



Fighting Hereditary Breast and Ovarian Cancer

November 1, 2016

Jeffrey E. Shuren, MD, JD
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration
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Dear Dr. Shuren,

On behalf of FORCE: Facing Our Risk of Cancer Empowered, I am sharing our public response to the recent FDA Safety Communication recommending against the use of screening tests for ovarian cancer. FORCE is the largest national organization representing people affected by hereditary breast, ovarian, and related cancers. Our constituents include individuals with a BRCA or other inherited genetic mutations, which place them and their relatives at significantly increased risk for breast, ovarian and other cancers. Ovarian cancer screening and prevention is of great concern for the women affected; they face difficult decisions due to their high risk of cancer. We greatly respect the FDA's stance on this matter and look forward to working with you to advance better screening, detection and prevention options for those at elevated risk for cancer.

Sincere Regards,

Lisa Schlager
Vice President, Community Affairs & Public Policy

FORCE Statement on Ovarian Cancer Screening

Recently, the FDA released a statement about screening for ovarian cancer, recommending against screening tests marketed to women at average or high risk for this disease. The FDA recommendation is based on the lack of evidence that these tests can detect ovarian cancer early in asymptomatic women, and the chance that false positives may lead to unnecessary surgery. The FDA also expressed concern that women at high risk for ovarian cancer may delay undergoing risk-reducing removal of their ovaries and fallopian tubes (also known as risk-reducing salpingo-oophorectomy, or RRSO), which has been shown to greatly decrease cancer risk.

Women with certain inherited genetic mutations face significantly increased lifetime risk of ovarian cancer. Genetic counseling and testing can help women understand their personal risk for ovarian cancer based on their family history and genetics, and make informed decisions about how to manage this risk.

There is broad agreement among experts that women with very high risk for ovarian cancer should undergo risk-reducing removal of their ovaries and fallopian tubes. Current National Comprehensive Cancer Network (NCCN) guidelines recommend RRSO for all women with a BRCA1 or BRCA2 mutation beginning at ages 35 and 40, respectively. The same guidelines recommend that women with Lynch Syndrome or a mutation in the BRIP1, RAD51C or RAD51D genes, which are also associated with significantly increased risk of ovarian cancer, consider removal of their ovaries and fallopian tubes as a risk-reduction option.

Women at high risk for ovarian cancer often have valid reasons for delaying surgery. Unfortunately, RRSO before natural menopause can be associated with significant side effects. Many women are in their 20s and 30s, younger than the recommended age for RRSO, when they learn of their increased ovarian cancer risk. Although rare, cases of ovarian cancer do occur in this age group. Women who are aware that they are at high risk for ovarian cancer but not yet ready to have surgery are faced with a difficult situation: utilize the available imperfect screening modalities such as CA125 testing and transvaginal ultrasound until they are ready to undergo surgery—or do nothing. Understandably, many feel that imperfect screening is better than no screening. There are a number of variables to consider in one's screening/treatment regimen, including age, stage of life, family history, and tolerance for false positive or false negative tests. With this in mind, FORCE suggests that women consult with medical experts who are familiar with the standards of care and risk management in high-risk women to determine the best course of action, and reevaluate as their situation changes and the data continue to evolve.

The lack of a reliable method of early detection for ovarian cancer highlights the crucial need for additional research in this field, taking into account the unique interests, concerns, and circumstances of women at high risk for ovarian cancer.