



Michael D. Maves, MD, MBA, Executive Vice President, CEO

June 14, 2011

The Honorable Lamar S. Smith
Chairman, Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, DC 20515

The Honorable John Conyers, Jr.
Ranking Member, Judiciary Committee
U.S. House of Representatives
2142 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Smith and Ranking Member Conyers:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express the AMA's opposition to a well-intentioned, but flawed amendment to H.R. 1249, the America Invents Act of 2011 offered by Congresswoman Debbie Wasserman Schultz that has been included in the Manager's Amendment. The Wasserman Schultz amendment purports to carve out an exemption to patent infringement claims that gene patent holders bring against other providers offering second opinions on genetic tests covered by gene patents. We do not support the Wasserman Schultz amendment because it would not increase the availability of providers willing to offer a second opinion on genetic test covered by a gene patent and the amendment could be misconstrued as authorizing, implicitly, the issuance of patents on human genes.

As a threshold matter, the AMA opposes the issuance of patents on human genes and has filed friend of the court briefs in support of plaintiffs challenging the legal validity of patents issued on human genes by the U.S. Patent and Trademark Office. Genes are products of nature and have never been patent eligible. Human gene patents conflict with long-standing principles of medical ethics regarding the sharing of natural scientific information that informs medical care and research. The issuance of patents on human genes remains very controversial and there is ongoing litigation as to whether or not gene patents are authorized by existing law. The Wasserman Schultz amendment has the potential to complicate pending litigation on the legality of patents on human genes.

In addition, the exemption to patent infringement liability contained in the Wasserman Schultz amendment is unlikely to provide much protection to providers offering second opinions because

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it is so narrowly drawn and marked by numerous exceptions. As a result, even assuming for the sake of argument that human genes may be patented, it would not establish a well-defined pathway for non-patent holders to follow in order to avoid lawsuits by current patent holders. Providers offering a second opinion would continue to face significant litigation risk.

The Wasserman Schultz amendment has the potential to undermine the ability of physicians to provide optimal care for patients, and further inhibit the development of quality diagnostic tests and access to those tests by physicians and patients. We appreciate the opportunity to share our concerns.

Sincerely,

A handwritten signature in black ink that reads "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA