

OFFICIAL STATEMENT

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm064756.htm>

Fetal Keepsake Videos

The FDA is aware of several enterprises in the U.S. that are commercializing ultrasonic imaging of fetuses by making "keepsake" videos. In some cases, the ultrasound machine may be used for as long as an hour to get a video of the fetus. We are concerned about this misuse of diagnostic ultrasound equipment.

Ultrasound is a form of energy used for many purposes in industry and medicine. Obstetricians routinely use ultrasound imaging to check the size, location, number or age of fetuses in the womb, the presence of some types of birth defects, and fetal movement, breathing and heartbeat. 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.

From a medical standpoint, ultrasonic fetal scanning is generally considered safe and is properly used when medical information on a pregnancy is needed. But ultrasound energy delivered to the fetus cannot be regarded as completely innocuous. Laboratory studies have shown that diagnostic levels of ultrasound can produce physical effects in tissue, such as mechanical vibrations and rise in temperature. Although there is no evidence that these physical effects can harm the fetus, public health experts, clinicians and industry agree that casual exposure to ultrasound, especially during pregnancy, should be avoided. Viewed in this light, exposing the fetus to ultrasound with no anticipation of medical benefit is not justified. For additional information about the "prudent use" of diagnostic ultrasound, see the statement from the American Institute of Ultrasound in Medicine (AIUM).



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.

FDA notified the medical community and the ultrasound industry in August 1994 regarding its concerns about the misuse of diagnostic ultrasound equipment for non-medical purposes, and asked them to discourage their patients from having sonograms for non-medical reasons.

AIUM - American Institute of Ultrasound in Medicine

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<http://www.aium.org/publications/viewStatement.aspx?id=31>

Keepsake Fetal Imaging

Approved June 22, 2005

The AIUM advocates the responsible use of diagnostic ultrasound for all fetal imaging. The AIUM understands the growing pressures from patients for the performance of ultrasound examinations for bonding and reassurance purposes largely driven by the improving image quality of 3D sonography and by more widely available information about these advances. Although there is only preliminary scientific evidence that 3D sonography has a positive impact on parental-fetal bonding, the AIUM recognizes that many parents may pursue scanning for this purpose.

Such "keepsake imaging" currently occurs in a variety of settings, including the following:

1. Images or video clips given to parents during the course of a medically indicated ultrasound examination;
2. Freestanding commercial fetal imaging sites, usually without any physician review of acquired images and with no regulation of the training of the individuals obtaining the images; these images are sometimes called "entertainment videos"; and
3. As added cost visits to a medical facility (office or hospital) outside the coverage of contractual arrangements between the provider and the patient's insurance carrier

The AIUM recommends that appropriately trained and credentialed medical professionals (either licensed physicians, registered sonographers, or sonography registry candidates) who have received specialized training in fetal imaging perform all fetal ultrasound scans. These individuals have been trained to recognize medically important conditions, such as congenital anomalies, artifacts associated with ultrasound scanning that may mimic pathology, and techniques to avoid ultrasound exposure beyond what is considered safe for the fetus. Any other use of "limited medical ultrasound" may constitute practice of medicine without a license. The AIUM reemphasizes that all imaging requires proper documentation and a final report for the patient medical record signed by a physician.

Although the general use of ultrasound for medical diagnosis is considered safe, ultrasound energy has the potential to produce biological effects. Ultrasound bioeffects may result from scanning for a prolonged period, inappropriate use of color or pulsed Doppler ultrasound without a medical indication, or excessive thermal or mechanical index settings. The AIUM encourages patients to make sure that practitioners using ultrasound have received specific training in fetal imaging to ensure the best possible results.

The AIUM also believes that added cost arrangements other than those of providing patients images or copies of their medical records at cost may violate the principles of medical ethics of the American Medical Association (E-8.0621 and E-8.0632) and the American College of Obstetricians and Gynecologists. 3 The AIUM therefore reaffirms the Prudent Use Statement⁴ and recommends that only scenario 1 above is consistent with the ethical principles of our professional organizations.

The market for keepsake images is driven in part by past medical approaches that have used medicolegal concerns as a reason not to provide images to patients. Sharing images with patients is unlikely to have a detrimental medicolegal impact. Although these concerns need further analysis and evaluation, we encourage sharing images with patients as appropriate when indicated obstetric ultrasound examinations are performed.⁵

References:

1. American Medical Association. E-8.062: Sale of Non-Health-Related Goods From Physician's Offices. Chicago, IL: American Medical Association; 1998.

2. American Medical Association. E-8.063: Sale of Health-Related Products From Physician's Offices. Chicago, IL: American Medical Association; 1999.

3. American College of Obstetricians and Gynecologists. Commercial Enterprises in Medical Practice. In: Ethics in Obstetrics and Gynecology. Washington, DC: American College of Obstetricians and Gynecologists; 2004.

4. American Institute of Ultrasound in Medicine. Prudent Use. Laurel, MD: American Institute of Ultrasound in Medicine; 1999.

5. American Institute of Ultrasound in Medicine. Providing Images to Patients. Laurel, MD: American Institute of Ultrasound in Medicine; 1998.