Breast Cancer Screening: Thermogram No Substitute for Mammogram

The Food and Drug Administration re-emphasizes that mammography is still the most effective breast cancer screening test.

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The U.S. Food and Drug Administration is reminding you that mammography—a low-dose X-ray image of the breast—is still the most effective breast cancer screening test. Proper breast cancer screening lets health care providers check for cancer even before there may be signs and symptoms of the disease.

Unfortunately, the FDA has received reports from health care providers and patients that some health centers are providing information that can mislead patients into believing that thermography—a type of test that shows patterns of heat and blood flow on or near the surface of the body—is a proven alternative to mammography. But the FDA is not aware of any scientific evidence to support these claims.

Indeed, thermography has not been shown to be effective as a standalone test for either breast cancer screening or diagnosis in detecting early stage breast cancer.

“Plenty of evidence shows that mammography is still the most effective screening method for detecting breast cancer in its early, most treatable stages,” reiterates Helen J. Barr, M.D., director of the Division of Mammography Quality Standards in the FDA’s Center for Devices and Radiological Health. “You should not rely solely on thermography for the screening or diagnosis of breast cancer.”

More About Misleading Thermography Claims—and FDA Actions to Protect the Public

The FDA regulates the medical devices used for breast cancer screening.

About 1 in 8 women will be diagnosed with breast cancer sometime in their lives, reports the National Cancer Institute, part of the National Institutes of Health. Rarely, men also can have breast cancer. But there has been a decline in breast cancer deaths in recent years, and one reason is because cancers have been detected earlier through mammography, according to the American Cancer Society.

In fact, the greatest danger from thermography is that those who opt for this method instead of

mammography may miss the chance to detect cancer at its earliest stage.

Thermography has only been cleared by the FDA as an “adjunctive” tool—meaning for use alongside a primary test like mammography. Patients who undergo a thermography test alone should not be reassured of the findings because the device was not cleared to be used other than with another testing method like mammography. (You can learn more about mammography—including how it works and how to find a certified facility—on the FDA’s website.)

Moreover, some websites claim that thermography can find breast cancer years before it would be detected through other methods and have unproven claims about improved detection of cancer in dense breasts. The FDA is aware of no evidence that supports these claims.

The FDA has taken regulatory action (including issuing warning letters) against health care providers and thermography manufacturers who try to mislead patients into believing that the thermography can take the place of mammography. To protect the public health, the FDA’s regulatory action can include scheduling a regulatory meeting, sending a warning letter or other correspondence, an establishment inspection, and judicial actions.

The FDA continues to monitor this situation.

Advice for Patients Getting Breast Cancer Screening

Some women have sought out thermography because it is painless and doesn’t require exposure to radiation.

If you’re worried about how a mammogram feels, talk to your health care provider about what you can expect. A mammogram can be uncomfortable for the person being screened because it briefly presses down on the breast to flatten out the breast tissue and increase the clarity of the X-ray image. (You can learn more about what to expect during a mammogram on the FDA’s website.)

Also talk to your health care provider if you have specific questions about mammography, including questions about when and how frequently you should be screened. As a rule, you should also call your health care provider if you notice any change in either of your breasts such as a lump, thickening or nipple leakage, or changes in how the nipple looks.

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