Congress of the United States

Washington, DC 20515

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December 8, 2003

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

Re: 01P-0075 over-the-counter status hearing for the morning-after pill

Dear Advisory Committee Members:

We urge you to reject the petition currently before you to make the morning-after pill as accessible to our nation's teenage daughters as aspirin or hairspray. Furthermore, we ask you to weigh the serious implications of allowing children access to a powerful drug without the knowledge of their parents or family physician, the very people who are most familiar with the minor's health needs and history.

As you may or may not be aware, both the House and the Senate have overwhelmingly voted to block schools from distributing the morning-after pill to minor children.[1] During Senate debate, the legislation's author Senator Helms said, "Under the proposed measure, elementary and secondary schools will be forbidden to use funds ... to distribute to school children the 'morning-after pill'—which is widely considered to be an abortifacient. In fact, many pharmacists nationwide have refused to fill prescriptions for the 'morning-after pill' because they, too, see it as an abortifacient.... Clearly, Congress simply must not ignore the fact that our schoolchildren deserve to be protected."

Allowing our schoolchildren to walk next door to the drugstore and pick the morning-after pill off the shelf as often as they want, without any parental consent or involvement, and without the advice of and prescription from a doctor, is seriously troubling. We are already deeply concerned that the federal government has, through regulations, kept parents in the dark when their minor daughters obtain prescription drugs and devices at federal Title X clinics. For the FDA to go a step further and make a potent drug available to minor children at the local drugstore, with only the "consultation" of the cashier, would be a serious error of judgment. It is not good public policy for a nation that spends hundreds of millions of dollars to promote healthy lifestyles for our teenagers, to turn around and allow the morning-after pill to be stacked casually on shelves next to toothpaste and cough drops.

In addition to urging you to reject the petition for over-the-counter status, we also ask that you revisit the FDA-approved morning-after pill package insert to ensure it is clearly explained how the drug

[1] June 30, 2000, Helms Amendment (SA 3697) adopted to H.R. 4577, CR pgs. S6094-6095; Motion to table rejected 41-54, http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=106&session=2&vote=00169 September 19, 2000, Coburn Motion to Instruct Conferees adopted 250-170, 1 present (Yes votes: 191 R, 58 D, 1 I) http://clerk.house.gov/cgi-bin/vote.exe?year=2000&rollnumber=481; Congressional Record H7817-7825. Note: Because of President Clinton's objections, the Helms provision was not signed into law, and thus there is currently legislation introduced that seeks to prohibit federal education funding for elementary or secondary schools that provide access to the morning-after pill (see H.R. 926, sponsored by Rep. Melissa Hart). This legislation is co-sponsored by 50 Members of Congress.

regimen works so that women are able to exercise completely informed consent. It is crucial that drug literature is not misleading or ambiguous especially when it comes to the affects of a drug on a woman or on a human embryo inside of her.

According to the FDA's own documents, the morning-after pill drugs:
"act by delaying or inhibiting ovulation, and/or altering tubal transport of sperm and/or ova (thereby inhibiting fertilization), and/or altering the endometrium (thereby inhibiting implantation)."
—Federal Register, Vol. 62, No. 37; 8611; FDA. "Prescription Drug Products;
Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception", February 20, 1997

Similarly, the Plan B manufacturer (one brand of morning-after pill) says on its website, "In addition, it may inhibit implantation by altering the endometrium."

Though both the FDA and the manufacturers say the morning-after pill may "inhibit implantation," it is not clear that women are fully informed that this phrase means a human embryo inside them may be adversely affected by this drug. In order to ensure that women have completely informed consent, it is crucial that the FDA revisit and review current packaging inserts and other literature.

We appreciate your attention to our concerns.

Sincerely,

NJ-05

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