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Emergency Contraception

Emergency contraception has been available for more than 25 years and could prevent 1.5 million unintended pregnancies and 800,000 abortions each year in the U.S. It is a safe and effective method of contraception, and women who have used it report high levels of satisfaction.

Despite its enormous potential, anti-choice groups oppose the use of emergency contraception. In order to hinder women's access to this important method of contraception, they falsely claim that emergency contraception (EC) is an abortifacient, and they disseminate other misinformation about its safety and efficacy.

Fortunately, public awareness and availability of emergency contraception has increased, and hopefully more women will benefit from this important backup birth control method in the future.

Widespread Use and Availability of Emergency Contraception Could Prevent More than Half of All Unintended Pregnancies and Abortions in the U.S.

Forty-three million, or seven in 10 women of reproductive age, are sexually active and do not want to become pregnant (AGI, 2005a). Nearly half of America's six million annual pregnancies are accidental; half of them are terminated by an abortion (AGI, 2004).

Seventy-four to 95 percent of teen pregnancies are unintended, and in 2000, an estimated 840,000 U.S. teenage women aged 15–19 became pregnant; more than half became mothers (Advocates for Youth, 2004; Henshaw, 2004; Ventura, et al., 2004).

Widespread use of emergency contraception could potentially prevent an estimated 1.5 million unintended pregnancies and 800,000 abortions each year in the United States (Glasier & Baird, 1998; Stewart, et al., 2004). In 2000, an estimated 51,000 abortions were prevented through the use of emergency contraception; moreover, ECPs were responsible for approximately 43 percent of the decrease in total abortions between 1994 and 2000 (Boonstra, 2003).

Emergency Contraception Is Not Just a "Morning-After Pill". Multiple Emergency Contraception Options Are Available.

Emergency contraception, also called postcoital contraception, can reduce the risk of pregnancy after unprotected intercourse. Emergency contraception is provided in two ways: using hormonal contraceptive pills — either progestin-only birth control pills or combined oral contraceptives — or inserting a copper-releasing IUD (intrauterine device).

The Yuzpe Regimen

This method of emergency contraception is named for Canadian Professor A. Albert Yuzpe who published the first studies demonstrating the method's safety and efficacy in 1974. This regimen uses two doses of oral contraceptive pills that combine estrogen and certain progestin hormones

(FDA, 1997). It can reduce the risk of pregnancy if taken within 120 hours (five days) of unprotected intercourse. The treatment is more effective the sooner it begins (Ellertson, et al., 2003; "FDA Approves...", 1999; Rodrigues, et al., 2001; Stewart, et al., 2004). (Because the emergency contraceptive pills (ECPs) have a five-day window of effectiveness, the popular term "morning-after pill" is misleading.) The doses are taken 12 hours apart. Various prescription products contain the appropriate hormone combination and can be used as ECPs:

- Many common oral contraceptive pills can be used as ECPs, although their manufacturers do not label the pills for this use. "Off-label" use of approved medications is legal and commonplace in American medicine. Further, in February 1997, the FDA declared emergency use of birth control pills, following the Yuzpe regimen, to be safe and effective. At that time, six suitable pill brands were available on the U.S. market (FDA, 1997). Currently, the following brands can be used as ECPs in the U.S.:

Pill Brand	Manufacturer	Pills per Dose
Alesse®	Wyeth-Ayerst	5 pink pills
Aviane®	Barr	5 orange pills
Cryselle®	Barr	4 white pills
Enpress®	Barr	4 orange pills
Lessina®	Barr	5 pink pills
Levlen®	Berlex	4 light-orange pills
Levlite®	Berlex	5 pink pills
Levora®	Watson	4 white pills
Lo/Ovral®	Wyeth-Ayerst	4 white pills
Low-Ogestrel®	Watson	4 white pills
Lutera™	Watson	5 white pills
Nordette®	Wyeth-Ayerst	4 light-orange pills
Ogestrel®	Watson	2 white pills
Ovral®	Wyeth-Ayerst	2 white pills
Portia®	Barr	4 pink pills
Seasonale®	Barr	4 pink pills
Tri-Levlen®	Berlex	4 yellow pills
Triphasil®	Wyeth-Ayerst	4 yellow pills
Trivora®	Watson	4 pink pills

(OPR, 2005a).

Progestin-Only ECPs

On July 28, 1999 the FDA approved the first progestin-only ECP available in the U.S. Produced by Barr Pharmaceuticals, Inc. and known as Plan B®, it consists of two pills, taken 12 hours apart, and contains only the hormone levonorgestrel, a progestin. While this treatment is also more effective the sooner it begins, Plan B can be started up to 120 hours after unprotected intercourse (von Hertzen, et al., 2002). Plan B contains no estrogen ("FDA Approves...," 1999).

Off-label administration of progestin-only oral contraceptives is also effective, but it requires taking 20 Ovrette® oral contraceptive pills, and then taking another dose of 20 pills 12 hours later (Stewart, et al., 2004).

A recent study has shown that a single administration of the two full doses of progestin-only ECPs is also effective (ACOG, 2005; von Hertzen, et al., 2002).

The IUD

A copper-releasing IUD (ParaGard®) can be inserted within five days of unprotected intercourse as a method of emergency contraception (WHO, 2004). It can be left in place for up to 12 years for very effective contraception. Or the IUD can be removed after the next menstrual period, when it is certain that pregnancy has not occurred (Hatcher, et al., 2005).

ECPs Reduce the Risk of Pregnancy by up to 95 Percent, and Emergency Contraception IUD Insertion Reduces the Risk by 99.9 Percent.

Two time factors influence the efficacy of ECPs: the amount of time elapsed after unprotected intercourse, and the point in a woman's cycle at which she had sex. The earlier ECPs are taken after unprotected intercourse, the more effective they are (TFPMFR, 1998). The closer a woman is to ovulation at the time of unprotected intercourse, the less likely the method will succeed (Stewart, et al., 2004). ECPs are not as effective as correct and consistent use of precoital, reversible contraceptive methods such as the pill, IUD, or contraceptive implants, injections, patches, or rings, and they do not protect against sexually transmitted infections (Knowles & Ringel, 1998; Roumen, et al., 2001; Zieman, et al., 2002).

- The Yuzpe regimen of combined estrogen and progestin ECPs reduces the *risk* of pregnancy by roughly 75 percent if started within 72 hours of unprotected intercourse. Not every woman *at risk* of pregnancy actually becomes pregnant. On average, only eight out of 100 women will become pregnant after having unprotected sex during the second or third week of their menstrual cycles. But if they take ECPs, only two out of those 100 women will

become pregnant. Combined hormonal ECPs thus reduce the risk of pregnancy by roughly 75 percent, preventing six of eight likely pregnancies (Knowles & Ringel, 1998; OPR, 2005b; Rodrigues, et al., 2001; Stewart, et al., 2004).

- When used within 72 hours of unprotected intercourse, progestin-only ECPs were found to reduce the risk of pregnancy by 89 percent in a World Health Organization-supported study involving nearly 2,000 women in 21 clinics around the world. When taken within 24 hours of unprotected intercourse, they were found to reduce the risk of pregnancy by 95 percent ("FDA Approves...," 1999; TFPMFR, 1998).

More than 9,400 copper-bearing IUDs have been inserted postcoitally since 1976, with only ten pregnancies occurring: a rate of fewer than one in 1,000, reducing the risk of pregnancy by more than 99 percent (OPR, 2005b; Stewart, et al., 2004).

Emergency Contraception is a Safe Backup Method of Birth Control.

Millions of women around the world have used ECPs safely and effectively (Glasier, 1997; Guillebaud, 1998). ECPs are less effective than the most popular precoital methods of contraception, and in general practice, women only turn to ECPs in emergencies — as a backup to their usual birth control method.

Almost every woman who needs emergency contraception can safely use ECPs — even women with contraindications to the ongoing use of oral contraceptives may use them (Guillebaud, 1998; Hatcher, et al., 2005). ECPs can also be used safely by adolescents. One study designed to evaluate the safety of ECP use in teenagers enrolled 52 teens between the ages of 13 and 16. ECPs were found to be safe and well tolerated by the teens. They took the medicine properly, and they returned to their normal menstrual cycles at the same rate as adult women taking ECPs (Harper, et al., 2004).

ECPs should not be used by women who are already pregnant, not because the pills are thought to be harmful, but because they are ineffective at terminating established pregnancies (Stewart, et al., 2004).

Emergency Contraception Is Not Abortion.

Emergency contraception cannot end a pregnancy. According to the Food and Drug Administration (FDA), “Emergency contraceptive pills are not effective if the woman is pregnant ...” (FDA, 1997). A recent study found that most often, ECPs reduce the risk of pregnancy by inhibiting ovulation (Marions, et al., 2002). More recent studies demonstrate that progestin-only ECPs only work by preventing ovulation or fertilization, and have no effect on implantation (Croxatto, et al, 2003; Ortiz, et al., 2004). Scientific authorities agree that emergency contraception reduces the risk of pregnancy and helps prevent the need for abortion; it itself is not a form of abortion (Grimes, 1997; Guillebaud, 1998; Hughes, 1972; Stewart, et al., 2004).

The copper IUD, used as a regular method of contraception, prevents fertilization by releasing copper that stimulates the body to alter the fluid within the uterus and the fallopian tubes to act as a spermicide (Grimes, 2004; Hatcher, et al., 2005). In theory, the copper IUD may prevent implantation by thinning the endometrial lining of the uterus, but there is no scientific evidence that this actually happens (Alvarez, et al., 1988; FHI, 2005). Postcoital emergency contraceptive insertion of a copper IUD may involve the same mechanism in some cases, but it is more likely to interfere with implantation (Stewart, et al., 2004).

Progestin-Only ECPs Greatly Reduce Side Effects.

- Combination hormone ECPs induce nausea in 30–50 percent of women, and vomiting in 15–25 percent of women. Anti-nausea or anti-emetic medications taken one hour before ingesting ECPs may reduce these side effects. Breast tenderness, fatigue, irregular bleeding, abdominal pain, headaches, and dizziness may also occur. These side effects usually taper off one or two days after ingesting ECPs (Knowles & Ringel, 1998; Raymond,et al., 2000; Stewart, et al., 2004).

- Nausea and vomiting are far less common using progestin-only ECPs than using the Yuzpe regimen (Stewart, et al., 2004). In a World Health Organization-supported study using levonorgestrel, nausea occurred in 23.1 percent of cases, and vomiting in 5.6 percent. Other side effects were also less common (TFPMFR, 1998).

- In about 10–15 percent of women treated, ECPs change the amount, duration, and timing of the next menstrual period. This effect is usually minor, and menstruation occurs a few days earlier or later than expected (Hatcher, et al., 2005). If ECPs are used frequently, periods may become irregular and unpredictable (Knowles & Ringel, 1998).

- Side effects of IUD insertion may include abdominal discomfort, vaginal bleeding or spotting, and infection. Possible side effects of IUD use include heavy menstrual flow, cramping, infection, infertility, and uterine puncture (Grimes, 2004; Stewart, et al., 2004).

- Neither ECPs nor IUDs prevent the spread of sexually transmitted infections, including HIV. Many women who need emergency contraception are at risk of these infections. At heightened risk are those who have had unprotected sex with infected partners, those who use IV drugs or have a partner who does, and victims of sexual assault. For those at risk of sexually transmitted infections, ECPs are likely to be a safer choice than IUD insertion (Knowles & Ringel, 1998). During IUD insertion, bacteria from a preexisting infection can be introduced into the sterile uterine cavity — untreated, such infections can lead to pelvic inflammatory disease. HIV infection can also increase the risk of pelvic inflammatory disease associated with an IUD (Grimes, 2004).

- Women should discuss with their clinicians any sign of pregnancy after using emergency contraception. The signs include a missed menstrual period, nausea, inexplicable fatigue, sore or enlarged breasts, headaches, and frequent urination (Cunningham et al., 1997; Stewart, et al., 2004).

- Emergency contraception, like other contraceptives, decreases the risk of ectopic pregnancy — a pregnancy that develops outside the uterus — by reducing the risk of pregnancy (ACOG, 2005). However, in the event of pregnancy following the use of emergency contraception, a clinician should test for ectopic pregnancy. Ectopic pregnancies, left untreated, will cause complications that can cause death. Women should seek medical attention if they have signs of ectopic pregnancy, which include severe pain on one or both sides of the lower abdomen, abdominal pain and spotting, especially after a very light or missed menstrual period, and faintness or dizziness (Knowles & Ringel, 1998; Stewart, et al., 2004).

Users of ECPs Report High Levels of Satisfaction.

- A study of 235 women who had used ECPs found that the overwhelming majority — 91 percent — were satisfied with the method, and 97 percent would recommend it to friends and family. These women also reported that they did *not* intend to substitute ECPs for regular contraceptive use (Harvey et al., 1999).

- Of 119 women who obtained ECPs at Planned Parenthood of New York City clinics, 92 percent stated that they would use the method again if necessary, but reported that they believed ECPs should be reserved for emergencies. Three-fourths of the sample indicated that since using ECPs, they were *more* likely to use precoital methods of contraception (Breitbart et al., 1998).

Anti-Choice Organizations, Pharmacists, Religious Hospitals, and Hotline Difficulties Threaten Women's Access to Emergency Contraception.

- Major anti-choice organizations such as the American Life League, Human Life International, and Stop Planned Parenthood International oppose emergency contraception and have launched national and international misinformation campaigns claiming that it is an abortifacient (ALL, 1997; Gallagher, 1998; STOPP International, 2000). In addition, they falsely assert that testing has not been done to confirm the safety of ECPs (ALL, 1997); they underreport statistics on the efficacy of emergency contraception (STOPP International, 2000), and they dismiss evidence of decreased side effects of progestin-only ECPs (Clarke, 2000).

- Individual pharmacists have refused to fill prescriptions for ECPs, presumably based on the false assumption that ECPs are an

abortifacient (Cohen, 1999). This problem received widespread attention in May 1999, when Wal-Mart® announced that it would not sell Preven® — a combined hormone ECP that is no longer on the market — in its approximately 2,400 pharmacies (Canedy, 1999). In February 2004, a Denton, Texas pharmacist refused to fill a rape survivor's prescription for ECPs, citing "religious convictions" (Austin, 2004). A survey of 195 pharmacies in New York City revealed that 25 percent did not carry ECPs, and of those, none had posted signs required by law, saying they do not carry the pills (Andreatta, 2004).

- Although the *Ethical and Religious Directives for Catholic Health Care Services* states that "A female who has been raped should be able to defend herself against a potential conception from the sexual assault" (USCCB, 2001), many Catholic hospitals do not provide emergency contraception, even to rape victims. A study of the nation's nearly 600 Catholic hospital emergency rooms found that only 28 percent offered EC to women who had been raped (CFFC, 2002). Sometimes a Catholic hospital is a community's only provider — leaving sexual assault survivors with very little chance of being taken to a hospital that will provide her with EC.

- An evaluation of the Emergency Contraception Hotline found that while at least 76 percent of callers were able to obtain a telephone prescription or an appointment with a hotline provider within 72-hours of unprotected intercourse, 11 percent failed (Trussell, et al., 2000). Although the hotline provides an important resource for women seeking emergency contraception, lack of available appointments and limited practice hours necessitate additional venues to facilitate access.

Efforts to Improve Access to Emergency Contraception

France became the first country in the world to distribute its brand of ECPs — NorLevo® — in pharmacies without prescription or parental consent. NorLevo is also distributed free-of-charge along with other methods of contraception at family planning centers (Ollivier, 1999).

In January 2000, France's Deputy Education Minister, Segolene Royal, took the unprecedented step of granting its school nurses the right to dispense ECPs in both junior and high schools (Daley, 2000; McNeil, 2000). The initiative was accompanied by a nationwide sex education campaign that included information on emergency contraception. Provision of ECPs in schools received widespread support from students, health practitioners, and the union of school nurses (Ollivier, 1999; McNeil, 2000).

However, in July 2000 the Council of State, France's highest administrative court, overruled this decision citing a 1967 law that says hormonal contraception may only be distributed under prescription by pharmacies. The ruling followed a strong show of opposition by the Catholic Church and was lauded by the National Confederation of Catholic Family Associations, which also expressed regret that the court did not take additional steps to reaffirm parental authority in such matters (McNeil, 2000). In October 2000, the French Parliament amended the law to once again allow school nurses to dispense emergency contraception (Kolata, 2000).

Restrictions on the dispensing of emergency contraception are easing in other countries as well. Women in 39 countries, including Albania, Belgium, Canada, Denmark, Finland, India, Israel, Morocco, Norway, Portugal, South Africa, Sweden, and the United Kingdom, can obtain emergency contraception without a prescription (Abboud, 2003; CRR, 2004; "Nod for Counter...," 2005; PPFC, 2005).

Steps are also being taken to make ECPs available over-the-counter or via collaborative practice agreement in the United States. In July 1997, an emergency contraception collaborative drug therapy agreement pilot project was launched in Washington. Collaborative drug therapy agreements between pharmacists and prescribers, such as physicians or nurse practitioners grant the pharmacist the authority to write prescriptions under a set of prescribing protocols. In the first 13 months of the project in the state of Washington, 9,333 ECP prescriptions were provided, preventing between 504 and 2,100 pregnancies, about half of which would have ended in abortion. ("Pharmacists, Providers...," 1999). Similar programs have been established in Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, and New Mexico, and more states are considering legislation that would allow pharmacists to dispense emergency contraception without a prescription (Greenberger, 2005; Haddix, 2004; Neergaard, 2005).

At public hearings held in June 2000, advocates including the National Women's Health Network, the Reproductive Technologies Project, and the National Abortion and Reproductive Rights Action League testified at the FDA in support of reclassifying ECPs as over-the-counter drugs ("Advocates Testify…," 2000). Prominent groups such as the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Medical Association, the American Medical Women's Association (AMWA), the American Public Health Association, and Planned Parenthood Federation of America have since voiced support of making ECPs available through a pharmacist (ACOG, 2001; AGI, 2005b; AMWA, 1996; Foubister, 2001).

- Improving women's access to emergency contraception does not increase women's reliance on it as a primary method of birth control. A study found that women who were given ECPs to take home used other birth control methods at the same rate as women who did not have the pills in their medicine cabinets. Women who had the pills at home were *more likely* to use emergency contraception once. But they *were not* more likely to use it repeatedly. Women who had home access to ECPs used the method correctly 98 percent of the time and had fewer unintended pregnancies than those who did not have ECPs at home (Glasier & Baird, 1998).

On February 14, 2001, the Center for Reproductive Rights filed a petition with the FDA on behalf of more than 70 medical, public health, and other organizations, to grant over-the-counter status to ECPs (CRR, 2003). No decision was ever issued for this petition. The makers of Plan B filed a second petition in 2003. In December 2003, two FDA advisory panels found that Plan B meets the criteria for availability without a prescription, and recommended granting over-the-counter status. Five months later, despite these recommendations, the FDA chose to deny the petition, citing concerns about adolescent use and potential increases in promiscuity. A dozen members of Congress called for the resignation of key FDA officials for denying the over-the-counter petition based on political and ideological — not scientific — reasons. Forty-one members of Congress asked that the FDA reconsider its decision (Kaufman, 2004).

The distributor of Plan B, Barr Pharmaceuticals, Inc., vowed to continue to work with health organizations and advocates to get the FDA to reverse its decision (Cox, 2004). Numerous studies have since been published that refute the FDA's claim that use of ECPs would lead to increased promiscuity. These studies demonstrate that while advanced access to EC does increase the chances of using EC, it does not alter sexual behavior or the risk for contracting STIs (Belzer, et al., 2003; "Easy EC access...", 2005; Marston, et al., 2005; "Plan B", 2005; Raine, et al., 2005).

- A study of adolescent mothers examined the impact of giving teenagers ECPs before they need them. One group of teen mothers received education about ECPs and were given an advance supply of the pills. Another comparison group received only education about ECPs. At the six-month follow-up, 83 percent of the group that received the pills used ECPs, as compared to only 11 percent of the education-only group. The group that received ECPs were not more likely to report having unprotected sex within the follow-up period (Belzer, et al., 2005).
- Another study about advance provision of ECPs to adolescents had similar findings — the teenagers were more likely to use ECPs they received, and their use of condoms did not decrease (Harper, et al., 2005).
- A 2004 study substantiated the findings of previous studies on advance provision. Adolescent women, aged 15 to 20, were randomized into two groups — one group received ECPs and education about emergency contraception and the comparison group received education alone. In the first month of the study, the teens in the group that received the pills were twice as likely to use ECPs as the comparison group. They also took the pills an average of 10 hours sooner than the teens in the education-only group — an important finding because ECPs' efficacy is time-limited. The two groups did not differ in their rates of hormonal contraceptive use at the six month follow-up. Notably, the group that received the pills was more likely to report condom use at six months than the education-only group (Gold, et al., 2004).

The FDA announced that it would, by January 21, 2005, issue its ruling on a subsequent application by Barr Pharmaceuticals, requesting over-the-counter sale of EC to women who are 16 and older. The FDA did not meet its deadline (Baer, 2005). On August 26, 2005, while acknowledging that Plan B could be safely sold to women over the age of 17, the FDA announced yet another delay on deciding whether or not to make Plan B available over-the-counter. Citing concerns associated with the difficulty in enforcing over-the-counter age

restrictions, the FDA opened a 60-day public comment period to address EC over-the-counter implementation strategies (Harris, 2005). This comment period ended November 1, 2005; the FDA is currently reviewing as many as 10,000 comments it received (Kaufman, 2005).

In light of emergency contraception's history of safety and efficacy, Planned Parenthood Federation of America strongly supports making ECPs available to women over-the-counter. We believe this is the best way to broadly increase access to emergency contraception, and consequently decrease unintended pregnancies and abortions in the U.S.

EC–OTC: Surveys Show High Levels of Support for Collaborative Practice Agreements between Physicians and Pharmacists.

A survey conducted on behalf of the Reproductive Health Technologies Project found widespread support for emergency contraception among voters and licensed pharmacists in New Jersey and Oregon. Among its findings

- Approximately 60–70 percent of voters and pharmacists, including Catholics, support the idea of emergency contraception being widely available.
- The majority of pharmacists — 56 percent in New Jersey and 67 percent in Oregon — support adding ECPs to the protocol of drugs that they can prescribe directly for patients through collaborative drug therapy agreements.
- Eight in 10 New Jersey voters and seven in 10 Oregon voters oppose refusal clause legislation, which would allow pharmacists to refuse to fill prescriptions because of religious or moral objections (RHTP, 2000).

A more recent nationwide survey of 824 physicians conducted by HCD Research, found that 65 percent believe that pharmacists should have the authority to dispense ECPs. Seventy-eight percent oppose state refusal clauses for legally prescribed medication ("Survey finds...", 2005).

Emergency Contraception Is Available at Planned Parenthood Health Centers and at Other Medical Facilities.

Planned Parenthood is the leading provider of emergency contraception in the U.S. The number of women receiving ECPs from Planned Parenthood has grown from roughly 17,000 in 1995 to 984,000 in 2004 (PPFA, 1996; PPFA, 2005). Some Planned Parenthood health centers offer "just-in-case" emergency contraception kits to keep at home, also called EC-to-Go. Planned Parenthood offers all safe, available emergency contraceptive choices, but not every method is available at every Planned Parenthood health center.

To contact the nearest Planned Parenthood for emergency contraception, call 1-800-230-PLAN. For a list of other nearby emergency contraception providers, call the national Emergency Contraception Hotline, operated by the Reproductive Health Technologies Project, at 1-888-NOT-2-LATE. Provider information is also available on the Emergency Contraception Web site (http://www.not-2-late.com or http://ec.princeton.edu).

Emergency contraception may also be available in health clinics, the offices of private physicians, and in hospital emergency rooms.

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