



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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Association for Molecular Pathology Hosted a Congressional Briefing to Urge Lawmakers to Consider the VALID Act of 2021 Separately from the Medical Device User Fee Agreement Process

Any legislation that would significantly impact clinical testing laboratories, healthcare providers, and patients throughout the United States should require sufficient time for a thorough, independent evaluation

ROCKVILLE, Md. – Apr. 5, 2022 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, called on Congress to allow for a thorough evaluation of the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021, or any other legislation to change regulations for laboratory developed testing procedures (LDPs). Representatives from AMP, the American Association for Clinical Chemistry (AACC), the American College of Medical Genetics and Genomics (ACMG), and the Association of Pathology Chairs (APC) hosted a congressional briefing yesterday to educate lawmakers about how diagnostic tests are currently regulated and the substantial impact the VALID Act would have on clinical testing laboratories, healthcare providers, and patients throughout the U.S.

The VALID Act is a complex bill proposing dramatic modifications to current oversight mechanisms and a wide range of stakeholders have expressed significant concerns with the current draft. In February, [AMP joined a number of other organizations](#) asking that Congress consider the VALID Act separately from the must-pass Medical Device User Fee Agreement (MDUFA V) legislative process. To allow for thorough discussions and appropriate stakeholder engagement, it is important that this legislation goes through regular order with its own independent hearing, mark-up, and scheduled votes. More time and diverse stakeholder agreement are needed to ensure the policy is sound and in the best interest of patients and public health.

Congress needs to consider the lessons learned during the COVID-19 pandemic about how over burdensome and unnecessary regulation of laboratory testing affects testing capacity within the U.S. In February 2020, the U.S. declared a public health emergency and in turn, the U.S. Food and Drug Administration (FDA) began requiring emergency use authorization of all countermeasures used for clinical care. Subsequently, the FDA asserted authority to require regulatory review of COVID-19 tests before they could be offered to patients, halting the development and deployment of these tests, and leaving laboratory professionals paralyzed and unable to provide the care they are trained to do. As a result, this country went weeks without access to these critical public health tools while COVID-19 spread undetected throughout our communities.

“AMP remains committed to working with and educating members of Congress and other key stakeholders to create an appropriate LDP oversight framework that modernizes the current regulatory system, demonstrates quality, enhances transparency, and fosters the rapid innovation and promise of new diagnostic technologies and tests,” said Mary Steele Williams, AMP Executive Director. “The current COVID-19 public health emergency highlights the critical need for laboratories to be allowed to respond quickly, and to continue advancing and offering the tens of thousands of high-quality, validated LDPs that benefit patients each and every day.”

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,500+ members practice various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Our members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees that

practice in a variety of settings, including academic and community medical centers, government, and industry. Through the efforts of its Board of Directors, Committees, Working Groups, and Members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high-quality, appropriate testing. For more information, visit www.amp.org and follow AMP on Twitter: [@AMPath](https://twitter.com/AMPath).

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