



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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FOR IMMEDIATE RELEASE

AMP has Strong Presence at FDA Workshop on LDTs, Delivers Message of Optimizing Patient Care through Molecular Diagnostics

FDA's Public Workshop - Framework for Regulatory Oversight of LDTs, includes presentations by ten AMP members.

Bethesda, MD, January 8, 2015:

The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular testing professionals, will speak at the U.S. Food and Drug Administration's (FDA) Public Workshop, Framework for Regulatory Oversight of LDTs, Jan. 8-9, 2015. During the two day event, representatives from AMP's leadership will join other stakeholders in providing feedback on the FDA draft guidance titled "Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)". This guidance document, released last year, outlines a regulatory framework for laboratory developed testing services which will effectively repurpose existing medical device regulations and imposes substantially new requirements on clinical laboratories, hospitals, physicians, and other health care providers.

AMP will have a significant presence at the workshop, indicating the importance of FDA's proposed framework to all clinical practice areas of molecular diagnostics. Of the 83 presenters, ten are AMP members, including Elaine Lyon, PhD, Federico Monzon, MD, and Roger Klein, MD, JD, with Dr. Klein speaking specifically on behalf of AMP. AMP members will also be participating in various discussion panels structured to address different aspects of the draft guidance (i.e. clinical validity/intended use, notification and adverse event reporting (MDRs), and Quality System Regulation, among others). For the full agenda visit

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm423537.htm#agenda>.

During the workshop, AMP members will address many concerns with the draft framework, including its interference with the practice of medicine and its potential impact on patient access to the vital molecular testing services that they and their laboratories offer. If the guidance is finalized, laboratories will be required to submit applications for premarket review as medical device manufacturers, a complex, time-consuming and costly process, for thousands laboratory developed testing services if they wish to continue offering them to patients. Moreover, the FDA proposed policy could potentially stifle innovation by not allowing these professionals the flexibility to make improvements to already approved or cleared tests, essentially freezing outdated tests in time.

Even if a laboratory did attempt to maneuver and finance the FDA's unpredictable premarket review process successfully, even for a selection of tests, it would be required to implement duplicative systems that inappropriately focus on documentation of "manufacturing" activities such as design control, rather than the accuracy and reliability of the test results themselves. Compliance with these requirements, and others outlined in the draft guidance, is likely to consume significant resources without an accompanying increase in patient safety. It is possible that many laboratories, including those in major

medical centers, will not be able to resource these demands and will be forced to discontinue offering these tests to patients.

"Regulations designed for implanted devices and distributed tests are not appropriate for LDPs because LDPs are medical services," said Elaine Lyon, AMP Immediate Past-President, "Board certified professionals are involved at every stage of the development, performance, and interpretation of LDPs. We continually monitor them and improve them based on emerging medical knowledge and patient care needs as expressed by our clinicians."

To clearly distinguish the professional services that molecular pathology professionals provide using their education and experience, AMP refers to these services as laboratory developed procedures (LDPs). AMP defines an LDP as "a professional service that encompasses and integrates the design, development, validation, verification, and quality systems used in laboratory testing and interpretive reporting in the context of clinical care." AMP introduced the term in its paper, "Revisiting Oversight and Regulation of Molecular-Based Laboratory-Developed Tests" (*The Journal of Molecular Diagnostics*, January 2014, V16, I1, pp3-6; online at <http://dx.doi.org/10.1016/j.jmoldx.2013.10.003>.)

"AMP members devote their professional careers to providing the highest quality of care. The Agency's proposed regulation will markedly dampen the ground-breaking innovations developed by these professionals as a part of their laboratory clinical practice – innovation that is the genesis of commercial test kits." said Janina Longtine, MD, AMP President in a [letter to the U.S. Energy and Commerce Committee](#), "The issues being considered by the Committee [and the FDA] have significant consequences regarding whether patients and their physicians will be able to obtain the testing services they need."

Roger Klein, AMP Professional Relations Committee Chair, stated, "Current Clinical Laboratory Improvements Amendments (CLIA) regulations, plus proficiency testing, lab accreditation, and other quality measures in routine use by molecular professionals, serves as appropriate oversight of LDPs. Patient access to LDPs performed in CLIA-certified laboratories should be maintained and not impaired through the implementation of additional, duplicative regulations."

ABOUT AMP:

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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