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NARAL
Reproductive Freedom & Choice

**Statement of Elizabeth A. Cavendish,
NARAL Legal Director and Vice President of the NARAL Foundation
at the FDA Hearing on Regulation Of OTC Drug Products,
June 28 and 29, 2000**

Thank you for holding this important hearing. I am delighted to submit a statement on behalf of NARAL, a 501(c)(4) national grassroots advocacy organization of over 200,000 members with a state affiliate network, and the NARAL Foundation, its 501(c)(3) counterpart. NARAL and the NARAL Foundation are committed to ensuring women's access to the full range of reproductive health options, including preventing unintended pregnancy, bearing healthy children, and choosing legal abortion. We believe that increasing access to emergency contraceptive pills (ECPs) is the single most promising avenue for reducing unintended pregnancy and the need for abortion, and we argue that ECPs 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

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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 sex⁵ – 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.

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.

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.