



May 22, 2022

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

The Honorable Richard Burr
Ranking Member
U.S. Senate Committee on Health, Education,
Labor, and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

RE: VALID Act of 2022

Dear Chair Murray and Ranking Member Burr,

On behalf of the LUNGevity Foundation, the nation’s preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the more than 230,000 Americans diagnosed with lung cancer each yearⁱ and the almost 600,000 Americans living with the disease,ⁱⁱ we appreciate the opportunity to submit our comments in response to the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022.

Lung cancer is at the forefront of precision medicine, with several biomarker-driven treatment options. Approximately fifty percent of patients with non-small cell lung cancer (the most common type of lung cancer) harbor a biomarker with a corresponding FDA-approved targeted therapy.ⁱⁱⁱ Use of these drugs is contingent upon results from *in vitro* clinical tests (IVCTs) confirming the presence of the appropriate biomarker. Carefully balancing the need to ensure that IVCTs used for patients with lung cancer deliver accurate, reliable results while also promoting continued innovation by test developers is critical for the optimal benefit of patients.

LUNGevity applauds the HELP Committee and its leadership for their continued efforts toward advancing legislation reforming the regulation of diagnostic tests. LUNGevity submits these comments specifically from the perspective of patients with cancer. We acknowledge that our feedback may align with other, but not necessarily all, patient advocacy groups. Furthermore, we are providing these comments under the assumption that bracketed text in the discussion draft will remain in the final bill. We feel that, as written, VALID strikes an appropriate balance between promoting patient safety and allowing regulatory flexibilities for both developers and the FDA; changes to the bracketed text could upend this balance and have unintended consequences on safety and/or innovation.

Overall Risk-Based Regulatory Framework

LUNGevity supports a risk-based approach to the regulation of IVCTs. We are pleased to see the changes made in the latest draft of the bill which clarify the definitions of high- and low-risk tests and add a moderate-risk category for IVCTs. These changes are important for aligning the level of regulatory oversight a test receives with risks posed to patient safety. We are concerned, however, with the draft’s definition of the term “developer,” which without further context may be too subjective and could result in high-risk tests being inappropriately excused from adequate regulatory review.



Exemptions from Premarket Review

LUNGEvity supports provisions that exempt certain types of tests from premarket review, toward the goal of removing unnecessary roadblocks to patient access to accurate diagnostic tools critical to their care. Specifically, we support exemption via grandfathering, through which tests currently in use will remain on the market and accessible to the patients who rely on them. This is of particular concern regarding the many academic labs that have developed biomarker tests used to inform patient care within that institution. Patients have benefited from these tests for years and we commend the committee for ensuring continued, unhindered access. Additionally, we appreciate that the draft legislation provides opportunities for developers to make certain modifications to IVCTs without unnecessary regulatory hurdles, as diagnostic tests often require modifications to improve performance.

Allowing approval for a representative diagnostic tool to apply to other similar tests via the proposed technology certification pathway has the potential to reduce regulatory burdens on test developers and speed the delivery of innovative diagnostics to patients with lung cancer. However, it is crucial that this pathway promote patient safety by providing adequate certainty that a test's benefits outweigh its risks to patient health. To that end, LUNGEvity commends the introduction of provisions deeming high-risk IVCTs without mitigating measures ineligible for exemption from full premarket review through the technology certification pathway into the VALID Act of 2022. Additionally, given that this pathway represents a significant departure from existing premarket review processes, as well as the high volume of diagnostic tests that could enter the market this way, we recommend that technology certification be introduced through a pilot program to allow for more thorough benefit-risk calibration and to allow the FDA time and experience to draft guidance on the pathway.

A Need for Transparency and Strengthened Postmarket Authorities

While LUNGEvity supports the exemption of certain IVCTs from FDA premarket review, patients and physicians should have access to information regarding the level of oversight to which a test has been subjected. We advocate requiring the inclusion of information regarding the level of review a test received within its labeling, including those exempt from premarket review through grandfathering or technology certification.

While we don't want to overburden test developers by requiring FDA review for every modification made to IVCTs, we agree that modifications impacting analytical or clinical validity, or intended use, are appropriate targets of FDA attention in order to ensure patient safety. Similarly, we welcome the inclusion of the Special Rule, which grants the FDA the authority to investigate when it becomes aware of health risks potentially attributable to grandfathered tests. We question, however, whether this authority should not apply to all exempt IVCTs, as it did in previous versions of VALID. In general, we feel FDA should have the authority to request relevant information from developers to ensure analytical and clinical validity of any IVCT.



Adequate Resources to Implement Diagnostics Regulatory Reform are Imperative

The VALID Act of 2022 proposes significant changes to the regulatory landscape of diagnostic tests by statutorily broadening FDA’s jurisdiction to include IVCTs, which LUNGEvity believes are justified and appropriate. However, the changes can and will succeed only if accompanied by meaningful funding increases for the FDA.

As others have pointed out, VALID does not include any supplemental appropriations for the agency to begin the work of implementing the reforms laid out within. User fees, which could only be collected pending development of prescribed guidance, would only be applicable to premarket activities whereas the majority of the authorities granted FDA via VALID are for postmarket activities. In order for FDA to successfully meet the ambitious goals specified by Congress, it is imperative that they receive necessary and sufficient resources.

LUNGEvity appreciates the opportunity to provide comments on this important legislation as well as the sponsors’ consideration of the feedback we have provided. We believe that, if resourced and implemented appropriately, the unified regulatory framework set forth in the VALID Act of 2022 could bolster patient access to and trust in well-validated tests that are integral to their treatment. Please feel free to reach me at ae Ferris@lungevity.org or at 240-454-3103, or you may contact Kristen Santiago, Senior Director of Public Policy Initiatives at ksantiago@lungevity.org or 240-454-3105, with any questions.

Sincerely,

A handwritten signature in blue ink that reads "Andrea Stern Ferris". The signature is written in a cursive, flowing style.

Andrea Stern Ferris
President and Chief Executive Officer
LUNGEvity Foundation

ⁱ Howlader N, Noone AM, Krapcho M, et al. (eds). SEER Cancer Statistics Review, 1975-2018, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2018/, based on November 2020 SEER data submission, posted to the SEER web site, April 2021.

ⁱⁱ Centers for Disease Control and Prevention. United States Cancer Statistics. Available at <https://gis.cdc.gov/Cancer/USCS/#/Prevalence/>.

ⁱⁱⁱ Thai AA, Solomon BJ, Sequist LV, et al. Lung cancer. *Lancet* 2021; 398(10299):535-554.