Ovarian Cancer Screening Tests: Safety Communication - FDA Recommends Against Use

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AUDIENCE: Patient, OBGYN, Oncology

ISSUE: The FDA is alerting women about the risks associated with the use of tests being marketed as ovarian cancer screening tests. The Agency is especially concerned about delaying effective preventive treatments for women who show no symptoms, but who are still at increased risk for developing ovarian cancer.

Despite extensive research and published studies, there are currently no screening tests for ovarian cancer that are sensitive enough to reliably screen for ovarian cancer without a high number of inaccurate results. However, over the years, numerous companies have marketed tests that claim to screen for and detect ovarian cancer.

FDA is concerned that women and their physicians may be misled by such claims and rely on inaccurate results to make treatment decisions. Based on the FDA's review of available clinical data from ovarian cancer screening trials and recommendations from healthcare professional societies and the U.S. Preventive Services Task Force, available data do not demonstrate that currently available ovarian cancer screening tests are accurate and reliable in screening asymptomatic women for early ovarian cancer. For example, some women may receive test results that suggest ovarian cancer even though no cancer is present (a false-positive). These women may undergo additional medical tests and/or unnecessary surgery, and may experience complications related to both. Or, test results may not show ovarian cancer even though cancer is present (a false-negative), which may lead women to delay or not seek surgery or other treatments for ovarian cancer.

Using unproven ovarian cancer screening tests also may be harmful for women with increased risk for developing ovarian cancer. For instance, these women and their doctors may not take appropriate actions to reduce their future risk if they rely on a

result that shows no cancer currently present. Yet, this group of women is still at high risk of developing ovarian cancer later based on their gene mutation and/or family history. The FDA believes that women at high risk for developing ovarian cancer should not use any currently offered test that claims to screen for ovarian cancer.

BACKGROUND: Ovarian cancer occurs when abnormal cells in or near the ovaries grow and form a malignant (cancerous) tumor. In the United States, ovarian cancer is the fifth leading cause of cancer-related death among women. The National Cancer Institute estimates that in 2016, more than 22,000 women will be diagnosed with ovarian cancer. Women who have reached menopause, women who have a family history of ovarian cancer, and women with the BRCA1 or BRCA2 genetic mutations have the highest risk for developing ovarian cancer.

RECOMMENDATION: Based on currently available information, the FDA recommends against using currently offered tests to screen for ovarian cancer.

For women, including those at increased risk of developing ovarian cancer:

- Be aware that there is currently no safe and effective ovarian cancer screening test.
- Do not rely on ovarian cancer screening test results to make health or treatment decisions.
- Talk to your doctor about ways to reduce your risk of developing ovarian cancer, especially if you have a family history of ovarian cancer, or have the BRCA1 or BRCA2 genetic mutations.

For physicians:

- Do not recommend or use tests that claim to screen for ovarian cancer in the general population of women. Be aware that testing higher risk asymptomatic patients for ovarian cancer has no proven benefit and is not a substitute for preventive actions that may reduce their risk.
- Consider referring women at high risk of developing ovarian cancer, including those with BRCA mutations, to a genetic counselor or gynecologic oncologist, or other appropriate health care provider for more specialized care.

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