

American College of Medical Genetics Medical Genetics: Translating Genes Into Health®

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ACMG Joins Lawsuit Challenging Patents on Breast Cancer Genes

Genes Are Naturally Occurring Substances and Should Not Be Patented, Says American College of Medical Genetics

BETHESDA, MD – May 12, 2009 | The American College of Medical Genetics (ACMG) has joined the Association for Molecular Pathology, the College of American Pathologists, and the American Society for Clinical Pathology in a lawsuit filed today charging that patents on the human genes associated with breast and ovarian cancer interfere with diagnostic testing, stifle research and limit women's options regarding their health care. The lawsuit challenges patents on the BRCA1 and BRCA2 genes, which are responsible for most cases of hereditary breast and ovarian cancers. Because these genes are "products of nature," the ACMG believes that granting patents on them is illegal.

ACMG has had a long-standing position against gene patenting. In the 1999 ACMG Position Statement on Gene Patents and Accessibility of Gene Testing, which was reaffirmed in 2005, ACMG stated that:

"It is the American College of Medical Genetics' position that genes and their mutations are naturally occurring substances that should not be patented."

With breast cancer affecting an estimated one in eight women, ACMG has grave concerns over the human cost of patents on genes such as BRCA1 and BRCA2 that are important in diagnosis, management, risk assessment and prevention. Patents on the BRCA1 and BRCA2 genes create a monopoly giving only one laboratory the right to do testing. This reduces consumer choice and removes the competitive incentives regarding price, quality assurance, or improvement of the tests.

"Imagine if one of your family members was making a decision about surgery to remove her breasts after a gene test result placed her at high risk for breast cancer and there was no place to get an independent test done to confirm the results," said Michael S. Watson, PhD, FACMG, Executive Director of the American College of Medical Genetics.

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ACMG believes that patenting of genes, and especially the restrictive licensing practices that limit testing to a single laboratory, stand in the way of good medical care, interfere with informed decision-making by patients, impede training of the next generation of genetics laboratory professionals, and restrict the flow of information that will add to medical knowledge. Furthermore, it is a major impediment to harvesting the vast potential of the sequencing of the human genome, which increasingly is making it possible to simultaneously study large collections of genes instead of individual genes one at a time.

"Gene patenting creates an obstacle course that will make true genomic analysis not only cost-prohibitive, but impossible, given that no single laboratory will ever own the rights to offer comprehensive testing," concluded Bruce R. Korf, MD, PhD, FACMG, president of the American College of Medical Genetics.

For more information on the BRCA1 and BRCA2 gene patent case, visit: www.aclu.org/brca.

About the American College of Medical Genetics

Founded in 1991, the American College of Medical Genetics (www.acmg.net) is the national non-profit professional organization that advances the practice of medical genetics by providing education, resources and a voice for more than 1400 biochemical, clinical, cytogenetic, medical and molecular geneticists, genetic counselors and other healthcare professionals committed to the practice of medical genetics. ACMG's activities include the development of laboratory and practice standards and guidelines, advocating for quality genetic services in health care and in public health, and promoting the development of methods to diagnose, treat and prevent genetic disease. *Genetics in Medicine*, published monthly, is the official ACMG peerreviewed journal. ACMG's website (www.acmg.net) offers a variety of resources including Policy Statements, Practice Guidelines, Educational Resources, and a Medical Geneticist Locator. The educational and public health programs of the American College of Medical Genetics are dependent upon grants and contracts and charitable gifts from corporations, foundations, and individuals. The **American College of Medical Genetics Foundation** (www.acmgfoundation.org) is a 501(c)(3) not-for-profit organization dedicated to funding the College's diverse efforts to translate genes into health.

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