



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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FOR IMMEDIATE RELEASE

The Association for Molecular Pathology Adds Late-Breaking Session on Laboratory Developed Procedures Oversight and Regulation to the 2014 Annual Meeting Program

Press Conference to Follow Late-Breaking Session

Bethesda, MD, October 23, 2014:

The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular testing professionals announced that it has added a late-breaking session addressing laboratory developed procedures (LDPs) oversight and regulation to its 2014 Annual Meeting program (www.amp.org/2014). The decision to add this important session stems from the recently published draft guidance, *Framework for Oversight of Laboratory Developed Tests*, issued by the U.S. Food and Drug Administration (FDA) on October 3, 2014. The AMP has reaffirmed its deep concern that attempts by the FDA to regulate providers of vital medical services the same way medical device manufacturers are regulated will greatly harm patients by reducing necessary test access, decreasing innovation, and substantially raising the cost of essential diagnostic testing. The late-breaking session, titled, “Framework for Oversight of LDTs: A Conversation with FDA” is scheduled for Thursday, November 13, 2014 at 1:00pm EST.

Following the “Conversations with FDA” late-breaking session, AMP will host a press conference, convening a panel of molecular pathology clinical professionals, from a variety of clinical laboratory settings, to appropriately frame the discussion regarding clinical care and appropriate regulation. In addition, they will share their current understanding of how the FDA draft guidance could impact patient care.

“AMP has been a long-time advocate that oversight of laboratory developed procedures should remain with the Clinical Laboratory Improvement Amendments or CLIA, which could be improved,” said Charles E. Hill, MD, Chair of the 2014 AMP Program and Director of the Molecular Diagnostics Laboratory at Emory University Hospital. “We’re glad to have the opportunity to host the FDA in this forum and look forward to having a productive presentation and discussion.”

In January 2014, AMP published an [updated position statement](#) in *The Journal of Molecular Diagnostics* on the regulation of laboratory developed procedures, or LDPs - a term coined by AMP that more appropriately captures the nature of these processes as medical services. Molecular pathology professionals are responsible for ensuring accuracy in development, application, and interpretation of testing.

AMP President, Elaine Lyon, PhD stated, “Molecular pathologists use professional expertise to design, develop, validate, and interpret lab tests. It’s important that the FDA recognize the entire process and the level of professional training and oversight that is already in place to ensure patient safety.”

Late-Breaking Session and Press Conference Details

Framework for Oversight of LDTs: A Conversation with FDA

Thursday, November 13, 2014, 1:00-2:30pm EST

Maryland Ballroom B, Level 2

Participating FDA representatives include Alberto Gutierrez, Elizabeth Mansfield, Zivana Tezak, Elizabeth Hillebrenner, and David Litwack

Press Conference

Thursday, November 13, 2014, 3:00-4:00pm EST

Chesapeake Room 3, Level 2

Note: Press Conference open to members of the media only. For press conference information and attendance, please contact Maurissa Messier at Maurissa@bioscribe.com.

About the Association for Molecular Pathology

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to what was, at the time, the newly-emerging field of molecular diagnostics. Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP has established itself as the primary resource for expertise, education, and collaboration on what is now 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.

AMP's 2,300+ members include individuals from academic and community medical centers, government, and industry; including, basic and translational scientists, pathologist and doctoral scientist laboratory directors, medical technologists, and trainees. AMP members span the globe with members in more than 45 countries and a growing number of AMP International Affiliate Organizations. The number of AMP members is growing rapidly; they are united by the goal of advancing the science and implementation of molecular and genomic laboratory medicine. For more information, please visit www.amp.org.

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