Association for Molecular Pathology and Association of Pathology Chairs Call on Congress to Pass the Verified Innovative Testing in American Laboratories (VITAL) Act

Legislation would enhance transparency, preserve innovation, and ensure broad patient access to essential laboratory developed testing procedures

ROCKVILLE, Md. and WILMINGTON, Del. – May 18, 2021 - The Association for Molecular Pathology (AMP) and the Association of Pathology Chairs (APC) commend U.S. Senator Rand Paul (R-KY) for introducing legislation that would allow molecular pathology professionals to continue advancing and offering high-quality laboratory developed testing procedures (LDPs) for patient care. The Verified Innovative Testing in American Laboratories (VITAL) Act of 2021 would enhance transparency, preserve innovation, and ensure widespread patient access to essential medical services.

Throughout the coronavirus pandemic, FDA has imposed a regulatory process that has impeded the ability of laboratories, including many academic medical centers, reference laboratories, and community health systems across the country, to rapidly develop, validate, and offer high-quality LDPs for use on their patient populations. The VITAL Act calls attention to the important role that LDPs have played in the current COVID-19 pandemic response and ensures that even in times of public health emergencies, laboratories will be allowed to work within the current regulatory system under the Clinical Laboratory Improvement Amendments (CLIA), which are administered by the Centers for Medicare and Medicaid Services (CMS). This legislation would help eliminate the duplicative oversight process by clarifying the federal regulatory authority over LDPs and encouraging the modernization of CLIA. The VITAL Act also correctly differentiates LDPs, which are medical services that are developed, validated, and performed within a laboratory, from the boxed and shipped *in vitro* diagnostic test kits.

"We are pleased that Senator Paul introduced legislation that will provide clinical laboratories with clarity and predictability in the federal oversight of testing procedures. The current coronavirus pandemic continues to highlight the inappropriateness of FDA medical device regulations for LDPs and underscore the integral role that public health, academic, and community laboratories play in providing patient care and public health surveillance," said Antonia R. Sepulveda, MD, PhD, AMP President and Professor and Chair of the George Washington School of Medicine Department of Pathology. "AMP remains committed to working with all key stakeholders to establish a more efficient regulatory framework that ensures high-quality patient care while continuing to foster the rapid innovation and promise of new diagnostic technologies. Passage of the VITAL Act is an important first step to achieving this goal and protecting patient access to these potentially life-saving procedures."

"This important support by members of Congress for the VITAL Act addresses the serious consequences experienced by our nation when laboratory tests are regulated like medical devices," added Lydia P. Howell, MD, APC President, Professor and Chair of the Department of Pathology and Laboratory Medicine at the University of California Davis School of Medicine. "In the earliest and most frightening days of the pandemic, CLIA-accredited academic clinical laboratories could have used their valuable expertise and resources to expand SARS-CoV-2 diagnostic testing in their communities, but were unable to do so due to inappropriate FDA restrictions. Priceless weeks were lost, making the urgency to address these issues now even more clear. We greatly appreciate the support from Senator Paul in allowing academic laboratories to use their unique skills to serve patients when they need us most, and to partner with other stakeholders in creating a healthier world through innovation, education, and clinical care."

ABOUT APC

The Association of Pathology Chairs (APC) is a non-profit society, founded in 1967, to serve and give voice to academic departments of pathology and laboratory medicine in North America. APC provides leadership and advocacy for this dynamic discipline and supports departments in meeting the demands of their three missions – medical education, research, and practice – through networking and professional development. In addition to training residents and educating medical students in pathology and laboratory medicine, APC's members play a critical role in patient care and research in academic medical centers and affiliated hospitals throughout the U.S. and Canada. APC publishes *Academic Pathology* – the premier, open access journal for peer-reviewed scholarship in the field. For more information, visit www.apcprods.org and follow APC on Twitter: @apcprods.

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

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