FDA Safety Communication: Breast Cancer Screening - Thermography is Not an Alternative to Mammography

U.S. Food & Drug Administration

Date Issued: June 2, 2011

Audience:

- Women
- Health Care Providers
- Cancer Advocacy Organizations
- National Association of Attorneys General

Medical Specialties: Radiology, Pathology, Internal Medicine, Obstetrics/Gynecology, Oncology, Nursing, General Practice, Breast Surgery, Acupuncture, Osteopathy, Chiropractic.

Product:
Thermographic systems use an infrared camera to produce images (thermograms) that show the patterns of heat and blood flow on or near the surface of the body.

Purpose:
The FDA is issuing this communication to alert the public, including women and health care providers, that thermography is not a replacement for screening mammography and should not be used by itself to diagnose breast cancer. The FDA is not aware of any valid scientific data to show that thermographic devices, when used on their own, are an effective screening tool for any medical condition including the early detection of breast cancer or other breast disease.

Public health agencies and national medical and professional societies agree with FDA that mammography is still the most effective method of detecting breast cancer in its earliest, most treatable stages. These organizations include the American Cancer Society [1], the American College of Radiology [2], the Centers for Disease Control and Prevention [3], the National Cancer Institute [4], and the Society for Breast Imaging [5]. [6]

Summary of Problem and Scope:

Certain facilities, websites, and mobile units are promoting the use of thermography as a stand-alone evaluation tool for screening and diagnosing breast cancer, claiming that is a substitute for or superior to mammography. They also claim that thermography can detect pre-cancerous abnormalities and diagnose breast cancer

long before mammography and that compressing the breast during mammography will cause or spread cancer by pushing cancer cells into additional locations in the body. **The FDA is concerned that women will believe these misleading claims about thermography and not receive needed mammograms.**

Recommendations to Women:

- Have regular mammograms according to screening guidelines or as recommended by your health care provider.
- Follow your health care provider's recommendations for additional breast diagnostic procedures such as various mammographic views, clinical breast exam, breast ultrasound, MRI or biopsy; additional procedures could include thermography.
- Remember that thermography is not a substitute for mammography and should not be used by itself for breast cancer screening or diagnosis.

FDA Activities:
This year the FDA has issued the following warning letters for marketing and promoting thermographic devices for uses that have not received marketing clearance or approval. In these warning letters, the FDA has instructed the providers to immediately cease making inappropriate claims about thermography devices.

- Warning Letter to Meditherm, Inc [7] (April 4, 2011)
- Warning Letter to Dr. Joseph Mercola, Dr. Mercola's Natural Health Center [8] (March 22, 2011)
- Warning Letter to Central Coast Thermography [9] (January 6, 2011)

The FDA will continue to monitor the promotional activity of the thermography manufacturers and practitioners.

Other Resources:

- FDA Press Release [10]
- FDA Consumer Update - Thermogram No Substitute for Mammogram [11]
- National Cancer Institute - Breast Cancer Screening [12] [6]
- National Cancer Institute at the National Institutes of Health - Tests that examine the breast are used to detect (find) and diagnose breast cancer [13] [6]
- FDA's Mammography Quality Standards Act and Program (MQSA) [14]
- FDA's Women's Health Topics: Mammography [15]

Contact Information:

If you have questions about this communication, please contact the Division of

Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV [16], 800-638-2041 or 301-796-7100.

The FDA will continue to monitor this problem and keep the public informed as new information becomes available.

SOURCE [17]

Source URL (retrieved on *12/17/2014 - 3:20pm*):
http://www.mdtmag.com/news/2011/06/fda-safety-communication-breast-cancer-screening-thermography-not-alternative-mammography?qt-most_popular=0

Links:
[1] http://www.cancer.org/Treatment/UnderstandingYourDiagnosis/ExamsandTestDescriptions/MammogramsandOtherBreastImagingProcedures/mammograms-and-other-breast-imaging-procedures-newer-br-imaging-tests
[2] http://www.acr.org/SecondaryMainMenuCategories/quality_safety/BreastImgResources/dca-BreastImagingPositionStatements.aspx
[3] http://www.cdc.gov/cancer/breast/basic_info/screening.htm
[4] http://www.cancer.gov/cancertopics/pdq/screening/breast/healthprofessional/page4#Section_390
[5] http://www.sbi-online.org/displaycommon.cfm?an=1&subarticlenbr=83
[6] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[7] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm249863.htm
[8] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm250701.htm
[9] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm245253.htm
[10] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm257633.htm
[11] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257499.htm
[12] http://www.cancer.gov/cancertopics/pdq/screening/breast/Patient
[13] http://www.cancer.gov/cancertopics/pdq/treatment/breast/Patient#Keypoint5
[14] http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/ConsumerInformation/default.htm
[15] http://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117967.htm
[16] mailto://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/DSMICA@FDA.HHS.GOV
[17] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm257259.htm