

August 12, 2005

Food and Drug Administration
Office of the Commissioner
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Subj: Over-the-Counter Use of Emergency Contraception

Dear Sir or Madam:

On December 5, 2003, on behalf of the United States Conference of Catholic Bishops, we submitted comments opposing a proposal to make emergency contraception ("EC") available without a prescription. Currently pending before the FDA is a modified application to make EC available without a prescription to women and girls over the age of 15.

The current application does not meet the objections raised in our December 2003 comments.

We have continuing concerns about the potential for misuse in the case of minors notwithstanding the proposed limitation to girls 16 years of age and older. If approved, the present proposal would undermine efforts to encourage parental participation in decisions affecting the health of their minor children at a time when the Administration has renewed its endorsement of 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), filed August 2005, urging the Supreme Court to uphold a requirement of parental notice for minors seeking an abortion. The proposed cutoff for teens 16 and older does not adequately address this problem and, indeed, may only confound government and private efforts to promote parental involvement. Over-the-counter availability also may increase risk-taking behavior and promiscuity, an especially acute problem in the case of teenagers, who have higher rates of sexually transmitted disease in this country than their counterparts in other developed nations.

The current application also fails to meet other objections made in our December 2003 comments. Five points warrant brief reiteration:

1. EC can have an abortifacient effect by preventing implantation or survival of an embryo. Its over-the-counter use would conflict with a trend in law and medicine that recognizes the human embryo as a human subject and patient deserving of protection.

2. Misperceptions about EC persist. Many women remain unaware that EC can have an abortifacient effect. Over-the-counter use does nothing to educate women in this regard, and will only increase the likelihood of continued unawareness, which has obvious implications for whether consent will be informed.

3. EC carries significant medical risks and is contraindicated for many women. Making it available over-the-counter will eliminate the clinical oversight and monitoring necessary to ensure that women are not harmed.

4. Availability of EC is not likely to significantly reduce abortions. EC itself can have an abortifacient effect, and jurisdictions that have made the drugs available have not seen a reduction in abortion.

5. Over-the-counter availability of EC will likely increase the pressure already being placed on pharmacies and pharmacists to violate their conscience.

A more complete discussion of these issues is set out in our December 2003 comments, on file with the FDA and available at <http://www.usccb.org/ogc/ec-fda.shtml>.

For the reasons set out here and in our earlier comments, we urge the Administration to reject the current application to make EC available over the counter.

Sincerely,

Michael F. Moses
Associate General Counsel