

# The benefits and risks of over-the-counter availability of levonorgestrel emergency contraception

S.L. Camp<sup>a</sup>, D.S. Wilkerson<sup>a,\*</sup>, T.R. Raine<sup>b</sup>

<sup>a</sup>Women's Capital Corporation, 1990 M Street NW, Suite 250, Washington, DC 20036, USA

<sup>b</sup>Department of Obstetrics, Gynecology, and Reproductive Science, Center for Reproductive Health Research and Policy, University of California, San Francisco, San Francisco, CA, USA

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## Abstract

Removing the prescription requirement for Plan B<sup>®</sup> will help ensure that the product plays a larger role nationally in the reduction of unintended pregnancy and abortion—important public health goals. Over-the-counter (OTC) sale of Plan B should present no serious safety issues. OTC consumers are able to understand and follow the instructions for proper use of Plan B. Efficacy of the OTC product is likely to be the same as, or better than, the prescription product, given more timely access to treatment. Based on the results of a growing body of literature and foreign marketing experience, the risk of unintended health consequences also appears to be minimal. There is no evidence to suggest that American women will abuse Plan B as an OTC product. © 2003 Elsevier Inc. All rights reserved.

*Keywords:* Emergency contraception; Over-the-counter; Levonorgestrel; Postcoital contraception; Unintended pregnancy

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## 1. Introduction

Levonorgestrel is a synthetic progestin effective in the prevention of unintended pregnancies following unprotected sex [1]. As an emergency contraceptive (EC), it is considered a back-up method for occasional rather than regular use and is intended to be used shortly after sex but before pregnancy has become established [2]. Levonorgestrel-only EC is 89% effective when used correctly within 72 h after unprotected sex and reduces the risk of pregnancy, following a single act of mid-cycle unprotected sexual intercourse, from 8% on average, to 1.1% [1]. Each 12 h of delay in starting EC treatment (analysis of Yuzpe and levonorgestrel regimens together) was found to reduce efficacy by about 50% ( $p < 0.01$ ) [3].

Levonorgestrel can prevent pregnancy several different ways, depending on the cycle day of unprotected sex and the day on which treatment is initiated; it may interfere with the process of ovulation, fertilization or implantation [4–9]. The levonorgestrel-only product used as EC is marketed as Plan B<sup>®</sup> in the United States and as Postinor-2<sup>®</sup>, Levonelle<sup>®</sup>, Norlevo<sup>®</sup>

and other names in Europe, Africa, Asia and Latin America. Plan B has been available in the United States since 1999.

Use of EC by US women is relatively low. In a 2003 survey of US women (ages 18–44) conducted by the Kaiser Family Foundation and *SELF* magazine, only 6% of respondents reported ever having used EC (National Survey of Women on their Sexual Health). Although it is widely known among medical practitioners that elevated doses of contraceptive steroids taken soon after unprotected sex can prevent pregnancy, only a minority of US women have any real knowledge of this uniquely important method and still fewer would know how to access it in a contraceptive emergency. In mid-2003, the distributor of Plan B estimated that approximately 3 million US women have used Plan B. In addition, the distributor of the older estrogen-progestin product recently estimated that over 1 million packages of Preven<sup>®</sup> have been distributed. This level of use is well below that in Western Europe.

The US need for back-up EC is, on the other hand, substantial. The United States has the highest rates of unintended pregnancy and abortion of any Western industrialized nation. In 1994, the last year for which complete data are available, 49% of pregnancies to US women were unintended and 54% of these pregnancies ended in abortion [10]. At these rates, a US woman can expect to have 1.4

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\* Corresponding author. Tel.: +1-202-969-8438; fax: +1-202-969-8439.

E-mail address: dwilkerson@go2planb.com (D.S. Wilkerson).

unintended pregnancies by the time she reaches 45 [10]. Although the US abortion rate among women aged 15–44 has declined in recent years, from 24 per 1,000 in 1994 to 21 per 1,000 in 2000, one quarter of all pregnancies (excluding miscarriages) in 2000 still ended in abortion [11].

Wider and easier availability of EC could help women avoid unintended pregnancy, consequently having a significant, positive impact on public health. In the US, EC is currently available by prescription only. In five states (Alaska, California, Hawaii, New Mexico and Washington State), EC can also be obtained directly from pharmacists. In addition to pharmacist provision, many support the switch from prescription to over-the-counter (OTC) availability of EC to increase awareness, access and use of the product [12–15].

The authors have undertaken a review of the available literature in order to assess the likelihood of unintended health consequences as well as the potential for positive health outcomes. The MEDLINE® and PubMed® databases were searched for articles relating to emergency contraception. Keywords used in this search included: emergency contraception, emergency contracept\*, abortion, condom use, consistent, contraceptive failure rates, levonorgestrel, mechanism of action, repeat use, risk, sex, STD, unintended pregnanc\*, United States, unprotected, young and youth. Key findings from the literature that pertained to the risks and benefits of OTC availability of levonorgestrel-only EC OTC were incorporated into this review.

## 2. Benefits of levonorgestrel as an OTC medication

### 2.1. Reduction in unintended pregnancies from contraceptive failure

Unintended pregnancies can be attributed to three main factors: failure to practice contraception, incorrect or inconsistent use of contraception and contraceptive failure. A significant proportion of unintended pregnancies are the result of contraceptive failures; 53% of all US women experiencing an unintended pregnancy report becoming pregnant while using a contraceptive method [10]. In a nationally representative sample of over 10,000 US abortion clients, 54% report becoming pregnant while using a contraceptive method [16].

Some 7.9 million women rely on male condom use for birth control and for disease prevention [17]. The typical-use failure rate for male condoms in the first year of use is about 15% [18]. Incorrect and inconsistent use may contribute to condom failures. Recent surveys have shown that condom users often do not know how to use condoms properly, report using them incorrectly and report wanting to use them but not having them when needed [19,20]. In one survey, nearly one third of users reported condoms breaking or slipping during intercourse [20]. In a recent survey of US abortion clients, condom breakage or slippage

was cited as a reason for pregnancy by 42% of condom users [16].

In addition, the most common reason women cite for needing EC is a condom accident. Various studies have found that from 23% to 85% of clients presenting for EC, or who had recently used EC, reported a condom failure (breakage and/or slippage) [16,21–33].

Other barrier methods of contraception, such as diaphragms and cervical caps, also have relatively high typical-use failure rates. The typical-use failure rate for diaphragms with spermicide in the first year is 16%. For cervical caps, the first year typical-use failure rate ranges from 16% for nulliparous women to 32% among women who have had at least one child [18].

Natural family planning or fertility awareness methods, which rely on periodic sexual abstinence, have typical-use failure rates within the first year of about 25% [18]. Withdrawal has a first year typical use failure rate of 27% [18]. Failure or inconsistent use of these two methods may account for 9.5% of abortions each year [16]. Various studies have found that from 4% to 12% of clients presenting for EC reported a withdrawal accident [21,29,31].

Over 10 million US women use oral contraceptives (OCs), the most popular form of reversible contraceptives in the United States [17]. Although OCs are highly effective when taken correctly and consistently, the typical-use failure rate in the first year of use is 8% [18]. Sporadic or interrupted use of OCs, poor compliance with daily dosing and failure to start a new cycle on time have all been shown to be associated with OC failure [34–38].

Other hormonal methods of contraception, such as injectables and the newer contraceptive patches and vaginal rings, which do not depend on daily compliance, may prove to have lower failure rates. However, injectable contraceptives, whose effectiveness depends on timely monthly or quarterly injections, still have an estimated typical-use failure rate of 3% in 12 months [18].

### 2.2. Reduction in the number of abortions

In the United States, one quarter of all pregnancies in 2000 ended in abortion [11]. Only 1.3% of women having abortions in 2000 reported having taken EC pills to prevent the pregnancy [16].

Trussell et al. [14] estimated that wider use of EC in the United States could, in theory, reduce the number of unintended pregnancies by 49% and reduce the overall number of abortions by 50%. More recently, in a study of over 10,000 US abortion clients, the Alan Guttmacher Institute estimated that use of EC—although still low—may have prevented as many as 51,000 abortions in 2000, and may account for 43% of the 11% decline in US abortions between 1994 and 2000 [16].

In France, the first country to make levonorgestrel EC available without a prescription, abortion numbers were rising steadily each year up until 2000. In June 1999, the

French government approved NorLevo® (levonorgestrel) for nonprescription sale by pharmacists. In January 2000, both junior high and high school nurses in France were given the right to dispense EC in school-based clinics. Women 18 years of age and younger may now obtain EC free of charge from a pharmacist.

It is important to note, however, that a cause and effect relationship cannot be concluded from data demonstrating an inverse relationship between EC access and abortion rates. In Washington State, abortion rates fell after the initiation of a statewide pilot project to increase access to EC in 1997, however, the national abortion rates were also declining during this period [39]. In Great Britain, a regional analysis in the early 1990s showed a positive association between abortion rates and use of EC, leading the authors to postulate that use of both abortion and EC may be high in populations at high risk of unintended pregnancy [40].

### 2.3. Reduction in healthcare costs

EC reduces healthcare costs by preventing unintended pregnancies [41–43]. A 1997 analysis around the economic benefits of adolescent contraceptive use found that the annual cost of unintended pregnancy ranged from \$541 in the public sector to \$1079 in the private sector [43]. In addition, a second analysis of women of all ages estimated the cost of an unintended pregnancy as \$3795 in a managed-care setting and \$1680 in a publicly funded program. Depending on the regimen of EC used, how it is dispensed, and the healthcare setting, EC could save between \$19 and \$498 per year per woman covered by public and managed-care health services [42].

In addition, a modeling of the cost and outcomes of pharmacist-prescribed EC found that obtaining EC directly from a pharmacy, rather than from a physician or clinic, resulted in a \$48 to \$158 savings for public and private payer settings, respectively [44]. While the overall cost of obtaining EC may be less in a deregulated environment, it should be stated that the individual cost to women may increase as insurance plans may not cover the OTC product.

## 3. Low risk of unintended health consequences from levonorgestrel as an OTC medication

### 3.1. Incidence of repeat use

A number of concerns have been raised about potential unintended health consequences resulting from OTC availability of levonorgestrel. One of the most common is the concern over repeat use.

There is no evidence that easier access to EC results in repeat use. On the contrary, the literature on EC indicates that frequent, repeated use of EC is uncommon, even among adolescents [33,45,46]. In an EC label comprehension

study, only 6% of women interviewed in shopping malls and family-planning clinics reported ever having used EC, although over 80% of the sexually experienced subjects reported having a pregnancy scare [47]. For US women presenting to a healthcare facility for EC, ever use of the method at the time of the EC request ranged from 9% to 40%, depending on the study [21,27,33].

In the UK, EC has been marketed since the mid-1980s and sold in pharmacies without a prescription since January of 2001 [48]. One UK study found a prior usage rate of EC at almost 70%. However, even with these high levels of EC usage at some time, this same study found that just 52% of women reported using EC over the past year; and 77% of this population used EC only once or twice over the previous 12 months [24]. Even with the length of time dedicated products have been marketed and the general high levels of awareness in the population, there is little evidence that most European women use the method more than one or two times a year [21,24,49,50].

### 3.2. Repeat use by adolescents

The data on repeat use of EC among adolescents, although not extensive, do not suggest any tendency on the part of adolescents to use the method frequently. Studies in the US and the UK suggest that the bulk of sexually active adolescents who are aware of the method do not abuse it. Among 263 California adolescents and young adults enrolled in a study of EC at a family planning center for youth, only 4% said they had used EC within the prior 4 months [51]. Among 126 Washington State adolescent respondents who received EC directly from a pharmacist, only 8% had used EC two or more times previously [52]. A large retrospective review of 95,007 UK women's patient files from 1994–1997 in the General Practice Research Database found that women aged 14–19 were more likely to have used the method multiple times than women 20–29. However, among users of EC, the levels of repeat use per year for this age cohort never exceeded 13% for using the method twice per year or 6% for using the method three or more times in the year [50]. It is possible that adolescent women are less likely to be in a stable relationship and thus more likely to rely on condoms or other barrier methods of contraception with relatively high failure rates, or they may have had more difficulty using their contraceptive method correctly than older, more experienced women. In either case, their multiple use of EC would not represent abuse of the method.

Information from other European countries also shows relatively low rates of repeat use among adolescents. In Finland, the first dedicated product, based on the Yuzpe regimen, was approved in 1987. A 1996 survey of 52,700 adolescents found that among those who had used EC and provided usable data: 74.6% had used it once, 19.7% used it twice, and 5.7% had used it three or more times [53]. The first dedicated product was approved in Switzerland in the

late 1980s. A 1996 survey of over 1000 adolescent girls in Switzerland found that 20% reported ever use of EC, of which 64.1% had used EC once, 18.5% used it twice and 17.1% had used it three or more times [54]. These rates of use in countries with relatively long exposure to EC products do not suggest any patterns of abuse.

### 3.3. Minimal impact on regular contraception

Related to the concern about repeat use is the concern that US women and their partners will substitute EC for regular contraception or that they will use their regular method less consistently. But studies show that women with access to EC typically do not abandon regular contraception or use their chosen method less consistently. A growing body of literature suggests that women with easier access to EC are more likely to use EC following an occasional episode of unprotected sex than women who must visit a clinic or doctor's office for a prescription [46,51,55–57], but they are generally not more likely to abandon regular contraception [55,56]. Women who use EC following a pregnancy scare may actually be more likely to use an effective ongoing contraceptive method afterwards [28,50].

A study of advanced provision of EC by Raine et al. [51] showed that advanced provision did not increase the incidence of unprotected sex, although there was some evidence of a shift to condoms and less consistent pill-taking. Those receiving EC in advance were less likely to report consistent OC use than women in the control group at follow-up (32% vs. 58%, respectively;  $p = 0.03$ ). The advanced provision group was more likely to have switched to a less effective method, such as a condom, than those in the control group (28% vs. 17%, respectively;  $p = 0.05$ ). However, outcome data among women who have easy access to EC are needed to determine the true impact on unintended pregnancy rates.

### 3.4. Impact on condom use

Specifically, easier access to EC does not appear to undermine condom use. In fact, EC is a useful backup method for couples who rely on condoms for birth control as well as disease prevention. Easier access to EC in the event of condom breakage, slippage or leakage may, in fact, allow more women to rely on condoms for both birth control and disease prevention.

Several studies have examined the effects of EC availability on condom use. In one study of low-income minority adolescents and young adults in San Francisco, there was no observed difference between the advanced provision and clinic access groups with respect to the consistency of condom use at the 4-month follow-up. The results further suggested that condom use might increase slightly among the partners of women with easier access to EC [51]. In a small study of 39 women given EC to keep at home, 39% of those who had not reported condom use at last intercourse during enrollment did report condom use at last intercourse

at a 3-month follow-up. Just 15% of those who had used a condom at last intercourse at enrollment were not using a condom after 3 months in the study, suggesting a net gain of 24% in condom use [58,59]. In a Scottish study comparing women who received an off-label regimen of EC in advance with those who had to obtain it from the clinic, there was no difference between the two groups with respect to the use of condoms at the 1-year follow-up [46].

### 3.5. Impact on sexual promiscuity

Concerns about use of an OTC product are very often raised with respect to sexual promiscuity among adolescents; however, there is no evidence to suggest that OTC availability of EC would increase sexual activity among adolescents. A randomized controlled trial of 3794 male and female adolescents in Great Britain demonstrated that education about EC did not increase sexual activity among young people. The intervention increased levels of knowledge about EC, but there were no differences observed in sexual activity or in the frequency of use of EC at a 6-month follow-up [60]. In addition, results have shown that adolescents do not represent a disproportionate share of consumers accessing EC directly from a pharmacist, either in Europe (Reproductive Health Alliance, Occasional Paper No. 1) or in the pharmacy access programs in the United States [61].

### 3.6. Impact on pregnancy rates

Concern has been expressed that OTC access to EC would encourage greater risk-taking, or use of less effective contraception, and therefore higher overall pregnancy rates. There is little evidence to support this concern. In most studies comparing different modes of access, pregnancy-rate trends were lower in the groups with easier access to EC, although the results were not statistically significant [46,55,56]. Of note, risk-taking is not a good surrogate marker for pregnancy. For example, if EC is 90% effective and were used after all risk-taking in an EC advance provision group, then risk-taking could still be 10-fold greater in the EC group and the same pregnancy rate would be observed in comparison to a group without increased access and less risk-taking.

In addition, the literature suggests that OTC access would reduce pregnancy rates by facilitating early treatment. One study attempting to model pharmacy access (behind-the-counter) to EC estimated that while the incidence of pregnancy would be 1.8% for women obtaining the method directly from the pharmacy, the incidence of pregnancy would be 4.9% for women who could not obtain it directly from a pharmacy, including women who eventually managed to obtain a prescription or the pills from a physician [44].

## 4. General safety profile of levonorgestrel

### 4.1. Side effects and drug interactions

The side effects of levonorgestrel are well-characterized, generally mild or moderate, and self-resolving [62–64]. Common side effects include nausea, vomiting, dizziness, fatigue, headache, breast tenderness, lower abdominal pain and menstrual irregularities [1].

Levonorgestrel has a significantly lower incidence of side effects compared to combination-method ECs [1]. In a randomized, double-blind clinical trial with full results for 1956 women at 21 sites worldwide, levonorgestrel (specifically Plan B) demonstrated a superior safety profile relative to the Yuzpe regimen (i.e., nausea was reduced from 50.5% with Yuzpe to 23.1% with Plan B; vomiting was reduced from 18.8% to 5.6%).

There are only three contraindications to the use of levonorgestrel EC: existing pregnancy, undiagnosed vaginal bleeding or a known allergy to any ingredient in the product.

There is only one report in the literature of a potential drug interaction with levonorgestrel-only EC; this was an apparent interaction with warfarin [65].

### 4.2. Overdose

Levonorgestrel-only EC (Plan B) is packaged as a single course of treatment and includes two 0.75 mg tablets in a blister pack. One tablet is to be taken within 72 h of intercourse, and the second tablet is taken 12 h after the first tablet. Recent studies suggest that taking both 0.75 mg tablets as a single dose is equally effective and that reported side effects did not differ greatly between the two regimens [64,66]. There are no published reports of administration of more than two tablets of levonorgestrel at one time, although such overdosing is unlikely to cause serious adverse events. In clinical studies of levonorgestrel EC for regular postcoital use, there were no serious adverse events reported for women who took up to seven tablets per cycle or who regularly took 0.75 mg tablets after each act of coitus, with no more than one tablet every 3 h [63,67].

### 4.3. Risk of ectopic pregnancy

Recent information released by the UK Committee on Safety of Medicines (CSM) in January 2003 indicated that there were 12 ectopic pregnancies out of a total of 201 total pregnancies reported to the CSM in the UK following use of levonorgestrel-only EC (Levonelle) [68,69]. The French Health Authority reported in February 2003 that it had received eight reports of ectopic pregnancies out of a total of 29 reports of unintended pregnancies since 1999 [70]. From August of 1999 through 19 August 2003, the distributors of Plan B EC report that there was 1 report of an ectopic pregnancy out of a total of 55 reports in the United States of unintended pregnancy from women who had taken

Table 1

Total pregnancies and ectopic pregnancies in clinical studies of levonorgestrel (0.75 mg tablets) for EC [68,69,73]

Studies	Total pregnancies	Ectopic pregnancies reported	Number of women
WHO [1]	11	0	976
Wu et al. [74]	20	0	643
Ho et al. [75]	12	0	410
Arowojolu et al. [66]	11	0	1,118
WHO [64]	44	1	2,712
Total	98	1	5,859

Plan B. Based on estimated patient exposure of over 2 million UK users and over 3 million US users to date, the number of reported ectopic pregnancies is very low. These adverse event reports do not indicate an increased risk in ectopic pregnancy for levonorgestrel-only EC, although the data available to date may be insufficient to completely rule out any increase in risk.

The number of ectopic pregnancies reported is high ( $n = 21$ ) compared to the number of unintended pregnancies reported ( $n = 285$ ). These data do not, however, allow for a valid and unbiased assessment of the risk of ectopic pregnancy following use of EC. Most notably, the denominator (i.e., total number of exposures or total number of pregnancies) is unknown. It is highly likely that many product failures (unintended normal pregnancies) go unreported. Unintended pregnancy is not usually a serious or unexpected adverse event, and there is typically no reason for a normal pregnancy to be reported. Indeed, pregnancy is not actually an adverse event, but rather a product failure. Ectopic pregnancies are much more likely to be reported than intrauterine pregnancies, because ectopic pregnancy is a serious adverse event, sometimes requiring hospitalization.

In clinical studies of users of low-dose progestins used for OC over extended periods, up to 10% of the pregnancies were ectopic [71]. According to the most recent data available, the incidence of ectopic pregnancy in the general US population, among women using no form of contraception, is 2% of all pregnancies [72]. In published, clinical trials of 0.75 mg tablets of levonorgestrel used for EC (including almost 6000 women), 98 pregnancies were reported; 1 of which was ectopic, giving an ectopic pregnancy rate of 1% (Table 1).

### 4.4. Low risk from contraindicated use

There is no evidence that levonorgestrel would harm a pregnant woman or would harm a developing fetus if the product is taken accidentally during early pregnancy. Use in pregnant women is contraindicated because the product would be ineffective, not because it has been shown to be unsafe [76–78]. No studies have examined potential teratogenic effects of levonorgestrel EC. However, there have

also been no reports of adverse birth outcomes in safety and efficacy studies of the drug covering over 6000 women. Only one adverse birth outcome has been reported to Women's Capital Corporation (the distributors of Plan B) since Plan B has been on the market, and this was following use of another brand of levonorgestrel-only emergency contraception in the UK.

Studies have not been undertaken in women with known allergies to the product or women with undiagnosed vaginal bleeding, although there is no evidence to suggest that serious health or medical problems would result from such use. Levonorgestrel, the active product ingredient, is not known to be an allergen, and the other ingredients in Plan B are generally recognized as safe by the Food and Drug Administration.

Levonorgestrel does not cause vaginal bleeding—it is presumed to be listed as a contraindication due to the concern that unusual vaginal bleeding could be a sign of an abnormal pregnancy or endometrial or cervical cancer. There is no evidence to suggest that levonorgestrel would worsen an abnormal pregnancy or reproductive tract cancers. Indeed, the most recent WHO Medical Eligibility Criteria for Contraceptive Use [79] does not mention unexplained vaginal bleeding as a concern for EC pills. The WHO does, however, discuss unexplained vaginal bleeding under combined OCs, but notes that “. . . [t]here are no conditions that cause vaginal bleeding that will be worsened in the short term by use of [combined oral contraceptives].” There should be even less concern with a progestin-only method.

#### 4.5. Safety of repeat use

Levonorgestrel-only EC is intended for occasional rather than regular use and should not be used as a regular contraceptive. However, the safety of repeat or frequent use of EC has been examined in several studies. There are substantial data from early studies of the 0.75 mg levonorgestrel tablet to show that repeated use, even in a single menstrual cycle, is not associated with serious or lasting side effects.

One such multicenter, international study enrolled 295 women who used EC for 6 consecutive months immediately after each act of intercourse as the only method of contraception [63]. No serious side effects occurred during the study, although 69.6% of participants reported a menstrual disturbance at one or more follow-up visits, including intermenstrual bleeding or spotting, premenstrual spotting and lighter than normal menses. Other complaints included nausea, breast tenderness, weakness, dizziness and headache—common side effects of levonorgestrel. Approximately one third of participants dropped out of the study before 6 months, reporting menstrual problems as the dominant reason for discontinuation.

Two other published studies of the use of single doses of levonorgestrel 0.75 mg regularly following sexual inter-

course reported subjects used as many as seven tablets per cycle [62,67]. In both of these studies, no relationship was found between the number of pills taken and the incidence of reported side effects.

#### 4.6. Low risk from incorrect use

The standard dosing regimen of levonorgestrel-only EC calls for two doses of 0.75 mg to be taken 12 h apart within 72 h of sexual intercourse. Possible types of incorrect use include taking only one dose, failure to take the second dose on time (12 h after the first dose), taking both doses at once or starting the regimen late.

Failure to take both EC tablets could make the regimen less effective; however, a single 0.75 mg dose of levonorgestrel EC was efficacious and well tolerated in several studies when taken soon after intercourse [62,63,67]. Two small pharmacokinetic studies examined the safety and efficacy of the standard EC dosing regimen compared to a dosing regimen in which the second dose is taken 24 h after the first dose. The results indicated that the drug was well tolerated and that no serious adverse events were seen for either regimen [80,81].

Several studies have compared the standard dosing regimen of levonorgestrel to a single 1.5 mg dose. Although more side effects might be anticipated with the single-dose regimen, one large study found no significant difference in side effects between the two regimens and another smaller study found slightly higher rates of just headache and breast tenderness in the 1.5 mg dose group [64,66]. A third pharmacokinetic study involving five women found that a single 1.5 mg dose was well tolerated, and there were no serious adverse events reported [81].

Finally, initiating treatment more than 72 h after unprotected sex, while less effective than early treatment, still provided a substantial reduction in the risk of pregnancy [64]. Overall, the studies suggest that no type of incorrect use poses any significant safety problems, and that the regimen remains at least somewhat effective in many cases.

## 5. Discussion and conclusions

Removing the prescription requirement for Plan B will help ensure that the product plays a larger role in the reduction of unintended pregnancy and abortion—important public health goals. OTC sale presents no serious safety issues, even if some women use the product more than once in a single menstrual cycle. There are no deaths and few reports of serious adverse events. Nor is there any evidence that Plan B would harm a pregnant woman or her developing fetus. Side effects are well-characterized and self-resolving. Medical oversight is not necessary and only serves to delay treatment.

Efficacy is likely to be the same, or better, given more timely access to the product and data indicating that early

treatment is more effective. The instructions for use are simple, and all users follow the same regimen. The fact that almost all communication objectives were understood by most subjects—regardless of age, educational attainment, literacy level or ethnicity—suggests that the high levels of understanding of the Plan B label may be translated into appropriate action when women in the general US population use the product in an OTC setting.

A growing body of studies also shows that women with easier access to EC—through advanced provision or pharmacy access—do not abuse the method, do not abandon regular contraception, do not use their regular method less conscientiously and do not engage in greater risk-taking. There is no evidence to suggest that American women will abuse EC if it is made available OTC.

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