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RE: FDA Warning Letters to thermographic equipment providers.

Dear Dr.

Medicine as an industry and a practice is more heavily regulated by the various agencies of Government than the nuclear power industry. Diagnostic infrared imaging in all of its iterations and by what-ever name we wish to use (thermography, Digital Infrared Thermal Imaging, infrared mammography or thermology) has been a notable exception to this pattern of regulation. Doubtless this exception is due, at least in part, to the completely non-invasive and non-harmful nature of infrared imaging and the fact that it has not been incorporated into Radiology, as has every other diagnostic imaging procedure. Consider that X-ray mammography is the most regulated application in the entire heavily-regulated field of Medicine and the contrast becomes clear for Diagnostic Infrared Imaging as it is applied to the detection of breast cancer. Medical thermographs (the instruments) were actively applied in the diagnostic process for breast cancer, cerebral and peripheral vascular disease and peripheral neuropathies long before the US Food and Drug Administration received a Congressional mandate to regulate medical devices. Due to the high costs related to the FDA's formal approval process for Class I Devices, new generations of medical thermographs have been submitted to the FDA in order to be 'determined to be substantially equivalent' with the "Grandfathered" instruments as Class III devices through the 510(k) process.

Diagnostic Infrared Imaging is has been known to and supported by various Federal regulatory agencies and institutes. In 1972, a letter from the Acting Commissioner of the US Health, Education and Welfare agency approved Diagnostic Infrared Imaging (thermography) as a diagnostic technique "beyond the experimental stage of development" for the detection of breast cancer, vascular disease and peripheral nerve disease as determined by an independent panel of experts as to be a Medicare benefit. In 1982, the FDA listed Diagnostic Infrared Imaging (thermography) as an adjunctive diagnostic screen for the detection of breast cancer. In 2005, the FDA reaffirmed Diagnostic Infrared Imaging for breast cancer screening. In 2002, the National Cancer Institute listed Diagnostic (Digital) Infrared Imaging as a means for the early detection of breast cancer and stated "images of these temperature variations, which may be among the earliest signs of breast cancer." During the span of approximately forty years, Diagnostic Infrared Imaging as an industry has grown considerably in the aura of relative regulatory neglect but also without any effective standards for application or practices. While the growth of this industry has spired innovation and entrepreneurs, it

has also attracted irresponsible claims for imaginary applications and pseudo-experts. While Medicine, as an institution, has either tried to ignore Diagnostic Infrared Imaging or exclude it as a medical practice, the growth of the industry has reached a scale that it is too widely recognized to ignore.

The FDA also has regulatory authority over the claims made by the manufactures and sellers of medical devices either from their literature or their websites. In the past few years, I have heard rumors of the FDA applying a new level of scrutiny to the Diagnostic Infrared Imaging industry while I have witnessed the promulgation of absurd claims for diagnostic application. Only recently has the rumored regulatory attention of the FDA been manifested in the form of Warning Letters that challenge the claims of some equipment sales companies. In their promotional material, these companies has misrepresented Diagnostic Infrared Imaging as a 'stand-alone' procedure, itself sufficient to diagnose breast cancer and made diagnostic claims for "Visceral Health", "Digestive Disorders: Irritable bowel syndrome, diverticulitis and Crohn's disease", "Immune Dysfunction", "Nutritional disease (alcoholism, diabetes)" "Fibromyalgia", "Chronic Fatigue" and "Gingivitis". The FDA contends these claims are "outside the 510(k) clearance of the device" and, then, the thermographic systems as "adulterated" and "misbranded". To the best of my knowledge and as a recognized expert in the field, I know of absolutely NO credible evidence for such novel applications for Diagnostic Infrared Imaging. These purported applications must be considered investigational at best and speculative by any objective standards. There is an implicit burden to substantiate the claims for applications of a medical device that has not been met (or, for that matter, even attempted) by these rogue companies. At least one company attempted to evade the regulatory scrutiny of their thermographic system by rebranding it with an entirely novel classification as a "health indicator". I wish I knew what that meant.

There are more than one thousand articles in the scientific and medical literature relevant to Diagnostic Infrared Imaging as applied as a screen for breast cancer and the experience of millions of world-wide case studies over more than fifty years. While not yet engrained into the mainstream of Medicine, any objective review must conclude that Diagnostic Infrared Imaging as a screen for breast cancer is beyond any investigational level of development. I urge that we should not abrogate our responsibility to our peers or our patients by representing Diagnostic Infrared Imaging as anything less than a legitimate diagnostic application for screening breast cancer in order to evade the scrutiny of the regulators.

I don't have any inside information relative to the scope or the scale of the FDA's recent regulatory actions for Diagnostic Infrared Imaging. While it is yet possible these actions could develop into a 'witch hunt'; thus far, the FDA's regulatory attention has been only been directed toward the most irresponsible claims of some of the rogue companies involved in Diagnostic Infrared Imaging and I would contend that this bit of regulation is not a bad thing.

Sincerely,

Philip P. Hoekstra, III, PhD, DABT

Bibilography:

06 January 2011 FDA Warning Letter to Ms. Gaea Powell of Central Coast Thermograhpy in San Luis Obispo, CA.

22 March 2011 FDA Warning Letter to Dr. Joseph Mercola of Thermography Diagnostic Center in Hoffman Estates, IL.

04 April 2011 FDA Warning Letter to Dr. Peter Leando of Meditherm, Inc. in Parkland, FL.