



## Office of the President

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Andrew C. von Eschenbach, MD  
Acting Commissioner  
Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Docket No. 2004P-0329

Dear Dr. von Eschenbach:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing 49,000 physicians and partners in women's health, we welcome the opportunity to provide comments on Docket No. 2004P-0329, Hand-Held Doppler Ultrasound Prenatal Listening Devices.

The American College of Obstetricians and Gynecologists opposes the citizen petition to grant over-the-counter (OTC) sales, distribution and status to hand-held Doppler prenatal listening devices for two principle reasons: potential safety concerns arising from lay use of medical equipment and ethical concerns related to lay interpretation of ultrasound.

### *Safety Concerns Arising from Lay Use of Medical Equipment*

Doppler prenatal listening devices use acoustic energy to monitor fetal heart rate externally and can be useful in determining fetal well-being, discovering inconsistency in the fetal heart rate, or indicating a fetal demise. As with other forms of sonography, Doppler listening devices should be used only when there is a valid medical indication. While Doppler is safe for use under the supervision of trained health care professionals, OTC purchase and use of Doppler fetoscopes by a lay user raises issues of safety and efficacy.

From a medical standpoint, fetal ultrasonography of any kind is considered safe when properly used and when medical information about a pregnancy is needed. However, ultrasound energy delivered to the fetus cannot be assumed to be completely innocuous. Diagnostic levels of ultrasonography can produce physical effects, such as mechanical vibrations (referred to as cavitation), or an increase in tissue temperature under laboratory conditions. Because of this, the lowest possible ultrasonic exposure setting should be used to gain the necessary diagnostic information under the as low as reasonably achievable (ALARA) principle. With lay use of this equipment, there would be no way to control the amount of time the fetus is exposed to ultrasound energy.

Although there is no reliable evidence of physical harm to human fetuses from diagnostic ultrasound imaging, public health experts and clinicians agree that casual use of ultrasonography, especially during pregnancy, should be avoided. Viewed in this light, exposing the fetus to ultrasonography with no anticipated medical benefit is not justified. [Stark et al., *Obstet Gynecol* 63:194-200 (1984); Lyons et al., *Radiology* 166:687-90 (1988); American Institute of Ultrasound in Medicine. *Bioeffects of diagnostic ultrasound with gas body contrast agents.* (2002)]

The U.S Food and Drug Administration views the promotion, sale or lease of ultrasound equipment for making “keepsake” fetal videos as an unapproved use of a medical device (FDA Consumer Magazine, Vol.38, No.1, Jan-Feb 2004). ACOG, the American Institute for Ultrasound in Medicine (AIUM) and the American Medical Association have expressed similar opinions about keepsake ultrasound [ACOG Practice Bulletin No. 58, *Ultrasound in Pregnancy*; ACOG Committee Opinion No. 299, *Guidelines for Diagnostic Imaging During Pregnancy*; American Institute of Ultrasound in Medicine. 1999. *Prudent Use*; American Medical Association, H480-955: “Keepsake” Fetal Ultrasonography.] ACOG believes that the use and availability of Doppler listening devices for nonmedical purposes should be similarly viewed.

#### *Ethical Concerns Related to Lay Interpretation*

In addition to safety concerns, the ACOG Committee on Ethics has expressed concerns about the inability of a lay person to properly interpret ultrasonography results [ACOG Committee Opinion No. 297, *Nonmedical Use of Obstetric Ultrasound.*] As a result, a pregnant woman may either have unfounded worry for the fetus or false reassurance of fetal health because of an inability to properly interpret the output of the Doppler listening device. Using the device in a nonmedical setting, a pregnant woman would be left without necessary support, information and follow-up for concerning findings.

If a pregnant woman does not hear a fetal heartbeat, she may experience unnecessary anxiety and concern for the health of the fetus, when in fact it may be the lay user’s inexperience and lack of training in correct probe placement that has led to the missed fetal heartbeat. These fears could lead pregnant women to seek unnecessary emergency department or urgent care and medical care, needlessly increasing health care costs and potentially overtaxing the health care system.

To the other end, a pregnant woman hearing a heartbeat using a Doppler listening device may mistake her own heartbeat for a fetal heartbeat, or in the case of multiple fetuses, hear one heartbeat and assume all fetuses are healthy when one, in fact, has expired. The false reassurance potentially provided by Doppler listening devices should also be prevented.

OTC availability of Doppler listening devices presents safety concerns and the probability of misuse of the equipment and misinterpretation of the fetal heart rate by a lay person, which are likely to lead to unnecessary anxiety or false reassurance. For these reasons, we believe the petition for OTC availability of ultrasound should be denied.

Sincerely,



Michael T. Mennuti, MD, FACOG  
President