



American Society for  
Clinical Pathology



June 20, 2011

The Honorable Lamar S. Smith  
Chairman, Judiciary Committee  
U.S. House of Representatives  
Washington, DC 20515

The Honorable David Dreier  
Chairman, Rules Committee  
U.S. House of Representatives  
Washington, DC 20515

The Honorable John Conyers  
Ranking Member, Judiciary Committee  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Louise Slaughter  
Ranking Member, Rules Committee  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairman Smith, Chairman Dreier, Ranking Member Conyers and Ranking Member Slaughter:

The Association for Molecular Pathology (AMP), the College of American Pathologists (CAP), the American Society of Clinical Pathology (ASCP), Association of Pathology Chairs (APC), and the American Society for Investigational Pathology (ASIP), representing the nation's leading organizations of pathologists, laboratory practitioners and the patients they serve, strongly oppose two amendments affecting gene patents offered by Congresswoman Debbie Wasserman Schultz to H.R. 1249, the *America Invent's Act*. We urge that both amendments be withdrawn.

Specifically, we oppose the Wasserman-Schultz amendment contained in the manager's amendment that purports to provide a safe harbor from patent infringement suits for providers who offer second opinion testing on patented genes. The safe harbor

includes significant restrictions that would prevent many patients and their physicians from obtaining independent second opinions to confirm initial diagnostic information.

We also oppose an alternative amendment offered by the Congresswoman that would replace the safe harbor with a study by the United States Patent and Trademark Office (USPTO) on second opinion genetic testing. The proposed study asks for recommendations on the best ways to provide independent second opinions within the current environment of exclusive patents. However, it does not address the broad harms of patent claims to genes and genetic associations, and could be construed as tacit Congressional endorsement of existing USPTO policies that are at the root of the problem for patients and innovators alike. Moreover, the proposed study could duplicate the studies contracted for and reported in the HHS' Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) April 2010 report, *"Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests,"*

Importantly, both the safe harbor and proposed USPTO study raise issues associated with gene patents that are the subject of the current court case that challenges the validity of patents on two hereditary breast and ovarian cancer genes, BRCA1 and BRCA2. In fact, in the next few months, a court decision is expected in the case. For this reason, we believe that both amendments should be withdrawn at this time.

As a matter of policy, we oppose the patenting of genes. Many of our members have experienced first-hand the harmful effects of gene patents on patients and their at-risk family members. Historically, enforcement of gene patents has forced many providers to discontinue testing, demonstrating that such patents have a chilling effect on innovation and advancing quality of care.

In closing, while we appreciate the spirit in which these amendments have been put forward, we again strongly urge that they both be withdrawn.

Sincerely,

American Society for Clinical Pathology  
American Society for Investigational Pathology  
Association for Molecular Pathology  
Association of Pathology Chairs  
College of American Pathologists