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16 February 2012

Re: Senate Bill 407:

Chairman Schmidt, and members of the Public Health and Welfare Committee:

I appreciate the opportunity to appear before this committee and discuss this important issue of breast density and its ramifications for women with regard to breast cancer.

I am an Assistant Professor of Radiology at the University of Kansas Medical Center, Kansas City, Kansas, and section head of breast imaging. My practice is very narrow, I am a breast imaging specialist. As opposed to most radiologists, I live and breathe breast cancer screening, at times it seems 24 hours per day. Breast imaging has been my focus for the past 22 years. I was the first radiologist in Kansas to perform needle breast biopsy, beginning in 1991, long before it became the standard of care 10 years later. More recently, my focus has turned to the limitations of mammography in patients with dense breasts. I became involved with a national, multicenter research project that began about 3 years ago on asymptomatic women with dense breasts. As the Principal Investigator for this study at the University of Kansas, I have had the opportunity to be involved and fully understand the ramifications and challenges of screening for breast cancer in women with dense breasts.

First, what are dense breasts? Breast tissue is composed of two primary components; fatty tissue and fibroglandular tissue. On mammograms, fat is dark gray, while fibroglandular tissue is white. For purposes of this discussion, fibroglandular tissue means dense breast tissue. In a population, the range of normal composition of breasts can vary from 100% fat to nearly 100% dense. Radiologists are trained to group these variations in quartiles, called BIRADS categories. For example, those breasts which are predominately fatty, with less than 25% density, are termed BIRADS 1. Those breasts that are 25-49% dense are termed BIRADS 2, and so on. The type of breast composition we are focusing on today are those that are greater than 50%, the so-called BIRADS 3 and 4 breasts, also known as heterogeneously dense and extremely dense.

If mammography is the recognized standard for detection clinically occult breast cancer, what is the issue here? The issue is that while mammography is very good at detecting breast cancer while it is at an early stage in breasts that are fatty or mostly fatty, the ability for radiologists to find breast cancer falls substantially in breasts that are dense. And the denser the breast, the

worse the performance. While the accuracy of mammography approaches 100% in very fatty breast, it falls to about 50% in dense breasts.

Radiologists have known for at least 16 years that mammography misses cancers in a significant number of patients with dense breasts, and that the use of ultrasound can indeed detect additional cancers that are mammographically occult. Dr. Paula Gordon authored one of the first articles in 1995, published in the medical journal, *Cancer*, showing a rate of 3.5 additional cancers per thousand detected by ultrasound that were not seen on mammograms. Indeed, there have been a total of 9 studies, with a total of over 59,000 patients, published in peer-reviewed journals which show remarkable similar detection rates of mammographically occult cancers detected by ultrasound. References to these studies are included in my written testimony.

At the University of Kansas, we were fortunate to be asked to be part of a multicenter trial to study ultrasound screening in patients with dense breasts; specifically those with greater than 50% breast density. This landmark study is the largest breast ultrasound screening study to date, enrolling greater than 17,000 patients nationwide. In our study at the University of Kansas, we have shown that the addition of ultrasound to mammography has resulted in a 50% increase in breast cancer detection. I would like to underscore the importance of this statistic. In a study such as this, a 10% improvement would be considered significant. Our study showed a 50% improvement in breast cancer detection.

The number of women with dense breasts is not insignificant, affecting about 50% of premenopausal women and up to 40% of post menopausal women. But there is another related issue that should be mentioned. With increased breast density comes a higher risk for breast cancer. Again, the greater the density, the larger the risk. The risk of breast cancer is 4-6X higher in a woman with the most dense breast when compared to a fatty breast. This is substantial, and outweighs nearly all other risk factors.

I support the general language of this bill. The need for a bill such as this is also illustrated by a Harris poll from 2009 in which results showed that about 95% of women not only did not know their breast density, but were unaware that breast density increased their risk of breast cancer. I have given testimony before on this issue. Last November, I appeared before the Mammography Quality Standards Act advisory committee in Washington DC, a federal group of experts that advises the FDA on mammography issues. I was part of a larger group of radiologists, a spokesman from the national head of Komen, and many passionate women telling their stories that brought nearly all to tears. All testimony was in support of this issue. The end result was that this advisory committee agreed that density notification to patients should be given.

Given my long experience with breast imaging, my current research on breast density and screening breast ultrasound, and the fact that I have sent out over 220,000 mammographic lay letters, I believe that I am well qualified to give comments on Senate Bill 410.

But I have some suggestions for improvement of the current bill.

First is the omission of language regarding supplementary tests such as ultrasound and MRI. Both are proven technologies. I previously discussed the peer reviewed papers proving the known benefits of screening ultrasound in breast cancer detection. The American College of Radiology is on record of this recognition as well (see statement below). MRI's benefit in conjunction with mammography is well established.

If there is language about the limitations of mammography, and no mention of the availability of additional adjunctive tools such as ultrasound and MRI, my concern is that women, upon reading the lay letter results and limitations of mammography get upset or depressed, know of nothing else to do regarding additional testing, and give up, even to the point of not having future mammograms.

Second, the verbiage of "If you have dense breasts..." is ambiguous. For the 95% of women who do not know if they have dense tissue or what dense tissue is— this vague wording will certainly not make it clear to her that THIS IS HER NOTICE that she does. My concern is that she will think that if she had dense breasts, surely someone would have told her by now. Why would she call her doctor for further discussion if she wasn't aware this even applied to her?

The language that is least likely to be misunderstood or ignored is: "Your mammogram demonstrates that **you have dense breasts...**" With this language, a woman is clearly informed. Why would you want to write a bill with potential for this life saving message to be lost on some women?

Allow me to make this point again in a different way. Patient lay letters typically state the results of their mammogram. The letter sometimes state that their mammogram is abnormal and ask them to return for additional testing. Should the verbiage say: "If your mammogram is abnormal, please call this number to schedule your appointment for further tests?, or better, "Your mammogram is abnormal, please call this number to schedule your appointment for further tests".

I believe the goal here is two fold. To make them aware of limitations of mammography if they have dense breasts and to provide information regarding what other tests are available.

I understand there is concern from insurers about costs from additional testing, and that is understandable. However, if we as society as a whole, or from an individual standpoint don't want to pay for this supplemental testing, then the bill should die right here.

Is it right to withhold important and life saving information from patients because of lack of reimbursement? I do not believe so. If a test such as screening breast ultrasound is valuable as determined by the medical community and by patients, reimbursement will surely come. Medicine is replete with examples of medical tests for screening that are introduced and proven to be effective prior to getting reimbursed by insurance. Some examples include screening mammography in the mid 1980s, virtual colonography, and a brand new type of mammography called tomosynthesis. All of these were introduced without initial insurance coverage.

Regarding this perplexing issue of breast density, I believe that the proverbial cat is out of the bag, and will not go back in willingly. Physicians have known for a long time the limitations of mammography in dense breasts, but have not shared this limitation with patients. It is time to fix the system rather than hide the problem.

Thank you for your time today.

Marc F. Inciardi, M.D.

From the ACR website:

ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF A BREAST ULTRASOUND EXAMINATION

II. INDICATIONS

8. As a supplement to mammography, screening for occult cancers in certain populations of women (such as those with dense fibroglandular breasts who are also at elevated risk of breast cancer or with newly suspected breast cancer) who are not candidates for MRI [8-9] or have no easy access to MRI.

PROPOSED AMENDMENT SENATE BILL No. 407

[Note: Material in strike type would be deleted, boldface material is new]

Section 1. (a) Each mammography report sent to a patient in this state pursuant to regulations implementing the federal mammography quality standards act promulgated by the United States food and drug administration shall include information regarding breast density, based on the breast imaging reporting and database system established by the American college of radiology.

(b) In those patients whose mammograms are characterized as having heterogeneously dense or extremely dense breasts, based on the breast imaging reporting and database system established by the American college of radiology, the report shall include the following notice:

"~~[If your]~~ **Your** mammogram demonstrates that you have dense breast tissue, which could hide abnormalities, you may benefit from supplemental screening tests **such as ultrasound or MRI (magnetic resonance imaging)** depending on your individual risk factors. Dense breast tissue, in and of itself, is a relatively common condition. Therefore, this statement is not provided to cause undue concern, but rather to raise your awareness of the limitations of mammography testing and to promote discussion with your physician regarding the presence of other risk factors, in addition to dense breast tissue, that may warrant supplemental screening. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns regarding this report."

~~[(b)]~~ (c) The state board of healing arts, in conjunction with the department of health and environment, shall develop and make available to the public information concerning mammography testing.

~~[(c)]~~ (d) This section shall be part of and supplemental to the Kansas healing arts act.