



## **Association for Molecular Pathology**

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

9650 Rockville Pike, Bethesda, Maryland 20814

Tel: 301-634-7939 • Fax: 301-634-7990 • Email: [amp@asip.org](mailto:amp@asip.org) • [www.amp.org](http://www.amp.org)

### **Secretary's Advisory Committee on Genetics, Health and Society March 13, 2008 Public Comment from the Association for Molecular Pathology**

Drs. Tucker and Teutsch, members of the committee, good afternoon. I am Michele Schoonmaker, and am speaking to you as a member of the Association for Molecular Pathology. I will forgo the explanation of the mission and membership of AMP, since we have provided comments to the committee on numerous occasions in the past.

Our purpose today is to summarize our written comments, submitted in response to the recent draft statement on oversight of genetic testing in the United States.

#### **1. Definition of Genetic Test**

Under SACGHS' definition, the tests would more accurately be called molecular tests rather than genetic tests. We would encourage the committee to define which intended uses are included in the intended oversight of genetic testing.

#### **2. Are Genetic Tests Different from Other Clinical Laboratory Tests?**

We recognize that tests for heritable diseases are unique in several respects. We are concerned that certain types of genetic testing marketed directly to consumers fall outside the current regulatory oversight of CLIA. We encourage the committee to further explore this issue of the potential harm of health-related direct-to-consumer marketed genetic testing on the public health and to state the distinction between clinical genetic testing and health-related direct-to-consumer marketed genetic testing.

#### **3. Requirements for Laboratory Personnel**

CLIA regulations already stipulate the responsibilities of the Laboratory Director and the Clinical Consultant. We recommend that these roles be re-emphasized with regard to genetic testing. We would like to encourage the committee to modify recommendation 1 B to include the recommendation that CMS work with professional organizations such as AMP to develop interpretative guidelines for their inspectors regarding the levels of expertise that are required for different kinds of genetic testing.

#### **4. The role of CMS (CLIA) and the FDA for Quality Assurance**

AMP offers our expertise to define the molecular targets that would be regulated analytes, to promote expansion of proficiency testing programs, better oversight of direct-to-consumer marketing of clinically dubious "genetic" tests, and reassurance of the public and members of Congress.

Voluntary standards organizations, such as the CLSI, create detailed practice guidelines which effectively fill many "holes" that some individuals believe exist in the FDA and CLIA regulatory framework. The "team approach" in which government, industry and practicing clinicians work together is a viable and desirable alternative to regulation for many genetic and genomic tests.

#### **5. Voluntary Registration**

AMP is concerned that registration of genetic tests would duplicate the information already submitted to CMS as required under CLIA. AMP strongly supports that CMS enhance the mandatory CLIA registration of non-waived laboratories by enhancing CMS infrastructure to achieve this goal.

#### **6. Proficiency Testing**

AMP supports the proficiency survey programs currently available, with additional analytes as necessary. We intend to begin publishing best laboratory and clinical practice guidelines and look forward to working with other organizations such as the CAP and ACMG to develop these guidelines.

#### **7. Clinical Validity**

We strongly favor reliance on the peer-reviewed literature, consensus statements by professional practice organizations as well as collaborative studies by CDC, other agencies, private investigators, and manufacturers. We also support integrated efforts to collect post-market data to meet clinical, regulatory, and reimbursement goals. AMP is concerned that the current recommendation 1.4 could develop a duplicative system of oversight for LDTs and laboratories performing these tests.

#### **8. Effective Communication and Decision Support**

We reiterate our commitment to participate not only in pursuing the success of this project, but in translating the results of this effort for the betterment of the public's health and well being. AMP remains available to the committee 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.