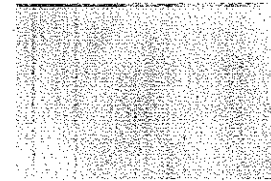




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A CHAPTER OF THE AMERICAN COLLEGE OF RADIOLOGY



Testimony of the Radiological Society of Connecticut (RSC) In
opposition to HB 6553
Insurance and Real Estate Committee
February 17, 2015

Rebuttal by Alexander Sepper, MD, PhD & Anthony Piana, DC, Directors of *The Professional Academy of Clinical Thermology* (comments in red)

Chairmen and members of the committee, the Radiological Society of Connecticut, the RSC, represents over 400 physicians in Connecticut who practice the specialty of diagnostic radiology in hospitals and/or our own offices in the community. We also represent medical physicists who help assure the quality of the equipment we use. The RSC is opposed to H.B. 6553, *An Act Requiring Health Insurance Coverage for Breast Thermography*, because the technique of thermography is unsubstantiated, and its use is not supported by any major medical, scientific, governing or regulatory body that relies upon scientific data.

Thermography is based upon the theory that temperature rises in areas with increased blood flow and metabolism, which could be signs of some tumors. However, because thermography maps heat only on the surface of the breast, only very large tumors, and those located immediately beneath the skin fall into this category, and even then, only some of the time. **Heat radiates from deeper tumors to the surface of the skin where it is detected. The Cornell Study published in the American Journal of Surgery in 2008 showed it identified 58 of 60 tumors successfully. This study was published by the American Society of Breast Surgeons. There are over 800 Published studies.** At this point in time, there is NO scientific evidence to support the use of thermography, as either a screening or diagnostic test for breast cancer. **This is obviously NOT true, see above.** The danger of thermography, according to the FDA, is that patients who substitute thermography for mammography may miss the chance to detect cancer at its early stage. **This is true, but the real DANGER is using ONLY Mammography that has been proven to be ineffective according to several major studies which have been published in the New England Journal of Medicine and the British Medical Journal. This is the reason Switzerland discontinued mammography as a screening test. The real benefit is seen using thermography in conjunction with anatomical testing, which includes either mammography, sonography, or MRI. Studies have been performed at the University of Wisconsin by Dr. Hobbins to demonstrate thermography can detect tumors BEFORE mammography in 70% of the cases studied.**

The Radiological Society of Connecticut strongly believes that legislation should not support scientifically unfounded procedures. **Exactly the reason mammography should be discontinued and thermography used adjunctively.** As an organization, we were among the first in the country to endorse breast screening ultrasound, but only did so after a major scientific study confirmed its benefits. **Thermography has been an accepted tool since the late 1960's and has credible studies to back its efficacy. We can help show this. Please refer to our published study. Contemporary Evaluation of Thermal Breast Screening, Sepper and Piana.** When, and if, thermography demonstrates scientifically proven benefit, we will readress our position. Until then, we agree with the position statements of organized medicine, including:

The American Cancer Society (ACS) has classified thermography as a method that is ineffective as a screening tool based on clinical evidence (Smith et al, 2003) stating that "no study has shown that thermography is an effective screening tool for the early detection of breast cancer." (ACS, 2010) **We**

have outlined the studies that prove this statement false in our article.

The US Food and Drug Administration (FDA): The US Food and Drug Administration (FDA) has warned women that breast thermography should not be substituted for mammography as a screen for breast cancer. **We can agree that thermography has been FDA cleared as an adjunct to anatomical testing. Preferably Ultrasound, not as a substitute, but alongside. That is exactly what this bill is about, to find additional information for these particular women.** In 2011, the FDA issued an alert warning the public about misleading claims by thermography practitioners and manufacturers on the screening benefits of the tool. To date, the FDA has not approved a thermography device for use as a stand-alone to screen or diagnose breast cancer." The FDA has gone on to issue warning letters to some health care providers who have been promoting the inappropriate use of thermography. Helen Barr, MD, director of the Division of Mammography Quality for the FDA, in the FDA's News Release of 6/2/2011 stated "Women should not rely solely on thermography for the screening or diagnosis of breast cancer." **Again this is not about relying solely on thermography. Thermography has been FDA Cleared since 1982.**

The Susan G. Komen For the Cure, the nation's largest breast care philanthropy, has opposed thermography, stating on their website, "Thermography cannot distinguish between benign and cancerous patterns. **Mammography is 80 percent deficient at doing the same. Neither mammography nor thermography can accurately differentiate this. The goal of screening is to identify aberrant patterns to study more closely. Biopsy is the only tool that can differentiate.**

The American College of Radiology, our parent organization, states that "Thermography has not been demonstrated to have value as a screening, diagnostic or adjunctive imaging tool. We are pleased that the FDA has taken this step (issuing a Warning to providers and patients) to clarify its view on thermography. Thermography is not a substitute for mammography screening...which remains the gold standard for breast cancer screening." (ACR website) **The next step will be a similar FDA warning for mammography and PACT is pleased that this information has been uncovered in the past few years, and the Swiss government was keen enough to realize the dangers of mammography in over diagnosis and up to 50% of treatment of breast cancer as being over treated and unnecessary.**

Finally, the Society of Breast Imaging's position is that "The Society of Breast Imaging does not currently support the use of thermography/ infrared imaging of the breast as either a screening tool in the detection of breast cancer or as an adjunctive diagnostic tool...There are currently no studies supporting the use of thermography alone or as an adjunct to mammography that show clear benefits of the technique." (SB! position statement from SB! website) **This must be because they do not know how to perform a simple Pub Med search. Again read our article.**

The above statements are in contrast to the universal support for mammography, which is appropriately reflected in Connecticut statute. **NOT TRUE, there is no universal support here. Many countries are looking at the recent evidence NOT supporting mammography.** Innumerable scientific studies, analyzing mammography in hundreds of thousands of women worldwide, have confirmed that mammography saves lives, with an annual decrease in breast cancer mortality of 2-3% every year since 1990. Furthermore, mammography, unlike thermography, is highly regulated by the 1992 Mammography Quality Standards Act, such that every facility offering mammography meets quality standards set forth and enforced by the FDA, with respect to equipment, personnel (radiologists, technologists and physicists), and reporting. It is unlawful to perform mammography in the USA without an FDA certificate. **The website www.cancer.gov is maintained by the National Cancer Institute and states that a mammogram will save 1 in 1000**

women screened and CAUSE cancer in 1 of 1000 women screened. Dr. Gilbert Welch, the co-author of several articles, including the one in the NEJM, states that mammography has done nothing to reduce late stage cancers, but has actually created many more cases of cancers found. He further deduces that about one-third of cancers (DCIS and localized cancers) never needed to be treated. Here is where the State legislation should focus. This is estimated to have harmed over 1 Million women.

The Radiological Society of Connecticut strongly concurs with all of the above named organizations in its support of mammography, and joins with organized medicine in opposing support for thermography, until such time as its benefit can be scientifically demonstrated. Until then, we concur with the Society of Breast Imaging, and the American College of Radiology in recommending that women should have regular mammograms according to guidelines or as recommended by their health care provider.

We are concerned that supporting it at the legislative level might encourage women to forego mammography for an unproven test, and in so doing, will miss out on the best way to detect early breast cancer: mammography.

We believe that defending mammography is closely related to protecting financial interests and not for the betterment of society. We would be willing to work with the organization to help reduce the rate of metastatic cancer presented (where mammography has failed as a screening test). By combining the technology we can improve mammography detection from 83.3% to over 95%.