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

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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 the audience that he was able to scan his baby-to-be at any time, but 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 medical community, it also rekindled the ongoing debate among its healthcare providers regarding the appropriate use for this technology.³

Unfortunately, the pace at which ultrasound services are spreading throughout the world, particularly in America, may be exceeding the abilities of regulatory agencies to monitor and maintain consumer safety. Notwithstanding any alleged safety risks ultrasound might pose to

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1. Sarah Hall, E!ONLINE, *Cruise Keeps Eye on Fetus*, Nov. 3, 2005, <http://www.eonline.com/News/Items/PF/0,1,17834,00.html>.

2. *See id.*

3. *See* Fran Kritz, *Doctors Not Fans of Tom Cruise's Baby Gift*, MSNBC, Dec. 6, 2005, <http://msnbc.msn.com/id/10309963/print/i/displaymode/1098/>.

consumers, the American public seems increasingly eager to purchase these services. Although some do see an economic upside for consumers in an environment where ultrasound services are easily purchased, this view may disguise 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 this readily available technology. While ultrasound technology is capable of conferring a variety of health benefits to its consumers, many individuals are now recognizing the economic benefits associated with an expanding market. Some of these clever entrepreneurs, seizing the moment to promote the nondiagnostic applications of this technology, have reached the point where they may be exposing consumers to its potential health risks. If this is the case, then state legislatures, not the Food and Drug Administration (FDA), will bear the responsibility for ensuring that consumers are shielded from harmful 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 ultrasound technology. 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.

Finally, Part V will show how states 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 stakeholders, especially consumers. Unfortunately, state legislative efforts may be unable to address the potential consumer safety issues raised by over-utilization of diagnostic medical ultrasound systems, especially if the branches of state government choose not to work in a spirit of bipartisanship. The final solution may require a fundamental change in diagnostic medical imagers' philosophy toward the practice of their craft and the way they do business.

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 that their customers and the modern medical community rely heavily on this 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 for an estimated 748 million U.S. dollars.⁸ In 2003, the U.S. ultrasound market rose to nearly 1.27 billion dollars.⁹ Today, this market share is estimated at 1.5 billion dollars and many experts 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 After HCDs were first introduced into the market in 1999, manufacturers watched a 5 million dollar market in the United States grow to an estimated 96 million dollars by 2003.¹² Recently, one analyst predicted that HCDs would impact the ultrasound market by their increased availability and

4. Barry B. Goldberg, *Internal Arena of Ultrasound Education*, 22 J. ULTRASOUND MED 549, 549 (2003); WAYNE R. HEDRICK, DAVID L. HYKES & DALE E. STARCHMAN, *ULTRASOUND PHYSICS AND INSTRUMENTATION 1* (Jeanne Rowland & Lisa Potts eds., Mosby 1995) (1985) (“*Ultrasound* is defined as high frequency mechanical waves that humans cannot hear . . .”).

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. *Id.* at 17.

7. Andrew Sinclair, *Strategis, Medical Imaging: Discussion Paper 11* (1998), <http://strategis.ic.gc.ca/pics/hm/finalver.pdf>.

8. *Id.*

9. U.S. Ultrasound Markets, Jan. 6, 2004, <http://www.frost.com/prod/servlet/report-brochure.pag?id=A675-01-00-00-00>.

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 expect this market to grow, especially in the area of Ob-Gyn, which by 2010 is expected to show an annual growth rate of 8 to 10 percent and yield 270 million dollars).

11. U.S. Ultrasound Markets, *supra* note 9.

12. *Id.*

lower cost.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 make their presence known as a more affordable technology. Could it be that HCDs will follow other technologies, such as pocket calculators, laptop computers, and cell phones, and make their way into the hands of consumers?

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 technology when compared to other cross-sectional imaging technologies, such as computerized axial tomography (CT), which exposes individuals to ionizing radiation.¹⁸ Thus, many branches of medicine have sought to incorporate ultrasound technology into their diagnostic armamentariums.¹⁹

Ultrasound now accounts for more than one quarter of all diagnostic medical imaging studies performed throughout the world.²⁰ Although most physicians and the lay public may perceive this technology as risk-free, the risks that do exist are far exceeded by the diagnostic benefits afforded to those scanned with this technology.²¹ The World Health Organization (WHO) underscored this point with its recent endorsement of the

13. See *id.* (stating that the availability of these machines to those who could previously not afford larger, more expensive models could broaden the market base, while touting them as lower cost replacements for these more sophisticated machines could reduce overall revenues).

14. See WAYNE R. HEDRICK, DAVID L. HYKES & DALE E. STARCHMAN, *ULTRASOUND PHYSICS AND INSTRUMENTATION 1* (Jeanne Rowland & Lisa Potts eds., Mosby 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 *id.* at 1, 3.

16. See *id.* at 3.

17. See *id.* at 249-79.

18. See *id.*

19. See *id.*

20. Forsberg, *supra* note 5.

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

distribution and utilization of this technology within third world countries.²² The WHO promoted increased utilization of these systems because they were cheaper than other cross-sectional imaging technologies, such as CT or magnetic resonance imaging (MRI) systems.²³ The WHO also realized that high quality diagnostic images require highly skilled ultrasound operators at their controls if these countries are going to reap the benefits.²⁴ Presumably for this reason, the WHO has encouraged countries to begin ultrasound education programs to ensure that operators will be well trained.²⁵ As long as skilled individuals are at the controls of these powerful diagnostic medical devices, the future of ultrasound use will remain bright; however, due to its wide availability, a dark-side looms on the horizon.

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.²⁶ Now any willing consumer can acquire diagnostic imaging studies without ever seeing his or her primary physician. Consumer-initiated studies have become big businesses because they can get the studies without a note, prescription, or order from a physician.²⁷ Of course, medical insurers may not cover these medical imaging costs²⁸ – but if consumers have the dollars to spend on these studies, then who really cares?

Some clever entrepreneurs have pushed American medical imaging markets to different levels of excess by establishing ultrasound photography and ultrasound entertainment studios.²⁹ Fetal keepsake imaging studios allow expectant mothers to view their developing fetuses for entertainment, rather than meet the medical necessities of either the mother or her baby-to-be.³⁰ Operators of these facilities boast that they can offer expectant mothers and their family members or friends an opportunity to see the fetus in a theater-like atmosphere, for a price.³¹ Ample opportunities await

22. Goldberg, *supra* note 4.

23. *Id.* at 549-50.

24. *Id.*

25. *Id.* at 550.

26. Joshua J. Fenton & Richard A. Deyo, *Patient Self-Referral for Radiologic Screening Tests: Clinical and Ethical Concerns*, 16 J. AM. BD. FAMILY PRACTICE 494, 494 (2003).

27. *See id.*

28. *Id.* at 499.

29. *Id.* at 494.

30. Marc Santora, *In Fetal Photos, New Developments*, N.Y. TIMES, May 17, 2004, at B3, available at <http://www.nytimes.com/2004/05/17/nyregion/17fetus.html?ex=1158379200&en=7b745af36bd6579b&ei=5070>.

31. Dulce Zamora, *Prenatal Portraits: Darling or Dangerous?*, Aug. 10, 2004, available at <http://www.medicinenet.com/script/main/art.asp?articlekey=50337>.

mothers wishing to purchase one of these experiences because keepsake imaging studios are springing up throughout the United States, from California³² to Washington D.C.³³ Other states have their share of centers with catchy titles such as Fetal Photos,³⁴ Womb with a View,³⁵ First Sight Ultrasound,³⁶ and Clearview Ultrasound.³⁷ 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.

B. Imaging Entrepreneurs May Be Using Ultrasound Inappropriately

While Tom Cruise's desire to purchase his very own ultrasound system may seem a bit bizarre or eccentric, the medical community cannot decide whether keepsake imaging qualifies as an inappropriate use for this technology. On one hand, the American Medical Association (AMA) House of Delegates has called for a resolution promoting responsible use of ultrasound technology during pregnancy.³⁸ On the other hand, some physicians, operators, and consumers believe that fetal keepsake imaging is both appropriate and beneficial, particularly for those parents who may use it as a bonding experience with their unborn child.³⁹ Overall, in spite of its purported bonding benefits, most major medical societies have aligned themselves with the FDA and adopted policies opposing the practice of keepsake imaging, as they do not believe this to be the manufacturers' intended use for this technology.⁴⁰

More specifically, the FDA and Code of Federal Regulations classify diagnostic medical ultrasound systems as medical devices.⁴¹ Due to this classification, a licensed physician must issue an order or prescription

32. First Look Sonogram, <http://www.4dbaby.com> (last visited June 29, 2006).

33. Baby Insight, <http://www.baby-insight.com> (last visited June 29, 2006).

34. Fetal Fotos, <http://fetalfotosusa.com> (last visited June 29, 2006).

35. Womb with a View, <http://www.wombwithaview.com> (last visited June 29, 2006).

36. First Sight Ultrasound-Houston, <http://www.expectantmothersguide.com/profiles/FirstSight/index.htm> (last visited June 29, 2006).

37. Clearview Ultrasound, <http://www.clearviewultrasound.com> (last visited Sept. 24, 2006).

38. *AMA Says Ultrasound In-Utero "Portraits" Are Bad Idea*, REUTERS HEALTH, June 21, 2005, available at http://www.acr.org/s_acr/sec_healthnews.asp?CID=3155&DID=21786.

39. Zamora, *supra* note 31.

40. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD & DRUG ADMIN., FETAL KEEPSAKE VIDEOS, <http://fda.gov/cdrh/consumer/fetalvideos.html> (last visited on Oct. 29, 2005).

41. 21 C.F.R. § 884.2225 (2006).

before imaging can take place.⁴² Therefore, not only is keepsake imaging of fetuses considered a potential misuse of a diagnostic medical device, but it also raises concerns related to the performance of medical imaging studies without a supervising physician who can formally report results,⁴³ provide standard counseling,⁴⁴ or perform diagnostic examinations.⁴⁵

A recent case report in medical imaging literature tragically demonstrated all of the aforementioned issues regarding the lack of physician involvement. A mother went to a keepsake imaging studio for scanning and left believing her baby was normal, only to discover during a later diagnostic scan that her baby had significant fetal anomalies.⁴⁶ Unfortunately, the fetus showed all of the ultrasonographic features of Trisomy 18 and Smith-Lemli-Opitz Syndrome, which went undetected or unreported by the operator at the fetal keepsake imaging studio.⁴⁷ Not only did that case raise issues related to failures in detection or reporting of major anomalies, but it also brought serious medical and ethical dilemmas to light for both parents and physicians. Perhaps the most disturbing aspect of this case was the realization that the parents received a false sense of security from the operators of the fetal imaging studio, who did not report the abnormality.⁴⁸ Although this case report illustrated some of the potential pitfalls associated with fetal keepsake imaging, it has done nothing to dissuade the continued performance of these studies by non-physicians.

In fact, some studio operators continue to perform these studies without medical oversight even though they are not licensed to perform such services for nonmedical purposes.⁴⁹ Moreover, the report's concerns did 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 it.⁵⁰ Unfortunately, any future psychological harms related to the mislabeling of abnormal "baby pictures" as normal, when they clearly are not, may never be fully known.⁵¹ More likely than not, the

42. *Id.*

43. American College of Radiology, *ACR Ultrasound Commission Chair Featured in Baltimore Sun Article on Fetal Keepsake Videos*, http://www.acr.org/s_acr/doc.asp?TrackID=&SID=1&DID=21103&CID=2580&VID=2 (last visited on Oct. 29, 2005).

44. *AMA Says Ultrasound In-Utero "Portraits" Are Bad Idea*, *supra* note 38.

45. Naomi Greene & Lawrence D. Platt, *Nonmedical Use of Ultrasound: Greater Harm than Good?*, 24 J. ULTRASOUND MED. 123, 123-24 (2005).

46. *Id.* at 123.

47. *Id.* at 123-24.

48. *Id.* at 124-25.

49. *Id.* at 124.

50. Peter M. Doubilet, Letter to Editor, *Entertainment Ultrasound*, 24 J. ULTRASOUND MED. 251, 251 (2005).

51. See Frank A. Chervenak & Laurence B. McCullough, *An Ethical Critique of*

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.⁵²

In fact, some operators who perform these studies without physician supervision have proclaimed that they will ignore fetal abnormalities even if a “fetus has three legs.”⁵³ The “why” underlying such ridiculous pronouncements remains unclear, but perhaps some 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 diagnosis.⁵⁴ 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 these attitudes probably 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.

In addition to the increasing number of fetal keepsake imaging studies, the number of screening studies obtained without physician referral is also growing.⁵⁵ Now consumers may select from a variety of high-tech imaging technologies, including diagnostic medical ultrasound, to satisfy their perceived imaging needs.⁵⁶ For example, 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.⁵⁷ These van-based ultrasound services now serve consumers in forty-three states.⁵⁸ For many, the lure of these studies is consumers’ belief that they will receive peace of mind after the completion of one of these screening studies.⁵⁹ However, this sense of

Boutique Fetal Imaging: A Case for the Medicalization of Fetal Imaging, 192 AM. J. OBSTETRICS & GYNECOLOGY 31, 32 (2005).

52. Emily Huhn, RESONANCE, *Photo Studio In-Utero*, <http://www.bu.edu/sjmag/scimag2004/storypages/fetalphotos1.htm> (last visited Oct. 16, 2006).

53. Press Release, Am. Institute of Ultrasound Med., AIUM Opposes Uses of Ultrasound for Entertainment (Nov. 5, 2005) (on file with author).

54. Louisiana State Board of Medical Examiners, Statement of Position, Self-Referred Diagnostic Ultrasound Screening, http://www.lsbme.louisiana.gov/position_statement.htm (then click Self-Referred Diagnostic Ultrasound Screening).

55. See Fenton & Deyo, *supra* note 26, at 494.

56. See Thomas H. Lee & Troyen A. Brennan, *Direct-to-Consumer Marketing of High-Technology Screening Tests*, 346 NEW ENG. J. MED. 529, 529 (2002) (explaining that an increasing number of entrepreneurs, including physicians, are offering high technology screening tests to the general public).

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

58. *Id.*

59. Lee & Brennan, *supra* note 56, at 529.

security may only be temporary once they realize that their “lack of a physician referral” means that they may not have access to a physician who is able to receive their report.⁶⁰ Even if a consumer has a physician who will take the report, there is no guarantee that the physician will know how to interpret any abnormal results from a van-based service.⁶¹ 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.⁶²

Nevertheless, the position that diagnostic medical ultrasound occupies within the medical imaging market place will likely continue to expand over the next decade as newer, smaller, and less expensive portable ultrasound systems meet FDA approval and enter into service.⁶³ This industry continues to provide big business to manufacturers, physicians, and entrepreneurs, and it will likely keep on growing with every new piece of ultrasound equipment that rolls off the assembly-line and into the medical imaging market.

Many states are only beginning to appreciate the inherent problems associated with fetal keepsake studies and other 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 this self-referral. Some states, such as Texas, have taken action against fetal keepsake imaging studios by enforcing both state and federal laws that regulate the use of ultrasound technology.⁶⁴ Other states, such as Arizona, have been unable to bring any actions because they lack state laws to regulate these imaging facilities.⁶⁵ In New York, lawmakers have only recently introduced legislation that would restrict the use of diagnostic medical ultrasound on pregnant women unless a licensed physician, nurse practitioner, or licensed midwife either ordered or referred such studies.⁶⁶ Louisiana has attempted to curb non-physician-based ultrasound screening studies by defining them as an unauthorized practice of medicine under

60. See Fenton & Deyo, *supra* note 26, at 494.

61. See *id.* at 494-95.

62. See *id.* at 497-99.

63. See Lidor, *supra* note 10.

64. See Press Release, Tex. Att’y Gen. Greg Abbott, Attorney General Abbott Obtains Agreements with Four Keepsake Ultrasound Imaging Companies (Apr. 7, 2003), <http://www.oag.state.tx.us/oagnews/release.php?id=885>.

65. See Carla McClain, *Parents-to-be Opt for Previews*, ARIZ. DAILY STAR, Jan. 8, 2005, 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).

66. Press Release, NY State Senate, Skelos Introduces Legislation Banning Use of “Keepsake” Ultrasounds (May 6, 2004), http://www.senatordeanskelos.org/press_archive_story.asp?id=8664.

Louisiana law.⁶⁷ 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, as it has yet to close a studio.⁶⁸

California is one state, however, that has taken a proactive approach to the issue of consumer safety by becoming the first state to draft and adopt legislation to regulate the practice of fetal keepsake ultrasound imaging.⁶⁹ In 2005, the California legislature passed a law that requires keepsake imaging providers to inform their consumers that the FDA does not approve of the use of diagnostic medical ultrasound for fetal keepsake imaging:

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 [F]ederal 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."⁷⁰

The California legislature hoped to address the issue of fetal keepsake imaging by increasing consumer awareness of the FDA's disapproval of this practice, and to protect consumers from potential exposure to longer periods of scanning at higher energies.⁷¹ The Legislature recognized that the practice is spreading nationwide and that modern ultrasound technologies produce higher energies, increasing the risk of exposure for women scanned by untrained or unlicensed technicians without a prescription from a physician.⁷² Apparently, the Legislature thought that informing the consumers of the risks in writing would ensure that they would have the opportunity to forego the experience and avoid potentially excessive exposures.

Nevertheless, the California Assembly was forced to revisit the potential consumer safety issues in April 2006, after Tom Cruise declared before a national television audience that he purchased his own ultrasound system and used it to image his fiancée and her developing fetus.⁷³ This time, the Assembly attempted to regulate the access and distribution of diagnostic

67. See Louisiana State Board of Medical Examiners, *supra* note 54.

68. Huhn, *supra* note 52.

69. See CAL. HEALTH & SAFETY CODE § 123620 (West 2006).

70. *Id.*

71. See 2004 Cal. Adv. Legis. Serv. 78 (Deering).

72. See *id.*

73. See *Calif. Lawmaker: Don't Copy Cruise*, CBS NEWS, May 3, 2006, available at <http://cbsnews.com/stories/2006/05/03/politics/main1584906.shtml>.

medical ultrasound systems from manufacturers to untrained persons.⁷⁴ Specifically, it targeted selling, leasing, or otherwise distributing ultrasound systems within the state to a specified group of persons or facilities.⁷⁵ The Assembly believed it was responding to requests from medical professionals at both state and national levels for more regulatory controls on the nonmedical uses of ultrasound imaging devices.⁷⁶ As in the prior legislation addressing the issue of keepsake imaging, the purpose of A.B. 2360 was to ensure consumer safety; the Assembly wanted to protect the fetus from potential neurological and organ damage as well as avoid unnecessary exposures that might potentially damage the internal organs of the mother.⁷⁷

In fact, A.B. 2360 was virtually unopposed when it was initially introduced into the Assembly.⁷⁸ Moreover, it sailed through both the Assembly and Senate, passing 28 ayes to 7 noes, and 72 ayes to 7 noes, respectively.⁷⁹ Unfortunately, Governor Schwarzenegger chose to terminate the process by vetoing it. The Governor cited his signing of A.B. 2049 in 2004, which requires both written notice that the FDA recommends against the use of ultrasound for nonmedical purposes, and the existence of other laws regulating the purchase and operation of ultrasound diagnostic equipment.⁸⁰ Governor Schwarzenegger was correct in stating that California has other laws regulating the ownership and operation of these systems.⁸¹ However, effective enforcement relies on action taken by local

74. *Hearing Before Assembly Comm. on Health*, Assemb. B. 2360 (Ca. 2006) Analysis Information, http://www.leginfo.ca.gov/pub/bill/asm/ab_23512400/ab_2360_cfa_20060403_154807_asm_comm.html (recognizing that fetal imaging with ultrasound is generally safe when performed by a physician, sonographer, or other trained professional, but if these systems are used improperly, they could potentially cause neurological damage to the fetus as well as potential damage to the internal organs of both the mother and her fetus).

75. A.B. 2360, 2005-06 Leg., Reg. Sess. (Cal. 2006).

76. Press Release, Am. C. of Radiology, *Tom Cruise's Reported Unsupervised use of Fetal Keepsake Ultrasound Raises Risk for Baby and Is Potentially Unlawful* (Nov. 29, 2005), http://www.acr.org/s_acr/doc.asp?TrackID=&SID=1&DID=22898&CID=1836&VID=2&RTID=0&CIDQS=&Taxonomy=False&specialSearch=False.

77. See *Hearing Before Assembly Comm. on Health*, *supra* note 74.

78. *Complete Bill History*, Assemb. B. 2360 (Ca. 2006), http://www.leginfo.ca.gov/pub/bill/asm/ab_23512400/ab_2360_bill_20060930_history.html.

79. See *id.*

80. See Press Release, Arnold Schwarzenegger, *Veto Message Addressing Members of the California State Assembly*, available at <http://gov.ca.gov/index.php/?/press-release/4237/>.

81. See CAL. HEALTH & SAFETY CODE § 101070 (West 2006); see also CAL. HEALTH & SAFETY CODE § 11352.1 (West 2006) (discussing dispensing of dangerous drugs including dangerous devices); see also CAL. BUS. & PROF. CODE § 4022 (West 2006) (supplying the definition of dangerous device, which relates to labeling requirements of the FDA); see also 21 C.F.R. § 801.109 (2006).

health officers, who must be made aware of an existing violation.⁸² Even though the reasoning underpinning the veto seems sound, one must wonder how effective the enforcement of these laws can be when lay consumers, like Tom Cruise, have not been charged with any violation of California law.

Modern medicine becomes more consumer-driven with each passing day. Consumers who want these services and are able to afford them will seek them out wherever and however they can. However, safety, not consumer-driven self-gratification or monetary gain, should be the primary driver in the regulatory debate. Moreover, the arguments should not be couched in terms of a turf war, with jealous physicians 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 their 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 ultrasound⁸³ and it requested assistance from members of the ultrasound industry, as well as the medical community, to discourage consumers from seeking these services.⁸⁴ The FDA's primary concern was patient safety because reports were surfacing that some pregnant consumers were scanned for up to one hour.⁸⁵ Some physicians question the position adopted by the FDA, even though the agency has left jurisdiction over ultrasound practices and personnel to the states.⁸⁶ These physicians appear to question FDA attempts to restrict the use of ultrasound devices based on the lack of documented injuries attributed to ultrasound in over three decades of use.⁸⁷

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

As Title 21 of the Code of Federal Regulations classifies diagnostic medical ultrasound systems as Class II devices, states may apply the existing federal regulations covering these systems whether intended for

82. See CAL. HEALTH & SAFETY CODE § 101070 (West 2006).

83. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *supra* note 40.

84. *Id.*

85. *Id.*

86. See Zamora, *Prenatal Portraits: Darling or Dangerous?*, *supra* note 31.

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

obstetrical⁸⁸ or non-obstetrical⁸⁹ use. The existing regulations further define ultrasound systems utilized in non-obstetrical imaging as either “ultrasonic pulsed [D]oppler imaging systems”⁹⁰ or “ultrasonic pulsed echo imaging systems.”⁹¹ Title 21 also covers ultrasound equipment, such as the diagnostic ultrasonic transducer, which is defined as a device that utilizes a piezoelectric material to generate sound waves from electrical impulses.⁹² These regulations also address the major accessories required in acoustical image acquisition, such as acoustical gel, by also classifying them as devices.⁹³ All of these items qualify as devices, so they fall under the definition of a “prescription device,” meaning that a physician must give an oral or written order for their use.⁹⁴

Moreover, the regulations require an operator of “device-user-facility” to report to the FDA any deaths or serious injuries that may have occurred during the operation of one of these devices.⁹⁵ A device user facility may be a “hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility . . . which is not a physician’s office”⁹⁶ An operator of a device user facility must also make Medical Device Reports (MDR) annually,⁹⁷ create written MDR reporting procedures,⁹⁸ and keep written MDR reports on file for inspection by the FDA.⁹⁹ Clearly, these Title 21 regulations acknowledge the concern for potential harm, which the FDA has also addressed by stating that operators who misuse ultrasound by performing imaging services “without

88. 21 C.F.R. § 884.2225 (2006) (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 structure, or fetus, for diagnostic purposes during a limited period of time. (b) Classification. Class II (performance standards).”).

89. *Id.* § 892.1560 (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.”).

90. *Id.*

91. *Id.* § 892.1550.

92. *Id.* § 892.1570.

93. *Id.*

94. 21 C.F.R. § 801.109 (2006).

95. *Id.* § 803.1.

96. *Id.* § 803.3.

97. *Id.* § 803.10.

98. *Id.* § 803.17.

99. *Id.* § 803.18.

a physician's order may be violating state or local laws or regulations regarding the use of a prescription medical device."¹⁰⁰

Unfortunately, states can have mixed results when bringing enforcement actions against those who perform fetal keepsake imaging studies because ultrasound devices fall under Class II, not Class III devices.¹⁰¹ Although a Class II device is subject to special controls,¹⁰² it is not subject to the more stringent requirements placed on Class III devices in terms of overall safety and potential for significant risk of illness or injury.¹⁰³ Even though operators may be performing nondiagnostic studies when they provide keepsake imaging services, this does not mean they have substantially altered the use of this technology to qualify it as a "new intended use" and thereby upgrade its classification to Class III.¹⁰⁴ Furthermore, operators may violate some sections of federal regulations but not others, which can prohibit states from successfully enforcing regulations that require a link between acts and specific code or regulatory violations.¹⁰⁵

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 have enacted drug laws to regulate the use of medical devices within its borders. Texas law classifies diagnostic medical ultrasound systems as a "device."¹⁰⁶ In addition, Texas considers this specific technology to be a "dangerous drug."¹⁰⁷ A person violates the Dangerous Drug Act (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)."¹⁰⁸ 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 nurse or physician assistant ... under sect. 157 of the Tex. Occ. Code."¹⁰⁹ A person may also

100. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *supra* note 40.

101. *See Rayford v. State*, 16 S.W.3d 203, 207-08 (Tex. App. 2000).

102. *See Federal Food, Drug, and Cosmetic Act*, 21 U.S.C.A. § 360c(a)(1)(B) (West 2006).

103. 21 U.S.C.A. § 360c(a)(1)(C) (West 2006).

104. *See Rayford*, 16 S.W.3d at 207-08.

105. *See id.* at 208.

106. *See TEX. HEALTH & SAFETY CODE ANN.* § 431.002(13) (Vernon Supp. 2006).

107. *See id.* § 483.001(2).

108. *Id.* § 483.041(a).

109. *Id.* § 483.042.

violate the Texas Food, Drug, and Cosmetic Act by using diagnostic medical ultrasound in a manner that the FDA did not intend, which thus “adulterates the device.”¹¹⁰ The same law also states that a violation occurs if the device is falsely or inappropriately labeled or advertised.¹¹¹ Texas clearly foresees the potential for misuse that could pose a risk to the public, and as a result seeks to regulate in this particular area. Unfortunately, not all physicians or members of the public appreciate the inherent risks associated with this technology because they assume that little or no risk exists.¹¹² Additionally, the courts may not agree on which practices or acts violate a given regulatory section.¹¹³

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 risk to those scanned with it? To answer this question, one must understand the basic physical principles underlying the generation of ultrasound waves and their relative theoretical risks. The physical principles key to any discussion of the risks associated with diagnostic medical ultrasound are related to sound wave generation, intensity, and mechanics.¹¹⁴ Periodic changes in the pressure within a medium, such as air or water, cause the molecules to oscillate in a repetitive fashion, thereby producing mechanical energy in the form of audible sound.¹¹⁵ 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.¹¹⁶ In order for sound to propagate through a medium, it must interact with a medium that is elastically deformable.¹¹⁷ Thus, sound propagates through tissue within an energy spectrum. Because it is outside of an energy spectrum for ionizing radiation or electromagnetic radiation, it lacks the risks associated

110. *See id.* § 431.111.

111. *Id.* § 431.112.

112. Zamora, *supra* note 31.

113. *See Rayford*, 16 S.W.3d at 208-11 (explaining why the practice of fetal keepsake imaging by non-physicians may violate certain sections of the Code of Federal Regulations, but not other sections, and demonstrating that different courts may interpret statutory language differently).

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

115. *Id.* at 1.

116. *Id.* at 3.

117. *Id.* at 1.

with conventional x-rays.¹¹⁸ Nevertheless, several physical parameters of ultrasound may cause biological effects worthy of regulation.¹¹⁹

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.”¹²⁰ Unfortunately, the absolute intensity of modern systems is difficult to determine because they utilize pulsating scanning technologies that produce complex ultrasound fields that vary over time.¹²¹ 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.¹²² Thus, the inherent characteristics of the beam that most modern ultrasound systems produce explain why the FDA and other organizations continue to oppose non-diagnostic uses.¹²³

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 on humans were methodologically flawed.¹²⁴ Some of these early studies were also performed with ultrasound systems that operate at much lower powers or output intensities than the systems used in most facilities today.¹²⁵ Moreover, many of these early studies were performed on animals that received ultrasound exposures at higher levels and longer durations than those achieved with the current clinical systems.¹²⁶ Any extrapolations from past animal studies to current human experience may be tenuous at best.¹²⁷ The bottom line is that the absolute risks posed by diagnostic

118. See *id.* at 249-55.

119. Stanley B. Barnett et al., *International Recommendation and Guidelines for the Safe Use of Diagnostic Ultrasound in Medicine*, 26 *ULTRASOUND MED. & BIOLOGY* 355, 356 (2000) (explaining that rising output levels on modern systems may substantially increase the intensity and exposure levels tissues receive).

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

121. *Id.*

122. See *id.* at 250-53.

123. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *supra* note 40.

124. See Barnett et al., *supra* note 119, at 357.

125. See *id.* at 356.

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

127. See *id.* at 260.

medical ultrasound may not be known until more rigorous research occurs at the higher energy levels employed by modern ultrasound systems.¹²⁸

Overall, system factors such as output levels and transmission frequencies, as well as operator associated factors, impact patient safety.¹²⁹ Operators now have the ability to control the intensity and transmission frequencies selected during an ultrasound exam, which in turn modulate the potential biological effects that could result.¹³⁰ 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.¹³¹ Scan times for operators may vary depending on the individual's skill, the degree of complexity of the subject, or the overall level of difficulty in obtaining a complete diagnostic.¹³² 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.¹³³ 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.¹³⁴ Thus, well-trained operators should scan only as long as necessary to acquire the appropriate diagnostic information.¹³⁵

C. Risk Related to Ultrasound 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.¹³⁶ 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 .¹³⁷ The intensity, measured as I_{SPTA} , for any ultrasound system varies depending upon the type of ultrasound study performed.¹³⁸ The FDA has allowed manufacturers to achieve these

128. See Barnett et al., *supra* note 119, at 358.

129. See *id.*

130. *Id.* at 359.

131. *Id.*

132. *Id.*

133. *Id.*

134. See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 267 (noting that the overlying tissue in humans may reduce the dose of ultrasound received).

135. 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> (last visited Oct. 18, 2006).

136. See Barnett et al., *supra* note 119, at 355-56.

137. *Id.* at 359.

138. 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

higher intensity levels as long as their systems can display output information related to the ultrasound intensity.¹³⁹ Thus, it may now be possible for a medical ultrasound system to expose the fetus or embryo to eight times the intensity previously allowed.¹⁴⁰ Additionally, a recent study performed on ultrasound equipment in the United Kingdom suggested that the intensity levels achievable with modern diagnostic systems might be greater than expected.¹⁴¹

The FDA currently allows ultrasound equipment manufacturers to achieve higher intensities up to the 720 mW/cm² maximum if their system can display two key potential predictors of biological effects, mechanical index and thermal index, on their output display screen.¹⁴² These two indices reflect the three potential interactions the ultrasound beam may have with human tissue that can cause damage: mechanical (direct or indirect tissue damage), thermal (tissue heating), and cavitation (inertial and noninertial forms).¹⁴³ Secondary effects of these interactions may cause additional tissue damage, though this depends on both the type of tissue affected as well as the type and intensity of the beam.¹⁴⁴ Still, modern system manufacturers may obtain FDA approval for their systems if they display the mechanical and thermal indices for the operator to manipulate and adopt the Output Display Standard (ODS).¹⁴⁵

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

The ODS was established as a means to inform the operator of the machine's outputs, and it includes parameters by which operators may gauge the potential for harmful effects due to the machine's intensity.¹⁴⁶ Unfortunately, no absolute index values are available for the thermal index and mechanical index, which are components of the ODS.¹⁴⁷ The current recommendation to the ultrasound operator is to keep these values as low as

phased array and mechanical scanners (2 to 200 mW/cm²), pulsed Doppler for obstetric studies (0.6 to 75 mW/cm²), and pulsed Doppler for peripheral vascular studies (350 to 700 mW/cm²).

139. See Fowlkes, *supra* note 135, at 2.

140. Barnett et al., *supra* note 119, at 356.

141. *Id.* at 359.

142. See *id.* at 358-59; see also John G. Abbott, *Rationale and Derivation of MI and TI—A Review*, 25 *ULTRASOUND MED. & BIOLOGY* 431, 431-32 (1998).

143. John G. Abbott, *Rationale and Derivation of MI and TI—A Review*, 25 *ULTRASOUND MED. & BIOLOGY* 431, 431-32 (1998).

144. Stanley B. Barnett et al., *The Sensitivity of Biological Tissues to Ultrasound*, 23 *ULTRASOUND MED. & BIOLOGY* 805, 805 (1997).

145. See Fowlkes, *supra* note 135, at 3.

146. See *id.* at 2.

147. See Barnett et al., *supra* note 119, at 358-60.

possible to satisfy regulatory requirements.¹⁴⁸ If display indices rise above one, then the operator should take appropriate countermeasures to lower it, keeping the exposure “as low as reasonably achievable (ALARA).”¹⁴⁹ Appropriate countermeasures may include reducing the pulse repetition frequency, reducing the dwell time, or any other parameter that will reduce exposure while maintaining image quality.¹⁵⁰

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 this information in a manner that is easily accessed or understood by the operator.¹⁵¹ One of the potential problems associated with both the system itself and the relaxation of the FDA requirements is that some operators may not understand the implications of the ODS.¹⁵² 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.¹⁵³ In fact, some operators were observed to be scanning healthy models at thermal indices that exceeded the upper limit.¹⁵⁴ Others were caught unaware of the British guidelines mandating that exposure levels be kept to a minimum when scanning models.¹⁵⁵ These observations are worrisome because they suggest that other less knowledgeable or less experienced operators in general practice may not be aware of the ODS.¹⁵⁶

If this anecdote is applicable throughout the field, then the ODS may not serve its purpose when operators do not understand its use. If it is not effective, then federal and state authorities may have an even greater need to regulate non-medical uses of this technology, as patients may be experiencing unnecessary exposures to higher acoustical energy levels during fetal keepsake imaging. In spite of this possibility, many continue to believe that the FDA classification of ultrasound as a “prescription device” and disapproval of non-medically related ultrasounds is misplaced because

148. Colin Deane, *Safety of Diagnostic Ultrasound in Fetal Scanning*, http://www.centrus.com.br/DiplomaFMF/SeriesFMF/doppler/capitulos-html/chapter_02.htm (last visited Oct. 16, 2006).

149. Barnett et al., *supra* note 119, at 360, 363.

150. *Id.* at 360, 362.

151. *See id.* at 358-60.

152. *See* Fowlkes, *supra* note 135, at 2.

153. Stanley B. Barnett, *Live Scanning at Ultrasound Scientific Conferences and the Need for Prudent Policy*, 29 *ULTRASOUND MED. & BIOLOGY* 1071, 1075 (2003).

154. *Id.*

155. *Id.*

156. *Id.*

no acute harmful effects have been definitively shown in humans in over three decades of scanning.¹⁵⁷

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

Unfortunately, much information on biological effects of ultrasound on humans is undiscovered. Many variables may determine if and when the ultrasound beam will cause a biological effect,¹⁵⁸ and whether it could potentially cause tissue damage. These effects will depend on the wave mechanics as well as the tissue system coming into contact with the beam.¹⁵⁹ Examples include the acoustical properties of the beam and the characteristics of the tissue scanned, such as its biological properties, functions, and location.¹⁶⁰ While these factors may limit any manifestation of tissue injury, if the tissue involves a critical pathway such as the nervous system or the rapidly dividing cells in a developing embryo, a higher sensitivity can be assumed.¹⁶¹

If ultrasound is going to cause a tissue injury, it will do so through mechanical, thermal, or cavitation effects on the surrounding tissues.¹⁶² Any mechanical effects that might occur generally do so near solid boundaries.¹⁶³ Yet the potential for thermal effects related to beam heating of tissues raises the most concern for production of biological effects.¹⁶⁴ Temperature alterations in tissue may be affected by the intensity of the ultrasound beam, as well as by the properties of the tissues and their physiologic surroundings.¹⁶⁵ 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 little, if any, of the acoustical energy of the beam.¹⁶⁶ Alternatively, skin, tendons, spinal

157. See Zamora, *supra* note 31.

158. See HEDRICK, HYKES & STARCHMAN, *supra* note 14, at 257-61.

159. Barnett et al., *supra* note 144, at 806.

160. *Id.* at 805.

161. *Id.* at 809.

162. See *id.* at 806-07.

163. See *id.* at 806 (discussing the physical principles underlying the production of mechanical injury, which may be caused either directly or indirectly).

164. See *id.* at 806-08.

165. See Barnett et al., *supra* note 144, at 806-07 (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 that additional factors, such as dwell time, absorption coefficients of the tissue, and thermal conduction properties of tissue also impact tissue heating).

166. See *id.*

cord, and bone all have increased protein content, putting them at risk for heating.¹⁶⁷ For example, recent recommendations warn that a diagnostic exposure that raises *in situ* temperature to four degrees Celsius above normal for more than five minutes should be considered hazardous.¹⁶⁸

Despite this understanding of the physical properties of diagnostic exposure, no unequivocal research directly addresses fetal development as it relates to ultrasound intensity.¹⁶⁹ Any ultrasound-induced thermal damage remains a theoretical risk, but the mere existence of this possibility suggests that operators must exercise caution when they scan these individuals above the recommended thermal index. 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,¹⁷⁰ especially in gas-containing organs, such as bowel.¹⁷¹ These inertial cavitation effects have the potential to break chemical bonds and form biological free radicals.¹⁷² Although these free radicals could bind with DNA and cause chromosomal damage, this event has not been demonstrated thus far.¹⁷³ When inertial cavitation effects have been detected, they occurred at gas-tissue interfaces, such as mammalian lung, at energy levels within the diagnostic range.¹⁷⁴ In one study that detected cavitation effects in animal models, these effects were associated with pulmonary capillary bleeding or extravasation.¹⁷⁵ This observation raised concern for similar effects in humans, especially in clinical situations where gas may be present, such as gas-forming infections or infusions.¹⁷⁶

Based on the foregoing discussion, the potential for biological effects on humans is real, but unfortunately very little epidemiological data is available to support the existence of such effects.¹⁷⁷ Some early studies demonstrated neurologic effects in children, such as an abnormal grasp, tonic neck reflex, or dyslexia, but these may have been chance findings due to multiple hypothesis testing.¹⁷⁸ Another study observed a higher

167. *Id.*

168. *See* Deane, *supra* note 148.

169. *See id.*

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

171. Barnett et al., *supra* note 144, at 807-08.

172. *Id.*

173. *Id.* at 808.

174. *Id.*

175. A. F. Tarantal & D. R. Canfield, *Ultrasound Induced Lung Hemorrhage in the Monkey*, 20 *ULTRASOUND MED. & BIOLOGY* 65, 69 (1994).

176. Barnett et al., *supra* note 144, at 808.

177. *See* Barnett et al., *supra* note 119, at 357.

178. Kjell Å. Salvesen & Sturla H. Eik-Nes, *Ultrasound During Pregnancy and Birthweight, Childhood Malignancies and Neurological Development*, 25 *ULTRASOUND*

incidence of delayed speech in children exposed to ultrasound *in utero* than in those not scanned with ultrasound.¹⁷⁹ However, the actual statistical significance of this observation is questionable because the number of children studied was small and bias could have been a factor.¹⁸⁰ Yet another study revealed reductions in birth weight, but this study may have been designed to test an unrelated hypothesis.¹⁸¹ Additionally, due to the potential for sister chromatid damage, studies have looked at childhood cancer, but so far none have demonstrated an association with *in utero* ultrasound exposure.¹⁸² Concern for the potential of left-handedness in children exposed to ultrasound *in utero* has been assessed, but no definite relationship has been confirmed.¹⁸³ A subgroup analysis has shown a slightly statistically significant difference in males.¹⁸⁴

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 results are gathered. Clearly, much of the data is methodologically flawed.¹⁸⁵ This alone should support further FDA enforcement of the current regulations, and unfettered scanning should be avoided until more studies are done.¹⁸⁶

IV. WORLDWIDE MEDICAL ORGANIZATIONS PROMULGATE POLICES 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 have also advised caution.¹⁸⁷ As such, all have recognized the potential for biological effects created by modern ultrasound systems.¹⁸⁸ For example, the WFUMB

MED. & BIOLOGY 1025, 1025 (1999).

179. *Id.* at 1026.

180. *Id.*

181. *Id.* at 1028.

182. *Id.* at 1025, 1028.

183. *Id.* at 1029.

184. Kjell Å. Salvesen & Sturla H. Eik-Nes, *Ultrasound During Pregnancy and Birthweight, Childhood Malignancies and Neurological Development*, 25 *ULTRASOUND MED. & BIOLOGY* 1025, 1029 (1999).

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

186. *See* Salvesen et al., *supra* note 178, at 1029-30.

187. *See* Barnett et al., *supra* note 119, at 360-63.

188. *See id.*

recommends that scanning time be as short as possible with controlled low power output, yet be sufficient enough to obtain “diagnostic information.”¹⁸⁹ The ASUM has also emphasized the use of care, recommending the prudent use of ultrasound through adherence to the ALARA principle to minimize exposures.¹⁹⁰ It also recognizes that the current FDA regulatory limit, set at the 720 mW/cm² (I_{SPTA}) maximum, may lead to temperature increases greater than two degrees Celsius, which can result in developmental abnormalities.¹⁹¹ Moreover, ASUM emphasized that users must appreciate the design of their equipment and realize that the indices of the ODS may not accurately predict the conditions at the tissue level during scanning.¹⁹² Additionally, EFSUMB stated that modern equipment is subject to output regulation, yet classified its statements as mere recommendations.¹⁹³ If the major world ultrasound organizations recognize the need for caution and advise prudence in the use of ultrasound, then it should be no surprise that their American counterparts advise the same and express opposition to nonmedical uses as well.

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 Ultrasound in Medicine (AIUM) has published an official statement regarding the need for the “prudent use” of diagnostic medical sonography,¹⁹⁴ even though it generally considers the technology to be safe.¹⁹⁵ The American College of Obstetricians and Gynecologists (ACOG) has also recognized this “prudent use” standard.¹⁹⁶ 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

189. *See id.* at 361.

190. *Id.* at 362.

191. *Id.*

192. *Id.*

193. *See Barnett et al., supra* note 119, at 363.

194. AIUM, Official Statements, Prudent Use (May 2, 1999), <http://www.aium.org/publications/statements/statements.asp> (then select “Prudent Use”).

195. AIUM, Official Statements, Clinical Safety (Mar. 26, 1997), <http://www.aium.org/publications/statements/statements.asp> (then select “Clinical Safety”).

196. The Am. Coll. of Obstetricians and Gynecologists, Committee on Ethics Committee Opinion No.297, *Nonmedical Use of Obstetric Ultrasonography*, 104 OBSTETRICS & GYNECOLOGY 423, 423 (2004).

medical reason, and performed at the lowest levels possible.¹⁹⁷ The Society of Diagnostic Medical Sonography (SDMS), in its practice guidelines, recommends that its members, as ultrasound technologists, “adhere to the standards, polices, and procedures adopted by the profession and regulated by the law.”¹⁹⁸ The likely goal of all organizations and their recommendations is to promote patient safety. Additionally, these organizations have shown that they understand the potential for harmful biologic effects and now oppose the nonmedical use of this technology.

B. American Organizations Oppose Fetal Keepsake Imaging

The same societies and organizations have addressed the nonmedical use issue with regard to keepsake fetal imaging. The AIUM recently issued a statement in which it recommended that “licensed medical professionals (either physicians or registered or . . . eligible sonographers) who have received specialized training in fetal imaging” perform these studies.¹⁹⁹ These professionals should have a working knowledge of medically important conditions and be able to distinguish imaging artifacts from pathology.²⁰⁰ The AIUM further stated that “[a]ny other use of ‘limited medical ultrasound’ may constitute the practice of medicine without a license.”²⁰¹ The AMA has also expressed its disapproval by adopting the FDA policy recognizing fetal keepsake videos as an “unapproved use of a medical device.”²⁰² Furthermore, its House of Delegates has urged the FDA to take action against this use.²⁰³ The ACR, in its practice guidelines related to obstetrical ultrasound, also takes the position that keepsake fetal imaging is an unapproved use.²⁰⁴ The SDMS also has weighed in on this issue, publishing a position statement opposing “the use of ultrasound solely for entertainment purposes.”²⁰⁵ It would seem that the opposition registered by

197. Am. Coll. of Radiology, ACR Practice Guidelines for Performing and Interpreting Diagnostic Ultrasound Examinations 836 (Oct. 1, 2006), http://www.acr.org/s_acr/sec.asp?CID=539&DID=14200 (then click ACR Practice Guidelines for Performing and Interpreting Diagnostic Ultrasound Examinations).

198. Soc’y of Diagnostic Med. Sonography, Diagnostic Ultrasound Clinical Practice Standards, <http://www.sdms.org/positions/clinicalpractice.asp> (last visited Sept. 25, 2006).

199. Press Release, AIUM, The AIUM Releases New Statement Regarding Keepsake Imaging (Aug. 1, 2005), http://www.aium.org/pressRoom/_releasesContent.asp?id=94.

200. *Id.*

201. *Id.*

202. *AMA Says Ultrasound In-Utero “Portraits” Are Bad Idea*, *supra* note 38.

203. *Id.*

204. Am. Coll. of Radiology, ACR Practice Guideline for the Performance of Antepartum Obstetrical Ultrasound 900 (2006), http://www.acr.org/s_acr/sec.asp?CID=539&DID=14200 (then click ACR Practice Guideline for the Performance of Antepartum Obstetrical Ultrasound).

205. Soc’y of Diagnostic Med. Sonography, SDMS Position Statement, Non-Diagnostic

laws, guidelines, and position statements would curb fetal keepsake imaging, yet the practice continues.

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

In addition to fetal keepsake imaging, ultrasound imaging entrepreneurs have also directed their attention to the medical screening market, where they are now soliciting customers in order to scan for disease within an asymptomatic population.²⁰⁶ Carotid ultrasound and heel ultrasound are only two of the many ultrasound-based studies that have been used as a screening tool for various diseases.²⁰⁷ For any study to be effective as a screening tool, it must have a relatively high positive predictive value, and a high prevalence of the disease must also exist within the population screened.²⁰⁸ Importantly, if the incidence or prevalence of disease within a population is low, then the positive predictive value of any positive screening test will also be low, even if the test has both a high sensitivity and specificity.²⁰⁹ If these assumptions are correct, as some authors believe, then performance of carotid or heel ultrasound may not satisfy the criteria for effective screening studies within an asymptomatic population.²¹⁰

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

In the case of carotid ultrasound, the goals of screening are to detect patients with carotid stenosis (CS) that is greater than fifty percent and then select those from that group who will benefit from remedial measures, such as carotid endarterectomy.²¹¹ Some authors, relying on data from existing ultrasound screening studies, estimate that the prevalence of an asymptomatic CS greater than fifty percent within the general population may be somewhere between two and eight percent, whereas the prevalence for a CS greater than eighty percent may reside somewhere between one and two percent.²¹² Assuming then that the yearly estimates of the risks for stroke and death for a CS of fifty percent or greater (sixteen percent), and

Use of Ultrasound (Oct.13, 2004), <http://www.sdms.org/positions/nondiagnostic.asp>.

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

207. *Id.* at 496.

208. *Id.* at 494.

209. *Id.*

210. *Id.* at 496.

211. Andrew B. Hill, *Should Patients be Screened for Asymptomatic Carotid Artery Stenosis?*, 41 CAN. J. SURG. 208, 208-13 (1998), available at http://www.cma.ca/index.cfm/ci_id/34790/la_id/1.htm.

212. *Id.* at 208-10.

for a CS of eighty percent (less than one percent), are correct, the detection of a single stroke from a population with this disease prevalence range may require the screening of hundreds or thousands of asymptomatic individuals.²¹³

The screening issue becomes further complicated when one realizes that the best sensitivity achievable with some modern ultrasound systems approaches ninety-five percent.²¹⁴ At that level of sensitivity, the best positive predictive value for detection of disease within the general population for a CS greater than fifty percent would approach fifty percent, and for a CS greater than eighty percent, it would only be sixteen percent.²¹⁵ Accepting these estimates of the number asymptomatic patients required for screening to avoid one stroke,²¹⁶ one can only guess at the possible number of ultrasound screening exams that might be needed at sensitivity levels below ninety-five percent.

As 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.²¹⁷ Therefore, these predictive values would be too low to qualify ultrasound as a screening study for carotid disease in an asymptomatic population.²¹⁸ Not only is this situation likely to lead to some patients receiving unwarranted studies and interventions, but it also may not be cost-effective based on the quality of life adjusted years achieved for this group of patients.²¹⁹

Notwithstanding the current body of literature questioning the use of carotid ultrasound to screen asymptomatic patients, some authors do believe that these patients can be screened in a cost-effective fashion with power Doppler (utilizing signal strength displayed in color rather than speed and direction).²²⁰ However, because the predictive value is low, the use of

213. *Id.*

214. *Id.*

215. *Id.*

216. *Id.*

217. *See Hill, supra* note 211, at 208-10.

218. *Id.* at 209-10.

219. Tina T. Lee et al., *Cost-Effectiveness of Screening for Carotid Stenosis in Asymptomatic Persons*, 126 ANNALS INTERNAL MED. 337, 343 (1997), available at <http://www.annals.org/cgi/content/full/126/5/337?maxtoshow=&HITS=10&hits=10&RESU LTFORMAT=&fulltext=Cost=Effectiveness+of+Screening+for+Carotid+Stenosis+in+Asy mptomatic+Persons&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>.

220. Edward I. Bluth et al., *Power Doppler Imaging: Initial Evaluation as a Screening Examination for Carotid Artery Stenosis*, 215 RADIOLOGY 791, 791-92 (2000), available at <http://radiology.rsna.org/cgi/content/full/215/3/791>.

carotid ultrasound to screen patients for asymptomatic stenosis remains questionable, with more research needed to resolve the controversy.²²¹

The same may be said for the use of heel ultrasounds to screen women at low risk for osteoporosis, the prevalence of which is estimated at six percent.²²² The current specificities reported for heel ultrasound may vary from sixty to eighty two percent.²²³ Moreover, the low prevalence of disease within the population screened, coupled with the low sensitivity of heel ultrasound, could lead to false negatives.²²⁴ Thus, both heel and carotid ultrasound screening may be inappropriate for use in the general population. Even so, the market is rich with those seeking consumers for these types of services. For example, one mobile ultrasound screening company alone has the ability to perform these tests without a referral in forty-three states.²²⁵

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 establish the efficacy of these studies.²²⁶ Similarly, the United States Preventive Services Task Force did not recommend ultrasound screening for carotid disease.²²⁷ While that organization has found evidence to support a one time scan for abdominal aortic aneurysms in men aged 65 to 75 who have ever smoked, the organization makes no recommendation for or against screening for men who have never smoked.²²⁸ Likewise, the American Academy of Family Physicians

221. C. J. M. Whitty et al., *Investigating Individual Subjects and Screening Population for Asymptomatic Carotid Stenosis Can Be Harmful*, 64 J. NEUROLOGY NEUROSURGERY PSYCHIATRY 619, 619 (1998), available at <http://jnnp.bmjournals.com/cgi/content/abstract/64/5/619?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=whitty&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT> (then click “full .pdf”).

222. Fenton & Deyo, *supra* note 26, at 496.

223. *Id.*

224. *Id.* at 497.

225. *Id.* at 494.

226. AIUM, Official Statements, Carotid Screening in the Asymptomatic Patient (June 2003), <http://www.aium.org/publications/statements/statements.asp> (then select “Carotid Screening in the Asymptomatic Patient”).

227. U.S. PREVENTIVE SERVS. TASK FORCE, GUIDE TO CLINICAL PREVENTIVE SERVICES 59 (2d ed. 1996), available at <http://odphp.osophs.dhhs.gov/pubs/guidecps/PDF/CH04.PDF>.

228. U.S. Preventive Servs. Task Force, Recommendation Statement, Screening for Abdominal Aortic Aneurysm, <http://www.ahrq.gov/clinic/uspstf05/aaascr/aaars.htm> (last visited Nov. 20, 2006).

recommends against using Doppler or duplex ultrasound to screen patients who are asymptomatic for peripheral arterial disease.²²⁹

The clinical benefits of screening asymptomatic patients with carotid ultrasound are unproven, with the potential for unintended consequences. For example, this type of screening may lead to additional unnecessary studies that might put the patient at risk, or conversely, the patient may use any results as a substitute for the advice of their physician.²³⁰ Moreover, health insurers generally do not cover these types of screening studies, meaning the purchaser covers its cost as an out-of-pocket expense.²³¹ As some studies will lead to false positive results, additional studies will be required, which will necessarily drive up costs.²³² The primary care physician and the healthcare system may also incur costs from 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.²³³ In spite of all this, the rapid growth of the ultrasound screening business continues.²³⁴

V. KEEPSAKE IMAGING COMPANIES MAY BE VIOLATING FEDERAL DRUG LAWS

A recent survey of keepsake fetal imaging services advertising on the Internet revealed multiple hits for services all over the country.²³⁵ Most, if not all, of these facilities have websites that advertise their use of both registered diagnostic medical sonographers and the most modern ultrasound imaging systems available.²³⁶ At least two keepsake imaging companies, Clearview and Baby Insight, have claimed that their technologists perform studies with modern, top-of-the-line systems.²³⁷ All of these companies must vie for the same set of consumers, so it should be no surprise that they

229. Am. Acad. of Family Physicians, Summary of Recommendations for Clinical Preventive Services 12 (Apr. 2006), available at http://www.aafp.org/online/etc/medialib/aafp_org/documents/clinical/CPS/rcps08-005.Par.0001.File.tmp/CPSfinalApril2006%20.pdf.

230. Alan B. Jotkowitz et al., *Screening for Carotid Artery Disease in the General Public*, 16 EUROPEAN J. INTERNAL MED. 34, 35 (2005).

231. See Fenton & Deyo, *supra* note 26, at 498-99.

232. Lee & Brennan, *supra* note 56, at 530.

233. *Id.*

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

235. First Look Sonogram, *supra* note 32; see also Clearview Ultrasound, *supra* note 37; see also Baby Insight, *supra* note 33; see also Fetal Fotos, *supra* note 34; see also Womb with a View, *supra* note 35.

236. Baby's First Images, <http://www.babysfirstimages.com/answers.htm> (last visited Sept. 24, 2006).

237. Clearview Ultrasound, *supra* note 37; Baby Insight, *supra* note 33.

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

Some of these companies further distinguish themselves from their competition by suggesting that their customers need not obtain a prescription before purchasing one of these studies. A quick Internet search will find businesses such as My Baby's Ultrasound.com²³⁸ and BabiesPics.com,²³⁹ which claim that they do not require a physician's note, while other businesses either do not expressly make such claims or even require a note from the consumer's physician prior to performing the service.²⁴⁰ 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.²⁴¹ The latter tactic seems to shift the onus of decision making from the service provider to the consumer and her primary physician, while allowing the service provider to opt out of the decision-making process.

The variation in the number of claims made by the owners of these businesses is vast, illustrating just how difficult it may be for regulatory agencies to monitor them and enforce regulations against them. The companies that claim to deliver their services without a physician prescription, and in fact do so, violate at least one regulation.²⁴² They may also be violating one or more additional safety regulations that flow from their lack of physician involvement.²⁴³ For example, the company that violates the regulation requiring a prescription or note from a referring physician may also violate additional regulations, such as section 801.109(b)(1) of the Code of Federal Regulations, which requires the posting of a cautionary statement on the ultrasound system related to usage by a licensed physician.²⁴⁴ Though an owner or operator of a keepsake imaging business who performs ultrasound studies without a prescription misbrands the device, the business does not necessarily adulterate the device because the manufacturer is not the one responsible for defining its intended use and labeling.²⁴⁵ Unfortunately, effective enforcement by the

238. My Baby's Ultrasound.com, http://www.jcenterprise.com/3d_ultrasound.htm (last visited Sept. 24, 2006).

239. BabiesPics.com, <http://www.babiespics.com> (last visited Sept. 24, 2006).

240. Baby's First Images, *supra* note 236; First Look Sonogram, *supra* note 32.

241. Baby Insight, *supra* note 33; *see also* 4D Fetal Imaging, <http://www.4dfetalimaging.com/faqs.asp> (last visited Sept. 24, 2006).

242. 21 U.S.C.A. § 360j(e)(1)(A) (West 2006); *see also* 21 C.F.R. § 884.2225 (2006).

243. 21 C.F.R. § 801.109 (2006).

244. *Id.* § 801.109(b)(1).

245. *See* Rayford v. State, 16 S.W.3d 203, 207-10 (Tex. App. 2000) (explaining that an owner or operator of a keepsake imaging business performing keepsake ultrasound studies

FDA requires the discovery of potential violators and their prosecution, and thus far not a single business has been closed by the FDA.²⁴⁶

FDA regulation of these devices may be further complicated by its traditional stance of noninterference with state regulation, especially where it encroaches on the practice of medicine or pharmacy within a given state.²⁴⁷ Operators of keepsake imaging or ultrasound screening services often claim that they are not breaking any regulations because they do not claim to be a medical practice or offer diagnostic exams.²⁴⁸ Some states, however, are beginning to take action by creating regulations to control the distribution and use of ultrasound technology.

A. Nonmedical Uses of Ultrasound May Violate Multiple State Laws

In 2003, some operators confessed their desire for more regulatory guidance from the states.²⁴⁹ Apparently, some states have heeded the call for regulatory guidance and intervention, but their mechanisms vary. The results have been mixed, with some states faring better than others. Texas began enforcing its laws against these facilities as early as 1996.²⁵⁰ Under Texas law, the Department of Health Services (DHS), under the Texas, Food, Drug, and Cosmetic Act (TFDCA), has the authority to adopt the federal regulations of the act of the same name.²⁵¹ DHS also has the authority to monitor Texas businesses that may not comply with federal law in their use of a Class II device,²⁵² which requires a written or oral authorization from a physician prior to its use.²⁵³ Class II devices are classified as prescription devices, so they cannot have adequate directions for lay use.²⁵⁴ These devices are also exempted from the requirement for directions regarding their use because they must be in the possession of a

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).

246. See Huhn, *supra* note 52.

247. 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).

248. Peter DeMarco, Third Trimester and Ready for You Close-Up: Parents Love 3-D Fetal Snapshots, but the Impact on Unborn Babies is Unclear, BOSTON GLOBE, Sept. 9, 2003, at F1, available at http://www.boston.com/news/globe/health_science/article/2003/09/09/impact_of_3_d_snapshots_on_unborn_babies_is_unclear/.

249. *Id.*

250. Rayford v. State, 16 S.W.3d 203, 205 (Tex. App. 2000).

251. TEX. HEALTH & SAFETY CODE ANN. § 431.241 (Vernon 2006); see also TEX. HEALTH & SAFETY CODE ANN. § 431.244 (Vernon 2006).

252. See 21 C.F.R. §§ 884.2225(a)-(b) (2006).

253. 21 U.S.C.A. § 360j(e)(1)(A) (West 2006).

254. See 21 C.F.R. § 801.109(b)(1) (2006); see also 21 U.S.C.A. § 502(f)(1) (West 2006); see also CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *supra* note 40.

physician in the first place.²⁵⁵ Clearly, these prescription devices fall under both federal and state law, as Texas follows the same federal classification and regulatory scheme.²⁵⁶ If any Texas company uses an ultrasound system or “device” without physician authorization, it violates both sets of regulations and also adulterates²⁵⁷ and misbrands the device under Texas law.²⁵⁸ It would seem relatively easy for a regulatory agency to match violators with the appropriate regulatory violations, but a relatively recent case demonstrated just how difficult the prosecution of a violator can be.²⁵⁹

In 1996, the State of Texas sued Ms. Erma Rayford and her business, Baby Images, Inc., for performing ultrasound scans on fetuses and providing videos to consumers without a physician’s prescription.²⁶⁰ A suit was brought after the DHS cited Ms. Rayford on multiple occasions for performing these services without any physician involvement.²⁶¹ 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.²⁶² As a Class III device, the State claimed that the owner adulterated the device because it did not receive pre-market approval from the FDA.²⁶³ Because the State viewed keepsake imaging as a new intended use, it also claimed that the owner had adulterated the device under Texas law.²⁶⁴ The State then alleged that Ms. Rayford misbranded the device by not properly labeling it.²⁶⁵ Under state law, a device may be misbranded if it is a restricted device that is used without a physician’s prescription.²⁶⁶ Although not specifically addressed in this case, the TFDCA does not treat a registered diagnostic medical sonographer as a physician,²⁶⁷ nor does it qualify him or her as a practitioner.²⁶⁸ Therefore, if a company violates these sections and definitions, it then violates Texas law.²⁶⁹

255. *See id.* § 801.110 (2006).

256. *See* TEX. HEALTH & SAFETY CODE ANN. § 431.002(13) (Vernon Supp. 2006).

257. *See id.* § 431.111.

258. *See id.* § 431.112.

259. *See* Rayford v. State, 16 S.W.3d 203 (Tex. App. 2000) (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).

260. *Id.* at 205.

261. *Id.*

262. *See id.* at 206-07.

263. *Id.*

264. *Id.* at 209.

265. *See* Rayford v. State, 16 S.W.3d 203, 209 (Tex. App. 2000).

266. *See id.*

267. *See* TEX. OCC. CODE ANN. § 151.002(12) (Vernon Supp. 2006).

268. TEX. HEALTH & SAFETY CODE ANN. § 483.001(12) (Vernon Supp. 2006).

269. *Id.* § 483.041.

Additionally, the State in *Rayford* also pursued a false advertising claim under its Deceptive Trade Practices Act (DTPA).²⁷⁰ Advertising for the purposes of the TFDCA is “deemed to be false” if it is in fact false or “misleading in any particular.”²⁷¹ The State believed Ms. Rayford falsely advertised her services by stating that no physician prescription was required, thereby violating the DTPA.²⁷² Specifically, the State alleged that when Baby Images, Inc. failed to disclose information for its goods or services, it also intended to induce a consumer to participate in a transaction, and the consumer would not have done so if aware of the undisclosed information.²⁷³ In this case, the court found that 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.²⁷⁴ 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 DTPA.²⁷⁵

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 succeeded, then it would have received additional advantages.²⁷⁶ Not only could the State have sought injunctive relief from the practice, but it also could have requested that civil fines be levied against the offending business.²⁷⁷ These fines may range from \$20,000 to \$250,000 depending on the offense and the particular consumer involved.²⁷⁸ If a consumer suffers a documented harm or injury related to a violation of the DTPA, and it is also shown that the harm is a cause of injury, the consumer may be entitled to actual damages from the business.²⁷⁹ A business that violates one or more sections of the DPTA could face substantial penalties. Even so, the result in *Rayford* demonstrates just how difficult it may be for a state to succeed in the prosecution of these types of claims.

270. See *Rayford v. State*, 16 S.W.3d 203 (Tex. App. 2000).

271. TEX. HEALTH & SAFETY CODE ANN. § 431.182 (Vernon 2006).

272. *Rayford*, 16 S.W.3d at 211; see also TEX. BUS. & COM. CODE ANN. §§ 17.01-17.885 (Vernon 2006).

273. *Rayford*, 16 S.W.3d at 210-11; see also TEX. BUS. & COM. CODE ANN. § 17.46(b)(24) (Vernon Supp. 2006).

274. See *Rayford*, 16 S.W.3d at 211.

275. See *id.*

276. See TEXAS BUS. & COM. CODE ANN. § 17.47(a) (Vernon Supp. 2006).

277. *Id.* § 17.47(c).

278. *Id.* § 17.47(c)(1).

279. *Id.* § 17.50.

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

Although the federal government and many states 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. Still, some professional organizations and states are attempting to place this issue 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.”²⁸⁰ The SDMS also addressed this issue in its clinical practices standards, where it stated that the “Diagnostic Ultrasound Professional . . . provides an oral or written summary of preliminary findings to the interpreting physician.”²⁸¹ 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.²⁸² Moreover, the AIUM now views performance of such studies without a physician as the “practice of medicine without a license.”²⁸³ These statements underscore the importance of the physician, but they also raise 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, each state’s definition of the practice will control. Unfortunately, medical practice acts of different states vary widely and may define the practice of medicine in either broad or narrow terms.²⁸⁴ Some states may adopt a broad statement where “practice” may include a “condition, physical or mental, real or imaginary.”²⁸⁵ Many jurisdictions include the term “condition,” which may be so broadly defined as to include any state of human health or disease.²⁸⁶ For example, California has a statute specially directed toward keepsake imaging, and it is also a state that classifies a normal pregnancy as a “physical condition” and not a disease.²⁸⁷ Therefore, in California, any

280. Am. Coll. of Radiology, *supra* note 197.

281. Soc’y of Diagnostic Med. Sonography, *supra* note 198.

282. See Press Release, AIUM, *supra* note 199.

283. *Id.*

284. See Lori B. Andrews, *The Shadows Health Care System: Regulation of Alternative Health Care Providers*, 32 HOUS. L. REV. 1273, 1299 (1996).

285. *Id.*

286. See *id.*

287. *Id.*

non-physician providing care during a normal pregnancy would be engaged in the unauthorized practice of medicine.²⁸⁸ Even with this broad definition of pregnancy, it remains unclear whether California views sonographers' performance of keepsake fetal imaging as violating the practice of medicine.

Louisiana is one state with a fairly broad definition of the practice of medicine that has addressed the issue of self-referred diagnostic medical screening.²⁸⁹ In 2000, the Louisiana State Board of Medical Examiners (Board) addressed the issue of businesses practicing screening vascular ultrasounds (carotid, peripheral vascular, and aortic ultrasounds) in the state without the involvement of a physician.²⁹⁰ The Louisiana Practice Act reads:

the "practice of medicine" explicitly encompasses "the examining, either gratuitously or for compensation, of any person . . . [w]hether 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.²⁹¹

Based on these terms, the Board stated that it would seek action against non-physicians that performed self-referred screening ultrasounds.²⁹² The Board took this position based on its concern for public safety, as the state did not have authority to regulate "ultrasound technicians."²⁹³ This included its apprehension regarding the potential for misdiagnosis and patient confusion based on inaccurate results.²⁹⁴ The Board also mandated that studies be supervised by a physician, obtained by physician referral, not interpreted by the screener or screening service, and performed with quality systems.²⁹⁵ Currently, any unlicensed personnel that perform these types of studies become subject to an injunction by the Board and to potential criminal sanctions.²⁹⁶

288. *See id.*

289. *See* LA. REV. STAT. ANN. § 37:1262 (2006).

290. Statement of Position, Louisiana State Board of Medical Examiners, Self-Referred Diagnostic Ultrasound Screening, Oct. 25, 2000, *available at* <http://www.lsbme.louisiana.gov/documents/positionstatements/UltrasoundScreening.pdf>.

291. *Id.*

292. *See id.*

293. *See id.*

294. *Id.*

295. *Id.*

296. Statement of Position, Louisiana State Board of Medical Examiners, Self-Referred Diagnostic Ultrasound Screening, Oct. 25, 2000, *available at* <http://www.lsbme.louisiana.gov/documents/positionstatements/UltrasoundScreening.pdf>.

Enforcement actions similar to those taken by the Louisiana Board may be more problematic for those states that have narrower 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 a person who (A) publicly professes to be a physician or surgeon; or (B) directly or indirectly charges money or other compensation for those services.²⁹⁷

Where the Texas State Board lacks jurisdiction to enforce actions for the unlicensed practice of medicine, state law allows the attorney general or other officials to investigate and prosecute any complaints before the Texas Board.²⁹⁸ Unfortunately, Texas law uses more restrictive language than the Louisiana statute by focusing on the “mental or physical disease or disorder or a physical deformity or injury.”²⁹⁹ Furthermore, the terms “disease” and “disorder” are not defined.³⁰⁰ However, based on the plain meaning of the term disease, it likely refers to “pathological conditions.”³⁰¹ It is doubtful that those performing keepsake ultrasound imaging would ever be considered as practicing medicine, unless the operator made a diagnosis of a pathological condition, which then led to treatment. The language is likely too narrow to characterize these practices as the unlawful practice of medicine.

However, this may not be the case for individuals who perform self-referred ultrasound screening studies for peripheral disease. Vascular ultrasound studies such as carotid, peripheral vascular, and aortic ultrasound are done for diagnostic purposes.³⁰² If any of these screening studies are done by a sonographer without physician involvement, 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, sonographers who perform an ultrasound screening study could be seen as holding themselves out as a physician to the public, particularly when the ultrasound system carries the FDA’s cautionary statement requiring physician use only. The technologist need not publicly profess that he or

297. TEX. OCC. CODE ANN. § 151.002(13) (Vernon 2006).

298. See 22 TEX. ADMIN. CODE § 198.1 (LexisNexis 2006).

299. TEX. OCC. CODE ANN. § 151.002(13) (Vernon 2006).

300. See *id.* § 151.002 (Vernon 2006).

301. MERRIAM WEBSTER’S COLLEGIATE DICTIONARY 259, 358 (Fredrick C. Mish ed., 11th ed. 2003).

302. Life Line Screening, *Why Ultrasound for Screening?* 1 (2005), <http://www.lifelinescreening.com/newsletter/pdf/vol2-issue1.pdf>.

she is a physician.³⁰³ The very nature of the activities that person does may be sufficient to hold oneself out to be a physician.³⁰⁴

For example, in *Weyandt v. State*, the court upheld the conviction of a nurse anesthetist for the unlawful or unauthorized practice of medicine where she never publicly professed that she was a physician.³⁰⁵ This case stemmed from an incident where an undercover police officer went to see Ms. Weyandt for an alleged shoulder injury.³⁰⁶ She told the officer she was a doctor, but never said she was a physician or licensed to practice medicine in Texas.³⁰⁷ She possessed a degree in medicine from a university in Mexico and was an advanced nurse practitioner and certified hypnotherapist.³⁰⁸ Additionally, the sign on her office door read “Dr. Linda J. Weyandt,” and her office looked like the office of a doctor.³⁰⁹ As part of her interaction with the officer, she attached wires from a peripheral nerve stimulator to the allegedly injured shoulder.³¹⁰ An expert witness at her trial testified that a peripheral nerve stimulator was a diagnostic, not therapeutic, device.³¹¹ In addition to the nerve stimulation, the defendant tried to hypnotize the officer and provided herbal tea.³¹² Based on these facts, the appellate court upheld her conviction for the unauthorized practice of medicine.³¹³

The court noted that the defendant’s lack of credentials was not the problem, but rather her failure to hold a valid license to practice medicine in Texas.³¹⁴ The court explained that the defendant did not need to make any affirmative representation that she was a physician to violate the Texas Medical Practice Act.³¹⁵ A defendant breaks the law by the very nature of “what one does, and not only what one says they are doing, to determine whether they are practicing medicine.”³¹⁶ The court concluded that the defendant “implicitly suggested” that she was physician when she purported

303. See 35 S.W.3d 144, 151 (Tex. App. 2000).

304. *Id.*

305. *Id.*

306. *Id.* at 148.

307. *Id.*

308. *Id.*

309. *Weyandt v. State*, 35 S.W.3d 144, 148 (Tex. App. 2000).

310. *Id.*

311. *Id.*

312. *Id.*

313. *Id.* at 154.

314. *Id.* at 155.

315. *Weyandt v. State*, 35 S.W.3d 144, 52 (Tex. App. 2000).

316. *Id.*

to diagnose and treat the officer.³¹⁷ 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 holding in *Weyandt*, a sonographer need not specifically state he or she is a physician in order to practice medicine without a license in Texas. Texas sonographers who perform diagnostic medical ultrasound screening studies could be found to be practicing medicine without a license when they issue a report rendering a diagnosis of a disease process. Additionally, these sonographers 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.³¹⁸ Following the reasoning in *Weyandt*, such notice could be seen as a representation that the individual performing the scan is a physician. Thus, it seems that in the appropriate instances, Texas authorities could seek assistance provided for under the law with regard to the unauthorized or unlawful practice of medicine. Ultimately, it may well be a question of fact for a judge or jury to determine.

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, people 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 resides in a collaborative effort between all stakeholders in the process.

As discussed above, the FDA and various state agencies may not be capable of effectively regulating these practices. 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, state enforcement agencies, medical societies, owners and technicians of ultrasound facilities, and consumers. Based on recent events, such as the previously discussed cases and Tom Cruise’s public purchase of the sonogram machine, a timely and heightened challenge is presented to the stakeholders. Though the achievement of total cooperation is unlikely, steps can be taken to ensure consumer safety without enacting overly restrictive regulations.

The first step in bringing reason into the current dynamic will require state legislatures to follow the path of California, by crafting sensible

317. *Id.*

318. See 21 C.F.R. 801.109(b)(1) (2006).

legislation that specifically regulates the ability of untrained consumers to purchase or operate these devices.³¹⁹ The next step requires state governors to do what Governor Schwarzenegger did not do, and that is to sign the bill so that it becomes law. By controlling distribution of these sophisticated 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 hand-carried devices out of the hands of untrained individuals, even if they have the financial means to purchase them.³²⁰ 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 enact legislation similar to the legislation crafted by the California Assembly and require that physicians be included as either buyers or providers, then states will foster access to qualified individuals. More importantly, this will likely enhance consumer safety 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.

Next, medical societies should rethink their position on the practice of fetal keepsake imaging. Current policies dissuade physicians and mothers 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 some physicians advocate fetal keepsake imaging for their patients in order to increase bonding, while others oppose it due to safety reasons, the time may have arrived for all parties to seek a common ground. The overall 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 any physician involvement or supervision. However, such regulations should not be so restrictive as to impact current medical practices, where

319. *See Hearing Before Assembly Comm. on Health, supra* note 74.

320. *See id.*

technicians perform studies that are later reviewed by physicians.³²¹ 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 under controlled conditions. The key is to avoid altering current practice to the point that it chokes off consumer access to ultrasound imaging services or creates unnecessary delays.

Many physicians and consumers view keepsake imaging studies as part of a nondiagnostic bonding experience, so sonographers should perform these studies only if they are aware that they are conducting these imaging experiences after a physician's formal diagnostic study. By meeting the latter step, sonographers may avoid potential violations of state and federal regulatory laws.

An even better approach would have physicians trained in diagnostic ultrasound offer keepsake imaging experiences to their patients as part of the standard obstetrical imaging experience, at a nominal charge to patients who want that 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 by the 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. Greater involvement and oversight should alleviate many of the medical and ethical issues currently raised by the practice of keepsake imaging. This will also serve to legitimize the process and will likely lead to further investigational studies, which could help resolve the current debate centered on the potential for harmful biological effects versus bonding benefits.

Finally, medicine needs to do a better job of evaluating medical imaging as applied to screening studies. The goal of any regulatory control scheme should be to curb fraud and abuse, not encourage it. Unfortunately, the dynamic of self-referral is ripe for abuse by physicians.³²² 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

321. AIUM, Official Statements, *Standards and Guidelines for the Accreditation of Ultrasound Practices* (Nov. 13, 2005), http://www.aium.org/publications/statements/_statementSelected.asp?statement=26.

322. *MedPAC Recommendation on Imaging Services, Before the Subcomm. On Health, H. Comm. On Ways and Means*, 109th Cong. 9 (Mar. 17, 2005) (statement of Mark E. Miller, Executive Director, Medicare Payment Advisory Commission), available at http://www.medpac.gov/publications/congressional_testimony/031705_TestimonyImaging-Hou.pdf.

over-utilization of imaging services.³²³ Still others point out that “scan all” strategies in certain patient groups may actually decrease, rather than increase, the overall costs of care.³²⁴ Nevertheless, all agree that some form of control may be necessary, which is best achieved through a collaborative effort at all levels.³²⁵

The collaborative process should begin 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 boards should take affirmative steps, 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. Medical societies that govern the behavior of diagnostic medical sonographers should also support their local medical boards by becoming more aggressive in policing the actions of their constituents. More importantly, they should encourage medical educators and researchers to perform more evidence-based analysis of screening studies, particularly in areas related to diagnostic medical imaging. 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

Diagnostic medical ultrasound is now, and always will be, a very powerful diagnostic tool – in the right hands. As such, 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 use their medical practice acts to ensure that physicians are brought into the process. Those states that lack the necessary laws to control the unrestricted access of untrained or unqualified individuals to these systems

323. Lee & Brennan, *supra* note 56.

324. *MedPAC Recommendation on Imaging Services Before the Subcomm. On Health, H. Comm. On Ways and Means*, 109th Cong. (Mar. 17, 2005) (statement of David Rollo, Chief Medical Officer, Phillips Medical Systems, Milpitas, California), available at <http://www.medpac.gov/search/searchframes.cfm>.

325. *See id.*

should follow the lead of California and draft laws to effectively control supply; however, they should complete what California failed to do, which is to actually enact them into law.

No one questions the lucrative nature of the ultrasound imaging market. Yet 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. Medicine does not truly know what the absolute risks or biological hazards are that may be associated with this technology, and until medicine discovers them, caution is warranted. All parties should act responsibly until more studies have been conducted to warrant 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, the individual informed consumer should be the one to enjoy the medical benefits of this technology, not just the providers of nondiagnostic imaging services who seek to entertain or take advantage of their clientele.