

FDA CAUTION ON 'KEEPSAKE' ULTRASOUND SCANS

The January/February 2004 issue of US Food and Drug Administration's (FDA) consumer magazine featured an article on "the risky business of taking pictures of unborn babies when there's no medical need to do so," and voiced the FDA's concerns at companies in the private health sector who are turning an important medical procedure into a marketing tool for prenatal photos and videos of the unborn baby.

The article described how businesses are setting up shop in shopping malls all over the United States promoting "keepsake videos" that use the latest ultrasound technology to produce high-resolution three-dimensional and four-dimensional (moving) images of the surface anatomy of babies in the womb. Women are able to have videos made at various stages of their pregnancy that show their baby's growth and development.

The FDA has cautioned women about the potential hazards of getting keepsake videos and warned 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 foetus are not fully known. In the light of all that remains unknown, having a prenatal ultrasound for non-medical reasons is not a good idea."

The warning has obviously not been noted by Ascot Radiology in Auckland which is currently promoting its "market-leading GE Voluson [which] has now been installed for the first time in New Zealand." Their flyer advertises "*Ultrasound in the 4th dimension*" and promotes an introductory offer of \$60 for a 3D image and short 4D scan up until the beginning of April. Ascot Radiology claims that "26 to 32 weeks is the ideal time for scanning as there is more amniotic fluid and the baby has developed some soft tissue about the face. However 4D imaging can be attempted at any stage beyond 12 weeks." The 4D scan can be performed at the end of the medical part of the examination and incurs an additional cost. After April the 4D package costs \$160 – this is in addition to \$40 for the basic scan!

The information provided about what exactly 4D ultrasound is does not make it clear whether the "realistic live action images" and "live action view" and use of "a large volume of data to reconstruct the images over and over giving a moving image" is an actual action replay of the baby's movements or simply a computer generated series of images.

The FDA article states that ultrasonic foetal scanning is generally considered safe if properly used when information is needed about a pregnancy. However, as ultrasound is a form of energy that has been shown to produce physical effects in tissue such as jarring vibrations and a rise in temperature the FDA says the fact these effects exist means that prenatal ultrasounds can't be considered completely innocuous.

Mel Stratmeyer, PhD, in the FDA's office of Science and Technology, says that most animal studies have not identified any foetal harm with low-dose ultrasound exposure, but warns that as technology advances and becomes more complex, the potential for physical effects to be identified in the future also increases.

The most consistent finding in the recent literature is a potential association between prenatal ultrasound exposure and subsequent left-handedness, especially in boys. At least three large follow-up studies involving thousands of school-age children in Sweden and Norway suggested such an association.

However, modern ultrasound equipment is capable of producing approximately eight times higher intensities than the equipment used in the 1970s and early 1980s for the ultrasound scans in these studies. This is why the possible long-term effects of prenatal ultrasound in both animal and human epidemiological studies continue to be studied.

The temptation is always there to use the ultrasound machine on higher energy exposures for longer lengths of time in order to get good pictures, whereas the procedure should always be done at the lowest possible energy output and for the least amount of time. The FDA cautions that exposure to ultrasound for longer than the time specified for foetal monitoring could pose a potential risk to the mother and her developing foetus.

The MSCC has written to the Minister of Health protesting the promotion of this latest form of marketing of ultrasound technology to pregnant women and the blatant commercialisation of what should be a medically indicated procedure, as well as the use of precious health dollars to subsidise such practices. While the benefits of ultrasound scans which are undertaken when medically indicated are undeniable, the MSCC is opposed to the increasing demand being created for unnecessary ultrasound scans.

The MSCC is urging the Ministry of Health to intervene and to refuse to provide public funding for 4D ultrasound scans and suggests there is need for the Ministry to contact those agencies which are advertising such keep-sake images and caution them about such practices.

As the FDA article states, "in the light of all that remains unknown, having a prenatal ultrasound for non-medical reasons is not a good idea."



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