



Association for Molecular Pathology

Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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FOR IMMEDIATE RELEASE

AMP Forms Working Group to Further Consider Oversight of Lab Tests

Bethesda, MD, May 2, 2012: The Association for Molecular Pathology (AMP) today announced that it has formed a working group that will focus on the oversight of laboratory-developed tests (LDTs). In 2009, the U.S. Food and Drug Administration (FDA) announced an intention to abandon its regulatory policy of enforcement discretion toward some laboratory developed tests. The announcement was followed by a two-day meeting that explored the current regulatory paradigm for LDTs, and considered alternatives and options for increased FDA oversight of LDTs. In response, a number of medical and business organizations put forth paradigms, and several legislative proposals have been discussed or introduced for strengthening LDT regulation.

In a published position statement and public comments, AMP has previously asserted that the CLIA program, in combination with laboratory accreditation programs, professional certification and licensure of laboratory directors, provides a rigorous and flexible framework for ensuring high quality laboratory testing in the United States. In light of the complexity of the area and the diverse proposals made, the AMP Working Group, which has been organized by AMP's Professional Relations Committee, will further consider possible approaches to LDTs oversight. The goal of the group is to produce a white paper that will outline the key issues, and provide AMP's recommendations for future LDT oversight.

Andrea Ferreira-Gonzalez, PhD, Director of the Molecular Diagnostics Laboratory in the Department of Pathology at Virginia Commonwealth University and a past president of AMP will chair the new working group. Other members of the group include:

- Stephen P. Day, PhD, Hologic, Inc.
- Rajyasree Emmadi, MD, University of Illinois at Chicago College of Medicine
- Robert F. Klees, PhD, New York State Department of Health
- Elaine Lyon, PhD, ARUP Laboratories and past chair of AMP's Professional Relations Committee
- Jan Nowak, MD, PhD, Northshore University Health System and a past president of AMP

"I am very pleased that our members took the initiative to form this working group and through Dr. Ferreira-Gonzalez's leadership, I anticipate that the white paper will be a valuable contribution to the ongoing discussions around regulating laboratory tests," said Iris Schriver, MD, President of AMP.

The working group expects to complete the white paper by the end of the calendar year. Roger D. Klein, MD, JD, Chair of the AMP Professional Relations Committee stated, "Oversight of LDTs raises complicated policy questions the resolution of which must ensure patient safety while allowing for the timely introduction of new assays that will benefit patients. The talented AMP members who have volunteered to complete this project have unparalleled knowledge, insights, and expertise that will enable them to put forth a thoughtful framework for the appropriate regulation of LDTs."

ABOUT AMP:

The Association for Molecular Pathology (AMP) is an international medical professional association dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of molecular biology, genetics, and genomics. For more information, please visit www.amp.org.

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