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Statement on the VALID Act of 2022

Washington, DC – June 9, 2022 - Friends of Cancer Research (*Friends)* applauds the thoughtful work in constructing the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022 – and particularly for including it in the Senate HELP user fee reauthorization bill (The FDA Safety and Landmark Advancements (FDASLA) Act). Diagnostic tests continue to be a growing component of cancer research and patient care. We believe that now is the time to establish a framework to sufficiently evaluate the performance of diagnostic tests and ensure their accuracy while providing appropriate flexibility to enable continued innovation.

We support the goal to create a regulatory framework that uses a risk-based approach for evaluating tests regardless of where the test is developed. Having a subset of tests excluded from such a framework would result in continued inconsistencies and jeopardize optimal patient care. We further recognize the need for a thoughtful approach that balances generation of robust and rigorous data to ensure patient safety without inadvertently impeding the pace of new discoveries at our nation's leading research institutions. We believe that such a balance is possible and is provided in the VALID Act of 2022.

A recent analysis showed that the number of biomarkers used in cancer drug development and routine care have more than doubled since 2006.[1] Our own research indicates that there are many tests being used every day for which performance and accuracy has not been independently verified. For example, an audit of hundreds of medical records from across the country found that nearly 30% of patients with lung cancer were evaluated for two critical biomarkers with tests that had not gone through premarket review, despite the availability an FDA approved assay.[2] These findings highlight that there is increased testing for recommended biomarkers, but providers may use tests with unknown performance or accuracy for treatment decisions.

Furthermore, we have previously demonstrated that particularly for complex biomarkers, numerous tests being used to evaluate patients and help determine treatment yield variable results.[3] Given the large number of tests currently in use, there is potential for wide variability in test performance and claims in the absence of appropriate regulatory processes.

These data provide just one example that many patients receive tests to inform their care that are subject to uneven, or in some cases, an absence of review of their accuracy. Therefore, tests that are used to guide medical decisions ought to be subject to the same standards no matter where they are developed or performed.

[1] Global Oncology Trends 2018. *Innovation, Expansion and Disruption*. IQVIA Institute of Human Data Science. May 2018. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/global-oncology-trends-2018.

[2] Wempe M, Stewart M, et al. *A National Assessment of Diagnostic Test Use for Patients with Advanced NSCLC and Factors Influencing Physician Decision-Making*. Am Health & Drug Benefits. Vol 13 No. 3, June 2020.

[3] Vega DM, et al. *Aligning tumor mutational burden (TMB) quantification across diagnostic platforms: phase II of the Friends of Cancer Research TMB Harmonization Project*. Ann Oncol. 2021 Oct 1:S0923-7534(21)04495-1. doi: 10.1016/j.annonc.2021.09.016. December 2021. PMID: 34606929

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) is working to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely. We unite scientists, pharmaceutical companies, and policy makers with shared trust and guide them toward meaningful cooperation. This collaboration among partners from every healthcare sector ultimately drives advances in science, policy, and regulation that speed life-saving treatments to patients. For more information, please visit https://friendsofcancerresearch.org/.

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