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February 23, 2009

Rep. Pat Widlitz

Rep. Deborah Heinrich

Dear Reps. Widlitz and Heinrich:

I am writing to you regarding the proposed House Bill 5635 being considered in your hearing scheduled for Friday, Feb 27, 2009. Unfortunately, due to a prior commitment I cannot attend the hearing in person to testify, though I hope this letter and attachments will be helpful.

I write both as a constituent and as an informed professional. I lived in Guilford for 18 years before moving to Madison in 2004. I am also a Professor of Obstetrics, Gynecology and Reproductive Sciences at Yale, with my clinical and academic expertise in prenatal ultrasound. Finally, I am currently the President of the American Institute of Ultrasound in Medicine (AIUM, <www.AIUM.org>), a multidisciplinary society of over 7500 physicians, sonographers and scientists dedicated to the safe and effective use of ultrasound.

The AIUM and the professional medical community have been concerned about the profusion of storefront entertainment ultrasound facilities for a number of years. Operating in a grey zone at the fringe of medical practice, they raise a number of important issues. While most of us who use clinical ultrasound believe that there is minimal risk in pregnancy when properly calibrated machines are used at appropriate power levels for short periods of time, the machines used at these non-medical facilities are bought from unknown sources and are not required to undergo any specific maintenance to ensure proper performance. The individuals performing the scans may or may not be trained professional sonographers, so there is no way to ascertain their knowledge of the potential for ultrasound bioeffects on the developing fetus, or their ability or willingness to practice safe sonography.

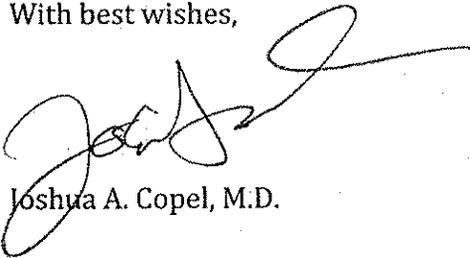
Some of the providers at keepsake ultrasound establishments have been known to produce reports of "limited fetal ultrasounds," which borders on the practice of medicine. At present there is no independent practice of sonography anywhere in the US, even by sonographers who have passed the Registry examinations offered by the American Registry of Diagnostic Medical Sonography (www.ardms.org).

More detail of these concerns is included in the attached manuscript of a paper I presented to a safety symposium on entertainment scans held at the International Society for Ultrasound in Obstetrics and Gynecology annual meeting in Florence, Italy in the October, 2007. I have also attached copies of the AIUM position paper on Keepsake Fetal Ultrasound, which was the product of a task force I chaired several years ago, and of an opinion from the AIUM Bioeffects Committee on the Prudent Use of Ultrasound in Obstetrics. The fourth attachment here is the American College of Obstetricians and Gynecologists Committee Opinion on non-medical use of ultrasound.

To date, the FDA has not pursued any actions against entertainment ultrasound businesses. While the FDA clearly regulates the production of ultrasound equipment as Class II medical devices, and has a statement on their web site opposing the use of fetal scans for this purpose (<http://www.fda.gov/cdrh/consumer/fetalvideos.html>, and also attached to this letter), their public stance has been that enforcement of use issues is the purview of the states rather than the FDA.

I hope all of these will be helpful in your Committee's deliberations. I would welcome the opportunity to meet with you or your staffs as this bill progresses to help in any way I can with it.

With best wishes,



Joshua A. Copel, M.D.

Non-clinical Use of Obstetric Ultrasound: Medico-Legal Implications
in the USA

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The United States is known as the land of free enterprise, so it should be no surprise that medical equipment has undergone a transformation to use by laypersons for commercial reasons. Eighty years ago the US Patent Office granted a patent to Dr. Jacob Lowe, a Boston physician, for a fluoroscopic device to aid in fitting shoes. The doses of radiation to which untold numbers of children and adults were exposed is not precisely known, but may have been as high as 7-14 Rads for a 20 second exposure¹.

Shoe-fitting fluoroscopes were regulated out of existence by the 1950s. There are a host of other non-medical uses of sophisticated technology available on the patient's initiative, however. CT of the heart is recommended for anyone fitting a variety of "risk factors" by one center. These risk factors include men over 35 and women over 40, high stress levels and a sedentary lifestyle². One company provides pricing on line, with a coronary artery scan for \$395 in Los Angeles or Chicago. For some reason the same scan costs \$100 more in Washington, DC³. Full body scans are also available. Insurance, the consumer is warned on these sites, does not cover these scans, although credit cards, checks or cash are welcome.

Coronary artery and full body CT scans use expensive equipment, and potentially dangerous ionizing radiation, unlike ultrasound. So, the development of a booming business of prenatal ultrasound entertainment centers in the US might have been predictable. With names like "Womb With a View", "Fetal Fotos", and "Baby Insight", these offices provide 3D and 4D sonography on demand, with convenient hours and packages including your baby's movements set to music on a CD, and comfortable theater style seating for guests. Perhaps worst of all, some offer reports of "limited medical ultrasounds".

Other companies offer franchising information on the web, including business plans, legal forms, practice standards, and even physician oversight⁴.

At present there is no way of estimating the number of such businesses in the US. There are no standards for the scans that are

performed, no federal or state oversight of the offices offering these services, and no way of knowing who is performing the scans on what machines.

The US Food and Drug Administration classifies ultrasound machines as "Class II devices", (21 CFR 892.1550, 1560 & 1570) subject to less stringent oversight than Class III devices, defined as those that that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. So, while ultrasound equipment comes with a label specifying that it is to be used by or on the order of a physician, the degree of oversight that the FDA expects to apply to the actual use of the machine is much less than for a device that produces ionizing radiation.

In fact, ultrasound machines, including 3D and 4D units, are readily available for purchase by anyone with sufficient cash on www.ebay.com. A recent search on that site (9/26/07) produced machines for purchase for as little as \$15,000, though the listings for each available unit included a warning that credentials of the purchaser would be verified to ensure compliance with FDA regulations.

In 2005 the AIUM developed a statement on Keepsake Fetal Imaging⁵, written by a task force that I chaired and approved by the Board of Governors. The AIUM statement addresses the issue of qualifications of the individual performing the sonogram. The position of the AIUM is that only qualified individuals should perform sonograms, and that anyone performing fetal sonograms must be able to recognize important conditions such as birth defects, and conversely artifacts that may mimic fetal pathology. The lack of regulation of entertainment sonography, and the absence of standards for the performance of the sonograms makes it impossible to know what is being done.

While there are anecdotal reports of missed diagnoses during entertainment scans⁶, we have no systematic collection of data to understand the likelihood of missed diagnoses, or false positive diagnoses of anomalies. Similarly, we have no data to appreciate

whether significant numbers of previously unsuspected anomalies are being detected during entertainment ultrasounds in medical or non-medical facilities.

What we do know in this area is that there is no standard method of training the franchisees who open freestanding facilities. One franchiser includes over 20 bullet points on its website elucidating the support offered to franchisees, but none of the points include training to perform ultrasounds⁴. Another offers protected territory and marketing assistance, as well as "comprehensive training in all areas of the business, including: Day-to-Day Operations; Employees; Bookkeeping and accounting procedures; Advertising and Marketing programs", but not specifically technical assistance in how to scan fetuses⁷. Unfortunately, while credentialed sonographers have opened some franchises, entrepreneurial businesspersons who do not share the professional training and attitudes expected of registered sonographers have opened others. One of these was quoted in the Wall Street Journal saying "I don't care if the fetus has three legs, I'd only point out two. I don't care if their uterus has fibroids, or if they have too much or too little amniotic fluid or where the placenta is. I have informed these people I'm not a doctor, that I'm not trying to find abnormalities."⁸.

The issue of reports generated by freestanding facilities has not been heavily scrutinized. Sonographers, and especially non-sonographers who perform entertainment scans, are not licensed in any state to practice medicine independently, and the issuance of any report of an imaging study is usually considered to be the purview of licensed physicians. Thus far, states have not extensively pursued this, nor are there cases of civil suits related to missed diagnoses or bad outcomes after entertainment ultrasounds. One case in Texas⁹ attempted to use the complex and technical concept of changing the use of the ultrasound machine from the original labeling, thus making it a Class III device. The Appellate Court denied this part of the complaint, though the court upheld a misbranding claim for use of a prescription device without the order of a physician.

In 2005, also in Texas, the Attorney General reached an agreement

with four fetal imaging companies requiring physician oversight of entertainment ultrasounds. How this is being accomplished is not specified in the legal documents¹⁰.

In California, in the wake of publicity regarding actor Tom Cruise's revelation that he had purchased an ultrasound machine to observe his fiancée Katie Holmes' fetus, the legislature considered and passed a bill in 2006 (AB 2360) making the sale of ultrasound machines to non-medical sites illegal. Although this might be considered something already prevented through FDA regulations, the legislature felt compelled to act. Governor Schwarzenegger vetoed the bill, saying that it conflicted with prior legislation requiring entertainment ultrasound sites to give clients written disclosure of the position opposing entertainment scans (AB 2049, 2004).

The AIUM Task Force on entertainment ultrasound examined professional codes of conduct to see if guidance in this area could be developed from existing statements. In preparing the statement, the committee considered the various settings in which entertainment scans might be performed. These included:

- In a physician's office as part of a medically indicated scan
- In a physician's office as a separate event and paid for by the patient outside of insurance payments for medical care
- In a freestanding commercial facility

The AIUM looked at standards from the American Medical Association and the American College of Obstetricians and Gynecologists. The AMA specifically comments on two types of products that might be offered in physicians' offices for additional costs, health-related and non-health-related. The policy provides that "physicians may sell low-cost non-health-related goods from their offices for the benefit of community organizations, provided that (1) the goods in question are low-cost; (2) the physician takes no share in profit from their sale; (3) such sales are not a regular part of the physician's business; (4) sales are conducted in a dignified manner; and (5) sales are conducted in such a way as to assure that patients are not pressured into making purchases."¹¹

The stipulations on health-related goods are more restrictive. They include (excerpted from ¹², deleted text indicated by [...]):

“(1) Physicians should not sell any health-related products whose claims of benefit lack scientific validity. [Based...] on peer-reviewed literature and other unbiased scientific sources that review evidence in a sound, systematic, and reliable fashion.

(2) Because of the risk of patient exploitation and the potential to demean the profession of medicine, physicians who choose to sell health-related products from their offices must take steps to minimize their financial conflicts of interest. The following guidelines apply:

(a) In general, physicians should limit sales to products that serve the immediate and pressing needs of their patients. For example, if traveling to the closest pharmacy would in some way jeopardize the welfare of the patient (eg, forcing a patient with a broken leg to travel to a local pharmacy for crutches), then it may be appropriate to provide the product from the physician's office. [...]

b) Physicians may distribute other health-related products to their patients free of charge or at cost, in order to make useful products readily available to their patients. [...]

(3) Physicians must disclose fully the nature of their financial arrangement with a manufacturer or supplier to sell health-related products. [...]

(4) Physicians should not participate in exclusive distributorships of health-related products which are available only through physicians' offices. [...]

The American College of Obstetricians & Gynecologists has adopted similar language to that of the AMA, saying “It is ethical and appropriate, however, to sell products to patients as follows: sale of devices or drugs that require professional administration in the office setting; sale of therapeutic agents, when no other facilities can provide them at reasonable convenience and at reasonable cost; sale of products that clearly are external to the patient–physician relationship, when such a sale would be considered appropriate in an external relationship; and sale of low-cost products for the benefit of community organizations.” ¹³

As the AIUM Task Force considered the options for scanning in physician offices, there were two possible ways to define the scan, as medical or non-medical procedures. If we define entertainment scans as non-medical, offering that service violates the guidelines of the AMA as they are not low-cost, the physician would gain profit from the transaction, and there is likely to be some subtle or overt pressure on the patient to have the scan. Similarly the ACOG guideline would be violated, as the scan would not be a low-cost item sold for the benefit of a community organization.

If the entertainment scans are defined as medical services, the AMA guidelines are violated because they do not serve immediate and pressing needs of patients, and are not offered free of charge or at cost. The ACOG guidelines would similarly seem to prohibit performing entertainment scans if they are defined as non-medical.

Conclusions

Where does this leave us? In the USA, the Food and Drug Administration has regulatory power over the manufacture and sale of ultrasound systems, but seems to have delegated the enforcement of violations of their rules to the states. The states are taking little or no action.

The market for entertainment scans has been driven in part by reluctance of some imagers to provide still or video images to patients. This has been due, at least in part, by concerns that images provided to patients could be used as evidence in claims of failure to diagnose a congenital abnormality. This argument has inherent weaknesses. Keeping a copy of any still images provided to the patient in the medical record covers at least part of this concern. Parallel video clips can also be retained. For some anomalies that develop later in gestation, for example duodenal atresia, the image provided to the patient may well help exonerate the physician.

Our practice is to give multiple still images to all patients having medically indicated scans, including 3D images if time permits and the fetus is in a good position. We also provide video clips to patients who bring their own tapes or discs. We do this in the belief that good

relations with patients are important, and a potential deterrent to future professional liability claims.

The American Institute of Ultrasound in Medicine is firm in its opposition to non-medical use of obstetric sonography, and the commercialization of fetal sonograms by non-professionals. We continue to encourage the FDA to enforce its regulations in this area. AIUM also encourages ultrasound equipment manufacturers to agree not to sell imaging systems to non-medical imaging facilities.

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Keepsake-Fetal Imaging

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.

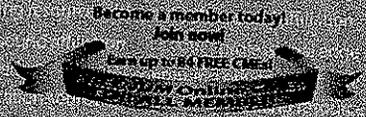
Although the general use of ultrasound for medical diagnosis is considered safe, ultrasound energy has the potential to produce biological effects. Ultrasound bioeffects may result from scanning for a prolonged period, inappropriate use of color or pulsed Doppler ultrasound without a medical indication, 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

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Official Statements

View an Official Statement from the list below.

Prudent Use in Obstetrics

Approved March 19, 2007

The AIUM advocates the responsible use of diagnostic ultrasound and strongly discourages the non-medical use of ultrasound for entertainment purposes. The use of ultrasound without a medical indication to view the fetus, obtain a picture of the fetus or determine the fetal gender is inappropriate and contrary to responsible medical practice. Ultrasound should be used by qualified health professionals to provide medical benefit to the patient.

ACOG

Committee on
Ethics

Committee Opinion



Number 297, August 2004

Nonmedical Use of Obstetric Ultrasonography

ABSTRACT: *The American College of Obstetricians and Gynecologists (ACOG) has endorsed the "Prudent Use" statement from the American Institute of Ultrasound in Medicine (AIUM) discouraging the use of obstetric ultrasonography for nonmedical purposes (eg, solely to create keepsake photographs or videos). The ACOG Committee on Ethics provides reasons in addition to those offered by AIUM for discouraging this practice.*

The American College of Obstetricians and Gynecologists (ACOG) has endorsed the following statement from the American Institute of Ultrasound in Medicine (AIUM) discouraging the use of obstetric ultrasonography for nonmedical purposes (eg, solely to create keepsake photographs or videos) (1):

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.

In addition to the concerns noted by AIUM, the ACOG Committee on Ethics believes that nonmedical use of ultrasonography should be discouraged for the following reasons:

- Nonmedical ultrasonography may falsely reassure women. Even though centers that perform nonmedical ultrasonography and create keepsake photographs and videos of the fetus may offer disclaimers about the limitations of their product, customers may interpret an aesthetically pleasing image or entertaining video as evidence of fetal health and appropriate development. Ultrasonography performed for psychosocial or entertainment purposes may be limited by the extent and duration of the examination, the training of those acquiring the images, and the quality control in place at the ultrasound facility. Women may incorrectly believe that the limited scan is, in fact, diagnostic.

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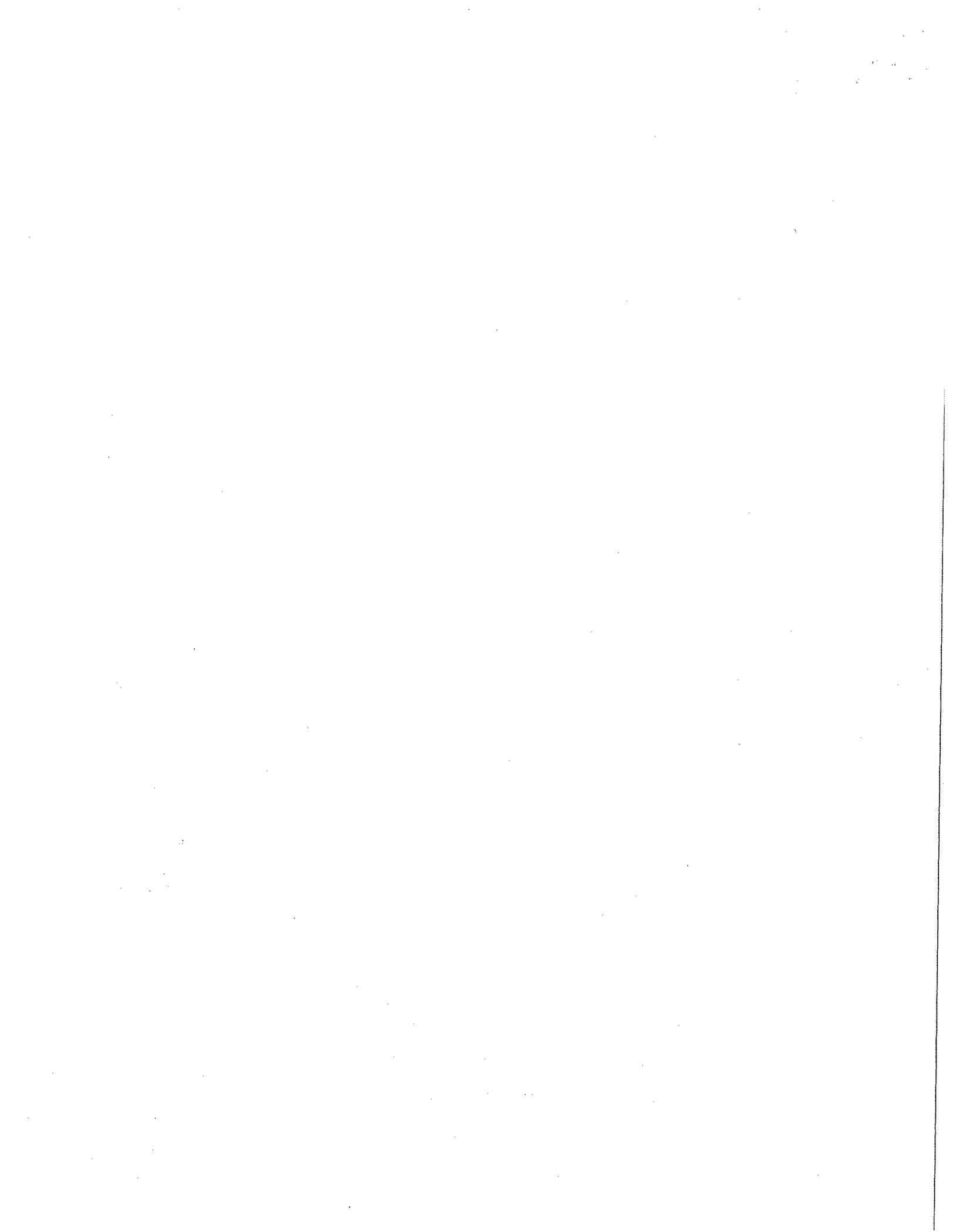
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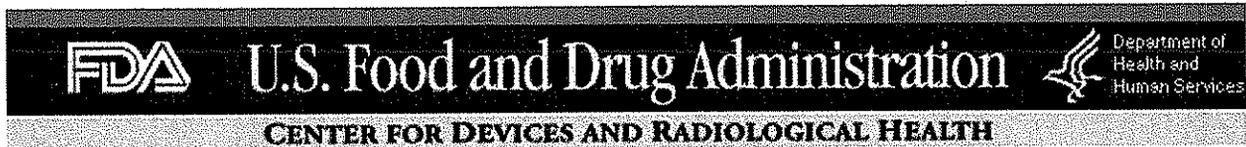


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- Abnormalities may be detected in settings that are not prepared to discuss and provide follow-up for concerning findings. Without the ready availability of appropriate prenatal health care professionals, customers at sites for nonmedical ultrasonography may be left without necessary support, information, and follow-up for concerning findings. For example, customers may interpret a minor finding (eg, an echogenic intracardiac focus) as a major abnormality, resulting in unnecessary anxiety and concern. Conversely, in the event of concerning findings

(eg, oligohydramnios), women may not receive appropriate follow-up. Obstetric ultrasonography is most appropriately obtained as part of an integrated system for delivering prenatal care.

Reference

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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.

Updated August 30, 2005

