ISSUE BRIEF

Plan B: A Grave Threat to Women's Health

On July 31, 2006, the U.S. Food and Drug Administration (FDA) announced that it was working with the manufacturer of the Plan B® "Morning after Pill," Duramed Research, Inc., to resolve the remaining policy issues preventing Plan B from being sold over-the-counter (OTC)—rather than by prescription (Rx). The Family Research Council opposes making Plan B available OTC for the following reasons related to women's health and matters of law:

Plan B Threatens the Health of Women:

- **Birth control pills, which are essentially a lower dose regimen of Plan B, require a prescription.** They are not available OTC. They require an appointment with a licensed clinician to determine contraindications, obtain a prescription, and provide for medical oversight throughout the usage period.

  "Birth control pills are available by prescription only for sound medical reasons: They can cause significant or life-threatening conditions such as blood clots and heart attacks. Birth control pills are contraindicated for women with diabetes, liver problems, heart disease, breast cancer, deep vein thrombosis, and for women who smoke and are over 35. A medical exam is necessary to ensure that none of these contraindications exists. For example, according to the Centers for Disease Control, approximately 1.85 million women of reproductive age (18-44) have diabetes; approximately 500,000 do not know that they have the disease."[1]

  The OTC status would increase access to Plan B to larger populations of women, including women who have not been screened for contraindications.

- **Lack of scientific studies examining risks.** There is a clear lack of scientific studies on the long-term-effects of Plan B with respect to high dosage and repeated use in both women and adolescents. While the patient package directions on Plan B state it is not to be used more than twice a month, the directions and promotions of Plan B state it is also to be used in emergencies.

  These emergencies include unprotected sex and the failure of other birth control devices—factors that may arise more than twice a month.[2]

FAMILY RESEARCH COUNCIL
801 G STREET NW, WASHINGTON, D.C. 20001
202-393-2100 • *fax* 202-393-2134 • (800) 225-4008 *order line*
www.frc.org

- **STD rates have skyrocketed** in countries where Plan B has been deregulated. Since becoming available in the United Kingdom in 2001, Plan B usage among teenage girls has more than doubled. STDs with sharp increases include chlamydia and gonorrhea, with the highest increases in 16 to 19 year olds.[3] Because STD's such as chlamydia can cause infertility in women, the impact that increased access to and usage of Plan B has on STD rates could have a direct causal relationship to increased future infertility rates of U.S. women.

- **Contrary to predictions, abortions have not decreased with Plan B deregulation.** In Scotland, where Plan B has been available for over 15 years, abortion rates showed an increase between 1990 and 1999. In Glasgow, where Plan B prescriptions increased 300 percent from 1992 to 1999, abortions did not decrease. In the United Kingdom, where deregulation to "pharmacy" status took place in 2001, abortions have not decreased.[4] Planned Parenthood clinics in the United States have experienced a simultaneous sharp increase in Plan B prescriptions and abortions performed in centers they operate.

- **Masking of sexual abuse**. The potential for Plan B to be given to women, especially sexually abused women and minors, without their consent or knowledge is a clear and present danger. Interaction with medical professionals is a major detection and prevention mechanism for victims of sexual abuse. The elimination of routine examination of sexually active girls and women could cover up both sexual abuse and exploitation.[5]

- **Link of Plan B to ectopic pregnancy**. Statements from the World Health Organization and leading medical officials taken together provide a warning that increased risk of ectopic pregnancy exists with Plan B usage.[6] Additionally, common physical side-effects a woman experiences following Plan B usage often mimic ectopic pregnancy symptoms, including cramping and severe pain. Consequently, there is valid concern for Plan B usage to actually mask ectopic pregnancy, an acute, life-threatening condition.

- **Violation of Informed Consent.** If the fact that Plan B can act as an abortifacient by one of its three operating mechanisms (by inhibiting implantation of a fertilized egg in a women's uterus) is not clearly communicated to women who use the drug, it is a direct abuse of informed consent.[7] Any efforts to communicate to women that Plan B physiologically acts strictly to *prevent* pregnancy infringes upon individually-held beliefs that pregnancy/life begins at conception. The literacy study results listed below indicating the high percentage of women miscomprehending Plan B's OTC label amplify concerns about possible violation of informed consent, particularly in low literacy-level women who believe life begins at conception. A clear example of this violation regarding human subjects has been in studies marketing Plan B as "emergency contraception" or "EC" to populations of low–income Hispanic women.[8]

- **Patient Literacy.** The fundamental question FDA must address when assessing a drug company's application to sell its product OTC is this: Can this drug be safely and effectively self-administered without the supervision of a physician? We believe that Plan B will not be safely self-administered.

  - Duramed's comprehension tests of its proposed Plan B OTC label found that only 75 percent of respondents answered that Plan B should not be taken in the presence of unexplained vaginal bleeding. Among the low-level literacy group that figure declined to 69 percent.

  - Many survey respondents did not understand that Plan B is not a substitute for oral contraceptives. In the same label study, only 67 percent of all respondents answered correctly that Plan B is designed to serve as a backup for regular contraception methods—not as a replacement for them. Among those of low-literacy this figure dropped to 46 percent.

    The deregulation of Plan B is without doubt, a women's health disaster waiting to happen.

    In addition, the deregulation of Plan B raises a number of Legal Concerns:

  - **OTC Plan B is legally unprecedented.** There is no precedent for the granting of dual status approval for the same drug to different age groups. The FDA does not have the legal authority to grant simultaneous OTC and Rx for a drug. Also, FDA does not have the enforcement authority to ensure that store clerks are checking age ID for dual status drugs.

    Moira Gaul and Chris Gacek are policy analysts in the Center for Marriage and Family Studies at the Family Research Council.

ENDNOTES

[1] Written Testimony of Wendy Wright, Concerned Women for America, Docket No. 2001P-0075, Proposal to Switch Status of Emergency Contraceptives from Rx to OTC, December 16, 2003, at 2.

[2] Compiled testimony of Wendy Wright, Carole Denner, and Jill Stanek, "The Morning-After Pill: An Ill Wind This Way Blows," *Center for Tomorrow Journal* (Sterling, Va.: Spring 2004): 1-18, 6-10 ("Compiled Testimony") (to: <http://www.care-net.org/news/pr/map.pdf>).

[3] Compiled Testimony at 11.

[4] Boggess, J.E. How Can Pharmacies Improve Access to Emergency Contraception? *Perspectives on Sexual and Reproductive Health.* 2002;34(3):162-165; Compiled Testimony at 11.

[5] Compiled Testimony at 16-17.

[6] Compiled Testimony at 17-18.

[7] Compiled Testimony at 6, 10.

[8] Many Women at High Risk for Unintended Pregnancy are Unaware of Emergency Contraception or How to Use It. *Family Planning Perspectives.* 2001;33(1):42-43.