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Education. Innovation & Improved Patient Care. Advocacy.
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Association for Molecular Pathology Files Lawsuit Against FDA to Challenge Final Rule on Regulation for Laboratory Developed Testing Procedures

Drastic policy change will stifle diagnostic innovation, impose billions of unnecessary dollars in healthcare mandates, and threaten patient access to essential medical procedures

ROCKVILLE, Md. – August 19, 2024 – The Association for Molecular Pathology (AMP), the premier global molecular diagnostic professional society, and world-renowned pathologist Michael Laposata, MD, PhD, today announced the filing of a lawsuit challenging the recent U.S. Food and Drug Administration (FDA) Rule that regulates laboratory developed test (LDT) procedures as medical devices under the *Federal Food, Drug, and Cosmetic Act*. The lawsuit was filed in the U.S. District Court for the Southern District of Texas against the FDA; Robert M. Califf, MD, in his official capacity as Commissioner of Food and Drugs; the U.S. Department of Health and Human Services (HHS); and Xavier Becerra, in his official capacity as Secretary of HHS.

"AMP remains very concerned about the wide-sweeping and long-lasting consequences the FDA rule will have for our members and patients across the country," said Maria Arcila, MD, President of AMP. "We filed this lawsuit to ask the Court to vacate the FDA rule given the agency's lack of authority to regulate LDTs and to avert the significant and harmful disruption to laboratory medicine. AMP will continue working with key stakeholders to develop a more effective and efficient legislative framework that ensures high-quality patient care while continuing to foster rapid innovation and the promise of new diagnostic technologies."

For decades, LDTs have led to significant clinical advancements and breakthroughs in rare and infectious diseases, human genetics, oncology biomarker testing, and more. Often created in response to unmet clinical needs, they are instrumental for early and precise diagnosis, disease monitoring, and treatment guidance. These medical procedures are designed, developed, validated, performed, and interpreted by highly trained medical and scientific experts in regulated clinical laboratories. LDTs are *not* manufactured, packaged, nor commercially distributed as medical devices. Importantly, Congress has not given FDA the authority to regulate LDTs as manufactured products, but instead delegated authority to the Centers for Medicare & Medicaid Services (CMS) to regulate these procedures as laboratory services under the *Public Health Service Act*. The FDA rule threatens the ability of professionals in clinical laboratories, including many academic medical centers, reference laboratories, and community health systems across the country, to create, adapt, and modify LDTs to meet patients' needs, account for supply chain issues, reflect advances in scientific understanding and practice standards, and improve performance characteristics.

AMP has long maintained that the best approach to ensuring the continued development of accurate and reliable LDT procedures and for correct utilization, precise interpretation, and proper application of molecular test results is through modernizing the current Clinical Laboratory Improvement Amendments (CLIA) regulations promulgated by CMS. AMP's legislative proposal to update CLIA builds on the existing oversight framework and provides enhancements where necessary to provide assurances of test quality. AMP believes this approach is a far more streamlined and cost-effective regulatory framework that improves oversight, enhances transparency, preserves innovation, avoids escalating healthcare costs, and ensures widespread patient access to vital medical services.

To read the full complaint, please visit https://www.amp.org/AMP/assets/File/advocacy/AMPvFDA_Complaint_8.19.2024.pdf.

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 2,900+ 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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