Diagnostic Ultrasound and Inappropriate Use of Fetal Imaging

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Apparently, Americans do not have enough electronic gadgets to stave off boredom during their leisure hours. Tom Cruise, considered by People Magazine as one of the “most fascinating people of 2005,” illustrated this point when he announced his purchase of a diagnostic medical ultrasound system during an interview with Barbara Walters of the ABC network. This revelation was quite surprising because the price tag for an ultrasound system can be as much as $200,000.1 He told viewers that he saw “a little baby,” but he did not know its gender.2 He also said medical technicians helped him image his baby, but this did not quell the firestorm of criticism that erupted from the medical community over Mr. Cruise’s inappropriate use of diagnostic medical ultrasound.3

Tom Cruise’s decision to purchase a medical system may seem a tad bizarre to most Americans, but it merely represents a refinement of a practice in vogue since 1994. In 1994, the United States Food and Drug Administration (“FDA”) and the medical community became aware of businesses performing fetal imaging while family and friends watch their baby-to-be in a theater-like atmosphere. Package deals and gift certificates are available for the “keepsake” fetal imaging experience. Businesses performing keepsake imaging employ a diagnostic medical sonographer, not a physician, and they do not formally evaluate the fetus. Proponents see no need for a physician because they are not making a medical diagnosis. Proponents also consider maternal-fetal safety a non-issue because no biological effects from ultrasound have been reported in over three decades.

Even as the fetal keepsake imaging business has continued to expand throughout America,4 the FDA and the medical community have increasingly expressed safety concerns about the unregulated imaging of fetuses.5 The FDA and most of the medical community consider fetal imaging a diagnostic medical procedure. Although it is true that the diagnostic medical ultrasound energies have not caused any human injuries to date, many of the studies on which safety data are based may be methodologically flawed. Moreover, the FDA now allows most ultrasound manufacturers to increase the ultrasound system output energies to levels that can be eight times higher than those used in the biological safety studies. Because the true effects remain unknown, many ultrasound organizations have adopted the “ALARA” principle, which requires keeping

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1 Staff, Names & Faces, DET. FREE PRESS, Nov. 24, 2005, at 2.
exposures “as low as reasonably possible.”\textsuperscript{6} This choice may be wise because one study has shown a tendency for left handedness in boys receiving in utero ultrasound.\textsuperscript{7}

Appreciating the possibility for future issues with ultrasound safety,\textsuperscript{8} the FDA has classified diagnostic medical ultrasound systems as prescription medical devices,\textsuperscript{9} the use of which should be ordered by a duly licensed physician. The FDA has also issued regulations that address the different diagnostic ultrasound modalities employed.\textsuperscript{10} The regulations require a device user facility to post a cautionary statement notifying both the user and the consumer that “federal law restricts this device to sale by or on the order of a ‘physician,’ ‘dentist,’ ‘veterinarian,’ or with descriptive designation of any other practitioner ….”\textsuperscript{11} A device user facility that does not comply may adulterate the device by not following performance standards, and it may misbrand the device by not properly labeling or falsely advertising the device.\textsuperscript{12} A facility may also violate the regulations when it fails to obtain a physician prescription, tells one of its consumers that it does not require a prescription, or fails to properly post a cautionary notice. Unfortunately, FDA enforcement activity in this area is limited, with the FDA generally relying on the states to police business activity within their borders.

State enforcement depends largely upon the drug laws and consumer protection statutes in a particular state.\textsuperscript{13} California, for example, recently passed a notice statute requiring user facilities to inform consumers that the “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.”\textsuperscript{14} Other states, such as Texas, have taken a much more aggressive approach, including reliance on federal law to attack the issue. In 2005, the Texas Attorney General took action against four companies that offered keepsake imaging services in Texas. Not only did Texas sue under federal law, but it also pursued claims under the state’s own drug laws and consumer protection statutes.\textsuperscript{15} Eventually, the Attorney General got agreements from the four imaging facilities to alter their practices by requiring involvement of a physician. One wonders how effective these efforts will be in the long run in our consumer-driven society. Ultimately, keepsake imagers, including Tom Cruise, may be unstoppable, and fetuses may continue to be scanned for no other reason than consumer self-gratification.

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\textsuperscript{8} \textit{Fetal Keepsake Videos, supra note 5}.
\textsuperscript{9} 21 C.F.R. § 801.109 (2005).
\textsuperscript{10} \textit{Id.} at §§ 892.1550-1560.
\textsuperscript{11} \textit{Id.} at § 801.109.
\textsuperscript{12} \textit{Id.} at §§ 351-352.
\textsuperscript{14} CAL. HEALTH & SAFETY CODE § 1223620 (Deering 2005).