FDA Warns Not to Use Thermography Devices to Detect Breast Cancer

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FDA issues warning letter to clinic illegally marketing unapproved thermography device, warns consumers to avoid using thermography devices to detect breast cancer

The U.S. Food and Drug Administration has issued a warning letter to Total Thermal Imaging Inc., of La Mesa, California, and its president and co-owner, Linda Hayes, for illegally marketing and distributing an unapproved thermography device as a sole screening device for breast cancer and other diseases. The FDA also issued a safety communication to warn patients that thermography is not cleared by the FDA as an alternative to mammography and should not replace mammography for breast cancer screening or diagnosis.

"Advancing and protecting women's health is a priority for the FDA. As part of these efforts, we will not tolerate individuals or companies who attempt to take advantage of patients by marketing unapproved devices that deceive patients and put them at risk," said FDA Commissioner Scott Gottlieb, MD. "The FDA is concerned that patients will rely on unapproved claims that thermography may be used as a sole screening device for breast cancer and not get screened with mammography, which is proven to save lives by detecting cancer and prompting patients to seek appropriate treatment. People who substitute thermography for mammography may miss the chance to detect breast cancer in its earliest and most treatable stages. We'll continue our efforts to protect patients from those individuals or companies who ignore the FDA's requirements intended to keep patients safe."

Thermography is a noninvasive tool that uses an infrared camera to produce images that show the patterns of heat and blood flow on or near the surface of the body. Thermography has been cleared by the FDA only as an adjunctive tool, meaning it should only be use alongside a primary diagnostic test like mammography, not as a standalone screening or diagnostic tool.

Total Thermal Imaging Inc. markets and distributes the Thermography Business Package, an unapproved device which includes a FLIR Systems Inc. thermographic camera and proprietary software, to individuals and clinics as a sole screening tool for breast cancer and other diseases. Such a device would require premarket approval by the agency. Total Thermal Imaging Inc.

illegally marketed the unapproved device via a website and promotional materials claiming that its device can enable the early detection or the diagnosis of many disorders including breast cancer, inflammatory breast cancer, pre-stroke, heart disease, deep vein thrombosis and other diseases.

In addition, the warning letter discusses the FDA's recent inspection of Total Thermal Imaging Inc. in which investigators observed several significant deviations from the agency's quality systems regulations, such as failure to establish procedures for taking corrective or preventive actions to address any defective products and failure to establish procedures for receiving and evaluating complaints (including a procedure for determining whether a complaint should be submitted to the FDA as a medical device report).

The warning letter requests that Total Thermal Imaging Inc. immediately cease distributing the Thermography Business Package. It also asks the firm to respond, within 15 working days from the date the warning letter was received, with details of how the violations noted in the warning letter will be corrected. Any violations not corrected could lead to enforcement action such as seizure, injunction or civil money penalties.

This warning letter is not the first time the FDA has cited firms for illegally marketing and promoting thermographic devices. In a safety communication issued today warning patients against using thermography, the FDA lists five warning letters issued to manufacturers for marketing unapproved thermographic devices and/or making misleading claims about thermography.

As noted in the safety communication, there is no valid scientific data to show that thermographic devices, when used on their own or with another diagnostic test, are an effective screening tool for any medical condition, including the early detection of breast cancer or other diseases and conditions. The agency stresses that mammography is the only screening method proven to reduce deaths from breast cancer through early detection. The FDA ensures that mammography facilities follow FDA-required quality standards through the agency's Mammography Quality Standards Act program.

The warning letter and safety communication issued today reflect the agency's commitment to advancing policies that enhance the FDA's oversight of medical device safety, including diagnostic and therapeutic devices unique to women. As part of the Medical Device Safety Action Plan and the agency's ongoing commitment to advancing women's health, the FDA has alerted the public when safety issues are identified, such as the Pocket Protector for breast implant scar tissue, breast implant-associated anaplastic large cell lymphoma, vaginal rejuvenation and unsafe silicone injections. The agency has also established the Women's Health Technologies Strategically Coordinated Registry Network to provide more complete evidence in clinical areas that are unique to women, such as uterine fibroids and pelvic floor disorders.

Health care professionals and consumers should report any adverse events related to imaging with thermographic devices to the FDA's MedWatch Adverse Event Reporting program. To file a report, use the MedWatch Online Voluntary Reporting Form. The completed form can be submitted

online or via fax to 1-800-FDA-0178. The FDA monitors these reports and takes appropriate action necessary to ensure the safety of medical products in the marketplace.

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