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

Ladies and Gentlemen:

I am writing in opposition to the Citizen's Petition in this matter. As a representative and advocate for injured persons, I am deeply concerned about the availability of abortion pills to the public as a general issue, much less without the guidance and counsel of a licensed medical practitioner. These so-called "Emergency Contraceptives" and more specifically the drugs brand-named *Preven* and *Plan B* are nothing short of controlled poisons, which are marketed as a "solution" to the "consequences" of unprotected sexual intercourse. Indeed, I am urging the FDA to m-evaluate its position on these drugs entirely and to withdraw FDA approval of these deadly substances entirely.

The petitioners in this matter are wholly invested in a definite political agenda which is ill concerned with the dire matters of public health involved in the illicit availability of a chemical designed to destroy living human cells. Indeed the overwhelming majority of the petitioners are intrinsically linked to the Planned Parenthood Federation of America, which has its roots in the eugenics movement.

In their petition, the petitioners falsely use inflammatory statements and conclusory language for which there is no factual basis. In fact, many of the petitioners' arguments are without any rational basis, to wit:

The petitioners state that EC's are not toxic to the woman, fetus or embryo. Such a statement is simply ludicrous. The very purpose of these pills is to ultiiately destroy the embryo or fetus through deprivation. Indeed the American Journal of Obstetrics and Gynecology has published at least one article noting that the "morning after" is too late for a contraceptive effect and that the actual effect is to "terminate a viable pregnancy by interfering with the endometrium.. . " (See "The morning-after pill; How long after?" *Am. J. Obstet. Gynecol.* 171: 1529-34 (1994).)

Additionally, studies have very clearly shown and born out the fact that severe risks can be had to women who ingest these "medicines." On a Princeton University website which promotes the use of these devices, (and therefore is not directly adverse to the availability of the same) it is noted that "It is possible . that a woman using ECPs could have one of the dangerous or even fatal complications that have been reported in very rare cases with normal, prolonged use of birth control pills. These include: thrombophlebitis (blood clots in the legs), lung clots, heart attack, stroke, liver damage, liver tumor, gallbladder disease, and high blood pressure." Further, women who smoke cigarettes and those who have experienced any of the following conditions are advised not to take ECPs: blood clots in the legs or lungs, cancer of the breast or reproductive organs, stroke, heart attack, and "any serious medical disorder such as diabetes, liver disease,

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heart disease, kidney disease, sever migraine headaches, or high blood pressure" (http://opr.princeton.edu/ec/ecpnyou.html and www.fwhc.org/ecinfo_n.htm).

The petitioners assert that EC's have "a low risk of abuse or overdose.. . " This is also not borne out by the research on the same. In fact, quite the opposite is true. In an effort to determine whether women would use ECPs too often if they were allowed to keep them in their medicine cabinet, Anna Glasier, M.D. and David Baird, D.Sc. studied two groups of women in Edinburgh, Scotland. A total of 1,083 women were recruited who had previously used ECPs or had a surgical abortion. These women are "not exactly" a representative group, according to Margaret Pfeifer, M.D., an ob/gyn at the Mayo Clinic in Rochester, Minnesota. Because of their history of abortion or ECP use, they were more likely than other women to use ECPs. They also had a fairly high educational level and were given detailed written and oral instructions concerning use. Data was available for analysis on 1,071 women (549 with ECPs at home and 522 in a control group who would first need to obtain a doctor's prescription for ECPs). Among the treatment group, 47% used ECPs at least once in the two-year period of study, compared to 27% use among the controls. Ten percent of each group used ECPs more than once. One woman was dropped from the study after she used ECPs more than four times in four months. There were 28 pregnancies (5%) in the treatment group and 33 pregnancies (6%) in the control group. Eight women in the treatment group and four in the control group appear to have become pregnant during a cycle in which emergency contraception was used. The children who survived the ECPs were subsequently aborted. (Glasier and Baird, "The Effects of Self-Administering Emergency Contraception," *N. Engl. J. Med.*, 339:1-4 (1998).)

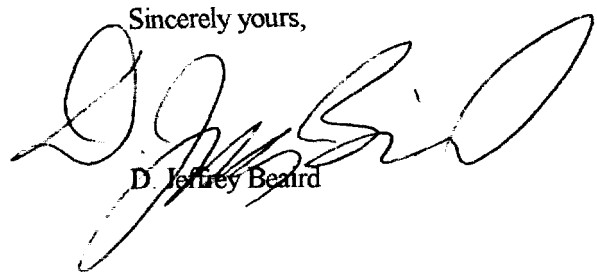
The petitioners cite the beneficial effects of enabling more women to "prevent unwanted pregnancies" as a benefit to public health. Ignoring, for a moment, the obvious public blight of the destruction of viable human fetuses, there are much more serious public health threats than that of "unwanted pregnancies" which must be considered. The so-called nominal side effects of these chemicals are no more well known at this point than were the side effects of Phen-Fen at the time of FDA approval, yet the serious risks which could be imposed upon unsuspecting women is phenomenal.

Of additional public health concern is the actual facilitation of the very real public health threat of increased unprotected sexual intercourse between unmarried persons. It is without question that the public health threat of increased sexually transmitted diseases has dramatically increased instead of decreased over the past 15 years. With the advent of the HIV virus and AIDS, the public health crisis of such diseases has moved from serious to fatal. Only the boldly foolish would assert that the increased availability of EC's via over-the-counter methods would not increase the instance of unprotected sexual intercourse by unmarried, non-monogamous persons. If for no other reason, this serious health threat justifies the denial of the petitioners' petition.

In an age of incredible scientific advance, it is truly without justification that such a falsely premised and foolhardy proposal should be advanced, particularly in a civilized culture. The unrestrained harm to both the public, to consumers and to women that would result from the granting of this petition has catastrophic potential.

I urge the FDA to deny the petition in this matter and to re-examine the approval of dispensing such inherently dangerous products within the United States.

Sincerely yours,



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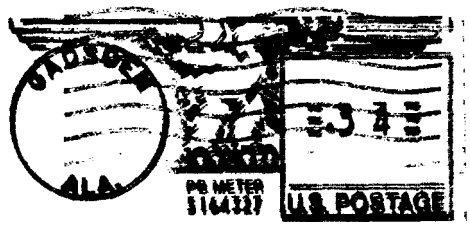


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