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FOR IMMEDIATE RELEASE

AMP Submits Written Comments to FDA on Proposed Regulation of Laboratory Developed Tests

Comments Further Detail AMP's Serious Concerns with the Proposed Regulation and Emphasize that FDA Oversight Interferes with the Practice of Medicine

Bethesda, MD, February 2, 2015:

The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular laboratory professionals today announced that it has submitted written comments to the U.S. Food and Drug Administration (FDA) in response to their request for feedback on the proposed draft guidance titled, "Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)." The framework would apply regulations designed for medical device manufacturers to clinical laboratories and the medical professionals who perform essential laboratory services within them. The requirements would be sweeping and would especially impact molecular testing and the clinicians and patients that rely on them.

During a public workshop hosted by the FDA on January 8-9, 2015, representatives from AMP's leadership joined nearly 75 other stakeholders who provided feedback on the FDA draft guidance. AMP had significant presence at the workshop with members from all over the country in attendance, many representing their own institutions. AMP Past President Elaine Lyon, PhD, Federico Monzon, MD, and AMP Professional Relations Chair, Roger D. Klein, MD, JD, voiced numerous concerns with the draft framework, including its interference with the practice of medicine and its potential impact on patient access to vital molecular testing services that they and their laboratories offer.

"Implementation of the proposed framework potentially threatens patient access to critical laboratory services," said Dr. Klein. "Laboratory professionals who testified at the FDA public workshop made it clear that they lack the resources to submit tests to FDA for premarket review. Moreover, compliance with FDA's Good Manufacturing Practices would be unnecessarily burdensome, and in many ways duplicative with oversight in place by CMS' CLIA program, as the GMP components relevant to clinical laboratory services are already mandated by the CLIA regulations."

AMP reaffirms these concerns in their written comments, expressing that medical device regulations are poorly suited for, and inapplicable to, the oversight of LDTs, which AMP refers to as Laboratory Developed Procedures (LDPs) to emphasize that they are medical services. If the guidance is finalized as written, FDA would require laboratories, as medical device manufacturers, to submit applications for premarket review for thousands of laboratory developed testing services. AMP members will likely be unable to continue offering these tests; therefore, FDA will have in effect significantly diminished or eliminated patient and physician access to these services. Additionally, FDA's proposal would not permit molecular pathology professionals the current flexibility to make improvements to already approved or cleared tests, such as analyzing specimens from minimally invasive procedures, essentially freezing outdated tests in time.

“LDTs are testing services and are tools in the hands of board-certified specialist physicians, geneticists, and other doctoral level laboratory professionals who apply their professional, scientific, and medical knowledge to optimize patient care," said AMP President, Janina Longtine, MD. “A nimble environment that promotes innovation and allows testing services to be quickly adapted and improved by appropriately qualified professionals is central to the continued advancement of personalized, or precision, medicine.

The FDA guidance would apply a regulatory paradigm to laboratories that AMP believes is neither appropriate nor justified. If implemented, the Draft Guidance risks thwarting innovation, and endangering patient access to necessary services. AMP continues to advocate that modernizing CLIA regulations rather than instituting an additional layer of regulatory bureaucracy is the best way to achieve desired improvements.

The written comments submitted to the FDA by AMP can be found online at http://amp.org/advocacy/documents/FDAcommentsonLDTguidance-FINAL.pdf.

About the Association for Molecular Pathology

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP is the primary resource for expertise, education, and collaboration on 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. More information about AMP is available at www.amp.org.

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