



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology
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AMP Presents at FDA Meeting on Regulating Diagnostics

College Park, MD (July 20, 2010): The Association for Molecular Pathology (AMP) participated in the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) public meeting on the oversight of laboratory developed tests (LDTs). Dr. Karen Mann, President of AMP, served on the second panel of the meeting titled, *Clinical Laboratory Challenges*. Additionally, Dr. Elaine Lyon, Chair of the AMP Professional Relations Committee, presented public comments.

“AMP believes that LDTs are an essential and central component of medical practice,” said Dr. Lyon, “Without LDTs, the practice of medicine that we know today would be severely reduced in scope.” LDTs continue to play essential and formative roles in delivery of preventative care, diagnosis, and disease management, and AMP believes that only high quality, clinically and analytically valid diagnostic tests should be performed in clinical laboratories. Also, all laboratories should meet CLIA standards, adhere to established guidelines, and seek appropriate certifications and accreditations.

AMP believes that a regulatory model should not interfere with the practice of medicine, and it is important to recognize the value of the current oversight system for enabling clinical laboratories to rapidly incorporate new findings into practice and to modify existing laboratory tests and their usage in accordance with advances in our understanding of clinical utility and disease pathogenesis. Dr. Lyon noted, “Nimble innovation in new test development is crucial to our ability to respond to emerging public health challenges, which was evident during the 2009 H1N1 influenza outbreak.”

There is a lack of review of current and proposed oversight models. In its remarks, AMP encouraged the FDA to collect data and assess the effectiveness of existing oversight models prior to implementing new approaches, as it will be extremely important to demonstrate that any proposed oversight system would lead to improved health outcomes.

AMP believes that LDTs in all disciplines of laboratory medicine should be subject to the same oversight mechanisms, and that molecular or genetic tests should not be singled out for heightened scrutiny simply due to the heritable nature of nucleic acids. AMP does agree that some tests may require greater scrutiny and may warrant additional regulatory review. An LDT that may require further regulation is one that:

- Uses a non-transparent algorithm with multiple markers that cannot be elucidated by other test developers, or
- Relies on technology that is not easily replicated by multiple laboratories, and for which
 - a false result would cause significant morbidity or mortality, or
 - a false result could have a widespread adverse effect for public health

However, Dr. Lyon expressed concern about the impact on low volume tests, “We feel it’s important to recognize the potential impact of increased oversight on infrequent or low volume tests. Overzealous regulation of such tests could prove to be overly burdensome and cost prohibitive for laboratories developing and offering important but infrequently utilized tests.”

To advance the field of molecular pathology, any new oversight policy should also work to address the barriers to test development. Specifically, AMP believes the recognition and implementation of advances in medical research may be hindered by a lack of certified reference materials and encourages the government to support the development of these materials at the National Institute of Standards and Technology. Dr. Lyon explained, “Molecular assays provide the cutting edge for many individualized therapies in oncology, transplantation, infectious disease and genetics, but the production of certified reference materials has fallen far behind the technical capabilities of these assays which are needed to ensure sensitivity, specificity and reproducibility of intra- and inter-laboratory test results.”

A major hurdle for laboratories is the reimbursement of diagnostic tests. Escalating costs for test development, performance, interpretation and reporting, compounded with additional costs to satisfy new regulatory requirements could result in the elimination of important clinical tests. In considering revisions to the current oversight processes, AMP urged FDA to realize the potential ramifications on test availability due to economic considerations.

Lastly, AMP recommended that the FDA convene an external advisory committee composed of individuals with expertise in the relevant diagnostic areas to assist in identifying the appropriate risk classifications. Dr. Lyon said, “There is much debate in the community about the criteria used to group LDTs into low, medium and high risk categories. An external advisory committee would be a very valuable tool for the FDA as it works to make these determinations.”

Dr. Lyon concluded, “As the FDA considers its approach to regulating LDTs, AMP encourages the agency to consider the unanticipated effects that significant modifications to the current oversight system could represent for clinical laboratories.” These unanticipated effects include the possibility that laboratories may be compelled to discontinue services and/or potentially lose flexibility to rapidly introduce and continually improve tests, all of which would adversely impact delivery of effective care to our patients.

In holding this meeting, AMP believes that the FDA has taken an important step forward and AMP looks forward to partnering with the FDA and continuing to work with the Agency for the benefit of patients.

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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