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Congressman Michael Burgess, MD, Speaks at Session on CLIA Modernization of Laboratory Developed Procedures at AMP Annual Meeting

Session updated attendees on the latest developments in Washington, DC

Bethesda, MD, November 9, 2015: The Association for Molecular Pathology (AMP), the premier global professional society serving molecular diagnostics professionals, held a session on CLIA modernization of laboratory developed procedures (LDPs), also known as laboratory developed tests (LDTs), at its annual meeting in Austin, Texas. The session, *Modernization of CLIA Regulations for Laboratory Developed Testing Procedures*, *an Update from Washington*, featured keynote speaker Congressman Michael Burgess, MD (R-TX), a member of the House Energy & Commerce Committee, who introduced legislation in 2011 to update the current CLIA regulations and is a long-time supporter of modernizing and strengthening the existing CLIA program.

Both the House and Senate are currently wrestling with the issue of LDP regulation. The House Energy and Commerce Subcommittee on Health has a hearing scheduled for November 17, 2015 to discuss the issue of LDP regulatory oversight. The Senate Committee on Health, Education, Labor, and Pensions is considering its own legislation on this topic, which is expected out later this year. Congressman Burgess updated the audience on these congressional activities and urged those in the audience to reach out to their Congressional Representatives to communicate their concerns.

Congressman Burgess, expressing his own views and not those of the Committee or the Republican Party, told the audience that FDA has yet to make a compelling case for presenting a problem with LDPs that can only be solved through new regulations by the agency. “What concerns me most about the direction that FDA is going with regulation of LDPs is that it will add to the significant economic burden that laboratories now face and slow their ability to develop new tests to respond to pressing public healthcare needs,” he said.

Roger D. Klein, MD, JD, AMP Professional Relations Chair, gave an overview of AMP’s CLIA modernization proposal to the audience. The proposal updates the existing CLIA regulations to address new technologies and services, providing reassurance to patients, ordering physicians, and the public that all laboratory tests are accurate and reliable, while continuing to preserve dynamism and innovation in genetic and genomic testing. Dr. Klein urged the audience to take action and communicate their support of AMP’s proposal to key members of Congress.

“The goals of our proposal are to ensure high-quality patient care while continuing to foster the rapid innovation and promise of new diagnostic technologies,” said Dr. Klein. “Although we maintain that there is no evidence of systemic problems with LDPs that would support the extreme step of FDA oversight, we recognize that the already rigorous CLIA regulations need to be updated to better accommodate advances in technology and laboratory science.”

The session also featured a panel discussion with representatives from various types of laboratories including a reference laboratory, an academic laboratory, and a community medical center. The discussion centered on how the US Food and Drug Administration draft guidance (Framework for Regulatory Oversight of Laboratory Developed Tests, October 3, 2014) would severely curtail laboratories’ ability to provide

accurate and reliable LDPs and hinder quality patient care.

Marc Grodman, MD, CEO of BioReference Laboratories, remarked that we often hear the concept of needing a level playing field between IVDs and clinical lab LDPs. “A level playing field has nothing to do with innovation or patient care,” he said. “We are not here to equalize commercial opportunities. We are here to practice laboratory medicine for the benefit of the patient. In that regard, the AMP proposal is the only one that makes clinical sense.”

The regulation of laboratory developed testing procedures will remain a priority for AMP in 2016. 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.

For more information on AMP’s CLIA Modernization Proposal, please see
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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