

Alpern, Dannette M**From:** JoeDeCook@aol.com**Sent:** Tuesday, January 11, 2005 9:58 AM 3122 5 19 15 11:00**To:** GalsonS@cder.fda.gov**Subject:** OTC EC Decision

The American Association of ProLife
Obstetricians and Gynecologists
339 River Ave
Holland, Mich 49423
January 11, 200

Dr. Steven Galson
Acting Commissioner
FDA CDER
5600 Fishers Lane
Rockville, MD 20852

Dear Dr. Galson,

AAPLOG is a Special Interest Group of the American College of OBGYN, consisting of 2200 physician members and associates committed to the welfare of women, pregnant or non-pregnant, and the unborn child. We are writing in regard to the issue of Over The Counter status for Emergency Contraception. We understand a decision is imminent.

We have previously written you (11-19-04) regarding this topic prior to your denial of the Barr Laboratory's first application, which you courageously and correctly denied on sound scientific grounds. That letter is attached for your reference. In that letter we pointed out studies from the U.K showing a threefold increase of ectopic pregnancy rate associated with EC use in cases where pregnancy had occurred. We further referenced studies from Sweden showing a 30% increase in both teen abortions and teen STD rates which occurred in the time frame that EC was OTC available in Sweden. Similarly, a 23% increase in teen STD rates was noted in Washington State concurrent with a 5 year "pharmacist direct" pilot program of OTC EC availability. We suggested that these were extremely serious public health concerns.

During the FDA hearings on Barr's application in December 2003, testimony was received from Dr. David Grimes and ACOG President Elect Dr. Vivian Dickerson, both of whom testified that OTC status is desirable because this would result in a greatly reduced incidence of unwanted pregnancy, with resultant greatly reduced rates of induced abortion in this country. Dr Dickerson stated that OTC availability of EC "has the potential to decrease by at least 50 percent the current incidence of unintended pregnancies and subsequent abortions

Two recent studies, (from Scotland, in May 2004, and U. of California at San Francisco, January, 2005, referenced below), whose purpose was to demonstrate the effectiveness of OTC EC to reduce unwanted pregnancy rates demonstrated, in fact, that in the real life world, there is NO DECREASE IN UNWANTED PREGNANCY RATES with over the counter availability of Emergency Contraception. It would seem imperative that Barr Laboratories produce studies demonstrating real world effectiveness for their product before receiving OTC approval. We would ask you to insist on such validation before considering their OTC approval request.

In addition, we remain extremely concerned about the adverse public health potential of OTC EC. Sixteen year olds will obviously obtain it for 13 year olds, so the "16 year old and above" requirement in the current application will do essentially nothing to protect younger teens. If this medication is OTC, physician contact for STD testing, pap smears, and counseling will be, for practical purposes, eliminated for most of these women. Undiagnosed and untreated STD will result in future infertility and future cervical cancer.

We are also extremely concerned that with OTC availability, this drug would become a major "date rape" facilitator. Even Dr. Dickerson, in her testimony to the FDA in 2003, alluded to its potential for use in date rape or forced sex situations. The ready availability of this drug will allow males to put immense pressure on women to be sexually active—and especially on teen age women, who would be subject to powerful peer pressure to acquiesce,

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For the above reasons, we cannot imagine how a policy of OTC availability could possibly be in the best public health interest of American women, and especially of teen-age women. As doctors who spend our lives dealing with the health concerns, and especially the sexual health concerns, of women, we strongly urge you to deny the Barr Laboratory's request for Over The Counter status for Emergency Contraception.

Sincerely,

Joseph L. DeCook, MD, FACOG
VP, AAPLOG

Studies referenced in paragraph 4:

Study from San Francisco: Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs A Randomized Controlled Trial Tina R. Raine, MD, MPH; Cynthia C. Harper, PhD; Corinne H. Rocca, MPH; Richard Fischer, MD; Nancy Padian, PhD; Jeffrey D. Klausner, MD, MPH; Philip D. Darney, MD, Msc; JAMA. 2005;293:54-62.

Study from Scotland Original research article: Advanced provision of emergency contraception does not reduce abortion rates; Anna Glasier, Fairhurst, Wyke, Ziebland, Seaman, Walker, Laha; Contraception, Vol 69, Issue 5, May 2004, Pages 361-366.