



National Partnership for Women & Families

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National Partnership for Women & Families
Submission to Public Comments: 2001p-0075 Joint Meeting of the Nonprescription Drugs Advisory
Committee and the Advisory Committee for Reproductive Health Drugs
December 5, 2003

The National Partnership for Women & Families is a nonprofit, nonpartisan organization that uses public education and advocacy to promote quality health care, fairness in the workplace, and policies that help women and men meet the dual demands of work and family. Founded in 1971 as the Women's Legal Defense Fund, the National Partnership has grown from a small group of volunteers into one of the nation's most powerful and effective advocates for women and families. Working with business, government, unions, nonprofit organizations, and the media, the National Partnership is a voice for fairness, a source for solutions, and a force for change.

The National Partnership dedicates a tremendous amount of its resources toward ensuring quality health care for women and their families. Underlying our health care work is the fundamental tenet that quality health care is a human right and access to the full range of reproductive health services is an essential component of quality health care for women. Thus, our work in this area is driven by two overarching goals: to ensure that all women, regardless of income, age, geography, race or ethnicity, have access to comprehensive high quality health services, and to protect women's reproductive rights and access to reproductive health services.

Access to safe and effective contraception is essential to women's reproductive health. Consistent with that goal, the National Partnership submits this testimony in support of making Plan B®, an emergency contraceptive pill which was approved in 1999 by the Food and Drug Administration, available over the counter. The clinical data submitted in support of the application to make Plan B® over-the-counter (OTC) includes research from 39 studies, which clearly demonstrate that Plan B® meets the criteria for OTC status:

- **The condition treated by emergency contraceptive pills like Plan B® – failure of contraception or unprotected sexual intercourse – is easily self-diagnosed by women.**
- **Plan B® is easy to self-administer. All patients take the same dose, and correct administration relies only on knowing how much time has elapsed since intercourse – information readily available to the woman.**
- **The side effects are well known and minor.**

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- **The labeling is simple and easy to follow.**

The American Medical Association (AMA), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG), along with *more than 70* medical and public health groups, have endorsed the Plan B® OTC application. The weight of the scientific evidence is clearly in favor of approving Plan B®'s sale over the counter.

We submit this testimony today in our role as longstanding advocates for policies that improve women's access to quality health care, including quality reproductive health care. Reducing unintended pregnancy is an essential component of good health care for women and therefore compels us to make emergency contraception more widely available for women in the United States. If Plan B is made available over-the-counter, it will allow for broader and more timely access to emergency contraception and could greatly reduce the number of unintended pregnancies in this country.

There are more than three million unintended pregnancies each year in the United States, and half of these are the result of contraceptive failure. Making emergency contraception (EC) easier to obtain would substantially reduce the incidence of unintended pregnancy. The Alan Guttmacher Institute estimates that prescription EC prevented 51,000 abortions in 2,000 and accounted for up to 43 percent of the decline in abortion rates from 1994 to 2000. The number of abortions averted through the use of EC would be even greater if Plan B® were easily accessible over the counter.

Although there is evidence that emergency contraception can be used up to five days after sexual intercourse, rapid administration of emergency contraception is critical to its efficacy. Emergency contraception is 89 percent effective if taken within 72 hours of intercourse – and Plan B® has been shown to be *95 percent* effective if taken within 24 hours of intercourse. The sooner a woman is able to obtain emergency contraception, the higher her chances are of preventing an unintended pregnancy.

But Plan B's current status requires women to obtain a prescription from a health care provider, making it far less effective at preventing unintended pregnancy. Many women do not have a regular health care provider – and even those who do may be unable to secure a prescription from the provider on short notice. Most professionals whose licenses allow them to prescribe medication will not do so without first seeing the patient, and it can be difficult – if not impossible – to secure a health care appointment within 24 hours, and the effectiveness of emergency contraception diminishes each day after the incidence of sexual intercourse. In addition, women who have been sexually assaulted do not always seek health care. A 2000 study showed that about one in four calls to the Emergency Contraception hotline (1-888-NOT-2-LATE) did *not* result in an appointment with a health care professional or telephone prescription for emergency contraceptive pills within the recommended 72-hour window.

Currently four states – Alaska, California, Washington and New Mexico -- have protocols in place to allow pharmacists to directly dispense emergency contraception to

women. Still, these women seeking emergency contraception are required to have an intimate conversation with the pharmacist before they can secure it, a requirement that also acts as a barrier to access for many women. If emergency contraception were available over the counter, women could still seek assistance from a pharmacist if they had any questions about administration or side effects – but they would not be *required* to have an uncomfortable discussion with a person who might be a complete stranger or even their neighbor before they could access the product. The requirement for an intimate conversation with a pharmacist is even more of a barrier for young women, women with limited English proficiency, or women with particular cultural norms.

The other critical barrier to access to emergency contraception is lack of knowledge of its existence. Although Plan B® has been available to women in the United States since 1999, knowledge about its availability remains low. This lack of knowledge has contributed to a lack of access to this important contraceptive tool. The AMA and ACOG both recommend that doctors make emergency contraception available to *all* women, yet only 20 percent of physicians actually tell their patients about it and 60 percent of women surveyed had never heard of it. A Kaiser Family Foundation survey conducted in 2000 found that only two percent of women ages 18-44 reported ever using emergency contraceptive pills. Approving Plan B® for over the counter use would substantially increase the financial incentives for the pill's distributor to expend significant resources to educate women about its availability and use.

Increased education about emergency contraception will also help clear up myths and confusion about how emergency contraception works. Emergency contraceptive pills prevent pregnancy the same way that daily birth control pills do: by delaying or preventing ovulation, inhibiting fertilization, or preventing implantation of a fertilized egg in the uterus. Unfortunately, emergency contraception is often confused with Mifeprex (also referred to as RU-486 or mifepristone) – but they are not the same thing. Emergency contraception like Plan B® *prevents* pregnancy. It will not work if a woman is already pregnant. Emergency contraception does not terminate an established pregnancy or harm a developing fetus.

It is shameful that the rate of unintended pregnancy in the United States is the highest among industrialized countries. As emergency contraceptive pills are already available over the counter in more than a dozen countries, the U.S. clearly lags behind other nations in giving women easy access to safe and effective contraception that will help them prevent unintended pregnancy.

We understand that some have suggested that if Plan B® is made available over-the-counter, it will be abused or misused. We believe such criticisms are based on mischaracterizations of women's reproductive decision making processes and are insulting to women's intelligence. Studies in the U.S., Scotland and India indicate that women who receive emergency contraceptives in advance of need are 2-3 times more likely to use them – but not more likely to use them repeatedly. Women with advance provision of emergency contraceptives are no more likely to engage in unprotected sex and no more likely to use their regular contraceptive methods less consistently. In

addition, teenagers living in countries with greater access to emergency contraception are no more likely to engage in unprotected sex if they know they can use EC. Moreover, teens can currently access condoms without a prescription, and emergency contraception is an effective back-up method to condoms.

According to the Office of Women's Health within the U.S. Department of Health and Human Services, women are not only responsible for making their own healthcare decisions – they typically also are solely or primarily responsible for making health care decisions for their families. Nearly two-thirds of women polled in a recent national survey indicated that they alone were responsible for health care decisions within their family, and 83 percent had sole or shared responsibility for financial decisions regarding their family's health. Women also typically are the primary caregivers for ill or disabled family members. It is patronizing and unacceptable to assume that women would be incapable of using emergency contraception responsibly. Every-day millions of women make decisions about over-the-counter medicines like cough suppressants, gastrointestinal drugs, antihistamines and pain relievers – for both themselves and their families. We should judge their capacity to understand and self-administer Plan B® by the same standard.

We thank you for the opportunity to submit this testimony and urge your swift approval of Plan B® for over-the-counter use.

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Advisory Committee for Reproductive Health Drugs**

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