The Business of Baby Pictures
Controversy Brews Over “Keepsake” Fetal Ultrasounds

Rebecca Voelker

ETAL IMAGES CREATED WITH 3-dimensional (3D) ultrasound as “keepsakes” for expectant couples have triggered a new debate about the provision of nonmedical services in physicians’ offices.

The controversy stems from the advent of commercial operations in malls and other nonmedical settings offering fetal ultrasounds for the purpose of producing mementos, not diagnoses. These procedures may be performed by noncertified personnel with little more than a weekend’s worth of training. It’s difficult to estimate how many keepsake ultrasound businesses there are in the United States, but some claim to have branches in more than 20 states and others report that they perform more than 100 scans per month.

Earlier this year, as the popularity of the keepsake industry seemed to soar, the American Institute of Ultrasound in Medicine (AIUM) reaffirmed its stance against ultrasound used for nonmedical purposes. Its “prudent use” statement says that the AIUM “strongly discourages the non-medical use of ultrasound for psychosocial or entertainment purposes.” It calls the use of 2-dimensional (2D) or 3D ultrasound only to view the fetus, take its picture, or determine its sex without a medical indication “inappropriate and contrary to responsible medical practice.” The statement notes that although diagnostic ultrasound so far has not been found to have “biological effects” on patients, such effects could be identified in the future.

For now, the group is assessing the legal, ethical, and professional ramifications of producing keepsake photos and videos in physicians’ offices. As the task force arrives at some conclusions over the next several months, the AIUM will then discuss the issue with other medical groups, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Registry of Diagnostic Medical Sonographers (ARDMS), which have endorsed the “prudent use” statement. “We hope we can develop some positions that generally are acceptable,” says Joshua Copel, MD, chair of the task force and vice chair of the Maternal-Fetal Medicine Section at Yale University School of Medicine.

Physicians and other professionals who use ultrasound in their practices seem to fall primarily into two camps: those who believe keepsake ultrasound products have no place in either physicians’ offices or commercial venues and those who believe a limited role to provide these mementos may exist in medical practice. Copel says the task force will try to determine the point where physicians would cross the line from professionalism to “hucksterism” if their practices offered keepsake ultrasound products. “We don’t want to look like we’re practicing medicine out of the back of a wagon,” he says.

It has long been customary for physicians to give their pregnant patients fetal photos from prenatal ultrasound scans. More recently, as technology has evolved, some have also put the images onto compact discs (CDs) and 1- or 2-minute videotapes. Among them are Delores Pretorius, MD, a member of the AIUM task force and professor of radiology at the University of California, San Diego, School of Medicine, and Lawrence Platt, MD, former AIUM president and director of the Center for Fetal Medicine and Women’s Ultrasound in Los Angeles.

“There’s nothing wrong with this in concept,” says Platt. “We have a copy for the record and one for the patient.”

Most, if not all, physicians say that for safety reasons, ultrasound should not be performed in malls and other commercial settings. Pretorius says one of her pregnant patients had a keepsake ultrasound done in a com-
mercial shop. “She brought me a video from the mall,” Pretorius recalls. “The settings were inappropriate; there was too much color Doppler on the heart for too long.” Some experts are concerned that Doppler or color Doppler ultrasound used during the first trimester might interfere with fetal organogenesis.

Pretorius telephoned the mall operation where her patient had gone, to ask if personnel were trained in the use of color Doppler ultrasound. “I took away [from the conversation] that they weren’t,” she says.

Physicians also point out that commercial ultrasound operations are not equipped to make diagnoses or referrals if a serious fetal anomaly is found and that some women may have keepsake scans performed too frequently, increasing the risk of harm.

**PRESCRIPTION DEVICE**

According to US Food and Drug Administration (FDA) regulations, ultrasound machines are prescription devices that should be used only for medical purposes and with a physician’s order. The FDA also sets standards for ultrasound power settings. It has issued vigorous warnings against nonmedical uses of ultrasound, and the agency can seize machines used without a prescription for entertainment purposes.

While the FDA regulates the machines, individual states have jurisdiction over the qualifications and conduct of professionals who use the machines. The agency encourages states to take action against technicians who perform nonmedical ultrasounds, but to date, only two have proposed or passed legislation on keepsake ultrasounds. A bill pending in New York would make it a misdemeanor offense to administer ultrasound without an order from a physician, nurse practitioner, or midwife. Legislation that takes effect next year in California requires women who have keepsake ultrasounds to sign a waiver stating they know that the FDA opposes the procedure.

The FDA warns of potential harm from ultrasound energy, but some physicians say the potential for risk is overstated. “There is no independent, confirmed evidence of harm from diagnostic medical sonography,” says Copel. “It probably is ethical to offer [keepsake ultrasound] to patients if there is no danger that we can discern.”

When ACOG endorsed the AIUM statement last August, its leadership specifically noted that ultrasound has to be considered in the complete context of prenatal care. “We didn’t want patients to read the statement and think the AIUM is concerned about [safety], so maybe they would not have ultrasound at all,” says Jeffrey Ecker, MD, vice chair of ACOG’s Committee on Ethics.

Unpublished evidence from animal studies by Pasko Rakic, MD, PhD, and colleagues at Yale University indicates that ultrasound can disrupt normal movement of cells through the brains of unborn mice; however, the relevance of the findings for humans is unclear. The group has just begun a $3 million study funded by the National Institute of Neurological Disorders and Stroke to examine the effect of ultrasound scans on rhesus macaque monkeys exposed during gestation.

**ETHICAL CONUNDRUM**

Another ethical conundrum is whether physicians should charge a fee if they offer the products. Commercial operations charge anywhere from $75 to determine fetal sex to $300 or more for a full package of photos and a CD, DVD, or videotape.

“There is a real cost of the print photograph, and to pass a nominal cost for that on to the patient is not of concern,” says Michael Goldrich, MD, chair of the American Medical Association’s (AMA’s) Council on Ethical and Judicial Affairs. “But if there is a substantial fee for the product, then there is significant concern for the impact of that on the physician-patient relationship.” The AMA opposes profit-making sales of non–health-related goods in physicians’ offices.

Proponents say consumer demand for keepsake ultrasounds has grown so much in recent years that the only way to ensure patient safety is to bring the practice into medical settings, where appropriately trained personnel follow a protocol that does not violate FDA regulations or AIUM standards.

One reason for the increased popularity of keepsake ultrasounds is the development of 3D ultrasound in the last decade. This allows expecting parents to clearly see facial features, fingers, and toes instead of the vague gray outlines of 2D fetal ultrasound.

“When you show a family the 3D image, they are awestruck,” says Robert Wolfson, MD, PhD, a Colorado specialist in maternal-fetal medicine. Wolfson advocates keepsake ultrasound in medical settings as a tool that helps soon-to-be parents develop a connection with their unborn child. He and other proponents say this connection facilitates compliance with medical advice, which improves health outcomes for the mother and child.

In recent years, Wolfson and several other physicians have worked with Arizona entrepreneur Berkeley Geddes, cofounder of the FlipDog.com online job search Web site, to develop criteria for the provision of keepsake ultrasounds in medical settings.

Geddes’ firm, Geddes Keepsake Inc, has developed software that would enable physicians or other health care professionals to easily produce CDs, DVDs, VHS videotapes, and PowerPoint slide shows of fetal 3D ultrasound images. The equipment includes a viewing station where pregnant women can select the images they want, make multiple copies, and choose scrapbook pages with flowers and other designs. Videos and DVDs can be set to music.

Geddes licenses the equipment to medical practices at prices ranging from $8000 to $22000, depending on the capabilities the practices want. Licensure includes an agreement to follow a protocol that adheres to FDA and AIUM standards. The protocol includes provisions that a diagnostic ultrasound be performed before a keepsake scan, that a patient’s obstetrician know the keepsake scan is being performed, that the lowest reasonable power levels are used, and

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that sonographers who perform keep-sake scans be certified by the ARDMS or eligible for certification.

Geddes is trying to encourage research that would show whether the keepsake scans really do promote fetal bonding and improved health outcomes for mothers and their infants. Positive results, he says, would justify keepsake as a medical procedure. If no benefit is found, Geddes says he would close the company. In August 2002, he opened the Geddes Imaging Center in Mesa, Ariz, a stand-alone imaging center with four board-certified radiologists who perform diagnostic and keepsake ultrasound.

Even though Geddes and Wolfson say they are responding to consumer demand that the medical community has ignored, physicians like Pretorius and Platt express skepticism.

“If you’re clever, you can already do what Geddes is doing,” says Pretorius. Platt says he provides patients with videos, CDs, or thermal prints at no charge. But, he adds, to create elaborate packages and scrapbooks in a medical practice’s sonography department lowers the level of professionalism in the physician’s office. “We are not photographers; we are there to provide health care diagnoses.” □

More Scrutiny for Dietary Supplements?

Tracy Hampton, PhD

I n an attempt to tighten the reins over control of dietary supplements, the US Food and Drug Administration (FDA) has announced several regulatory initiatives. The actions come following criticism that the government has reacted too slowly to the dangers posed by supplements such as ephedra and androstenedione, both of which were taken off the market earlier this year.

The new initiatives include a regulatory strategy designed to further implement the Dietary Supplement Health and Education Act of 1994 (DSHEA), an open public meeting, and a draft guidance document for industry. Passage of DSHEA allowed dietary supplements—defined by Congress as products that contain ingredients including vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites—to be sold over the counter without oversight unless the FDA could demonstrate a product posed a clear danger to public health.

“With this strategy, we will now have a clear roadmap to share with the dietary supplement industry and at the same time give consumers a higher level of assurance about the safety of dietary supplement products and the truthfulness of their labeling,” said FDA Acting Commissioner Lester Crawford, DVM, PhD, during the annual conference of the Council for Responsible Nutrition, held in Lansdowne, Va.

But critics of the current lack of oversight of dietary supplements say that while the effort is a worthwhile one, the agency continues to operate in a reactionary mode so that unsafe products will remain on the market for extended periods before any enforcement action is taken.

IDENTIFYING SAFETY CONCERNS

As part of its plan, the FDA is enlisting the help of other federal partners, such as the National Institutes of Health Office of Dietary Supplements and National Center for Complementary and Alternative Medicine and the National Toxicology Program in the Department of Health and Human Services, to make safety decisions about dietary supplements. Officials will evaluate safety concerns by a process that starts with identifying signs of possible safety concerns. These can arise from adverse event reports, international regulatory actions, media reports, information from consumer groups, and other sources. If the agency finds enough evidence for action, it could issue public health advisories, require labeling changes, or make a determination of unreasonable risk, which could result in a ban of the sale of a product.

Of particular importance to the new initiative for monitoring dietary supplements is a clarification of when a food supplement ingredient is considered a “new dietary ingredient” for which notification and safety information must be sent to the agency. (Under DSHEA, dietary supplements do not need FDA approval if the ingredients were marketed in the United States before October 15, 1994.)

The agency, which is seeking input from the public on the issue, held an open meeting on November 15 to hear stakeholders’ remarks regarding potential content and format requirements for new dietary ingredient notification.

Critics, however, question whether the new initiatives will add up to better oversight of potentially unsafe supplements. Donald Marcus, MD, a professor of medicine and immunology at Baylor College of Medicine, in Houston, Tex, and an author of several published reports examining safety issues relating to dietary supplements,