

Yale University

SCHOOL OF MEDICINE
333 Cedar Street
P.O. Box 208063
New Haven, Connecticut 06520-8063
(203) 785-2671
(203) 785-6885 Fax
Email: joshua.copel@yale.edu



JOSHUA A. COPEL, M.D.
*Professor, Obstetrics, Gynecology &
Reproductive Sciences and Pediatrics
Vice Chairman, Obstetrics*

February 23, 2009

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. Unfortunately, due to a prior commitment I cannot attend the hearing in person to testify, though I hope this letter and attachments will be helpful.

I write both as a constituent and as an informed professional. I lived in Guilford for 18 years before moving to Madison in 2004. I am also a Professor of Obstetrics, Gynecology and Reproductive Sciences at Yale, with my clinical and academic expertise in prenatal ultrasound. Finally, I am currently the President of the American Institute of Ultrasound in Medicine (AIUM, <www.AIUM.org>), a multidisciplinary society of over 7500 physicians, sonographers and scientists dedicated to the safe and effective use of ultrasound.

The AIUM and the professional medical community have been concerned about the profusion of storefront entertainment ultrasound facilities for a number of years. Operating in a grey zone at the fringe of medical practice, they raise a number of important issues. While most of us who use clinical ultrasound believe that there is minimal risk in pregnancy when properly calibrated machines are used at appropriate power levels for short periods of time, the machines used at these non-medical facilities are bought from unknown sources and are not required to undergo any specific maintenance to ensure proper performance. The individuals performing the scans may or may not be trained professional sonographers, so there is no way to ascertain their knowledge of the potential for ultrasound bioeffects on the developing fetus, or their ability or willingness to practice safe sonography.

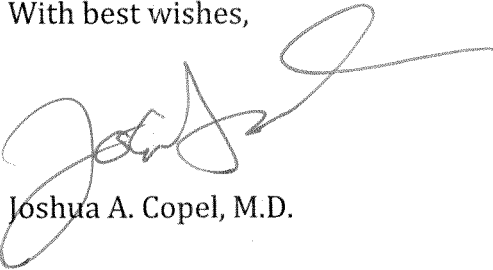
Some of the providers at keepsake ultrasound establishments have been known to produce reports of "limited fetal ultrasounds," which borders on the practice of medicine. At present there is no independent practice of sonography anywhere in the US, even by sonographers who have passed the Registry examinations offered by the American Registry of Diagnostic Medical Sonography (www.ardms.org).

More detail of these concerns is included in the attached manuscript of a paper I presented to a safety symposium on entertainment scans held at the International Society for Ultrasound in Obstetrics and Gynecology annual meeting in Florence, Italy in the October, 2007. I have also attached copies of the AIUM position paper on Keepsake Fetal Ultrasound, which was the product of a task force I chaired several years ago, and of an opinion from the AIUM Bioeffects Committee on the Prudent Use of Ultrasound in Obstetrics. The fourth attachment here is the American College of Obstetricians and Gynecologists Committee Opinion on non-medical use of ultrasound.

To date, the FDA has not pursued any actions against entertainment ultrasound businesses. While the FDA clearly regulates the production of ultrasound equipment as Class II medical devices, and has a statement on their web site opposing the use of fetal scans for this purpose (<http://www.fda.gov/cdrh/consumer/fetalvideos.html>, and also attached to this letter), their public stance has been that enforcement of use issues is the purview of the states rather than the FDA.

I hope all of these will be helpful in your Committee's deliberations. I would welcome the opportunity to meet with you or your staffs as this bill progresses to help in any way I can with it.

With best wishes,



Joshua A. Copel, M.D.