



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology
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AMP Asks FDA to Address Barriers to Device Innovation

Washington, DC (June 25, 2010): Yesterday, the Association for Molecular Pathology (AMP) gave public comments at the FDA's Center for Devices and Radiological Health (CDRH) Council meeting on *Medical Device Innovation: Barriers to Market for Molecular Diagnostic Tests*.

AMP commends the Federal departments and agencies that compose the Council on Medical Device Innovation for making efforts to identify and remove barriers to innovation and progress in transitioning basic and transitional research findings into routine clinical practice. In its remarks, AMP identified three barriers that impede the path to FDA clearance or approval for diagnostic tests and reduce the motivation to submit some medically useful tests for review.

Barrier 1. The paucity of standard reference materials for all areas of molecular diagnostics, i.e., genetic, oncology, and infectious disease testing, inhibits the production of appropriate control materials and methods. “AMP is eager to see more progress and investments in this area,” said Dr. Mark Sobel, AMP’s Executive Officer. “FDA can assist by providing a list of needed standard reference materials to relevant organizations such as the National Institute of Standards and Technology (NIST) and World Health Organization (WHO).”

Barrier 2. The difficulty of obtaining rare specimens for studies presents a barrier to submission of applications for the approval of new indications for currently approved tests. Herpes Simplex Virus (HSV) testing has been the standard of care for the diagnosis of central nervous system (CNS) disease (HSV encephalitis and meningitis) for over a decade, yet an FDA approved test does not yet exist. HSV CNS infections are relatively rare and any individual laboratory may receive only 1-2 HSV encephalitis positive specimens a year. Manufacturers who developed assays for the novel 2009 influenza H1N1 strain encountered similar difficulties in validating their assays using prospective clinical specimens after the peak of the pandemic had passed.

Dr. Sobel identified a potential solution to the shortage of specimens, “The FDA should work to establish a biorepository of clinically relevant infectious agents, including strain variants and subtypes, to facilitate the rapid development and validation of assays for infectious agents, particularly those with pandemic potential.” Alternatively, AMP also asked the FDA to consider establishing alternative validation strategies that are independent of primary clinical specimens, but are, nonetheless, rigorously grounded in sound science and infectious disease medicine.

Barrier 3. Test manufacturers perceive that there is an inconsistent and unclear regulatory pathway for their submissions. Manufacturers have faced uncertainty and/or inconsistency in the review of device submissions, in enforcement discretion, in device classification [510(k), 510(k) *de novo*, PMA, ASR, etc.], in requirements for acceptable analytical and clinical

validations, and in requirements changing from the time of pre-IDE meetings through mid-trial. “IVD test manufacturers must then function within this uncertain regulatory environment, which makes it difficult to anticipate regulatory requirements and appropriately amend their business models,” said Dr. Sobel.

To address the barriers identified above, AMP believes that the FDA can take several steps that would improve the regulatory process for molecular diagnostic tests without impinging upon an appropriate review to ensure that the public is protected.

- FDA should ensure that policies and requirements are consistently applied, and that the scientific evidence and rationale for decisions are communicated effectively to diagnostic test manufacturers.
- Communication from FDA to diagnostic test manufacturers should be as clear and as comprehensive as possible at the outset of the submission process. This will help manufacturers better plan their resources and time. It will also assuage undue angst that the regulatory bar will change during the process.
- FDA should improve communication between government branches and agencies so that consistent requirements are developed and applied and demonstrations of clinical utility in one branch are recognized by the other branches.
- FDA should involve the expert opinion of medical professional associations regarding clinical utility.

The Association for Molecular Pathology recognizes the difficulties that regulatory agencies face in the context of the rapidly changing landscape of diagnostic devices and technology and appreciates the transparent process FDA is undertaking to improve the review process for medical devices. AMP believes that a consistent, clear, and flexible regulatory process will result in improved public access to additional higher quality innovative tests; and could conceivably lower healthcare costs.

“AMP stands ready to assist the FDA through our expertise, creative problem solving, and unique perspective,” added Dr. Sobel. “We would like to offer our input and interaction with the member departments and agencies to assist in developing a more consistent, evidence-based, and transparent process for regulating diagnostic devices.”

About AMP

The Association for Molecular Pathology 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. Through the efforts of an enthusiastic membership from across the United States and around the world, AMP continues to grow in numbers and influence. The organization is divided into the scientific subdivisions of genetics, infectious diseases, hematopathology, and solid tumors. Each subdivision addresses issues, identifies goals, shapes policy, and provides member benefits specific to that particular discipline. The AMP membership includes individuals from academic medical centers, independent laboratories, government, and industry, including physicians,

laboratory directors, scientists, medical technologists, and trainees. AMP members populate the majority of clinical molecular diagnostic laboratories in the United States. AMP members are at the forefront of the development and implementation of novel molecular diagnostic tests, whether these are laboratory developed or commercially developed. AMP promotes molecular testing that is consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. AMP members proudly accept their responsibilities in assessing the analytical validity, clinical validity, clinical utility, and the clinical utilization of molecular tests for each specific patient.

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