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EMERGENCY CONTRACEPTION

History and Access

Every woman deserves every chance to prevent an unintended pregnancy. Emergency contraception (EC) provides women with a second chance at prevention in cases of unanticipated sexual activity, contraceptive failure, or sexual assault. EC has been available for nearly 40 years. 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 EC. In order to hinder women's access to this important method of contraception, they falsely claim that EC ends a pregnancy, and they disseminate other misinformation about its safety and effectiveness.

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

Emergency contraception is not just a "morning-after pill." Multiple emergency contraception options are available.

EC can reduce the risk of pregnancy after unprotected intercourse. It is provided in four ways: using a progestin-only branded product such as Plan B One-Step® or Next Choice One Dose®; using a product that contains ulipristal acetate, such as ella®; using hormonal contraceptive pills (either progestin-only birth control pills or combined oral contraceptives); or inserting a copper-releasing IUD (intrauterine device).

Yuzpe regimen

This method of EC is named for Canadian Professor A. Albert Yuzpe, who published the first studies demonstrating the method's safety and effectiveness in 1974. This regimen uses two doses of oral contraceptive pills that combine estrogen and certain progestins (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 EC has a five-day window of effectiveness, the popular term "morning-after pill" is misleading.) The doses are taken 12 hours apart.

Many common oral contraceptive pills can be used as emergency contraception, 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 EC in the U.S., in two doses, 12 hours apart:

Pill Brand	Manufacturer	Pills per Dose
Altavera®	Sandoz	4 peach pills
Amethia®	Watson	4 white pills
Amethia Lo®	Watson	5 white pills
Amethyst®	Watson	6 white pills
Avaine®	Teva	5 orange pills
Camrese®	Teva	4 light-blue-green pills
Camrese Lo®	Teva	5 orange pills
Cryselle®	Teva	4 white pills
Enpress®	Teva	4 orange pills
Introvale®	Sandoz	4 peach pills
Jolessa™	Teva	4 pink pills
Lessina®	Teva	5 pink pills
Levora®	Watson	4 white pills
Lo/Ovral®	Wyeth-Ayerst	4 white pills
LoSeasonique®	Teva	5 orange pills
Low-Ogestrel®	Watson	4 white pills
Lutera®	Watson	5 white pills
Lybrel®	Wyeth-Ayerst	6 yellow pills
Nordette®	Wyeth-Ayerst	4 light-orange pills
Ogestrel®	Watson	2 white pills
Portia®	Teva	4 pink pills
Quasense™	Watson	4 white pills
Seasonale®	Teva	4 pink pills
Seasonique™	Teva	4 light-blue-green pills
Stronyx®	Watson	4 pink pills
Tri-Levlen®	Berlex	4 yellow pills
Trivora®	Watson	4 pink pills

OPR, 2013c

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Progestin-only emergency contraception

On July 28, 1999, the U.S. Food and Drug Administration (FDA) approved the first progestin-only EC available in the U.S. Produced by Barr Pharmaceuticals, Inc. (now Teva Women's Health, Inc.), it was known as "Plan B." Today, it is known as "Plan B One-Step." It and a newer brand of progestin-only EC — Next Choice One Dose — — and the generic levonorgestrel tablets consist of the hormone levonorgestrel, a progestin. Using EC is more effective the sooner it begins; levonorgestrel EC pills can be taken up to 120 hours (five days) after unprotected intercourse (von Hertzen et al., 2002). Plan B contains no estrogen ("FDA Approves...," 1999).

Plan B One-Step is available to anyone over-the-counter in the family planning aisle of drug stores. All other brands are available behind the counter for anyone 17 and older without a prescription, or with a prescription for anyone 16 and younger.

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).

ella

On August 13, 2010, the U.S. Food and Drug Administration (FDA) approved ulipristal acetate (UPA) for emergency contraception. It became available to women in the U.S. only by prescription on December 1, 2010. The registered trademark in the US is "ella." The treatment consists of a single, oral dose that is to be taken no later than 120 hours (five days) after unprotected intercourse.

The European Medicines Agency approved UPA for use as emergency contraception in May 2009 (Glasier et al., 2010). Currently, UPA is marketed in 22 European countries under the brand name "ellaOne" (Personal communication, HRA Pharma).

The IUD

A copper-releasing IUD (ParaGard®) can be inserted within five days of unprotected intercourse as a method of EC (WHO, 2004). It can be left in place for up to 12 years for extremelly 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).

Emergency contraception reduces the risk of pregnancy by up to 95 percent, and emergency IUD insertion reduces the risk by 99 percent.

Two factors influence the effectiveness of EC: the amount of time elapsed after unprotected intercourse, and the point in a woman's cycle at which she had sex. With the exception of ella, the earlier EC pills are taken during the first five days after unprotected intercourse, the more effective it is (Fine et al., 2010; Glasier et al., 2010; 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). EC is not as effective as correct and consistent use of ongoing reversible contraceptive methods such as the pill, IUD, or contraceptive implants, injections, patches, or rings, and it does not protect against sexually transmitted infections (STIs) (Knowles & Ringel, 1998; Roumen et al., 2001; Zieman et al., 2002).

- The Yuzpe regimen of combined estrogen and progestin EC 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 EC, only two out of those 100 women will become pregnant. Combined hormone EC reduces the risk of pregnancy by roughly 75 percent, preventing six of eight likely pregnancies (Knowles & Ringel, 1998; OPR, 2013a; Rodrigues et al., 2001; Stewart et al., 2004).

- When used within 72 hours of unprotected intercourse, progestin-only EC was found to reduce the risk of pregnancy by 88 percent. When taken within 24 hours of unprotected intercourse, progestin-only EC was found to reduce the risk of pregnancy by 95 percent ("FDA Approves...," 1999; OPR, 2013a; TFPMFR, 1998).

Early studies show that, over the course of 120 hours (five days) after unprotected intercourse, UPA remains equally effective for longer than progestin-only emergency contraception in reducing the risk of pregnancy:

- UPA reduces the risk of becoming pregnant equally well over the entire course of 120 hours (five days) after unprotected intercourse. On the other hand, the effectiveness of progestin-only EC diminishes substantially after 72 hours have passed (Fine et al., 2010)
- UPA is also more likely to suppress imminent ovulation than progestin-only EC. This means that it is more effective than progestin-only EC throughout a woman's fertile period (Glasier et al., 2010).

Only 10 pregnancies occurred after more than 9,400 emergency insertions of copper-bearing IUDs since 1976: a rate of fewer than one in 1,000, reducing the risk of pregnancy by more than 99 percent (OPR, 2013a; Stewart et al., 2007).

Emergency contraception is a safe backup method of birth control

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

Nearly every woman who needs EC can safely use it — even women with contraindications to the ongoing use of oral contraceptives (Guillebaud, 1998; Hatcher et al., 2005). EC can also be used safely by adolescents. One study designed to evaluate the safety of EC use in teenagers enrolled 52 teens between the ages of 13 and 16. EC was 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 EC (Harper et al., 2004).

EC 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 a method of abortion

EC cannot end a pregnancy. According to the FDA, "Emergency [contraception is] not effective if the woman is pregnant ..." (FDA, 1997). A study in 2002 found that, most often, EC reduces the risk of pregnancy by inhibiting ovulation (Marions et al., 2002). Further studies demonstrate that progestin-only EC works only by preventing ovulation or fertilization and has no effect on implantation (Croxatto et al., 2003; Ortiz et al., 2004). Scientific authorities agree that EC 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). In its Statement on Mechanism of Action, the International Consortium for Emergency Contraception and the International Federation of Gynecology & Obstetrics reported that hormonal EC cannot inhibit implantation or harm the embryo (ICEC & FIGO, 2008).

Like hormonal contraceptives, including progestin-only emergency contraceptives such as Plan B One-Step and Next Choice One Dose, UPA works by suppressing or delaying ovulation. Theoretically, it could also alter the environment of the uterus and interfere with implantation, but that mechanism of action is unlikely for two reasons. First, it is very effective at suppressing or delaying ovulation, which makes fertilization from unprotected intercourse unlikely if the medication is taken within 120 hours. Second, the 30-mg dose is unlikely to be strong enough to prevent implantation of an already fertilized egg (Glasier et al, 2010).

Ongoing use of the copper IUD prevents fertilization by releasing copper, which alters fluids in the uterus and fallopian tubes to act as spermicide (Grimes, 2004; Hatcher et al., 2007). In theory, ongoing use of 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). Emergency insertion of a copper IUD may work somewhat differently than ongoing use. It may prevent fertilization, but it may also prevent implantation (Stewart et al., 2007).

Progestin-only and UPA emergency contraception greatly reduces side effects.

- Combined hormone EC induces 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 EC 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 EC (Knowles & Ringel, 1998; Raymond et al., 2000; Stewart et al., 2004).
- Nausea and vomiting are far less common using progestin-only and ulipristal acetate EC than using the Yuzpe regimen (OPR, 2013b; 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, EC changes 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).
- 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).
- 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 health care provider any sign of pregnancy after using EC. 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).
- EC, 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 EC, 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 emergency contraception report high levels of satisfaction.

- A study of 235 women who had used EC 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 EC for regular contraceptive use (Harvey et al., 1999).
- Of 119 women who obtained EC 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 EC should be reserved for emergencies. Three-fourths of the sample indicated that since using EC, they were more likely to use ongoing methods of contraception (Breitbart et al., 1998).

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Anti-women's health organizations, pharmacists, religious hospitals, and hotline difficulties threaten women's access to emergency contraception.

- Major organizations that want to end safe and legal abortion, such as the American Life League, Human Life International, and Stop Planned Parenthood International oppose EC and have launched national and international misinformation campaigns claiming that it works by causing abortion (ALL, 1997; Gallagher, 1998; STOPP International, 2000). In addition, they falsely assert that testing has not been done to confirm the safety of EC (ALL, 1997); they underreport statistics on the effectiveness of EC (STOPP International, 2000), and they dismiss evidence of decreased side effects of progestin-only EC (Clarke, 2000).
- Individual pharmacists have refused to fill prescriptions for EC, presumably based on the false assumption that EC works by causing abortion (Cohen, 1999). This problem received widespread attention in May 1999, when Wal-Mart® announced that it would not sell PREVEN™ — a combined hormone EC that is no longer on the market — in its approximately 2,400 pharmacies (Canedy, 1999). In February 2004, a Denton, TX, pharmacist refused to fill a rape survivor's prescription for EC, citing "religious convictions" (Austin, 2004). A survey of 195 pharmacies in New York City revealed that 25 percent did not carry EC, 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, "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 EC, even to rape survivors. 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 them with EC.
- When EC was available by prescription only, 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 EC, lack of available appointments and limited practice hours necessitate additional venues to facilitate access.

A history of the efforts to improve access to emergency contraception

In 1999, France became the first country in the world to distribute a brand of EC — 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 EC in both junior and high schools (Daley, 2000; McNeil, 2000). The initiative was accompanied by a nationwide sex education campaign that included information on EC. Provision of EC in schools received widespread support from students, health practitioners, and the union of school nurses (McNeil, 2000; Ollivier, 1999).

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 EC began to ease in other countries, as well. By 2006, women in 42 other countries, including Albania, Belgium, Canada, Denmark, Finland, India, Israel, Morocco, Norway, Portugal, South Africa, Sweden, and the United Kingdom, could obtain EC without a prescription (Trussell & Wynn, 2006).

In the United States, steps were taken to make EC available over the counter (OTC) or via collaborative practice agreement. In July 1997, an EC collaborative drug therapy agreement pilot project was launched in Washington State. 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 EC prescriptions were provided, preventing between 504 and 2,100 pregnancies — about half of which would have ended in abortion ("Pharmacists, Providers...," 1999). Similar programs were established in Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, and Vermont, and other states considered legislation that would allow pharmacists to dispense emergency contraception without a prescription (Greenberger, 2005; Haddix, 2004; Neergaard, 2005; "Vermont Law…," 2006).

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 EC as an OTC drug ("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 voiced support for making EC available OTC or through a pharmacist (ACOG, 2001; AMWA, 1996; Foubister, 2001; Guttmacher Institute, 2005).

These organizations agreed that improving women's access to EC would not increase their reliance on it as a primary method of birth control. A study found that women who were given EC 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 EC once. But they were not more likely to use it repeatedly. Women who had home access to EC used the method correctly 98 percent of the time and had fewer unintended pregnancies than those who did not have EC 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 OTC status to EC (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 met the criteria for availability without a prescription, and recommended granting OTC 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 OTC 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, Teva Women's Health, vowed to continue to work with health organizations and advocated 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 EC 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 EC before they need it. One group of teen mothers received education about EC and was given an advance supply of the pills. Another comparison group received only education about EC. At the six-month follow-up, 83 percent of the group that received the pills used EC, as compared to only 11 percent of the education-only group. The group that received EC was not more likely to report having unprotected sex within the follow-up period (Belzer et al., 2005).
- Another study about advance provision of EC to adolescents had similar findings — the teenagers were more likely to use EC they received, and their use of condoms did not decrease (Harper et al., 2005).
- A 2004 study substantiated the findings of previous studies about advance provision. Adolescent women, aged 15 to 20, were randomized into two groups — one group received EC and education about EC, 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 EC as the teens in 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 EC's effectiveness 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 Teva Women's Health, which requested OTC 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 OTC age restrictions, the FDA opened a 60-day public comment period to address EC OTC implementation strategies (Harris, 2005). This comment period ended November 1, 2005 (Harris, 2005; Kaufman, 2005).

On November 14, 2005, the Government Accountability Office (GAO) released its report on Plan B calling the handling of the application by the FDA "unusual." It found that the high-level involvement of top FDA officials was atypical, that the decision not to approve the application may have been made before the review was even completed, that Plan B was the only application in the last 10 years that did not receive approval according to the FDA's advisory committees recommendations, that no other FDA-approved contraceptive has age-related marketing restrictions, and that the rationale for not approving the application was novel (GAO, 2005).

In March 2006, Senators Hillary Clinton (D–NY) and Patty Murray (D–WA) brought the fight to bring EC OTC to the forefront of the Senate. They vowed to place a hold on the confirmation hearing for FDA Commissioner-nominee Andrew von Eschenbach until EC was approved for sale OTC.

On July 31, Teva Women's Health received a letter from Dr. von Eschenbach requesting that the company amend its application for the sale of Plan B. As acting commissioner of the FDA, von Eschenbach requested that the age restriction for the sale of Plan B be raised to 18 years, and that Teva Women's Health consider revising the packaging for EC and the location of sale — e.g., in pharmacies, where the age of the consumer could be closely monitored (Tanne, 2006).

On August 24, 2006, the FDA announced its approval of the sale of EC OTC to women and men 18 and older (Barr Pharmaceuticals, 2006). While Planned Parenthood was pleased that the FDA finally took action on this issue, we were troubled by the scientifically baseless restriction imposed on teenagers. Research shows that OTC access to EC does not increase or encourage sexual activity among teens, and better access to proven pregnancy prevention methods, such as accurate sex education and EC, is the best way to reduce the alarming rate of teen pregnancy nationwide.

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On March 23, 2008, the U.S. District Court of the Eastern Division of New York ordered the FDA to permit the current manufacturer of Plan B — Duramed Research Inc. of Bala Cynwyd, PA — to make it available to women 17 and older without a prescription (Reuters, 2009). On April 22, 2009, the FDA announced that it would not appeal the court's decision and notified Duramed "that it may, upon submission and approval of an appropriate application, market Plan B without a prescription to women 17 years of age and older" (FDA, 2009). Since ella came on the U.S. market at the end of 2010, it has been available only by prescription (Watson, 2010).

In February of 2011, Teva Women's Health Inc., submitted a supplemental application seeking to remove the prescription-only status for women younger than age 17, expanding over-the-counter access for women of all ages. The Center for Drug Evaluation and Research (CDER) reviewed the application, paying particular attention to whether young teens could understand how to use emergency contraception.

The CDER concluded that Plan B One-Step was "safe and effective in adolescent females, that adolescent females understood the product was not for routine use, and that the product would not protect them against sexually transmitted diseases." Additionally, the data supported a finding that adolescent women could use Plan B One-Step properly without the intervention of a health care provider" (Hamburg, 2011). FDA Commissioner Margaret Hamburg agreed that "there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential," and the FDA recommended approval of the application (Hamburg, 2011).

However, in a surprising move on December 7, 2011, Health and Human Services Secretary Kathleen Sebelius rejected the FDA's recommendation that Plan B One-Step be available over the counter without age restrictions. Despite the evidence presented, Sebelius stated that "I have concluded that the data, submitted by Teva, do not conclusively establish that Plan B One-Step should be made available over the counter for all girls of reproductive age. ... It is common knowledge that there are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age" (Sebelius, 2011).

On April 4, 2013, Judge Edward R. Korman, United States District Judge for the Eastern District of New York, ruled in *Tummino v. Hamburg* that the FDA must lift age and point of sale restrictions on emergency contraception, citing solid scientific and medical research showing that it is safe and effective in preventing unintended pregnancy (*Tummino v. Hamburg* Memorandum & Order, 2013).

On April 30, 2013, the U.S. Food and Drug Administration announced that it approved an amended application from Teva Women's Health, Inc. for use of Plan B One-Step without a prescription by women 15 years of age and older, with proof of age required. Additionally, Plan B One-Step will be available in the family planning or female health products aisles, and no longer behind the pharmacy counter (FDA, 2013).

While this was an important step forward to expand access to emergency contraception and prevent unintended pregnancies, the Department of Justice announced the very next day that it would appeal U.S. District Judge Edward Korman's ruling in *Tummino v. Hamburg*, the decision that lifted the age and point of sale restrictions on emergency contraception.

Finally, on June 10, 2013, the Obama administration announced that would drop its appeal, and on June 10 the FDA approved Plan B One-Step for sale without age or point-of-sale restrictions (Rowan, 2013). Plan B-One Step is now available over the counter in the family planning aisle of drug stores with no age requirement. Other brands of levonorgestrel EC remain behind the counter with pharmacists for purchase by anyone 17 or older without a prescription, or anyone younger than 17 with a prescription. ella requires a prescription at any age.

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Planned Parenthood is the leading provider of EC in the U.S. The number of women receiving EC from Planned Parenthood has grown from roughly 17,000 in 1995 to 1,425,746 in 2011 (PPFA, 1997; PPFA, 2012). Planned Parenthood offers all safe, available EC choices, but not every method is available at every Planned Parenthood health center. If you need a prescription for EC, contact your nearest Planned Parenthood health center at 1-800-230-PLAN or at http://www.plannedparenthood.org/.

Cited References

ACOG — American College of Obstetricians and Gynecologists. (2001, accessed July 31, 2002). "Statement of the American College of Obstetricians and Gynecologists Supporting the Availability of Over-the-Counter Emergency Contraception." [Online]. http://www.acog.org/from_home/publications/press_releases/nr02-14-02.htm.

_____. (2005, December). "ACOG Practice Bulletin #69: Emergency Contraception." *Obstetrics & Gynecology*, 106(6), 1443–52.

"Advocates Testify at the FDA in Support of Making Emergency Contraceptive Pills Available Over-the-Counter." (2000, June 30). *PR Newswire*.

ALL — American Life League. (1997, accessed 2000, March 3). "Birth Control: Emergency Contraception: The Morning-After Pill." [Online]. http://www.all.org/issues/bc05.htm.

Alvarez, Frank, et al. (1988). "New Insights on the Mode of Action of Intrauterine Contraceptive Devices in Women." *Fertility and Sterility*, 49(5), 768–73.

AMWA — American Medical Women's Association. (1996, accessed 2000, February 22). *Position Statement on Emergency Contraception.* [Online]. http://www.amwa-doc.org/publications/Position_Papers/contraception.htm.

Andreatta, David. (2004, February 9). "Pharmacies Fail to Heed 'Morning After' Wakeup Call." *The New York Sun*, p.2.

Austin, Liz. (2004, February 21). "Emergency Contraception Denial Raises Moral, Legal Issues." *The Associated Press*.

Baer, Susan. (2005, January 30). "'Morning After' Pill; Still Delayed by FDA." *The Baltimore Sun*, p. A16.

Barr Pharmaceuticals, Inc. (2006, August 24). *FDA Grants OTC Status to Barr's Plan B(R) Emergency Contraceptive: Historic Dual Status Decision Provides OTC Access to Those 18 Years of Age and Older; Remains Prescription for Women 17 and Younger.* [Online]. http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=899120.

Belzer, Marvin, et al. (2005). "Advance Supply of Emergency Contraception: A Randomized Trial in Adolescent Mothers." *Journal of Pediatric and Adolescent Gynecology*, 18, 347–54.

Belzer, Marvin, et al. (2003). "Advanced Supply of Emergency Contraception for Adolescent Mothers Increased Utilization without Reducing Condom or Primary Contraception Use." *Journal of Adolescent Health*, 32(2), 122–3.

Breitbart, Vicki, et al. (1998). "The Impact of Patient Experience on Practice: The Acceptability of Emergency Contraceptive Pills in Inner-City Clinics." *Journal of the American Medical Women's Association*, 53(5 Supplement 2), 255–8.

Canedy, Dana. (1999, May 14). "Wal-Mart Decides Against Selling a Contraceptive." *The New York Times*, p. 1.

CFFC — Catholics for a Free Choice. (2002). *Second Chance Denied: Emergency Contraception in Catholic Hospital Emergency Rooms*. Cambridge, MA: Ibis Reproductive Health.

Clarke, Jenny. (2000, February 7). "Counter Measures to Fight Abortion." *Aberdeen Evening Express*, p. 18.

Cohen, Susan A. (1999, accessed 2000, February 18). "Issues and Implications: Objections, Confusion Among Pharmacists Threaten Access to Emergency Contraception." *The Guttmacher Report on Public Policy*, 2(3), 1–3.

Cox, Carol. (2004, May 6). "Barr Receives Not Approvable Letter for Over-the-Counter Emergency Contraceptive." Barr Press Release.

Croxatto, Horatio B. et al. (2003). "Mechanisms of Action of Emergency Contraception." *Steroids*, 68, 1095–8.

CRR — Center for Reproductive Rights. (2003, accessed 2004, June 14). "Emergency Contraception (EC): A Safe and Effective Way to Prevent Unplanned Pregnancy." [Online]. http://www.reproductiverights.org/pub_fac_ecdomestic.html.

Cunningham, F. Gary, et al. (1997). *Williams Obstetrics*, 20th ed. Stamford, CT: Appleton & Lange.

Daley, Suzanne. (2000, February 8). "France Provides Morning-After Pill to Schoolgirls." *The New York Times*, p. 1.

"Easy EC Access Doesn't Increase Risky Behavior." (2005). *Contraceptive Technology Update*, 26(3), 32–3.

Ellertson, Charlotte, et al. (2003). "Extending the Time Limit for Starting the Yuzpe Regimen of Emergency Contraception to 120 Hours." *Obstetrics & Gynecology,* 101, 1168–71.

FDA — U.S. Food and Drug Administration. (1997). "Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception." *Federal Register*, 62(37), 8609–12.

_____. (2009, April 22, accessed May 5, 2009). "Updated FDA Action on Plan B (levonorgestrel) Tablets." [Online]. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149568.htm.

_____. (2013, April 30). "FDA approves Plan B One-Step emergency contraceptive without a prescription for women 15 years of age and older." [Online]. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350230.htm.

"FDA Approves Progestin-Only Emergency Contraception." (1999). *The Contraception Report*, 10(5), 8–10 & 16.

FHI — Family Health International. (2005, accessed 2005, September 7). "Mechanisms of Action: Mechanisms of the Contraceptive Action of Hormonal Methods and Intrauterine Devices (IUDs)." [Online]. http://www.fhi.org/en/RH/Pubs/factsheets/mechact.htm.

Fine, Paul T. et al. (2010). "Ulipristal Acetate Taken 48-120 Hours After Intercourse for Emergency Contraception." *Obstetrics and Gyecology*, 115(2), 1–7.

Foubister, Vida. (2001, March 5, accessed July 31, 2002). "OTC Emergency Contraceptives Pushed, But Not Imminent." [Online]. http://www.ama-assn.org/sci-pubs/amnews/pick_01/prsc0305.htm.

Gallagher, Paul. (1998, accessed 2000, March 3). "FDA Approves Morning-After Pills." [Online]. *HLI Reports*. http://www.hli.org/publications/hlir/1998/hr109806.html.

GAO — United States Government Accountability Office. (2005, November). *Food and Drug Administration Decision Process to Deny Initial Application for Over-The –Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual.* Washington, DC: United States Government Accountability Office.

Glasier, Anna. (1997). "Drug Therapy: Emergency Postcoital Contraception." *New England Journal of Medicine,* 337(15), 1058–64.

Glasier, Anna & David Baird. (1998). "The Effects of Self-Administering Emergency Contraception." *New England Journal of Medicine*, 339(1), 1–4.

Glasier, Anna F. et al. (2010). "Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis." *The Lancet*, 365, 555–562.

Gold, Melanie, et al. (2004). "The Effects of Advance Provision of Emergency Contraception on Adolescent Women's Sexual and Contraceptive Behaviors." *Journal of Pediatric and Adolescent Gynecology*, 17, 87–96.

Greenberger, Scott S. (2005, September 16). "Lawmakers Override Governor's Contraception Veto: Move Will Ease Morning-After Pill's Availability." *The Boston Globe*.

Grimes, David A. (2004). "Intrauterine Devices (IUDs)." Pp. 495–530 in Robert A. Hatcher et al., eds., *Contraceptive Technology*, 18th Revised Edition. New York: Ardent Media, Inc.

Grimes, David A. (1997). "Emergency Contraception: Expanding Opportunities for Primary Prevention." *New England Journal of Medicine*, 337(15), 1078–9.

Guillebaud, John. (1998). "Commentary: Time for Emergency Contraception with Levonorgestrel Alone." *The Lancet*, 352(9126), 416–7.

Guttmacher Institute. (2005, accessed 2005, August 30). "FDA Again Stalls on Over-the-Counter Status for Emergency Contraception." [Online]. http://www.guttmacher.org/media/inthenews/2005/08/29/index.html.

Haddix, Dar. (2004, May 7). "Plan B Now in Round 2." United Press International.

Hamburg, Margaret. (2011, December 7, accessed 2013, May 6). "Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step." Washington, DC: U.S. Department of Health and Human Services. [Online]. http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm.

Harper, Cynthia C., et al. (2005). "The Effect of Increased Access to Emergency Contraception Among Young Adolescents." *Obstetrics & Gynecology,* 106(3), 483–91.

Harper, Cynthia C., et al. (2004). "Tolerability of Levonorgestrel Emergency Contraception in Adolescents." *American Journal of Obstetrics & Gynecology*, 191, 1158–63.

Harris, Gardiner. (2005, August 27). "U.S. Again Delays Decision on Next-Day Pill." *The New York Times*, p. A2.

Harvey, S. Marie, et al. (1999). "Women's Experience and Satisfaction with Emergency Contraception." *Family Planning Perspectives*, 31(5), 237–40 & 260.

Hatcher, Robert A., et al. (2005). *A Pocket Guide to Managing Contraception*, 2005–2007 Edition. Tiger, GA: Bridging the Gap Foundation.

_____. (2007). *Contraceptive Technology — Nineteenth Revised Edition. New York*: Ardent Media.

Hughes, Edward C., ed. (1972). *Obstetric-Gynecologic Terminology.* Philadelphia: F.A. Davis Company.

ICEC & FIGO — International Consortium for Emergency Contraception & International Federation of Gynecology and Obstetrics. (October 2008). *Statement on Mechanism of Action.*

Kaufman, Marc. (2005, November 2). "FDA Comment Period on 'Morning-After Pill' Ends." *The Washington Post*, p. A14.

Kaufman, Marc. (2004, May 13). "2 FDA Officials Urged to Resign Over Plan B." *The Washington Post*, p. A3.

Knowles, Jon & Marcia Ringel. (1998). *All About Birth Control.* New York: Three Rivers Press.

Kolata, Gina. (2000, October 8). "Without Fanfare, Morning-After Pill Gets a Closer Look." *The New York Times*, p. 1.

Marions, Lena, et al. (2002). "Emergency Contraception with Mifepristone and Levonorgestrel: Mechanism of Action." *Obstetrics and Gynecology,* 100(1), 65–71.

Marston, Cicely, et al. (2005). "Impact on Contraceptive Practice of Making Emergency Hormonal Contraception Available Over the Counter in Great Britain: Repeated Cross Sectional Surveys." *BMJ*, doi:10.1136/bmj.38519.440266.8F.

McNeil, Donald G. Jr. (2000, July 1). "No More 'Morning-After Pills' at School, French Court Says." *New York Times*, p. A6.

Neergaard, Lauran. (2005, August 8). "BC-HEALTH-Morning-After-Pill." *The Canadian Press*.

Ollivier, Debra S. (1999, December 6, accessed 2000, February 22). "Sex Education with a Contraceptive Chaser" *Salon.*

OPR — Office of Population Research, Princeton University. (2005, accessed 2005, November 29). *Questions about Emergency Contraception.* [Online]. http://ec.princeton.edu/questions/index.html.

_____. (2013aJune 12, accessed 2013, July 9). "Answers to Frequently Asked Questions About… Effectiveness." [Online]. http://ec.princeton.edu/questions/eceffect.html.

_____. (2013b, June 12, accessed 2011, July 9). "Answers to Frequently Asked Questions About… Side Effects." [Online]. http://ec.princeton.edu/questions/ecsideeffects.html.

_____. (2013c, June 12, accessed 2011, July 9). "Answers to Frequently Asked Questions About… Types of Emergency Contraception." [Online]. http://ec.princeton.edu/questions/dose.html.

Ortiz, M. E., et al. (2004). "Post-Coital Administration of Levonorgestrel Does Not Interfere With Post-Fertilization Events in the New-World Monkey Cebus paella." *Human Reproduction*, 19, 1352–6.

"Pharmacists, Providers Linking to Provide Emergency Contraception." (1999). *Contraceptive Technology Update*, 20(8), 85–7.

"Plan B." (2005, January 18). *The Washington Post*, p. A16.

PPFA — Planned Parenthood Federation of America. (1997). Planned Parenthood CL-7 Service Report, 1996. *San Francisco: The Innovations Group of Planned Parenthood.*

_____. (2012). *Annual Affiliate Service Census Report*, 2011. New York: Planned Parenthood Federation of America, Inc.

Raine, Tina R., et al. (2005). "Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs: A Randomized Controlled Trail." *JAMA,* 293(1), 54–62.

Raymond, Elizabeth G., et al. (2000), "Meclizine for Prevention of Nausea Associated with Use of Emergency Contraceptive Pills: A Randomized Trial." *Obstetrics & Gynecology*, 95(2), 271–7.

Reuters. (March 23, 2009, accessed May 5, 2009). "RPT-UPDATE 1-U.S. court tells FDA to rethink Plan B."

Rodrigues, Isabel, et al. (2001). "Effectiveness of Emergency Contraceptive Pills Between 72 and 120 Hours After Unprotected Sexual Intercourse." *American Journal of Obstetrics and Gynecology*, 184(4), 531–7.

Roumen, F.J.M.E., et al. (2001). "Efficacy, Tolerability and Acceptability of a NovelContraceptive Vaginal Ring Releasing Etonogestrel and Ethinyl Oestradiol." *Human Reproduction*, 16(3), 469–75.

Rowan, Andrea. (2013). "Obama Administration Yields to the Courts and the Evidence, Allows Emergency Contraception to Be Sold Without Restrictions." *Guttmacher Policy Review*, 16(2), 23-24. [Online]. http://www.guttmacher.org/pubs/gpr/16/2/gpr160223.pdf.

Sebelius, Kathleen. (2011, December 7, accessed 2011, December 7). "A Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius." Washington, DC: U.S. Department of Health and Human Services. [Online]. http://www.hhs.gov/news/press/2011pres/12/20111207a.html.

Stewart, Felicia, et al. (2004). "Emergency Contraception." Pp. 279–303 in Robert A. Hatcher et al., eds., *Contraceptive Technology —18th Revised Edition*. New York: Ardent Media, Inc.

_____. (2007. "Emergency Contraception." Pp. 87–116 in Robert A. Hatcher et al., eds., *Contraceptive Technology — 19th Revised Edition*. New York: Ardent Media.

STOPP International — Stop Planned Parenthood International. (2000, accessed 2005, December 8). "'Emergency Contraception' by the Numbers." [Online]. http://www.all.org/stopp/numbers.htm.

Tanne, Janice Hopkins. (2006, August 12). "FDA Appointment Is Stalled As Revelations Emerge Over Plan B." *BMJ*, 333, 317.

TFPMFR — Task Force on Postovulatory Methods of Fertility Regulation. (1998). "Randomised Controlled Trial of Levonorgestrel Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception." *The Lancet*, 352(9126), 428–33.

Trussell, James & Lisa Wynn. (2006, April 1, accessed 2006, April 26). "Dedicated Emergency Contraceptive Pills Worldwide." [Online]. http://ec.princeton.edu/questions/dedicated.html.

Trussell, James, et al. (2000). "Access to Emergency Contraception." *Obstetrics & Gynecology*, 95(2), 267–70.

Tummino v. Hamburg, Memorandum & Order at _, No. 12-CV-763 (E.D.N.Y. April 4, 2013). [Online]. https://www.nyed.uscourts.gov/sites/default/files/opinions/Tummino%20SJ%20memo.pdf.

USCCB — United States Conference of Catholic Bishops. (2001, accessed 2002, March 5). *Ethical and Religious Directives for Catholic Health Care Services, Fourth Ed.* [Online]. http://www.nccbuscc.org/bishops/directives.htm.

"Vermont Law Allows Minors Access to Morning-After Pill." (2006, August 26). *Times Argus*.

von Hertzen, Helena, et al. (2002). "Low Dose Mifepristone and Two Regimens of Levonorgestrel for Emergency Contraception: A WHO Multicentre Randomised Trial." *The Lancet*, 360, 1803–10.

Watson. (2010). Watson Launches ella® (ulipristal acetate) "Emergency Contraception" (Press release, December 1).

WHO — World Health Organization. (2004). *Selected Practice Recommendations for Contraceptive Use, 2nd Edition*. Geneva, Switzerland: World Health Organization. [Online]. http://www.who.int/reproductive-health/publications/spr/spr.pdf.

Zieman, Miriam, et al. (2002). "Contraceptive Efficacy and Cycle Control with the Ortho Evra/Evra Transdermal System: The Analysis of Pooled Data." *Fertility and Sterility*, 77(2 Suppl.2), S13–S8.