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## Q & A

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### ***EMERGENCY CONTRACEPTION: ALL TALK, NO ACTION?***

**December 18, 1997**

#### **WHAT ARE EMERGENCY CONTRACEPTIVES? HOW LONG HAVE THEY BEEN AVAILABLE IN THE UNITED STATES?**

There are three forms of emergency contraception currently available in the United States: emergency contraceptive pills, emergency minipills, and the Copper-T intrauterine device (IUD). Emergency contraceptive pills are regular oral contraceptives that contain the hormones estrogen and progestin and are taken in a different way than they are for ongoing birth control. The first studies using combined oral contraceptives for emergency contraception occurred in the 1970s by Canadian physician Albert Yuzpe and colleagues. His emergency contraceptive pill regimen – accepted today as the standard protocol -- involves taking 100 mcg of estrogen coupled with 0.5 mg of levonorgestrel (a progestin) within 72 hours after unprotected sex and again 12 hours later. The seven brands of pills that contain the hormones studied for use as an emergency contraception and are available in the U.S. include Alesse, Ovral, Lo/Ovral, Levlen, Nordette, Tri-Levlen, and Triphasil.

Emergency contraceptive minipills are oral contraceptives that contain progestin, but no estrogen. First studied for use as an emergency contraceptive in the 1990s, this method involves taking 20 Ovrette pills (0.75 mg of levonorgestrel) within 72 hours after unprotected sex and again 12 hours later. Emergency contraceptive minipills are just as effective at preventing pregnancy as regular emergency contraceptive pills, but are less likely to cause nausea or vomiting. They are less commonly used as emergency contraception, in part, because of the number of pills required per dose.

The IUD was first studied in the 1970s for use as emergency contraception. It is a highly effective emergency contraceptive, reducing the risk of pregnancy by 99%. For many women, however, insertion of an IUD is not an ideal option for emergency treatment due to various risk factors.

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Although there are no products currently on the market specifically approved by the FDA for use as emergency contraception, it is legal to prescribe oral contraceptives or the Copper-T IUD for emergency contraceptive use. Advertising campaigns by health care providers, clinics, or other health programs to raise awareness of emergency contraception is also generally legal. However, advertising by pharmaceutical companies that manufacture the methods is not legal until they apply and receive FDA approval for emergency contraceptive use of their products.

## **WHERE DOES THE U.S. MEDICAL AND SCIENTIFIC COMMUNITY STAND ON EMERGENCY CONTRACEPTION?**

Many prominent health and professional organizations have recently focused greater attention on emergency contraception. Most striking was the unprecedented announcement by the FDA earlier this year declaring certain brands of oral contraceptives safe and effective for use as emergency contraceptives. The FDA's announcement in the *Federal Register* on Tuesday, February 25, 1997, also stated that "the notice is intended to encourage manufacturers to make this additional contraceptive option available."

In 1996, the American College of Obstetrics and Gynecologists (ACOG) published a Practice Pattern on emergency contraception encouraging members to prescribe it. Practice Patterns are published when ACOG believes there is a disparity between the published literature on a treatment and actual provider practice, which was the case with emergency contraception. This marked only the second time that ACOG had issued such guidelines.

Planned Parenthood affiliates, college health services, and other family planning organizations have been offering emergency contraceptive services for many years. Recently, Planned Parenthood Federation of America broadened its medical protocol for all affiliates to allow emergency contraceptive pills to be prescribed over the phone.

Finally, in 1997, twelve medical and health organizations, including ACOG, the American Medical Association, the American Medical Women's Association, the American Society for Reproductive Medicine, the National Association of Nurse Practitioners in Reproductive Health, the National Family Planning and Reproductive Health Association, the National Asian Women's Health Organization, the National Latina Health Organization, the North American Society for Pediatric and Adolescent Gynecology, Planned Parenthood Federation of America, and the Society for General Internal Medicine, endorsed an emergency contraception resource kit for health care providers to encourage them to counsel on and offer emergency contraceptive services. This kit has been distributed to over 50,000 health care providers across the U.S.

## **WHAT HAS BEEN THE PHARMACEUTICAL INDUSTRY'S RESPONSE TO THE FDA DECISION?**

Two firms in the U.S. market oral contraceptives that contain the hormones studied for use as emergency contraception: Wyeth-Ayerst and Berlex. Neither company has announced an intention to apply to the FDA for approval of their oral contraceptives for this use, nor did the FDA notice force these companies to re-label their products. One firm in the U.S. has expressed interest in bringing a new emergency contraceptive pill product to market: Gynetics, based in Belle Mead, NJ, which has announced its intention to do so sometime in 1998.

## **CAN PHARMACISTS PRESCRIBE EMERGENCY CONTRACEPTIVE PILLS DIRECTLY TO CLIENTS?**

In 18 states, independent prescribers, such as physicians can delegate prescriptive authority to a pharmacist, allowing pharmacists to prescribe medication directly to clients, based on a protocol established between the pharmacist and the independent prescriber. Pharmacists with this prescriptive authority can then serve all clients, not just clients of the sponsoring prescriber. Prescriptive practice by pharmacists is developing out of need to expand access to primary care basic services in a cost-effective way. For example, pharmacists in many states today provide flu shots to adults.

Emergency contraceptive pills are another area where pharmacists may be able to play a role using prescriptive authority. The Program for Appropriate Technology in Health (PATH) is piloting a demonstration project in the Puget Sound region of Washington state to increase access to emergency contraceptive pills by making them available through pharmacists.

States with prescriptive authority laws that potentially could be used in this way include: Arkansas, California, Florida, Hawaii, Indiana, Iowa, Kansas, Kentucky, Michigan, Mississippi, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Texas, Vermont, and Washington.

## **HOW DOES USE OF EMERGENCY CONTRACEPTION AFFECT USE OF REGULAR CONTRACEPTIVES?**

A recent survey of obstetrician-gynecologists, family practice physicians, nurse practitioners, and physician assistants by the Kaiser Family Foundation demonstrates that the majority of health care providers do not think that use of emergency contraceptive pills encourages contraceptive risk-taking or discourages correct use of other contraceptive methods. When women aged 18-44 in a companion survey were asked “How likely would you be to use condoms for birth control knowing you could use emergency contraceptive pills as a back up?” one in four women reported that they would be more likely to use condoms than they would have been before knowing the pills existed.

## **HOW OFTEN CAN EMERGENCY CONTRACEPTION BE USED?**

Repeated use of emergency contraceptive pills is not recommended for ongoing contraceptive protection, but repeated use does not pose known health risks to women. When used on an ongoing basis, regular contraceptives are more effective at preventing pregnancy than emergency contraceptive pills or minipills. The Copper-T IUD is a highly effective method when left in a used as an ongoing method. *Also, emergency contraception offers no protection against sexually transmitted diseases.* In the United Kingdom, where emergency contraceptive pills have been widely promoted, repeated use of ECPs is not common.

## **WHAT IS THE DIFFERENCE BETWEEN EMERGENCY CONTRACEPTION AND MIFEPRISTONE (RU-486) OR METHOTREXATE?**

Mifepristone (also known as RU-486 or the French abortion pill), methotrexate, and emergency contraceptive pills are three different drugs from entirely different drug families. Mifepristone and methotrexate can be used to terminate a pregnancy whereas emergency contraceptive pills cannot terminate a pregnancy. Mifepristone also has been studied for use as an emergency contraceptive in other countries but is not currently available for this use in the U.S. Studies of mifepristone in the U.S. have focused on its use as an abortifacient, not emergency contraception to date.

## **WHAT COST BENEFITS DO EMERGENCY CONTRACEPTIVES OFFER?**

From the perspective of health insurers, emergency contraceptives have the potential to save health care dollars in both public and private sector plans. They are cost-effective whether provided when an emergency arises or in advance to be used when needed. A single treatment of emergency contraceptive pills saves \$142 in a private sector setting and \$54 in a public sector setting. Advance provision of emergency contraceptive pills to women using barrier contraceptives, spermicides, periodic abstinence, or withdrawal, saves from \$263 to \$498 in a private sector setting and from \$99 to \$205 in a public sector setting. The health care savings derive from avoiding expensive health care costs resulting from unintended pregnancies, including abortion, ectopic pregnancies, and births.

## **HOW WIDESPREAD IS EMERGENCY CONTRACEPTIVE USE IN OTHER COUNTRIES?**

Emergency contraception is more widely used in countries where it is actively promoted to potential clients. In the United Kingdom and the Netherlands, emergency contraception is discussed in all family planning materials and public education campaigns. It is an accepted part of family planning services and awareness and use among the public is much broader than in the United States. These countries also have much lower unintended pregnancy rates than the U.S.

A 1994 study of Finland women showed that 10 percent of women younger than 25 years and 4 percent of all women aged 18-44 years had used hormonal emergency contraception. In the United States, a Kaiser Family Foundation survey showed that only 1 percent of women aged 18-44 years had ever used emergency contraceptive pills. Pill products packaged specifically for emergency contraceptive use are also available in some countries, including Finland and the United Kingdom.

There are also several international efforts that endorse emergency contraception as well. In 1981, the International Planned Parenthood Federation Medical Advisory Panel recommended that all of its affiliates should provide emergency contraception (IPPF has 136 family planning association members worldwide). More recently, the World Health Organization added emergency contraception to the international Essential Drugs List. The Consortium on Emergency Contraception is an international group committed to making emergency contraception a standard part of reproductive health worldwide. It recently introduced emergency contraceptive products into Kenya and Sri Lanka.

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