



Office of the General Counsel

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October 27, 2005 9 8 7 0 '05 OCT 27 P 2 :27

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subj: Docket No. 2005N-0345
RIN 0910-AF72

Dear Sir or Madam:

On August 26, 2005, the Food and Drug Administration invited public comment on the circumstances under which an active ingredient may be simultaneously marketed in both prescription and over-the-counter form. The August 26 notice of proposed rulemaking comes on the heels of, and is in response to, an earlier proposal to make the Plan B "morning-after" or "emergency contraception" pill available over the counter to persons over the age of 16. The FDA's stated concern about the legality and practicability of making any active ingredient available over the counter to a subpopulation, of which Plan B would be one instance if that application were granted, prompted the August 26 notice of proposed rulemaking.

In response to the August 26 notice, we submit the following comments on behalf of the United States Conference of Catholic Bishops. Our views, while specific to Plan B, have a bearing on the broader question whether and when, as a practical matter, the FDA would be able to enforce a regimen in which a product is made available to a subpopulation by prescription only.

We believe, as we stated in previously filed comments, that permitting over-the-counter sale of Plan B would be detrimental to minors (and adults) notwithstanding any effort to limit marketing to adults. See our comments of August 12, 2005, and December 5, 2003, on file with the FDA and available at www.usccb.org/ogc/ruleind.shtml.

First, if Plan B became available over-the-counter, even if such availability were ostensibly limited to adults, it would as a practical matter make it easier for minors to obtain the drug without a physician's or parent's involvement. A minor could procure the drug indirectly through a non-parental adult, or might obtain it directly as a result of lax enforcement by the pharmacy, misrepresentation, or theft.

Second, without parental involvement and professional oversight, minors with access to Plan B may rely upon and use it to the detriment of their health. It can be

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expected, for example, that many girls (indeed many adult women) will take Plan B multiple times rather than as recommended. See Scottish Council on Human Bioethics, "Briefing Paper on the Morning-After-Pill" ¶ 2.2 (Jan. 2002) (citing studies showing high repeat use). In our previous comments, we pointed out the significant health risks that would be occasioned by the absence of clinical oversight and monitoring. A child will not always appreciate these risks or necessarily understand where to turn when complications arise.

Third, over-the-counter availability will undermine efforts to encourage parents' participation in decisions affecting the health of their dependent minor children at a time when the Administration, in other contexts, has been promoting and defending such efforts. See, e.g., Brief for the United States as Amicus Curiae Supporting Petitioner, *Ayotte v. Planned Parenthood of Northern New England* (U.S.) (No. 04-1144), urging the Supreme Court to uphold a requirement of parental notice for minors seeking an abortion.

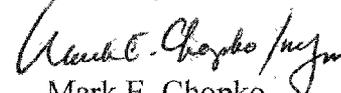
Fourth, over-the-counter availability has implications for whether consent will be truly informed. Girls (and many adult women, for that matter) may be unaware that in some circumstances Plan B can have an abortifacient effect by interfering with the survival of a newly conceived human being. Over-the-counter use does nothing to educate potential users of Plan B in this regard – indeed, Plan B has been widely promoted as *not* causing abortion – and will only increase the likelihood of continued ignorance about the drug's mechanisms, which in turn affects whether consent to its use is truly informed.

Fifth, over-the-counter availability will likely compound the pressure already being placed upon health care providers and professionals to violate their conscience. Even now there are published reports in some jurisdictions of efforts to require pharmacies and pharmacists to carry Plan B and make it available notwithstanding their conscientious objection to the drug, and that effort has already resulted in litigation.

In raising these issues, we do not write on a blank slate. Our previous comments of December 5, 2003, and August 12, 2005, referenced above, discuss these and related concerns at greater length. For the reasons set out here and in our previously filed comments, Plan B is one instance of a drug in which over-the-counter availability, either generally or to a subpopulation, would be injurious to many – children and adults, as well as health care providers and professionals.

We ask the FDA to reject the current application, and any subsequent application, to make Plan B available over the counter either generally or to any subpopulation.

Sincerely,


Mark E. Chopko
General Counsel