



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

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Association for Molecular Pathology Comments to the SACGHS
AMP Addresses Comparative Effectiveness Research, Evidence for Coverage of Genetic Tests, and Gene Patents

Washington, DC – June 12, 2009 – In public comments given today before the Secretary of Health and Human Services Advisory Committee on Genetics, Health and Society (SACGHS), the Association for Molecular Pathology (AMP) addressed three areas: Comparative Effectiveness Research (CER), evidence for coverage of genetic and genomic tests, and gene patents.

AMP first summarized the organization's recent extensive comment letter to the Federal Coordinating Council on Comparative Effectiveness Research:

- AMP encourages the development of a comprehensive infrastructure for CER and laboratory tests, which should include a panel of expert stakeholders with molecular diagnostics experience.
- AMP urges that funding for large, carefully designed comparative effectiveness trials for molecular tests be coupled with funding for comparative effectiveness studies that complement randomized controlled trials by including patients who do not necessarily meet the inclusion criteria for prospective trials.
- AMP calls for funding to develop new reference materials and innovative testing methods to advance laboratory quality measures.

AMP next addressed the closely related issue of reimbursement, summarizing the organization's comments to the CMS MEDCAC. AMP maintains that the evidence required for coverage of most genetic and genomic tests should not differ from the requirements for other diagnostic tests.

Last, AMP referred to their extensive comments to the SACGHS draft report on gene patents and licensing practices. AMP believes that while the Draft Report raises many key questions, it misses an opportunity to more definitively explore the negative impact on public health that derives from exclusive and restrictive licensing practices, such as with the case of the genes associated with SMA and the Connexin-26, and Connexin-30 genes. AMP encouraged the Secretary's Advisory Committee to consider additional case studies that demonstrate this point.

A copy of AMP's comments to the SACGHS as well as the full comments to the Federal Coordinating Council and MEDCAC can be found at www.amp.org.

About AMP

The Association for Molecular Pathology 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. Through the efforts of an enthusiastic membership from across the United States and around the world, AMP continues to grow in numbers and influence. The organization is divided into the scientific subdivisions of genetics, infectious diseases, hematopathology, and solid tumors. Each subdivision addresses issues, identifies goals, shapes policy, and provides member benefits specific to that particular discipline. The AMP membership includes individuals from academic medical centers, independent laboratories, government, and industry, including physicians, laboratory directors, scientists, medical technologists, and trainees. AMP members populate the majority of clinical molecular diagnostic laboratories in the United States. AMP members are at the forefront of the development and implementation of novel molecular diagnostic tests, whether these are laboratory developed or commercially developed. AMP promotes molecular testing that is consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. AMP members proudly accept their responsibilities in assessing the analytical validity, clinical validity, clinical utility, and the clinical utilization of molecular tests for each specific patient.

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