



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

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**Comments of The Association for Molecular Pathology  
The Secretary's Advisory Committee on Genetics, Health and Society  
October 8-9, 2009**

This week, the Secretary's Advisory Committee is focusing on three areas of policy of great interest to AMP, and we would like to express our gratitude to the Committee for highlighting the concerns and challenges with gene patents, direct- to-consumer genetic testing and genetic nondiscrimination.

First, as many on the committee are probably aware, AMP is a lead plaintiff in the recent lawsuit brought by the American Civil Liberties Union challenging the validity of the BRCA 1 and BRCA 2 patents. While we have significant concerns about the patenting of DNA, our concern extends beyond that to the negative impact of exclusive and restrictive licensing practices, such as is the case for the genes associated with spinal muscular atrophy and the Connexin-26, and Connexin-30 genes. At the last meeting, we encouraged the Committee to consider exploring additional case studies that demonstrate this point in the final report. AMP looks forward to reading the final report on gene patents and licensing practices and is hopeful that it will also comment on the challenge of sole source providers of molecular diagnostic tests. AMP commends the Committee for taking the time to examine the practices and consequences of patenting genetic material.

AMP completed its position statement on direct access to genetic testing in 2007 and it is posted in its entirety on our website, [www.amp.org](http://www.amp.org). AMP views genetic testing as an integral part of health care with a great potential for future test development and use. However, AMP believes that genetic tests should be provided to the public only through the services of an appropriate health care professional and a properly certified laboratory. Additionally, we are concerned that genetic tests sold directly to the consumer have the potential to do harm, mislead consumers about the significance of the results and promote the purchase of products not proven to be medically useful.

When considering this nascent industry, AMP requests that the Committee review the practices of these companies, including the testing offered, the laboratory certification, the claims made about test results and access to qualified health professionals throughout the testing process. Additionally, the Committee should solicit feedback from the "every day" consumers of these services to learn about any benefits, harms, misconceptions, genetic literacy, changes in health behavior, and other health outcomes.

Last, AMP has been a supporter of the Genetic Information Nondiscrimination Act (GINA) for almost 20 years. We actively participated in the long struggle to see these protections enacted by Congress and we are currently working to ensure that GINA's

protections are not weakened or otherwise undermined. Earlier this year, in the healthcare reform debate, members of the Senate proposed offering an amendment that would make employer based wellness programs exempt from complying with the Civil Rights Act, the Americans with Disabilities Act, and GINA. GINA currently allows wellness programs to collect genetic information (including family history) if the program meets the criteria of voluntary as defined by the American's with Disabilities Act (ADA). According to the ADA, if an employer offers a cash incentive to participate in a wellness program, then the program is not voluntary. Employers wanted to offer cash incentives to encourage people to enroll and participate in their wellness programs, and instead of attempting to directly address the definition of voluntary, they simply tried to circumvent these civil rights and privacy protections. AMP joined 28 organizations in signing a letter urging the Senate Finance Committee to defeat this amendment. And fortunately, the GINA advocates won.

AMP is hopeful that the regulations currently being finalized by the agencies will eliminate many of the potential loopholes for employers and health insurers to avoid complying with GINA. Recently, we were made aware of the likelihood of genetic testing companies partnering with health insurers to offer tests to enrollees. While insurers can inform enrollees about the existence of a genetic test without violating GINA, AMP is concerned that the public is not armed with sufficient knowledge to understand that they have the right to decline testing without any consequences to their coverage. AMP encourages the Committee to explore these ongoing attempts to weaken or circumvent GINA, bring attention to this recent activity and work to educate the public about the protections afforded by GINA. The amendment in the Finance Committee served as a strong reminder that those who oppose GINA will continue their efforts to weaken and unravel its protections, and supporters will have to continue their fight to protect patients from genetic discrimination.

Thank you very much for your attention. Complete comments and materials on these issues can be found at [www.amp.org](http://www.amp.org).