DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Russel J. Thomsen, M.D.
11018 Peony Place NW
Silverdale, Washington 98383

Re: 2003P-0438

Dear Dr. Thomsen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition dated September 8, 2003 and filed by FDA on September 25, 2003. In your petition, you request that the Commissioner of Food and Drugs change the regulatory status of Doppler fetoscopes. Specifically, you request that the Commissioner grant over-the-counter (OTC) status to fetoscopes having a maximum Doppler ultrasound output of no greater than 20mW/cm^2, and having specific labeling and design features that distinguish them as OTC products. You also state that your petition expands the materials presented in your previous petition, docket number 2002P-0338. After reviewing all relevant information, we must deny your petition for the reasons discussed below.

I. Preamendment Status

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360c(f)), devices that were in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments (the Amendments), are considered preamendment devices by the FDA. You assert that FDA wrongly regulates Doppler fetoscopes as class II, prescription medical devices because the technology underlying hand-held, battery-powered Doppler fetoscopes predates the Amendments, and because devices with a similar intended use were manufactured and sold both in the United States and abroad before the passage of the Amendments. As examples, you reference the "English made Sonicaid" and the "American made Medsonics' FP3A."

It is true that the devices you reference were in commercial distribution before the Amendments. However, the evidence does not suggest that these devices were available OTC. Rather, FDA has concluded that the material you provided regarding the Pocket

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Sonicaid, Oxford Instruments, and Medsonics, Inc. is promotional material. The absence of a prescription statement in these advertisements does not mean that these products were ever sold OTC. Indeed, these promotional materials discuss diagnostic applications clearly intended for a professional audience. For instance, Sonicaid, advertising in Contemporary Ob/Gyn magazine, represents that its device can be used for "early diagnosis of multiple pregnancy," "location of placenta prior to amniocentesis," and "identification of umbilical cord flow." Similarly, Medsonics, Inc. states in its promotional material that its instrument is used for "the detection of fetal life," "confirms fetal life throughout pregnancy," and "augments the obstetrician's diagnostic skill." Finally, Oxford Instruments describes itself as a "patient monitoring company that serves health care professionals working in cardiology, neurophysiology and obstetrics," and as a company that it is a "solid company on which the medical community can rely." Accordingly, we believe the language in the materials you provided fails to support your contention that these products were sold OTC prior to 1976.

II. Prescription vs. OTC Use

In both your petitions and supplemental correspondence, you state that FDA should grant OTC status to Doppler fetoscopes because they have been used safely and effectively for years. You state that FDA's decision to classify hand-held Doppler fetoscopes as class II prescription devices was based on invalid scientific and medical assumptions, and that it was made absent legislative intent. You discuss the absence of adverse event reports relating to the use of Doppler fetoscopes, and the absence of any agency warning statement regarding dangers associated with using these devices, particularly any agency warning statement addressing pregnant ultrasound technicians. You compare the regulation of Doppler fetoscopes with the regulation of the cell phone, arguing that cell phones were introduced into interstate commerce without scientific data regarding their safety. Finally, you question whether the constitutional rights of consumers are being subverted by FDA's regulation of Doppler fetoscopes. I will try to address each of your assertions and explain why FDA does not find them persuasive.

FDA regulations (21 C.F.R. 801.109) define a prescription device as "[a] device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which 'adequate directions for use' cannot be prepared . . . ." FDA agrees with you that Doppler fetoscopes have been used safely and effectively for years, but underscores that this is true because these devices are used under the supervision of a practitioner. OTC purchase and use of Doppler fetoscopes by lay users raises new issues of safety and effectiveness because of the potentiality for harmful effect.

These products introduce acoustic energy into the body. The potential for adverse effects from long-term exposure of the fetus to acoustic energy in early pregnancy is not known. Some studies suggest that exposure to diagnostic ultrasound during pregnancy can have an effect on human development. (Keiler et al., Early Human Development 50:233-245 (1998); Keiler et al., Epidemiology 12:618-623 (2001).) You may be aware of ultrasound bone healing devices, which have been shown to produce biological effects in humans when used for only 20 minutes daily (Warden, S.J. et al., Calcified Tissue International 66:157-163, 2000; Heckman et al., Journal of Bone and Joint Surgery 76A:26-34, 1994; Kristiansen et al., Journal of Bone and Joint Surgery 79A:961-973, 1997). Although a comparison of the acoustic outputs of ultrasound bone healing devices and fetal Doppler monitors (limited to 20 mW/cm^2) shows that both the heating potential and peak ultrasonic pressure levels (and thus the potential for biological effects) of the bone fracture healing device are 2-3 times greater than in the Doppler fetoscope, we believe that these studies could indicate a potentiality of harm from fetal Doppler monitors. From the standpoint of having the potential to produce biological effects in humans, the outputs of the two devices would have to be considered similar until demonstrated otherwise, especially for the case of unsupervised fetal exposures. The agency has concluded that unsupervised exposure to ultrasound may pose a risk to the health of the mother or a developing fetus. This is particularly true when the exposure may be of uncontrolled duration, and may occur at any and all times, including early pregnancy. Moreover, since this device does not provide an image, the user will have no idea what parts of the fetus are being subjected to the possible risk associated with prolonged exposure.

Other available information regarding the use of ultrasound in pregnancy confirms FDA's position. For example, the American Institute of Ultrasound in Medicine (AIUM) is a professional organization of physicians, sonographers, and other scientists whose emphasis is on "making available to members the most up-to-date and accurate information and skill training so they can make the best use of this [technology] while ensuring the safety of the patients who depend on them." In an official statement made on May 2, 1999 regarding the use of ultrasound, the AIUM stated: "[a]lthough there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient." Put differently, simply because no adverse effects have been revealed, it is not acceptable to conclude that no adverse effects exist. FDA cannot ignore this potential risk to the public health.

You minimize the importance FDA places on the available scientific literature by reiterating that these studies do not show a deleterious effect on fetal outcome. It would be the burden of the manufacturer to establish that the risk presented by introducing energy into the body can be adequately addressed by labeling for lay users in order to allow OTC use of Doppler fetoscopes. You dispute FDA's reasoning by comparing

Doppler fetoscopes to the sale and use of cell phones, citing that "cell phone output must fall within FDA mandated limits." Cell phones, however, do not meet the definition of a "device" in section 201(h) of the Act because they are not "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," nor are they "intended to affect the structure of any function of the body." (21 U.S.C. 321(h)(2).) FDA, which derives its authority to regulate cell phones as electronic products from the Radiation Control provisions of the Act, is limited to monitoring the health effects of wireless telephones. The Federal Communications Commission (FCC) ensures that all wireless phones sold in the United States follow safety guidelines that limit radiofrequency energy. The FCC derives its authority to regulate cell phones from the National Environmental Policy Act of 1969 and the Telecommunications Act of 1996.

Unlike cell phones, Doppler fetoscopes are regulated as medical devices under the Act. FDA does not agree with your statement that "if acoustical listening devices simply had label [sic] declaring that they were not medical devices, the FDA would not consider them to be medical devices." As noted above, a medical device is defined in relevant part under the Act as "an instrument . . . intended for use in the diagnosis of disease or other conditions . . . ." (21 U.S.C. § 321(h)(2).) Because ultrasonic (Doppler) fetoscopes are intended to verify fetal heart activity, FDA has determined that they are medical devices within the meaning of the Act.

Finally, you note the absence of any FDA warning statements directed to the public generally or to pregnant ultrasound technicians specifically. In fact, the National Institute of Occupational Safety and Health (NIOSH), the agency responsible for developing and enforcing workplace safety and health regulations, has issued a guideline for controlling the health hazard presented by ultrasound equipment. (NIOSH Recommended Guidelines for Controlling Noninfectious Health Hazards in Hospitals, 5.2.4.5.)

III. Constitutional Issues.

In your petition, you contend that consumers have a constitutional privacy right to obtain and use Doppler fetoscopes without restriction. However, in cases where consumers have challenged FDA restrictions on constitutional privacy grounds, courts have firmly held that consumers have no "constitutional right to obtain medical treatment that is encompassed by their right to privacy." United States v. Burzynski Cancer Research Inst., 819 F.2d 1301, 1313 (5th Cir. 1987); accord, e.g., Mitchell v. Clayton, 995 F.2d 772, 775 (7th Cir. 1993) ("a patient does not have a constitutional right to obtain a particular type of treatment . . . ."); Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) ("a patient's selection of a particular treatment . . . is within the area of governmental interest in protecting public health."); Carnohan v. United States, 616 F. 1120, 1122 (9th Cir. 1980) ("Constitutional rights of privacy and personal liberty do not

give individuals the right to obtain [an unapproved drug] free of the lawful exercise of government police power). We therefore believe that a court would not recognize a right to unfettered use of Doppler fetoscopes within the constitutional right to privacy.

We believe a challenge to FDA's restriction of Doppler fetoscopes on equal protection grounds would be similarly unsuccessful. First, it is not clear how one would define the class of persons that is allegedly adversely affected by the restricted status of the device. Second, the Act does not single out any particular class for distinctive treatment, nor is any discriminatory treatment implied in the Act or any administrative action. Absent such disparate or discriminatory treatment, there can be no equal protection claim. See Duncan v. United States, 590 F. Supp. 39, 41 (W.D. Okla. 1984). Moreover, FDA's justifications for its restriction on Doppler fetoscopes, which are set forth above, are rationally related to the legitimate purpose of protecting the public health. Under such circumstances, we do not think that an equal protection claim could be sustained. See Smith v. Shalala, 954 F. Supp. 1, 4 (D.D.C. 1996).

IV. Present Day OTC Use.

Your petition recognizes the OTC availability of other acoustic prenatal listening devices, but you argue that these devices are unreliable and inferior. You suggest, alternatively, that hand-held Doppler fetoscopes be made available OTC, with appropriate labeling, but only those devices that have a maximum output of 20mW/cm^2. You also suggest that these devices are already widely available without valid prescriptions.

As you are aware, certain prenatal listening products do not require a prescription. An example is the BébéSounds Prenatal Heart Listener™. While you refer to this passive type of product as inferior, it allows the user to hear the sound of an unborn baby's heartbeat. At the same time, the device does not introduce energy into the body. Conversely, although you maintain that Doppler fetoscopes emit a relatively low level of energy, you have not demonstrated that the risks presented by introducing energy into the body can be adequately managed by lay users without the supervision of a physician.

FDA also disagrees with your statement that there is and always has been unrestricted use of hand-held Doppler fetoscopes outside a medical setting. These devices are available only by prescription because of the agency's determination that their safe use requires the supervision of a licensed practitioner. The Act requires the manufacturer to place a prescription label on its device. (21 U.S.C. § 352(r).) FDA is aware that there are Doppler devices being promoted and sold over the Internet without prescription legends. As FDA uncovers illegal activities, we follow-up with appropriate authorities or take necessary enforcement action, but we are unable to provide information on ongoing investigations.

V. Conclusion.

FDA agrees that consumers may want the opportunity to hear their unborn babies' heartbeats. At the same time, FDA does not believe that consumers would purchase devices enabling them to do so if the device might potentially cause harm to the fetus through uncontrolled and unlimited use. The agency believes that professional health care providers should determine when circumstances indicate hand-held acoustic ultrasound devices may contribute to helping patients properly monitor the progress of their pregnancies. The prescription status of these products ensures that patients will have professional guidance to use these devices, as appropriate, to contribute to the well-being of the mother and fetus.

FDA has carefully considered the information provided in your petition. For the reasons discussed above, the agency has concluded that the interest of public health would not be served by making hand-held Doppler fetoscopes available OTC. If you have any questions about this response, please contact Mr. Joseph M. Sheehan at 301-827-2974.

Sincerely,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health