



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

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AMP Commends SACGHS on their DNA Patent Report

WASHINGTON, DC (October 14, 2009)—The Association for Molecular Pathology (AMP) provided comments at the Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS) meeting on October 8. AMP opposes the patenting of all naturally occurring genetic material and has signed on as a lead plaintiff in the ACLU case challenging Myriad Genetics’ patents on the BRCA 1 and BRCA 2 genes. AMP thanked SACGHS for studying how both patents and restrictive licensing limit patient access and potentially reduce the quality of tests.

The Committee met to review their final draft report on gene patents and licensing practices, and recommended that the administration promote exemptions from liability for infringing on patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes or in the pursuit of research. They also called for enhanced transparency in licensing activities, public access to information about licensing actions and Federal adoption of efforts to promote broad licensing practices. AMP views this report as a call to action for policymakers to protect all patients from restricting patents and licensing practices.

AMP commends the SACGHS for taking a strong stance against business practices that harm patients, restrict innovation and reduce access to life saving tests. AMP President Dr. Jan Nowak commented, “This report is a milestone in our efforts to improve access to genetic tests. The threat of enforcement from a patent holder and the ensuing litigation costs has created a chilling effect on clinical laboratories making us reluctant to develop new tests that could directly benefit patients.”

The task force drafting the report represented the full spectrum of stakeholders and completed a very transparent process with unlimited opportunities for public comment. The final report is authoritative and articulate, and provides a balanced assessment of the consequences of DNA patents. Dr. Nowak further complimented the task force, “The final report represents years of discourse, analysis of expert testimony and data, and the completion of a strong consensus building process. I’m proud of the task force and feel confident that if implemented, this report will benefit patients throughout the country.”

AMP congratulates the SACGHS on the publication of their report and encourages Secretary Sebelius to work quickly to adopt and implement their recommendations to protect all Americans from the harms of DNA patents.

AMP’s gene patent position statement 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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