US Supreme Court rules against gene patenting

On June 13, the U.S. Supreme Court unanimously ruled that the breast cancer genes, BRCA1 and BRCA2, cannot be patented, taking a strong stand to limit the rights of companies to own human genes. The patent on the BRCA1/2 genes has been held by one laboratory, Myriad Genetics, since the late 1990s. Mutations in BRCA1 and BRCA2 genes increase the risk of breast and ovarian cancer, and are also linked to increased risk of other cancers including prostate, male breast cancer, pancreas cancer and melanoma.

“The U. S. Supreme Court’s unanimous rejection of patenting human genes is a clear victory for patients that will expand medical discovery and preserve access to innovative diagnosis and treatment options,” the American Medical Association said in a published statement. Myriad’s lawyers argued that patents are essential to development of diagnostic tools to help patients and doctors assess the risks of cancer. However, Justice Clarence Thomas wrote that “Myriad did not invent these genes” and therefore the patent was deemed invalid. The court’s 9-0 decision in the case involving Utah-based Myriad Genetics has made it possible for more laboratories to offer this testing, resulting in competitive pricing and more testing options for patients. Furthermore, scientists will have greater access to perform genetic research involving BRCA1 and 2, which will lead to an improved understanding of the hereditary basis of breast and ovarian cancer. The decision has been hailed as a victory for families with genetic risk of cancer and for geneticists and researchers around the world.
ASCO UPDATES ON RISK REDUCTION FOR BREAST CANCER

The American Society of Clinical Oncology (known as ASCO) recently published newly updated clinical practice guidelines on pharmacologic prevention for women at increased risk for breast cancer. These updated guidelines strongly recommend discussing the use of Tamoxifen in premenopausal women, and Tamoxifen and Raloxifene in post menopausal women who are at an increased risk of developing breast cancer. There is also a newer option of Exemestane (an Aromatase inhibitor) as an alternative for post-menopausal women at increased risk.

The new guidelines were published as an ASCO special article in the Aug. 10, 2013 issue of the Journal of Clinical Oncology. This represents an update from the 2009 guidelines on the same topic.

Women at increased risk for breast cancer over age 35 should be advised of the option of Tamoxifen (20 mg a day for five years) to reduce the risk of breast cancer. In addition, postmenopausal women have the option of Raloxifene (60 mg per day for five years), and more recently Exemestane (25 mg a day for five years) as an option.

Individuals at increased risk of breast cancer are defined as patients with a five-year projected absolute risk of breast cancer greater than or equal to 1.67, based on the National Cancer Institute breast cancer risk assessment tool, known as the Gail model. Women with lobular carcinoma in situ are also included in these guidelines.

Healthcare providers are encouraged to discuss the option of using these agents among women at increased risk for breast cancer. The discussion should include a review of the specific risks and benefits associated with each agent. These agents should be offered to women 35 years or older who are at increased risk of developing invasive breast cancer based on risk factors such as age, race, medical and reproductive history, which are included in the Gail risk model.

Breast cancer is the most frequently diagnosed cancer in the world, and the second most common cause of cancer-related death in the United States. According to the American Cancer Society, more than 234,000 women will be diagnosed with breast cancer and more than 40,000 women will die of the disease in 2013. It is estimated that millions of women in the United States may be eligible to use agents for breast cancer prevention, and the benefits of these agents far outweigh the risks. It is therefore important for providers to be able to identify high risk women and to offer them these FDA-approved cancer prevention agents.

BEAUMONT’S 2ND ANNUAL BRCA SYMPOSIUM A SUCCESS

Beaumont’s Cancer Genetics Program hosted the second annual BRCA symposium on Sept. 21, 2013 for patients and family members who are BRCA positive. The symposium was organized by Beaumont’s certified genetic counselors under the direction of Dana Zakalik, M.D., director of Cancer Genetics. The facilitator of the symposium, Lindsay Dohany, MS, CGC, was the driving force behind the event. Patients and family members convened at Royal Oak to hear various experts discuss BRCA-related topics, including BRCA genetics, pancreatic cancer screening, breast reconstruction, targeted therapies and pre-implantation genetic diagnosis. Lisa Schlager, vice president of Community Affairs and Public Policy for FORCE (Facing our Risk of Cancer Empowered), presented on the role of FORCE in advancing key topics relating to BRCA, including the recent U. S. Supreme Court ruling. “The program continues to raise awareness and discuss pertinent topics related to BRCA. We had a great turnout and the speakers provided cutting-edge information,” says Dohany. “The symposium was again a success and planning for next year’s symposium is already in motion.”
Updates in genetic testing

Recent advances in genetics are changing the way we approach testing for hereditary predisposition to cancer. New technologies now allow laboratories to analyze multiple candidate genes that may be responsible for an individual’s risk of cancer.

A process known as Next Generation Sequencing (NGS) allows rapid, simultaneous analysis of multiple genes at a considerably lower cost compared to traditional sequencing techniques. This innovation has allowed the introduction of new genetic testing panels for hereditary breast, colon, ovarian and other cancers.

With NGS, each panel focuses on a targeted group of genes, some of which are very rare, in order to determine whether a hereditary predisposition to cancer exists within a family. These gene panels evaluate high and moderate penetrance genes, and allow for time and cost efficiency. This analysis, also referred to as Multiplex genetic testing, is particularly useful in situations where it is not obvious which genetic syndrome may be present within a family.

There are, however, new challenges with this technology, not the least of which is the importance of providing patients with proper pre- and post-test counseling along with a thorough understanding of the rare genes which are being evaluated. In addition, there is the challenge of ensuring appropriate interpretation of variants of uncertain significance. By testing for multiple genes, many of which are exceedingly rare causes of hereditary cancer in the population, one may find a variant of undetermined significance (VUS). This result may or may not be functionally significant for cancer risk. In most cases, the detection of a VUS should not alter medical management guidelines, as often, these variants are not associated with risk of cancer.

Appropriate education of providers and patients is important to optimally utilize these new technologies. In addition, it is important for the testing laboratories and scientists to share their data regarding the VUS results.

There is currently significant debate in the oncology community whether these gene panels should be utilized outside the context of a clinical research study. If used by genetics professionals with expertise in understanding and analyzing the results of these panel tests, there is the potential for improving our understanding of the causes of hereditary predisposition to cancers. The genetic counseling team at the Beaumont Cancer Genetics Program is available to answer any questions regarding this new technology and its optimal utilization and interpretation.
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Cancer Awareness

September
Ovarian Cancer awareness month
Prostate Cancer awareness month

Week of September 29 – October 5
Hereditary Breast and Ovarian Cancer week

October 2
National Previvor Day

October
Breast Cancer awareness month

November
Family History awareness month
Lung Cancer awareness month
Pancreatic Cancer awareness month

Welcome to Our New Staff Member

Julie Ellis, RN, BSN, OCN, CRNI, joins us as our new nurse navigator. She joins the Cancer Genetics team with more than 21 years of oncology experience. Her duties include coordinating care for patients who require long-term follow-up, and collaborating with the genetic counselors to guide patients through the genetic counseling program.