USAID FACT SHEET ON EMERGENCY CONTRACEPTION
September 2001

1. What are Emergency Contraceptive Pills (ECPs)?

The term "emergency contraception" primarily refers to the use of oral contraceptive pills (OCs) within 72 hours (3 days) of unprotected intercourse to prevent pregnancy. The regimen involves taking two doses, 12 hours apart, of certain formulations of a combination of estrogen and progesterone (combined OCs) or progestin-only (levonorgestrel) pills.

**Effectiveness**

It is estimated that if 100 women have a single act of unprotected intercourse during the second and third weeks of their cycle, 8 would become pregnant without treatment with ECPs and only 2 with treatment, a reduction in the risk of pregnancy of 75%. A WHO study published in the Lancet, August 1998, showed that levonorgestrel-only ECPs are more effective (85% vs. 57% pregnancies prevented) and produce less side effects than combined ECPs. With progestin-only ECPs, 23% of women experienced nausea compared to 51% of combined ECP users. In addition, 6% of progestin-only ECP users experienced vomiting compared to 19% of combined ECP users.

The WHO trial also indicated that effectiveness of both combined and progestin-only ECPs is significantly greater the earlier after exposure to unprotected intercourse the first dose is given. Effectiveness, especially with combined OCs, drops if taken more than 48 hours after unprotected sex.

The U.S. Food and Drug Administration (USFDA) guidance notes that: "ECPs are meant for one-time, emergency protection," meaning that ECPs are for exceptional circumstances and should not be used as one's primary contraceptive method, and that "ECPs are not as effective as other forms of birth control used in a routine basis."

**Availability**

The combined OCs that USAID supplies in its programs are among the formulations that the USFDA has approved for use as emergency contraception. In September 1998, the USFDA approved the first dedicated EC product, Preven, a high dose combined ECP product distributed by Gynetics. In July 1999, the Women's Capital Corporation received FDA approval for Plan B, the first progestin-only (levonorgestrel)

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EC product in the United States. Other dedicated products that are available internationally include Postinor 2 and Norlevo, both containing levonorgestrel.

2. Who needs ECPs?

A wide variety of women at risk of pregnancy from unprotected intercourse can benefit from ECPs. Situations where a woman needs ECPs include: a woman who has experienced forced or coerced sex, a woman whose male or female condom breaks or is used incorrectly, a woman who runs out of other contraceptive methods, a woman who forgets to take several consecutive OCs, and a woman who was not expecting to have sex. Adolescent girls and young women often fall into these categories. This is a particularly important method of contraception for women who have been victims of rape; ECPs are the only choice these women have to mitigate an already dire situation.

3. How do Emergency Contraceptive Pills (ECPs) work?

**ECPs do not interrupt an established pregnancy.** Several studies have shown that ECPs prevent or delay ovulation; this appears to be the main mechanism of action. A common belief has been that ECPs may work by preventing implantation of a fertilized egg. However, while an effect on the endometrium has been observed in some studies, it is not at all clear that the observed effect would be sufficient to prevent implantation. Likewise, it has been hypothesized that ECPs may also affect transport of sperm or ova, yet no data exist that are sufficient to allow an evaluation of these possible mechanisms of action. There is no evidence that administration of progestins or estrogen in ECPs during pregnancy will have a negative effect on a fetus should the woman be pregnant at the time of ECP use.

5. What are the USFDA Guidelines?

The USFDA published a formal notice regarding ECPs on February 25, 1997 in the *Federal Register*. This document states that any one of six different (and now 12) common brands of combined oral contraceptive pills, all containing norgestrel or levonorgestrel and ethinyl estradiol, are safe and effective for use as emergency contraception up to 3 days after unprotected sex. The FDA recommends that ECP treatment involves taking a dose of either 2 high dose or 4 low dose oral contraceptive pills, within 72 hours after having unprotected sex, followed by a second dose 12 hours after the first dose. Based on a unanimous FDA Advisory Committee recommendation in June, 1996 the FDA has officially endorsed the use of ECPs. Prior to the USFDA approval of dedicated EC products, the Food and Drug Administration ruling officially sanctioned the legality of the "off label" use of oral contraceptives for emergency contraception which has been practiced for 30 years in the US, Canada and widely in Europe. Furthermore, the FDA ruling paved the way for specially packaged oral contraceptive pills in the U.S. for use as emergency contraceptives, as has already occurred in other countries.
6. What are the views of other Donors and International Agencies on ECPs?

The organizations that have endorsed and/or support the use of ECPs include but are not limited to: World Health Organization, United Nations Population Fund, International Planned Parenthood Federation, World Bank, Department for International Development/UK, CARE, International Federation of the Red Cross, United Nations High Commission for Refugees, and UNICEF. ECPs are in the Essential Drug List of the World Health Organization and are in the Handbook for Refugee Reproductive Health.

7. Policy Regulations

ECPs are a method of contraception. ECPs are not subject to the USAID policies and legislation concerning abortion such as the Mexico City Policy. However, as a contraceptive ECPs should not be subject to targets, incentives or denials of rights or benefits. ECP users should receive complete information on the risks and benefits of the method including conditions under which ECPs should not be used and side effects.

8. Does USAID include ECPs in its Program?

Providing information about ECPs has become a medical norm. In fact, the American College of Obstetricians and Gynecologists (ACOG) recommends that women be informed of ECPs as standard good medical practice. Further, both ACOG and the American Medical Association (AMA) support ECPs availability over the counter in the United States, and the USFDA action (see item 5) further reinforces this norm.

Accordingly, USAID supplies information about the use of ECPs in a variety of its technical and training materials, and supports sharing information with family planning clients about this contraceptive option. Roles for USAID-supported programs include support to collect data on the need, use and potential impact of ECPs in participating countries, to conduct operations research on how the provision of ECPs can be integrated within family planning and other reproductive health programs, to discover who are the groups that would benefit most from having ECPs available, to include in social marketing campaigns, and to conduct biomedical research on the mechanism of action, use and effectiveness of ECPs.

Although USAID-supplied oral contraceptive pills are among the FDA-approved formulations that can be used for emergency contraception, USAID does not currently fund separate packaging of pills for this purpose nor has USAID purchased any of the two USFDA-approved dedicated ECP products. If USAID Missions overseas requested that USAID provide ECPs, there would be no restrictions preventing USAID from responding to these requests. ECPs constitute an integral part of the voluntary service delivery mix that USAID supports, and USAID will promote a variety of approaches to support this choice so vital for women.
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