

“Just Scanning Around” with Diagnostic Medical Ultrasound: Should States Regulate the Non-Diagnostic Uses of This Technology?

I. Introduction.

Yes, America has become the land of medical imaging opportunity, where anyone can participate in the ultrasound imaging experience. Perhaps, the actor Tom Cruise reached the pinnacle of the self-referral imaging indulgence, when he revealed to Barbara Walters and her national television audience that he had recently purchased his very own ultrasound system.¹ He told his listening audience that he was able to scan his baby-to-be at anytime, but he had not yet learned its sex.² Suddenly, it became crystal clear to his listening audience that anyone with money could purchase one of these highly sophisticated medical systems to just “scan around” in his or her living room. Not only did this revelation rattle the many different medical communities worldwide, but it also rekindled the ongoing, contentious debate among its health care providers concerning the appropriate uses for this technology.³

Unfortunately, the pace at which ultrasound services are spreading throughout the world, and in particular America, may be exceeding the abilities of the regulatory agencies to monitor and maintain consumer safety. Notwithstanding any alleged safety risks ultrasound might pose to consumers, the American public seems increasingly eager to purchase these services. Although some do see an economic upside for consumers in

¹ Sarah Hall, *Cruise Keeps Eye on Fetus*, <http://wwwonline.com/News/Items/PF/0,1527,17834,00.html> (recounting discussion between Barbara Walters and Tom Cruise during an interview where he admitted that he had purchases an ultrasound system and had technologists showing him how to use it).

² See Sarah Hall, *supra* note 2.

³ Fran Kritz, *Doctors Not Fans of Tom Cruise’s Baby Gift*, <http://msnbc.msn.com/id/10309963/print/i/displaymode/1098/> (discussing the various responses issued from major medical organization that opposed the new acting gig taken by Tom Cruise, as an ultrasound technologist, after he announced to a national television that he had purchased an ultrasound system so he and his wife, actress Katie Holmes, could view their developing baby).

an environment, where ultrasound services are easily purchased, it may be disguising the potential health risks for those who overutilize them.

Part I of this article will explain why the role of ultrasound in medicine is rising, and why some entrepreneurs are now seeking to take advantage of the ready availability of this technology. Although ultrasound technology is capable of conferring many health benefits to its consumers, entrepreneurs are now recognizing the economic benefits associated with an expanding market. Unfortunately, some clever entrepreneurs have seized the moment to promote the nondiagnostic applications for this technology to the point where they may be exposing consumers to its potential health risks. If this is the case, then state legislatures, not the FDA, will bear the responsibility for ensuring that their consumers are shielded from needless exposures. Part II of this article will cover the existing regulatory options available at both the federal and state levels to check nondiagnostic uses of this technology. The discussion in Part III will identify the underlying scientific principles of ultrasound and explain why overexposing consumers to sound energy may put them at risk. If risks do exist, then more physician involvement, not less, is needed to ensure prudent use of this technology. In Part IV, the existing policies related to the prudent use of diagnostic medical ultrasound as promulgated by the major world organizations will be reviewed. Part V will show the way states, such as California and Texas, have used legislative initiatives as well as federal and state regulations to protect their consumers from ultrasound overexposure. This section will also argue that a total ban on these practices may be counterproductive, and that control will only be achieved through a collaborative effort between all stake holders, especially consumers. The final solution, however, will not come without state legislative efforts

such as those currently unfolding in the California legislature. Such efforts may be necessary to ensure the safety of consumers and to check the over-utilization of this technology by some imaging entrepreneurs.

I. A. The Role Diagnostic Medical Ultrasound Plays in Medicine Is Rising.

Diagnostic medical ultrasound has played an increasingly important role in modern diagnostic medicine. Over the past three decades, diagnosticians have relied on ultrasound devices to produce sound waves that travel at speeds inaudible to the human ear to create diagnostic images of the human body.⁴ Manufacturers of these devices know their customers, and they know the modern medical community relies heavily on their technology. They introduce new ultrasound technologies into the medical market place to feed the needs of their customers.⁵ Manufacturers are very successful at what they do, because they commit substantial portions of their engineering resources toward improving the diagnostic capabilities and clinical applications of these sophisticated devices.⁶ One need only look at the financial contributions this technology has made to the medical market place to understand its importance to modern clinical practice.

In 2000, the total global market for the major cross sectional imaging modalities was estimated at 8.1 billion U.S. dollars.⁷ Ultrasound procedures contributed to 2.6 billion U.S. dollars of the total market, and of this total, the U.S. market share accounted

⁴ See Barry B. Goldberg, *Internal Arena of Ultrasound Education*, 22 JOURNAL ULTRASOUND MEDICINE 549 (2003) (noting a rapid rise of ultrasound occurred beginning in the early 1970s).

⁵ See Fleming Forsberg, *Ultrasonic Biomedical Technology; Marketing Versus Clinical Reality*, 42 ULTRASONICS 17, 17 (2004), available at <http://www.elsevier.com/locate/ultras> (citing that new imaging technologies come to the market to improve diagnostic capability).

⁶ See Forsberg, *supra* note 5, at 17.

⁷ Medical Technology Roadmap—The Current Situation, <http://strategis.ic.gc.ca/epic/internet/inmitr-crtim.nsf/print-en/hm01493e.html> (comparing the current Canadian medical imaging market to the world markets, where the total imaging market for the world (composed of ultrasound (2.61 billion), MRI (2.17 billion), and nuclear medicine (3.32 billion)) was estimated at 8.1 billion dollars in 2000, where ultrasound accounted for 2.6 billion dollars).

for an estimated 746 million U.S. dollars.⁸ In 2003, the U.S. ultrasound market rose to nearly 1.27 billion dollars,⁹ and now, it is estimated at 1.5 billion dollars, which has led many experts to predict further growth during the next decade.¹⁰ One of the primary reasons for this rosy economic prediction is the introduction of hand-carried devices (HCDs) into the market place.¹¹ When these devices were first introduced into the market, they generated manufacturers nearly 5 million U.S. dollars, which then increased to an estimated 96 U.S. million dollars in 2003.¹² Recently, one analyst predicted that the ultrasound market will only grow as HCDs make ultrasound technology more available through cost reductions.¹³ Although these devices have not been sighted in fetal keepsake imaging studios or self-referral practices, it is only a matter of time before these devices do make their presence known, as a more affordable technology. Could it be that HCDs will follow other technologies, such as pocket calculators, laptop computers, cell phones, and other technologies, into the hands of consumers?

⁸ See *supra* note 7 and its accompanying text.

⁹ U.S. Ultrasound Markets, <http://www.frost.com/prod/servlet/report-brochure.pag?id=A675-01-00-00-00> (identifying potential growth areas in the ultrasound market with three areas as the introduction of hand-carried devices or HCUs, the increased utilization in the field of cardiology; and the adoption of ultrasound technology by new user groups, such as surgeons, anesthesiologists, and emergency medicine physicians, and these areas will spur further growth in the market from its estimated worth of 1.27 billion dollars in 2003).

¹⁰ Daniel Lidor, *The 'Baby Face' Phenomenon*, FORBES, May 5, 2006, http://www.forbes.com/2006/05/09/cruise-ge-ultrasound-cx_dl_0509ultrasound.html (noting that the research group of Frost and Sullivan claim that Obstetrics-Gynecology ultrasound will account for 225 million dollars of the total ultrasound market, which is now estimated to be 1.5 billion dollars, and they also expect this market to grow, especially in the area of Ob-Gyn, where by 2010, it will show an annual growth rate of 8 to 10 percent to yield 270 million dollars).

¹¹ U.S. Ultrasound Markets, *supra* note 9 (noting that hand-carried devices are ultrasound systems that can be carried in the palm of the human hand, and they are also high performance portable systems that are capable of accelerating the proliferation of imaging systems to medical specialties other than cardiology, radiology and Obstetrics-Gynecology).

¹² See U.S. Ultrasound Market, *supra* note 9.

¹³ See U.S. Ultrasound Market, *supra* note 9 (citing HCDs as capable of expanding the access of ultrasound imaging systems to users, who previously could not afford high-end cart-based units, and making HCDs less expensive, but attractive options).

Perhaps, the best explanation for such lofty predictions for the diagnostic medical ultrasound market may be related to the physical properties of sound waves used to acquire ultrasound images.¹⁴ Unlike the ionizing radiation emitted from conventional diagnostic x-ray imaging systems, ultrasound imaging systems produce sound waves, which are a form of mechanical energy that creates changes in pressure through a series of molecular collisions.¹⁵ The resulting changes in pressure are responsible for propagating the waves through a tissue medium such as the human body.¹⁶ These systems utilize ultrasound transducers to generate sound waves within frequency ranges that pose little, if any, risk to those scanned by them.¹⁷ Almost everyone believes this is a safe, unadulterated technology, when it is compared to the other cross sectional imaging technologies, such as CT, which expose individuals to ionizing radiation. Thus, all branches of medicine have sought to incorporate ultrasound technology into their diagnostic armamentariums.¹⁸

Ultrasound now accounts for more than one quarter of all diagnostic medical imaging studies performed throughout the world.¹⁹ Although most physicians and the lay public perceive this technology as risk free, risks do exist, but they are far exceeded by the diagnostic benefits afforded to those scanned with this technology.²⁰ This point is underscored by the World Health Organization (WHO), and its recent endorsement of the

¹⁴ See WAYNE R. HEDRICK, DAVID L. HYKES & DALE E. STARCHMAN, *ULTRASOUND PHYSICS and INSTRUMENTATION 1* (Jeanne Rowland and Lisa Potts eds., Mosby – Year Book 1995) (1985) (distinguishing diagnostic medical ultrasound from technologies that utilize ionizing radiation to capture images of the human body that include conventional diagnostic x-rays, nuclear medicine imaging studies, and computed tomography).

¹⁵ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 3.

¹⁶ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 3.

¹⁷ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 249.

¹⁸ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 249.

¹⁹ See Forsberg, *supra* note 5, at 17.

²⁰ See HEDRICK, HYKES & STARCHMAN, *supra* note 10, at 249.

distribution and utilization of this technology within third world countries.²¹ The WHO promoted increased utilization of these systems, because ultrasound systems were also cheaper than other cross-sectional imaging technologies, such as CT or magnetic resonance imaging (MRI) systems.²² The WHO also realized that high quality diagnostic images required highly skilled ultrasound operators at their controls, if these countries are going to reap its benefits.²³ Because this technology has been, and always will be, operator dependent, the WHO has encouraged countries to begin ultrasound education programs to ensure that operators will be well-trained.²⁴ As long as skilled operators are at the controls of these powerful diagnostic medical devices, its future will remain bright, but a dark-side to its ready availability in medical market place looms on the horizon.

Yes, indeed, American entrepreneurs have tapped into the lucrative medical imaging market by taking advantage of the rising number of consumers, who are ready, willing, and able to access the cornucopia of diagnostic imaging services.²⁵ Now, any willing consumer can acquire diagnostic imaging studies without ever seeing his or her primary physician. Consumer initiated studies have become big business, because they can get them without a note, prescription, or order from a physician.²⁶ Of course, medical insurers may not cover these medical imaging costs, but who really cares, if consumers have the dollars to spend on these studies.²⁷

²¹ See Goldberg, *supra* note 4, at 549.

²² See Goldberg, *supra* note 4, at 549-50.

²³ See Goldberg, *supra* note 4, at 549-50.

²⁴ See Goldberg, *supra* note 4, at 550 (noting that the WHO appreciates that operators must be educated in the proper skills required for operating these powerful systems, and it is encouraging the formation of ultrasound education programs worldwide).

²⁵ See Joshua J. Fenton & Richard A. Deyo, *Patient Self-Referral for Radiologic Screening Tests: Clinical and Ethical Concerns*, 16 Journal AM. BD. FAMILY PRACTICE 494, 494 (2003) (noting that Americans for a price will purchase an ultrasound examination from private facilities).

²⁶ Fenton & Deyo, *supra* note 25, at 494.

²⁷ Fenton & Deyo, *supra* note 25, at 494.

Some clever entrepreneurs have pushed American medical imaging markets to different levels of excess by establishing ultrasound photography and ultrasound entertainment studios.²⁸ Fetal “keepsake” imaging studios allow newly expectant mothers to view their developing fetuses for entertainment, rather than meeting the medical necessities of the mother or her baby-to-be.²⁹ Yes, operators of these facilities boast that they can offer expectant mothers and their family members or friends an opportunity to see their baby-to-be in a theater-like atmosphere for a price.³⁰ Ample opportunities await mothers wishing to purchase one of these experiences, because keepsake imaging studios are springing up throughout the United States from California³¹ to Washington, D.C.³² Even Texas has its share of centers with catchy titles such as Fetal Photos,³³ Womb with a View,³⁴ First Sight Ultrasound,³⁵ and Clearview Ultrasound.³⁶ Yes, the heartland of America has morphed itself into a land of imaging opportunity, where the savvy imaging entrepreneur can cash-in on the needs of willing consumers with medical imaging dollars to spend.

²⁸ Fenton & Deyo, *supra* note 25, at 494.

²⁹ Posting of Marc Santora to forums.obgyn.net, <http://forums.obgyn.net/ultrasound/ULTRASOUND.0405/0037.html> (May 17, 2004)

³⁰ Dulce Zamora, *Prenatal Portraits: Darling or Dangerous?* (2004), <http://www.medicinenet.com/script/main/art.asp?Articlekey=50337&pf=3&page=1> (noting that dozens of sites have opened nationwide, and one company, Fetal Fotos, has offices in 22 states, and another San Francisco firm boasts of performing 200 screenings per month) (last visited on Oct. 29, 2005).

³¹ First Look Sonogram, <http://www.4dbaby.com/> (advertising locations in Ridondo, Beach; CA, Aiea, Hawaii; and Los Angeles, CA). (last visited June 29, 2006).

³² Baby Insight, <http://www.baby-insight.com/> (citing the availability of 3D and 4D ultrasound to “capture the magic of first seeing your baby” with offices in Virginia and Maryland) (last visited on June 29, 2006).

³³ Fetal Fotos, <http://fetalfotousa.com/> (listing locations in Arizona, Georgia, Idaho, Minnesota, North Carolina, Oregon, Texas, and Utah) (last visited on June 29, 2006).

³⁴ Womb with a View, <http://www.wombwithaview.com/> (posting office locations in Pennsylvania and New Jersey) (last visited June 29, 2006).

³⁵ First Sight Ultrasound, <http://www.expectantmothersguide.com/profiles/FirstSight/index.htm> (listing offices in Illinois, Connecticut, New Jersey, Pennsylvania, and Texas) (last visited on June 29, 2006).

³⁶ Clearview Ultrasound, <http://www.clearviewultrasound.com/> (advertising that it performs 3D and 4D ultrasounds of expectant mothers, and it is part of one of the largest and most respected, elective ultrasound providers in the country) (last visited on Oct. 26, 2005).

I. B. Imaging Entrepreneurs May Be Using Ultrasound Inappropriately.

Yes, Tom Cruise's desire to image his baby-to-be with his very own ultrasound system may seem a tad bizarre or eccentric, but even the medical community cannot decide whether keepsake imaging qualifies an inappropriate use for this technology. Although some physicians believe keepsake imaging is inappropriate, others see no problems whatsoever.³⁷ In fact, there are physicians, operators, and consumers who say that fetal keepsake imaging is both appropriate and beneficial, especially for the future parents, as consumers, who may use it to further their bonding experiences.³⁸ Notwithstanding its purported benefits related to bonding, most major medical societies have aligned themselves with the Food and Drug Administration (FDA) and have adopted policies that oppose the practice of "keepsake" imaging. They do not believe it to be one the manufacturers intended for this technology.³⁹

More specifically, the FDA and Code of Federal Regulations classify diagnostic medical ultrasound systems as medical devices. Because these devices are classified as medical devices, they also require a licensed physician to issue a note, an order, or a prescription before anyone is imaged with one of these systems.⁴⁰ Not only do these groups consider keepsake imaging of fetuses a potential misuse of a diagnostic medical device, but also they raise concerns related to the performance of medical imaging studies

³⁷ *AMA Says Ultrasound In-Utero "Portraits" Are Bad Idea*, REUTERS HEALTH, June 21, 2005, available at <http://www.acr.org> (citing House of Delegates of the American Medical Association disapproval of the use of ultrasound for "keepsake" imaging) (last visited on Oct. 29, 2005).

³⁸ See Dulce Zamora, *supra* note 30.

³⁹ *Fetal Keepsake Videos*, FDA, Centers for Devices and Radiological Health (Aug. 30, 2005), available at <http://fda.gov/cdrh/consumer/fetalvideos.html> (stating that persons who engage in the practice of fetal keepsake imaging are using ultrasound in a manner unapproved by the FDA) (last visited on Oct. 29, 2005).

⁴⁰ See *Fetal Keepsake Videos*, FDA, Centers for Devices and Radiological Health, *supra* note 39.

without a supervising physician who can, formally report results,⁴¹ do standard counseling,⁴² or perform standard diagnostic examinations.⁴³

All of the aforementioned issues related to the lack physician have been tragically demonstrated in a recent case report in the medical imaging literature. In that case, a mother went to one of these keepsake imaging studios for scanning, and left it believing that her baby-to-be was normal, only to discover during a later diagnostic scan that her baby-to-be had significant fetal anomalies. Unfortunately for her fetus, it had all the ultrasonographic features of Trisomy 18 and Smith-Lemli-Opitz Syndrome that went undetected or unreported by the operator at the fetal “keepsake” imaging studio.⁴⁴ Not only did that case raise issues related to failure in detection or reporting of major anomalies, but also it raised serious medical and ethical issues for both the parents and their physicians. Perhaps, the most disturbing aspect of this case was the realization that the parents, who believed their baby-to-be was normal, were given a false sense security by the operators of the fetal imaging studio who did not report the abnormality, regardless of their reasons for not doing so.⁴⁵ Although this case report illustrated all the potential pitfalls associated with fetal keepsake imaging, it has done nothing to dissuade the continued performance of these studies by non-physicians.

⁴¹ *ACR Ultrasound Commission Chair Featured in Baltimore Sun Article on Fetal Keepsake Videos*, available at http://www.acr.org/s_acr/doc.asp?TrackID=&SID=1&DID=21103&CID=2580&VID=2 (citing Carol M. Rumakc, M.D., as chair of the ACR Commission on Ultrasound, statement on the position of the ACR that ultrasound is performed for medical purposes) (last visited on Oct. 29, 2005).

⁴² *AMA Says Ultrasound In-Utero “Portraits” Are Bad Idea*, *supra* note 35.

⁴³ Naomi Greene & Lawrence D. Platt, *Nonmedical Use of Ultrasound: Greater Harm than Good*, 24 JOURNAL ULTRASOUND MEDICINE 123, 124-25 (2005).

⁴⁴ See Greene & Platt, *supra* note 43, at 123.

⁴⁵ See Greene & Platt, *supra* note 43, at 124-25 (expressing concern for the mother or family member who sees their baby-to-be, as normal but no one, including the ultrasound operator or technologist, recognizes or informs the mother that an obvious problem is present during the scanning session).

In fact, some studio operators continue to perform these studies without ever asking for or receiving a formal order from a physician, or even getting a physician to review their work.⁴⁶ Moreover, it has done nothing to alter the opinion of some physicians and studio operators who believe that “keepsake” imaging provides a pleasurable experience to those willing to pay for them.⁴⁷ In fact, any future psychological harms related to the mislabeling of abnormal “baby pictures” as normal, when they clearly are not, may never be fully known.⁴⁸ More likely than not, the actual number of missed cases will never be known, because many operators do not see themselves as performing diagnostic services and thus, they do not report their findings.⁴⁹

In fact, some operators, who perform these studies without physician supervision, have said they will ignore fetal abnormalities, even if a “fetus has three legs.”⁵⁰ The “why” underlying such ridiculous pronouncements remains unclear; but perhaps, operators choose this stance in order to avoid any legal sanctions that might be levied against them for the unauthorized practice of medicine, if they make a medical

⁴⁶See Greene & Platt, *supra* note 43, at 124.

⁴⁷ See Peter M. Doubilet, Letter to Editor, *Entertainment Ultrasound*, 24 JOURNAL ULTRASOUND MEDICINE 251, 251 (2005) (stating the belief that “resourceful entrepreneurs have found willing client for nonmedical use of ultrasound: providing a pleasurable experience and keepsake images or videos for expectant mothers and parents.”)

⁴⁸ See Frank A. Chervenak & Laurence B. McCullough, *An Ethical Critique of Boutique Fetal Imaging: A Case for the Medicalization of Fetal Imaging*, 192 AM. JOURNAL OF OBSTETRICS AND GYNCOLOGY 31,31 (2005).

⁴⁹ Emily Huhn, *Photo Studio In-Utero*, <http://www.bu.edu/sjmag/pfstories/pffetalphotos.htm> (recognizing Ms. Twiss of Sneak Peek’s acknowledgement that Ms. Twiss operates in gray area and would welcome regulation, but she also does not claim to run a medical practice or offer medical procedures, and she also requires her patients to be under care to avoid concerns about diagnosis of fetal abnormalities nor does she do anyone’s first ultrasound).

⁵⁰ Press Release, AIUM Opposes Uses of Ultrasound for Entertainment (Nov. 5, 2005) (on file with author) (noting that one operator from an article in the *Wall Street Journal* was quoted as saying ‘I don’t care if the fetus has three legs, I’d only point out two. I don’t care if the 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’).

diagnosis.⁵¹ Has the almighty dollar become so important that trained professionals will forsake their professional responsibilities along with their common sense just to make a buck and avoid legal sanctions? Although such attitudes, more likely than not, reflect those of a fringe element rather than the majority of honorable diagnostic medical sonographers, such pronouncements only bolster the need for more physician oversight, not less.

Not only is the number of fetal keepsake imaging studies increasing, but also the number of screening studies obtained sans physician referral is growing.⁵² Now, consumers may select from a variety of high-tech imaging technologies including diagnostic medical ultrasound, to satisfy their perceived imaging needs.⁵³ Ultrasound imaging studies, such as heel ultrasounds for osteoporosis and carotid ultrasounds for atherosclerotic disease, are coming to rural medical imaging market places via mobile ultrasound services.⁵⁴ These van-based ultrasound services now serve consumers in forty-three states.⁵⁵ The lure for these studies for many consumers is their belief that they will receive a peace-of-mind after the completing of one of these screening studies.⁵⁶ This state of nirvana for its recipients may only be a temporary one, once they realize that their

⁵¹ Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, [http://www.lsbme.org/documents/positionstatement/Ultrasound Screening.pdf](http://www.lsbme.org/documents/positionstatement/Ultrasound%20Screening.pdf) (explaining that the Louisiana State Board of Medical Examiner believes, after reviewing the scope of the Louisiana Medical Practice Act and practices of ultrasound screening within the State, that “undertaking to perform and/or providing the results of ultrasound screening constitutes the practice of medicine. Strict application of this conclusion, would, thus, constrain the Board in the discharge of its responsibility to safeguard the public health, welfare, and safety against the ‘unauthorized and unqualified practice of medicine,’ to take appropriate enforcement action against persons and firms who, through personnel other than licensed physicians, provide ultrasound screening to the public.”).

⁵² See Fenton & Deyo, *supra* note 25, at 496-99.

⁵³ See Thomas H. Lee & Troyen A. Brennan, *Direct-to-Consumer Marketing of High-Technology Screening Tests* 346 NEW ENG. J. MED. 529, 529 (2002) (increasing number of entrepreneurs, including physicians, are offering screening tests to the general public, which are not covered by insurance for fees that generally range from 300 to 1000 dollars).

⁵⁴ See Fenton & Deyo, *supra* note 25, at 496.

⁵⁵ See Fenton & Deyo, *supra* note 25, at 494.

⁵⁶ See Lee & Brennan, *supra* note 53, at 529.

“lack of a physician referral” means that they may not have access to a physician who is able to receive their report.⁵⁷ Even if one of these consumers has a physician who will take their report, there is no guarantee that the physician will know how to interpret the abnormal results contained within the report.⁵⁸ Moreover, many of these self-referred imaging tests, including those acquired with diagnostic medical ultrasound, have yet to prove themselves, as effective screening tools within the general population.⁵⁹

Nevertheless, the position that diagnostic medical ultrasound occupies within the medical imaging market place is likely to continue expanding over the next decade as the newer, smaller, less expensive portable ultrasound systems meet FDA approval and enter into service.⁶⁰ Yes, the ultrasound business continues to be big business for its manufacturers, physicians, and consumers, and the business will just keep on growing with every new piece of ultrasound equipment that rolls off the assembly-line into the medical imaging market.

Many states are only beginning to appreciate the inherent problems associated with fetal keepsake studies, and ultrasound screening studies obtained through the process of consumer self-referral.. States have taken a variety of approaches to deal with the health and safety concerns related to self-referral by consumers. Some states, such as Texas, have taken action against fetal keepsake imaging studios by enforcing both state

⁵⁷ See Fenton & Deyo, *supra* note 25, at 496.

⁵⁸ See Fenton & Deyo, *supra* note 25, at 494.

⁵⁹ See Fenton & Deyo, *supra* note 25, at 497-99.

⁶⁰ Danit Lidor, *The 'Baby Face' Phenomenon*, *supra* note 10 (noting predictions from Frost and Sullivan that Obstetrics-Gynecology ultrasound will account for 225 million dollars of the total ultrasound market, where the total market for ultrasound is estimated at 1.5 billion dollars for 2006 and both the total market and market for Obstetrics-Gynecology devices should grow until 2010 when it begins to taper off to a five to six percent annual growth in which portable devices will show a sustained growth at twenty percent during the same period).

and federal drug laws,⁶¹ Other states, such as Arizona, have been unable to bring any actions, notwithstanding calls for action from its medical community, because they lack state laws to regulate these imaging facilities.⁶² Still other states, such as New York, have only recently introduced legislation that would restrict the use of diagnostic medical ultrasound on pregnant women unless such studies were either ordered or referred by a licensed physician, nurse practitioner, or licensed midwife.⁶³ Louisiana, on the other hand, has attempted to curb non-physician-based ultrasound screening studies by placing under Louisiana law by defining them as an unauthorized practice of medicine.⁶⁴ Unfortunately, regulatory agencies within most states have found these practices very difficult to control. Even the FDA has demonstrated its impotence in regulating practices, such as keepsake imaging, where it has yet to close a studio.⁶⁵

California, however, has taken a proactive approach to the problem by becoming the first state to address consumer safety related to keepsake imaging by drafting and adopting legislation to regulate this practice. In 2005, the California legislature passed a law requiring keepsake imaging providers to inform their consumers that the FDA does

⁶¹ See Press Release, Texas Att’y Gen. Greg Abbott, Attorney General Abbott Obtains Agreements with Four Keepsake Ultrasound Imaging Companies (Apr. 7, 2003) *available at* <http://www.oag.state.tx.us/oagnews/release.php?id=885> (announcing that four ultrasound companies in Texas had agreed to initiate physician oversight as required by law. Moreover, the businesses were offering ultrasounds in a “storefront setting,” and they must use ultrasound only with physician oversight since these machines are not “toys.”) (last visited on Oct. 25, 2005).

⁶² *Parents-to-be Opt for Previews*, Ariz Sun, Jan. 8, 2005, *available at* http://www.acr.org/s_acr/sec_healthnews.asp?TrackID=&SID=1&DID=19975&CID=31 (stating that Arizona does not regulate the use of ultrasound for keepsake imaging) (last visited on Oct. 29, 2005).

⁶³ Posting of Art Fougner to forums.obgyn.net, <http://forums.obgyn.net/ultrasound/ULTRASOUND.0405/0037.html> (May 16, 2004) (posting states that New York Senate Deputy Majority Leader Dean G. Skelos introduced, on May 6, 2004, legislation prohibiting the non-medical use of ultrasound solely for entertainment purposes) (last visited on Oct. 29, 2005).

⁶⁴ See *supra* text and accompanying note 61.

⁶⁵ Emily Huhn, *Photo Studio In-Utero*, <http://www.bu.edu/sjmag/pfstories/pffetalphotos.htm> (noting that technically the FDA regulates these devices and has issued warning letters, but has yet to close any of the businesses down) (last visited on May 27, 2006).

not approve of the use of diagnostic medical ultrasound for fetal keepsake imaging.⁶⁶

After Tom Cruise recently announced his purchase of one of these sophisticated systems for home use in the fall of 2006, the California Assembly went back into action over the issue of fetal keepsake imaging.⁶⁷ On May 4, 2006, it passed AB 2360, which may be the first legislative effort by a state that specifically aims to regulate access and distribution of diagnostic medical ultrasound systems from manufacturers to consumers.⁶⁸ This Bill prohibits manufacturers or other persons from “selling, leasing, or otherwise distributing” ultrasound systems within the state to a specified group of persons or facilities.⁶⁹

Legislative efforts may not stop here since recent events have spurred renewed requests from the medical professionals for more regulatory controls on the nonmedical uses of ultrasound imaging devices.⁷⁰

After all, modern medicine is becoming more consumer-driven with each passing day. Consumers, who are able to afford these services, apparently, want them, and they will seek them out wherever and however they can. Safety, not consumer-driven self-gratification or monetary gain, should be the primary driver in the regulatory debate.

⁶⁶See CAL. HEALTH & SAFETY CODE § 123620 (Deering 2006) (“A person or facility that offers fetal ultrasound, or similar procedure, for keepsake or entertainment purposes shall disclose to client prior to performing the procedure, in writing, the following statement: ‘The federal Food and Drug Administration has determined that the use of medical ultrasound equipment for other than medical purposes, or without a physician’s prescription, is an unapproved use.’”).

⁶⁷ *Beyond Tom Cruise-The Bigger Ultrasound Picture*, <http://medicalnews.today.com/printerfriendlynews.php?newsid=34749>.

⁶⁸ AB 2360 Assembly Bill-Vote Information, http://www.leginfo.ca.gov/pub/bill/asm/ab_2351-2400/ab_vote_20060504_1135_asm_floor.html (reporting results of a vote cast on May 4, 2006 with sixty-six members recording yeas and ten members registering noes).

⁶⁹ A.B. 2360, 2005-06 Leg., Reg. Sess. (Cal. 2006) (as passed by Assembly, May 4, 2006) (prohibiting a manufacturer or other person in California from selling, leasing, or otherwise distributing diagnostic ultrasound imaging systems to any person other than a licensed practitioner who is authorized to use said system within the scope of their practice, licensed medical facility, a person or entity that provides diagnostic ultrasound services to said persons or entities, and who is also under their general supervision as well as other specified persons and entities).

⁷⁰ *Tom Cruies’s Reported Unsupervised use of Fetal Keepsake Ultrasound Raises Risk for Baby and Is Potentially Unlawful*, http://www.acr.org/s_acr/doc.asp?CID+2540&DID=22897 (last visited on Jan. 29, 2006).

Moreover, the debate should not be couched in terms of a turf war, where jealous physicians are attempting to protect their practices. On the contrary, the primary goal of regulatory enforcement should be consumer safety and protection, as a way to maintain the availability of ultrasound services without overly restricting its use.

II. The Unintended Uses of Diagnostic Medical Ultrasound Is a Regulatory Issue.

In August 1994, the FDA became aware of these nonmedical uses of diagnostic medical ultrasound,⁷¹ and it requested assistance from members of the ultrasound industry as well as the medical community with discouraging consumers from seeking these services.⁷² The primary concern for the FDA was patient safety since reports were surfacing that some pregnant consumers were scanned for up to one hour.⁷³ Even so, some physicians still question the position adopted by the FDA regarding fetal keepsake imaging,⁷⁴ because no documented acute injuries related to diagnostic medical ultrasound have been reported in over three decades of use.⁷⁵ Since 1994, the FDA has encouraged states, such as Texas, to apply their existing drug laws to curb the nonmedical use of diagnostic medical sonography.

II. A. States May Use Federal Law to Regulate the Unintended Use of Ultrasound.

States may apply the existing federal regulations covering diagnostic medical ultrasound systems, where Title 21 of the Code of Federal Regulations classifies these systems as Class II devices, whether these devices are intended for obstetrical⁷⁶ or non-

⁷¹ See *Fetal Keepsake Videos*, FDA, Centers for Devices and Radiological Health, *supra* note 39.

⁷² See *Fetal Keepsake Videos*, FDA, Centers for Devices and Radiological Health, *supra* note 39.

⁷³ See *Fetal Keepsake Videos*, FDA, Centers for Devices and Radiological Health, *supra* note 39.

⁷⁴ See Dulce Zamora, *Prenatal Portraits: Darling or Dangerous?*, *supra* note 30.

⁷⁵ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 249.

⁷⁶ See Food and Drugs, 21 C.F.R. § 884.2225 (2005) (identifying an ultrasonic imager in obstetrics and gynecology in part (a) as a device designed to transmit and receive ultrasound energies from a female patient by “pulsed echoscopy,” which can provide visual images of “some physiological or artificial

obstetrical⁷⁷ use. The existing regulations further define ultrasound systems utilized in non-obstetrical imaging, as either “ultrasonic pulsed [D]oppler imaging systems”⁷⁸ or “ultrasonic pulsed echo imaging systems.”⁷⁹ Title 21 also covers ultrasound equipment, such as the diagnostic ultrasonic transducer, which defined as a device that utilizes a piezoelectric material to generate sound waves from electrical impulses.⁸⁰ These regulations address the major accessories required in acoustical image acquisition, such as acoustical gel, by also classifying them as devices.⁸¹ Because all of these items qualify as devices, they come under the definition of a “prescription device,” which means a physician must give an oral or written order for an ultrasound study.⁸²

Moreover, the regulations require an operator of “device-user-facility” to make reports related to any deaths or serious injuries that may have occurred during the operation of one of these devices to the FDA.⁸³ A device-user-facility may be a “hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility ... that is not a physician’s office.”⁸⁴ An operator of a device- user-

structure, or fetus, for diagnostic purposes during a limited period of time. ... (b) Classification. Class II (performance standards).”).

⁷⁷ See Food and Drugs, 21 C.F.R. § 892.1560 (2005) (identifying “an ultrasonic pulsed echo imaging system as a device intended to project a pulsed sound beam into body tissue to determine the depth or location of tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment’s supports, component parts, and accessories. (b) *Classification*. Class II.”).

⁷⁸ See *id.*

⁷⁹ See Food and Drugs, 21 C.F.R. § 892.1550 (2005) (stating that “an ultrasonic pulsed [D]oppler imaging system is a device that combines the features of continuous wave [D]oppler-effect technology with pulsed-echo effect technology”).

⁸⁰ See Food and Drugs, 21 C.F.R. § 892.1570 (2005).

⁸¹ See *Id.*

⁸² See Food and Drugs, 21 C.F.R. § 801.109 (2005) (defining, in part, a prescription device as one which potentially has harmful effects, and directing the use of such device by a practitioner licensed under state law)

⁸³ See Food and Drugs, 21 C.F.R. § 803.1 (2005) (requiring user facilities to report deaths and serious injuries caused or contributed to by a medical device).

⁸⁴ See Food and Drugs, 21 C.F.R. § 803.3 (2005) (providing the definitions for device user, and the reporting requirements for a device user facility and includes “... Device user facility means a hospital,

facility must also make Medical Device Reports (MDR) annually,⁸⁵ create written MDR reporting procedures,⁸⁶ and keep written MDR reports on file for inspection by the FDA.⁸⁷ These Regulations recognize the concern for potential harm, and the FDA has also stated that operators who misuse ultrasound (“a prescription device”) by performing imaging services “without a physician’s order may be violating state or local laws or regulations regarding the use of a prescription medical device.”⁸⁸

Unfortunately, states have had mixed results when they have tried to bring enforcement actions against those who perform fetal keepsake imaging studies, because ultrasound devices are Class II, not Class III devices.⁸⁹ Although a Class II device is subject to special controls,⁹⁰ it is not subject to the more stringent requirements placed on those put into Class III.⁹¹ Even though operators may be performing nondiagnostic

ambulatory surgical facility, nursing home, outpatient diagnostic facility, ... Outpatient diagnostic facility. (1) Outpatient diagnostic facility means a distinct entity that: (i) Operates for the primary purpose of conducting medical diagnostic tests on patients, (ii) Does not assume ongoing responsibility for patient care, and (iii) Provides its services for use by other medical personnel.”)

⁸⁵ See Food and Drugs, 21 C.F.R. § 803.10 (2005) (stating essentially that a device user facility must submit reports of adverse events).

⁸⁶ See Food and Drugs, 21 C.F.R. § 803.17 (2005) (establishing that a user facility, importer or manufacturer must put into place written MDR report procedures).

⁸⁷ See Food and Drugs, 21 C.F.R. § 803.18 (2005) (establishing that a user facility must create ‘MDR event files’ in written or electronic form, and the information related to adverse events must be in the possession of the user facility).

⁸⁸ *Fetal Keepsake Videos* FDA, Centers for Devices and Radiological Health, *supra* at note 39.

⁸⁹ See *Rayford v. State*, 16 S.W.3d 203, 207-8 (Tex. App.—Dallas 2000, pet. denied) (explaining that ultrasound devices are Class II, not Class III, devices and that the operator of such devices as an obstetrical ultrasound system may acquire fetal keepsake images, where the operator may misbrand the device, but it does not adulterate the device, because this nondiagnostic use, such as fetal keepsake imaging, was not so substantial an alteration in use that it became a “new intended use,” which is ultimately determined by the party responsible for labeling i.e. the manufacturer, and not the party who owns or operates the system under 21 U.S.C.A. § 360c(I)(E)(I)).

⁹⁰ See Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 360c(a)(1)(B) (West 1999) (providing that a device must be placed into Class II if general controls by themselves are insufficient to reasonably assure safety and effectiveness of the device, where specific information is available that indicate special controls are need to provide “such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines ...”).

⁹¹ See Food and Drugs, 21 U.S.C.A. § 360c(a)(1)(C) (West 1999) (providing that a device cannot be placed into Class II, if there is insufficient information is available to determine whether special controls would provide reasonable assurance of its safety and effectiveness, it supports or sustains human life or its use is

studies when they provide keepsake imaging services, this does not mean that the operators have also substantially altered the use of this technology to qualify it as a “new intended use.”⁹² In fact, operators may violate some sections of federal regulations, but not other sections, which means successful state enforcement actions requires linkage of specific acts to specific code or regulatory violations before a given state may effectively prosecute a case.⁹³

II. B. States May Regulate Through Their Existing Drug Laws, if They Have Them.

Although not all states have enacted legislation to help control the misuse of this technology, Texas is one of several states that has enacted drug laws to regulate the use of medical devices within its borders. Texas law classifies diagnostic medical ultrasound systems as a “device.”⁹⁴ Not only does it classify this technology as a “device” but it also considers this type of “device” a “dangerous drug.”⁹⁵ A “person” violates the Dangerous Drug Act when he or she “... possesses a dangerous drug unless the person obtains the drug from ... a practitioner acting in the manner described by sect. 483.042(a)(2).”⁹⁶ Moreover, the Act states that “a person commits an offense if the person delivers or offers to deliver a dangerous drug ... (2) unless (A) the dangerous drug is delivered or offered for delivery by: (i) a practitioner in the course of practice, or (ii) a registered

substantially important to preventing human impairment, and it presents a potentially unreasonable risk of illness or injury).

⁹² See *id* at 208.

⁹³ See *id* at 208.

⁹⁴ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.002(13) (Vernon Supp. 2005) (defining ‘Device’ as an “instrument, apparatus, implement, machine, contrivance ...”).

⁹⁵ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.001(2) (Vernon Supp. 2005) (defining a ‘Dangerous Drug’ as a “device ...”).

⁹⁶ See Texas Dangerous Drug Act, TEXAS HEALTH & SAFETY CODE ANN. § 483.041(a) (Vernon Supp. 2005).

nurse or physician assistant under sect. 157 of the Tex. Occ. Code.”⁹⁷ A person may also violate the Texas Food, Drug, and Cosmetic Act where that person uses diagnostic medical ultrasound in a manner that the FDA did not intend, and thus “adulterates the device.”⁹⁸ The Code also provides that if the device is falsely or inappropriately labeled or falsely advertised, then person has committed a violation.⁹⁹ Clearly, Texas perceives the potential for misuse that could harm that diagnostic medical ultrasound as a “device” may be a potential risk to the public, and it may regulate such a device. Unfortunately, not all physicians or members of the public appreciate the inherent risks associated with this technology because they assume there is little or no risk,¹⁰⁰ and the courts may not agree on which practices or acts violate a given regulatory section.¹⁰¹

III. The Potential Bioeffects from Ultrasound May Explain Why Regulation Is Needed.

Why should federal and state authorities enforce their current laws, or enact new ones directed toward drug enforcement, if diagnostic medical ultrasound poses little if any, risks to those scanned with it? To answer this question, one must understand the basic physical principles underlying the generation of ultrasound waves, and their relationship to the theoretical risks related to ultrasound waves. The physical principles key to any discussion of the risks associated with diagnostic medical ultrasound are

⁹⁷ See Texas Dangerous Drug Act, TEXAS HEALTH & SAFETY CODE ANN. § 483.042 (Vernon 2003).

⁹⁸ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.111 (Vernon 2003).

⁹⁹ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.112 (Vernon Supp. 2005) (stating that “A drug of device shall be deemed to misbranded (o) in the case of any restricted device distributed or offered for sale in this state, if: (1) its advertising is false or misleading in any particular;”).

¹⁰⁰ Dulce Zamora, *Prenatal Portraits: Darling or Dangerous?*, *supra* at note 30.

¹⁰¹ *Rayford*, 16 S.W.3d at 208-11 (explaining why the practice of fetal keepsake imaging by nonphysicians may violate certain sections of the Code of Federal Regulations, but not other sections, where keepsake imaging may qualify as an unintended use, but not a new intended use of ultrasound imaging systems during imaging of the fetus).

related to the generation of sound waves, the intensity or power of sound waves, and the mechanical properties of sound waves.¹⁰² Audible sound, as a mechanical energy, is produced by periodic changes in the pressure within a medium, such as air or water, where molecules of the medium are caused to oscillate in a repetitive fashion or cycle.¹⁰³ These oscillating molecules interact with each other to create periodic changes in pressure, which then propagate the wave through a distance within the medium, such as tissue.¹⁰⁴ In order for sound to propagate through a medium, it must interact with a medium, which is elastically deformable.¹⁰⁵ Thus, sound, as a mechanical energy, propagates through tissue within an energy spectrum, which is also outside the energy spectrum for ionizing radiation or electromagnetic radiation, and therefore, it lacks the risks associated with conventional x-rays.¹⁰⁶ Nevertheless, several physical parameters of the ultrasound may cause biological effects worthy of regulation.¹⁰⁷

III. A. Ultrasound Beam Intensity and Output Levels Impact Patient Safety.

One of the key considerations in the production of biological effects by ultrasound is its intensity or the “rate of energy flow through a unit area.”¹⁰⁸ Unfortunately, modern systems utilize pulsating scanning technologies that produce complex ultrasound fields that vary over time, which makes any determination of the absolute intensity of their

¹⁰² See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 1-8.

¹⁰³ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 1 (explaining that sound audible to the human ear oscillates in the range of 20 kHz).

¹⁰⁴ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 3.

¹⁰⁵ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 3.

¹⁰⁶ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 250.

¹⁰⁷ Stanley B. Barnett et al., *International Recommendation and Guidelines for the Safe Use of Diagnostic Ultrasound in Medicine*, 26 *ULTRASOUND MEDICINE & BIOLOGY* 355, 356 (2000) (citing rising output levels on modern systems may substantial increase the intensity and thus exposure levels tissues receive, especially in cases where the human embryo is scanned).

¹⁰⁸ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 250.

beams difficult.¹⁰⁹ Moreover, the intensity of these modern pulsating transducers exhibits a temporal and spatial dependence, where temporal variations that occur within any given pulse further complicate determinations of an absolute intensity for the beam.¹¹⁰ Thus, the inherent characteristics of the beam produced by most modern ultrasound system explain why the FDA and other organizations continue to oppose the non-medical applications of diagnostic medical ultrasound.¹¹¹

III. B. Safety Remains the Issue for Modern Ultrasound Technologies.

Patient safety remains an issue for the FDA because many of the early epidemiological studies related to the biological effects of ultrasound beam on humans were methodologically flawed.¹¹² Some of these early studies were also performed with ultrasound systems that operate at much lower powers or output intensities than the systems in most user facilities today.¹¹³ Moreover, many of these early studies were animal studies, where test subjects received ultrasound exposures at higher levels and longer durations than those achieved with the current clinical systems.¹¹⁴ Any extrapolations from past animal studies to current human experience may be tenuous at best.¹¹⁵ The bottom line is the absolute risks posed by diagnostic medical may not be known until more studies are done at the higher energy levels employed by modern ultrasound systems.¹¹⁶

¹⁰⁹ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 254 (noting that any given ultrasound field may be defined by a limited set of parameters, such as intensity or power of the beam, which indicates the potential for tissue damage).

¹¹⁰ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 250-53.

¹¹¹ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 254.

¹¹² See Barnett, *supra* note 107, at 357.

¹¹³ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 260.

¹¹⁴ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 249.

¹¹⁵ See Barnett, *supra* note 107, at 356.

¹¹⁶ See HYKES & STARCHMAN, *supra* note 14, at 254.

Not only do the system factors, such as the output levels and transmission frequencies of the modern ultrasound system impact patient safety, but also non-system factors, such as those associated with the operator of these systems, influence safety.¹¹⁷ Operators are now given the ability to control the power output or intensity and transmission frequencies selected during an ultrasound exam, which in turn, modulate the potential biological effects that could result from an exam.¹¹⁸ Modern ultrasound system operators determine the amount of energy a given volume of tissue receives during a study by the controlling the amount of time they spend scanning.¹¹⁹ Scan-times for any one operator may vary depending on the skill of the individual operator or the degree of complexity or difficulty in obtaining diagnostic information to complete a study.¹²⁰ So, the longer the scan-time or dwell time on a particular volume of tissue, the more likely the volume of tissue scanned may experience biological effects.¹²¹ Even the thickness of the tissue scanned by an operator may impact ultrasound exposure levels, where the more superficial tissues may receive a higher dose of ultrasound energy.¹²² Thus, well-trained operators should spend only the necessary amount of time scanning needed to acquire the appropriate diagnostic information.¹²³

¹¹⁷ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 254.

¹¹⁸ See Barnett, *supra* note 107, at 359 (noting that longer pulses and higher pulse repetition frequency rates may increase the potential for biological effects, such as those caused by heating, which could potentially cause tissue damage, which theoretically could impact patient safety).

¹¹⁹ See Barnett, *supra* note 107, at 359 (explaining that the impact of ultrasound on tissue is influenced by the duration of time over which tissue remains in contact with the beam, where the amount of time is the dwell time).

¹²⁰ See Barnett, *supra* note 107, at 359

¹²¹ See Barnett, *supra* note 107, at 359

¹²² See Barnett, *supra* note 107, at 359; *see also* HEDRICK, HYKES & STARCHMAN, *ULTRASOUND PHYSICS & INSTRUMENTATION*, *supra* note 14, at 267 (noting that the overlying tissue in humans may reduce the dose of ultrasound received as well as the segment or portion of an organ scanned where only a portion of the organ is scanned for a short period of time, reducing the dose).

¹²³ J. Brian Fowlkes, *Ultrasound Bioeffects and NCRP On Needed US Exposures: The Status of Current Output Limits and Displays*, <http://www.aapm.org/meetings/02AM/pdf/8407-24103.pdf> (explaining that the goal of a skilled ultrasound operator is to obtain the necessary diagnostic information in the shortest period

III. C. Risk Related to US May Increase as Manufacturers Raise Their Beam Intensities.

Each ultrasound system or device has a range of power outputs or intensities that it can achieve to improve the resolution of a particular system.¹²⁴ In 1993, the FDA allowed ultrasound manufacturers to raise the intensity levels of their systems by setting the overall maximal limit for an I_{SPTA} of all equipment at 720 mW/cm^2 .¹²⁵ The intensity, as measured as I_{SPTA} , for any given ultrasound system varies, depending upon the type of ultrasound study performed with a given ultrasound system.¹²⁶ The FDA has allowed manufacturers to achieve these higher intensity levels as long as their systems can display output information related to the ultrasound intensity.¹²⁷ Unfortunately, a 1997 evaluation of equipment conducted in the United Kingdom suggested that the intensity levels achievable with modern diagnostic systems may be greater than the expected maximum intensities.¹²⁸ Thus, it may now be possible for a medical ultrasound system to expose the fetus or embryo to eight times the intensity previously allowed.¹²⁹

The FDA currently allows ultrasound equipment manufacturers to achieve higher intensities up to the 720 mW/cm^2 maximum, if their system can display on their output

of time adhering to the principle that exposure of the patient to ultrasound should be as “Low As Reasonably Achievable”).

¹²⁴ See Barnett, *supra* note 107, at 357.

¹²⁵ See Fowlkes, *supra* note 123 (providing FDA Track 3 limits for ultrasound systems as defined for 510k as $I_{SPTA.3}$ (720 mW/cm^2) and $I_{SPPA.3}$ (190 mW/cm^2))

¹²⁶ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 250-54 (explaining that the current intensity levels, as measured by $I(SPTA)$, for any given ultrasound system vary for phased array and mechanical scanners (2 to 200 mW/cm^2), pulsed Doppler for obstetric studies (0.6 to 75 mW/cm^2), and pulsed Doppler for peripheral vascular studies (350 to 700 mW/cm^2))

¹²⁷ See Fowlkes, *supra* note 123 (noting that the FDA relaxed its pre-amendment levels as long as the manufacturers use the Output Display Standard (ODS), where the system operator is able to monitor both the thermal and mechanical effects of the ultrasound beam by monitoring two display indices—the mechanical and thermal indices).

¹²⁸ See Barnett, *supra* note 107, at 359 (citing data from J Henderson et al., *A Review of the Acoustic Output of Modern Diagnostic Ultrasound Equipment*, 10 BMUS BULLITEN 10 (1997) in Table 2 (supplying data that show a greater than expected maximum intensities ($I(SPTA)$) for a conventional B-mode scan (1000 mW/cm^2), pulsed Doppler scan (9000 mW/cm^2), and Color flow scans (2000 mW/cm^2)).

¹²⁹ See Barnett, *supra* note 107, at 356.

display screen the two key potential predictors of biological effects: mechanical index and thermal index.¹³⁰ The two indices reflect the three potential interactions the ultrasound beam may have with human tissue that cause damage: mechanical (direct or indirect tissue damage), thermal (tissue heating), and cavitation (inertial and noninertial forms).¹³¹ These events may also lead to secondary events, such as microstreaming and altered chemical reaction rates, which can produce tissue injury.¹³² Thus, modern system manufacturers may obtain FDA approval for their systems, if they can display the mechanical and thermal indices for the operator to manipulate, and they adopt the Output Display Standard (ODS).¹³³

III. D. The ODS May or May Not Reduce the Risk for Injury.

The ODS was established to help reduce the potential for biological effects related to thermal and mechanical damage by setting a reasonable upper limit on index values.¹³⁴ Unfortunately, there are no absolute index values, only approximations of these values are available.¹³⁵ The current recommendation to the ultrasound operator is to keep these values as low as possible with an MI less than 1.9, to satisfy regulatory requirements.¹³⁶ If display indexes rise above one, then the operator should take appropriate countermeasures to lower the index to lower it, keeping the exposure “as low as

¹³⁰ See Barnett, *supra* note 107, at 359.

¹³¹ See John G. Abbott, *Rationale and Derivation of MI and TI—A Review*, 25 *ULTRASOUND MEDICINE BIOLOGY* 431-432 (1998)

¹³² Stanley B. Barnett et al., *The Sensitivity of Biological Tissues to Ultrasound*, 23 *ULTRASOUND MEDICINE BIOLOGY* 805,806-808 (1997).

¹³³ See Fowlkes, *supra* note 123.

¹³⁴ See Fowlkes, *supra* 123 (citing the current upper limits for the mechanical index (MI) for modern systems is 1.9 and for the thermal index (TI), it should be kept as low as achievable, which is generally less than 1, and if not below that level then scanning should be as brief as allowable for the acquisition of diagnostic information).

¹³⁵ See Barnett, *supra* note 107, at 358.

¹³⁶ See Colin Deane, *Safety of Diagnostic Ultrasound in Fetal Scanning*, http://www.centru.com.br?DiplomaFMF?Series/doppler/caitulos-html/chapter_02.htm (last visited on May 21, 2006).

reasonably allowed (ALARA).”¹³⁷ Appropriate countermeasures may include: reducing the pulse repetition frequency, reducing the dwell time, or any other parameter that will reduce exposure, but maintain image quality.¹³⁸

In order for these countermeasures to be effective, the ultrasound operator needs to understand the ODS, and appreciate its significance. Unfortunately, many of the current ultrasound display systems do not present the information in a manner that is easily accessed or understood by the operator.¹³⁹ One of the potential problems with the ODS and relaxation of FDA requirements is some operators may not understand the ODS.¹⁴⁰ This potential pitfall was illustrated at a 2002 meeting of the British Medical Ultrasound Society, where a survey of manufacturers and their technical support staff revealed that many of them were unaware of the ODS.¹⁴¹ In fact, some operators were observed scanning healthy models at thermal indices that exceeded one.¹⁴² Others were caught unaware of the British guidelines mandating that exposure levels be kept to a minimum when scanning models.¹⁴³ These observations are worrisome, since they suggests that other, less knowledgeable or experienced operators in general practice, may not be aware of the ODS.¹⁴⁴

If this possibility is confirmed, then the ODS may not be effective, because operators do not understand it. If it is not effective, then federal and state authorities may

¹³⁷ See Barnett, *supra* note 107, at 360-63.

¹³⁸ See Barnett, *supra* note 107, at 360.

¹³⁹ See Barnett, *supra* note 107, at 358-60.

¹⁴⁰ See Fowlkes, *supra* note 123 (noting the intent of the ODS was the FDA would relax limits in favor of informed and responsible decision making where limits would be exceeded only if necessary, but this is not likely to be achieved until the ODS is more widely understood).

¹⁴¹ See Stanley B. Barnett, *Live Scanning at Ultrasound Scientific Conferences and the Need for Prudent Policy*, 29 *ULTRASOUND MEDICINE BIOGOGY* 1071, 1073 (2003).

¹⁴² See Barnett, *supra* note 141, at 1074.

¹⁴³ See Barnett, *supra* note 141, at 1074.

¹⁴⁴ See Barnett, *supra* note 141, at 1074-75.

have an even greater need to regulate the nonmedical uses of this technology, since patients may be experiencing unnecessary exposures to higher acoustical energy levels during fetal keepsake imaging. Even so, many continue to believe that the FDA classification of ultrasound as “prescription device” and disapproval of nonmedically related ultrasounds is misplaced, because no acute harmful effects have been definitely shown in humans in over three decades of scanning.¹⁴⁵

III. E. The Biological Effects Related to Ultrasound Have Not Been Completely Elucidated.

Unfortunately, much information on biological effects of ultrasound on humans is undiscovered. There are many variables that may determine if, and when, the ultrasound beam is going to cause a biological effect.¹⁴⁶ Biological effects will depend on the wave mechanics as well as the tissue system coming into contact with the beam.¹⁴⁷ Multiple variables may play a role in determining whether ultrasound could potentially cause tissue damage. Some of these variables may include the acoustical properties of the beam as well as the characteristics of the tissue scanned, which may also include the biological properties, metabolic or physiologic functions and location.¹⁴⁸ These factors may also limit any manifestation of tissue injury, where tissue targets are small, unless the tissue involves some critical pathway such as the nervous system or rapidly dividing cells, like those in the developing embryo.¹⁴⁹

¹⁴⁵ Zamora, *Prenatal Portraits: Darling or Dangerous?*, *supra* note 30.

¹⁴⁶ See HEDRICK, HYKES & STARCHMAN, *supra* note 14 at 257-60.

¹⁴⁷ Barnett et al., *supra* note 132, at 806-807.

¹⁴⁸ Barnett et al., *supra* note 132, at 805.

¹⁴⁹ Barnett et al., *supra* note 132, at 810.

If ultrasound is going to cause a tissue injury, it will do so through mechanical, thermal, or cavitation effects on the surrounding tissues.¹⁵⁰ Any mechanical effects that might occur, generally, do so near solid boundaries.¹⁵¹ The potential for thermal effects related to beam heating of tissues, on the other hand, raises the most concern for production of biological effects.¹⁵² Temperature alterations in tissue may be affected by the intensity of the ultrasound beam as well as the properties of the tissues along with their physiologic surroundings.¹⁵³ Body fluids, such as urine, amniotic fluid, or cerebral spinal fluid, experience negligible elevations in temperature, because their protein content is low and thus, they absorb very little, if any, of the acoustical energy of the beam.¹⁵⁴ Skin, tendons, spinal cord, and bone (highest), all have increased protein content, which puts them at risk for heating.¹⁵⁵ If tissue heating occurs, then it must be extremely rapid and reach the critical 5° Celsius temperature rise before it causes tissue damage.¹⁵⁶ Any heat related injuries occurring in humans would likely be seen in the developing fetus.¹⁵⁷

Fortunately, any ultrasound-induced damage related to heat remains only a theoretical risk, but the mere existence of this possibility should suggest that sonographers exercise caution when they scan these individuals at a thermal index greater

¹⁵⁰ Barnett et al., *supra* note 132, at 806-807.

¹⁵¹ Barnett et al., *supra* note 132, at 806 (discussing the physical principles underlying the production of mechanical injury, which may be caused either directly or indirectly, as ultrasound effects lead to microstreaming of particles, radiation pressure, and radiation torque).

¹⁵² Barnett et al., *supra* note 132, at 806-808. (explaining that thermal effects result from the reduction in the intensity of the beam as energy is absorbed and converted into heat within the surrounding tissues as well as additional factors, such as dwell time, absorption coefficients of the tissue which, thermal conduction properties of tissue).

¹⁵³ See Barnett et al., *supra* note 132, at 806-807 (explaining that thermal effects result from the reduction in the intensity of the beam, as its energy is absorbed and converted into heat within the surrounding tissues, and additional factors, such as dwell time, absorption coefficients of the tissue which, thermal conduction properties of tissue also affect thermal conduction, which also impacts tissue heating).

¹⁵⁴ See Barnett et al., *supra* note 132, at 806-807.

¹⁵⁵ See Barnett et al., *supra* note 132, at 806-807.

¹⁵⁶ See Deane, *supra* 136.

¹⁵⁷ See Deane, *supra* 136.

than one. Not only can the ultrasound beam heat tissues and cause tissue damage, but the beam itself may also generate pressure amplitudes of sufficient pressure to form gas bubbles,¹⁵⁸ especially in gas containing organs, such as bowel.¹⁵⁹ These inertial cavitation effects have the potential to break chemical bonds and form biological free radicals.¹⁶⁰ Although these free radicals may bind with DNA and cause chromosomal damage, this event has not been demonstrated thus far.¹⁶¹ If inertial cavitation effects are detected, they have occurred at gas-tissue interfaces, such as mammalian lung, at energy levels within the diagnostic range.¹⁶² In the one study that detected cavitation effects, they were associated with pulmonary capillary bleeding or extravasation.¹⁶³ This observation raised concern for affects in humans, especially in clinical situations where gas may be present, such as gas-forming infections or infusions.¹⁶⁴

Based on the foregoing discussion, the potential for biological effects on humans is real, but unfortunately, very little, if any, epidemiological data is available to support the existence of such effects.¹⁶⁵ Some early studies demonstrated neurologic effects in children, such as an abnormal grasp or tonic neck reflex or dyslexia, but these findings may have been due to multiple hypotheses testing or chance.¹⁶⁶ One study has observed a higher incidence of delayed speech in children exposed to ultrasound in utero than in

¹⁵⁸ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 255-57.

¹⁵⁹ See Barnett et al., *supra* note 132, at 807-08.

¹⁶⁰ See Barnett et al., *supra* note 132, at 807-08.

¹⁶¹ See Barnett et al., *supra* note 132, at 807-08.

¹⁶² See Barnett et al., *supra* note 132, at 807-08.

¹⁶³ A F Tarantal & D. R. Canfield, *Ultraound Induced Lung Hemorrhage in the Monkey*, 20 ULTRASOUND MEDICINE BIOLOGY 65 (1994).

¹⁶⁴ See Barnett et al., *supra* note 132, at 807-08.

¹⁶⁵ See Barnett et al., *supra* note 107, at 357.

¹⁶⁶ Kjell Å. Salvesen & Sturla H. Eik-Nes, *Ultrasound During Pregnancy and Birthweight, Childhood Malignancies and Nuerological Development*, 25 ULTRASOUND MEDICINE BIOLOGY 1025, 1025 (1999).

those not scanned with ultrasound.¹⁶⁷ The actual statistical significance of this observation is questionable, since the number of children studies was small and bias could have been a factor.¹⁶⁸ Reductions in birthweight have also been reported in the literature, but this study may have been designed to test an unrelated hypothesis.¹⁶⁹ Because of the potential for sister chromatid damage, studies have looked at childhood cancer, but no studies to date have demonstrated an association between *in utero* ultrasound exposure and cancer.¹⁷⁰ Concern for the potential of non-right handedness in children exposed to ultrasound *in utero* has been assessed, but no definite relationship has been confirmed.¹⁷¹ A subgroup analysis has shown a slightly statistically significant difference in males.¹⁷²

Considering the lack of hard data on the intensities generated by modern systems and their potential for causing biological effects, perhaps the FDA should keep ultrasound systems classified as prescription medical devices, until more information and experience is gathered. Clearly, many of the previous clinical studies were performed at intensities that may be inapplicable to most modern ultrasound systems, and many of these early studies were on animal, not humans, and many existing epidemiological studies have methodological flaws.¹⁷³ These issues alone should support further FDA enforcement of the current regulations, and unfettered scanning should be avoided until more studies are done.¹⁷⁴

¹⁶⁷ See Salvesen et al., *supra* note 166, at 1026.

¹⁶⁸ See Salvesen et al., *supra* note 166, at 1026.

¹⁶⁹ See Salvesen et al., *supra* note 166, at 1028.

¹⁷⁰ See Salvesen et al., *supra* note 166, at 1028.

¹⁷¹ See Salvesen et al., *supra* note 166, at 1029.

¹⁷² See Salvesen et al., *supra* note 166, at 1029.

¹⁷³ See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 260-64.

¹⁷⁴ See Salvesen et al., *supra* note 166, at 1029-30.

IV. Worldwide Medical Organizations Promulgate Policies Favoring Safety.

Worldwide organizations, such as The World Federation of Ultrasound in Medicine and Biology (WFUMB), the Australian Society of Ultrasound in Medicine (ASUM), and the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB), have issued policy statements regarding the safe use of ultrasound, but they also have advised caution.¹⁷⁵ All of these organizations have recognized the potential for biological effects created by modern ultrasound systems.¹⁷⁶ For example, the WFUMB recommends that scanning time be kept as short as possible and the output should be controlled so power levels will be low, but sufficient to obtain “diagnostic information.”¹⁷⁷ The ASUM also has emphasized the use of care, where it has recommended the prudent use of ultrasound during examinations through adherence to the ALARA principle to minimize exposures.¹⁷⁸ It, too, recognizes that the current FDA regulatory limit, which is set at the 720 mW/cm² (I_{SPTA}) maximum, may lead to temperature increases greater than 2°C.¹⁷⁹ Moreover, ASUM emphasized that “users” must appreciate the design of their equipment, and they must realize that the indexes of the ODS may not accurately predict the conditions at the tissue level during scanning.¹⁸⁰ More importantly, EFSUMB stated that modern equipment is subject to output regulation, but they also noted that their statements were only recommendations.¹⁸¹ If the major world ultrasound organizations recognize the need for caution and advise prudence

¹⁷⁵ See Barnett et al., *supra* note 107, at 360-63.

¹⁷⁶ See Barnett et al., *supra* note 107, at 360-63.

¹⁷⁷ See Barnett et al., *supra* note 107, at 361-62.

¹⁷⁸ See Barnett et al., *supra* note 107, at 362-63.

¹⁷⁹ See Barnett et al., *supra* note 107, at 362-63.

¹⁸⁰ See Barnett et al., *supra* note 107, at 362-63.

¹⁸¹ See Barnett et al., *supra* note 107, at 363.

in the use ultrasound, then it should be no surprise that their American counterparts express opposition to the non-medical uses of ultrasound.

IV. A. American Medical Organizations Also Favor Prudent Uses of Ultrasound.

The major medical associations and many of the technical and medical organizations responsible for policies related to the use of diagnostic medical ultrasound have called for the prudent use of this technology to gather diagnostic information. The American Institute of Medicine and Biology has published an official statement regarding the need for the “prudent use” of diagnostic medical sonography¹⁸² even though it considers it safe.¹⁸³ The “prudent use” standard has been recognized by the American College of Obstetricians and Gynecologists (ACOG).¹⁸⁴ The American College of Radiology (ACR) Practice Guideline for diagnostic ultrasound studies recommends that a diagnostic ultrasound should be supervised by a physician, obtained for a valid medical reason, and performed at lowest levels possible.¹⁸⁵ The Society of Diagnostic Medical Sonography (SDMS) in its practice guidelines recommends that its members, as ultrasound technologists (operators), “adhere to the standards, polices, and procedures

¹⁸² See AIUM Official Statement, *Prudent Use*, <http://www.aium.org/patient/enertainment/entIntro.asp>. (May 1999) (last visited Oct. 5, 2005 (“[S]trongly discourages the non-medical use of ultrasound for psychological or entertainment purposes.”)).

¹⁸³ See AIUM Official Statement, *Prudent Use*, <http://www.aium.org/patient/enertainment/entIntro.asp>. (Mar. 1999) (last visited Oct. 5, 2005) (“There are no confirmed biological effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweighs the risks, if any, that may be present.”)

¹⁸⁴ See Committee on Ethics, *Nonmedical Use of Obstetric Ultrasonography*, 104 OBSTETRICS GYNECOLOGY 423, 423 (2004) (“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”).

¹⁸⁵ See ACR Practice Guidelines, ACR Practice Guidelines for Performing and Interpreting Diagnostic Ultrasound Examinations, *available at* http://www.acr.org/s_acr/bin.asp?TrackID=&SID+1&DID=1226&CID=539&VID=2&DOC=file.pdf. (last visited on Oct. 25, 2005).

adopted by the profession and regulated by the law.”¹⁸⁶ The likely primary goal of all organizations and their recommendations is the promotion of patient safety. More importantly, all of these organizations have understood that the potential biological effects exist and they have now opposed the non-medical uses of this technology.

IV. B. American Organizations Oppose Fetal Keepsake Imaging.

The same societies and organizations have addressed the issue of nonmedical uses of diagnostic medical sonography to acquire “keepsake” fetal images. The AIUM issued a new statement on August 1, 2005, on the use of “fetal keepsake” imaging, where it recommended that “licensed medical professionals (either physicians or registered or eligible sonographers) who have received specialized training in fetal imaging” perform these studies.¹⁸⁷ These professionals should have a working knowledge of medically important conditions and be able to distinguish imaging artifacts from normal and abnormal pathology.¹⁸⁸ The AIUM further stated that “Any other use of ‘limited medical ultrasound’ may constitute the practice of medicine without a license.”¹⁸⁹

The American Medical Association has also expressed its disapproval by adopting the FDA policy that recognizes “keepsake” fetal videos as an “unapproved use of a medical device.”¹⁹⁰ Its House of Delegates had urged the FDA to take action against this use.¹⁹¹ The ACR in its practice guidelines related to obstetrical ultrasound also takes the

¹⁸⁶ See Society of Diagnostic Medical Sonography, Diagnostic Ultrasound Clinical Practice Standards, http://www.sdms.org/positions/clinical_practice.asp. (last visited on Oct. 6, 2005).

¹⁸⁷ Press Release, American Institute of Ultrasound in Medicine (AIUM), The AIUM Releases New Statement Regarding Keepsake Imaging (Aug. 1, 2005), *available at* http://www.aium.org/pressRoom/_releasesContent.asp?id=94 (last visited on Oct. 5, 2005).

¹⁸⁸ Press Release, AIUM, *supra* note 187.

¹⁸⁹ Press Release, AIUM, *supra* note 187.

¹⁹⁰ *AMA Says Ultrasound In-Utero “Portraits” Are Bad Idea*, REUTERS HEALTH, June 21, 2005, *available at* <http://www.acr.org> (citing House of Delegates of the American Medical Association disapproval of the use of ultrasound for “keepsake” imaging) (last visited on Oct. 29, 2005).

¹⁹¹ *AMA Says Ultrasound In-Utero “Portraits” Are Bad Idea*, REUTERS HEALTH, *supra* note 188.

position that “keepsake” fetal imaging is an unapproved use.¹⁹² Moreover, the SDMS (an organization responsible for registering diagnostic medical sonographers) published its position statement on this issue in 2004 opposing “the use of ultrasound solely for entertainment purposes.”¹⁹³ It would seem that the law, guidelines, and position statements would fetal “keepsake” imaging, but it continues.

IV. C. Consumer Driven Self-Referral May Not Be Backed by Science.

Many of the issues related to companies that perform fetal “keepsake” imaging also apply to the entrepreneurs who solicit consumers for these self-referred ultrasound screening studies.¹⁹⁴ Carotid ultrasound and heel ultrasound are only two of the many ultrasound-based studies that have been used to screen patients.¹⁹⁵ For any study to be an effective screening study, the study must have a relatively high positive predictive value, and the prevalence of the disease within the population screened must also be high.¹⁹⁶ Some authors believe the prevalence of disease within the given population must approach twenty percent for any screening study to be effective.¹⁹⁷ As shown below neither carotid nor heel ultrasound will meet these two criteria for screening.

¹⁹² See ACR Practice Guidelines, ACR Practice Guidelines for the Performance of Antepartum Obstetrical Ultrasound, *available at* http://www.acr.org/s_acr/bin.asp?TrackID=&SID+1&DID=121855&CID=539&VID=2&DOC=file.pdf (last visited on Oct. 25, 2005) (“The promotion, selling, or leasing of ultrasound equipment for making ‘keepsake fetal videos’ is considered by the U.S. Food and Drug Administration to be an unapproved use of a medical device.”).

¹⁹³ See Society of Diagnostic Medical Sonography, SDMS Position Statement, Non-Diagnostic Use of Ultrasound, <http://www.sdms.org/positions/nondiagnostic.asp> (last visited on Oct. 6, 2005).

¹⁹⁴ Andrew B. Hill, *Symposium: Controversies in Cerebrovascular Disease 2. Should Patient be screened for Asymptomatic Carotid Stenosis?*, 41 CANADIAN JOURNAL SURGERY 208 (1998), *available at* http://epe.lac-bac.gc.ca/100/201/300/cdn_medical-association/cjs/vol-41/issue-3/0208.htm (last visited on Nov. 4, 2005).

¹⁹⁵ See Fenton & Deyo, *supra* note 25, at 496.

¹⁹⁶ See Fenton & Deyo, *supra* note 25, at 498.

¹⁹⁷ See Hill, *supra* note 194.

IV. C.1. Epidemiological Support May Be Lacking for Some, But Not All Ultrasound Screening Studies.

In the case of carotid ultrasound, the goal of screening is to detect patients with carotid stenosis that is greater than fifty percent, and to select patients who will benefit from remedial measures, such as carotid endarterectomy.¹⁹⁸ The estimated prevalence of greater than fifty percent carotid stenosis within the general population may lie somewhere between two and eight percent.¹⁹⁹ The best sensitivity achievable with a modern ultrasound systems approaches ninety-five percent for detecting a greater than fifty percent stenosis, so the best positive predictive value for detection of disease within the general population would approach fifty percent.²⁰⁰ Because the reported sensitivity and specificity for modern color and pulsed Doppler systems is, generally, less than ninety five percent, both the positive and negative predictive values would also be less than fifty percent.²⁰¹ Therefore, these predictive values would be too low to qualify ultrasound as a screening study for carotid disease in an asymptomatic population.²⁰² Not only is this situation likely to lead to some patients receiving unwarranted studies and interventions, it may not be cost-effective based on the quality of life adjusted years achieved for this group of patients.²⁰³

Notwithstanding the current body of literature questioning the use of carotid ultrasound for screening of asymptomatic patients, some authors do believe that these patients can be screened in a cost-effective fashion with power Doppler (utilizing signal

¹⁹⁸ See Hill, *supra* note 194.

¹⁹⁹ See Hill, *supra* note 194.

²⁰⁰ See Hill, *supra* note 194.

²⁰¹ See Hill, *supra* note 194.

²⁰² See Hill, *supra* note 194.

²⁰³ Tina T. Hill et al., *Cost-Effectiveness of Screening for Carotid Stenosis in Asymptomatic Persons*, 126 ANNALS INTERNAL MEDICINE 337 (1997), available at <http://www.annals.org/cgi/contentfull/126/5/337> (last visited on Oct. 3, 2005).

strength displayed in color rather than speed and direction).²⁰⁴ Because the predictive value is low, the use of carotid ultrasound to screen patients for asymptomatic stenosis in the general population remains questionable, and more research is needed to resolve the controversy.²⁰⁵

The same may be said for the use of heel ultrasounds to screen women at low risk for osteoporosis where the prevalence of the disease is estimated at six percent.²⁰⁶ The current sensitivities reported for heel ultrasound are reported to vary from sixty to eighty two percent.²⁰⁷ Moreover, the low prevalence of disease within the population screened coupled with the low sensitivity of heel ultrasound could lead to some women with osteoporosis being falsely reassured that they have a normal bone density.²⁰⁸ Thus, heel ultrasound screening, as well as carotid ultrasound, may not be inappropriate for use in the general population. Even so, mobile ultrasound screening companies exist in forty three states. Internet services are now available that will match people with providers of self-referred screening studies.²⁰⁹

IV. C. 2. Major Medical Organizations Question the Use of Ultrasound for Routine Screening.

In June 2003, the AIUM issued an official statement that ultrasound screening of asymptomatic patients had “no proven benefit,” and that more research was needed to

²⁰⁴ Edward I. Bluth et al., *Power Doppler Imaging: Initial Evaluation as a Screening Examination for Carotid Artery Stenosis*, 215 *RADIOLOGY* 791 (2000), available at <http://radiology.rsna.org/cgi/content/full/215/3/791> (last visited on Oct. 3, 2005).

²⁰⁵ C. J. M. Whity et al., *Investigating Individual Subjects and Screening Population for Asymptomatic Carotid Stenosis Can Be Harmful*, 64 *JOURNAL NEUROLOGY NEUROSURGERY PSYCHIATRY* 619 (1998), available at <http://jnnp.bmjournals.com/cgo/content/full/64/5/619> (last visited on Nov. 4, 2005).

²⁰⁶ See Fenton & Deyo, *supra* note 25, at 496.

²⁰⁷ See Fenton & Deyo, *supra* note 25, at 496.

²⁰⁸ See Fenton & Deyo, *supra* note 25, at 497.

²⁰⁹ See Fenton & Deyo, *supra* note 25, at 494.

establish the efficacy of these studies.²¹⁰ The United States Preventive Services Task Force did not recommend ultrasound screening for carotid disease.²¹¹ The same organization only recommends ultrasound screening for abdominal aortic aneurysms related to atherosclerotic disease in men who have ever smoked.²¹² The American Academy of Family Physicians recommends against using Doppler or duplex ultrasound to screen patients who are asymptomatic for peripheral arterial disease.²¹³ The clinical benefits of screening of asymptomatic patients with carotid ultrasound are unproven, and the potential exists for falsely labeling people as “unhealthy,” which could lead to more invasive studies.²¹⁴

Others may use the test results as a reason not to alter their potentially deleterious lifestyles.²¹⁵ Moreover, health insurers generally do not cover these sorts of screening studies, which means the “purchaser” covers its cost as an out-of-pocket expense.²¹⁶

²¹⁰ See Official Statement, American Institute of Ultrasound in Medicine (AIUM), Carotid Screening in the Asymptomatic Patient (June 4, 2003), http://www.aium.org/publications/statement/_statement_Selected.asp?statement=28 (last visited on Oct. 6, 2005) (“There is insufficient evidence in the peer-reviewed literature establishing the value or carotid screening using ultrasound in asymptomatic patients without clinical risk factors. Therefore, the AIUM states that, at this time, the use of ultrasound in carotid artery screening in these patients has no proven clinical benefit.”).

²¹¹ See U.S. PREVENTIVE SERVICES TASK FORCE, GUIDE TO CLINICAL PREVENTIVE SERVICES (2nd ed. 1996), available at <http://www.ncbi.nlm.gov/books/bv.fcgi?rid=hstat.chapter.10062> (last visited on Dec. 11, 2005) (*Screening for Asymptomatic Carotid Artery Stenosis; Recommendation*).

²¹² See U.S. PREVENTIVE SERVICES TASK FORCE, *supra* note 201 (providing summary of recommendations as first published in 142 ANNALS INTERNAL MEDICINE 198 where the Task Force recommended that men between the ages of sixty five and seventy five who ever smoked should get a one-time screening ultrasound for an abdominal aortic aneurysm, but made no recommendation for men in this same age group who never smoked.).

²¹³ American Academy of Family Physicians, Recommendations for Periodic Health Examinations, available at <http://www.aafp.org/x24973.xml> (last visited on Dec. 11, 2005) (recommending that neither Doppler nor [D]uplex ultrasound in asymptomatic patients).

²¹⁴ Alan B. Jotkowitz et al., *Screening for Carotid Artery Disease in the General Public*, 16 EUROPEAN JOURNAL INTERNAL MEDICINE 34, 35 (2005) (suggesting ‘labeling’ of people as not healthy following a noninvasive screening test when the patient is not suitable for surgery may lead to further testing, with risks, which may lead some not to change their behavior. This could have deleterious effects.).

²¹⁵ See Jotkowitz, *supra* note 214, at 35.

²¹⁶ See Fenton & Deyo, *supra* note 25, at 498-99.

Because some studies will lead to false positive results, additional studies will be required that will necessarily drive up costs.²¹⁷ The primary care physician and the healthcare system may also incur “costs,” such as lost clinical time, especially when a primary care physician must spend time explaining the unintended results of a self-referred screening study to a dissatisfied consumer.²¹⁸ Still, the rapid growth of the ultrasound screening business continues to grow.²¹⁹

V. Keepsake Imaging Companies May Be Violating Federal Drug Laws.

A recent survey for “keepsake” fetal imaging services advertising on the internet revealed multiple “hits” for such businesses as 4D Sonograms in San Diego, CA; First Glimpse in Baton Rouge, LA; Clearview Ultrasound in Austin, TX; Fetal Fotos in Frisco, TX; Womb with a View in Arlington, TX, and Baby Insight in Potomac, MD.²²⁰ Most, if not all, of these facilities have websites that advertise their use of registered diagnostic medical sonographers (board certified) to perform all keepsake imaging studies, and they also utilize the most modern ultrasound imaging systems available²²¹ At least two, keepsake imaging companies, Clearview and Baby Insight, have claimed that their technologists perform studies with the modern, GE Voluson 730 “Pro” or “Expert” systems, which are, as advertised, “top-of-the-line” systems.²²² Because all of these companies must vie for the same set of consumers, it should be no surprise that they all

²¹⁷ See Lee & Brennan, *supra* note 53, at 529-30.

²¹⁸ See Lee & Brennan, *supra* note 53, at 531.

²¹⁹ See Fenton & Deyo, *supra* note 25, at 494.

²²⁰ See First Look Sonogram, *supra* note 31; see also First Glimpse, <http://www.firstglimpseusa.com/>; see also Clearview Ultrasound, *supra* note 36; see also Baby Insight, *supra* note 32; see also Fetal Fotos, *supra* note 33; see also Womb with a View, *supra* note 34.

²²¹ See Baby’s First Images, <http://www.babysfirstimages.com/answers.htm> (responding to the question on the necessity of a physician’s note prior to the performance of their services by stating that “No, however, it is essential that you contact your physician if you have questions about having this service done. Our services do not and should not replace any facet of your prenatal care. You should address all your medical concerns with your physician prior to having a session ...”).

²²² See Baby’s First Images, *supra* note 221.

employ the latest technologies, have registered diagnostic medical sonographers, and claim that ultrasound technology is safe, almost risk free.

Some of these companies further distinguish themselves from their competition by making additional claims suggesting that their customers need not obtain a “physician’s prescription” or a “note” before purchasing one of these studies. If one surveys the Internet for postings, one will “hit” businesses, such as My Baby’s Ultrasound.com²²³ and BabiesPics.com,²²⁴ which may claim that they do not require a note, while other businesses either do not make any claims, or make claims cover a range of options.²²⁵ Some businesses, such as First Look Sonogram, expressly state that they do require a note from a physician before they will perform one of these studies.²²⁶ Still others recommend that anyone requesting one of these studies should obtain a prenatal diagnostic ultrasound from their primary obstetrician and then discuss the options with their physician before purchasing a fetal keepsake imaging study.²²⁷ The latter tactic seems to shift the onus of decision making from the service provider to the consumer and

²²³ See My Baby’s Ultrasound.com, http://www.jcenterprise.com/3d_ultrasound.htm (“No. Since this is NOT a diagnostic ultrasound, it will not play a role in your prenatal care with your obstetrical provider or physician.”).

²²⁴ See BabiesPics.com, <http://www.babiespics.com> (stating that No note is needed from your Doctor to have a 3D 4D Ultrasound. However, we do require that you are receiving active prenatal care.

²²⁵ See Baby’s First Images, *supra* note 221.

²²⁶ See First Look Sonogram, *supra* note 31 (stating that each patient should consult with a physician before participating in the service they provide and their exam does not replace of a diagnostic ultrasound).

²²⁷ See Baby Insight, *supra* note 27 (“No, you do not need a note from your doctor. We do require, however, that you be receiving active prenatal care and encourage you to speak with your doctor about your intention to visit Baby Insight. In no way can Baby Insight’s limited medical ultrasound be substituted for a diagnostic or medically indicated ultrasound. We do not take measurements or determine due dates.”); see also 4D Fetal Imaging, <http://www.4dfetalimaging.com/faqss.asp> (“Women seeking an elective prenatal ultrasound with 4D Fetal Imaging must already be receiving prenatal care with a healthcare provider and have already undergone a medical, diagnostic ultrasound to confirm their due date, screen for fetal anomalies, and to diagnose any other pregnancy related issues. We include a limited diagnostic scan to confirm the gender, number of babies, baby’s presentation, placental location and measure the heart rate. Please note, at no time is this exam to be used in place of a complete diagnostic ultrasound.”).

her primary physician, while allowing the service provider to opt out of the decision-making process.

Yes, the variation in the number of claims made by the owners of these businesses is vast, and it also illustrates just how difficult it may be for regulatory agencies to monitor them and enforce regulations against them. The companies that claim they deliver their services without a physician prescription, and do deliver them without a physician being involved in the loop violate at least one regulation.²²⁸ They may also be violating one or more additional safety regulations that flow from their lack of physician involvement.²²⁹ For example, the company who violates the regulation requiring a prescription or note from a referring physician, may violate additional regulations, such as section 801.109(b)(1) which requires the posting of a cautionary statement on the ultrasound system related to usage by a licensed physician.²³⁰ It may also misbrand the device, since it did not require a prescription from a physician, but it may, or may not adulterate the ultrasound device.²³¹ Unfortunately, effective enforcement by the FDA requires that it both discover potential violators, and prosecute them, and thus far, the FDA has not closed one of these businesses down.²³²

²²⁸ See Food and Drugs, 21 C.F.R. § 884.2225 (2005) (pertaining to the use of a “prescription device,” and clearly, ultrasound qualifies as a Class II device).

²²⁹ See Food and Drugs, 21 C.F.R. § 801.109 (2005) (explaining that ultrasound device is one that has potentially harmful effects or is, by its method of use, not safe unless a practitioner licensed by law directs the use of such a device).

²³⁰ See Food and Drugs, 21 C.F.R. § 801.109(b)(1) (2005) (“Caution: Federal law restricts this device to sale by or on the order of a ‘physician’, ‘dentist’, ‘veterinarian’, or with descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device ...”).

²³¹ See Rayford, 16 S.W3d at 207-10 (explaining that an owner or operator of a keepsake imaging business performing keepsake ultrasound studies without a prescription from a physician misbrands the device, but the business does not adulterate the device, because it is not the manufacturer who is the one responsible for defining its intended use and labeling of the device).

²³² See Huhn, *supra* note 65 (noting that technically the FDA regulates these devices and has issued warning letters, but has not closed any of these businesses down) (last visited on May 27, 2006).

Regulation of these devices by the FDA may be further complicated by its traditional stance of noninterference with respect to state regulation, especially where it encroaches on the practice of medicine or pharmacy within a given state.²³³ Operators of keepsake imaging services or ultrasound screening services often claim that they are not breaking any regulations, because they are not performing diagnostic services.²³⁴ Some states, however, are beginning to take action by creating state-based regulations to control the distribution and use of ultrasound technology.

V. A. Nonmedical Uses of Ultrasound May Violate Multiple State Laws.

In 2003, some operators confessed their desire for more regulatory guidance from the states, where they have their businesses and provide these services.²³⁵ Apparently, some states have heeded their call for state-based regulatory guidance and intervention, but the mechanisms states are pursuing do vary. Even so, the results have been mixed with some states fairing better than others. Texas began enforcing its laws against these facilities as early as 1996.²³⁶ In Texas, the Department of Health Services (TDHS), under the Chapter 431 titled the Texas, Food, Drug, and Cosmetic Act (“TFDCA”), has the authority to adopt the Federal Food, Drug, and Cosmetic Act and make the rules.²³⁷ It also has the authority to monitor Texas businesses who may not comply with 21 C.F.R. §

²³³ Ross D. Silverman, *Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards*, 26 AM. J. L. & MED. 255, 275 (2000) (noting that the FDA does not usually regulate either the practice of pharmacy or medicine, but defers to the states).

²³⁴ See Peter DeMarco, *Impact of 3-D Snapshots on Unborn Babies Is Unclear*, http://www.boston.com/news/globe/health_science/article/2003/09/09/impact_of_3_d_snapshots_on_unborn_babies_is_unclear/ (noting that operators do not claim to be a medical practice or offer diagnostic exams).

²³⁵ See DeMarco, *supra* note 234 (citing local operator of establishment in the Boston area as welcoming state guidelines, but no agreeing that her services endangered her patients).

²³⁶ See Rayford, 16 S.W3d at 206.

²³⁷ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.241 (Vernon 2003); See also Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.244 (Vernon 2003) (adopting Federal Regulations as State rules);

884.2225(a) and (b) in their use a Class II device,²³⁸ which requires a written or oral authorization from a physician prior to its use.²³⁹ Because these devices are classified as prescription devices, they cannot have adequate directions for lay use.²⁴⁰ They are also exempted from the requirement for directions in their use, because they must be in the possession of a physician.²⁴¹ Not only do these devices fall come under the FFDCa, but also they are under the Texas Food, Drug, and Cosmetic Act (“TFDCA”).²⁴² The Texas Act follows the same federal classification and regulatory scheme . If any Texas company uses an ultrasound system or “device” without a “note,” it violates federal regulations, and under the “TFDCA,” the company also “adulterates”²⁴³ and it “misbrands” the “device.”²⁴⁴ It would seem relatively easy for a regulatory agency to match violators with the appropriate regulatory violations, but a case adjudicated by Texas demonstrated just how difficult prosecution of a violator can be.²⁴⁵

In that case, the State of Texas sued Ms. Erma Rayford and her business, Baby Images, Inc., in 1996 for performing ultrasound scans on fetuses and providing videos to consumers without a prescription from a physician.²⁴⁶ The suit was brought after the TDHS cited Ms. Rayford on multiple occasions for performing these services without a

²³⁸ See Food and Drugs, 21 C.F.R. § 814.2225(a)-(b) (2005) (stating that an obstetrical-gynecologic ultrasonic imager is a device designed to emit and receive ultrasonic energy into a female patient and her fetus, and it falls under Class II performance standards).

²³⁹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 360j(e)(1)(A) (West 1999) (“The Secretary may by regulation require that a devise be restricted to sale, distribution, or use—(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, ...”).

²⁴⁰ See Food and Drugs, 21 C.F.R. § 801.109(b)(1) (2005)

²⁴¹ See Food and Drugs, 21 C.F.R. § 801.110 (2005).

²⁴² See TEXAS HEALTH & SAFETY CODE ANN. § 431.002(13) (Vernon Ann., Westlaw through Sept. 2005)

²⁴³ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.111 (Vernon 2003).

²⁴⁴ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.112 (Vernon Supp. 2005)

²⁴⁵ See *Rayford*, 16 S.W.3d 203 (discussing enforcement actions against Baby Images, Inc. brought by the State of Texas under federal and state regulations where the business partial summary judgment was upheld only on a claim of misbranding but not on adulteration or violations of consumer protection laws).

²⁴⁶ See *id.* at 205.

physician prescription, or physician supervision.²⁴⁷ The State alleged that keepsake imaging with an ultrasound device qualified as a “new intended use,” which moved the device from Class II to Class III.²⁴⁸ As a Class III device, the State claimed that the owner adulterated the device because the device did not receive premarket approval from the FDA.²⁴⁹ Because the State viewed keepsake imaging as a new, intended use, it also claimed that the owner had adulterated the device under the Texas Act.²⁵⁰ The State then alleged that the company misbranded the device by not properly labeling it.²⁵¹ A device may be misbranded if it is a restricted device that is used without a physicians prescription.²⁵² Although not specifically addressed in the aforementioned case, the TFDCA does not treat a registered diagnostic medical sonographer as a physician²⁵³ nor does it qualify them as a practitioner.²⁵⁴ If a company violates one of these sections and definitions, it then violates Chapter 483 (Dangerous Drugs) of the Health and Safety Code.²⁵⁵

²⁴⁷ *See id.*

²⁴⁸ *See id.* at 206.

²⁴⁹ *See id.* at 207.

²⁵⁰ *See* TEXAS HEALTH & SAFETY CODE ANN. § 431.111 (Vernon 2003).

²⁵¹ *See Rayford*, 16 S.W.3d at 210 (citing section 431.112(f)(1) and (r) of the Texas Health and Safety Code Annotated as indicating misbranding may occur through improper labeling or unapproved use of a device).

²⁵² *See id.* (citing section 431.112(r) of the Texas Health and Safety Code Annotated § 431.112(r) determining that a device is misbranded if the device is used in violation of 21 U.S.C.S § 360j(e), where a restricted device may be used only under the written or oral authorization of a physician).

²⁵³ *See* Medical Practice Act, TEXAS OCC. CODE ANN. § 151.002(12) (Vernon Supp. 2005) (“Physician” means a person licensed to practice medicine in this state.).

²⁵⁴ *See* Texas Dangerous Drug Act, TEXAS HEALTH & SAFETY CODE ANN. § 483.001(12) (Vernon Supp. 2005) (“Practitioner means a person licensed: (A) by the Texas State Board of Medical Examiners, ... to prescribe or administer drugs; ... (B) an advanced practice nurse or physician assistant to whom a physician delegated the authority to carry out or sign prescription drug orders ...”, but the Code does not mention a registered or unregistered diagnostic medical sonographer.)

²⁵⁵ *See* Texas Dangerous Drug Act, TEXAS HEALTH & SAFETY CODE ANN. § 483.041 (Vernon Supp. 2005) (defining the possession of dangerous drug as (a) “A person commits an offense if the person possesses a dangerous drug unless the person obtains the drug from a ... practitioner acting in the manner described by Section 483.042(a)(2).”).

The State in *Rayford* also pursued a false advertising claim as well as a claim under its Deceptive Trade Practices Act.²⁵⁶ The trial court found that a business, who advertises that it does not require a note from a physician prior to the acquisition of an ultrasound in its advertising violated TFDSA section governing the false advertisement of a device, although the appellate court in *Rayford* found otherwise.²⁵⁷ Advertising for the purposes of the TFDSA is “deemed to be false,” if it is false or it is “misleading in any particular,” and the appellate determined that law applied to the seller, rather than the owner or operator of a scanning business²⁵⁸ Thus, Ms. Rayford was able to escape a civil fine or criminal proceedings brought by the attorney general or local officials.²⁵⁹ Because the State believed she falsely advertised her services, then she also violated the Texas Deceptive Trade Practices Act (TDTPA).²⁶⁰

In *Rayford*, the State alleged that a business, who falsely advertises that no physician prescription is needed also violated the TDTPA.²⁶¹ Under the Act, Baby Images, Inc. violated the Act when it failed to disclose information for its goods or services, which was also intended to induce a consumer to participate in a transaction it

²⁵⁶ See *Rayford*, 16 S.W.3d at 210 (citing section 431.002(1) of the Texas Health and Safety Code Annotated as defining advertising as ‘all representation disseminated in any manner or by any means, other than labeling, for the purposes of inducing, or that are likely to induce, directly or indirectly, the purchase of ... devices ...’, where the representations pertain to the selling of a device, not scanning services).

²⁵⁷ See *id.* at 210.

²⁵⁸ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.182 (Vernon 2003)..

²⁵⁹ See Texas Food, Drug, and Cosmetic Act, TEXAS HEALTH & SAFETY CODE ANN. § 431.0585 (Vernon 2003) (providing for ... (b) a civil penalty that may not exceed \$25,000 a day for each violation, and (c) also provides that the court may consider multiple factors in its determination of the penalty such as (1) previous history of violations, (2) seriousness of the violation, (3) any public health or safety hazards, and (4) good faith on the part of the person charged ...).

²⁶⁰ See Deceptive Trade Practices-Consumer Protection Act, TEXAS BUS. & COM. CODE ANN. §§ 17.01-17.885 (Vernon 2002).

²⁶¹ See *Rayford*, 16S.W.3d at 210-11.

would not have had it been made aware of the information.²⁶² Although the State was granted summary judgment on this point at the district court level, the appellate court found that the trial court erred, because State did not meet its burden as a matter of law.²⁶³ In fact, the State had failed to present evidence to show that a mother would not have purchased keepsake imaging services had she been made aware of the need for a physician prescription.²⁶⁴ By winning on this point, Ms. Rayford and her business were able to avoid summary judgment and a permanent injunction against performance of keepsake imaging services based upon violation of the TDTPA.

Although the State ultimately received injunctive relief based on its misbranding claim, it might have preferred a successful outcome on its DTPA claim. If the State had won its claim, then it would have received additional advantages under the TDTPA.²⁶⁵ Not only could the State ask for injunctive relief from the practice, but also it could request a civil fine be levied against the offending business.²⁶⁶ Civil fines may range from \$20,000 up to \$250,000, depending on the offense and the particular consumer involved.²⁶⁷ If a consumer suffers some documented harm or injury from one of these studies, and it is also shown that the harm is a producing cause of injury, then the consumer may be entitled to actual damages from the business.²⁶⁸ A business that violates one or more sections of the Act could face substantial penalties. Even so, the result in the

²⁶² See Deceptive Trade Practices-Consumer Protection Act, TEXAS BUS. & COM. CODE ANN. § 17.46(b)(23) (Vernon Supp. 2005).

²⁶³ See *Rayford*, 16S.W.3d at 211.

²⁶⁴ See *id.* at 211.

²⁶⁵ See Deceptive Trade Practices-Consumer Protection Act, TEXAS BUS. & COM. CODE ANN. §§ 17.47(a) (Vernon Supp. 2005).

²⁶⁶ See Deceptive Trade Practices-Consumer Protection Act, TEXAS BUS. & COM. CODE ANN. §§ 17.47(c) (Vernon Supp. 2005).

²⁶⁷ See Deceptive Trade Practices-Consumer Protection Act, TEXAS BUS. & COM. CODE ANN. §§ 17.47(c)(1) (Vernon Supp. 2005).

²⁶⁸ See Deceptive Trade Practices-Consumer Protection Act, TEXAS BUS. & COM. CODE ANN. §§ 17.50 (Vernon Supp. 2005).

Rayford case demonstrates just how difficult it may be for a State to succeed in the prosecution of its claims.

V. B. Ultrasound Without a Physician May Violate State Medical Practice Acts.

Although the federal government and many states, including Texas, want more physician involvement, especially when it comes to fetal keepsake imaging, it may not be easily achieved under the existing drug or device regulations. Some professional organizations as well as states, such as Louisiana, are attempting to put these practices within the scope of medical practice. For example, the Practice Guidelines promulgated by the ACR state that ultrasound studies should be “performed by a qualified and knowledgeable physician and/or sonographer using appropriate equipment and techniques.”²⁶⁹ The Society for Diagnostic Medical Sonographers (a society that licenses or registers diagnostic medical sonographers or technologists) also addressed this issue in their Diagnostic Ultrasound Clinical Practices Standards, where it stated that the “Diagnostic Ultrasound Professional: 1.6.5 Provides an oral written summary of preliminary findings to the interpreting physician.”²⁷⁰ The AIUM has also gone one step further by declaring that it proscribes the practice of “limited medical ultrasound” or “keepsake” imaging, where it relates to the performance of fetal imaging. Moreover, the AIUM now views performance of such studies without a physician as the “practice of medicine without a license.”²⁷¹ This statement underscores the importance of the

²⁶⁹ See ACR Practice Guidelines, ACR Practice Guidelines for Performing and Interpreting Diagnostic Ultrasound Examinations, *supra* note 175.

²⁷⁰ See Society of Diagnostic Medical Sonography, Diagnostic Ultrasound Clinical Practice Standards, *supra* note 184.

²⁷¹ Press Release, American Institute of Ultrasound in Medicine (AIUM), The AIUM Releases New Statement Regarding Keepsake Imaging, *supra* note 185 (“The AIUM recommends that licensed medical professionals (either physicians or registered or registry-eligible sonographers) 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

physician, but it also raises the possibility for an additional state cause of action through the unlawful or unauthorized practice of medicine.

Although it would seem reasonable for a state to consider the performance of diagnostic medical ultrasound as the practice of medicine, the definition of the practice of medicine controls for the given state. Unfortunately, medical practice acts of the various states may define the practice of medicine in either broad or narrow terms.²⁷² Some states may adopt a broad statement of the practice of medicine where “practice” may include a “condition, physical or mental, real or imaginary.”²⁷³ Many jurisdictions include the term “condition,” which may be so broadly defined as to include any state of human health or disease.²⁷⁴ For example, California, the only state that has a statute specially directed toward “keepsake” imaging, classifies a normal pregnancy as a “physical condition,” not a disease.²⁷⁵ So, any nonphysician caring for a normal pregnancy would constitute the unauthorized practice of medicine.²⁷⁶ Even with this broad definition of pregnancy, it remains unclear whether California views the sonographers performing “keepsake” fetal imaging as violating the practice of medicine.

Louisiana is one state with a fairly broad definition of the practice of medicine²⁷⁷ that has addressed the issue of self-referred diagnostic medical screening. In 2000, the

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.”).

²⁷² See Lori B Andrews, *The Shadows Health Care System: Regulation of Alternative Health Care Providers*, 32 HOUS. L. REV. 1273, 1299 (1996), available at <http://lexis.com>.

²⁷³ See Andrews, *supra* note 270, at 1299-1300.

²⁷⁴ See Andrews, *supra* note 270, at 1299.

²⁷⁵ See Andrews, *supra* note 272, at 1299.

²⁷⁶ See Andrews, *supra* note 272, at 1299.

²⁷⁷ See LA. REV. STAT. ANN. § 37:1262 (LexisNexis 2005) (“The practice of medicine ... means holding out of one’s self to the public as being engaged in the business of, or the actual engagement in, the diagnosing, treating, curing, or relieving of any bodily or mental disease, condition, infirmity, defect, ailment, or injury in any human being other than himself”).

Louisiana State Board of Medical Examiners (the “Board”) addressed the issue of businesses practicing screening vascular ultrasounds (carotid ultrasound, peripheral vascular ultrasound, and aortic ultrasounds for screening) in the state without the involvement of a physician.²⁷⁸ The Louisiana Practice Act reads “the ‘practice of medicine’ explicitly encompasses ‘the examining, either gratuitously or for compensation, of any person ... Whether such drug, instrument, force, or other agency or means is applied to or used by the patient or by another person,’ for the purpose of diagnosing a bodily or mental condition.”²⁷⁹ Based on the interpretation of the Act, the “Board” sought action against those other than a licensed physician that performed self-referred screening ultrasounds.²⁸⁰ The “Board” took this position based on its concern for public safety, where the State did not have authority to regulate “ultrasound technicians.”²⁸¹ It also expressed its concern for the potential for misdiagnosis and patient confusion based on inaccurate results.²⁸² The “Board” also mandated that studies should be supervised by a physician, not interpreted by the screening study, obtained by physician referral, and performed with quality systems.²⁸³ Currently, any unlicensed

²⁷⁸ Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, *available at* http://www.lsbme.org/documents/position_statement/UltrasoundScreening.pdf.

²⁷⁹ *See* Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, *supra* note 280.

²⁸⁰ *See* Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, *supra* note 280.

²⁸¹ *See* Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, *supra* note 276.

²⁸² *See* Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, *supra* note 276.

²⁸³ *See* Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, *supra* note 276.

personnel that performs these types of studies becomes subject to an injunction and/or criminal sanctions.²⁸⁴

Enforcement actions similar to those taken by the Louisiana State Board of Medical Examiners may be more problematic for those states, such as Texas, who have rather narrow definitions of medical practice. For example, the Texas Occupation Code defines the practice of medicine as “the diagnosis, treatment, or offer to treat a mental or physical disease or disorder or physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by person who (A) publicly professes to be a physician or surgeon; or (B) directly or indirectly charges money or other compensation for those services.”²⁸⁵ Where the Texas State Board (TSB) lacks jurisdiction to enforce actions for the unlicensed practice of medicine, the Code contemplates the attorney general or other officials making investigations and handling prosecutions, or seeking injunctive relief.²⁸⁶ Unfortunately, the Code uses more restrictive language than the Louisiana statute, because Texas focuses on the “mental or physical disease or disorder or a physical deformity or injury.” The Code does not define either the term “disease” or “disorder.”²⁸⁷ Based on the plain meaning of the term disease,²⁸⁸ it refers to “pathological

²⁸⁴ See Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, *supra* note 276.

²⁸⁵ See Medical Practice Act, TEX. OCC. CODE ANN. § 151.002(13) (Vernon Supp. 2005) (“Practicing Medicine” means for diagnosis, treatment, or offer to treat a mental or physical disease or disorder or physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by as person who: (A) publically professes to be physician or surgeon; or (B) directly or indirectly charges money or other compensation for those services.”)

²⁸⁶ See 22 TEX. ADMIN. CODE § 198.1 (LexisNexis 2005) ([P]erformance of any medical procedure with the required permit, registration, or license shall be routed to one or more of the following for appropriate handling including further investigation, prosecution, and/or injunctive relief: (1) the Office of the Attorney-General . . .”).

²⁸⁷ See Medical Practice Act, TEX. OCC. CODE ANN. § 151.002 (Vernon Supp. 2005) (providing definitions for the Code).

²⁸⁸ MERRIAM WEBSTER’ COLLEGIATE DICTIONARY 331 (Fredrick C. Mish ed., Merriam-Webster, Inc. 10th ed. 1998) (“[D]isease is a condition of the living animal or plant body or of one of its part that impairs normal functioning”).

conditions.”²⁸⁹ It is unlikely that those performing keepsake ultrasound imaging would ever be considered practicing medicine unless the person made a diagnosis of a pathological condition that led to treatment. The language of the Code is likely too narrow to characterize these practices as the unlawful practice of medicine.

This may not be the case for individuals who perform self-referred ultrasound screening studies for peripheral disease. Vascular ultrasound studies such as carotid ultrasound, peripheral vascular ultrasound, and aortic ultrasound for aorta aneurysm are performed to diagnose disease.²⁹⁰ The very purpose of these studies is to screen for disease. If any of these screening studies are done by a sonographer without having a physician in the loop, it is hard to envision how any report could be issued that would not violate the unlawful or unauthorized practice of medicine. Where no physician is involved, technologists who perform an ultrasound screening study could be holding themselves out as a physician to the public, where the ultrasound system has the cautionary statement mandated by the FDA for use by a “physician” posted on it. The technologist need not publicly profess that he or she is a physician.²⁹¹ The very nature of the activities that person does may be sufficient to hold oneself out to be a physician.²⁹²

In *Weyandt v. The State of Texas*, the Fourteenth Court of Appeals upheld the conviction of a nurse anesthetist for the unlawful or unauthorized practice of medicine

²⁸⁹ MERRIAM WEBSTER’ COLLEGIATE DICTIONARY, *supra* note 288, at 240 (“[C]ondition as a defective state of health.”).

²⁹⁰ See Life Line Screening, *Why Ultrasound Screening?*, available at <http://www.lifelinescreening.com/newsletter/pdf/vol2-issue1.pdf>. (last visited on Oct. 10, 2005) (stating that a physician who published an article in a medical journal recommended that all men and women between ages fifty and sixty with high blood pressure, family history of stroke, or diabetes get a carotid ultrasound screening study. The company offers a complete wellness package including multiple different ultrasound screening studies.).

²⁹¹ See *Weyandt v. State*, No. 14-98-00194, 2000 Tex. App LEXIS 8189, at **12 (Tex. App.—Houston [14th] 2000) (noting that “The practice of medicine as contemplated and defined by the law, is not restricted to the treatment of disease and disorders of the human body by the use of drugs or surgery.”).

²⁹² See *id.*

where she never publically professed that she was a “physician.”²⁹³ She was charged and convicted of the unauthorized practice of medicine stemming from incident where she saw an “undercover” police officer for an alleged shoulder injury. The defendant told the undercover officer she was a “doctor,” but she never said she was a physician or licensed to practice medicine in Texas.²⁹⁴ She did possess a degree in medicine from a university in Mexico, and she was a Certified Registered Nurse Anesthetist (CRNA), an advanced nurse practitioner, and a certified hypnotherapist. She also had a sign on her office door stating “Dr. Linda J. Weyandt,” and her office looked like the office of a doctor. She proceeded to attached wires from a peripheral nerve stimulator to the allegedly injured shoulder of the investigator. During the process of stimulation, the investigator experienced some mild pain and muscle twitching. An expert witness at her trial testified that a peripheral nerve stimulator was a diagnostic, not therapeutic device. In addition to the nerve stimulation, the defendant tried to hypnotize the investigator, and she also gave the investigator some herbal tea to drink.²⁹⁵ Based on these facts, the court upheld her conviction for the unauthorized practice of medicine.²⁹⁶

The court noted that the lack of credentials by the defendant was not the problem, but her failure to hold a valid license to practice medicine in Texas.²⁹⁷ The court explained that the defendant need not make any affirmative representation that she was a medical doctor, a physician, or a surgeon to violate the Act.²⁹⁸ Moreover, a defendant may violate the Act by the very nature of “what one does, and not only what one says

²⁹³ *See id.*

²⁹⁴ *See id.* at **14.

²⁹⁵ *See id.* at **4.

²⁹⁶ *See id.* at **19.

²⁹⁷ *See id.* at **19.

²⁹⁸ *See id.* at **12.

they are doing, to determine whether they are practicing medicine.”²⁹⁹ The court concluded, based on the facts presented at trial, that the defendant “implicitly suggested” she was physician, when she purported to diagnose and treat the investigator.³⁰⁰ Thus, the court was not swayed by the testimony of the expert regarding the lack of known therapeutic uses of a peripheral nerve stimulator.

Based on the statements by the court in *Weyandt*, a sonographer need not specifically state he or she is a physician to practice medicine without a license. Texas sonographers who perform diagnostic medical ultrasound screening studies could be practicing medicine without a license, where they issue a report rendering a diagnosis of a disease process, such as atherosclerosis or osteoporosis. Not only may these sonographers be practicing medicine without a license, but they may also be violating federal regulations that require posting of a statement that the FDA “restricts this device to sale by or on the order of a physician or other licensed practitioner” under laws of the state.³⁰¹ As in the *Weyandt* case, such a notice or sign on the ultrasound, if seen by a patient, could, in theory, be treated as a representation that the technologist performing the scan is a physician. Certainly, the device user facility, as any other clinic or physician office, could easily lead a patient to believe that a technologist performing ultrasound could be a physician. Thus, it seems that Texas State Board could, in those cases involving self-referred screen studies, seek assistance from the attorney general or local authorities to pursue the unauthorized or unlawful practice of medicine. Ultimately, it may well be a question of fact for a judge or jury to determine.

²⁹⁹ *See id.*

³⁰⁰ *See id.* at **14.

³⁰¹ *See* Food and Drugs, 21 C.F.R. 801.109(b)(1) (2005).

V. C. Successful Regulation May Require a Collaborative Effort Between the State Legislatures and Professionals.

If the parties participating in the process of diagnostic medical ultrasound behaved reasonably, then perhaps, regulatory interventions would be unnecessary. Unfortunately, some people, such as Tom Cruise or ultrasound imaging entrepreneurs, do not always recognize or honor what others might consider as reasonable behavior. Perhaps, the best approach to controlling the use and potential misuse of diagnostic medical ultrasound might reside in a collaborative effort between all stake holders in the process.

It has been demonstrated throughout this article that the FDA as well as various state agencies may not be capable of effectively regulating these practices. After all, effective regulation often requires cooperation from all participating parties. The ultimate solution to the problem may require a collaborative effort between all parties including state legislatures, branches of government responsible for enforcing regulations, medical societies, owners and technicians of the ultrasound facilities, and consumers. Based on recent events, total cooperation among the stake-holders is highly unlikely, but steps can be taken to ensure consumer safety without enacting overly restrictive regulations.

The first step in bringing reason back to the current dynamic will require the legislatures of the several states to follow the path of California, and draft sensible legislation that specifically regulates the ability of non-medically trained consumers to purchase or operate these devices.³⁰² By controlling distribution of these sophisticated

³⁰² See AB 2360 Assembly Bill-Vote Information, *supra* note 52 (discussing summary of AB 2360, which is the restriction of the sale, lease, and distribution of ultrasound imaging machines by prohibiting manufacturers or other persons in California from doing any of these acts unless it is a licensed practitioner of the healing arts, a licensed medical facility, a dealer, distributor, or representative of a manufacturer or sales agent that purchases or acquires one of these systems from a manufacturer, or a person who has the

medical systems at the level of the manufacturer, legislatures will address the supply side of the equation by limiting who may purchase these systems. Such legislation will keep both cart-based and HCDs out of the hands of untrained individuals,³⁰³ even if individuals including Tom Cruise, have the financial means to purchase them. It will also serve as a brake on manufacturers who may be willing to sell their systems to untrained consumers to boost their profit margins. By controlling manufacturers who are willing to sell to anyone with the dollars to buy, it will force all parties to play by the existing rules.

If all states legislatures will follow the lead of California by drafting legislation that put physicians into the loop, as either buyers or providers, then states will foster access to qualified individuals. More importantly, consumer safety will likely be enhanced, because physicians will become responsible for quality control and monitoring technical performance. This arrangement could serve to initiate a system of checks-and-balances, where both physicians and diagnostic medical sonographers must adhere to the ALARA and ODS principles. This dynamic will offer consumers the opportunity to be scanned under the safest conditions possible without overly restricting their access to ultrasound imaging opportunities. Although the California Senate Health Committee has yet to formally pass this Bill, it has recently voted to recommend passage of the Bill, which is certainly a step in the right direction.³⁰⁴

sole purpose to sell, lease, or otherwise distribute one of these systems, or a bank, a leasing company, or financial institution, or an educational facility).

³⁰³ See AB 2360 Assembly Bill-Bill Analysis, http://info.sen.ca.gov/pub/bill/asm/ab_2351-2400/ab2360_cfa_20060612_1536.html (explain the purpose of AB 2360 is the prevention of any future sales of ultrasound systems to persons who lack training).

³⁰⁴ Complete Bill History, http://info.sen.ca.gov/pub/bill/asm/ab_2351-2400-2360_bill_20060525_history.html (last visited on June 16, 2006) (reporting that the Committee, by a vote of seven ayes as opposed as two noes, that the Bill receive a Do pass, and re-refer to Committee on Judiciary).

Next, medical societies must rethink their position on the practice of fetal keepsake imaging, where current policies frown or dissuade physicians and mothers, as willing consumers, from participating in these studies. As this article has pointed out, the current regulations and policies are not entirely successful, and it may be time for the members of the medical societies to adopt a more flexible approach. Since many physicians advocate fetal keepsake imaging for their patients in order to increase bonding, while others cite medical and biological safety reasons for opposing it, the time may have arrived for all parties to seek out a common ground. The goal should be to interject more physician involvement, not less. More importantly, the societies that control diagnostic medical sonographers should adopt regulations that would either restrict or revoke the licenses of technologists who perform ultrasound studies without either a supervising of physician or an order from a physician. Such regulations should not be so restrictive that it would alter current medical practices, where technicians perform studies that are reviewed and interpreted by a physician at a later time.³⁰⁵ The key here is not to so alter current practice that it chokes off access of consumers to ultrasound imaging services or creates unnecessary delays. On the contrary, physicians specializing in ultrasound should work with diagnostic medical sonographers to create referral networks so consumers can have greater access to imaging, but under controlled conditions.

³⁰⁵ AIUM, *Standards and Guidelines for the Accreditation of Ultrasound Practices*, http://www.aium.org/publications/statements/_statementSelected.asp?statement=26 (providing the license and educational criteria for the medical staff and personnel who perform and interpret ultrasound studies that meet AIUM standards and guidelines for accreditation of ultrasound practice, where “ultrasound studies must be supervised and interpreted by a physician with training and experience in the specific areas of sonography ...”).

Because many physicians and consumers view keepsake imaging studies as part of a nondiagnostic, bonding experience, sonographers should perform these studies only if a physician is in-the-loop, that is—a physician has ordered these imaging experiences after a formal diagnostic study. By meeting the latter step, sonographers may avoid potential violations of state and federal regulatory laws. A still better approach would have physicians trained in diagnostic ultrasound offering keepsake imaging experiences to their patients as part of the standard obstetrical imaging experience at a nominal charge to patients who want the experience. Of course, clinical practices will have to upgrade at least one of their imaging suites to mirror the theater-like experience. Yes, it will require a capital expense, but such an expense might be offset by the revenues from patients who wish to purchase the experience, and from its potential of these services to attract new patients from the family and friends who feel and see the experience. Moreover, endorsement of this practice by major medical organizations will ensure that physicians are involved from the very beginning of the process. Great involvement and oversight should alleviate many of the medical and ethical issues currently raised by the practice of keepsake imaging. Greater physician involvement will also serve to legitimize the process, and it will likely lead to further investigational studies, which could help resolve the current debate related to the potential biological effects of ultrasound scanning and bonding benefits.

Finally, medicine needs to do a better job of evaluating medical imaging as it is applied to screening studies. Again, the goal of any regulatory control scheme should be to curb waste, fraud, and abuse, not encourage it. Unfortunately, the dynamic of self-

referral is ripe for abuse by physicians.³⁰⁶ Although Medicare may not pay for consumer driven imaging studies done to screen for diseases, some are concerned that these practices may also contribute to over-utilization of imaging services.³⁰⁷ Still others point out that “scan all” strategies in certain patient groups may actually decrease rather than increase the overall costs of care.³⁰⁸ Nevertheless, all agree some form of control may be necessary, which is best achieved through a collaborative effort at all levels.³⁰⁹

The process should begin, as in California, with states passing laws to control the supply-side of the technology in order to limit its access to untrained or unqualified personnel. Next, medical societies and medical boards should take affirmative action, similar to those taken by the Louisiana State Board Medical Examiners, to bring self-referral screening studies and those who perform them under their medical practice acts. Moreover, medical societies that govern the behavior of diagnostic medical sonographers

³⁰⁶ *MedPAC Recommendation on Imaging Services* Before the Subcomm. On Health, H. Comm. On Ways and Means, 109th Cong. (2005) (statement of Mark E. Miller, Executive Director, Medicare Payment Advisory Commission), *available at* http://www.medpac.gov/publications_testimony/031705_TestimonyImaging-Hou.pdf (identifying imaging as the fast growing aspect of Medicare payments which may be driven by factors such as technological innovations that have improved the ability of physicians to identify disease, desire on the part of patients to receive imaging in more convenient settings, physicians practicing defensive medicine, possible misalignments in fee schedule payment rates and costs, and physicians wishing to supplement their professional fees with revenues from ancillary services).

³⁰⁷ Lee & Brennan, *supra* note 51.

³⁰⁸ *MedPAC Recommendation on Imaging Services* Before the Subcomm. On Health, H. Comm. On Ways and Means, 109th Cong. (2005) (statement of David Rollo, Chief Medical Officer, Phillips Medical Systems, Milpitas, California), <http://waysandmeans.house.gov/hearings.asp?formmode+printerfriendly&id=2557> (last visited on June 23, 2006) (providing rebuttal testimony related to the assertion that growth in utilization is also *per se* proof of its inappropriateness or excessiveness, where medical imaging may be less costly than more invasive therapies and it may provide better diagnoses through acquisition of more information).

³⁰⁹ *See MedPAC Recommendation on Imaging Services* Before the Subcomm. On Health, H. Comm. On Ways and Means, 109th Cong. (2005) (statement of David Rollo, Chief Medical Officer, Phillips Medical Systems, Milpitas, California), *supra* note 306 (discussing roles of various government organizations, medical societies, and manufacturers have played in regulating imaging and making it safe and cost-effective technology, and that Medicare should promote safety, quality, and medical effectiveness of diagnostic imaging services by making any standards development process open to all including the manufacturers, administrative and financial burdens should be minimized on providers and the Medicare program, any standards program that is adopted should be updateable, any program should be administered by multiple, objective entities that are accessible to all parties and there should be timely process and transition mechanisms in place to avoid interruption of access to care by Medicare beneficiaries).

should also support their local medical boards by becoming more aggressive in policing the actions of their constituents. More importantly, medical societies should encourage medical educators and researchers to do more evidence based analysis of screening studies, especially in areas related to diagnostic medical imaging. Unfortunately, effective regulatory control may also require participants to notify the appropriate agencies of the existence of potential violations. Until all the parties come together to formulate an acceptable policy, it is unlikely that current practices are going to change in the near future.

VI. Conclusion.

In closing, it is important for everyone to recognize that diagnostic medical ultrasound is now, and always will be, a very powerful diagnostic tool in the right hands. Patient safety should always be the primary focus of any attempt to regulate the use of ultrasound devices. Although ultrasound is currently recognized as a safe technology, the preexisting animal and epidemiological studies may not be sufficiently complete to draw definitive conclusions about the current energies utilized by modern systems, especially if individuals are now exceeding the uses intended by the manufacturers. States should support the FDA in its efforts to curb the abuses by aggressively enforcing federal and state regulations to restrict use without physician involvement. States, where possible, should also use their medical practice acts to ensure that physicians are brought into the process. States that lack the necessary laws to control the unrestricted access of untrained or unqualified individuals to these systems should follow the lead of California, and begin enacting laws that will effectively control supply. No one questions the lucrative nature of the ultrasound imaging market, and because it is so lucrative, it will likely

continue to grow. It is only natural for manufacturers to further their economic advantages by selling systems to willing buyers. Until sensible laws are enacted to check current practices, patients will be at risk, where the unknowledgeable have access to systems and perform scans that needlessly expose individuals to potentially harmful biological effects. The problem is medicine does not truly know what the absolute risks or biological hazards that may be associated with this technology, and until medicine discovers them, caution is warranted. All parties should act responsibly by adhering to the ALARA standard, until more studies have been conducted to affirm that ultrasound at the newer energy levels is virtually risk free. Moreover, medicine needs to rethink its policies, and consider adopting more flexible approaches to less conventional practices to meet the needs of modern consumers. In the end, it should be the individual, as an informed consumer, who should enjoy the medical benefits of this technology, not the providers of nondiagnostic imaging services, who seek to entertain or just take advantage of their clientele.