

# Yale University

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Rep. Pat Widlitz  
Rep. Deborah Heinrich

Dear Reps. Widlitz and Heinrich:

I am writing to you regarding the proposed House Bill 5635 being considered in your hearing scheduled for Friday, Feb 27, 2009.

I am testifying before you as a concerned citizen as well as an informed professional. By way of background, I am an Associate Professor of Obstetrics, Gynecology and Reproductive Sciences at Yale School of Medicine and am the Chief of Obstetrics at Yale-New Haven Hospital. Much of the work I do is related to diagnosing and treating problems in unborn babies. I have been a resident of Shelton for the past 7 years.

I, as well as the professional bodies of which I am a member (The American Institute of Ultrasound In Medicine and the American College of Obstetricians and Gynecologists), have been concerned about the profusion of storefront entertainment ultrasound facilities for a number of years. The issue in question is the use of medical ultrasound equipment to create a keepsake image of the growing fetus.

While medical use of appropriate levels of ultrasound to diagnose fetal conditions is considered safe, please note that ultrasound is a form of energy used for many purposes in industry and medicine. At somewhat higher exposure levels, given daily for weeks at a time, ultrasound is used to speed the healing of bone fractures. At much higher exposure levels, ultrasound produces a heating effect in tissue, which is useful in treating sprains and pulled muscles. At very high levels, ultrasound is used to shatter kidney stones.

I wish to bring your attention to the following:

1. The FDA has expressed concern about this misuse of diagnostic ultrasound equipment in this way. The FDA has stated "Persons who promote, sell or lease ultrasound equipment for making

'keepsake' fetal videos should know that FDA views this as an unapproved use of a medical device. In addition, those who subject individuals to ultrasound exposure using a diagnostic ultrasound device (a prescription device) without a physician's order may be in violation of State or local laws or regulations regarding use of a prescription medical device." To date, the FDA has allowed enforcement to be at the local level.

2. I concur with the AIUM assertion that "The use of either two-dimensional (2D) or three-dimensional (3D) ultrasound to only view the fetus, obtain a picture of the fetus or determine the fetal gender without a medical indication is inappropriate and contrary to responsible medical practice. Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient.

3. Nonmedical ultrasonography may falsely reassure women. Even though centers that perform nonmedical ultrasonography and create keepsake photographs and videos of the fetus may offer disclaimers about the limitations of their product, customers may interpret an aesthetically pleasing image or entertaining video as evidence of fetal health and appropriate development.

4. Abnormalities may be detected in settings that are not prepared to discuss and provide follow-up for concerning findings. Without the ready availability of appropriate prenatal health care professionals, customers at sites for nonmedical ultrasonography may be left without necessary support, information, and follow-up for concerning findings.

The use of ultrasound to create "keepsake" images or for entertainment purposes in no way promotes the health of the citizens of Connecticut or the public good. I would urge you to limit the use of such equipment and technology to a physician's prescription only.

Sincerely,



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