

## **Getting From A to Z, With Plan B in the Middle of it All**

Government approval of a drug typically rests upon overwhelming scientific evidence and positive public demand. However, government action via the FDA has swaggered along when faced with the debate surrounding making the “morning after” pill available to female patients. The “morning after pill”, also known as Plan B emergency contraception, has been riddled amongst a political turmoil despite scientific evidence of its efficacy. After years of debate and turmoil, the FDA announced on August 24 that Barr Pharmaceutical’s Plan B would be allowed an over-the-counter status. However, the FDA did implement some restrictions to this policy -- the drug can only be purchased by individuals over 18 years of age, and private insurance policies as well as Medicaid are not obligated to cover the drug. While proponents praise the increased availability of the drug, the discussion involving emergency contraception is far from reaching its conclusion.

The Centers for Disease Control and Prevention has listed family planning as one of the ten most important public health developments of the 20<sup>th</sup> century in the United States<sup>1</sup>. The importance of family planning and awareness stems from the fact that approximately 3.14 million unplanned pregnancies occur in the United States each year, 42 percent (1.32 million) of those ending up in abortion<sup>2</sup>. Some health professionals and policy makers believe that an increased awareness of emergency contraception can help decrease the number of unplanned pregnancies and abortions that occur each year.

Plan B, a form of emergency contraception, prevents pregnancy through the use of the hormone levonorgestrel. The drug is available in the form of two pills (0.75 mg of levonorgestrel in each) that females can take by mouth after unprotected intercourse, or after another form of contraception fails during that episode of intercourse, such as a broken condom. Levonorgestrel is a synthetic hormone which contains the active ingredient progestin, and is also found in birth control pills (OCP’s). Plan B contains higher levels of this hormone than in daily OCP’s. Levonorgestrel works by preventing the ovary’s release of an egg, by inhibiting fertilization of an egg, or by preventing implantation (attachment) of the egg to the lining of the uterus, thus reducing the risk of a woman becoming pregnant after having unprotected sex<sup>3</sup>. Much controversy arose when Plan B was initially introduced to the public due to concerns of the drug being an abortifacient (something that facilitates aborting an already fertilized egg), but research has

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<sup>1</sup> CDC. “CDC Now: Protecting Health for Life.” Centers for Disease Control and Prevention: 2005.

<sup>2</sup> Finer, Lawrence B and Stanley K. Henshaw. “Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001.” Perspectives on Sexual and Reproductive Health 2006; 38(2): 90-96.

<sup>3</sup> FDA. “FDA’s Decision Regarding Plan B: Questions and Answers.” Food and Drug Administration: 2006.

shown that Plan B does not affect a fertilized egg already implanted in the womb<sup>4</sup>.

The FDA's decision for Plan B's over-the-counter status will increase the availability of this form of emergency contraception for a substantial proportion of females in the United States. Supporters feel that the decision represents a positive direction toward the goal of improving access for women to birth control options. However, many feel that a very important group of females has been neglected in this new decision and leaves them at a substantial disadvantage. Data from the National Survey of Family Growth reveals that a teen female having a birth before the age of 20 is 18 percent. Among those teens that do not use any contraception, the risks become substantially higher. Teens report greater numbers of months and/or years of having a baby "too soon." Thirty-five percent of births to teens occurred three or more years too soon, as opposed to only 10 percent among women aged 20-24 and two percent among women aged 24-44<sup>5</sup>. However, in May 2004, the FDA overturned a December 2003 recommendation by two advisory committees established by the FDA to make Plan B available as an over-the-counter drug to all age groups. The FDA did not follow the recommendations commenting that data was not made available regarding the safety of the drug in adolescents. The acting director of the FDA's Center for Drug Evaluation and Research, Dr. Steven Galson, faulted the committees in not providing adequate data to demonstrate exactly how adolescent women would use the drug<sup>3</sup>.

Others believe that the FDA's decision was grounded more in ideology than science. Data on adolescents and use of emergency did in fact exist. In a five-year randomized trial, Gold et al. revealed significant data to support the notion that providing advance emergency contraception to adolescents is not associated with more unprotected intercourse or less condom or hormonal contraception use<sup>6</sup>. Despite a fighting effort to at least include 16 and 17-year olds in the policy, the FDA only approved Plan B OTC status and access for women over the age of 18. Women 18 and older will have to show ID to a pharmacist, who will keep the drugs behind a counter. Younger teens will still need a prescription and the pills will not be sold at outlets that do not have a pharmacist. On the positive side, men can purchase the medication.

Other access problems exist for women under the current policy; 14 states have drafted legislation that would allow pharmacists to decline to dispense emergency contraception, including Plan B. Should pharmacists be legally

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<sup>4</sup> Camp, SL, DS Wilkerson, and TR Raine. "The Benefits and Risks of OTC Availability of Levonorgestrel Emergency Contraception." *Contraception* 2003; 68(5): 309-317.

<sup>5</sup> Abma, JC, GM Martinez, WD Mosher. "Teenagers in the US: Sexual Activity, Contraceptive Use, and Childbearing." *National Center for Health Statistics, Vital Health Stat* 23(24) 2004.

<sup>6</sup> Gold, MA, JE Wolford, KA Smith, and AM Parker. "The Effects of Advance Provision of Emergency Contraception on Adolescent Women's Sexual and Contraceptive Behaviors." *Journal of Pediatric Adolescent Gynecology* 2004; 17(2): 87-96.

obligated to provide emergency contraception to individuals if they are morally opposed to it? If one views Plan B as what it is, contraception, then the answer should be yes, as all pharmacies currently carry other forms of oral contraception. It is women with limited means and limited pharmacy options (i.e. rural or small towns) that will be particularly affected by such policies.

In addition, Medicaid does not cover any OTC drugs, and therefore will not be covering Plan B. To insure access for low-income women, states will have to devise specially designed state-funded programs. To date, California and Minnesota have committed to providing such funds. In general, insurance policies do not cover OTC drugs as well, and with new packaging and distributing costs associated with OTC drugs, Plan B could become a hefty out-of-pocket cost for women. Estimated cost per dose is estimated to range between \$25 and \$40.

The reality of providing timely access to Plan B for women remains a point of contention. For ultimate efficacy, Plan B needs to be taken within 72 hours of unprotected intercourse, and earlier administration ensures even better effectiveness. Therefore, decreasing the difficulty and number of barriers that stand between women seeking emergency contraception and an effective product remains a critical key in the current discussion surrounding Plan B and its future on pharmacy shelves.

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For more information, go to:

<http://www.fda.gov/cder/drug/infopage/planB/planBQandA20060824.htm>

<http://www.backupyourbirthcontrol.org/#>

<http://www.pphouston.org>