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Dr. Mark McClellan
Commissioner of the FDA
5600 Fisher Lane
Rockville, Maryland 20857

Dear Dr. McClellan:

Since the FDA is considering making the Emergency Contraceptive Pill--Plan B over the counter, I am recommending that this not be done. As a Reproductive Endocrinologist who has done considerable research in both hormone replacement therapy and oral contraceptive use since 1970, this is of great concern to me. I think that being able to get these pills without any medical evaluation is a risk for women's reproductive health. The Plan B Emergency OC consists of 0.75 mg of levonorgestrel and one is to be taken immediately followed by a second 0.75 mg 12 hours later for a total dosage of 1.50 mg in one day, actually within 12 hours. Ovral, which is a good and safe high dosage birth control pill contains 0.5 mg of levonorgestrel (plus 0.05 mg of ethinylestradiol). Lo-Ovral, a very effective lower dosage OC contains 0.3 mg of levonorgestrel (plus 0.030 mg of ethinylestradiol). So Plan B contains 3X as much levonorgestrel as Ovral and 5X as much levonorgestrel as Lo-Ovral. Furthermore, levonorgestrel is the most biologically potent of all the synthetic progestogens used in the oral contraceptives, 15X as biologically potent as the most frequently OC progestogen, norethindrone (e.g., Ortho-Novum 1/35 has 1.0 of norethindrone plus 0.035 mg of ethinylestradiol). Of course, levonogestrel was chosen for Plan B because it is the most potent progestogen.

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As you know, the morning-after pill is taken after unprotected intercourse if a girl thinks she may get pregnant. It's mechanism of action is different, depending where in the menstrual cycle the unprotected intercourse occurs. If it is before ovulation, it can inhibit ovulation, working like regular OC's. But if the unprotected intercourse is after ovulation and conception has already occurred, these potent hormones so disrupt the endometrium that the embryo cannot implant. In this case Plan B acts as an abortifacient..

My concern is that the unrestricted, free use of Emergency Contraceptives without any medical supervision or control can cause too frequent use and so disrupt menstrual cycles to cause permanent reproductive dysfunction. By it's freedom to get, it may also increase promiscuity and since Plan B offers no protection from STD's (Sexually Transmitted Disease) as does regular oral contraception, produce future infertility problems. In the many years I have been treating infertile couples, I have seen so much heartbreak in young ladies for past mistakes. There have been studies in England where school nurses passed out Emergency Contraceptives, and there was more frequent use by the coeds than when a prescription was required.

Please do not make the Plan B Emergency Contraceptive Pill an over-the-counter medication, it is just too dangerous!!!

Sincerely,

A handwritten signature in black ink, appearing to read "R. Don Gambrell, Jr.", written in a cursive style.

R. Don Gambrell, Jr., M.D.