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November 24, 1999

Jane Henney, M.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: "Home Uterine Activity Monitors; Guidance for the Submission of 510[k] Premarket Notifications" to the Dockets Management Branch (HFA-305)

Dear Dr. Henney:

This letter is in response to the FDA's request for comments on the Change of Approval Status for home uterine activity monitors that was published in the Federal Register dated July 30th, 1999.

First, I would like to explain why our organization, the Coalition for Positive Outcomes in Pregnancy (CPOP), has an interest in this subject. We are a coalition of national and regional women's health organizations with a special interest in advancing and safeguarding high risk treatment options for pregnant women. Collectively, the organizations represent approximately 10,000 members, and we communicate routinely with hundreds of thousands of women through our Internet sites and our information and referral hotlines. All of our organizations are actively involved in current prenatal care issues.

A number of our member organizations have followed issues related to home obstetrical care over the last 10 years. Representatives have participated at numerous FDA Panel meetings on home uterine activity monitoring and tocolytic therapies over the years. Some of our constituent organizations have medical advisory boards whose members are well-known clinicians and researchers in these fields. CPOP supports the use of home obstetrical care services because they are more cost-effective than hospitalization and beneficial to the pregnant woman and her family in terms of having care delivered without separating the mother from her family.

Almost every medical discipline in this country currently utilizes home health care. For example, oncologists prescribe the delivery of chemotherapy drugs in the home environment. Internists prescribe the delivery of antibiotic therapy through infusion of drugs in the home environment. Pulmonologists care for patients who are ventilator dependent and cannot breathe on their own in

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the home environment. Virtually, every medical discipline has accepted home care because it is both clinically effective and cost effective compared to hospitalization. Unfortunately, a small group of obstetrical specialists has fought home obstetrical care for a decade. Their desire is to have hospital-based perinatologists, and particularly academic hospital-based perinatologists, control high-risk obstetrical patients and to keep them hospitalized, ostensibly to bolster sagging departmental revenues and provide a source of subjects for research projects. There are strong economic incentives for this group of specialists and their academic hospitals to discourage home obstetrical care.

After attending the various FDA Panel meetings over the years, it has become evident to our members that the FDA has been influenced by this small group of academicians who have used their positions on certain American College of Obstetricians and Gynecologists (ACOG) committees to thwart obstetrical home care. However, surveys of obstetricians in the field demonstrate that these academicians do not represent the views of the thousands of practicing obstetricians in this country.

We do not believe that the process which the FDA has utilized to judge the effectiveness of either the use of terbutaline therapy or home uterine activity monitors has been either fair or reasonable. A recent response to the July 30th, 1999 Federal Register notification from some of the physicians who do not support home obstetrical care called for the FDA to remove the prior approvals that had been granted through the Premarket Approval (PMA) process to three different home uterine activity monitoring devices! Their argument was based on a recent study that claimed the use of home uterine activity monitors was not effective. However, this study was not performed with either an FDA approved uterine activity monitor or with FDA approved study protocols. How can academic researchers acting with integrity ask your agency for withdrawal of three previous approvals under such circumstances? It seems posterous.

Relative to the disclosure in the Federal Register and the FDA's desire for comments, we would like to specifically highlight the problems associated with the documentation issues that the FDA is proposing. In today's health care environment, the managed care industry has been unreasonable and in many cases abusive relative to providing routine care under their programs. There has been a groundswell of opposition to the techniques that have been used to manage health care costs as opposed to managing health care. When a procedure or process does not have the FDA's full consent or approval, managed care effectively uses the FDA position to deny coverage. In this way, the FDA contributes directly to denial of care such as when it issued a warning letter concerning the prescribed use of terbutaline in November of 1997.

CPOP views the FDA's current proposal in the Federal Register requiring a patient registry according to diagnostic criteria as another means of making it very difficult for the practicing obstetrician to prescribe routine and effective care for their patients. In essence, the FDA is intruding on a physician's ability to practice medicine. In the Federal Register, the FDA stated the proposed Guidance Document would "discourage off-label use." These statements directly conflict with initiatives found in the FDA Modernization Act of 1997 which supports appropriate off-label use of prescription drugs and devices.

The FDA previously approved, through an arduous eight year PMA process, three different home

uterine activity monitors for certain clinical conditions. Practicing obstetricians and perinatologists have used these devices in the hospital for over 30 years and in the home care environment for almost 15 years. There are over ten thousand physicians who know the effectiveness of these devices and when it is clinically prudent to recommend their use. Further burdening the practicing obstetrician and the health care system with additional unnecessary documentation requirements will simply reduce the availability of this care to America's high risk pregnant women and their unborn infants. This threatens to remove one of the few tools in the limited medical arsenal available to physicians in their fight to prolong pregnancy and ultimately save premature babies.

On behalf of the organizations and individuals we serve, we urge you to uphold the present status of HUAM. In addition, we ask that your agency strive for a more balanced approach to issues pertaining to home obstetrical care. It is our hope that you can see beyond the interests of a small, albeit influential, group of obstetrical specialists focused on financial interests. Please remember, thousands of babies' lives are at stake. Thank you for your consideration.

Sincerely yours,



Sherokee Ilse  
Family Focus Coordinator

- c: Dockets Management Branch (HFA-305)  
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5630 Fishers Lane, Room 1061  
Rockville, MD 20852
  
- c: Senator Paul Coverdell  
Senator John McCain  
Senator Ernest Hollings  
Senator Bill Frist  
Senator Rod Grams  
Senator Connie Mack