July 24, 2000

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

Dear Dr. Henney:

Enclosed please find the American College of Obstetricians & Gynecologists' Analysis of Possible FDA Mifepristone Restrictions.

I have also sent a letter with E. Ratcliffe Anderson, Jr., MD of the American Medical Association that touches our joint concerns with the proposed restrictions and requests a meeting with you.

Thank you for your interest in this important issue.

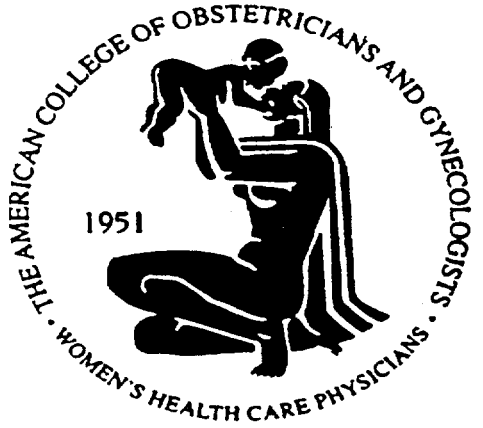
Sincerely,

Ralph W. Hale MD

Ralph Hale, MD
Executive Vice President
The American College of Obstetricians and Gynecologists

APPEARS THIS WAY
ON ORIGINAL

00-4973



American College of Obstetricians and Gynecologists

Analysis of the Possible FDA Mifepristone Restrictions

July 27, 2000

FDA Proposal 1: Distribution and use of the drug would be limited to only licensed physicians.

a. Prohibiting the prescription, dispensing, or use of the medication by anyone other than licensed physicians interferes with state medical, pharmacy, and nursing scope of practice laws. These laws, not the FDA, determine which professionals are allowed to prescribe and dispense medications within each state. There is no reason to treat this drug as a controlled substance. There are many other medications, some of which are abortifacients, that are available through prescription to a pharmacy.

b. Marketing mifepristone directly to physicians or facilities rather than through pharmacies may be a reasonable way that the company would choose to begin marketing this drug. However, a requirement to do so by the FDA will be difficult to change and may restrict wider distribution in the future.

c. Any information about physician offices, pharmacies, hospitals, or any other facilities that receive the drug must remain strictly confidential in order to protect those who use the drug from anti-abortion violence. Any government requirement that would result in a list would immediately place those who provide the drug in jeopardy.

FDA Proposal 2: The physician must be "trained and authorized by law" to provide surgical abortion.

Requiring that a physician be trained as a provider of surgical abortion is not necessary to administer mifepristone correctly and safely. Nor is such training necessary to treat spontaneous abortion. Requiring certification of this training does not reflect current medical practice. In fact, there is no method to certify physicians as surgical abortion providers or for any other type of surgery. Responsibility for certification of medical

professionals in this case rests with state licensing boards and the American Board of Obstetrics and Gynecology, a professional body established for this purpose.

FDA Proposal 3: The physician must have "certification" for ultrasound dating of pregnancy and detecting ectopic pregnancy.

a. Requiring ultrasound to date a pregnancy or determine if there is an ectopic pregnancy is not required to administer the drug safely and correctly. Physicians and patients can quite accurately date a woman's pregnancy.[1]

b. Currently the American Institute of Ultrasound in Medicine (AIUM) and the American College of Radiology, which are the only certifying bodies for ultra-sound in the United States, do not certify physicians to provide specific ultrasound procedures, including dating pregnancies and detecting ectopic pregnancies. Furthermore, ultrasound certification is controversial, with implications for third party reimbursement issues, and is not related to prescribing this drug.

FDA Proposal 4: Distributing physicians must be certified to provide mifepristone through a curriculum approved by the FDA.

Requiring special training is also not necessary to safely administer mifepristone. Evidence from the clinical trials is unequivocal in demonstrating the drug's safety and efficacy as the FDA approvable letter states. Further, the FDA is not an educational institution and has no mechanism in place to develop medical curricula.

[1] Ellertson, Charlotte, et al. "Accuracy of assessment of pregnancy duration by women seeking early abortions." *THE LANCET* March 11, 2000: 355: 877-881.

FDA Proposal 5: Prescribing physicians must have admitting privileges at a hospital within an hour of the offices where the drug is dispensed or administered.

Privileges at a hospital are not necessary for prescribing mifepristone safely. The complication rates for mifepristone are very low, with a small number of patients requiring emergency room care or hospitalization. The April 30th, 1998, New England Journal of Medicine article, "Early Pregnancy Termination with Mifepristone and Misoprostal in the United States," states that only 2% of women using these drugs required hospitalization, underwent surgical intervention, or received intravenous fluid.[2] Another New England Journal of Medicine article states, "This regimen appears to be as safe as surgical abortion performed under the safest conditions."[3]

The prescribing physician does not need to be in the emergency room or to be the admitting physician if a patient requires follow-up emergency care. Women experiencing miscarriages and spontaneous abortions frequently require the same services and care and appropriately receive this care at their physicians' offices.

The FDA has imposed no similar requirements on drugs that are far more likely to cause complications requiring emergency care. This requirement discriminates against physicians in rural areas, and creates a significant barrier to access for women in these areas.

---

[2] Spitz, I.M. et al. "Medical termination of pregnancy." *New England Journal of Medicine* 1998: 338: 1241-1247.

[3] Spitz, I.M., Bardin, C.W. "Mifepristone (RU486): a modulator of progestin and glucocorticoid action. *New England Journal of Medicine* 1993: 329: 404-412.