



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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AMP Applauds FDA's Decision to Delay Final Regulatory Guidance for Laboratory Developed Procedures

Organization of molecular diagnostics professionals reaffirms commitment to preserving broad access to essential patient care

Bethesda, MD - November 21, 2016 - The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular diagnostic professionals, today applauds the U.S. Food and Drug Administration (FDA) on its decision to re-evaluate its proposed regulatory guidance for laboratory developed tests or procedures (LDPs). AMP believes this decision is in the best interest of patients, healthcare providers, and the entire field of molecular pathology.

AMP has long maintained that the involvement of appropriately trained and qualified laboratory professionals is critical to the development of accurate and reliable LDPs, as well as for correct utilization, precise interpretation, and appropriate application of molecular test results. In October 2015, AMP submitted a [detailed proposal](#) to the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP) that modernizes the current Clinical Laboratory Improvement Amendments (CLIA) regulation program, expands its current network of third-party medical experts, and utilizes scientific expertise from FDA and Centers for Disease Control and Prevention (CDC). The AMP proposal provides assurance of quality, analytical validity, and clinical validity without jeopardizing innovation or patient access to necessary care, and does so in a tiered, risk-based structure that avoids duplication of activities within and between federal agencies.

"We are pleased that the FDA has decided not to finalize the guidance and we look forward to our continued discussions and professional collaborations to ultimately develop a streamlined approach that ensures high-quality patient care, enhances transparency, and preserves innovation," said Mary Steele Williams, Executive Director, AMP. "Challenging the FDA's initial draft guidance has been one of our top priorities. I'd like to thank all of our members for their countless hours spent developing and advocating for a CLIA-centric approach to LDP oversight and for their ongoing commitment to putting the patient first and preserving broad access to essential care."

For more information on AMP's past position statements and letters on LDPs, please visit:

- [AMP Responds to FDA Report on Oversight of Laboratory Developed Testing Procedures](#)
- [AMP Submits Written Testimony for Hearing on "Examining the Regulation of Diagnostic Tests and Laboratory Operations"](#)
- [Congressman Michael Burgess, MD, Speaks at Session on CLIA Modernization of Laboratory Developed Procedures at AMP Annual Meeting](#)
- [AMP Meets with Senate HELP Committee and Presents a CLIA Modernization Proposal](#)
- [AMP Submits Written Comments to FDA on Proposed Regulation of Laboratory Developed Tests](#)

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 2,300+ members practice in the various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions and oncology. They include

individuals from academic and community medical centers, government, and industry; including pathologist and doctoral scientist laboratory directors; basic and translational scientists; technologists; and trainees. 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.

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