ASSOCIATION FOR MOLECULAR PATHOLOGY
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Association for Molecular Pathology Honors Michael Laposata with Champion for Innovation Award

Renowned pathologist recognized for leadership in shaping effective oversight of laboratory-developed tests

ROCKVILLE, Md. – Oct. 23, 2025 – The Association for Molecular Pathology (AMP), the premier global molecular diagnostic professional society, has awarded Michael Laposata, M.D., Ph.D., its Champion for Innovation Award. Laposata was recognized for his countless contributions to the clinical laboratory field and for his role as a joint plaintiff in AMP's lawsuit challenging the U.S. Food and Drug Administration's rule on laboratory-developed test (LDT) procedure regulation. Earlier this year, 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. The award will be presented in November during the AMP 2025 Annual Meeting & Expo in Boston.

Previously recognized by *The Pathologist* as the most influential pathologist in the United States, Laposata is a professor and the former chair of the Department of Pathology and the director of the M.D.–Ph.D. program at the University of Texas Medical Branch at Galveston. He is the author of *Laposata's Laboratory Medicine*, now in its fourth edition. During his career, Laposata has published more than 200 peer-reviewed articles and received 14 major teaching awards at Harvard University, Massachusetts General Hospital and the University of Pennsylvania School of Medicine. He earned his M.D. and Ph.D. from Johns Hopkins University and completed a fellowship and residency in laboratory medicine at Washington University School of Medicine.

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 developed 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. For these reasons, AMP pursued litigation challenging the FDA's rule on LDTs, and Laposata's role as co-plaintiff was instrumental in the court's decision to vacate it.

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 grateful for Dr. Laposata's unwavering commitment to improving clinical laboratory practice and willingness to be a joint plaintiff in our suit against the FDA," said Gibson. "Thanks to our combined efforts and the U.S. District Court's decision, we have been able to preserve diagnostic innovation, avoid escalating healthcare costs and continue to ensure widespread patient access for these essential medical services."

AMP has consistently 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 clarification of 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 court ruling, please visit the AMP website.

For more information about the AMP 2025 Annual Meeting, please visit www.amp25.amp.org.

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, 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.

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