

Plan B: Emergency Contraceptive Pill ^[1]

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Plan B is a [progestin](#) ^[4]-only emergency contraceptive pill (ECP) that can be taken within seventy-two hours of unprotected sex in order to prevent an unwanted [pregnancy](#) ^[5]. Plan B was created in response to the United States Food and Drug Administration's (US FDA) 1997 request for new drug applications (NDAs) for a dedicated ECP product, and was approved for sales in the US in 1999. Duramed, a subsidiary of [Barr Pharmaceuticals](#) ^[6], manufactures Plan B for The Women's Capital Corporation (WCC), which owns the patent for Plan B. This technology is important in part because it expands women's [reproductive rights](#) ^[7] by giving them greater control over their fertility. The mechanism of action of Plan B also raises questions about the moral status of the [zygote](#) ^[8].

Plan B consists of two 0.75 mg tablets of [levonorgestrel](#) ^[9], a type of synthetic [progesterone](#) ^[10] or [progestin](#) ^[4]. Current evidence suggests that the [hormone](#) ^[11] works similarly to normal [birth control](#) ^[12] by preventing [ovulation](#) ^[13], but previous studies have shown that it prevents [implantation](#) ^[14] of a [fertilized egg](#) ^[15]. ECPs had been prescribed off-label during the 1960s as high doses of hormonal [birth control](#) ^[12] pills or as high doses of diethylstilbestrol (DES), a type of synthetic [estrogen](#) ^[16], for women who had been raped. Due to the many harmful side effects of DES, in the 1970s Dr. [Albert Yuzpe](#) ^[17] did the first formal studies of combined [estrogen-progestin ECPs](#) ^[18] with the goal of reducing the number of unintended pregnancies. At this time, studies on [progestin](#) ^[4]-only ECPs (like Plan B) were also being conducted in Latin America. The first dedicated ECP product was [Postinor](#) ^[19] (containing only [levonorgestrel](#) ^[9]), distributed by Gedeon-Richter, a Hungarian firm, in Eastern Europe during the 1980s. Plan B was developed in response to the US FDA's request for NDAs for a dedicated ECP product. ECPs were first used for rape victims, but today they are more widely used by women for any type of situation where unprotected sex occurred and there is the risk of an unintended [pregnancy](#) ^[5].

The creation of this technology was facilitated by the existence of hormonal [birth control](#) ^[12] pills and synthetic [hormones](#) ^[20]. The development of the technology was motivated by population control and [family planning](#) ^[21] concerns, as well as the desire to ensure [reproductive rights](#) ^[7]. The FDA's 1997 request for NDAs was in response to the Center for Reproductive Law and Policy's 1994 request to the FDA that the packaging of certain oral contraceptives contain directions on how many pills to take for use as emergency [contraception](#) ^[22]. They denied this request, but instead put out the 1997 request for NDAs for a dedicated EC product, citing Dr. Yuzpe's studies and the history of off-label use as proof of the safety and efficacy of such a technology. On 24 August 2006, Plan B was approved for over-the-counter (OTC) sales to individuals eighteen years and older. This was after a 2003 application for OTC status for Plan B submitted by the WCC was rejected and the application was resubmitted in 2004 with the provision that it be sold OTC to individuals sixteen years and older.

This technology is important to the embryo project because it is a method that expands women's ability to control their fertility. Its mechanism, specifically the evidence that it works

by preventing [implantation](#) ^[14] of a fertilized [egg](#) ^[23], has provoked a spectrum of reactions. Much of the opposition to Plan B stems from the belief that life begins at [fertilization](#) ^[24] and that the [zygote](#) ^[8] has moral status. One manifestation of this controversy is the creation of conscience clauses or claims that allow a pharmacist to refuse to dispense Plan B (as well as other drugs) on moral grounds. Access to the drug has been framed as a moral and political concern. For example, when Wal-Mart first refused to sell Plan B, they explained that there was low demand for the drug, but others questioned the personal politics of individuals within the corporation. Later in May 2006, however, the corporation decided to begin selling the drug because of individual state mandates and because they were the only major chain not selling it. Ever since Plan B became an OTC emergency contraceptive, most pharmacies have begun distributing the product.