Public Hearing Transcript – February 26, 2008

PRESIDING CHAIRMEN: Senator Crisco

Representative Connor

COMMITTEE MEMBERS PRESENT:

SENATORS: Hartley, Caligiuri

REPRESENTATIVES: Witkos, Altobello, Dargan, Harkins, Nardello, Schofield, Williams, Fontana, Geragosian, Megna, Roldan

SENATOR CRISCO: --the doors are closed and sealed, nobody leave.

REP. O'CONNOR: Moving on to Senate Bill 172.

REP. O'CONNOR: The next speaker is Dr. Jean Wiegert.

JEAN WIEGERT: Good afternoon Senator Crisco, Representative O'Connor, and members of the Committee. My name is Jean Wiegert. I am a medical physician and a practicing radiologist with a specialty in breast imaging and have been practicing in Connecticut for over 22 years.

I would like offer my comments on the Raised Senate Bill 172 AN ACT REQUIRING COMMUNICATION OF MAMMOGRAPHIC BREAST DENSITY INFORMATION TO PATIENTS.

I am appearing here today on behalf of the Radiological Society of Connecticut to express our strong concern and reservation about this proposal.

This legislation will require that patient mammography reports include information about breast density and reference that certain insurance plans will pay for an ultrasound screening in the event of heterogeneous or dense breast tissue as identified.

With all do respect, we do not believe that it is appropriate for the legislature to prescribe in any manner what is or is not included in our patient reports.

That decision should be left to the professional judgment of the reviewing radiologist. Moreover, we believe the intended consequence of this bill may unnecessarily scare and inflame patients.

The fact that a woman has dense or heterogeneously dense breast tissue is of course a concern to us, but it does not mean that she has cancer nor does it mean that an additional test in the form of an ultrasound screening is warranted.

It might be, but that is a decision that needs to be made by the physician after taking into consideration a multitude of factors such as patient age, physical make-up, family, or personal history with cancer, genetic testing and, many other issues.

Requiring that we place this kind of warning statement on our reports will trigger an immediate reaction by patients.

They will and quite understandably be concerned and will want or demand an additional ultrasound screening. The referring physician is then placed in a position where they may have to say no, or explain to them why they may not.

Connecticut law provides that certain insurance plans cover ultrasound screenings when a mammogram shows evidence of dense or heterogeneous dense breasts. It does not mandate or guarantee that additional procedure should be done.

So again, we feel that enclosing my colleagues and I and the radiological profession are committed to providing accurate readings and interpretations of mammography images.

We pride ourselves and our ability to detect even the smallest cancers and, we provide reports to our patients, but we must oppose this legislation as an infringement on our professional judgment that may alter the patient/doctor relationship. I would be happy to answer any questions. Thank you.

REP. O'CONNOR: Chairman Crisco.

SEN. CRISCO: Well, thank you, Mr. Chairman. Thank you Doctor. We've had extensive hearings in regards to this issue of density over the past several years and we've received substantial mount of testimony in regards to false readings and that's when we decided that we would require ultrasound examination and testing be implemented.

I am having a very difficult time to understand why would you want to relate to density which may be an indication of the disease. I'm just having trouble understanding your opposition.

No one is questioning the professionalism of the radiologists, but when there has been numerous indications of false readings, I would think that forgetting the pain and suffering of the individual, the cost savings would be fantastic.

So I'm just trying to understand. Why, is it one of professional status, or I just have a difficult time understanding your objection.

JEAN WIEGERT: I appreciate your question, Sir, and with due respect this is certainly the state government.

The FDA has mandated many aspects of how we interpret and how we review mammograms and that we certainly include a variety of descriptor terms and we have a Bi-Rad code in which we do indicate whether or not there are issues that need to be evaluated further and this does go to both the patient and to the referring physician.

We also did describe breast tissue density in our reports that go to the referring physician and we will always do a breast ultrasound or require a breast ultrasound when we see a problem or when we have areas that we have problems with interpreting on just the mammogram.

But the concept of actually mandating that we put in our plain language report to the patient a qualifier of breast tissue density may be actually more problematic.

Because number one, we would be then forced to decide at what point do we say the patient has those quote, dense breasts that mandate this additional ultrasound?

There are many, many ways that we look at a mammogram and there are many things that we are looking at as breast imagers. We always recommend additional imaging when it is necessary.

That being said, it would then be a very difficult burden for us to decide exactly what patient would then always get these additional imagining. I think it would also put, again, another burden on the referring physician who would feel compelled to order these additional tests.

There is an additional layer of perhaps potential litigation if these tests are not performed, even if it's not felt that it might be necessary.

Also, breast ultrasounds have not yet, in terms of screening been determined to be a dedicated adjunct. The American College of Radiology is in the process of evaluating that with its ACRIN study.

This is a study that has actually been designed to evaluate the role of breast ultrasound as a screening tool. That data has not been completely evaluated. The report is not back. We believe that we should do things in a scientific manner.

SEN. CRISCO: Now Dr., I respect what you are saying, and based on the testimony and information we received over the past several years my concern is that you speak of a burden to the radiologists and the referring physician, but what about the burden on the patient who had a misdiagnosis.

I would think that we would want to weigh which is the greater and as far as I'm concerned it's the burden upon the patient that we should be concerned about. But if you could explain what you mean by burden, I would appreciate that.

JEAN WIEGERT: Well, number one, there are many patients, and we are still trying to make sure that every woman who should get a mammogram gets a screening mammogram as you are well aware that there is still a high percentage of patients in this state that do not get their screening mammograms.

That being said, a breast ultrasound requires a very high level of skill to be done by the technologist. And not that I don't think it's an important adjunctive test, it would require a tremendous number of additional resources, certainly financial resources and educational resources, to make sure that we have enough trained technologists to do this study as well in the appropriate manner.

And the other problem I really this concept of having patients decide for themselves that based on a terminology in a report whether or not it is appropriate for them to have this test.

We do not certainly disagree with you that mammograms are very difficult to interpret. A breast ultrasound is a very, very important adjunct for us and most of us who are breast imagers use this very, very liberally, but to be mandated to do screening ultrasounds on every patient with a dense breast may indeed be a very difficult thing to do at this point in time.

We look forward to, and the State Radiology Society looks forward to helping perhaps work with a way that we could in the foreseeable future be able to educate patients, educate doctors and make aware the various other adjunct tests available including MRI and other nuclear medicine tests such as breast specific gamma imaging that are also very helpful in sorting out problems with dense or complicated breast tissue.

SEN. CRISCO: Would the, and I don't want to prolong this, would the Radiologist Association have a recommendation? How do we address this density issue which has been proven to be a serious issue among one of the leading killers of women.

JEAN WIEGERT: Well, we certainly don't disagree with you about that and we would like to work on formulating terminology that would make it more feasible for us as the radiologists and for the patient's and the referring physicians to be able to get the appropriate testing that they need. We do worry about the way this particular Bill is worded.

SEN. CRISCO: Well, would you be interested in recommending language to us?

JEAN WIEGERT: We would be interested in recommending language.

SEN. CRISCO: We would appreciate that. Thank you.

JEAN WIEGERT: Thank you.

REP. O'CONNOR: Thank you Mr. Chairman. Any other questions?

SEN. CRISCO: Doctor, I don't know if there still may be more questions.

JEAN WIEGERT: Oh, I'm so sorry.

REP. O'CONNOR: Actually, I have a quick question now. Maybe I just didn't understand some of the process of the care, but wouldn't the physician be making the call and not the radiologist as far as interpreting the density as far as whether or not to go for an ultrasound after the initial mammography.

JEAN WIEGERT: Well, yes, but if we put this in the plain language report that goes to every patient and we put a qualifier and say normal mammogram dense breasts, then you got the patient who would be then calling their physicians, I have

dense breasts, I need an ultrasound. We put in every report a descriptor of breast tissue density that goes to the physician.

It is in the technical report to the doctor and part of the way we describe our mammograms is always an inclusion of whether there is fatty breasts, mildly dense, moderately dense, or significantly dense.

And yes, then the physician certainly, and we do this all the time, a physician may order an additional study on that patient including a breast ultrasound.

We, as radiologists, if we feel that there is something that needs further evaluation we will recommend that in our reports as well. What we have a problem with is the qualifier to the patient with that word dense which may not indicate that there is even a problem, but that may invoke tremendous anxiety and will mandate by this rule that she can then tell her physician, I want a breast ultrasound.

REP. O'CONNOR: Thank you. I guess align with that thought, and if my memory serves me correctly and I'm sure we get some of the information from some of the next speakers, but that an individual with a dense breast tissue, you know the mammography is only right about 50% of the time. It doesn't pick it up about 50% of the time.

Our Committee has been taking an approach of trying to promote preventative care and if it is an actual ultrasound of that, if it's needed, its much better practice. But I guess, can you talk to maybe that statistic and if I'm way off then please provide that as well.

JEAN WIEGERT: Breast mammography is only accurate approximately 60 to 70% in dense breasts and that is absolutely correct. We absolutely would want the right tests done for the right patients. We feel this is a physician decision.

We include the information necessary in our reports so that the referring physician can certainly make the adequate decision as to whether or not the patient needs additional ultrasound performed or MRI or nuclear study.

That being said, our concern is that it would not be the physician's decision with the wording of this bill.

We have absolutely no problem in performing ultrasound when they are ordered in the appropriate manner and we will do as many as we possibly can to help prevent a misdiagnosis in terms of breast cancer.

We are very liberal with our performance of breast ultrasound and as a breast imager I do these all day long. Our concern is that this does not stay within the ability of the referring physician and the radiologist to make that decision.

REP. O'CONNOR: I agree. We don't want to be practicing medicine, but I think there is also a fundamental right of the patient to understand a little bit more about their body, what the implications are of the overall diagnosis or what alternatives.

I think education is one of the key components of the health care and that's the way I look at this bill. Chairman Crisco.

SEN. CRISCO: Thank you, doctor, I appreciate your time. I just want a clarification. When you go to your referring physician and say you need a lipid profile and he gives you a slip and you go to the blood lab to have your blood test done, on that is a little block saying to send a copy to the patient of the report.

So the physician gets the report and the patient gets a report and whether there is anxiety there or not, I don't know, but when you perform a test and you send it to the referring physician does the patient have the option of getting a copy of that report, or do you send it only to the referring physician?

JEAN WIEGERT: Yes. The patient always has an option to get a copy of the actual report that goes to the referring physician.

SEN. CRISCO: But I mean, when they come to you for the test, does the form state please send a copy of this report to the patient if it was signed by the referring physician? Do you do that now? And if you don't would you be opposed to that?

JEAN WIEGERT: No. We would not be opposed to that and we do that whenever a patient or referring physician puts that in the report.

And we have plain language reports that have been mandated by the MQSA, the FDA mandated these plain language reports backing 1998, so we are constantly in communication with our patients and our physicians and we are not certainly in disagreement about the need for as much education as possible.

SEN. CRISCO: But in that report, you would state what the degree of density is? So if your patient could get it in that report, why would you be opposed to the legislation, unless I'm misunderstanding.

Right now, the patient has a right to that report. In that report that you are sending to the referring physician you are saying there is a certain degree of density.

Now the concern that we've had based on experiences is that sometimes the referring physician has not communicated that to his patient, but that's another issue.

But to try to resolve that, if they could get a copy of their report which states that there is a density then I would think that it's up to the patient and the referring physician to decide where they go from there? Am I missing something here?

JEAN WIEGERT: No. You are correct. Certainly, if the patient is willing and the referring physician is willing to talk to the patient regarding this, that is certainly appropriate and there is nothing to say that in terms of how our reports are worded right now that the referring physician and the patient can't talk about that. Our concern is to have something like this mandated by the state.

This would be something that goes well beyond what the MQSA mandates already and our concern certainly is that we have the ability to work this through with you, to have a way of making it so that it is not something that will be more frightening for patients than it needs to be and that the concept of having dense breasts is not a cancer-make and that we have the ability to determine how this gets done and how we perform these studies.

REP. O'CONNOR: Thank you, Mr. Chairman. Any other questions? Oh, I'm sorry, Senator Caligiuri.

SEN. CALIGIURI: Thank you, Mr. Chairman, and, Doctor, thank you for testifying today, and I'm sorry for missing part of your testimony.

I don't think I am asking you something that has been repeated already, but, I'm listening to the exchange and what I think your view is and I guess the question what I have for you is, when I look at this legislation I view it as an opportunity for patients to get information individuals to get information that

allows them to be better educated so that they can be advocates for themselves, ask questions, and be somewhat more proactive in terms of looking out for their own health in that regard.

Assuming that's an accurate description of what the bill tries to do, I wonder how it could be that the benefit of that doesn't outweigh whatever burdens you think come along with it.

Could you address that balancing please? Because, on balance, the notion of giving individuals more information that they can in turn use to be active about seeking advice and talking to doctors and being better informed seems to be a valuable thing to achieve and I'm trying to see how the balance comes out in your mind Doctor.

JEAN WIEGERT: Well, I suppose our concern really is that the right people get the right tests done at all times. We do not waste our precious medical healthcare doctors, that the right person gets the right tests and that we as the interpreting physician is the one best judged to determine who perhaps should have those additional tests done.

We do not want to deny anyone the right tests at the right time. We want to make sure, however, that with the scope of all the technology that we have available that the right tests are done for the right person all the time.

We also are very concerned that screening ultrasound as I said is not a panacea, we do not have the data yet to prove that screening ultrasound will be the benefit for every patient to get.

We are waiting for the ACRIN study to be finished. We waited for the ACRIN study before we went ahead with digital mammography, we used the ACRIN study in terms of working with the American Cancer Society and the decisions as to who should get screening MRI and it takes a lot of data and a lot of sensitizing of this data to decide who should get what test.

Our concern is not that we do not want to provide, obviously this is my life and I do this all day long and the ability to diagnose breast cancer is the key importance, but we want to make sure it's done appropriately and at the right time and that to send out a statement like this before all the information is available to us as to the benefits or risks of these tests there are risks in over diagnosing.

We may be putting many, many more patients at risks for biopsies that don't need to be done. Again, how often do we follow patients? It takes a while to formulate these concepts.

SEN. CALIGIURI: Doctor, perhaps I'm misreading the bill, but I did not read it as mandating that the additional tests be performed, but rather only as giving someone the information to allow them to go back to their doctor and say, doctor here is this information that I have, what additional testing would be appropriate?

It seems to me it's still ultimately about a conversation between a patient and a physician about whether additional testing would be appropriate and required because I don't read this as mandating the additional testing to be done.

JANE WIEGERT: Well, we would certainly hope that would be the way any law of this nature would be formulated. However, we are very concerned that it might not be utilized in this manner.

SEN. CALIGIURI: Thank you, Doctor.

JANE WIEGERT: Thank you.

REP. O'CONNOR: Thank you very much for your patience today. Any questions? Thank you very much.