



**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@amp.org](mailto:amp@amp.org) • [www.amp.org](http://www.amp.org)

**AMP Applauds SACGHS on Release of Final Report on DNA Patents**

**Washington, DC**-February 5, 2010. The Association for Molecular Pathology (AMP) commends the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) for its thoughtful, deliberative exploration into the challenges of gene patents and is hopeful that the Secretary of the Department of Health and Human Services will act swiftly to adopt measures that would protect patients from the harms of gene patents and exclusive licensing practices. The SACGHS today approved the final version of its long-awaited report on the effects of patenting genetic material titled "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests."

The Association for Molecular Pathology provided public comments to the SACGHS on February 4 and urged the committee to finalize and release the recommendations presented last October to limit or eliminate exclusive patents on DNA sequences. AMP believes an unintended consequence of Bayh-Dole has been that patent holders and their exclusive licensees have frequently chosen to monopolize molecular testing by restricting other health care providers and facilities from developing, performing, and improving tests covered by these patents and licenses. This restriction precludes laboratories from developing tests that would directly benefit patients.

The AMP Executive Officer, Dr. Mark E. Sobel, expressed AMP's position, "We believe that attaching intellectual property rights to true acts of invention such as new therapeutics, diagnostics, or technology platforms is essential to encourage investment and reward innovation. A single gene or a sequence of the genome, however, is not only a product of nature, but contains heritable information that should not be patentable." Dr. Sobel continued, "The SACGHS expended great effort and sufficient time to analyze and fully consider the recommendations on the issue of DNA patents. The release of this report is truly a milestone."

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.

**CONTACTS:**

Mary Steele Williams  
mwilliams@amp.org  
(301) 634-7921