

Emergency contraception: The right to full disclosure

Emergency contraception (EC) is a method of reducing the chance of pregnancy after unprotected intercourse. In the United States, two hormonal products are approved by the Food and Drug Administration (FDA) for this indication: (1) levonorgestrel (Plan B, Barr Pharmaceuticals) and (2) levonorgestrel plus ethinyl estradiol (Preven, Gynetics, Inc.). Earlier this year, FDA rejected a proposal to make levonorgestrel available without a prescription, reportedly because of concerns about the drug's safety in teenage girls. Nonprescription sales of levonorgestrel were endorsed previously by two FDA expert advisory panels and several prominent medical organizations, including the American Medical Association. The progestin levonorgestrel is available without a prescription in more than 30 countries and in a limited number of pharmacies in Alaska, California, Hawaii, New Mexico, and Washington. According to the drug's distributor, prescription sales for levonorgestrel have doubled within the past year, with an estimated 10,000 prescriptions written monthly.¹

With the potential for widespread use should nonprescription status be granted, questions have been raised regarding the safety and ethical implications of EC. Concerns regarding safety are currently being evaluated by FDA and the medical community at large. The ethical implications surrounding levonorgestrel's pharmacodynamic effects also should be addressed in a balanced, nonjudgmental manner. To achieve this objective, health care providers who prescribe, dispense, or administer EC must understand all of the proposed mechanisms of action and have an obligation to convey this information to patients in a clear manner that acknowledges and respects each individual's beliefs. Only then can prospective recipients of the drug—clients, patients, and research subjects—make an informed choice regarding EC use.

While the precise mechanism of action remains unclear, animal and human studies suggest that levonorgestrel may affect ovulation by interfering with signaling from the pituitary gland, thereby preventing or delaying the luteinizing

hormone surge.² Other evidence suggests that levonorgestrel may interfere with tubal transport of sperm or ova and alter the endometrium.³ According to its labeling, levonorgestrel likely acts by preventing ovulation or fertilization or by inhibiting implantation.⁴ Levonorgestrel will not terminate a pregnancy after implantation of the embryo. Since some medical authorities believe that pregnancy begins when the fertilized egg is implanted in a woman's uterine wall (typically within five to seven days after conception), advocates of EC assert that levonorgestrel acts before the onset of pregnancy. However, others believe that pregnancy, as defined in some medical dictionaries, begins at conception.^{5,6} Because prevention of implantation is a possible mechanism of action of levonorgestrel, some believe that a contraceptive method that may prevent implantation of a fertilized egg could lead to the loss of human life.

Our primary concern regarding EC is that many patients are not informed that Plan B may prevent the implantation of a fertilized egg, which, for some, amounts to the termination of a pregnancy. While we acknowledge that this information is controversial and has broad political, social, and cultural ramifications, patients have the right to full disclosure regarding this aspect of the drug's pharmacologic action, as described in the FDA-approved labeling. Without such information, some individuals would be effectively denied the ability to make an informed decision.

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