

Emergency Contraception (EC) An Affirmative Agenda to Improve Access



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Emergency Contraception (EC) A Safe and Effective Way to Prevent Unplanned Pregnancy

It is estimated that over three million American women have unplanned pregnancies each year, and over half of these end in abortion. Emergency contraception (EC), sometimes called the "morning-after pill," is an effective method of preventing unwanted pregnancy.¹

EC IS SAFE AND EFFECTIVE TO USE

EC prevents pregnancy via a course of hormonal contraceptive pills, taken in one- or two-dose regimens. EC is most effective if the first dose is taken within 24 hours after unprotected sex; however, it can be effective up to 5 days after intercourse. If the regimen is started within 24 hours, EC can be 95% effective.

EC comes in two formulations:

REPRODUCTIVE

- Combined Emergency Contraceptive Pills ordinary oral contraceptive pills containing estrogen and progestin hormones
- Progestin-only Emergency Contraceptive Pills or "minipills" – regular oral contraceptive pills, taken in higher doses and containing progestin only. These have been used as EC for 30 years.

Today there are two pre-packaged, specially-designated EC kits on the market, Preven and Plan B.

EC is well tolerated by most women, including those who have had trouble using oral contraceptives regularly. Reported side effects are generally mild, including headache, nausea and stomach discomfort, and vary with the brand used.

Because EC can be used at all stages of a woman's menstrual cycle, its mode of action varies. After intercourse, EC may prevent pregnancy by preventing ovulation, blocking fertilization or preventing implantation of a Some extreme anti-choice groups oppose EC by equating it with abortion, which they also oppose. These groups are out of step with the mainstream medical community, and their views find almost no support in laws and policies at the state and federal level.

fertilized egg.

EC IS NOT ABORTION

According to both medical science and legal convention, pregnancy begins only after implantation of a fertilized egg in the uterus. EC therefore acts to prevent a pregnancy. Studies show that EC has no effect on established pregnancies.

Some extreme anti-choice groups oppose EC by equating it with abortion, which they also oppose. These groups are out of step with the mainstream medical community, and their views find almost no support in laws and policies at the state and federal level. The attacks against EC are unwarranted and must therefore be seen as part of an agenda to ban all contraceptives.

EC IS SUPPORTED BY THE FDA AND MEDICAL ASSOCIATIONS

The Food and Drug Administration (FDA) has deemed the use of EC safe and effective in the prevention of pregnancy. The Center for Reproductive Rights petitioned the FDA in 1994 on behalf of medical associations to improve access to EC. In response to the petition and other advocacy efforts, in 1997, the FDA announced that six brands of oral contraceptive pills were safe and effective for use as EC. This announcement put the

FDA's explicit "stamp of approval" on agency reviewed EC regimens. Since then, two products of oral contraceptive pills packaged, sold, and marketed specifically for use as EC have been approved by the FDA: Preven in 1998 and Plan B in 1999.

Increasing Access to EC

ACCESS TO EC WILL IMPROVE NATIONWIDE IF THE FDA APPROVES A CHANGE OF STATUS AND MAKES EC AVAILABLE OVER-THE-COUNTER.

On February 14, 2001, the Center for Reproductive Rights petitioned the FDA on behalf of more than 60 medical, public health, and other organizations, to change the status of

Many women, and even some health care professionals, remain unaware of the availability of EC. Detailed information, including nearby clinics that offer EC, can be obtained from the Emergency Contraception Hotline at 1-888-NOT-2-LATE or via the web at www.not-2-late.com. EC from prescription to over-the-counter, based on the fact that EC is safe and effective for use without a prescription. In 2003, Plan B (an EC manufacturer) also petitioned the FDA for over-the-counter

status for EC. Both the American Medical Association and the American College of Obstetricians and Gynecologists approve of a change to over-the-counter status, recognizing that over-the-counter availability may be the only way for some women to obtain EC in time to prevent a pregnancy. EC is now available either over-the-counter or directly from a pharmacist in many countries, including Canada, France, Portugal, Great Britain and Finland, and increasing availability is part of a world-wide trend.

PARTNERSHIPS BETWEEN HEALTHCARE PROVIDERS

Some states authorize pharmacists to prescribe medications pursuant to collaborative agreements with physicians or other healthcare professionals, clinics or HMOs. Pharmacists in these states may be able to develop collaborative agreements that will allow them to provide EC to patients without an individual prescription. For example, in the state of Washington, women are able to obtain EC from a pharmacist, avoiding a potentially costly and time-consuming visit to a physician's office or hospital. From 1998 until June 2001 Washington pharmacists prescribed and filled nearly 35,600 prescriptions

If made available over-the-counter, EC has enormous potential to alleviate the public health problem of unplanned and unwanted pregnancies.

for EC. The project prevented an estimated 2000 pregnancies, of which about half would have ended in abortion. Through legislative and regulatory efforts, other states are beginning to establish similar programs to improve access to EC.

OBSTACLES TO WOMEN'S ACCESS TO EC

Despite the recognized value of EC, EC is not always made available to women.

Refusal clauses (or so-called "conscience clauses") are provisions in state and federal legislation that permit doctors, other medical personnel, and sometimes pharmacists, to refuse to perform any procedure or dispense medication that conflicts with the provider's religious or moral beliefs. Advocates are exploring ways to reduce the scope of refusal clauses in order to protect access to EC and other reproductive health services, and to ensure that such provisions are not added to new laws.

Additionally, Catholic healthcare systems and other hospital networks also try to avoid providing EC in their hospitals, even to sexual assault survivors who seek treatment in their emergency rooms. As Catholic healthcare providers increasingly merge with their secular counterparts, the restrictions on access to the fullest range of reproductive health services become more and more troubling. Reproductive rights advocates in the states are working to pass legislation to ensure that all hospital emergency rooms that treat women after a sexual assault inform them about EC as part of this care and provide EC upon request.

A final obstacle to women's access to EC is a lack of awareness about EC. For example, one study found that only 68% of women are aware that they can prevent pregnancy after intercourse, and only 6% have ever used EC². In order to increase awareness about EC, the U.S. Congress and state legislators are considering bills that would increase public awareness about EC and encourage healthcare providers to inform their patients about EC.

1 See e.g. Stanley K. Henshaw, Unintended Pregnancy in he United States, 30 Family Planning Perspectives 24-29, 46 (January/February 1998): see also Rachel K. Jones, Jacqueline E. Darroch and Stanley K. Henshaw, Contraceptive Use Among U.S. Women Having Abortions in 2000-2001, 34 Perspectives on Sexual and Reproductive Health (November/December 2002) (or strangetine that EC is responsible for up to 42% of the 11% docline in particip rate between 1994 8: 2000)

2002) (estimating that EC is responsible for up to 43% of the 11% decline in abortion rates between 1994 & 2000).
2 See Kaiser Family Foundation/SELF magazine, National Survey of Women on their Sexual Health (June 2003); see generally Kate Zernike, Use of Morning-After Pill Rising and It May Go Over the Counter, New York Times, May 19, 2003, at A1.



State Trends in Emergency Contraception Legislation

It has been over four years since the Food and Drug Administration (FDA) approved a specific regime for emergency contraception (EC). It has been over two years since the Center for Reproductive Rights (formerly the Center for Reproductive Law and Policy) petitioned the FDA to make EC available over the counter (OTC). Yet EC is still not available OTC, and many women are still unaware of EC or are unable to obtain EC in a timely manner. Increasingly, states have become aware of the potential for EC to decrease the number of unplanned pregnancies and abortions, and are taking action to increase access to EC.

Pharmacy Access

Until the FDA makes EC available OTC, a doctor's prescription is required to obtain EC. This is problematic since EC must be taken within a short time period after intercourse (preferably 24 - 72 hours, but up to 120 hours) to be effective in preventing pregnancy. Many women have difficulty accessing their doctors within this short time frame – especially in rural areas or over weekends.

In 1998, Washington became the first state to allow women to obtain EC through a pharmacist directly. Washington's pilot project set up collaborative drug therapy agreements between doctors and pharmacies based on prescriptive protocols. Under the agreements, pharmacists were able to dispense EC to women who met screening criteria outlined in the protocols. From February 1998 until June 2001, Washington pharmacists filled nearly 35,600 prescriptions for EC, preventing an estimated 2000 pregnancies, of which about half would have ended in abortion.

Washington's program has become a model for other states. In the past few years, Alaska, California, Hawaii and New Mexico have begun allowing pharmacists to dispense EC directly to women without an individual doctor's prescription. Other states have been considering similar legislation to provide direct pharmacy access to EC^1 .

Increased access to EC is supported around the world: women in Albania, Belgium, Canada, Denmark, Finland, France, Israel, Morocco, Norway, Portugal, South Africa, Sweden, the United Kingdom and other countries can get EC without a prescription.

EC in Emergency Rooms

Despite EC's proven ability to prevent unwanted pregnancy, many hospital emergency rooms (ERs) do not inform women about EC nor make EC available to them. Sexual assault advocates have been particularly concerned about the failure of ERs to make EC a standard practice of care for women who have been sexually assaulted. In 2001, Illinois became the first state to legislate on this issue, enacting a law requiring hospitals to provide rape survivors with medically accurate information about EC. Since then, Washington, California, New Mexico and New York have passed laws requiring hospital ERs to provide rape survivors with information about EC and to dispense EC upon request. Other states and the U.S. Congress are considering similar legislation.²

Given EC's efficacy in preventing pregnancy, EC should be a standard of care for all women in ERs who want to prevent unwanted pregnancy.

EC Education

Polling data consistently shows that many women in the United States are unaware of EC. For example, in a study released in November 2000 by the Kaiser Family Foundation, one-fourth of the women aged 18-44 surveyed said they had never heard of EC, and nearly two-thirds said they didn't realize it was available in the United States³. A more recent study shows that 68% of American women know there is *something* they can do within days of unprotected intercourse to prevent pregnancy, but are often confused as to the exact details.⁴ The same study shows that only 6% of American women have ever used EC.⁵

Given the lack of awareness about EC, several states are contemplating the passage of legislation that would raise awareness about EC through the creation of public education campaigns.⁶ Similar EC education bills have also been introduced in Congress.⁷ These bills are a crucial step towards increasing awareness and access to EC.

Short timeline of emergency contraception

Late 1970s - Doctors first begin to use doses of several regular birth control pills as EC

1997 – FDA approves six common types of births control pills to be safe and effective for use as EC

1998 - Preven, the first specific emergency contraception regime, is approved by the FDA

1999 – Plan B is approved for sale by the FDA

2001 – The Center for Reproductive Rights petitions the FDA to make EC available OTC

2003 – Plan B petitions the FDA to make EC available OTC

- 1. Bills relating to pharmacy access were introduced in several state legislatures in 2003, including Maryland, Maine, New York, Oregon, Texas and West Virginia.
- Bills requiring hospitals to provide sexual assault victims with medically accurate information about EC and/or to provide EC upon request were introduced in several legislatures in 2003, including Arkansas, Arizona, Colorado, Hawaii, Massachusetts, Minnesota, New Jersey, and Wisconsin. The U.S. House of Representatives also introduced a federal version, entitled the "Compassionate Assistance for Rape Emergencies Act," H.R. 2527, 108th Congress (2003).
- 3. See e.g., Leslie Lawrence, Special Report: The Last Chance Contraceptive, Kaiser Family Foundation: Daily Reproductive Health Report (Jan 2002), at http://www.kaisernetwork.org/daily reports/rep_index.cfm?hint=2&DR_ID=8923 (discussing 2000 study). A 1997 study by the Kaiser Family Foundation showed that 66% of women surveyed had heard of EC but only 52% of the 66% knew that EC could prevent pregnancy after intercourse; 72% were unaware that EC was available in the U.S.; and only 11% actually knew the key facts about EC. See Summary of Findings: Survey of Americans on Emergency Contraception at http://www.kff.org/content/archive/1352/contraception_2.html.
- 4. Kaiser Family Foundation/SELF magazine, National Survey of Women on their Sexual Health (June 2003).

5. Id.

- 6. For example, in 2003, EC education bills were introduced in Kansas, Michigan, Missouri, New Mexico and West Virginia.
- 7. Emergency Contraception Education Act, H.R. 1812, 108th Congress (2003); S. 896, 108th Congress (2003).

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CENTER FOR REPRODUCTIVE RIGHTS ("EC") Talking Points

There is a strong need for EC in the United States:

In the U.S., there are over 3 million unintended pregnancies each year. Half of these pregnancies end in abortion (i.e., 1.5 million abortions). Use of EC could prevent an estimated 700,000 abortions each year.

EC is safe and effective:

There are no serious side effects or medical consequences of taking EC. EC is 95% effective if taken within 24 hours of intercourse.²

EC is not an abortifacient:

EC *prevents* pregnancy by blocking ovulation, fertilization or implantation. Unlike EC, medical abortion, or RU-486, *ends* an *existing* pregnancy.

Availability of EC will not reduce the use of birth control:

Over 50% of women with unintended pregnancies were using birth control when they became pregnant.³ Contraceptive use does not decline in women supplied with EC.⁴ EC is more expensive, less effective and less widely available than birth control. Women who are sexually assaulted often do not have the option of using birth control.

EC must be made more widely available:

A recent survey revealed that almost half of all university-based health clinics do not offer students access to EC.⁵ Only five states currently have programs allowing pharmacists to dispense EC directly to women without requiring an individual doctor's prescription.⁶

Only four states mandate that hospital emergency rooms (ERs) provide EC to victims of sexual assault,⁷ and no state requires that ERs give EC to <u>all</u> women upon request.

Many women do not know about EC.³

¹ See e.g. Stanley K. Henshaw, Unintended Pregnancy in the United States, 30 Family Planning Perspectives 24-29, 46 (January/February 1998); see also Rachel K. Jones, Jacqueline E. Darroch and Stanley K. Henshaw, Contraceptive Use Among U.S. Women Having Abortions in 2000-2001, 34 Perspectives on Sexual and Reproductive Health (November/December 2002) (estimating that EC is responsible for up to 43% of the 11% decline in abortion rates between 1994 & 2000). ² Plan B is 95 % effective if taken within 24 hours, 85% effective between 25-48 hours and 61% effective if more than 48 hours have passed. See

http://www.go2planb.com/tools_for_clinicians/tools_for_clinicians_faq.html#5. Preven is 75% effective if taken within 72 hours. See http://www.preven.com/prodinfo/prescinfo.asp.

³ See e.g. Rachel K. Jones, Jacqueline E. Darroch and Stanley K. Henshaw, *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 Perspectives on Sexual and Reproductive Health (November/December 2002). Another recent study showed that two-thirds of unplanned pregnancies occur when contraception is used. Nathalie Bajos, Henri Leridon, Helene Goulard et. al, *Contraception: from Accessibility to Efficiency*, 18 Human Reproduction 994-999 (2003).

⁴ See e.g., Rebecca Jackson, Eleanor Schwarz, Lori Freedman and Philip Darney, Advance Supply of Emergency Contraception: Effect on Use and Usual Contraception – A Randomized Trial, 102 Obstetrics & Gynecology 8-16 (July 2003); Anna Glasier and David Baird, The Effects of Self-Administering Emergency Contraception, 339 New England Journal of Medicine 1-4 (July 1998); see also Kaiser Daily Reproductive Health Report, Contraceptive Use Does Not Decline Among Teenage Mothers Supplied with Emergency Contraception, Study Says (March 21, 2003) at http://www.kaisernetwork.org/daily reports/rep_index.cfm?hint=2&DR_ID=16724.

⁵ S. K. McCarthy, *Availability of Emergency Contraceptive Pills at University and College Student Health Centers*, 51 Journal of American College Health 15-22 (2002). ⁶ These states are Alaska, California, New Mexico, New York and Washington.

⁷ These states are California, New Mexico, New York and Washington. Illinois mandates that ERs provide women with information about EC but does not mandate provision of EC upon request.

⁸ A 2003 survey found that only 68% of women are aware that they can prevent pregnancy after intercourse, and only 6% have ever used EC. *See* Kaiser Family Foundation/SELF magazine, *National Survey of Women on their Sexual Health* (June 2003); *see generally* Kate Zernike, *Use of Morning-After Pill Rising And It May Go Over the Counter*, New York Times, May 19, 2003, at A1. A 2000 study found that one-fourth of the women aged 18-44 surveyed said they had never heard of EC, and nearly two-thirds said they didn't realize it was available in the United States. *See e.g.*, Leslie Lawrence, *Special Report: The Last Chance Contraceptive*, Kaiser Daily Reproductive Health Report (January 2002), *at* <u>http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=8923</u> (discussing 2000 study). A 1997 study by the Kaiser Family Foundation showed that 66% of women surveyed had heard of EC but only 52% of the 66% knew that EC could prevent pregnancy after intercourse; 72% were unaware that EC was available in the U.S.; and only 11% actually knew the key facts about EC. *See Summary of Findings: Survey of Americans on Emergency Contraception* at <u>http://www.kff.org/content/archive/1352/contraception_2.html</u>.