ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

Association for Molecular Pathology Celebrates U.S. District Court's Decision to Vacate FDA Rule on Laboratory-Developed Test Procedure Regulation

Professional society will continue to work with stakeholders to develop a more effective and efficient legislative regulatory framework that ensures high-quality patient care while fostering rapid innovation and the promise of new diagnostic technologies

ROCKVILLE, Md. – March 31, 2025 – The Association for Molecular Pathology, the premier global molecular diagnostic professional society, and pathologist Michael Laposata, M.D., Ph.D., today announced a favorable ruling in their lawsuit against the U.S. Food and Drug Administration over the regulation of laboratory-developed test procedures. The ruling by Judge Sean D. Jordan of the U.S. District Court for the Eastern District of Texas granted AMP's motion for summary judgment and vacated the FDA rule that would have regulated LDTs as medical devices under the Federal Food, Drug and Cosmetic Act.

AMP President Jane S. Gibson, Ph.D., is a Pegasus-awarded professor of pathology, chair of the Department of Clinical Sciences and director of molecular diagnostics at the University of Central Florida College of Medicine. "AMP is extremely pleased with the court's clear and decisive ruling in our favor, and we hope this will finally end the FDA's attempts to exert an unwarranted overreach of authority of LDTs," said Gibson. "This judgment is a significant victory for our members and for patients across the country. The decision to vacate the FDA rule will avoid adding billions of dollars to healthcare costs and protect access to high-quality care for hundreds of millions of Americans."

For decades, LDTs have led to significant clinical advancements and diagnostic breakthroughs in rare and infectious diseases, human genomics, oncology biomarker testing and more. They are often created in response to recent medical advances and unmet clinical needs, and have been instrumental for early and precise diagnosis, disease monitoring and treatment guidance. LDTs are designed, developed, validated, performed and interpreted by highly trained medical and scientific experts in regulated clinical laboratories. Importantly, LDTs are not manufactured, packaged or commercially distributed like medical devices.

Eric Konnick, M.D., is AMP's Professional Relations Committee chair and an associate professor and the associate director of the Genetics and Solid Tumor Laboratory at the University of Washington Department of Laboratory Medicine and Pathology. "The FDA LDT rule would have created an undue burden on laboratories tasked with keeping patients healthy and safe, and would have led to extensive additional requirements in addition to the existing CLIA regulations," said Konnick. "AMP members continue to work with key stakeholders to develop a more effective and efficient legislative framework that clarifies oversight, enhances transparency, preserves innovation, avoids escalating costs and ensures widespread patient access for these essential medical services."

AMP has long maintained that the best approach to ensuring the continued development and deployment of accurate and reliable LDT procedures —and the correct utilization, precise interpretation and proper application of molecular test results — is through clarifying the current CLIA regulations. AMP's legislative proposal builds on the existing oversight framework and offers test quality enhancements where appropriate.

To read the full ruling, please visit the AMP website.

ABOUT AMP

The Association for Molecular Pathology was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's more than 3,100 members practice various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions and oncology. Our members are pathologists, physicians, clinical laboratory directors, basic and translational scientists, technologists and trainees who 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 X: @AMPath.

MEDIA CONTACT:

Andrew Noble
anoble@amp.org
415-722-2129