

Thermogram No Substitute for Mammogram

Despite widely publicized claims to the contrary, thermography should not be used in place of mammography for breast cancer screening or diagnosis.

The Food and Drug Administration (FDA) says mammography— an X-ray of the breast—is still the most effective way of detecting breast cancer in its earliest, most treatable stages. Thermography produces an infrared image that shows the patterns of heat and blood flow on or near the surface of the body.

The agency has sent several warning letters to health care providers and a thermography manufacturer who claim that the thermal imaging can take the place of mammography.

Web sites have been touting thermography as a replacement for mammography and claim that thermography can find breast cancer years before it would be detected by mammography.

The problem is that FDA has no evidence to support these claims.

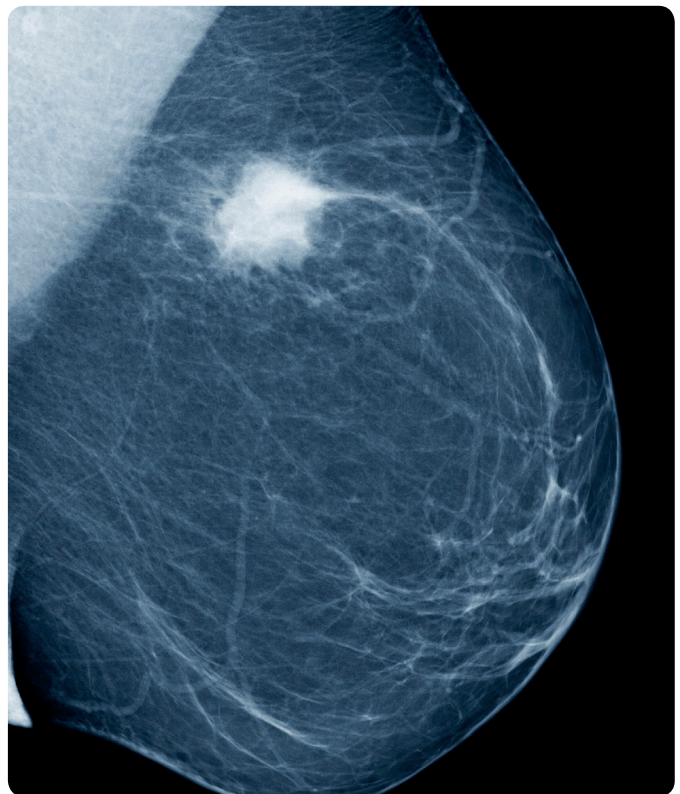
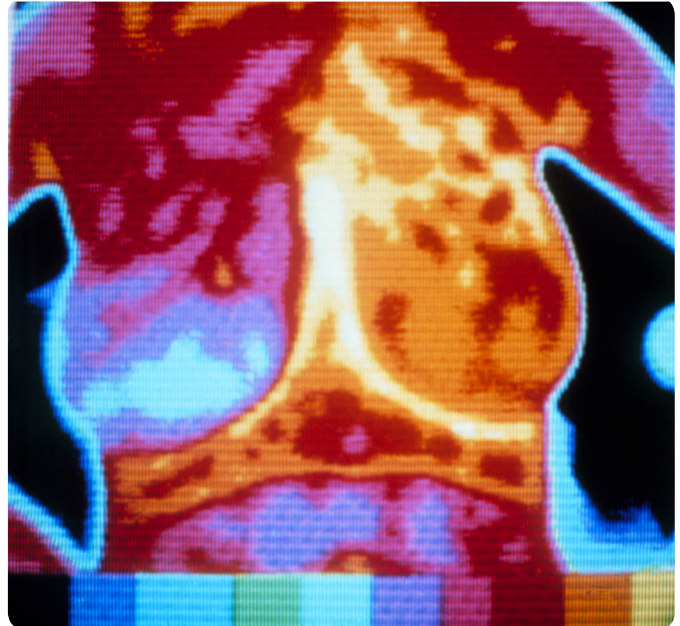
“Mammography is still the most effective screening method for detecting breast cancer in its early, most treatable stages” said Helen Barr, M.D., director of the Division of Mammography Quality and Radiation Programs in the FDA’s Center for Devices and Radiological Health. “Women should not rely solely on thermography for the screening or diagnosis of breast cancer.”

“While there is plenty of evidence that mammography is effective in breast cancer detection, there is simply no evidence that thermography can take its place,” said Barr.

Thermography devices have been cleared by the FDA for use as an adjunct, or additional, tool for detecting breast cancer. Toni Stifano, a consumer safety officer in FDA’s Center for Devices and Radiological Health, explains that this means thermography should not be used by itself to screen for or to diagnose breast cancer.

The National Cancer Institute (NCI), part of the National Institutes of Health, estimates that about 1 in 8 women will be diagnosed with breast cancer sometime in her life.

The greatest danger, says Stifano, a breast cancer survivor herself, is that patients who substitute thermography for mammography may miss the chance to detect cancer at its earliest stage. There has been a steady decline in breast



Thermography (top) produces an infrared image that shows the patterns of heat and blood flow on or near the surface of the body. A **mammogram (bottom)** is an X-ray of the breast in which a cancerous mass shows up in white.

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cancer deaths and one of the reasons is early detection through mammography, according to FDA.


As for concerns about exposure to radiation from a mammogram, evidence shows that the benefits outweigh the risks of harm, especially when compared to the danger of breast cancer.

FDA is advising patients to continue to have regular mammograms according to screening guidelines or as recommended by their health care professional.


Patients are also advised to follow their health care professional’s recommendations for additional diagnostic procedures, such as other mammographic views, clinical breast exam, breast ultrasound, MRI or biopsy. Additional procedures could include thermography.

This year alone, the agency has sent warning letters to the following practitioners and manufacturer making misleading claims about thermography:

- Warning Letter to Meditherm, Inc (April 4, 2011) - (www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm249863.htm)
- Warning Letter to Dr. Joseph Mercola, Dr. Mercola’s Natural Health Center (March 22, 2011) - (www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm250701.htm)
- Warning Letter to Central Coast Thermography (January 6, 2011) - (www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm245253.htm)

FDA’s position on thermography is shared by prominent organizations active in the fight against breast cancer, including the Susan G. Komen for the Cure, a nonprofit that has raised billions of dollars for education and research, and the American Cancer Society. 

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