

# Mile Bluff Clinic

1040 Division St.  
Mauston, WI 53948  
Insurance 608-847-5050  
General Info 608-847-5000

January 29, 2004

Dr Mark McClellan  
Commissioner of the FDA  
5600 Fisher Ln  
Rockville, MD 20857

Dear Dr McClellan:

As a practicing obstetrician/gynecologist I am writing to you to urge you to reconsider the decision to change the status of "emergency contraception" to an over-the-counter medication. It is surprising that such a decision could be made by a regulatory body contrary to established medical guidelines and without consideration of the medical and social ramifications of the decision. Medically, this is a hazardous decision for the following reasons:

- 1) Contraceptive counseling is a primary means of establishing gynecologic health care with young women. Allowing young women (especially 11-16 year olds, with little knowledge and a great deal of fear) to self-prescribe and self-treat removes these high-risk young women from any form of medical surveillance, including STD and Pap screening, not to mention counseling.
- 2) There is a known increased risk of ectopic pregnancy with progestins. Will emergency contraception increase that risk? We will never know for certain if the medication is sold over the counter, as there will be no means of tracking such treatment. This same argument applies to the monitoring of other possible complications and side effects.
- 3) The effects of oral contraceptives have not been tested in very young teens as they were not developed for use in that patient population, and the **doses** under consideration are higher than today's standard oral contraceptive. If **such** medication is available over the counter, it is also probable that it will **be** used repeatedly by very young teens who don't understand "cycles" or "fertile periods" (and who now have no reason to visit a physician and receive such education), and so will take the medication after each sexual encounter, however frequently that may be. There is no safety data to support it such usage.
- 4) It is obvious to any of us who **care** for women that some of the most frequent users of this medication will be the very young teens—those who have no money for a doctor visit, no money for oral contraceptives, and who don't want their parents or the doctor to know that they are sexually active. We have allowed them to have sex without parental guidance, and now we remove medical guidance and care as well. The mental and physical health of our young teens seems a high price to pay for the convenience of adults.

I implore you to consider the medical facts and to reconsider your decision for the sake of our young teens. Thank you for your attention to this matter.

Sincerely,



Susan M. Haack M.D., F.A.C.O.G.

OIP 0075

C 897