



ASSOCIATION FOR MOLECULAR PATHOLOGY
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FOR IMMEDIATE RELEASE

The Association for Molecular Pathology Voices Concern with U.S. FDA Anticipated Details of Laboratory Developed Test Draft Guidance

Reaffirms Position that Current CLIA Program at the Centers for Medicare & Medicaid Services Provides Appropriate Oversight for LDTs

Bethesda, MD, July 31, 2014:

The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular testing professionals and leading education initiatives, discussions, and policy actions central to improving the development and application of molecular diagnostics, today reaffirmed its position that the vast majority of laboratory developed tests (LDTs), or laboratory developed procedures (LDPs)—a term coined by AMP to more appropriately capture the nature of these processes as medical services—should continue operating under the regulation of the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare & Medicaid Services (CMS), and not be subject to pre-market review by the U.S. Food and Drug Administration (FDA), as suggested in the draft guidance notification issued to Congress on July 31, 2014.

“The CLIA program, in combination with laboratory accreditation programs and professional certification, provides the level of rigor, as well as the flexibility necessary, for ensuring high-quality laboratory testing in the U.S. Over-regulation or inappropriate regulation has the potential to negatively impact patient care and limit the availability of medically necessary laboratory developed procedures,” said Elaine Lyon, PhD, AMP President and ARUP Medical Director of Molecular Genetics. “We have always had positive, productive interactions with FDA and look forward to being active in the public comment process.”

AMP recently published an updated position statement on the regulation of LDPs and believes that the current oversight mechanisms already in place are sufficient for the majority of tests currently in practice. Moreover, LDPs are often the standard-of-care, the highest quality test available, and at times, the only available testing option. This Special Article was published in the *Journal of Molecular Diagnostics* in January 2014 and can be found online at [http://jmd.amjpathol.org/article/S1525-1578\(13\)00221-3/pdf](http://jmd.amjpathol.org/article/S1525-1578(13)00221-3/pdf).

“Laboratory developed molecular pathology procedures have made enormous contributions to patient care in areas as diverse as oncology, infectious diseases, and inherited disorders. We are deeply concerned that attempts to regulate providers of these vital medical services as manufacturers, will harm patients by reducing access, decreasing innovation, and substantially raising the costs of essential diagnostic testing,” said Roger Klein, Chair of the Professional Relations Committee at AMP.

As part of the 2014 AMP annual meeting, to be held November 12-15 just outside of Washington, D.C., members will participate in an Advocacy Day on Wednesday, November 12th that will feature a full day of meetings with Congress addressing regulation of LDPs, coverage and reimbursement of LDPs and other important issues. Room is still available for this registration-only event. For AMP members interested in lending support and meeting with congressional staff, please visit <https://secure.amp.org/login.cfm> for more information.

About the Association for Molecular Pathology

The Association for Molecular Pathology (AMP) was founded in 1994 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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