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

Nov 19, 2004

Dear Dr. Galson,

AAPLOG is a 2000 member special interest group of ACOG. We are very concerned with the issue at hand, the possible approval of OTC EC. The safety of levonorgestrel is taken for granted, piggybacking off of the experience with levonorgestrel in standard birth control pills—a very different clinical situation. The basic issue of patient well-being involves much more that the pharmaceutical effects of Levonorgestrel. The Public Health issue necessarily involves the long term health interests of the women using the medication.

You have asked Barr Laboratories for more safety data in early teenagers. We urge you to insist on adequate safety data for all ages, with special reference to ectopic pregnancy in EC "failures." The postmarketing surveillance experience in the UK, with specific reference to 201 EC failures, found 12 ectopic pregnancies, or a 6% rate—triple the expected rate for both UK and US. The British Government issued a warning to the doctors in the country to be especially aware of this potential complication. This material may be found at
http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/CMOUpdate/CMOUpdateArticle/fs/en?CONTENT_ID=4003844&chk=2uZJEX
This is CMO update #35, dated 4-2-03, content # 20.

We have not seen authoritative studies in the United States experience that contradict this finding. To make matters worse, the proposed OTC status would result in lack of physician oversight for these patients, compounding the potential disaster of ectopic pregnancy. Surely this is not acceptable public health policy.

It was also strongly suggested to the December 03 FDA panel that OTC status of EC would result in a 50% decrease in elective abortion in this country. This contention is sharply contradicted by the Swedish experience in the 5 years following non-prescription EC availability. Sweden experienced a 31% increase in teen abortion during this time. Abstract may be found at:
http://sti.bmjjournals.com/cgi/content/full/78/5/352
which references the following: K Edgardh. Adolescent sexual health in Sweden. Sex Transm Inf 2002;78:352-356
It would seem to us that the association of an increased induced abortion rate among teens corresponding to the availability of OTC EC in Sweden is a very red flag. The FDA should consider this very carefully before granting OTC approval. After all, this is the very "problem" that OTC EC would purport to improve.

Finally, we have the troubling problem of increased STD rates noted in both Sweden (see: http://sti.bmjjournals.com/cgi/content/full/78/5/352) and Washington state (see:
http://www.doh.wa.gov/cfh/STD/morbidity.htm

In Sweden, following OTC availability of EC in the late 1990's, there was a 30% increase in Chlamydia infections from l999 to 2001. In Washington state, in the five years following the start of the "pharmacist direct pilot project," (l997-2002), teenage women showed a 23% increase in Chlamydia infection. Without physician oversight, these undiagnosed and untreated STD's will lead to infertility and cervical disease, surely not a good public health result for these women.

There is ample evidence that the use of Emergency Contraception OTC is attendant with very serious long term risks for the health of the women involved. Mandatory physician oversight, with STD testing, pap smears, and pregnancy tests as indicated, is essential for the well being of these women. The Pharmacist cannot fill this role.

Barr Laboratories must be held to a very high standard in demonstrating the "safety" of their product with regard to the adverse health effects associated with OTC EC in the above instances. American women deserve to be

protected from this type adversity. As we understand it, protecting them is your mandate.

We would urge you to make a final decision on this matter that is in the best interest of responsible medical care, and in the best long term health interest of the women of the country.

Sincerely,

Joseph L. DeCook, MD, FACOG
Vice President, AAPLOG