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August 26, 2005

Lester M. Crawford, D.V.M., Ph.D.
Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

Dear Dr. Crawford:

Secretary Leavitt has promised that the Food and Drug Administration would announce a decision by September 1 about whether to allow emergency contraception, such as Plan B, to be sold in pharmacies without a prescription.

As you are aware, the Food and Drug Administration last year denied a request from Plan B's manufacturer to allow over-the-counter sale of this drug combination. The FDA based its decision to deny this request on two issues, as reported by the Agency:

1) Adequate data were not provided to support a conclusion that young adolescent women can safely use Plan B for emergency contraception without the professional supervision of a licensed practitioner and

2) a proposal from the sponsor to change the requested indication to allow for marketing of Plan B as a prescription-only product for women under 16 years of age and a nonprescription product for women 16 years and older was incomplete and inadequate for a full review.[1]

The FDA has also concluded that it is not "well understood" that Plan B is "not for regular use," should not be used if there is unexplained vaginal bleeding, or that one should get medical help as soon as possible where there is severe abdominal pain after taking the drug.[2] These are serious issues that justify requiring a prescription for Plan B.

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[1] FDA's Decision Regarding Plan B: Questions and Answers, available at http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm (last visited August 25, 2005).

[2] Karen Lechter, J.D., PhD, Division of Surveillance, Research and Communication Support, Office of Drug Safety, Food and Drug Administration, in a presentation before the December 16, 2003 meeting of the FDA Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs. Transcript is available online at http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.DOC (last visited August 26, 2005).

I share the concerns that millions of Americans have about allowing emergency contraception products to be sold over-the-counter, without a prescription, and I hope that the FDA once again denies the request to distribute Plan B without a prescription.

The FDA requires that typical, standard oral contraceptives—which contain the same hormones as emergency contraception but in much lower doses—be given by *prescription only*, under the supervision of a physician. This a necessary safety measure, considering the dangerous possible side effects of oral contraceptives, which include increased risk of developing liver tumors, liver cancer, breast cancer, heart attack, stroke or serious blood clots.[3] Such risks are even higher among women who smoke.[4]

In arguing for over-the-counter availability of emergency contraceptives, advocates rely on the fact that emergency contraceptives and oral contraceptives are made of virtually the same ingredients. In fact, Planned Parenthood has made available on their website the number of oral contraceptive pills needed of various brands for the "off label" use of those prescription pills as a form of emergency contraception.[5]

Although emergency contraceptive drugs such as Plan B contain the same hormones that compose standard oral contraceptives, emergency contraceptives contain a much higher dosage than oral contraceptives. Specifically, the dosage of *prescription-only* oral contraceptives equivalent to one dose of Plan B is *twenty pills*, followed by *twenty more pills 12 hours later.*[6]

But over-the-counter availability of Plan B would remove the necessary safety precautions required for standard oral contraceptives, and would allow the widespread distribution of this powerful drug without any physician supervision, and without any checks on the frequency of use for any particular patient, despite the fact that Plan B's manufacturer says it does not have any data on overdosage of this powerful drug.[7]

Moreover, allowing over-the-counter sales would also give adolescent girls uncontrolled access to this drug. The FDA's own administrative rules allow approval for pediatric use of a drug "based on adequate and well-controlled studies in adults, *with other information supporting pediatric use.*"[8]

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[3] See Medline Plus, by the U.S. National Library of Medicine and the National Institutes of Health, at http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a601050.html#side-effects (last visited August 25, 2005).
[4] Id.
[5] For instance, Planned Parenthood recommends taking "5 pink pills" of the Alesse brand oral contraceptive pill manufactured by Wyeth-Ayers as the dosage needed for its off-label use as an emergency contraceptive. See http://www.plannedparenthood.org/pp2/portal/files/portal/medicalinfo/ec/fact-emergency-contraception.xml (last visited August 25, 2005).
[6] Van Look, Paul F.A. & Felicia Stewart. (1998). "Emergency Contraception." Pp. 277-295 in Robert A. Hatcher et al., eds., *Contraceptive Technology*, 17th edition. New York: Ardent Media (as cited by Planned Parenthood, at http://www.plannedparenthood.org/pp2/portal/files/portal/medicalinfo/ec/fact-emergency-contraception.xml, last visited August 25, 2005).
[7] Barr Pharmaceuticals information about Plan B, available at http://www.go2planb.com/PDF/PlanBPI.pdf (last visited August 25, 2005).
[8] 21 C.F.R. 314.70.

In addition to the fact that there is a lack of information about overdosage of Plan B, Plan B's manufacturer has not established the safety of the drug for pediatric use.[9] It would be highly irresponsible for the FDA to allow adolescent girls to have unchecked access to this drug by approving Plan B for over-the-counter sales, particularly when there is inadequate information as to whether the drug is safe for pediatric use.

Finally, the experience in Britain with emergency contraception has demonstrated other serious negative consequences of allowing over-the-counter sales of this drug, including increased rates of sexually transmitted diseases corresponding to over-the-counter availability of emergency contraception,[10] as well as the discovered increase in ectopic pregnancies related to emergency contraceptive use.[11]

Commissioner Crawford, based on the known health risks for prescription-only oral contraceptives and the lack of information available on adolescent use of emergency contraceptives, I would be very disappointed if the FDA approved over-the-counter sales of this drug. Such a decision would expose women and girls to grave risks without any physician supervision.

I hope these important factors regarding the health and safety of women and adolescent girls are part of a decision *against* allowing the over-the-counter sale of emergency contraception.

Sincerely,

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Government Reform Committee

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[9] Barr Pharmaceuticals information about Plan B, available at http://www.go2planb.com/PDF/PlanBPI.pdf (last visited August 25, 2005).

[10] "Teen Sex Epidemic" Daily Mail (London) March 8, 2004, reporting that the number of new cases of sexual diseases rose by almost two-thirds in five years. Available at http://www.dailymail.co.uk/pages/live/articles/health/womenfamily.html?in_article_id=299672&in_page_id=1799 (last visited August 25, 2005).

[11] "UK warns of ectopic risk with 'morning-after' pill" Reuters Health, London, January 30, 2003.