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## **AMP Comments Re: The NIH Genetic Test Registry**

**November 2, 2010**

The Association for Molecular Pathology (AMP) appreciates the opportunity for further discussion of elements for the GTR. We provided written comments previously based on a survey of AMP membership, and will refer to them here.

- 1. Based on an analysis of RFI comments and other operational issues, NIH is considering a phased approach to developing the GTR in which some types of tests would be eligible for early entry in the GTR and other types of tests would be added later. If NIH adopts this approach, what criteria should be used to determine which genetic tests should be included in the first phase of the GTR, and what types of tests would meet these criteria?**

As an intent of the GTR is to facilitate research (<http://oba.od.nih.gov/gtr/gtr.html>), AMP believes that the GTR should address those tests that are most likely to achieve this goal, namely, new clinical tests translated from genome wide association studies, pharmacogenomics, or tests that are offered from sole source providers.

- 2. Several RFI responders, who are potential data submitters, noted that it makes more sense for clinicians and genetics professionals to be the source of clinical utility evidence rather than test developers and/or test providers. Given that data submitters are unlikely to have clinical utility information, how is this data element best addressed in the GTR?**

Individual laboratories are responsible for understanding the clinical utility of their tests, as a CLIA requirement. However, for tests for which the majority of providers generate the same or similar results, the clinical utility can be addressed most efficiently in a centralized manner rather than by having each laboratory submit clinical utility data. We recommend that clinical utility be provided by experts in the field as well as professional societies (e.g., AMP, ACMG, ASCO), and CDC's EGAPP, AHRQ reviews. A format similar to the existing GeneReviews is easily accessed and readable. Other reviews are available in Europe, such as Orphanet (<http://www.orpha.net/consor/cgi-bin/home.php?Lng=GB>) that includes clinical utility summary reports.

- 3. Among responders to the RFI question about including a data element for test cost, half were in favor of including cost information and half were opposed. What are the benefits, risks, and challenges of including cost information in the GTR?**

AMP notes that cost and price are two different issues, and we will address each separately. Laboratory costs are based on price of reagents from manufacturers, labor (which can vary based on location of the laboratory), and other costs such as royalties, equipment depreciation, overhead and other expenses. Based on our survey, only 23% of respondents were willing to provide the cost of testing. Most respondents consider cost to be confidential information.

With respect to price of the test, contracts with various payers reflect a negotiated price that is often quite different than the list price. Thus, there is no one price that a respondent can list easily. In addition, most tests are currently paid by federal payers in accordance with a fee schedule of method-based stacking codes. Based on our survey, only 52% of respondents were willing to provide CPT codes.

As part of academic, hospital or institutional settings, some laboratories may not know the actual costs, billing prices or reimbursement of the tests they produce. These may be managed by administrative units.

We believe that the NIH should respect the user's right not to disclose cost and price information. This is essential to the GTR's credibility.

**4. What safeguards can be put in place to prevent GTR users from misunderstanding, misinterpreting, or misusing the information in the Registry?**

Sections containing definitions and hyperlinks to other sources of relevant information will encourage and facilitate proper understanding of the information provided.

But, as any information can be misunderstood, misinterpreted, or misused, AMP recommends that proprietary information not be included in the GTR. The GTR will be most useful if it remains a scientific resource.

**5. What mechanisms can be used to provide materials that explain the GTR's data elements to audiences with varying technical expertise?**

A majority (88%) of survey respondents indicated that the genetic test registry would be most relevant for healthcare providers and other laboratories. Notably, only half of the respondents felt that the current concept of the GTR would be relevant for genetic research. The elements, approach and format in a registry designed for diagnostic or treatment oriented information will be very different than a registry intended for genetic research or for public education. The GTR must differentiate between the goals of each potential audience. We question whether this can be achieved by a single product. This dichotomy is evident in the NIH's own disease information websites wherein the data available is different for the general public and the medical community and differentiated upfront in the menu selection. Effort to distinguish these intended audiences seems warranted.

Thank you for the opportunity to respond in this Public Meeting and for the consideration of our comments. AMP respectfully offers our assistance in designing a practical, useful genetic test directory that will be beneficial to all stakeholders.