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AMP Meets with Senate HELP Committee and Presents a CLIA Modernization Proposal

Bethesda, MD, August 4, 2015: The Association for Molecular Pathology (AMP), the premier global professional society serving molecular diagnostic professionals, announced today its recommendation for modernization of The Clinical Laboratory Improvement Amendment (CLIA) regulations for laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). AMP's Proposal for Modernization of CLIA Regulations for Laboratory Developed Testing Procedures provides assurance of quality, analytical validity, and clinical validity without jeopardizing innovation or patient access to necessary care in a tiered, risk-based structure that avoids duplication of activities within and between federal agencies.

The Senate Health, Education, Labor, and Pensions (HELP) Committee is in the process of drafting legislation that would provide avenues for enhanced support for medical innovation and patient access to new medicines and technologies. "In an effort to support the Senate HELP committee's review of laboratory test regulation, we prepared a proposal that reflects the work of dedicated molecular pathology testing professionals whose common goal is high quality patient care," said Roger D. Klein, MD, JD, AMP Professional Relations Chair. "While we maintain that there is no evidence of systemic problems with laboratory testing or LDPs that would necessitate an increase in what is already rigorous oversight, the CLIA statute and regulations are over 20 years old. Given the advances in technology and laboratory science, these regulations can be modernized to better fit with contemporary practice. Our proposal is a streamlined, cost-effective approach that enhances transparency, ensures quality, and preserves innovation."

Earlier this year, AMP provided written comments to the U.S. Food and Drug Administration (FDA) in response to their request for feedback on a proposed draft guidance, which would apply regulations designed for medical device manufacturers to clinical laboratories and the medical professionals who perform crucial laboratory services. AMP reaffirmed its position that FDA regulations are not appropriate for professional services.

"The regulation of laboratory developed testing procedures is exceedingly important to AMP, especially in light of the FDA's intention to regulate them as medical devices. LDPs are absolutely distinct from *in vitro* diagnostic devices, which are manufactured, boxed, and shipped throughout the country. In crafting our proposal, we were diligent in soliciting input from various professional organizations. We received numerous useful suggestions and are very proud of the results," said Janina A. Longtine, MD, AMP President. "As the professionals who are the experts in these procedures, AMP is eager to assist leaders in Congress as well as at CMS to enhance the CLIA framework and update the regulatory paradigm in a way that will preserve broad patient access to essential care."

The proposal as presented to the Senate HELP Committee is available online at:
http://www.amp.org/advocacy/documents/AMPCLIAmodernizationproposalFINAL.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 2,300+ members 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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