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July 11, 2005

Lester M. Crawford, D.V.M., Ph.D.,
Acting Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane
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The Food and Drug Administration (FDA) has been investigating organizations that provide expecting families with the opportunity to take "keepsake" images, or sonograms, of their unborn children. The FDA has stated "that anyone promoting, selling or leasing ultrasound equipment for making keepsake fetal videos could be breaking the law." The agency has asked organizations to notify the FDA of any keepsake sonography services in their communities and to actively discourage women from having "keepsake" ultrasound procedures.

The FDA website states: "It's risky business taking pictures of unborn babies when there's no medical need to do so. That's the word from the Food and Drug Administration, which is concerned about companies trying to turn an important medical procedure into a prenatal portrait tool. … As compelling as these sneak previews may be, the FDA is warning women about the potential hazards of getting keepsake videos."[1]

Yet there is no scientific evidence to support the FDA's claims that ultrasound "keepsake" videos are hazardous. In fact, new longitudinal data published in the medical journal *The Lancet* on December 4, 2004 concluded that having several ultrasounds during pregnancy does *not* harm the unborn baby or restrict the child's growth or development

Professor John Newnham, of King Edward Memorial Hospital in Subiaco, Australia, and his team studied the progress of about 2,700 children. Half had been exposed to repeated ultrasounds before birth. None had any congenital abnormalities. The researchers assessed the growth and development of the children up to eight years old. At one year, both groups of children were similar in size. By the end of the study,

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[1] FDA Consumer Magazine, "FDA Cautions Against Ultrasound 'Keepsake' Images," January-February 2004 Issue, available at http://www.fda.gov/fdac/features/2004/104_images.html (last visited July 11, 2005).

there was no difference between the two groups in their results of standard speech, language, behavior or neurological tests.

"Our results also provide reassurance that multiple prenatal ultrasound scans are not followed by smaller body size in infancy or childhood," concluded Dr. Newnham.

Nevertheless, despite the Newnham study and the FDA's own notice that animal studies have not identified any fetal harm with low-dose ultrasound exposure,[2] the FDA continues to apply a very stringent standard on keepsake ultrasounds: "the issue of keepsake videos has to be that if there's even a possibility of potential risk, why take the chance."[3]

This mere-possibility-of-potential-risk standard is totally inconsistent with the FDA's approach with respect to any other public health issue. Notably, concerning women's sexual health and well-being, the FDA allows the promotion of condoms with inaccurate labeling despite indisputable evidence showing they are not effective in preventing the transmission of deadly human papillomavirus (HPV). As you know, since 1999, Congressional committees have requested the FDA to require medically and scientifically accurate labeling on condoms to reflect the lack of effectiveness in preventing HPV infection.

The FDA has failed to act on this critical public health matter, even after President Clinton, in December 2000 signed a law[4] requiring the FDA to ensure that condom labels were accurate. Rather, the FDA continues to promote condoms, even claiming on its website, "Condoms Can Save Your Life!"[5]

While the FDA continues to promote condoms as a way to "protect" from sexually transmitted diseases (when, in fact, they are ineffective against HPV) it is a great irony that one of the criticisms that the FDA cites against keepsake images is that they might provide couples with a "false sense of security."[6]

In sharp contrast with the harsh approach that the FDA takes against "keepsake" images, the agency's position on another commercial imaging procedure is merely advisory. Regarding "full-body CT scans," where the effective radiation dose can be hundreds of times greater than that of conventional x-rays,[7] the FDA's official recommendation is that consumers "carefully investigate and consider the potential risks and benefits and discuss them with [their] physician."[8]

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[2] Id.
[3] Id.
[4] Public Law 106-554.
[5] Condom Brochure, "Condoms and Sexually Transmitted Diseases... Especially AIDS," available at http://www.fda.gov/oashi/aids/condom.html (last visited July 11, 2005).
[6] "FDA Cautions Against Ultrasound 'Keepsake' Images," *supra*, note 1.
[7] FDA Consumer Magazine, "Full-Body CT Scans: What You Need to Know," November-December 2001, available at http://www.fda.gov/fdac/features/2001/601_ct.html (last visited July 11, 2005).
[8] FDA Brochure, "Full-Body CT Scans: What You Need to Know," available at http://www.fda.gov/cdrh/ct/ctscansbro.pdf (last visited July 11, 2005).

It is also ironic, in light of our persistent communications with the FDA regarding accuracy in condom labeling and the empirical evidence that condoms are not effective in protecting from HPV, and the FDA's position on commercial full-body CT scans, that "fetal ultrasound monitors" have appeared in FDA presentations describing the agency's "top priorities,"[9] and that this technological application has been subject to a nearly zero-tolerance standard.

The subcommittee believes that the FDA's enforcement actions against the taking of keepsake images of unborn children is unjustified by the science, in conflict with its approach to similar technologies, and insupportable in light of the major public health issues that the agency is otherwise neglecting, such as condom labeling.

Based upon these conclusions, we would request that the FDA

(1) Cease its warnings to organizations that provide "keepsake" imaging to expectant families;
(2) Remove any statements from the FDA's website and other publications that organizations promoting, selling or leasing ultrasound equipment for making keepsake fetal videos could be breaking the law;
(3) Notify organizations previously issued warning letters by the agency that such imaging has *not* been found to harm unborn children; and
(4) Provide this subcommittee with copies of all warning letters the agency has sent to groups, organizations and individuals regarding the use of "keepsake" ultrasound images by July 26, 2005.

If there are any questions, please have a member of your staff contact Malia Holst, the Subcommittee clerk, at 202-225-2577. Thank you for your timely response to this request.

Sincerely,

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

[9] http://www.fda.gov/cdrh/ocd/CDRHToppriorities.pdf (last visited July 11, 2005).