

## **PRESS/NEWS RELEASE August 8, 2006**

### **Sonograms Safe If Done Properly**

PLANO, TEXAS - The Society of Diagnostic Medical Sonography (SDMS) today urged caution in light of media reports about a Yale University study that showed ultrasound used on mice fetuses could adversely affect brain cell development.

According to a letter issued by the Food and Drug Administration to the SDMS, "From a medical standpoint, ultrasonic fetal scanning is generally considered safe, and should be used without hesitation when clinical benefit is expected. But ultrasound energy delivered to the fetus cannot be regarded as innocuous. Viewed in this light, exposing the fetus to ultrasound with no anticipation of medical benefit is not justified. Thus, we believe that these prenatal entertainment videos should not be performed. Persons who promote, sell or lease ultrasound equipment for making "keepsake" fetal videos should know that we view this as an unapproved use of a medical device, and that we are prepared to take regulatory action against those who engage in such misuse of medical equipment."

Jean Spitz, MPH, RDMS, President of the SDMS and a professor at the University of Oklahoma's Health Sciences Center stated "Sonograms in humans are very safe when done properly. However, the SDMS has long opposed 'entertainment' sonograms – those that have no medical necessity or those repeatedly done to 'get a good picture' of the baby." Ms. Spitz added, "We have continued to work to convince the Food and Drug Administration to stop the proliferation of 'entertainment' use of ultrasound. Unfortunately, the FDA has failed to take action despite many reports/concerns filed with the agency."

In December, 2005, the SDMS expressed concern about actors Tom Cruise and Katie Holmes purchase of an ultrasound machine to do their own in-home ultrasounds without proper training. As a result, SDMS has also supported state legislation in California and New Jersey to restrict the sale or lease of ultrasound equipment to qualified health care professionals educated and trained in the proper use of the equipment.

SDMS' Executive Director, Donald F. Haydon, CAE points out that "the problem is compounded by the lack of any national requirement for the person performing the sonogram to be credentialed." While more than 50,000 sonographers have been credentialed through the American Registry for Diagnostic Medical Sonography, currently there are no state or federal laws that ensure that the person performing the sonogram has been credentialed and is knowledgeable or skilled in the diagnostic procedures being performed. SDMS supports required sonographer credentialing in the performance of all diagnostic medical sonography examinations.

Credentialed sonographers provide sonograms that use "as little as reasonably achievable" energy (also known as ALARA standards) to ensure the fetus is not exposed to high levels of ultrasound energy for significant periods of time during normal sonograms. Ms. Spitz concludes, "In the hands of a credentialed sonographer, the benefits of a medically indicated sonogram outweigh the risks, and should not cause undue concern to the patient."

The complete SDMS policy on non-diagnostic use of ultrasound and links to additional Food and Drug Administration information may be found at: <http://www.sdms.org/positions/nondiagnostic.asp>

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The Society of Diagnostic Medical Sonography is a professional membership organization founded in 1970 to promote, advance, and educate its members and the medical community in the science of diagnostic medical sonography. The SDMS, with over 18,500 members, is the largest association of sonographers and sonography students in the world.