

Conflicts of Interest: Understanding the Safety Issues Around Prenatal 3D Ultrasound

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Like many things, the safety of ultrasound depends on the level of exposure. Studies of the lower exposures common in the 1970s and 1980s are fairly reassuring. But since 1993, allowable exposure levels have risen dramatically, and little research has been done on the effects of these higher doses.

Meanwhile the use of prenatal ultrasound continues to expand in what one consumer advocate calls “the biggest uncontrolled experiment in history.” [\(1\)](#) In 2000, approximately 2.7 million women in the United States received prenatal sonograms—some 67 percent of pregnant women. [\(2\)](#)

When ultrasounds provide useful medical information, such as due date or indications of malformations, most doctors consider the risks acceptable. After a medical ultrasound exam, parents typically take home a simple 2D printout showing their fetus, and such pictures have become a virtual ritual of pregnancy in many industrialized countries.

Now, manufacturers are pushing hard to win acceptance for a much more extensive new ritual: a 4D (full motion 3D) movie of the unborn infant, provided by “fetal portrait” studios in shopping malls. These movies are captured on DVD using state-of-the-art ultrasound equipment such as the Voluson 730 made by General Electric.

A recent General Electric TV ad bypasses doctors to promote these videos directly to parents, saying, “When you see your baby for the first time on the new GE 4D ultrasound system, it really is a miracle.” [\(3\)](#)

Who could resist?

General Electric’s website provides links to commercial facilities where the new technology is available. With names like “Womb with a View” and “Peek-a-Boo,” these businesses advertise heavily in parents’ magazines and on the Internet, offering a variety of packages, ranging from a basic 2D ultrasound video (\$75) to a deluxe package that includes a 20-minute 4D video set to music and stored on DVD, a set of wallet photographs, and a set of larger photographs suitable for framing (\$285).

And the videos are in hot demand. Seeing their unborn baby thrills and comforts many parents. Writes British doctor Stuart Campbell, “Both maternal and paternal reaction to the moving 3D image is something we have not previously encountered. I have seen fathers kiss the screen or, more appropriately, their partner’s abdomen in an ecstasy of recognition and pleasure.” [\(4\)](#)

The Safety Question

But what about safety? On their websites, providers offer sweeping assurances that

using ultrasound to view unborn infants is devoid of any risk. One confidently states, “Extensive studies over 30 years have found that ultrasound has not been shown to cause any harm to mother or baby.” [\(5\)](#) Another says flatly, “There has never been a harmful effect shown by the use of ultrasound. Many women have multiple ultrasounds during pregnancy with no negative effect on the baby.” [\(6\)](#) Yet another: “Thousands of studies have been conducted. Nothing has surfaced yet that indicates any harmful effects in the use of ultrasound on animals or on humans.” [\(7\)](#)

Yet even as business interests strive to reassure their customers, government health officials and professional medical associations issue warnings.

In 1999, the American Institute of Ultrasound in Medicine (AIUM) released the following statement: *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.* [\(8\)](#)

In February 2004, the American Food and Drug Administration (FDA) issued the following statement: *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.* [\(9\)](#)

Which is right, the claim that fetal ultrasound is perfectly safe or the cautions against it? Why the concern over a technology that has been in everyday use in doctors’ offices for decades?

How Ultrasound Impacts Fetal Tissue

Ultrasound is a form of energy—sound waves vibrating at approximately a hundred times the frequency of normal sound—and the waves can affect tissue in a variety of ways. Heat is one effect. In addition, although ultrasound itself does not produce audible noise, secondary vibrations can produce noises as loud as 100 decibels, causing fetuses to move. [\(10\)](#) Other effects, still poorly understood, include tiny bubbles in tissue (a process known as cavitation), sheering forces within tissues, induced flows within fluids, and creation of minute quantities of toxic chemicals. [\(11\)](#)

Ethical restrictions preclude the direct study of ultrasound effects on humans. So scientists are using animal studies as well as data from populations of humans exposed to ultrasound in the past.

Animals studies have verified that heating of brain tissue does occur, and they have also begun to unravel the mechanism by which such heating affects brain development.

According to one 1998 study, temperature increases of 4.5 degrees Centigrade (8.1 degrees Fahrenheit) were measured in the brains of late-gestation live guinea-pig

fetuses insonated in utero for 2 minutes by pulsed Doppler-type ultrasound. [\(12\)](#) Other guinea-pig studies have shown adverse effects on cell division in bone marrow following ultrasound exposure. [\(13\)](#)

In October 2004, Pasko Rakic, Chairman of the Neurobiology Department at Yale University, announced that he and his colleagues had observed disruption of normal migration of cells in the brains of fetal mice following exposure to ultrasound. Rakic is now conducting a \$3 million study to see if the same effects occur in the offspring of rhesus macaque monkeys scanned during pregnancy. In humans, such disruption is known to be caused by certain viruses, mutations, and drugs, and it is linked to a range of disorders including autism and learning disabilities. [\[14\]](#)

In 2001, a team of Polish researchers published actual temperature readings obtained from an adult human brain during ultrasound exposure. The results showed no temperature increase, causing the researchers to hypothesize that the human brain enjoys better cooling capacities than the brains of smaller mammals. [\(15\)](#) But no one knows whether the rapidly developing brain of the human fetus is similarly protected from ultrasound-induced heat. To determine whether such heating may produce subtle brain damage in human populations, scientists have sought to compare the health histories of children exposed to ultrasound and the same data for children not exposed.

To date, epidemiological studies of humans exposed to ultrasound have shown the following possible adverse effects: growth retardation, dyslexia, and delayed speech development. [\(16\)](#) But only one effect, a higher rate of left-handedness among boys exposed to neonatal ultrasound, has been observed in at least three separate studies. [\(17\)](#)

Why Worry about Left-handed Boys?

If the only proven result of neonatal ultrasound is more left-handed boys, why be concerned? The answer is twofold. First, left-handedness is statistically linked to many cognitive and developmental problems ranging from learning difficulties to autism to epilepsy.

Second, many researchers view a rising rate of left-handedness as the neurological equivalent a “canary in a coal mine,” a suggestion that other types of minor brain damage may also arise. According to medical reporter Robert Matthews, the increase in left-handedness associated with neonatal ultrasound exposure could be the result of subtle brain damage causing people who ought genetically to be right-handed to become left-handed. [\(18\)](#)

The left-handedness findings were based on health data from children whose mothers underwent lower-intensity scanning in the late 1970s and early 1980s. But by the mid-1990s, average exposure levels had risen significantly. In 2003, the ECMUS Safety Committee noted that time-averaged values of intensity in the most common ultrasound scanning mode, “are now up to 1000 times greater than those reported in the 1970s.” [\(19\)](#) Scientists need to repeat the left-handedness studies, as well as studies of other possible effects, on this younger, more intensively exposed population. To date, such follow-up studies have not been done. [\(20\)](#) Thus, claims that “there has never been a

harmful effect shown” simply do not apply to today’s ultrasound equipment.

FDA Reduces Oversight While Increasing Risk Levels

A milestone came in 1993 when the FDA raised the maximum output of ultrasound machines used in obstetrics eightfold, from 94 up to 720 milliwatts per square centimeter. [\(21\)](#) The FDA was persuaded that operators needed greater flexibility, especially when confronting life-and-death situations such as determining blood flows in tiny coronary arteries in the midst of an ongoing heart attack.

At the time it raised the exposure ceiling, the FDA began requiring manufacturers to add two on-screen safety indexes. One measures the heating of bone or tissue; the other “mechanical” effects, including cavitation caused by the expansion of gas bubbles, sheering forces within tissues, and induced flows within fluids.

The FDA expected that a well trained sonographer using the on-screen safety indexes properly would not subject patients to greater levels of ultrasound exposure than under the previous system of regulation. But then the FDA failed to ensure that sonographers are properly trained. According to ultrasound experts, the actual state of sonographer training is dismally inadequate. Dr. Jacques Abramowicz, Professor of Obstetrics and Gynecology and Radiation at the University of Chicago, said, “Only two to three percent of the population doing ultrasound really know what the thermal index and the mechanical index mean.”

Even trained operators are confused by the complexity of interactions between sound waves and human tissues, the ways different ultrasound modes affect exposure, and the different responses caused in different parts of the body. Bones respond differently than muscles, for example. And bone is extremely sensitive to ultrasound heating: the skull of a third-trimester fetus heats up 50 times more quickly than brain tissue when exposed to ultrasound. [\(22\)](#) This means that brain structures lying close to the skull, such as the pituitary and the hypothalamus, are especially at risk of secondary heating. [\(23\)](#)

Yet another wild card is the difference in sensitivity between fetal tissue and adult tissue: fetal brain tissues are more sensitive to disturbance because of the developmental changes taking place.

The on-screen temperature safety indexes can give false assurance, even when operators are perfectly trained. According to Dr. Abramowicz, the actual amount of tissue heating may exceed the level predicted by the safety index by a factor of 2 to 6. Thus, actual heating may reach a dangerous level even when the safety index shows otherwise.

Finally, researchers cannot agree where to set the “safety baseline” for temperature effects. Most researchers regard a temperature rise of .5 degrees Centigrade to be safe. But according to John Abbott, PhD, director of standards communication for Philips Medical Systems, the indexes “cannot be considered as absolute measures of anything. They apply to the machine, transducer and operating condition in use at the

time. A thermal index of 4 is more than a thermal index of 3. That's all.”

Acceptable Levels of Risk

Despite the uncertainties, doctors continue to use medical ultrasound because the diagnostic benefits are believed to outweigh any potential harm. Says Dr. Abramowicz, “The common rationale is that ultrasound has been in use for 45 years now and we haven’t had missing arms and legs.”

In other words, doctors accept that there may be risks, but they believe that medical ultrasound remains a beneficial practice when performed by a trained operator for diagnostic purposes. According to Dr. Joshua Copel, Professor of Obstetrics and Gynecology and Pediatrics at Yale University, “It’s impossible to prove ultrasound is completely safe, but if you’re getting medically helpful information, then the tradeoff is reasonable.”

As for keepsake fetal portraits, Dr. Copel advises his patients to steer clear: “We don’t know what equipment they’re using, what the acoustic output is, and what the training of the personnel is.”

Because tissue heat increases over the length of exposure, well-trained sonographers limit the duration of any medical ultrasound procedure. But in multiple investigations of keepsake fetal portrait studios, FDA investigators found patients being exposed to higher machine settings for as long as an hour in order to obtain fetal pictures, much longer than is considered prudent. [\(24\)](#)

What Protection from the FDA?

Despite the FDA’s own findings and expressed concerns, the federal government has recently adopted a notably softer stance toward the practice of “keepsake” fetal ultrasound. When keepsake portrait studios first appeared in the 1990s, the FDA cracked down—hard. In 1994, the agency issued warnings against seven companies to stop making videos or face seizure, injunction, or other regulatory action. By May 1995, five of the companies had shut down. [\(25\)](#)

As late as 1999, the FDA continued to issue official warning letters, such as the following to PK Ultrasound of Coral Springs, Florida: “...to use the UM4A Ultrasound System for non-diagnostic video taping sessions of the fetus for keepsake videography ... is in violation of the law.”

Now, although fetal portrait studios are rapidly proliferating, the agency has stopped issuing any warning letters. In response to queries, FDA press officer Sharon Snider said, “We’re considering what our options are.”

According to “The Gray Sheet,” a medical devices trade publication, the FDA changed course after the arrival of Bush-appointed Dan Troy as chief legal counsel. [\(26\)](#) Prior to joining the FDA, Troy represented pharmaceutical and tobacco companies on legal cases against the FDA. [\(27\)](#) At the FDA, Troy issued a new policy requiring all warning letters to drug companies and medical device manufacturers to be approved by his

office. In the wake of the new policy, the number of warning letters issued by the agency dropped by 70 percent. [\(28\)](#) In November, 2004, Troy left the FDA after being widely criticized for intervening on behalf of drug companies, including his former client Pfizer, but to date there is no indication that his departure has resulted in any shift toward more active enforcement of the FDA's policy on keepsake fetal portraits.

Under a passive FDA, the ultrasound industry is openly flouting regulations. Despite the official ban on non-diagnostic use of ultrasound equipment, most keepsake fetal portrait studios routinely advertise non-diagnostic examinations.

Clearly, there is money to be made at all levels of the ultrasound food chain: worldwide sales of ultrasound equipment reached \$3.2 billion in 2004 according to one trade association. [\(29\)](#) And that figure does not include the incomes of franchisers such as Geddes Keepsake, or mom-and-pop keepsake portrait studios. Equipment sales alone are projected to triple by 2009. [\(30\)](#) Market researcher Harvey Klein recently noted that for General Electric 4D technology has been an area of surprising growth, helping that company achieve an 18 percent increase in ultrasound equipment sales in 2003, three times the 6 percent average growth for other manufacturers. [\(31\)](#)

Social Agendas Complicate the Safety Discussion

The biggest wildcard in the politics of ultrasound — even bigger than big money — is the anti-abortion movement's embrace of the technology. Calling the images a "miracle," activist newsletters and magazines abound in reports of women who change their minds about abortion after seeing 3D videos of their unborn fetus.

In 2003, Congressman Clifford Stearns (Republican from Florida) introduced the "Informed Consent Act," which would subsidize ultrasound equipment for anti-abortion "crisis pregnancy counseling" centers. If passed, the law would provide up to 50 percent of the cost of ultrasound equipment for such centers, and would also require that all pregnant women be shown images of their unborn fetus.

Has abortion politics played a role in the FDA's shift toward a passive enforcement stance? Neither FDA officials nor business leaders are willing to answer the question on the record. "Off the record, I don't doubt it for a minute," said one expert.

We've Seen This Before

Some observers compare the fetal portrait fad to earlier crazes involving "perfectly safe" imaging technologies and the natural desire to look inside the human body. Beginning in the 1920s, a device known as the "shoe-fitting fluoroscope" was a common feature in shoe stores, displaying x-ray images of customers' feet. Despite decades of warnings by medical professionals and increasing attempts by regulatory agencies to stop the practice, shoe-fitting fluoroscopes remained popular until the early 1960s. [\(32\)](#)

A Gap in the Safety Net

At the center of the fetal portrait fad are the simple, normal desires of expectant parents to be reassured about the health and well being of their new baby. Sadly, that very

desire for reassurance and enjoyment makes parents vulnerable to sales pitches for technologies whose safety remains uncertain. Ultrasound, of course, plays a vital role when needed for a legitimate medical purpose. But as with any powerful technology, caution is advised. Says Dr. Abramowicz: "I recommend against keepsake ultrasounds. The principle is simple. You should not use a medical device for a non-medical purpose."

Meanwhile, the issue of prenatal ultrasound has highlighted a serious gap in the regulatory system. Unlike new drugs, medical devices are not subjected to rigorous animal and human testing prior to being released. While it is reassuring that researchers are finally beginning to understand just how ultrasound may affect brain development, the best time for such research would have been before the FDA loosened the ceilings on ultrasound exposure. Since 1993, when the rules were changed, some 28 million pregnant women have been exposed to ultrasound.

Concerned citizens should push for full enforcement of the FDA's existing rules on ultrasound, so that prenatal ultrasound is limited to appropriate medical uses. But action needs to go further than that. The approval process needs to be changed so that medical devices, including the new higher intensity ultrasound machines, are fully tested before – not after – being put into widespread use.

Notes and Links

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