

Avoid Fetal “Keepsake” Images, Heartbeat Monitors

While ultrasonic fetal scanning is generally considered a safe medical procedure, the use of it for unapproved and unintended purposes raises concerns.

The use of ultrasound imaging devices for producing fetal keepsake videos is viewed as an unapproved use by the Food and Drug Administration (FDA). Doppler ultrasound heartbeat monitors are not intended for over-the-counter (OTC) use. Both products are approved for use only with a prescription.

“Although there are no known risks of ultrasound imaging and heartbeat monitors, the radiation associated with them can produce effects on the body,” says Robert Phillips, Ph.D., a physicist with FDA’s Center for Devices and Radiological Health (CDRH). “When ultrasound enters the body, it heats the tissues slightly. In some cases, it can also produce small pockets of gas in body fluids or tissues.”

Phillips says the long-term effects of tissue heating and of the formation of partial vacuums in a liquid by high-intensity sound waves (cavitation) are not known.

Using ultrasound equipment only through a prescription ensures that pregnant women will receive professional care that contributes to their health and to the health of their babies, and that ultrasound will be used when medically indicated.

Fetal Keepsake Videos: “Performing prenatal ultrasounds without medical oversight may put a mother and her unborn baby at risk,” says Phil-



Jim Haynes for FDA

As enticing as this practice may be, FDA is warning women about the potential hazards of getting keepsake videos.

lips. “The bottom line is: Why take a chance with your baby’s health for the sake of a video?”

Fetal keepsake videos are viewed as a problem because there is no medical benefit derived from the exposure. Further, there is no control on how long a single imaging session will take or how many sessions will occur.

FDA is aware of entrepreneurs 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.

Doppler Ultrasound Heartbeat Monitors: Similar concerns surround the OTC sale of Doppler ultrasound heartbeat monitors. These devices, which people use to listen to the heartbeat of a fetus, are currently marketed legally as “prescription devices” that should only be used by or under the supervision of a health care professional.

“When the product is purchased over the counter and used without prior consultation with a health care professional, there is no oversight of how the device is used and little or no medical benefit derived from the exposure,” Phillips says. “The number of sessions or the length of a session to which a fetus is exposed is uncontrolled, thus raising the potential for harm to the fetus.” [FDA](#)

For More Information

Taking a Close Look at Ultrasound
www.fda.gov/consumer/updates/ultrasound032408.html

Fetal Keepsake Videos (FDA-CDRH)
www.fda.gov/cdrh/consumer/fetalvideos.html

FDA Cautions Against Ultrasound ‘Keepsake’ Images
www.fda.gov/fdac/features/2004/104_images.html