



Association for Molecular Pathology

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

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AMP Responds to Genetic Test Registry Request for Information

Bethesda, MD (July 29, 2010): Today, the Association for Molecular Pathology (AMP) submitted written comments in response to the Request for Information made by the National Institutes of Health (NIH) for its Genetic Test Registry (GTR). AMP conducted a survey of its membership to formulate a comprehensive response to the RFI. “With the vast majority of respondents working in a clinical laboratory setting, AMP is able to inform the NIH on the general reaction to the GTR, including insight to the community’s concerns and guidance to ensure the GTR is a valued resource,” said Dr. Karen Mann, President of AMP.

AMP members reported the following reasons for participating in a voluntary registry: to provide a resource for clinicians and the public about what tests are offered, to increase transparency of testing, to provide a resource for health care professionals, to streamline testing, to improve data sharing, and to standardize tests. While the respondents were supportive of participating in a voluntary registry, the type of information they felt should be included varied greatly. Less than 60% of survey respondents were willing to provide analytical and clinical validation information to a GTR. Additionally, two-thirds of respondents indicated that the GTR would have a moderate to significant impact to their laboratory; and, twelve percent said they would discontinue offering a test if required to participate in a GTR.

Many expressed concerns about how the registry would interface with currently available registries such as GeneTests; they want NIH ensure that any new registry would avoid redundancy and would not overly burden laboratories’ limited resources to comply and update information. Survey respondents also felt that if the GTR were not curated for accuracy, then the value of the information would be limited. Last, respondents were concerned with how competitors, payers and regulators would use the information in the GTR.

AMP members would like to be actively involved in the process to develop a GTR.

“We hope the NIH will continue to actively engage the molecular laboratory community as it works to implement a GTR,” said Dr. Mann, “That is the only way to ensure that the registry is a useful tool that provides valuable information for all stakeholders.”

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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