



NARAL
Pro-Choice America

Emergency Contraception (EC): An Important and Underutilized Contraceptive Option

Emergency contraception (EC), also known as the “morning-after” pill, can substantially reduce a woman’s chance of becoming pregnant when taken soon after sex.¹ EC does not cause abortion; rather it *prevents* pregnancy.² There are two main kinds of EC available in the United States. The first contains the same active ingredient as ordinary birth-control pills, the hormone progestin, and is marketed under the name Plan B One-Step®, and, in its generic form, take action™, as well as other generics that include Next Choice ONE DOSE™ and My Way®.³ The second, known as ellaOne®, is a single-dose ulipristal acetate pill that acts like birth control.⁴ In addition to these medications, 26 brands of daily birth-control pills that can be used as EC in appropriate doses are available in the United States.⁵ EC is safe, effective, and simple to use and is not associated with any serious or harmful side effects.⁶ Moreover, EC is not dangerous to women with pre-existing medical conditions.⁷

Since the U.S. Food and Drug Administration (FDA) first approved the emergency contraceptive Plan B® for prescription use in 1999, there have been many efforts to block its availability:⁸

- In 2006, after stalling for more than three years, the FDA approved Plan B® for over-the-counter (OTC) sales for individuals ages 18 and older.⁹ While the medication was available to some without a prescription, because of the age restriction, it was kept behind the pharmacy counter which affected all purchasers.
- In April 2009, the FDA announced that it would comply with a federal court ruling calling for the agency to allow 17-year-olds to have OTC access to EC and to reconsider its policy on age restrictions.¹⁰
- In June 2009, the FDA approved Next Choice®, the first-ever generic version of Plan B®, for prescription use for individuals ages 17 and under.¹¹ Two months later, the FDA approved the generic medication for over-the-counter use for individuals 17 and over.¹²
- In 2010, the FDA approved the emergency contraceptive ella® for use in the United States. Available only by prescription, ella® is safe and effective for use up to five days (120 hours) after sex.¹³
- In 2011, Teva, the manufacturer of Plan B® and the one-dose version, Plan B One-Step®, filed an application with the FDA requesting that the contraceptives be made available OTC for women of all ages.¹⁴
- Unfortunately, in December 2011, in response to Teva’s application the Department of Health and Human Services (HHS) overruled a recommendation from the FDA to

eliminate the age restriction on over-the-counter access to emergency contraceptives Plan B® and Plan B One-Step®.¹⁵

- In February 2012, the 2005 case against the FDA for imposing unnecessary age restrictions on EC was reopened and HHS then-Secretary Kathleen Sebelius was added as a defendant.¹⁶
- In July 2012, the FDA approved Next Choice ONE DOSE™, a generic version of Plan B One-Step®.¹⁷
- In April 2013, a federal judge ruled that HHS and FDA must lift all age or point-of-sale restrictions placed on levonorgestrel-based EC and make the medication available OTC. The judge added that Secretary Sebelius' decision to overrule the FDA's recommendation was "politically motivated, scientifically unjustified, and contrary to agency precedent."¹⁸
- Also in April 2013, HHS announced that it had approved an amended application from Teva thereby lowering the age restriction on this particular type of EC to those younger than 15. The medication would be allowed to be on the shelf, but would include a "proof of age" requirement to be triggered at the cash register. Additionally, the medication would only be sold on the shelf at stores that include a retail pharmacy.¹⁹
- The very next day, the Department of Justice (DOJ) filed an appeal to challenge the court decision.²⁰ The judge in the case refused to grant DOJ a stay, stating that the appeal "is frivolous and is taken for the purpose of delay." However, he did allow DOJ to seek a stay from the court of appeals before the order went into effect.²¹ DOJ appealed the decision and a federal appeals court temporarily granted a stay.²²
- Before a decision was handed down, however, the Obama administration agreed to drop its appeal to the federal court judge's ruling that all age restrictions on EC be lifted. With that decision, Teva and the FDA reached a compromise that Plan B One-Step® would be available OTC without an age restriction. However, an age restriction for those 16 and younger remained in place for all other brands of EC.
- Several months later, the FDA announced its intention to remove age restrictions on generic EC, but also announced that the labels for the medication would continue to state they were intended only for women ages 17 and older—leading to significant confusion on the part of pharmacists and customers.²³
- On April 30, 2016, Teva's market exclusivity—a market protection that allowed it to be the only brand of EC available on the shelves—expired, allowing all generics to also be available on the shelves, to any person regardless of age or point-of-sale restriction.²⁴

Emergency Contraception Availability²⁵

Product	Product Placement	Age Restriction
Plan B One-Step and generic Take Action	OTC - on shelves	No age restriction. No ID check required.
Other generic one-pill Levonorgestrel EC product(s)	OTC - on shelves	No age restriction. No ID check required.
ellaOne	Prescription only - behind pharmacy counter	Prescription-only for all ages.

As of November 2016

Although EC has tremendous potential to help reduce unintended pregnancy, this years-long fight over its access likely has contributed to the fact that too few Americans are aware that contraceptive methods are available that can prevent pregnancy after sex or too few women have timely access to the medication. Among women aged 15-44 who have ever had sex, 86 percent have heard of emergency contraception, but only 11 percent had ever used EC in 2006-2010.²⁶ In order for EC's full benefits to be realized, women must be educated about the medication's availability and effectiveness, they must have broader access to it, and they must use it correctly and consistently.

Greater Use of Emergency Contraception has the Potential to Prevent Unintended Pregnancies and Improve Women's Reproductive Health

EC and Unintended Pregnancy

- Half of all pregnancies in the United States are unintended. Approximately 3.4 million unintended pregnancies occurred in the United States in 2006.²⁷ Increased use of EC could reduce unintended-pregnancy rates, and thereby reduce the need for abortion.
- At least one study has shown that many women do not use EC because they underestimate their chances of becoming pregnant.²⁸ Education about increased access to EC is therefore a critical component of the effort to reduce the rate of unintended pregnancy. Similarly, improved access to EC for individuals under the age of 17 has the potential to impact teen-pregnancy rates significantly.²⁹

EC Can Improve Women's and Children's Health

Unintended pregnancies have serious health consequences for both women and children:³⁰

- Women facing an unintended pregnancy are less likely to identify health risks associated with pregnancy prior to conception and often do not take full advantage of the health options available to manage such conditions safely during pregnancy.³¹
- Unfortunately, research shows that children of unintended pregnancies are at greater risk of suffering low birth weight, dying before reaching their first birthday, enduring child abuse, and lacking sufficient resources in order to ensure healthy development.³²

Barriers to the Use of Emergency Contraception

Despite the potential for EC to reduce unintended pregnancy, and thus prevent the need for abortion, anti-choice activists have mounted major campaigns to limit women’s access to EC. Much of the opposition to EC arises from the misguided belief, and corresponding anti-choice rhetoric, that EC terminates pregnancy. In truth, *EC prevents* pregnancy. Pregnancy, as defined by the medical establishment (including the American College of Obstetricians and Gynecologists (ACOG) and HHS, among others), is the implantation of the fertilized egg in the uterine lining.³³ *EC prevents* pregnancy before implantation occurs, acting as regular birth control, not as abortion.³⁴

Women’s ability to obtain information about EC breaks down in many important settings:

Many Hospitals Fail to Provide EC to Sexual-Assault Survivors

Providing EC to sexual-assault survivors is an important means to help alleviate some of the trauma associated with sexual assault by restoring a sense of control and offering a safeguard to avoid the additional trauma of a resulting unintended pregnancy. Hospitals can play an important role in ensuring that information about and access to EC is distributed consistently. In fact, legal precedent indicates that failure to provide EC, a crucial preventive-health service, can constitute inadequate care, and give a woman standing to sue the hospital.³⁵ Nevertheless, many emergency rooms fail to offer this important medication.

- A 2005 nationwide telephone survey found that 42 percent of non-Catholic hospitals and 55 percent of Catholic hospitals do not provide EC under any circumstance, including to sexual-assault survivors. Among staff working in these hospitals, only about half gave callers a referral for EC, and most referrals proved ineffective.³⁶ (The most vocal opponents of EC tend to be Catholic hospitals. A directive for Catholic health-care services states that a sexual-assault survivor “may be treated with medications that would prevent sperm capacitation or fertilization”; however, it does not permit treatments that would interfere with the implantation of a fertilized ovum.³⁷)
- The same survey revealed that even in states with “EC in the ER” laws—which require EC to be provided in hospital emergency rooms—a large portion of staff reported over the phone that EC was not available on-site. This legal violation may occur because

mandates are not carefully enforced or because staff is not informed of policy changes regarding the required provision of EC.³⁸

- A 2005 study revealed that more than 25 percent of Illinois hospitals “never” or “sometimes” offer counseling on EC to sexual-assault survivors, even though Illinois law requires hospitals to develop protocols that ensure sexual-assault patients receive medically accurate written and oral information about EC, including a description of how and where to obtain EC.³⁹
- A 2012 study found that the problem of limited access to EC, or outright refusal to provide or even counsel for its use, is especially pervasive among Native-American women, who experience sexual assault at a higher rate than all other U.S. populations.⁴⁰ Because most Native-American women rely on the Indian Health Service (IHS) for their medical care, which is subject to federal restrictions such as the Hyde amendment, abortion is not available except in cases of rape, incest, or to save a woman’s life. However, the study found that in cases of sexual assault, abortion referral is very rarely given by IHS personnel. Without access to abortion care, Native-American women are acutely in need of greater access to EC, in order to prevent pregnancy.⁴¹

Pharmacist Refusals Create Unnecessary Barriers to EC

Unfortunately, anti-choice refusal clauses that permit a broad range of individuals and institutions to refuse to provide, pay for, counsel for, or even refer for medical treatment deny women access to this important reproductive-health option.

A number of states have laws that could be construed to permit pharmacists to refuse to fill women’s prescriptions for contraception, including EC. Currently, six states explicitly allow pharmacists to refuse to dispense EC, while six additional states have broad refusal clauses that could be interpreted as applying to pharmacists.⁴²

Specific Problems Related to Pharmacist Refusal

- When women are denied EC, they are left with the task of finding it elsewhere – and quickly, given the time sensitivity of preventing pregnancy. Low-income women and women of color in particular already face numerous barriers to accessing health-care services that make it particularly burdensome for them to find alternate providers, should their primary provider refuse to offer services. A study by the Kaiser Family Foundation found that low-income women face twice as much difficulty as other women in obtaining the flexible work schedules, transportation, and childcare necessary to access health-care services for themselves.⁴³ In addition, the United States Office on Women’s Health in HHS found that multiple factors limit the access of minority women to the U.S. health care system, including social disadvantages, discrimination, lack of translators or

culturally appropriate services, difficulty securing childcare, and lack of adequate transportation.”⁴⁴

- In 2010, Walgreens stores in Texas and Mississippi routinely denied EC to male customers. In response to pressure from the American Civil Liberties Union (ACLU), Walgreens’ headquarters instructed all pharmacies nationwide that EC could be sold to men and women age 17 and older, and that men seeking to purchase EC did not need to be accompanied by a female or identify for whom they were purchasing the medication.⁴⁵ Finding the problem occurring elsewhere, in 2012, the ACLU began a similar campaign to pressure Rite-Aid pharmacies to stop discriminating against men attempting to purchase EC.⁴⁶
- A 2009 survey found that EC is not adequately available at IHS facilities as an over-the-counter option. Fewer than half of all IHS pharmacies stock any form of EC at all. Pharmacists surveyed gave several reasons for not stocking the medication, including that EC is not included in drug formularies, medical staff deem EC to be unnecessary, and pharmacies do not handle “symptoms” of this nature, despite carrying daily contraceptives. The report suggests that because of its limited availability, many Native-American women may not even know EC exists.⁴⁷ In late 2013, IHS issued a statement that emergency contraception would be available in its federally operated facilities. However, IHS does not have any retail pharmacies, so getting the medication in a timely manner from an emergency care clinic simply may not be possible, though it is the only option available to many native women.⁴⁸
- In 2015, the Department of Health and Human Services released a revised Indian Health Manual that will significantly improve access to emergency contraception for Indian Health Service beneficiaries.⁴⁹ The new manual creates an explicit policy that emergency contraception (EC) must be available over the counter, without a prescription, and without an age restriction, consistent with the rest of the nation. This is an important step forward and one that has been called for by Native-American women's groups, Senate pro-choice champions, and allies. With strong enforcement of the revised manual, this policy finally provides the necessary documentation for IHS clients to ensure their health-care needs are met in this area.

On the Shelf Access That Isn’t Really Accessible

When Plan B One-Step® and its generic equivalent take action™ were allowed to be placed on store shelves rather than behind pharmacy counters, access to the medication was supposed to be greatly improved. Researchers have found that some women are able to get the medication more easily, but the availability is largely dependent upon the retail establishment. In 2014, the American Society for Emergency Contraception released a study examining the “real-world access” of EC. Only 49 percent of the stores surveyed stocked EC, and of those, about two-thirds locked the product in a “portable box or fixed

case” that has to be unlocked by a store employee. Other stores held the product behind the counter because of its cost. All in all, only 13 percent of stores sold EC in a way that did not require assistance from a store employee.⁵⁰

Strategies for Improving Access to Emergency Contraception

Although the FDA lifted the age restriction on Plan B One-Step[®], women still face barriers to obtaining the medication. Research demonstrates that EC is more effective the earlier it is taken.⁵¹ Thus, finding ways to facilitate access to EC without delay is crucial. There are at least six ways to improve women’s access to EC: (1) ensure that sexual-assault survivors receive information about and access to EC in hospital emergency rooms; (2) require pharmacies to dispense emergency contraception or to ensure timely access for their customers; (3) ensure access to affordable EC; (4) provide women with information about and access to EC at routine check-ups; and (5) label ordinary birth-control pills with instructions for use as EC.

Provide Information About and Access to EC in Hospital Emergency Rooms

- In 2012, more than 345,000 rapes or sexual assaults were reported in the United States.⁵² EC, when used correctly and consistently, can significantly reduce a woman’s chances of becoming pregnant. Thus, hospitals can alleviate some of the trauma associated with sexual assault by offering EC to sexual-assault survivors. However, too few women know about the medication. Educational efforts should be carried out to ensure that all women know to request EC if they are victims of sexual assault.

EC IS A COST-EFFECTIVE WAY TO PREVENT UNINTENDED PREGNANCY
Estimates show that for each dollar spent on a single treatment of EC, a savings of \$1.94 - 4.47 occurs, depending on the EC regimen and assumptions about savings from avoided mistimed births. EC is cost-effective whether provided at the time it is needed or in advance. More extensive use of EC could save considerable medical costs by reducing unintended pregnancies.⁵³

- Currently, 17 states and the District of Columbia have laws that improve sexual-assault survivors' access to EC or information about EC in hospitals: AR, CA, CO, CT, DC, HI, IL, MA, MN, NJ, NM, NY, OR, SC, TX, UT, WA, WI.⁵⁴

- Nearly 80 percent of American women believe that hospitals should provide EC to rape survivors – regardless of whether the hospital is affiliated with the Catholic church.⁵⁵

Require Pharmacies or Pharmacists to Dispense Emergency Contraception

- Seven states (CA, IL, ME, NV, NJ, WA, WI) have policies requiring pharmacies and/or pharmacists to dispense contraception, including EC, or to ensure timely access to the medication. In some states, must-dispense policies have the force of law, either through statute or regulation; in others, pharmacy boards have interpreted state laws and regulations to require distribution of all medication, including contraception. Pharmacy board interpretations do not have the force of law, but provide important guidance about standards of practice.⁵⁶

Ensure Access to Affordable EC

- Under the Affordable Care Act, all health plans must cover EC without a copay or deductible.⁵⁷ In 2011, as part of its implementation of Section 2713(a)(4) of the health-care law, which requires health plans to cover—at no cost—certain preventive-health services that are specific to women, HHS appointed an Institute of Medicine (IOM) panel to recommend which services should be defined as preventive care. The IOM panel recommended that the full range of FDA-approved contraceptive methods, including EC, be covered.⁵⁸ In August 2011, HHS adopted this recommendation in full.⁵⁹ In August 2012, all newly issued health plans were required to cover the full range of FDA-approved methods of contraception, including EC. The policy explicitly exempts religious houses of worship. Religiously affiliated non-profit employers and closely held, for-profit companies are eligible for an accommodation, which allows them to register their objection to providing contraceptive coverage; in those cases, then the benefit is delivered directly to employees through the insurance company or third party administrator.

Ensure Medicaid Coverage of Emergency Contraception

- While the FDA's approval of generic EC and over-the-counter sale of EC marked significant steps forward in advancing women's access to contraception, the medication's retail cost is too expensive for many women. In many states, women eligible for Medicaid need to obtain a prescription in order to have the cost of the medication covered. Because EC is effective only if used within a very brief time period, going to a physician to obtain a prescription for the medication hinders timely access to the medication. Accordingly, state efforts to provide Medicaid coverage of EC without a prescription are critical to ensuring access to the medication.
- Medicaid coverage of EC is particularly important for women of color, who disproportionately work in low-wage jobs that do not offer benefits⁶⁰ and therefore turn at higher rates to public programs such as Medicaid to access affordable health care.
- Currently, six states provide Medicaid coverage of over-the-counter EC without a prescription: IL, MD, NM, NY, OR, and WA.⁶¹

Provide Women with Information about and Access to EC at Routine Check-Ups

- Health-care providers, well-positioned to provide women with accurate information about and access to EC, should include information about the medication in routine office visits.⁶² The American College of Obstetricians and Gynecologists recommends this approach.⁶³ In addition, at least one study has found that advance provision of EC increases the likelihood that women will use it; women who received an advance supply of EC were nearly three times more likely to use the treatment than women who received only information about the medication.⁶⁴ In fact, a 2008 report found that use of EC was strongly linked to having received counseling from a clinician within the past year.⁶⁵
- Studies suggest that women still rarely discuss EC in clinical settings. In 2008, only three percent of women ages 15-44 reported that they had discussed EC with their health-care provider in the past year, and only four percent had received counseling on EC from their gynecologists.⁶⁶

Label Ordinary Birth-Control Pills for Use as EC

- More than 10 million American women are currently using birth-control pills and 82 percent of sexually experienced women have used birth-control pills at one time or another.⁶⁷ The FDA has approved several types of oral contraceptives for use as emergency contraceptives.⁶⁸ If these ordinary birth-control pills were labeled with instructions for use as emergency contraceptives, millions more women and their physicians would be aware that something can be done to prevent unintended pregnancy if unprotected sex occurs.

Public and Professional Education will Improve Access to and Increase Use of Emergency Contraception

Much more needs to be done to increase education among women and their doctors about EC, including where to obtain it, how it works, and how to take it, in order to improve its use and effectiveness. Many women do not know of the medication's availability – and many doctors fail to include EC information as part of their routine check-ups. Until this information is commonly known and distributed, EC's full potential to prevent unintended pregnancy, and therefore the need for abortion, will not be realized.

- Studies have shown that physician-knowledge deficits regarding EC are significantly associated with lower prescription rates.⁶⁹ Emergency medicine physicians are twice as likely to prescribe EC to adolescents if they are knowledgeable about EC and when it should be administered.⁷⁰
- A 2009 study found that most emergency medicine physicians infrequently prescribe EC to adolescents (fewer than five times a year). Lack of physician knowledge about

emergency contraception was a key reason for why EC was not prescribed in the emergency department setting.⁷¹ This is particularly problematic, as many adolescents use the emergency room as their primary source of health care, and teens often choose to seek EC at an emergency room - rather than from their pediatrician - to preserve confidentiality and anonymity.⁷²

- One survey found that almost 25 percent of North Carolina pharmacists thought that EC was the same as mifepristone, the medication that induces abortion. Some even told callers that EC caused an abortion and that if “the egg is fertilized, you have a live person.” Only one pharmacist out of 583 knew that EC could be effective up to 120 hours after unprotected sex.⁷³

EC Public-Education Campaigns Can Increase Awareness of EC

- Nearly 20 years ago, the Reproductive Health Technologies Project inaugurated a national toll-free hotline to provide information about EC and referrals to health-care professionals able to prescribe it. In conjunction with Princeton University, the project later launched the Emergency Contraception Website (www.not-2-late.com) that includes similar information. The website is completely confidential and is available in multiple languages.
- A paid public-education media campaign in Philadelphia and Seattle resulted in significant increases in knowledge about EC. In addition, the number of calls to the Emergency Contraception Hotline also significantly increased.⁷⁴
- In 2010, Shippensburg University in Pennsylvania began making EC available to students through a vending machine inside the student health center. This unusual method of dispensing the medication initially attracted some national attention, but university officials explained they are simply responding to a student survey, in which 85 percent of respondents supported making EC available. Only students and employees can gain access to the student health center, and the university has confirmed that all are of the necessary age to receive OTC EC.⁷⁵
- In 2011, New York City began a pilot program to dispense EC in its school-based health centers. Private schools across the city have had a similar program in place for years. With this program, nearly 30 percent of public high-school students have access to EC and basic health care. This program is in response to the city’s 7,000 young women who become pregnant by age 17, with 90 percent of those pregnancies unplanned.⁷⁶

Conclusion

Emergency contraception is an important but underutilized contraceptive option that has the potential to improve women’s reproductive health significantly. Ensuring that women have

timely access to EC at doctor's offices, pharmacies, and hospitals, and encouraging women to use the medication correctly and consistently, may help reduce unintended pregnancy and the need for abortion. Instead of blocking access to EC, policymakers should focus on public education, education for health-care professionals, and innovative programs to make EC more accessible to all women.

January 1, 2017

Notes:

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- ² Robert A. Hatcher et al., *EMERGENCY CONTRACEPTION: THE NATION'S BEST KEPT SECRET* 29-30 (1995); American College of Obstetricians & Gynecologists (ACOG), *Statement on Contraceptive Methods* (July 1998). In fact, EC does not work if a woman is already pregnant.
- ³ *Emergency Contraception: A Guide for Pharmacies and Retailers* (October 2014), at http://americansocietyforec.org/uploads/3/2/7/0/3270267/pharmacy_ec_access_overview.pdf (last visited Nov. 3, 2014).
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- ⁹ Press Release, Barr Pharmaceuticals, Inc., *FDA Grants OTC Status to Barr's Plan B® Emergency Contraceptive* (Aug. 26, 2006); Press Release, U.S. Food and Drug Administration, *FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older, Prescription Remains Required for Those 17 and Under* (Aug. 24, 2006).
- ¹⁰ Press Release, Reproductive Health Technologies Project, *FDA revises restriction on over-the-counter access to Plan B emergency contraception to women 17 and over* (Apr. 22, 2009).

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- ¹¹ Press Release, Food and Drug Administration, *FDA Approves Generic Prescription-Only Version of Plan B Emergency Contraception for Women Ages 17 and Under* (Jun. 24, 2009) at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm168870.htm> (last Dec. 11, 2015).
- ¹² Emergency Contraception: A Guide for Pharmacies and Retailers (October 2014), at http://americansocietyforec.org/uploads/3/2/7/0/3270267/pharmacy_ec_access_overview.pdf (last visited Dec. 11, 2015).
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