Ryan Hohman, VP - Public Affairs, Friends of Cancer Research
rhohman@focr.org; 717.333.6248

Statement by Friends of Cancer Research on the VALID Act of 2022

Washington, DC – December 8, 2022 - Friends of Cancer Research (*Friends*) is pleased to support the most recent version of the Verifying Accurate Leading-edge IVCT Development Act (VALID Act) and urges Congress to include this as part of the 2023 omnibus appropriations bill. The VALID Act would resolve longstanding uncertainty associated with the regulation and use of diagnostic tests that play a critical role in patient care, including laboratory developed tests (LDTs) and in vitro diagnostics (IVDs).

Over a decade of public debate, extensive stakeholder engagement, and policy development have created an historic opportunity to establish a modernized approach and verify high-quality diagnostic test performance, which support advances in science and technology.

The VALID Act will create a risk-based framework for evaluating tests regardless of where it is developed, a process that does not currently exist. Appropriate test evaluation is critically important given the growing role that such tests play in providing optimal patient care, especially in oncology. This bill provides a thoughtful and flexible approach that balances demonstrating accuracy and promoting patient safety through rigorous data generation while ensuring that the pace of new discoveries continues.

Congress must act now to ensure that our Nation's patients and their health care professionals continue to have robust access to innovative and high-quality diagnostic tests.

What others are saying…

"An individual's best chance to fight cancer should never be affected by something

as easily preventable as a faulty diagnostic test. Congress has the opportunity today to do what is right for patients."

Jeff Allen, PhD
President & CEO, Friends of Cancer Research

Lisa Lacasse
President, American Cancer Society Cancer Action Network.

MASSACHUSETTS GENERAL HOSPITAL

"Many cutting-edge cancer treatments rely on accurate diagnostic tests to help identify patients that are most likely to benefit. We need clear regulation based on sound regulatory science. Tech certification, Rare Disease and Academic Medical Center exemptions, and other VALID provisions included in the updated bill are meaningful steps towards increased diagnostic test quality."

Jochen Lennerz, MD, PhD
Medical Director, Center for Integrated Diagnostics, Massachusetts General Hospital
Associate Professor of Pathology, Harvard Medical School

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"If VALID doesn't pass now, the FDA has signaled it would start actively regulating all lab-developed tests by issuing a regulation that would declare them subject to the provisions of its existing medical device review process. This ill-fitted process would be far less efficient than what VALID prescribes, and the uncertainty about how it would be applied would thwart investment and innovation."

Scott Gottlieb, MD
Senior fellow at the American Enterprise Institute
Commissioner of the Food and Drug Administration from 2017 to 2019

Mark B. McClellan, MD, PhD
Director of the Duke-Margolis Center for Health Policy at Duke University
Commissioner of the Food and Drug Administration from 2002 to 2004

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/.

Contact Us

Friends of Cancer Research
1800 M Street NW Suite 1050 South
Washington, District of Columbia 20036
(202) 944-6700
info@focr.org

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