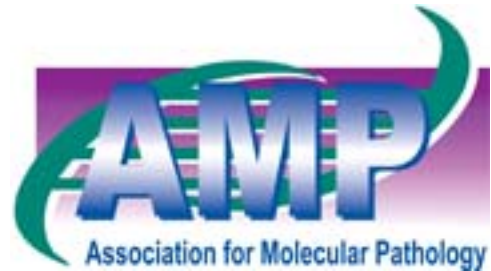


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FOR IMMEDIATE RELEASE

Proposed NIH Genetic Testing Registry Lacks Clarity, Understates Costs

WASHINGTON, DC, September 26 , 2011—The Association for Molecular Pathology (AMP) submitted comments to the National Institutes of Health (NIH), in which the Association voiced concerns about the proposed Genetic Testing Registry (GTR) as currently designed, and requested that NIH take clarity and cost into consideration when designing a test registry.

According to the NIH, the purpose of the GTR is to provide access to information about genetic tests, such as indications for use, validity data, and evidence of the test's usefulness. The information would be based on voluntary data submissions by test developers and manufacturers.

In its two-page comment letter, AMP stressed that the format of the proposed test registry is unclear and confusing, and would provide information that is not relevant, useful or suitable for the purposes of the GTR.

"AMP continues to have concerns regarding the format and the data elements proposed for the Genetic Test Registry. Some data elements include a level of detail that could cause confusion and raise legal and liability concerns for a wide range of organizations," said Mary Steele Williams, AMP's Executive Director.

AMP also noted that the NIH has grossly underestimated the time and costs involved in creating and maintaining the GTR.

"Because many of the genetic tests are complex, those entering the data will most likely need to be genetic counselors, laboratory supervisors or laboratory directors, all of whom are paid more than the mean hourly wage of \$22.85 listed by NIH for laboratory technicians," said Elaine Lyon, PhD, the Chair of AMP's Professional Relations Committee.

"Additionally, contrary to the current design of the GTR, laboratory tests do not necessarily fall into neat discrete categories. The rigid inclusion requirements may create unintended consequences and vague categories."

AMP made several recommendations for improving the registry, including ways to enhance the quality, utility and clarity of the information to be collected. AMP also recommended that the data fields be customized for each category of submitters as a way to minimize the burden of the collection of information.

"In general, AMP believes NIH should proceed with more caution and more forward-looking planning in order to design a truly useful Genetic Test Registry that isn't fraught with unintended consequences," said Williams.

AMP's membership consists of approximately 2,000 physicians, doctoral scientists and medical technologists who perform genetic and genomic diagnostic laboratory testing. Their efforts are central to the development and clinical introduction of genetic and genomic assays that are applied daily for diagnosis, prognosis and patient management in all medical specialty areas, including cancer, infectious diseases, heritable disorders, and histocompatibility testing.

To view the comments in full, visit:

http://www.amp.org/publications_resources/position_statements_letters/documents/AMPCommentsGTR_Sep2011_Final.pdf

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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