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Emergency Contraception vs. Medication Abortion: A Primer and Update on the FDA's Recent Actions

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On June 24, 2022, the U.S. Supreme Court held that there is no federal constitutional right to abortion. Dobbs v. Jackson Women's Health Organization, 597 U.S. __ (2022). The decision overruled Roe v. Wade, the 1973 case that had established the right to abortion, and Planned Parenthood of Southeastern Penn. v. Casey, the 1992 decision that had reaffirmed the right to abortion and established the "undue burden" test for pre-viability abortion regulations.

In the immediate wake of the Dobbs decision, many states took actions to restrict or ban abortion or to revive abortion restrictions that had been unenforceable under *Roe* and *Casey*. Some states' actions have resulted in bans or limitations on the use of abortion pills—medications that may be used to

terminate an established pregnancy of up to 10 weeks. In some areas, policymakers and others have questioned whether such restrictions might also ban or limit the use of emergency contraceptive pills—medications that must be used within 5 days after sexual intercourse to prevent pregnancy.

On December 23, 2022, the U.S. Food and Drug Administration (FDA) released new labeling and patient information requirements for over-the-counter emergency contraceptive medications (also known as "morning-after pills") to clarify that the medications cannot disrupt an established pregnancy and thus are distinct from medication abortion.

This post explains the key differences between emergency contraception and medication abortion and summarizes the FDA's recent changes to the patient information materials and labeling of "Plan B" and similar medications.

Emergency Contraception vs. Medication Abortion

Emergency Contraception

Most contraceptive methods are designed to be used before or at the time of sexual intercourse. Emergency contraception refers to methods for preventing pregnancy that may be used after sexual intercourse has occurred. Emergency contraception is not intended for routine use, but as a back-up method of pregnancy prevention when contraceptives fail or are not used. It is also an important component of treatment for victims of sexual assault.

Effective methods for emergency contraception have been in use since at least the 1970s, when regimens were developed for prescribing ordinary birth control pills in particular dosages for use after intercourse. The first FDA approval for a medication to be used specifically for emergency contraception was issued in 1999. Today, there are two types of emergency contraceptive medications approved for use in the U.S.:

- Levonorgestrel, which is sold as a one- or two-dose regimen under a variety of brand names such as Plan B One-Step or My Way. This medication is available over the counter, without a prescription. It is most effective if used within 72 hours but may be effective for up to 5 days after intercourse.
- Ulipristal acetate, sold under the brand name ella. This medication requires a prescription and is effective up to 5 days after intercourse. A prescriber must confirm that a patient is not pregnant before prescribing it.

A fundamental requirement of FDA approval is that a medication be both safe and effective for its intended use. Both types of emergency contraception pills are expressly contraindicated for individuals who are already pregnant because they are ineffective at that point—they can no longer prevent the pregnancy, nor can they terminate it. If a pregnant individual takes them mistakenly, they will not harm the pregnancy.

Medication Abortion

Medication abortion terminates an established pregnancy. In 2000, the FDA authorized use of a drug called mifepristone (also known as RU-486) to terminate a pregnancy within the first seven weeks. Today, a two-drug regimen comprised of mifepristone followed by misoprostol is approved by the FDA for use during the first 10 weeks of pregnancy. It is intended for use by patients who are known to be pregnant and want to terminate their pregnancies.

The regimen for medication abortion is subject to an FDA Risk Evaluation and Management Strategy (REMS) program, which imposes certain requirements on health care providers who prescribe it. In the past, the REMS permitted mifepristone to be dispensed only in-person in a clinic, medical office, or hospital, but the COVID-19 pandemic prompted the FDA to permanently lift this requirement and allow for telehealth prescribing and dispensing via certified pharmacies, including those that use mail delivery. (Some states, including North Carolina, still impose in-person requirements through state law.) The patient must also sign a form that clearly states that the purpose of the medication is to terminate the patient's pregnancy.

North Carolina law imposes additional requirements on medication abortion. A pregnant woman must receive certain information, including information about her condition and the medical risks of both abortion and of carrying a pregnancy to term, at least 72 hours before the medication is dispensed. In addition, a physician must be physically present in the same room as the patient when the first dose of the medication is administered. G.S. 90-21.82.

Recent FDA Label Changes to Emergency Contraception

The FDA has always stated that emergency contraception is only for the prevention of pregnancy, is not effective at terminating pregnancy, and is contraindicated for pregnant patients. However, the agency's original labeling and patient information requirements for over-the-counter levonorgestrel pills created confusion because of the way they described the mechanism of action for the medications—that is, how they work to prevent pregnancy.

Levonorgestrel pills prevent pregnancy by inhibiting or delaying ovulation, so that there isn't an egg available to be fertilized while sperm are still present in the woman's body. An early question about the pills' mechanism of action was whether they might also prevent pregnancy by preventing a fertilized

egg from implanting in the uterus. This hypothesis was ultimately not supported by evidence obtained from mechanism-of-action research. Nevertheless, the labeling requirements for the pills included a statement that they could prevent a fertilized egg from implanting.

The manufacturers of the pills have long sought to have the statement removed as scientifically unfounded. Last week, the FDA announced that the labeling and patient information requirements for levonorgestrel pills will be changed accordingly. The revised wording will state that the medication "works before release of an egg from the ovary"—in other words, before fertilization can occur. It will also state clearly that levonorgestrel pills cannot affect an existing pregnancy.

Significance of the FDA's Action

The distinction between abortion and contraception is important as a matter of law as well as medicine. Although the decision to have an abortion is no longer protected by the U.S. Constitution, the right to use contraception still is. Griswold v. Connecticut, 381 U.S. 479 (1965) (holding that married persons' use of contraception is constitutionally protected); Eisenstadt v. Baird, 405 U.S. 438 (1972) (extending the constitutional protection for use of contraception to unmarried persons); see also *Dobbs*, slip op. at 66 & 71 (expressly stating that the decision should not be understood to cast doubt on Supreme Court precedents involving issues other than abortion). Nevertheless, the FDA's original labeling and patient information requirements for emergency contraception—which have long been criticized by scientific and medical groups—took on particular urgency after Dobbs, as state-by-state abortion debates have reflected that there is not universal agreement about when pregnancy begins.

Pregnancy cannot be medically established until the hormone hCG is detected in either blood or urine, and this does not occur until a fertilized ovum implants (normally in the uterus, but ectopic pregnancies also implant and produce hCG). But some Americans hold the philosophical or religious belief that pregnancy begins at fertilization, and this view is reflected in some states' abortion restrictions. See, e.g., Louisiana Rev. Stat. § 40:1061 (defining pregnancy to include the period from fertilization to childbirth); Tennessee Code § 39-15-213 (similar). However, the presence of a fertilized ovum in a woman's body cannot be detected before implantation. Further, it is estimated that in the natural course of things, up to one-half of fertilized ova never implant but pass through the genital tract undetected, followed by normal menstruation. Therefore, no one can say whether fertilization has occurred if pregnancy is never medically established–not a doctor, not the woman herself. Given that abortion procedures are used only in cases of established pregnancy, state laws that define pregnancy as

beginning at fertilization rather than implantation seem unlikely to have an effect on actual abortion practices–but they could intrude on the right to use contraception if lawmakers attempt to restrict contraceptives that they believe act after fertilization.

The FDA's prior labeling requirements demonstrated how, in the post-*Roe* era, the agency's conclusions can create significant policy debates with real-world consequences for individuals who do not wish to become pregnant. In this case, the FDA concluded that the statement about the potential post-fertilization action of levonorgestrel pills was incorrect. It is possible, however, that similar concerns will be raised about other forms of contraception. How the FDA will respond, and how the issue will play out in a country where the right to use contraception is constitutionally protected, remains to be seen.