

# U.S. Food and Drug Administration

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**FDA Consumer magazine**  
[January-February 2004 Issue](#)

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## FDA Cautions Against Ultrasound 'Keepsake' Images

*By Carol Rados*

It's risky business taking pictures of unborn babies when there's no medical need to do so. That's the word from the Food and Drug Administration, which is concerned about companies trying to turn an important medical procedure into a prenatal portrait tool.

Facilities with captivating names such as Fetal Fotos, Peek-a-Boo, Womb with a View, and Baby Insight are popping up in strip malls and shopping centers all over the country. And they're promoting "keepsake videos" that use the latest ultrasound technology to produce high-resolution three-dimensional and four-dimensional (moving) images showing the surface anatomy of babies developing in the womb. The lure of this burgeoning industry is that parents-to-be get to see characteristics like facial features, hair, and even the baby's sex, and often they can count fingers and toes before their baby is born. Some women even have videos made at various stages of their baby's growth. And the videos are often being marketed as a prized addition to collections of childhood memorabilia.

As compelling as these sneak previews may be, the FDA is warning women about the potential hazards of getting keepsake videos. The agency also is warning companies against creating them for entertainment purposes. While ultrasound has been around for many years, expectant women and their families need to know that the long-term effects of repeated ultrasound exposures on the fetus are not fully known. In light of all that remains unknown, having a prenatal ultrasound for non-medical reasons is not a good idea.

### What is Ultrasound?

Ultrasound imaging is a common diagnostic medical procedure that uses high-frequency sound waves to produce dynamic images (sonograms) of organs, tissues, or blood flow inside the body. Prenatal ultrasound examinations are performed by trained professionals, such as sonographers, radiologists, and obstetricians. The procedure involves using a transducer, which sends a stream of high-frequency sound waves into the body and detects their echoes as they bounce off internal structures. The sound waves are then converted to electric impulses, which are processed to form an image displayed on a computer monitor. It is from these images that videos and portraits are made.

Obstetricians use ultrasound at a very low power level to check the size, location, number, and age of fetuses, the presence of some types of birth defects, fetal movement, breathing, and heartbeat. When ultrasound is used by a qualified clinician to check for this kind of medical information, the FDA says the medical benefit far outweighs any risk.

At somewhat higher exposure levels, given daily for weeks at a time, ultrasound is used to speed the healing of bone fractures. At even higher levels, the technology produces a heating effect in tissue that is useful in treating sprains and pulled muscles.

### Why All the Fuss?

Ultrasonic fetal scanning, from a medical standpoint, generally is considered safe if properly used when information is needed about a pregnancy. Still, ultrasound is a form of energy, and even at low levels, laboratory studies have shown it can produce physical effects in tissue, such as jarring vibrations and a rise in temperature. Although there is no evidence that these physical effects can harm a fetus, the FDA says the fact that these effects exist means that prenatal ultrasounds can't be considered completely innocuous.

As more advanced ultrasound technologies (usually using higher ultrasound intensities) become available, greater numbers of expectant mothers and their families are requesting fetal keepsake videos and portraits for souvenirs. Sometimes these images may be made by people not well trained, or for longer exposure times and at higher levels than are usually used in medical situations. At the same time, the medical community is discouraging the use of ultrasound unless it is medically necessary.

Mel Stratmeyer, Ph.D., in the FDA's Office of Science and Technology, says that most animal studies have not identified any fetal harm with low-dose ultrasound exposure.

"But the issue of keepsake videos has to be that if there's even a possibility of potential risk, why take the chance?" Stratmeyer says. Animal studies have been performed during the last 30 years to investigate the effects of the procedure on a fetus, due to the increased use of obstetrical ultrasound in the 1970s. Human studies, however, are not feasible for the same reason that experts are cautious about casual ultrasound: It's too risky to subject unborn babies to any unknown effects.

"The problem with experimental research," Stratmeyer says, "is that you really need both animal and human studies to make more predictable outcomes." He adds that as technology advances and becomes more complex, the potential for physical effects to be identified in the future also increases.

However, a few studies, Stratmeyer says, suggest that exposure to diagnostic ultrasound during pregnancy may have an effect on human development, such as delayed speech in children.

Danica Marinac-Dabic, M.D., an epidemiologist in the FDA's Office of Surveillance and Biometrics, says that the most consistent finding in the recent literature is a potential association between prenatal ultrasound exposure and subsequent left-handedness, especially among boys. At least three large follow-up studies involving thousands of school-age children in Sweden and Norway suggested such an association.

"Since ultrasound examinations in these studies took place in the late 1970s and early 1980s," says Marinac-Dabic, "and the fact that modern ultrasound equipment is capable of producing approximately eight times higher intensities than equipment used a decade ago, we continue to study the possible long-term effects of prenatal ultrasound in both animal and human epidemiologic studies."

### **The History of Fetal Photos**

The FDA first learned about keepsake video productions from consumers in Texas in 1994. The Texas Department of Health and the FDA's Dallas district office jointly inspected three firms. The FDA then initiated investigations of similar firms in other parts of the country. Investigators uncovered numerous companies offering a wide variety of ultrasound packages. Among the agency's findings were that ultrasound was being performed by untrained, unlicensed technicians and often without a doctor's supervision.

The FDA wrote about its concerns to 10 health professional organizations and the National Electrical Manufacturers Association, stating that anyone promoting, selling or leasing ultrasound equipment for making keepsake fetal videos could be breaking the law. The agency asked the organizations to have their members discourage patients from having ultrasound procedures for non-medical reasons and to notify the FDA of any keepsake video operations in their communities.

### **Not a Wise Choice**

For every reason a mother-to-be wants a keepsake video, there are good reasons she shouldn't have one. Women cite early bonding with their babies, determining the baby's sex, and a desire to share their prenatal experiences with friends and families as major reasons in favor of the videos. And the quality of images in commercial videos makes them especially tempting. Because many obstetricians still use two-dimensional imaging, which is considered standard in prenatal care, women may seek the more advanced three- and four-dimensional images used by some keepsake businesses, in which the features of an unborn infant are more easily recognizable to the non-professional.

But health experts say these are not medical reasons for having an ultrasound. Lawrence D. Platt, M.D., president-elect of the International Society of Ultrasound in Obstetrics and Gynecology and a practicing obstetrician-gynecologist in Los Angeles, adds that while physicians need to be sensitive to expectant mothers' feelings, "We have to go beyond emotions in this case. We have to do the right thing," he says. "Ultrasound is a form of energy and it must be respected."

Besides concern that unskilled technicians could be performing and interpreting such ultrasounds and that the procedure is not always done under the supervision of a qualified physician, some facilities may be using equipment that's not in good working order.

"Not all ultrasounds are created equal," says Nancy Hueppchen, M.D., a maternal fetal medicine specialist at Johns Hopkins Hospital in Baltimore. "Patients don't know the level of expertise of the person performing the procedure." Hueppchen says there's also the worry about ultrasounds not being conducted in medical settings. "These portrait facilities are not equipped to provide counseling should something go wrong, or proper guidance if a gross abnormality is suspected," she says.

The FDA also notes that some video companies have been known to use the ultrasound machine on higher energy exposures for as long as an hour to get the pictures. The procedure should always be done at the lowest possible energy output and for the least amount of time. Exposure to ultrasound for longer than the time specified by the FDA for fetal monitoring could pose a potential risk to the health of the mother and her developing fetus.

Some companies make it clear that they are not providing diagnostic ultrasounds, but those that don't may wrongly give women the impression that their ultrasound examination will identify problems.

The FDA and the American Institute of Ultrasound in Medicine (AIUM), which also strongly discourages the non-medical use of ultrasound, have concerns that women are being wrongly reassured by commercial sonograms. Women may misinterpret the studio ultrasound as a medical examination, thus giving them a false sense of security. And inaccurate findings may cause them to undergo unnecessary follow-up tests.

"Even in the best of hands," says Hueppchen, "fetal structural problems can be missed due to technical and gestational age limitations, thus falsely reassuring the patient."

### **Understanding the Laws**

Ultrasound is conducted with a prescription medical device that is regulated by the FDA. The agency sets the standard for the level of energy to be used for various treatments or diagnoses, including fetal ultrasounds. This standard restricts ultrasound exposure to levels that produce few, if any, effects on the fetus, based on epidemiological evidence.

The FDA can take action against the keepsake industry in two ways: for promoting a device for other than its approved use, and for using a prescription device without a prescription from a medical professional. By promoting and advertising keepsake videos, the advertiser is creating a new intended use for the device, and this requires premarket review by the FDA. And many keepsake facilities do not appear to be requiring doctors' prescriptions from their customers.

Kimber C. Richter, M.D., a deputy director in the FDA's Office of Compliance, says that regulation of the commercial ultrasonic imaging of fetuses is complicated because each video company scenario is different.

"In some cases, there may be no prescription and no physician oversight," she says. "In others, there may be a physician involved but no clear doctor-patient relationship." And in still others, "the video might be made through an extra visit to the physician that the patient normally sees." Richter says the regulatory approach in all these cases varies. "FDA regulates devices, but the qualifications and behavior of technicians and physicians would be regulated by the states," Richter says.

The FDA announced in 2002 that anyone administering ultrasound to consumers without a medical prescription is breaking the law. "In the past," says Richter, "the FDA has taken regulatory action, such as a warning letter or even seizure, when these devices were used for entertainment purposes without a prescription."

Margaret T. Tolbert, deputy director of the FDA's Division of Device User Programs and Systems Analysis, says the agency is updating its current Web statement warning consumers about the unknowns of using ultrasound equipment for entertainment purposes and is developing a set of questions and answers to educate those considering keepsake videos as a business opportunity.

Since a number of advertising examples recently have come to the FDA's attention--suggesting an increase in entertainment ultrasounds--the FDA is currently taking a closer look at these businesses. "We are reviewing these cases and will consider regulatory action as appropriate," says Richter.

### **The Bottom Line**

The prescription status of ultrasound equipment ensures that pregnant women will receive professional care that contributes to their health and to the health of their babies. Performing prenatal ultrasounds without following state and federal guidelines puts a mother and her unborn baby at risk. Therefore, the procedure should only be used to provide medical benefit. Besides being inappropriate and contrary to responsible medical practice, the bottom line is: Why take a chance with your baby's health for the sake of a video?

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### **Legitimate Uses for Ultrasound Imaging**

- Diagnosing pregnancy
- Determining fetal age
- Diagnosing congenital abnormalities
- Evaluating position of placenta
- Determining multiple pregnancies

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**To report keepsake video operations in your community, write to: Diagnostic Devices Branch, Office of Compliance, Center for Devices and Radiological Health, HFZ-322, 2098 Gaither Road, Rockville, MD 20850.**

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### **Official Statements on Ultrasonic Fetal Imaging**

#### **Food and Drug Administration:**

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.

**American Institute of Ultrasound in Medicine (AIUM):**

The AIUM advocates the responsible use of diagnostic ultrasound. The AIUM strongly discourages the non-medical use of ultrasound for psychosocial or entertainment purposes. 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.

**European Committee for Medical Ultrasound:**

The embryonic period is known to be particularly sensitive to any external influences. Until further scientific information is available, investigations should be carried out with careful control of output levels and exposure times. With increasing mineralization of the fetal bone as the fetus develops, the possibility of heating fetal bone increases. The user should prudently limit exposure of critical structures such as the fetal skull or spine during Doppler studies (a type of ultrasound that detects movement, direction and speed, such as fetal heartbeat).