



May 13, 2016

U.S. Department of Health and Human Services  
Office for Civil Rights  
200 Independence Avenue, SW, Suite 515F, HHH Building  
Washington, DC 20201

To whom it may concern,

We submit this letter in support of the HIPAA complaint filed by patients regarding access to genetic information.

Breast Cancer Action (BCAction) is a national education and activist organization working to achieve health justice for all women at risk of and living with breast cancer. We advocate for systemic change to stop breast cancer before it starts, while also addressing the needs of women at risk of and living with breast cancer. With 60,000 members nationwide, we are a patient watchdog working to put public health and patient needs first.

In 2009, we were a plaintiff in the suit brought against Myriad Genetics to challenge the company's patent claims on the human BRCA1 and BRCA2 genes, the *Association for Molecular Pathology v. Myriad Genetics, Inc.* In June 2013 the U.S. Supreme Court ruled unanimously in our favor that genes found in nature are not patentable. Soon after the ruling the cost of commercial testing dropped and more women were able to get access to this potentially life-saving information.

Our interest in this issue goes beyond the extremely important issue of cost and access. We are also deeply concerned about the ways that the patent monopoly held by Myriad Genetics for nearly 20 years impeded scientific and medical progress.

Despite the significant progress that identification of the BRCA 1/2 genes sparked for families with strong histories of breast and ovarian and other cancers, many questions remain. For example, some families carry variants of uncertain significance (VUS), which labs have not yet classified as linked or not linked to increased risk of cancer. Such families urgently want answers about these rare mutations. Other families have a strong history of cancer even without carrying a recognized deleterious mutation. Additionally, even for families with a known deleterious mutation, questions remain why some individuals get cancer while others do not.

As a patient watchdog, we recognize that in order to answer these and other patient questions, researchers and clinicians must have access to properly protected and anonymized data from millions of individuals. Although there are a number of labs seeking to address these and other issues, so long as Myriad Genetics continue to hold hostage vast quantities of data accumulated under an unjust patent, advancements will be delayed.

We believe that access to these data is critical for the medical and scientific community to learn from clinical genomic research and to advance medical options for women living with and at risk of breast cancer. For this reason, BCAction believes that all patients should have the same right to access genetic information as she would to records about physical exams, mammograms, MRIs, and other medical procedures. No company should be able to withhold a patient's genetic information

from her. All patients should have the right to access their own genetic information which would allow them to monitor any scientific developments that might affect them and their families as well as contribute their data to research.

We urge you to affirm patient rights to their genetic information under HIPAA.

Sincerely,

A handwritten signature in black ink, appearing to read "Karuna Jagger". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Karuna Jagger  
Executive Director  
Breast Cancer Action