of bracketed text would be detrimental, but in general we would hope to see the bracketed text included in the final text.

### **Risk Classification**

We support the concept of a risk-based oversight framework, which focuses oversight proportionally on tests based on risk to a patient if a test result is incorrect. We have previously expressed concerns about the two-tiered system and the ability for otherwise high-risk tests to be treated as low risk via mitigating measures, which would remove them from any sort of review. We are therefore pleased to see the formal creation of a moderate risk category, which was implied in previous versions. Mitigating measures should be seen as a way to protect patients from erroneous results rather than a way to reduce regulatory categorization and oversight.

### **Grandfathering**

We recognize the importance of continued availability of tests that have become embedded into regular medical care. However, under this legislation grandfathered tests will not have undergone the same level of review as those fully reviewed by FDA. Therefore, we support a requirement for grandfathered tests to include a disclaimer that they have not been reviewed by FDA within their report template, a provision that is included in bracketed text in this draft.

We also stress that modifications to grandfathered tests that affect clinical validity, analytical validity, or intended use should be cause for the loss of grandfathered status. Further, we recommend reinstating the threshold that a test must be marketed 90 days prior to bill passage as was included in previous iterations of the legislation.

### **General Exemption Authority**

The driving force for the creation of a new oversight framework for *in vitro* clinical tests is the current landscape in which tests for the same intended purpose may be subject to vastly different oversight. Among the categories of exemptions in this draft of the legislation is a new and sweeping ability to exempt entire classes of persons from the provisions included in the legislation (section 587C (f)). The Secretary would be able to “...exempt a class of persons from any section under this subchapter...[]for the protection of the public health and other relevant considerations.” The effect of exempting an entire class of test developers from the framework contained in VALID would be significant and risk a return to the status quo of a fragmented system. Further, it is unclear what considerations other than public health would be a relevant cause for such an exemption and why this broad authority to circumvent the intent of VALID is needed. If the provision is not stricken in the final bill, the process for exempting persons should be more formalized, for example requiring a public meeting or requiring an external advisory committee to weigh in on such exemptions. The exemption authority should also not be so broad as to allow circumvention of basic post-market protections such as the adulteration and misbranding provisions.

### **Humanitarian Exemption**

We support reduced regulatory burdens on rare tests to ensure that market forces do not deprive individuals with rare diseases from accessing important diagnostic tests. The risk of an inaccurate result, however, is based on the number of individuals subject to a test rather than the number of individuals with a positive result. It is for this reason we supported previous versions of this provision in which the exemption was based on the number of tests performed or individuals exposed to a test. We urge the Committee to retain the language contained in the previous versions.

The current legislation has changed the exemption to be based on disease incidence regardless of test volume, meaning that a test that millions of Americans could be subject to could still be exempt from review so long as the underlying disease of interest was rare. We believe this language could result in unintended consequences. For example, a large exposure to a test

could include screening tests. In the draft, there is bracketed text indicating that screening tests would not be eligible for the pathway and should the Committee retain the current language it is critical that the bracketed text remain in the final draft.

### **Special Rule**

The concept behind VALID has always been to create a balance between limiting premarket requirements via exemptions and reduced-effort approval pathways with sufficient post-market authority for FDA to subject tests with questionable performance to additional scrutiny or to remove them from the market altogether. In previous versions of the legislation, the “Special Rule” has played a critical role in creating this balance. It provided FDA the ability to require additional materials or full applications from tests found to have questionable performance or unsupported claims that utilized any route to market, including the premarket exemptions in the legislation.

The role of the “Special Rule” has been drastically reduced in the latest version of legislation, and now it only applies to grandfathered tests. This leaves no ability for FDA to employ these powers for any other available tests that have questionable performance and represents a drastic shift in the balance between easing market access and ensuring safety through post-market protections. This is a move in the wrong direction for patients and one for which we have serious concerns.

While this legislation does offer FDA recall authority as another means of addressing problematic tests, this authority is only for tests that have undergone premarket review or tech certification, leaving FDA with incomplete oversight of all tests on the market that may pose risks to patients. Post-market authorities need to be bolstered to ensure that any problematic test, regardless of its market entry pathway, can be subject to additional scrutiny and removal if necessary.

### **Patient awareness issues**

Patients are not typically well versed in concepts like analytical and clinical validity or in regulatory procedures, nor should they be in order to trust the results of their diagnostic tests. Nonetheless, it is important to provide patients and practitioners with useful information to make sense of their test results, and to empower them to report incorrect results and adverse events. We support the test labeling requirements within this legislation that provide performance information, intended use, warnings, limitations, and the process for reporting

adverse events. These requirements recognize the importance of providing context to results for end users, and it is important that the language be accessible by patients. Similarly, we support the adverse event reporting requirements that ensure any known harms caused by a diagnostic test are promptly reported to the FDA and these, along with less serious reports, are made publicly available. Lastly, as mentioned above, we support the disclaimer required on grandfathered test result templates.

### **Diversity in Clinical Trial Enrollment**

Today, the majority of clinical trials fail overwhelmingly to achieve diverse enrollment - despite the fact that many serious and chronic diseases disproportionately impact underrepresented racial and ethnic minority groups. This lack of diversity in trial enrollment inhibits a full understanding of how safe and effective new drugs might be across their intended populations. It also exacerbates disparities in access to treatment when enrolling in a clinical trial may be a patient's most effective treatment option.

Improving clinical trial diversity is an imperative both for patient access and comprehensive scientific research. Despite racial and ethnic minority groups comprising nearly 40% of the US population, about 75% of participants in trials for drugs approved by the FDA in 2020 were white.<sup>1</sup> When compared against the disproportionate burden of acute and chronic disease across racial and ethnic minority groups, this stark contrast highlights a growing problem contributing to both health and socioeconomic disparities.<sup>2</sup>

Clinical trials should be available to all patients who qualify, including those who experience barriers to care and/or those who are from underrepresented communities. Reducing barriers to clinical trial participation is also good science. As America becomes more racially and ethnically diverse, a clinical trial system that fails to enroll patients from growing demographics will not support the pace of innovation that will help us meet our potential.

We are grateful for the work that the HELP Committee has done to address this issue as part of the *Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act)* and encourage the committee to consider further action on this issue

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<sup>1</sup> US Food and Drug Administration, 2020 Drug Trials Snapshots: Summary Report, February 2021, <https://www.fda.gov/media/145718/download>

<sup>2</sup> Thorpe, KE. et al., The United States can reduce socioeconomic disparities by focusing on chronic diseases, August 17, 2017, Health Affairs Blog, <https://www.healthaffairs.org/doi/10.1377/hblog20170817.061561/full>.

as the user fee reauthorization moves through the process and the House and Senate reconcile their respective bills.

**Summary**

We applaud your efforts to move this critical reform forward and are encouraged by the ongoing engagement with stakeholders. Comprehensive diagnostic reform will not only improve care delivery in the short-term but will also ensure patients continue to benefit from emerging personalized therapies. As you work to finalize the legislative language, we encourage you to consider our comments and ensure that the final legislation provides an appropriate balance of authorities to ensure patient safety and confidence in diagnostic tests and that it addresses diversity in clinical trial enrollment. We look forward to continuing to work with you. If you have any questions regarding our comments, please contact Illy Jaffer ([Illy.Jaffer@cancer.org](mailto:Illy.Jaffer@cancer.org)) or Mark Fleury ([mark.fleury@cancer.org](mailto:mark.fleury@cancer.org)).

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa A. Lacasse". The signature is fluid and cursive, with a long, sweeping underline.

Lisa A. Lacasse, MBA

President

American Cancer Society Cancer Action Network