Pro-choice

NARAL
Reproductive Freedom & Choice

Memorandum

To: Bruce Reed, Assistant to the President and Director of the Domestic Policy Council
✓ Ann O'Leary, Special Assistant to the President for Domestic Policy
Heather Howard, Associate Director of Domestic Policy
From: Betsy Cavendish, VP NARAL Foundation, Legal Director
Allison Herwitt, Director of Government Relations
Date: November 20, 2000
Re: Executive Order Regarding Emergency Contraception for Rape Victims

Thank you for your interest in promulgating an Executive Order providing that rape victims be offered emergency contraception in the emergency rooms of hospitals receiving federal funds. We have attached some materials in support of this proposal.

More broadly, NARAL has been so grateful for the President's support of reproductive rights, demonstrated at the outset of his administration by the signing of five pro-choice Executive Orders. It is only fitting that the administration issue at least one more pro-choice Executive Order as a legacy document. We think that this proposal is appropriate for several reasons:

- ✓ First, part of being pro-choice is being pro-contraception. This Executive Order would locate the president's support for abortion rights in the larger context that he himself espouses, in that abortion will be more rare as contraception is more accessible.
- ✓ Second, wider information about and access to emergency contraception is the single best way to reduce unintended pregnancy. Thus, by issuing this Executive Order, the President would shine a spotlight on the promise of emergency contraception and the effect of the Order would be far broader than the help it would provide to women victimized by rape.
- ✓ Third, while in principle NARAL supports much more robust measures to expand access to emergency contraception through the Title X program, this Executive Order would pose no danger to the Title X program, a frequent target of anti-choice animus in Congress.
- ✓ Finally, should Congress try to undo this Executive Order as it has so many of the President's pro-choice Executive Orders, it would expose the opponents' radical agenda to deny women vital health information and contraception.

If you have any further questions about this matter, we would be glad to assist. Allison's direct line is 973-3003 and Betsy's is 973-3012. She is reachable the rest of the week at (614) 486-7478.

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Memorandum

To: Interested Parties
From: NARAL Legal Department
Date: November 2000
Re: **Requiring hospitals to provide emergency contraception to rape survivors**

Few Americans are aware that, in emergency situations, contraceptive methods are available that can prevent pregnancy after sexual intercourse. Emergency contraception may be used when contraceptive methods fail or when women are sexually assaulted. Emergency contraceptive pills (ECPs) – the most commonly used method of emergency contraception – are ordinary birth control pills that reduce a woman's chance of becoming pregnant by 75 to 89 percent when a specific dose is taken within 72 hours of unprotected sex and a second dose is taken 12 hours after the first dose. ECPs do not cause abortion; rather, they inhibit ovulation, fertilization or implantation *before* a pregnancy occurs.

Emergency contraception is a safe and effective way to prevent unintended pregnancy and reduce the need for abortion. When a woman is raped, emergency contraception can be an important tool to help her avoid the additional trauma of an unwanted pregnancy by the rapist. Emergency contraception should be hospitals' standard of care for treating survivors of sexual assault.

Why Requiring Hospitals to Provide Emergency Contraception to Rape Survivors is Necessary

- Over 300,000 women are raped in the U.S. each year.[1]

- Each year, over 32,000 women become pregnant as a result of rape and approximately 50 percent of these pregnancies end in abortion.[2] Emergency contraception is not only a safe and effective method to prevent unwanted pregnancy, but it also can empower women who

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have been raped with a sense of control and provide an important way to help them to cope with the trauma of sexual assault.

- Very few women know about emergency contraception. A national survey found that only one in ten women aged 18-44 have heard of and know the key facts critical to using emergency contraceptive pills.[3] Unless hospitals inform women of the option to use emergency contraception, women are unlikely to know enough to ask for the treatment.

- Standards of emergency care established by the American Medical Association (AMA) require that rape survivors be counseled about their risk of pregnancy and offered emergency contraception.[4]

- Despite these facts, recent studies have found that many hospitals do not provide emergency contraception to women requesting it, even to women who have been sexually assaulted. For example:

  - Only half of all Minnesota hospitals provide emergency contraception to rape survivors.[5]

  - Nearly one in three New York hospitals fail to offer emergency contraception to rape survivors, and an additional 23 percent have no clear policy on the issue.[6]

  - In Pennsylvania, two-thirds of the general hospitals in the state do not provide emergency contraception to survivors of sexual assault.[7]

  - Nationwide, 82 percent of Catholic hospitals do not provide emergency contraception to women who have been raped.[8]

  - In 1995, 14 Catholic hospitals in Chicago treated 1004 rape victims but refused to offer them emergency contraceptive pills.[9]

Requiring hospitals to provide emergency contraception to rape survivors would rectify the current gap in emergency care and ensure that women who have been raped have access to every available means to protect their health and well-being.

Notes

[1] This estimate is limited to women 18 years or older and is not based on whether the rape is reported. Patricia Tjaden and Nancy Thoennes, "Prevalence, Incidence, and Consequences of Violence Against Women: Findings from the National Violence Against Women Survey," *Research in Brief* (Washington, DC: U.S. Department of Justice, National Institute of Justice, Nov. 1998, NCJ 172837), 4 <http://ncjrs.org/pdffiles/172837.pdf> (8/22/00).

[2] Melisa M. Holmes, Heidi S. Resnick, Dean G. Kilpatrick, and Connie L. Best, "Rape-Related Pregnancy: Estimates and Descriptive Characteristics from a National Sample of Women," *American Journal of Obstetrics and Gynecology*, vol. 175, no. 2 (Aug. 1996): 322.

[3] Kaiser Family Foundation, *Emergency Contraception: Is the Secret Getting Out?*, Summary of Findings (CA: KFF, 1997), 7-8.

[4] American Medical Association, "Strategies for the Treatment and Prevention of Sexual Assault" (1995), 18.

[5] Minnesota NARAL Foundation, "Access in Crisis: The Continuing Decline of Hospital-Based Emergency Contraceptive Services in the State of Minnesota" (2000), 7.

[6] New York State Affiliate of the National Abortion and Reproductive Rights Action League Foundation, "Preventing Pregnancy After Rape: Does Your Hospital Provide Emergency Contraception to Rape Survivors?" (Dec. 1999), 9-11.

[7] Rebecca Simons, "Emergency Contraception for Sexual Assault Survivors: A Survey of Hospital Emergency Rooms in Pennsylvania," (Clara Bell Duvall Education Fund, May 2000).

[8] Catholics for a Free Choice, *Catholic Health Restrictions Updated* (Washington, D.C.: Catholics for a Free Choice, 1999), 7.

[9] Miriam Berg, "In Merger, Catholic Hospital Can Compromise," *New York Times,* Oct. 19, 1997, Sec. 4, p. 14.

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EMERGENCY CONTRACEPTION: AN IMPORTANT AND UNDERUTILIZED CONTRACEPTIVE OPTION

Emergency contraceptive pills (ECPs), the most commonly used method of emergency contraception, are ordinary birth control pills that reduce a woman's chance of becoming pregnant by 75 to 89 percent when a specific dose is taken within 72 hours of unprotected sex and a second dose is taken 12 hours after the first dose. ECPs do not cause abortion; rather, they inhibit ovulation, fertilization or implantation before a pregnancy occurs. ECPs do not disrupt an established pregnancy.

GREATER USE OF ECPs WILL IMPROVE REPRODUCTIVE HEALTH AND REDUCE ABORTION

- Increased use of ECPs could reduce the number of unintended pregnancies and abortions by half annually.

BARRIERS TO ACCESS

- Eighty-two percent of Catholic hospitals do not provide emergency contraception even to women who have been raped, although in cases of sexual assault, the Catholic Church permits using medication to prevent pregnancy.
- Sixteen states have laws that permit health care facilities, health care professionals, or other individuals to refuse to provide contraception or family planning, which may include emergency contraception.

EDUCATION AND DIRECT DISTRIBUTION BY PHARMACISTS WILL INCREASE ACCESS TO AND USE OF EMERGENCY CONTRACEPTION

- Only one percent of women aged 18-44 have used ECPs, and 89 percent have not heard of or do not know the key facts critical to use of the pills.
- One survey found that 37 percent of New York City pharmacists knew nothing about emergency contraception or provided only incorrect information about emergency contraception.
- A Washington state project enabled women to receive ECPs directly from pharmacists. In 16 months, ECPs were provided to nearly 12,000 women, preventing an estimated 700 unplanned pregnancies and 350 abortions.

DO SOMETHING! **Call 1-877-YOU-DECIDE (1-877-968-3324) or log-on to www.naral.org.**

For a complete fact sheet on Emergency Contraception, please contact the NARAL Information Line at (202) 973-3018.

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EMERGENCY CONTRACEPTION: AN IMPORTANT AND UNDERUTILIZED CONTRACEPTIVE OPTION

Emergency contraception is often called "the nation's best-kept secret" because few Americans are aware that, in emergency situations, contraceptive methods are available that can prevent pregnancy after sexual intercourse. Emergency contraception may be used when contraceptive methods fail,[1] are misused or not used at all, and when women are sexually assaulted. Although emergency contraceptive methods are not a substitute for ongoing contraceptive use and do not protect against the transmission of sexually transmitted diseases, these important and underutilized contraceptive options can reduce unintended pregnancy and the need for abortion. American women should have broader access to a full range of contraceptive services, including postcoital emergency methods.

Emergency contraceptive pills (ECPs) are the most commonly used method of emergency contraception. ECPs are ordinary birth control pills that reduce a woman's chance of becoming pregnant by 75 to 89 percent when a specific dose is taken within 72 hours of unprotected sex and a second dose is taken 12 hours after the first dose.[2] ECPs do not cause abortion; rather, they inhibit ovulation, fertilization or implantation before a pregnancy occurs.[3] The FDA has approved the Gynétics Incorporated's PREVEN Emergency Contraception Kit, which became available, via prescription, in October of 1998.[4] In July of 1999, the FDA approved another ECP called Plan B developed by the Women's Capital Corporation.[5] The copper-T intrauterine device can also be used as an emergency contraceptive.[6]

Greater Use of Emergency Contraception Will Improve Reproductive Health

- Estimates show that increased use of ECPs could reduce the number of unintended pregnancies and abortions by half annually.[7] Lack of access to emergency contraception may contribute to higher rates of unplanned pregnancy in the U.S. compared to countries where emergency contraception is widely available.[8]

- A study of women who had used ECPs found that 91 percent were very satisfied or somewhat satisfied with the ECPs, and 97 percent would recommend ECPs to a friend or family member.[9]

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- Emergency contraception is cost-effective in preventing unintended pregnancy. Estimates show that in a managed care setting, a single treatment of ECPs saves $142; and advance provision of ECPs to women using spermicides, periodic abstinence, barrier contraceptives or withdrawal saves $263 to $498 annually.[10]

- The need for emergency contraception can bring women, and young women in particular, into family planning centers, where they can receive other health care services and counseling. For those who remain sexually active, emergency contraception provides a bridge to ongoing contraception and disease prevention.[11]

Barriers to Access

Despite the promise of using ECPs to reduce unintended pregnancy, efforts to limit access to them have been significant. Much of the opposition to ECPs arises from the mistaken belief that ECPs cause abortion. ECPs, however, do not disrupt an established pregnancy, which begins with implantation of the fertilized egg in the uterine lining. Rather, ECPs delay or inhibit ovulation or implantation prior to pregnancy and therefore, do not cause abortion. Nevertheless, consider the following:

- Eighty-two percent of Catholic hospitals do not provide emergency contraception even to women who have been raped, although the Catholic Church permits, in cases of sexual assault, using medication to prevent ovulation, sperm capacitation, or fertilization before conception.[12] A study conducted by NARAL of New York found that more than one-half of non-Catholic hospitals in New York have no clear policy of providing rape survivors with emergency contraception. Twenty-four percent of non-Catholic hospitals in New York do not provide emergency contraception to rape survivors.[13]

- Fewer than 10 percent of Missouri hospitals provide emergency contraception, according to the preliminary results of a survey conducted by Missouri NARAL. A study by Wyoming NARAL found that only one-third of responding hospitals and clinics in Wyoming provide emergency contraception.[14]

- Twenty percent of family planning coordinators of Title X grantees in Michigan believe that "ECPs are primarily an abortion-inducing agent." In explaining why their family planning programs did not provide ECPs, several respondents cited politics and the debate over abortion.[15]

- Wal-Mart, one of the nation's largest drug distributors, refused to carry PREVEN, but later issued a policy requiring pharmacists who object to dispensing ECPs to find someone who will.[16] A study conducted by NARAL New Mexico/Right to Choose found that nearly 15 percent of New Mexico pharmacists would not fill prescriptions for ECPs.[17]

- A 1998 South Dakota law permits pharmacists to refuse to dispense medication if there is reason to believe it would be used to "destroy an unborn child," which includes a human organism from fertilization until birth.[18] In 1999, five states (IN, KS, LA, OR, WI) introduced legislation to allow pharmacists to refuse to provide certain medicines, including ECPs.[19]

- Sixteen states (AR, CO, FL, GA, IL, ME, MA, MN, NJ, NY, OR, TN, VA, WV, WI, WY) have laws that permit health care facilities, health care professionals, or other individuals to refuse to provide contraception or family planning, which may include emergency contraception.[20]

- In 1999, North Carolina enacted a contraceptive coverage bill specifically excluding coverage for PREVEN or any equivalent drug.[21] Seven states (CA, CT, HI, ME, MD, NV, NC) with contraceptive coverage laws permit employers and/or insurers to refuse, on moral or religious grounds, to cover contraception, which includes emergency contraception.[22]

Public and Professional Education Will Improve Access and Increase Use of Emergency Contraception

- Only one percent of women aged 18-44 have used ECPs, and 89 percent of women aged 18-44 have not heard of or do not know the key facts critical to use of the pills.[23]

- Although nearly 100 percent of obstetrician-gynecologists believe ECPs are safe and effective, only 24 percent prescribe them on a regular basis (more than five times a year).[24] This low prescription rate may be due to the fact that clinicians often lack adequate knowledge about emergency contraception, and therefore do not discuss it with patients during routine contraceptive counseling sessions. In addition, many patients are not aware of emergency contraception and do not ask that it be made available. To help reverse this trend, the American College of Obstetricians and Gynecologists (ACOG) and others are conducting a national physician education campaign supporting "women's right to know about all birth control methods" and encouraging doctors to discuss and prescribe emergency contraception when appropriate.[25]

- One survey found that 37 percent of New York City pharmacists knew nothing or provided only incorrect information about emergency contraception.[26]

- A national toll-free hotline (1-888-NOT-2-LATE) that provides information on emergency contraception and referrals to health care professionals who are able to prescribe it was inaugurated on February 14, 1996 by the Reproductive Health Technologies Project. The hotline has received 201,682 calls as of December 1999. Additionally, the emergency contraception website (http://www.not-2-late.com or http://opr.princeton.edu/ec/) has been visited 519,252 times as of October 1999.[27]

- The Hawaii Health Department conducted a public service advertising campaign about emergency contraception in 1999. The ads directed listeners to contact the national toll-free hotline or the state's family planning information line. The average number of calls to the family planning information line increased from eight to ten calls per day to 40 to 50 calls per day during the month the radio spots aired.[28]

Direct Distribution by Pharmacists Will Also Increase Access to and Use of Emergency Contraception

- Although ECPs are typically available by prescription only, some state regulations permit pharmacists to dispense certain medications through a collaborative drug therapy agreement between a pharmacist and a physician or other prescriber.[29] In 1999, Washington state completed a two-year pilot project that enabled women to receive ECPs directly from pharmacists. In 16 months, the program provided ECPs to nearly 12,000 women, preventing an estimated 700 unplanned pregnancies and 350 abortions.[30] The success of Washington's program prompted the Oregon Medical Association's House of Delegates to pass a resolution in April of 1999 to work with the Oregon Board of Pharmacy to establish a one-year pilot project to permit pharmacists to dispense the PREVEN Kit.[31] In addition, in 1999, the California legislature considered a bill to allow pharmacists to initiate emergency contraception drug therapy under a collaborative agreement.[32]

- ECPs should be more readily available, such as directly through a pharmacist, because the need for ECPs can almost always be self-diagnosed, they are simple to use, the doses do not need to be adjusted to a woman's particular situation or medical condition, accidental overdoses are not dangerous, and it is doubtful that the regimen constitutes a serious risk to any identifiable group of women.[33]

Conclusion

Emergency contraception is an important but underutilized contraceptive option. Increasing access to emergency contraception will reduce unintended pregnancy and the need for abortion, and will improve women's reproductive health. Instead of restricting access to emergency contraception, policy makers should focus on better public education, professional education, and innovative programs to make emergency contraception more available.

01/17/2000

NOTES:

1. Nine in ten women at risk of unintended pregnancy use a contraceptive method. The Alan Guttmacher Institute (AGI), "Contraception Counts: State-by-State Information," *Issues in Brief* (Jan. 1998): 5.

2. James Trussell, Charlotte Ellertson and Felicia Stewart, "The Effectiveness of the Yuzpe Regimen of Emergency Contraception," *Family Planning Perspectives*, vol. 28, no. 2 (Mar./Apr. 1996): 58, 64; Women's Capital Corporation, "A New Generation of Emergency Contraception Has Arrived," July 28, 1999 (press release).

3. Robert A. Hatcher et al., *Emergency Contraception: The Nation's Best-Kept Secret* (Atlanta: Bridging the Gap Communications, 1995), 29-30; Judy Peres, "Fears Keeping 'After Sex' Pill on Back Shelf," *Chicago Tribune*, Feb. 14, 1996, A1.

4. Food and Drug Administration (FDA), "FDA Approves Application for Preven Emergency Contraceptive Kit," Sept. 2, 1998 (talk paper).

5. Plan B contains only levonorgestrel, a progestin. Women's Capital Corporation, "A New Generation of Emergency Contraception Has Arrived." PREVEN contains a combination of estrogen and progestin. Office of Population Research, Princeton University, *Emergency Contraceptive Pills* <http://opr.princeton.edu/ec/ecp.html> (1/7/2000). One study found that women using the progestin-only regimen were about one-third as likely to become pregnant, as compared to women using estrogen-progestin ECPs. The study also found that 23% of women taking only progestin experienced nausea, whereas 51% of women using estrogen-progestin ECPs experienced nausea. Task Force on Postovulatory Methods of Fertility Regulation, "Randomised Controlled Trial of Levonorgestrel Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception," *The Lancet*, vol. 352, no. 9126 (Aug. 8, 1998): 428, 430, 431.

6. The copper-T IUD is an effective method of emergency contraception that reduces the risk of pregnancy by 99 percent. AGI, The Henry J. Kaiser Family Foundation (KFF) and National Press Foundation, "Emergency Contraception: All Talk, No Action?," Dec. 18, 1997 (Q & A factsheet), 1. The copper-T IUD may be inserted up to five days after intercourse or five days after ovulation, whichever is later. Office of Population Research, Princeton University, *Copper-T IUD as Emergency Contraception* <http://opr.princeton.edu/ec/eciud.html> (1/7/2000).

7. Based on data from the 1980s, it is estimated that increased use of ECPs could reduce the number of unintended pregnancies by 1.7 million annually and the number of abortions by 800,000. James Trussell et al., "Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies," *Family Planning Perspectives*, vol. 24, no. 6 (Nov./Dec. 1992): 269-70.

8. Richard A. Grossman and Bryan D. Grossman, "How Frequently Is Emergency Contraception Prescribed?" *Family Planning Perspectives*, vol. 26, no. 6 (Nov./Dec. 1994): 270-71. A 1998 publication concluded that 33 million U.S. women were at risk of unintended pregnancy. AGI, "Contraceptive Services," *Facts In Brief* (Jan. 1998): 1.

9. S. Marie Harvey et al., "Women's Experience and Satisfaction with Emergency Contraception," *Family Planning Perspectives*, vol. 31, no. 5 (Sept./Oct. 1999): 240.

10. James Trussell et al., "Preventing Unintended Pregnancy: The Cost-Effectiveness of Three Methods of Emergency Contraception," *American Journal of Public Health*, vol. 87, no. 6 (June 1997): 932, 934-35.

11. Reproductive Health Technologies Project (RHTP), "Emergency Contraception Hotline, Questions and Answers," Aug. 1996 (factsheet), 10.

12. Catholics for a Free Choice, *Catholic Health Restrictions Updated* (Washington, D.C.: Catholics for a Free Choice, 1999), 7; Susan Yanow, "A Successful Campaign -- Catholic Hospitals Agree to Offer Emergency Contraception," *ProChoice IDEA* (Aug. 1999): 12 (quoting *Ethical and Religious Directives for Catholic Health Care Services*, Directive 36).

13. "Preventing Pregnancy After Rape: Does Your Hospital Provide Emergency Contraception to Rape Survivors?" (New York: NARAL/NY Foundation, 1999), 9.

14. Missouri NARAL Foundation, "Abortion and Reproductive Health: The Access Project Survey" (1999 preliminary results); Wyoming NARAL, "Reproductive Health Services Survey Questionnaire" (1999 preliminary results); *see also* Tara Tuckwiller, "Well-Kept Secret: 'Morning-After' Contraceptive Available by Prescription in West Virginia," *Charleston Gazette & Daily Mail*, Oct. 11, 1999, 1D (survey of four major hospitals and clinics found that none provides emergency contraception).

15. Joseph Winchester Brown and Matthew L. Boulton, "Provider Attitudes Toward Dispensing Emergency Contraception in Michigan's Title X Programs," *Family Planning Perspectives*, vol. 31, no. 1 (Jan./Feb. 1999): 39, 40, 41.

16. Bill Saporito-Bentonville and David E. Thigpen, "Wrestling with Your Conscience Wal-Mart Wants to Avoid Controversy on its Shelves, but Consumers Won't Let It," *Time*, vol. 154, no. 20 (Nov. 15, 1999): 72; Dana Canedy, "Wal-Mart Decides Against Selling a Contraceptive," *New York Times*, May 14, 1999, C2.

17. Nancy Ellefson, "New Mexico NARAL Surveys Pharmacists," *ProChoice IDEA* (Winter 1998-1999): 14-15.

18. S.D. Codified Laws §§ 22-1-2(50A), 36-11-70.

19. NARAL/NARAL Foundation, *Who Decides?: A State-By-State Review of Abortion and Reproductive Rights* (Washington, D.C.: NARAL/NARAL Foundation, 2000), ix.

20. NARAL/NARAL Foundation, *Who Decides?*, xviii, 89.

21. N.C. Gen. Stat. §58-3-176(c)(4)(b).

22. NARAL/NARAL Foundation, *Who Decides?*, xviii.

23. KFF, *Emergency Contraception: Is the Secret Getting Out?*, Summary of Findings (CA: KFF, 1997), 7-8.

24. KFF, *Emergency Contraception*, 12-13.

25. The American College of Obstetricians and Gynecologists, "Physicians Emphasize Availability of Emergency Oral Contraception," Apr. 1997 (press release); Marilyn Elias, "Docs Spread Word: Pill Works On Morning After," *USA Today*, Apr. 29, 1997, A1.

26. Tammy A. Draut, *Emergency Contraception: Do Pharmacists Know About This Important Method to Prevent Pregnancy?*, (New York City: Planned Parenthood of New York City, 1999), 5.

27. RHTP, "Emergency Contraception Update - February 1998," Feb. 1998 (factsheet); Correspondence from Heather Zesiger, Program Assistant, RHTP, to Rachel Kramer, NARAL Legal Department (Jan. 7, 2000) (on file with NARAL).

28. Esme M. Infante, "State Promotes 'Morning After' Pill: Perky Radio Spots Upset Opponents," *Honolulu*

Advertiser, June 25, 1999, A1; "State Says Not Indoctrinating on Use of 'Morning-After' Pill," *Associated Press Newswires*, June 25, 1999; Correspondence from Sara Kuzmanoff, Acting Supervisor, Family Planning Services Section, Hawaii Department of Health, to Sharon Terman, NARAL Legal Department (Oct. 5, 1999).

29. The following states may permit pharmacists to establish collaborative agreements for dispensing ECPs: CA, FL, HI, IN, IA, KS, KY, MI, MS, NV, NM, ND, OR, SD, TX, WA. Program for Appropriate Technology in Health (PATH), *Emergency Contraception: A Resource Manual for Providers*, (Seattle: PATH, 1997), 14-15.

30. PATH, "Increasing Women's Access to Emergency Contraceptive Pills through Direct Pharmacy Provision" (Dec. 1999).

31. Oregon Medical Association House of Delegates, 125th Annual Meeting, Resolution No. 2 (Apr. 23-25, 1999).

32. S.B. 404, 1999-2000 Reg. Sess. (Cal. 1999).

33. Charlotte Ellertson et al., "Should Emergency Contraceptive Pills Be Available Without Prescription?" *Journal of the American Medical Women's Association*, vol. 53, no.5, supp. 2 (1998): 227-29.

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EMERGENCY CONTRACEPTIVE PILLS SHOULD BE AVAILABLE OVER-THE-COUNTER

Emergency contraceptive pills (ECPs) are ordinary birth control pills that significantly decrease a woman's chance of becoming pregnant when administered within 72 hours of unprotected sex.[1] Estimates show that increased use of ECPs could reduce the number of unintended pregnancies and abortions by half annually.[2] In recent years, the FDA has approved two types of ECPs – the PREVEN Emergency Contraception Kit and Plan B – both of which are available by prescription.[3]

Currently, ECPs can be difficult to obtain in a timely manner because women must obtain a prescription in order to use them. For example, a woman faced with a broken condom on a Friday night, whose doctor's office is closed over the weekend, might have to wait until the following Monday – three days later – to obtain a prescription for ECPs. Women in rural areas may have to travel great distances to reach the nearest doctor or clinic, making a prescription within 72 hours of unprotected sex difficult, if not impossible to obtain. Even under less extreme circumstances, obtaining a prescription for ECPs can be problematic. A recent study of the Emergency Contraception Hotline (1-888-NOT-2-LATE), a 24-hour, automated phone line that provides the names and telephone numbers of clinicians who prescribe ECPs in the caller's geographic area, found that even when calls to clinicians were made during business hours, only three out of every four attempts to obtain ECPs resulted in appointments or telephone prescriptions within 72 hours.[4] Because ECPs are more effective the earlier they are used – and most effective within the first 12 hours of unprotected sex[5] – the obstacles associated with obtaining a prescription for ECPs pose a serious threat to women's health.

Because ECPs are safe, effective, and easily self-administered, they are suitable for non-prescription (i.e. over-the-counter) availability. Making ECPs available over-the-counter would eliminate an unnecessary barrier to women's access to this important contraceptive option.

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FDA CRITERIA FOR OVER-THE-COUNTER DRUGS

To be approved by the FDA for over-the counter distribution, a drug must meet certain criteria:

- the drug must be safe and effective;
- taking the drug must be safe enough that medical supervision – and thus, a prescription – is not necessary to preserve public health due to the drug's toxicity, its potential for harmful side-effects, or its method of use; and
- the drug must be simple enough to use that instructions on the drug's packaging are sufficient to ensure safe and correct self-medication.[6]

The FDA requires a prescription for drugs that, because of their toxicity, their potential for harmful side-effects, or their method of use, are not safe to use except under the supervision of a medical professional.[7] ECPs meet the criteria for non-prescription status and can be safely marketed over-the-counter.

ECPs ARE SAFE AND EFFECTIVE

- Oral contraceptives, the same drugs found in ECPs, have been studied for three decades. They have been studied more extensively and have been found safer than most drugs in medicine. No serious medical consequences from an overdose of oral contraceptives have been reported.[8]
- ECPs are 75 to 89 percent effective when a specific dose is taken within 72 hours of unprotected sex and a second dose is taken 12 hours after the first dose.[9]

ECPs HAVE MINIMAL SHORT-TERM SIDE-EFFECTS

- The most common side-effects of ECPs are nausea and vomiting; other side-effects include dizziness, fatigue, and headache. These short-term side effects are not serious and are easily manageable without medical supervision.[10]
- Long-term side-effects are unlikely given the very short duration of treatment.[11]
- All of the side-effects of ECPs are less dangerous than either pregnancy or childbirth.[12]

ECPs ARE EASY AND SAFE TO SELF-ADMINISTER

- In a study of Scottish women who were given an advance supply of ECPs to keep at home, 98 percent of the women who used ECPs used them correctly, and none experienced serious adverse effects.[13]
- Women can diagnose their own need for ECPs; taking the drug involves simply swallowing pills.[14]
- The dosage and timing of ECP use are the same regardless of the individual characteristics of the woman.[15]
- No specific medical conditions preclude a woman's use of ECPs. In fact, the only contraindication to ECPs is pregnancy – not because ECPs can harm a pregnant

woman or a developing embryo, but because ECPs will not work once pregnancy begins.[16]

NON-PRESCRIPTION ACCESS TO ECPs DOES NOT DISCOURAGE ONGOING CONTRACEPTIVE USE

- Claims that increased access to emergency contraception might encourage riskier sexual behavior or lead to less frequent use of other forms of contraception have not been supported by recent data. A Scotland study found that, compared to women who had to go through their doctors to obtain ECPs, women who had a supply of ECPs available at home did not differ in their use of other forms of contraception and were not more likely to use ECPs more frequently. In addition, 98 percent of the women reported that they did not take more risks as a result of having ECPs readily available.[17]

BETTER ACCESS TO ECPs WILL IMPROVE WOMEN'S HEALTH

- Nearly 50 percent of pregnancies in the U.S. are unintended, and over half of those pregnancies end in abortion.[18] An estimated one half of these unintended pregnancies and abortions could be prevented each year through wider use of ECPs.[19]
- Lack of access to emergency contraception may contribute to higher rates of unplanned pregnancy in the U.S. compared to countries where emergency contraception is widely available.[20] Negative health outcomes – including delayed or inadequate prenatal care, increased likelihood of low birth weight and death in the first year of life, increased risk of the mother being physically abused, and economic hardship – are strongly associated with unintended pregnancy.[21]
- ECPs are more effective the earlier they are used: delaying the first dose of ECPs more than 12 hours after unprotected sex increases a woman's chance of becoming pregnant by 50 percent. Thus, immediate access to ECPs is crucial for maximizing effectiveness.[22]
- By increasing women's contraceptive options, better access to ECPs will give women greater control over their reproductive lives.

In short, ECPs have all of the characteristics of an over-the-counter drug: they are safe, effective, and simple to use; they are not associated with any serious or harmful side-effects; they are not dangerous to women with particular medical conditions; and they do not lead to riskier behavior or less frequent use of other forms of contraception. ECPs have enormous potential to reduce unintended pregnancy and the need for abortion. In fact, wider access to and use of them is perhaps the single most promising avenue for reducing this country's high rate of unintended pregnancy. If women simply saw them in pharmacies, awareness of ECPs would increase tremendously. This could make a crucial difference to millions of women. However, without speedy and uncomplicated access to ECPs, women cannot take full advantage of this important contraceptive option. Making ECPs available over-the-counter would remove this barrier to access, and help to improve women's health.

6/22/2000

Notes

[1] James Trussell, Charlotte Ellertson and Felicia Stewart, "The Effectiveness of the Yuzpe Regimen of Emergency Contraception," *Family Planning Perspectives*, vol. 28, no. 2 (Mar./Apr. 1996): 58, 64; Women's Capital Corporation, "A New Generation of Emergency Contraception Has Arrived," July 28, 1999 (press release).

[2] Based on data from the 1980s, it is estimated that increased use of ECPs could reduce the number of unintended pregnancies by 1.7 million annually and the number of abortions by 800,000. James Trussell et al., "Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies," *Family Planning Perspectives*, vol. 24, no. 6 (Nov./Dec. 1992): 269-70.

[3] PREVEN contains a combination of estrogen and progestin. Plan B contains only levonorgestrel, a progestin. Food and Drug Administration (FDA), "FDA Approves Application for Preven Emergency Contraceptive Kit," Sept. 2, 1998 (talk paper); Women's Capital Corporation, "A New Generation of Emergency Contraception Has Arrived."

[4] James Trussell, et al., "Access to Emergency Contraception," *Obstetrics & Gynecology*, vol. 95, no. 2 (Feb. 2000): 267-270.

[5] G. Piaggio, et al., "Timing of Emergency Contraception with Levonorgestrel or the Yuzpe Regimen," *The Lancet*, vol. 353 (Feb. 27, 1999): 721.

[6] Prescription-exemption procedure, 21 C.F.R. § 310.200(b) (2000).

[7] 21 U.S.C.A. § 353(b)(1)(A) (1999).

[8] Maureen B. Gardner, Office of Research Reporting, National Institute of Child Health and Human Development (NICHD), "Facts About Oral Contraceptives," June 1983 (factsheet), reprinted by the National Institutes of Health <http://www.nih.gov/health/chip/nichd/oralcnt/> (6/13/00); Charlotte Ellertson, et al., "Should Emergency Contraceptive Pills Be Available Without Prescription?" *Journal of the American Medical Women's Association*, vol. 53, no. 5 (Supplement 2, 1998): 227 *citing* M. Smith and P. Kane, *The Pill Off Prescription* (London: The Birth Control Trust, 1975).

[9] Trussell, Ellertson and Stewart, "The Effectiveness of the Yuzpe Regimen of Emergency Contraception," 58, 64; Women's Capital Corporation, "A New Generation of Emergency Contraception Has Arrived."

[10] Task Force on Postovulatory Methods of Fertility Regulation, "Randomised Controlled Trial of Levonorgestrel Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception," *The Lancet*, vol. 352, no. 9126 (Aug. 8, 1998): 431, tbl. 4; Ellertson, et al., "Should Emergency Contraceptive Pills Be Available Without Prescription?" 228.

[11] Ellertson, et al., "Should Emergency Contraceptive Pills Be Available Without Prescription?" 228.

[12] Anna Glasier, "Safety of Emergency Contraception," *JAMWA*, vol. 53, no. 5 (Supplement 2, 1998): 219.

[13] Anna Glasier and David Baird, "The Effects of Self-Administering Emergency Contraception," *New England Journal of Medicine*, vol. 339, no. 1 (Jul. 2, 1998): 1-4.

[14] Ellertson, et al., "Should Emergency Contraceptive Pills Be Available Without Prescription?" 227.

[15] Ellertson, et al., "Should Emergency Contraceptive Pills Be Available Without Prescription?" 227.

[16] Ellertson, et al., "Should Emergency Contraceptive Pills Be Available Without Prescription?" 227.

[17] Anna Glasier and David Baird, "The Effects of Self-Administering Emergency Contraception," 1-4.

[18] Stanley Henshaw, "Unintended Pregnancy in the United States," *Family Planning Perspectives*, vol. 30, no. 1 (Jan./Feb. 1998): 27.

[19] James Trussell et al., "Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies," *Family Planning Perspectives*, vol. 24, no. 6 (Nov./Dec. 1992): 269-270.

[20] Richard A. Grossman and Bryan D. Grossman, "How Frequently Is Emergency Contraception Prescribed?" *Family Planning Perspectives*, vol. 26, no. 6 (Nov./Dec. 1994): 270.

[21] Committee on Unintended Pregnancy, Institute of Medicine, *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families*, Sarah S. Brown and Leon Eisenberg, eds. (Washington, DC: National Academy Press, 1995), 81.

[22] Piaggio, et al., "Timing of Emergency Contraception," 721.