



## **Association for Molecular Pathology**

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

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### **Secretary's Advisory Committee on Genetics, Health and Society**

**March 26, 2007**

#### **Public Comment from the Association for Molecular Pathology**

Dr. Tuckson, members of the committee, good afternoon. I am Debra Leonard, and am speaking to you now as a member of the Association for Molecular Pathology (AMP). I will forgo the explanation of the mission and membership of AMP, since we have provided comments to the SACGHS on numerous occasions in the past.

The purpose of these comments is to provide AMP's perspective on three issues relevant to the charge to the SACGHS and of concern to AMP.

#### **1. Proposed Federal legislation related to oversight of genetic testing**

Recently, two bills have been introduced into the US Senate relating to regulation of laboratory developed tests. Senator Kennedy has introduced a bill entitled "The Laboratory Test Improvement Act" and Senator Obama has introduced a bill entitled "The Genomics and Personalized Medicine Act." AMP agrees with the intended goal of these bills, which is to protect the public health by ensuring safe and effective diagnostic tests to inform clinical decision-making. However, we are deeply concerned that these bills if enacted into law would have unintended negative consequences, including severely restricted access to genetic testing services by the public, as well as decreased innovation in the implementation of novel genetic tests. As in other areas of medical practice, laboratory medicine advances by incremental steps as new information about clinical targets and test performance become available. AMP strongly believes that the same intended goals of these bills can be achieved by strengthening existing laboratory oversight mechanisms and a strong collaboration with the private sector.

The purpose of raising these issues with SACGHS today is to ensure that this advisory committee is aware of these bills and the potential negative impact that may result for genetic testing services. Furthermore, AMP asks SACGHS to request that the Secretary of Health and Human Services convene a meeting to engage key stakeholders who may be affected by these bills with members of Congress and relevant regulatory officials to reach a common understanding of the purpose of the legislation and the best ways of achieving those goals without unintended harmful outcomes.

#### **2. Assessment of Coverage and Reimbursement for Genetic Testing Services**

AMP members perform genetic tests and other types of molecular tests for the management of patient care. We continue to struggle with the economic reality that the reimbursement levels set for the CPT codes used for genetics testing are less than the cost to perform these tests. While the SACGHS report on Coverage and Reimbursement Issues made recommendations to the Secretary that CMS develop a plan to address this issue, AMP is not aware of any action taken to date. AMP applauds SACGHS for its report and recommendations, and asks that SACGHS follow up to determine if action will be taken to correct the inadequate payment levels for these CPT codes.

### **3. Gene Patents and Patient Access**

AMP asks that SACGHS continue to give full consideration to the negative impact of gene patent exclusive licensing and enforcement practices on the future of genetic testing. We are encouraged by the approach that SACGHS is taking to investigate the impact of gene patents on patient access to genetic tests. AMP wants to assure SACGHS that gene patent enforcement continues to limit the tests clinical molecular pathology laboratories can perform for their patients. We encourage SACGHS to thoughtfully consider and develop recommendations to the Secretary of Health and Human Services that will address the negative clinical impact of these practices.

AMP remains available to the SACGHS to assist with or provide additional information for your thoughtful deliberations and important work. On behalf of AMP, I thank the committee for your time and for listening to the concerns of AMP.