

BEFORE THE UNITED STATES FOOD AND DRUG ADMINISTRATION

In re:)
)
Barr Laboratories and the 'Morning After' Pill)
)
July 23, 2004)

TO:

**Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852.**

Dear Sirs,

I am writing on behalf of the Institute for Human Rights, Inc., a non-profit organization, which is very troubled by the proposal from Barr Laboratories seeking permission to market the 'morning after' pill over-the-counter at drug stores throughout the United States. (See Exhibit A.)

This proposal should be denied by the FDA, as it is bad public policy, and would endanger the physical and mental health of young women.

On a grading scale of A through F, we would give the proposal an "F," as there are no safeguards at pharmacies that would prevent girls 16 and younger from obtaining access to the drugs.

Furthermore, there are no safeguards which can prevent women 18 and over from obtaining the drugs – and reselling them to younger girls.

Young women should be encouraged to abstain from sexual intercourse, not encouraged to engage in that licentious behavior, for the mere commercial gain of a corporation like Barr Laboratories.

Very Respectfully,
Nancy Koprowski
Nancy Koprowski
Executive Director
The Institute for Human Rights, Inc.
1415 North Dearborn Parkway
Chicago, Illinois 60610
Telephone: 312-951-9663

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Exhibit A

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Morning-after pill maker tries again for OTC sales

July 23, 2004

BY LAURAN NEERGAARD

WASHINGTON -- A maker of morning-after birth control asked the government Thursday to reconsider allowing over-the-counter sales of the pills -- but only for women 16 and older.

The Food and Drug Administration in May rejected nonprescription sales of emergency contraception, overruling its own scientific advisers, who had overwhelmingly called easier access to morning-after pills a safe way to prevent thousands of abortions.

The FDA argued that its decision reflected concern about how young teenagers might use the pills. Agency officials pledged to reconsider if manufacturer Barr Laboratories either provided data on young teens' use -- or proposed a way to sell over-the-counter only to those 16 and older.

The FDA has never formally approved such a mixed-marketing approach, which would require drugstores to check customers' ages. But Barr, maker of the Plan B emergency contraception brand, on Thursday sent the FDA a formal application to try. Under the proposal, younger teens could continue to buy Plan B with a doctor's prescription, as they can today, while older teens and adults skipped that step.

"Our counsel does believe we have found a way to do that" that meets all FDA regulations, said Barr spokeswoman Carol Cox.

The FDA doesn't usually comment on drug applications, but the agency by law will have six months to review Barr's application and make a decision.

Until then, Plan B remains available as a prescription product for all ages except in six states -- Maine, California, Washington, Alaska, Hawaii and New Mexico -- that already allow women to buy morning-after pills from certain pharmacists without the doctor's note.

The morning-after pill is a higher dose of regular hormonal contraception. Taken within 72 hours of unprotected intercourse, it can cut a woman's chances of pregnancy by up to 89 percent. But it can be hard to find a doctor to write a prescription in time, especially on weekends and holidays -- and the earlier it's taken, the more effective it is.

If a woman already is pregnant, morning-after pills have no effect.

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