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Alert: Cancer Genetic Testing Should Be Performed in the Health Care Setting

There is a flood of information available about genetic tests for cancer risk in the media, and even at community events, such as health fairs and senior centers. If these promotions have caught your attention and you are considering testing, there is important information that you should know first.

Facing Our Risk of Cancer Empowered (FORCE) is a national nonprofit organization that provides resources to help people make informed decisions about genetic testing for cancer risk. National standard-of-care guidelines recommend genetic counseling with a qualified expert **before** and **after** genetic testing. FORCE agrees that [talking to a health care provider](#) with expertise in cancer genetics **pre-** and **post-**genetic testing is important. This helps assure that:

- The right test is performed (there are *many* available) at a reliable, high-quality lab.
- Your results are interpreted correctly.
- You receive accurate information about what the results mean and your medical options.

When genetic testing for cancer risk is conducted outside of a health care setting—as described below—the likelihood of misinformation is high, which could lead to harm.

Tests Sold in Non-Health Care Settings

Members of our community have reported sales representatives aggressively promoting genetic tests directly to consumers at health fairs, senior living facilities, on Facebook, and in other non-medical settings. These sales representatives have been evasive about the actual lab performing the testing and have provided misleading information, making false promises of “free” genetic testing to people who don’t qualify and billing insurance companies or Medicare for tests which may not be medically necessary.

BRCA Testing Through 23andMe

In March 2018, the FDA approved marketing of **23andMe**’s test for the three BRCA mutations most commonly found in people of Ashkenazi Jewish ancestry. Over 6,000 different mutations—in BRCA1, BRCA2 and [other](#) genes—are associated with an increased risk of cancer. The 23andMe BRCA test only looks for three of these many mutations (two in BRCA1 and one in BRCA2). This extremely limited test may provide people with a misleading understanding of their cancer risk. (FORCE released a [public statement](#) to educate people about the limitations and drawbacks of this test.)

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The FDA label warns people not to use the 23andMe BRCA test results to make medical decisions, and advises individuals to have a confirmatory test with a clinically certified lab to assure accuracy of the results. The agency also emphasizes “it is important for patients to consult their health care professional who can help them understand...their individual cancer risk.”

Using Ancestry Testing to Assess Cancer Risk

Many companies (Ancestry, MyHeritage, 23andMe, etc.) offer genetic testing to help people locate relatives or learn more about their ethnicity. These tests are intended for recreational purposes and not meant to guide medical decision-making. Some third-party online programs (Promethease or Livewello, for example) allow people to submit their ancestry test results to discover additional information about their risk for cancer and other diseases. Ancestry tests, however, often do not produce comprehensive, high-quality DNA data.

FORCE has received numerous reports of people receiving incorrect information about their cancer risk after running DNA results through a third-party tool. A study published in 2018 revealed a high number of [false positives](#) in this type of information; as a result, people incorrectly thought they had a genetic mutation that increased their risk for cancer, which they do not have. Further, it is impossible to know how many people receive false negative results, leading them to believe that they do not have a predisposition to a disease such as cancer when, in fact, they do have a mutation that increases their risk.

Genetic Testing is Regulated

You have a right to know the name of the lab performing your genetic testing. Beware of representatives selling genetic tests for unnamed labs.

Genetic tests are currently regulated by the FDA and [CLIA](#). When ordering lab work such as a genetic test, health care providers typically order them through a trusted, CLIA-certified lab, which is regularly evaluated for quality assurance. The FDA aims to ensure that test marketing materials and claims are accurate, and that they address the information needs of the approved audience—health care providers or the public. If you have concerns or a complaint about a laboratory, you or your health care provider can [file a complaint](#) with CLIA and/or the FDA.

Considering Genetic Testing? Don't Go It Alone.

Genetic testing can provide important, life-saving information. Seeing a genetics expert can alleviate much of the uncertainty about whether to test, which test to order, and what the results mean for you and your family. If you are considering genetic testing to learn more about your cancer risk, or if you have already received genetic test results, consider speaking with a genetic counselor, doctor or other provider who has advanced training in genetics. This is the most reliable way to obtain and understand information about your risk. Details on how to [find a genetic counselor](#) are available through the FORCE website. If you would like to speak with others who have faced similar decisions around genetic testing, sign up for our [Peer Navigation Program](#) to be matched with a volunteer and receive a personalized guide.

