

In March, the FDA announced that they would again allow 23andMe, a direct-to-consumer genetic testing company, to start offering testing for mutations in the BRCA1 and BRCA2 genes known to increase the risk for breast, ovarian, and prostate cancer without the involvement of a healthcare provider. This may raise questions among consumers and their healthcare providers.

Consumers and healthcare providers should be aware of the limitations of this testing and the alternatives. The testing offered by 23andMe only tests for 3 specific mutations out of the 1000s of known mutations in the BRCA genes and also does not test for mutations in the dozens of other genes associated with increased risk for breast, ovarian, or other cancers. These 3 mutations are most commonly found in individuals of Ashkenazi (Eastern European) Jewish ancestry.

23andMe states that even if a mutation is found through their test, consumers should not use the results to make any medical decisions without first having confirmatory testing. Therefore, consumers concerned about their cancer risks could likely have more appropriate and comprehensive genetic counseling and testing for about the same expense (or less if covered by insurance) if they started by pursuing these services through a qualified healthcare provider and clinical laboratory.

Individuals should also keep in mind that 23andMe is a for-profit company that profits not only from individuals buying their test but also from selling their customers' genetic information. So although they may truly care about their customers, they do have a significant financial interest in encouraging them to pursue their testing.

The National Society of Genetic Counseling (NSGC) released a response to the FDA announcement that aligns well with the views of the Smilow Cancer Genetics and Prevention program as well as many other experts in the field.

The NSGC response is as follows:

[The National Society of Genetic Counselors](#) *commends the FDA for recognizing that these tests are limited and should not be used for medical treatment without consulting with a medical professional, such as a genetic counselor.*

*Genetic testing is complicated and is only one piece of the puzzle when determining one's risk for developing a disease. Genetic counselors can guide and support patients seeking more information about their genetic health and help interpret test results. The 23andMe test detects only three out of more than 1,000 known BRCA mutations and doesn't rule out other BRCA mutations that increase cancer risk. Consumers who test positive for these mutations need to be retested in a clinical setting under the supervision of a medical professional before moving forward with any medical decisions. Those who test negative, yet have a strong family history of cancer, may be appropriate candidates for testing and should also consult with medical professionals.*

To read the rest of their statement and to learn more, click [here](#).

If you have questions, have learned that you carry a mutation through direct-to-consumer testing, or are concerned about your personal and/or family history of cancer, please contact Smilow Cancer Genetics and Prevention for more information or to schedule an appointment at 203-200-4362.