FDA Approves New Direct-to-Consumer Genetic Test for 3 BRCA Mutations

March 6, 2018 – Today, the Food and Drug Administration (FDA) announced approval of a new direct-to-consumer genetic test for three BRCA mutations most commonly found in people with Ashkenazi Jewish (Eastern European) ancestry, often referred to as founder mutations. With thousands of known BRCA1 and BRCA2 mutations, 23andMe's "Personal Genome Service Genetic Health Risk (GHR) Report for BRCA1/BRCA2 (Selected Variants)" provides consumers with an extremely limited snapshot of potential hereditary cancer risk.

In its news release, the FDA states, "While the detection of a BRCA mutation on this test does indicate an increased risk, only a small percentage of Americans carry one of these three mutations and most BRCA mutations that increase an individual's risk are not detected by this test. The test should not be used as a substitute for seeing your doctor for cancer screenings or counseling on genetic and lifestyle factors that can increase or decrease cancer risk…Consumers and health care professionals should not use the test results to determine any treatments, including anti-hormone therapies and prophylactic removal of the breasts or ovaries."

FORCE agrees with the above FDA comments. The new 23andMe test is an incomplete panel that offers limited information about cancer risk for the vast majority of people who undergo genetic testing. We are concerned that individuals who receive this GHR Report may not receive or understand information about the limitations of this test, their cancer risk, and ways to manage that risk.

Following is information that should be communicated to anyone who opts for this test:

- The best way for anyone to learn about his or her risk of cancer is to consult with a genetics expert before undergoing genetic testing for increased cancer risk. Information on how to find a genetic counselor is available through the FORCE website.
- People who receive a positive BRCA test result from 23andMe should speak to a genetics expert to better understand their cancer risk and how to manage it.
- People who test negative for a BRCA mutation through 23andMe may still be at increased risk for cancer.
- This 23andMe test only looks for the three most common BRCA1 or BRCA2 mutations found in Ashkenazi Jewish people. BRCA1 and BRCA2 mutations have been found in people of every race and ethnicity. Over 5000 different BRCA mutations have been identified through genetic testing. People of Jewish ancestery can carry one or more of the other thousands of BRCA1 or BRCA2 mutations, or in other high-risk cancer genes.

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- Testing only for the three founder mutations is most helpful for people of Ashkenazi Jewish descent. About 2.5% of Ashkenazi Jewish people carry one of the inherited BRCA mutations tested for in 23andMe's panel. It's important to note, however, that some Jewish people carry a mutation other than one of the three founder mutations tested for in this panel. As such, a Jewish person may falsely assume that they do not carry a BRCA genetic mutation if the GHR test is negative. Beyond the Jewish community, an estimated one in 400 people in the "general population" carry an inherited mutation that puts them at increased risk of certain cancers. Approximately 98% of the U.S. population is not Jewish so this test is a very poor indicator of hereditary cancer risk for the majority of Americans.
- Inherited mutations in many other genes are associated with increased cancer risk. The genes that cause Lynch syndrome, Cowden's syndrome, and newly identified genes such as PALB2, CHEK2, BRIP1, ATM and many other gene mutations have also been linked to increased risk for breast, ovarian, or other cancers. Consumers who receive a negative 23andMe GHR Report may falsely believe that they do not carry an increased risk of hereditary cancer when they actually do. A list of genes associated with hereditary breast, ovarian, and related cancers is available on the FORCE website.
- There are comprehensive panel tests available through testing laboratories that can identify any of the mutations associated with increased cancer risk. A genetics expert can determine if genetic testing is warranted, assure that the appropriate test is ordered, and once testing has been completed, correctly interpret the results. Genetic counseling and testing can help women and men understand their risk for cancer based on family history and genetics, and make medical decisions about managing their cancer risk.
- Under the Affordable Care Act (ACA), most health insurers are required to cover BRCA testing at no cost for women who meet certain family history criteria. Outside of those covered by ACA, genetic testing for mutations associated with hereditary cancer is typically covered by health insurance for men and others. Financial assistance and reduced-cost options are available for people who do not have, or prefer not to utilize, health insurance.

For more information about hereditary cancer and related issues please visit the FORCE website at www.facingourrisk.org.

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