



# Emergency Contraception: Plan B

**Judith A. Johnson**

Specialist in Biomedical Policy

**Vanessa K. Burrows**

Legislative Attorney

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## Summary

On August 24, 2006, the Food and Drug Administration (FDA) announced the approval of an application to switch Plan B, an emergency contraceptive, from a prescription-only drug to an over-the-counter (OTC) drug for women 18 years of age and older. Plan B will only be sold in pharmacies or healthcare clinics. It will continue to be dispensed as a prescription drug for women 17 years old and younger. Plan B is a brand of post-coital contraceptive that is administered within a few hours or days of unprotected intercourse. Emergency contraception prevents pregnancy; it does not disrupt an established pregnancy.

Approval of the switch to OTC status for Plan B has been controversial. Some Members of Congress urged the FDA to deny OTC status for Plan B. Individuals who criticize the three-year delay in deciding to switch to OTC believe that Bush Administration policy and FDA actions were based on political and ideological considerations rather than on sound science. Conservative religious and pro-life groups believe Plan B may increase unsafe sexual activity and should be used only under the supervision of a healthcare professional and, therefore, should not be available OTC. Their major concern with Plan B, however, is that it might prevent the implantation of an embryo in the uterus, which to pro-life groups constitutes abortion. However, the medical community does not consider prevention of implantation to be an abortion, and FDA does not classify Plan B as an abortion drug.

Emergency contraceptives are currently available without a prescription in more than 40 countries. According to Barr Pharmaceuticals, sales of Plan B in the United States have doubled since August 2006, “rising from about \$40 million a year to what will probably be close to \$80 million for 2007.” Women’s health advocates claim that OTC status will improve access to the drug, thereby reducing the number of unintended pregnancies and reducing the number of abortions. However, a medical literature review, published in April 2007, found that “advance provision of emergency contraception did not reduce pregnancy rates when compared to conventional provision.... The interventions tested thus far have not reduced overall pregnancy rates in the populations studied.”

The Office of Violence Against Women within the Department of Justice (DOJ) has developed guidelines for the treatment of sexual assault victims. The guidelines, released in September 2004, have been criticized by numerous organizations because they do not mention offering emergency contraception to female rape victims. In January 2005, a letter signed by 97 Members of Congress was sent to the Director of the Office on Violence Against Women expressing concern over the failure to mention emergency contraception and urging that the guidelines be changed to include such information.

Legislation introduced in the 110<sup>th</sup> Congress (S. 21/H.R. 819, H.R. 464, S. 1240, H.R. 2064/S. 1800, H.R. 2503, H.R. 2596/S. 1555) aims to ensure that Plan B is made available to women in general and sexual assault victims in particular or encourage education and provide information about Plan B. This report will be updated as events warrant.

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## Introduction

On August 24, 2006, the Food and Drug Administration (FDA) announced the approval of an application to switch Plan B, an emergency contraceptive, from a prescription-only drug to an over-the-counter (OTC) drug for women 18 years of age and older. Plan B will only be sold OTC in pharmacies or healthcare clinics. It will continue to be dispensed as a prescription drug for women 17 years old and younger. Both men and women will be able to purchase Plan B, but all individuals will need to show the pharmacist identification for proof of age before purchasing the OTC version.<sup>1</sup> Anonymous shoppers will be used to test compliance with the age restriction. A booklet will be distributed with Plan B that explains proper use of the drug. The manufacturer, Barr Pharmaceuticals, began shipping the OTC version of the drug to U.S. pharmacies early in November 2006.<sup>2</sup>

Approval of the switch to OTC for Plan B has been controversial. Critics believe that initial policy decisions made by the Bush Administration regarding Plan B were based on political and ideological considerations rather than on sound science.<sup>3</sup> Conservative religious and pro-life groups believe that readily available Plan B may increase the occurrence of unsafe sexual activity and that such a drug should be used only under the supervision of a healthcare professional. Their primary concern with Plan B, however, is that it might prevent the implantation of the embryo in the uterus, which, for those who believe human life begins at conception, would constitute an abortion. However, the medical community does not consider prevention of implantation to be an abortion, and FDA does not classify Plan B as an abortion drug. Although the precise mechanism of action remains undetermined, scientific evidence suggests that prevention of ovulation or fertilization is the most likely mode of action for Plan B, rather than prevention of implantation of a developing embryo.<sup>4</sup>

This report discusses the FDA approval of Plan B as a prescription drug, as well as the more recent and controversial FDA approval of Plan B as an OTC drug. Legal issues regarding the recent FDA decision are also discussed as well as various state policies that affect access to emergency contraceptives. In addition, the report discusses the Department of Justice guidelines for the treatment of sexual assault victims, which have been criticized by numerous organizations because they do not mention offering emergency contraception to female rape victims. The DOJ guidelines were the focus of legislation introduced in the 109<sup>th</sup> Congress. Lastly, this report discusses the likely impact of the FDA Plan B OTC decision.

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<sup>1</sup> See the FDA approved label for Plan B (levonorgestrel) at <http://www.fda.gov/cder/foi/label/2006/021045s011bl.pdf>, and, Joyce Howard Price, "Plan B Allowed Over The Counter," *The Washington Times*, August 25, 2006.

<sup>2</sup> Stacy Forster, "Now, consumers weigh in on Plan B debate: Over-the-counter sales of contraceptive begin," *The Milwaukee Journal Sentinel*, November 20, 2006, p. A1.

<sup>3</sup> Jeffrey M. Drazen et al., "The FDA, Politics, and Plan B," *The New England Journal of Medicine*, v. 350, April 8, 2004, pp. 1561-1562.

<sup>4</sup> Horacio B. Croxatto et al., "Mechanisms of Action of Emergency Contraception," *Steroids*, v. 68, 2003, pp. 1095-1098.

## Background Information on Emergency Contraception

Emergency contraception is a therapy that may prevent pregnancy for women who have had unprotected sexual intercourse. There are two methods of emergency contraceptive therapy: insertion of an intrauterine device, or IUD, within five days of intercourse; or, ingestion of a pill containing the hormones commonly found in the contraceptive pill. Although hormonal emergency contraception is often referred to as the “morning-after pill,” it can be given up to 72 hours after unprotected intercourse and can involve taking more than one pill. Reasons for using emergency contraception include problems with a contraceptive (condom breakage, missed pill), sexual assault, or exposure to an agent which may cause a birth defect (e.g., live vaccine, cytotoxic drug, or radiation).

The current approach to emergency conception began with the recognition in the 1920s that estrogen prevented pregnancy in mammals. In the mid-1960s, a Dutch physician gave high-dose estrogen to a 13-year-old rape victim in order to prevent pregnancy. During the 1960s and 1970s high-dose estrogen became the standard emergency contraceptive treatment. In the early 1970s, Canadian physician A. Albert Yuzpe began studying emergency contraception and published his first study in 1974. The Yuzpe method used conventional birth control pills, a combination of estrogen and progestin, taken in two doses 12 hours apart.<sup>5</sup> In 1984, the United Kingdom became the first country to approve such a combination pill regimen as an emergency contraceptive.

In January 2001, the United Kingdom began allowing pharmacies to dispense emergency contraception without a prescription.<sup>6</sup> In April 2005, an emergency contraceptive (Plan B, a progestin-only pill) was approved by the Canadian government for use by all women without a prescription.<sup>7</sup> Emergency contraceptive pills are used by women in more than 100 countries; in over 40 countries the pills are sold without prescription either by a pharmacist or OTC (see **Table 1**, below).<sup>8</sup>

**Table 1. Nonprescription Availability of Plan B**

<b>Over-the-counter</b>
India, Netherlands, Norway, Sweden
<b>Directly from a Pharmacist</b>
Aruba, Australia, Belgium, Benin, Burkina Faso, Cameroon, Canada, China, Congo, Denmark, Estonia, Finland, France, French Polynesia, Gabon, Ghana, Greece, Guinea-Conakry, Iceland, Israel, Jamaica, Latvia, Libya, Luxembourg, Mali, Mauritania, Mauritius, New Zealand, Niger, Portugal, Senegal, Slovakia, South Africa, Sri Lanka, Switzerland, Togo, Tunisia, United Kingdom

<sup>5</sup> Progestin is a synthetic form of the hormone progesterone.

<sup>6</sup> Haroon Ashraf and Michael McCarthy, “UK Improves Access to Morning After Pill,” *The Lancet*, December 16, 2000, p. 2071.

<sup>7</sup> “Health Canada Gives Canadian Women a Plan B,” *Canada NewsWire*, April 20, 2005, p. 1.

<sup>8</sup> NOT-2-LATE.com The Emergency Contraception Website <http://ec.princeton.edu/questions/dedicated.html>.

## FDA Approval of Preven and Plan B

Following the 1974 publication by Yuzpe, physicians often instructed patients to take multiple pills from a standard one-cycle oral contraceptive package for emergency contraception; this is referred to as an “off-label” use of the drug.<sup>9</sup> On February 25, 1997, a notice in the *Federal Register* stated that the Commissioner of FDA had concluded that certain oral contraceptives are safe and effective for use as emergency contraception and asked manufacturers to submit a new drug application for this use. In 1998, FDA approved Preven for use as an emergency contraceptive available by prescription. Preven utilized the Yuzpe method; two pills, containing estrogen and progestin, taken 12 hours apart.

A 1993 study conducted on about 800 women in Hong Kong found that use of progestin alone was somewhat more effective for emergency contraception than the Yuzpe method and had fewer side effects.<sup>10</sup> In 1998, the World Health Organization (WHO) followed up with a larger international trial using almost 2,000 women comparing the Yuzpe method and a progestin-only pill.<sup>11</sup> The WHO trial found that progestin alone was significantly more effective than the Yuzpe method at preventing pregnancy, and caused fewer side effects. **Most importantly, for either method, the WHO trial found that the earlier the pill is taken, the better it works.**

In the WHO trial, the progestin-alone regimen reduced the risk of pregnancy by 85% when taken within 72 hours of intercourse. Progestin prevented 95% of expected pregnancies when taken within 24 hours, 85% when taken between 25 and 48 hours, and 58% when taken between 49 and 72 hours. In contrast, Yuzpe reduced the risk of pregnancy by 57% when taken within 72 hours. Yuzpe prevented 77% of expected pregnancies when taken within 24 hours, 36% for 25 to 48 hours, and 31% for 49 to 72 hours. WHO also found that the Yuzpe method resulted in significantly more side effects than progestin alone. The incidence of nausea was 50% with Yuzpe and 23% with progestin. Vomiting with Yuzpe was 3 times higher than with progestin (19% vs. 6%), which is significant as women who vomit after taking the first combination pill may need to take an extra dose.<sup>12</sup>

On July 28, 1999, FDA approved Plan B, a progestin-only emergency contraceptive, for use by prescription. Plan B consists of two pills each containing 0.75 mg of levonorgestrel (a progestin).<sup>13</sup> One pill is taken as soon as possible after unprotected intercourse and the second is

<sup>9</sup> Off-label use is defined as “use for an indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling.” Found at <http://www.fda.gov/cder/present/diamontreal/regappr/sld003.htm>. FDA does not regulate the practice of medicine; section 906 [21 U.S.C. 396] of the Food, Drug & Cosmetic Act states “Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”

<sup>10</sup> P.C. Ho and M.S.W. Kwan, “A prospective randomized comparison of levonorgestrel with the Yuzpe regimen in post-coital contraception,” *Human Reproduction*, v. 8, 1993, pp. 389-392.

<sup>11</sup> Task Force on Postovulatory Methods of Fertility Regulation, “Randomized Controlled Trial of Levenorgestrel Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception,” *Lancet*, v. 352, August 8, 1998, pp. 428-433.

<sup>12</sup> The manufacturer of Preven elected to discontinue making the product in 2004, probably because of the difference in side effects. Planned Parenthood, A Brief History of Emergency Hormonal Contraception, September 2005 <http://www.plannedparenthood.org>.

<sup>13</sup> Unlike the Yuzpe method, progestin-only oral contraceptive preparations do not lend themselves to use as emergency contraception because of the large number of pills that need to be taken. For example, the “off-label” equivalent (continued...)

taken 12 hours later.<sup>14</sup> The FDA-approved labeling for Plan B states that it is 89% effective if taken within three days (72 hours) after unprotected sex. In other words, 7 of every 8 women who would have become pregnant will not become pregnant. As mentioned earlier, Plan B is even more effective (95%) if taken within 24 hours of unprotected sex.

## **Mechanism of Action**

In humans, the fertile days when sexual intercourse can result in pregnancy include the five days before ovulation (release of the egg from the ovary) and the day of ovulation. Although the precise mechanism of action by which Plan B prevents pregnancy remains undetermined, scientific evidence suggests that prevention of ovulation or fertilization is the most likely mode of action for Plan B, rather than prevention of implantation.<sup>15</sup> The active ingredient in Plan B, levonorgestrel, has been used in birth control pills for more than 35 years. Emergency contraception is not as effective as the regular use of oral contraceptives. However, the higher dose of levonorgestrel in Plan B works like a birth control pill to prevent pregnancy, most probably by stopping ovulation. Several studies indicate that hormonal emergency contraception interferes with the events in the ovary that lead up to release of the egg.<sup>16</sup>

Plan B may also interfere with fertilization by altering the transport of sperm and/or egg within the female reproductive system. In one study, administration of levonorgestrel after sexual intercourse reduced the number of sperm within the uterus, increased the pH of the uterine fluid (which immobilized sperm), and increased the viscosity of cervical mucus (which impeded entry of sperm into the uterus).<sup>17</sup>

It is possible that Plan B may inhibit implantation of the fertilized egg within the uterus by altering the endometrium (the uterine lining). Three studies of hormonal emergency contraception in human subjects found alterations in the endometrium, but whether such changes had an impact on implantation was “open to question.”<sup>18</sup> Four other studies found either negligible or no alterations in the endometrium. However, in the case of levonorgestrel, “publications in refereed journals do not support the hypothesis that it alters endometrial receptivity or impedes implantation.”<sup>19</sup> In addition, studies in the rat and monkey indicate that levonorgestrel does not disrupt post-fertilization events such as implantation.<sup>20</sup>

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(...continued)

treatment is 40 tablets of a progestin-only oral contraceptive (Ovrette) taken within 120 hours after unprotected sex. NOT-2-LATE.com, The Emergency Contraception Website <http://ec.princeton.edu/worldwide/default.asp>.

<sup>14</sup> A study conducted by WHO found that taking two 0.75 mg levonorgestrel pills together (one dose of 1.5 mg) was just as effective. Helena von Hertzen et al., “Low Dose Mifepristone and Two Regimens of Levonorgestrel for Emergency Contraception: a WHO Multicentre Randomised Trial,” *Lancet*, v. 360, December 7, 2002, pp. 1803-1810.

<sup>15</sup> Horacio B. Croxatto et al., “Mechanisms of Action of Emergency Contraception,” *Steroids*, v. 68, 2003, pp. 1095-1098.

<sup>16</sup> Ibid.

<sup>17</sup> E. Kessuru et al., “The Hormonal and Peripheral Effects of dl-Norgestrel in Postcoital Contraception,” *Contraception*, v. 10, 1974, pp. 411-424.

<sup>18</sup> Horacio B. Croxatto et al., “Mechanisms of Action of Emergency Contraception,” *Steroids*, v. 68, 2003, pp. 1095-1098.

<sup>19</sup> Ibid.

<sup>20</sup> Ibid.

Plan B is not effective after the embryo has implanted in the uterus and therefore cannot interfere with an established pregnancy, which is defined as an embryo implanted in a uterus. Plan B is used before a pregnancy can be diagnosed. Plan B does not use the same active ingredient as Mifeprex (also known as the abortion pill, RU-486, or mifepristone). Mifeprex (in combination with misoprostol) is used after a positive pregnancy test to terminate an early pregnancy (up through seven weeks).<sup>21</sup>

## **Contraindications and Adverse Reactions**

The fact that there are relatively few side effects for Plan B was a major factor in the approval of OTC status for this drug. The FDA-approved OTC labeling lists known pregnancy and hypersensitivity to any component of the product as contraindications. For Preven or the Yuzpe regimen, the FDA, WHO, and the American College of Obstetricians and Gynecologists (ACOG) list known pregnancy as the only contraindication. (Pregnancy is listed as a contraindication only because these drugs won't work to prevent pregnancy if the patient is already pregnant; no harm will result if a pregnant patient takes either pill.) The FDA, however, lists some relative contraindications based on evidence from combination estrogen-progestin oral contraceptives. These include clotting problems, stroke, and migraine, among others, which are related to the presence of estrogen in the combination pill. A 1997 review found that since the Yuzpe regimen was approved in 1984 in the UK, the product was used more than 4 million times; only six serious stroke or blood clot events were reported, and there was no clear-cut relationship between drug administration and any of these events.<sup>22</sup> In contrast, such events are much more likely during pregnancy (60 cases/100,000 women). Without the presence of estrogen, the incidence of such events for use of Plan B should be even lower than the Yuzpe regimen.

Adverse reactions to Plan B listed in the FDA-approved label include nausea (23%), abdominal pain (18%), fatigue (17%), and headache (17%). Less common adverse events listed on the label include menstrual changes, dizziness, breast tenderness, vomiting, and diarrhea. There is no medical evidence that Plan B will harm a developing fetus if taken accidentally while pregnant.<sup>23</sup> Several studies have shown that availability of Plan B does not lead to an increase in unprotected sex.<sup>24</sup>

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<sup>21</sup> CRS Report RL30866, *Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone)*, by (name redacted).

<sup>22</sup> Anna Glasier, "Emergency Postcoital Contraception," *The New England Journal of Medicine*, v. 337, October 9, 1997, pp. 1058-1064.

<sup>23</sup> Comments by Dr. Daniel Davis, Medical Officer, FDA Division of Reproductive and Urologic Drugs, FDA Advisory Committee Meeting on Plan B, December 16, 2003 <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.htm>.

<sup>24</sup> Cynthia C. Harper et al., "Tolerability of Levonorgestrel Emergency Contraception in Adolescents," *American Journal of Obstetrics and Gynecology*, v. 191, 2004, pp. 1158-1163; Tina R. Raine et al., "Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs," *Journal of the American Medical Association*, v. 293, January 5, 2005, pp. 54-62; and, Cynthia Harper et al., "The Effect of Increased Access to Emergency Contraception Among Young Adolescents," *Obstetrics and Gynecology*, v. 106, September 2005, pp. 483-491.

## FDA Approval of Over-the-Counter Status for Plan B

In April 2003, Women's Capital Corporation (WCC) submitted an application to the FDA requesting that Plan B be switched from prescription to OTC.<sup>25</sup> Requiring a prescription for emergency contraception may create barriers to access for many women. The woman must: (1) identify a physician who will prescribe Plan B; (2) obtain a prescription via a telephone call or a physician visit and pay the financial cost of the visit; and, (3) find a pharmacy that stocks the product and employs a pharmacist who will dispense the product. Because the effective use of Plan B is time dependent (the earlier it is used, the more effective it is), a switch from "prescription only" to "over-the-counter" (OTC) would likely benefit women who may need to use this product.

FDA formalized the process of switching a prescription drug to OTC status in 1975 and has approved over 90 such applications. The requirements for making the switch from prescription-only to OTC include making sure the drug is safe for self-medication and has a low toxicity or other potentiality for harmful effect.<sup>26</sup> The patient must be able to recognize the condition and require minimal health care provider intervention in order to use the drug correctly. The OTC applications are reviewed by FDA's Center for Drug Evaluation and Research (CDER). Because it is considered to be a "first in class" drug, the Plan B application was reviewed by two (rather than one) of the six offices within CDER, one office with expertise in reproductive health and a second office that reviews all OTC switch applications.

CDER also requested a joint meeting of two advisory committees of outside experts in order to obtain scientific advice on the Plan B application. The two committees, the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs, met in December 2003.<sup>27</sup> After reviewing over 15,000 pages of data and 40 scientific studies, the committees voted unanimously that Plan B is safe for use in the nonprescription setting, and voted 23 to 4 that the Plan B switch to OTC status should be approved.<sup>28</sup>

In May 2004 the FDA rejected the advice of its scientific committee and issued a "not-approvable" letter for the Plan B switch to OTC. The FDA cited "inadequate sampling" of women

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<sup>25</sup> WCC submitted a supplemental new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plan B. In February 2004, WCC sold the rights to market Plan B to Barr Pharmaceuticals. Barr had begun acting as the agent for WCC regarding Plan B in October 2003. [GAO Report, November 2005.] Duramed Research, Inc., the current sponsor of Plan B, is a subsidiary of Barr.

<sup>26</sup> See 21 C.F.R. 310.200(b) (2005).

<sup>27</sup> A transcript of the December 16, 2003, meeting can be found at <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.htm>.

<sup>28</sup> The FDA advisory committee members voted on six questions; actual vote count is in brackets. **Question 1:** Does the actual use study demonstrate that consumers used the product as recommended in the proposed labeling? [27 yes, one no] **Question 2:** Are the actual use study data generalizable to the overall population of potential non-Rx users of Plan B? [27 yes, one no] **Question 3:** Based on the actual use study and literature review, is there evidence that non-Rx availability of Plan B leads to substitution of emergency contraceptive for the regular use of other methods of contraception? [zero yes, 28 no] **Question 4:** Do the data demonstrate that Plan B is safe for use in the nonprescription setting? [28 yes, zero no] **Question 5:** Are the plans for introduction of Plan B into the non-Rx setting adequate with respect to consumer access and safe use? [22 yes, five no, one abstain] **Question 6:** Should Plan B be switched from prescription to non-prescription status? [27 votes: 23 yes, four no].

under 16 years of age as the reason for the rejection and concerns about use of the drug without supervision by a physician or other health care provider. However, studies published in 2004 and 2005 do not support an association between wider availability of emergency contraception and an increase in unsafe sexual behavior among teenagers.<sup>29</sup> Counseling against unsafe behavior in this age group is presumably the reason why FDA believed the supervision of a physician was required.

Barr Labs reapplied in July 2004, requesting that Plan B be available over the counter only to women 17 years and older. The FDA did not issue a decision by its regulatory deadline of January 2005. At his confirmation hearing in March 2005, FDA Commissioner Lester M. Crawford indicated that “the science part is generally done” for the Plan B approval process, and “we’re just now down to what the label will look like.”<sup>30</sup>

FDA announced on August 26, 2005, that an immediate decision on the OTC switch could not be determined. FDA Commissioner Lester Crawford cited “novel regulatory issues,” “profound” policy questions, and specific concerns over how the exact same formulation of the drug could be available OTC for an older group of women while remaining prescription only for the younger group. A 60-day “public comment” period was opened to help decide these issues. This announcement led to the resignation on August 31 of the director of the FDA’s Office of Women’s Health, Susan Wood, in protest of the agency’s action. FDA Commissioner Crawford resigned abruptly on September 23, 2005, reportedly due to financial improprieties unrelated to the ongoing controversy over Plan B.

When the comment period ended on November 1, 2005, FDA had received approximately 47,000 comments.<sup>31</sup> On that same day Senators Hillary Clinton and Patty Murray delivered a 10,000-name petition urging the agency to “expeditiously make a decision on the application for OTC status for Plan B based strictly on scientific evidence.”<sup>32</sup>

Members of Congress asked the Government Accountability Office (GAO) to investigate if there was political interference in the FDA decision process. The GAO report, released in November 2005, stated that the process was “unusual” and that the decision may have been made months before the scientific reviews were completed. It noted that it was “not typical of the other 67 proposed prescription-to-OTC switch decisions made from 1994 through 2004” for two reasons. First, it was the only decision that was not approved after the members of the advisory committees voted to approve the application. Second, the GAO reported that three high-level FDA officials had declined to sign the letter that refused approval. “This action removed decision-making authority from the directors of the reviewing offices who would normally make

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<sup>29</sup> Melanie A. Gold et al., “The Effects of Advance Provision of Emergency Contraception on Adolescent Women’s Sexual and Contraceptive Behaviors,” *Journal of Pediatric and Adolescent Gynecology*, v. 17, April 2004, pp. 87-96; and, Cynthia Harper et al., “The Effect of Increased Access to Emergency Contraception Among Young Adolescents,” *Obstetrics and Gynecology*, v. 106, September 2005, pp. 483-491.

<sup>30</sup> U.S. Congress, Senate Committee on Health, Education, Labor and Pensions, Nomination of Lester M. Crawford, Hearing, 109<sup>th</sup> Congress, 1<sup>st</sup> sess., March 17, 2005, p. 16.

<sup>31</sup> ICF International, Comment Summary of FDA’s Advanced Notice of a Proposed Rulemaking on September 1, 2005, Drug Approvals: Circumstances under which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-counter Drug Product, May 19, 2006. Document found at <http://www.fda.gov/oc/planb/summary051906.html>.

<sup>32</sup> Petition found at <http://clinton.senate.gov/news/statements/details.cfm?id=248085> and <http://murray.senate.gov/news.cfm?id=248094>.

the decision,” stated the GAO. The GAO urged Health and Human Services Secretary Mike Leavitt to assure that an upcoming decision about the pill’s status “is based on the best available science instead of ideology.”

In July 2006, FDA stated that it had evaluated the public comments and decided that it could proceed without creating a new regulation to allow the drug to be offered without a prescription to adults. Barr resubmitted its OTC application to FDA in mid-August 2006 and FDA approved the switch to OTC on August 24, 2006. The manufacturer agreed to the use of anonymous shoppers to test compliance with the age restriction. Barr also agreed that a booklet will be distributed with the drug that explains proper use of the drug. The age restriction was changed from 17 to 18 because it is the “age of majority” and sales of nicotine replacement treatments (gum and patch) are allowed at 18 years of age.<sup>33</sup> In approving nicotine replacement treatments for OTC sales, FDA also restricted sales to individuals 18 and over.

## Legal Issues<sup>34</sup>

At least three lawsuits have been filed with regard to the FDA’s approval of Plan B, or the approval process itself. In *Tummino v. von Eschenbach*,<sup>35</sup> representatives of several reproductive health organizations filed a complaint against FDA Commissioner Andrew von Eschenbach, on behalf of women seeking emergency contraception. The suit was filed on January 21, 2005, over a year and a half before the FDA announced its approval of the OTC switch for Plan B for women 18 and older.<sup>36</sup> The case has yet to go to trial. In light of the FDA’s bifurcated approval, the plaintiffs amended their filing and asked the court to require the FDA to approve Plan B for all ages, remove the agency’s requirement that pharmacists keep Plan B behind the counter, and allow all businesses to sell Plan B.<sup>37</sup>

The plaintiffs, some as young as 13, argue that the FDA did not follow proper agency procedures when it mandated age and point-of-sale restrictions for Plan B.<sup>38</sup> Because the drug is used only by women, they contend that the FDA engaged in sex discrimination in violation of the Fifth Amendment right to Equal Protection. The plaintiffs also assert that the agency violated their Fifth Amendment right to privacy “without serving any compelling, significant, or even legitimate government interest” by restricting access to certain ages, the location of the drug

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<sup>33</sup> Memorandum, Andrew von Eschenbach, FDA Acting Commissioner, August 23, 2006 <http://www.fda.gov/cder/drug/infopage/planB/avememo.pdf>.

<sup>34</sup> This section was written by (name redacted), American Law Division, CRS.

<sup>35</sup> No. 05-366 (E.D.N.Y. filed January 21, 2005). Lester M. Crawford, former Acting Commissioner of the FDA, was the original named defendant.

<sup>36</sup> The State of Wisconsin filed a motion on March 20, 2006 seeking to be named as an additional plaintiff. The state cited its interests in pregnant teenagers and adolescent mothers, in current and potential Medicaid beneficiaries, in ensuring all children born in the state are wanted children, and in reducing the number of abortions and unwanted births. Wisconsin’s motion to intervene was denied.

<sup>37</sup> No. 05-366, pp. 13, 34, 42 (fifth amended complaint filed October 10, 2006). The FDA did not approve Plan B for sale in locations such as supermarkets, gas stations, or convenience stores. *Id.* at 34. Plan B can only be distributed “through licensed drug wholesalers, retail operations with pharmacy services, and clinics with licensed healthcare practitioners.” Press Release, FDA, FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older, Prescription Remains Required for Those 17 and Under (August 24, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html>.

<sup>38</sup> No. 05-366, pp. 35-39 (fifth amended complaint filed October 10, 2006).

behind the counter, and sales in certain businesses.<sup>39</sup> Next, the plaintiffs object to alleged violations of the right to informational privacy that will occur because they must disclose their ages and possibly other information, such as names and addresses, to obtain Plan B from behind the counter. The plaintiffs view this as a “disclosure of information to third parties about [their] personal sexual activity.”<sup>40</sup> Finally, the plaintiffs contend that the agency ignored certain requirements under the Administrative Procedure Act (APA).<sup>41</sup>

With regard to the alleged APA violations, the plaintiffs specifically argue that the agency’s imposition of age and point-of-sale restrictions was arbitrary, capricious, and an abuse of agency discretion. The FDA allegedly required greater information for the approval of Plan B than the agency required for past approvals of OTC medications.<sup>42</sup> Additionally, the plaintiffs argue that the FDA had enough data regarding Plan B’s safety and effectiveness to make the drug available OTC without further restrictions.<sup>43</sup> The plaintiffs also contend that the agency took improper action when determining age restrictions for Plan B, despite recommendations within the agency that the FDA approve Plan B without age limits.<sup>44</sup> According to the lawsuit, the FDA also violated the APA by overstepping its statutory mandate in two ways. First, the FDA’s denial was purportedly influenced by logic other than scientific or medical evidence:

Sworn depositions taken by lawyers from the Center for Reproductive Rights, a legal advocacy organization, show that some of the [FDA]’s staff members were convinced that no amount of scientific evidence would have persuaded the [FDA]’s political appointees to approve the application. Dr. John Jenkins, director of the Office of New Drugs at the agency, said in a deposition that his boss, Dr. Steven Galson, told him “that he felt he didn’t have a choice” but to reject the application.<sup>45</sup>

Second, the plaintiffs assert that “the FDA lack[ed] the statutory authority to restrict the types of businesses that can sell OTC drugs,” and the “authority to control the point of sale of nonprescription drug products.”<sup>46</sup>

In response to the amended complaint, the FDA moved to dismiss the case on the grounds that (1) the court lacks jurisdiction, (2) the plaintiffs do not have standing to bring the case, (3) the complaint’s allegations fail to state a claim for which the court may grant relief, (4) the plaintiffs’ claims are moot, and (5) the court lacks the authority to grant the requested relief.<sup>47</sup>

Furthermore, the FDA acknowledged that it has received at least four citizens petitions on Plan B and denied at least one.<sup>48</sup> The FDA also admitted that, for the ten years prior, the agency either

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<sup>39</sup> *Id.* at 38, 41.

<sup>40</sup> *Id.* at 6, 41-42.

<sup>41</sup> *Id.* at 2; 5 U.S.C. § 706(1) - (2)(a), (c).

<sup>42</sup> No. 05-366, pp. 35-36 (fifth amended complaint filed October 10, 2006).

<sup>43</sup> *Id.* at 40.

<sup>44</sup> *Id.* at 31-33.

<sup>45</sup> Gardiner Harris, “FDA Approves Broader Access to Next-Day Pill,” *New York Times*, August 25, 2006, p. A1.

<sup>46</sup> No. 05-366, pp. 13, 40 (fifth amended complaint filed October 10, 2006).

<sup>47</sup> No. 05-366, p. 33 (answer to fifth amended complaint filed March 5, 2007). The defendant did not have to file an answer to the plaintiffs’ fourth amended complaint because the FDA approved Plan B for individuals 18 and older before the deadline for the defendant’s answer.

<sup>48</sup> *Id.* at p. 11. The FDA allows citizens to petition for a switch of a drug from prescription to OTC status. 21 C.F.R. 310.200(b).

approved applications for OTC status after its advisory committee recommended granting the applicant OTC status, or the agency did not reach a final determination on the application.<sup>49</sup> The FDA said that in those ten years, it requested subsequent information on teen use not only for Plan B, but also for OTC nicotine replacement therapies, and noted that several past supplemental new drug applications included information on teen use of prescription drugs when requesting OTC status.<sup>50</sup> In addition, the FDA specifically denied that it created a behind-the-counter “regime” for Plan B and that the FDA mandated that it be kept behind-the-counter.<sup>51</sup>

In response to the plaintiffs’ suggestions that the FDA’s Plan B review procedures were politicized and unusual, the agency initially claimed that privilege protected it from discussing its deliberative process, including advice, opinions, and ideas received by the agency and presented by those involved in the process.<sup>52</sup> In an amended answer, the FDA later stated that such allegations were irrelevant and immaterial to the complaint’s causes of action, as well as beyond the court’s jurisdiction.<sup>53</sup> Notably, scientific data reviewed by the FDA’s Center for Drug Evaluation and Research determined that Plan B could be safely used by women age 17 and older.<sup>54</sup>

As noted above, the suit was filed before the FDA approved the application to switch Plan B to OTC status for women ages 18 and older, but the plaintiffs are currently pursuing the case with respect to women younger than 18. Most recently, the plaintiffs have asked for summary judgment, a request made because, allegedly, no material issues of fact exist and thus the plaintiffs are entitled to a judgment in their favor.

In *Judicial Watch, Inc. v. FDA*,<sup>55</sup> the conservative non-profit sued the FDA for violating the Freedom of Information Act with regard to the agency’s communications with Members of Congress about Plan B. The relevant provision of that Act requires that the agency, upon receiving a request for records, decide whether it will comply with such request within 20 business days after receiving such request.<sup>56</sup> Judicial Watch had requested records of any and all communications between the FDA and Senators Clinton, Murray, and Enzi and their staff members with regard to Plan B. The FDA filed a motion to dismiss, noting that it had “produced all responsive records,”<sup>57</sup> which the agency argued renders the case moot because “it gives the

<sup>49</sup> See No. 05-366, p. 29 (answer to fifth amended complaint filed March 5, 2007) (referencing a letter from former FDA Commissioner Lester Crawford).

<sup>50</sup> *Id.* at 24. The FDA also noted that the data required for OTC approval depends on the product. *Id.* at 30.

<sup>51</sup> *Id.* at 2, 28. The question as to whether the FDA has created a third class of behind-the-counter drugs—in addition to prescription drugs and OTC drugs—is controversial. See *infra* text accompanying notes 63 to 67; Inside Washington Publishers, *FDA Policy Chief Reignites Debate over Third Drug Class*, FDA Week, May 18, 2007.

<sup>52</sup> No. 05-366, p. 11-12 (answer to third amended complaint filed February 14, 2006). As a preliminary matter, the plaintiffs filed and a magistrate judge granted their motion seeking discovery of documents withheld under the deliberative process privilege. The judge also denied the FDA’s request for a protective order quashing discovery or alternatively “an order prohibiting discovery from the White House,” as he had done in February 2006 with a previous FDA request for a protective order preventing discovery. No. 05-366, pp. 1, 5 (Decision and Order, November 11, 2006). The FDA appealed the magistrate’s decision on December 1, 2006.

<sup>53</sup> No. 05-366, p. 14, 16 (answer to fifth amended complaint filed March 5, 2007).

<sup>54</sup> *Id.* at 18.

<sup>55</sup> No. 07-0561 (D.D.C. filed March 21, 2007) (plaintiff’s amended complaint).

<sup>56</sup> 5 U.S.C. § 552(a)(6)(A)(i).

<sup>57</sup> No. 07-0561, p. 1, 8 (D.D.C. filed July 16, 2007) (memorandum of law in support of defendant’s motion to dismiss or, in the alternative, for summary judgment).

requester the relief sought in the FOIA complaint.”<sup>58</sup> Alternatively, the FDA moved for summary judgment on the issue of the adequacy of the agency’s records of its communications with the Senators and their staff members, asserting that its search was adequate and “reasonable as a matter of law.”<sup>59</sup> These motions are pending before the federal district court for D.C.

In *Association of American Physicians & Surgeons, Inc. v. FDA*,<sup>60</sup> a not-for-profit organization representing physicians in typically small or solo practices and three conservative women’s and reproductive health groups filed suit seeking to overturn the FDA’s approval of Plan B as an OTC drug so that the drug would become available, again, only by prescription. First, the plaintiffs argue that Plan B is unsafe for OTC distribution because the label “does not adequately warn consumers of Plan B’s ineffectiveness for routine contraception” and because information submitted to the FDA in support of the change to an OTC drug did not “establish either Plan B’s safety or effectiveness.”<sup>61</sup> Second, the plaintiffs allege that the FDA lacked the authority to approve a drug both OTC and as a prescription because the Federal Food, Drug, and Cosmetic Act (FFDCA) does not authorize approval or distribution of the same drug for sale both OTC and as a prescription. Third, citing the FDA’s inability to enforce age restrictions and alleged errors in waiving pediatric research requirements, the complaint asserts that the FDA could not lawfully “bifurcate a drug product’s OTC versus Rx status based on the patient’s age,” under the FFDCA.<sup>62</sup> Fourth, the plaintiffs assert that the FDA does not have the power to create a new, third class of drugs, those “that require pharmacists to supplement the labeling or that certain subpopulations might misuse with direct access.”<sup>63</sup> Next, the plaintiffs assert that the FDA did not engage in the necessary rulemaking under the APA when amending its interpretation of a statutory provision to approve Plan B as an OTC drug.<sup>64</sup> In addition, the plaintiffs allege that the FDA did not follow the FFDCA when it removed Plan B from prescription status without a rulemaking.<sup>65</sup> Finally, they argue that the FDA unlawfully approved Plan B as an OTC drug “under improper pressure from Senators Clinton and Murray.”<sup>66</sup> As a result, according to the plaintiffs, the FDA’s approval of Plan B and the agency’s avoidance of the rulemaking process was arbitrary and capricious.

In response, the FDA moved to dismiss the suit on five grounds: (1) the plaintiffs lack standing to challenge the FDA’s approval decision of Plan B’s supplemental new drug application, (2) the court lacks subject matter jurisdiction to review the FDA’s approval of the Plan B supplemental new drug application, (3) the plaintiffs failed to state a claim as far as their allegations that the FDA lacked the authority to approve Plan B both OTC and as a prescription drug and that the FDA did not have the power to create a third class of behind-the-counter drugs, (4) the plaintiffs’ contentions that the FDA violated the APA and the FFDCA by failing to engage in a rulemaking were incorrect as a matter of law, and (5) FDA Commissioner Von Eschenbach was improperly

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<sup>58</sup> *Id.* at 9.

<sup>59</sup> *Id.* at 2, 11-12.

<sup>60</sup> No. 07-668 (D.D.C. filed April 12, 2007).

<sup>61</sup> No. 07-668, p. 25 (D.D.C. filed April 12, 2007) (plaintiffs’ complaint for declaratory and injunctive relief).

<sup>62</sup> *Id.* at 2, 26-28.

<sup>63</sup> *Id.* at 28.

<sup>64</sup> *Id.* at 2-3, 29.

<sup>65</sup> *Id.* at 29-30.

<sup>66</sup> *Id.* at 2, 30-31.

named as a defendant in his individual capacity because the plaintiffs' claims related to official FDA actions.<sup>67</sup> The case has yet to go to trial.

## State Policies<sup>68</sup>

About half the states have adopted policies that affect access to emergency contraceptives. Several states have passed pharmacy access laws that allow women to obtain emergency contraception directly from a pharmacy without first going to a doctor or clinic.<sup>69</sup> With the FDA's decision, these measures will now apply only to minors.<sup>70</sup> Plan B is available from pharmacists, without a physician's prescription, under certain conditions in the following nine states: Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington.<sup>71</sup> In these states, pharmacists are allowed to sell emergency contraception to women who ask for the product. After speaking with the woman, the pharmacist determines if emergency contraception is appropriate. In order to participate, the pharmacy and the pharmacist must fill out application forms and undergo training. Access is still limited in these states by the number of pharmacies that participate.

Several states have laws that specifically pertain to emergency room practices with respect to emergency contraceptives. For example, in seven states—California, Massachusetts, New Jersey, New Mexico, New York, South Carolina, and Washington—hospital emergency rooms must dispense emergency contraceptives upon request to sexual assault victims; similar policies in Ohio and Oregon do not have an enforcement mechanism. In May 2007, Governor Jodi Rell signed into law a measure that requires all hospitals in Connecticut, including Catholic hospitals, to provide emergency contraception to rape victims; the law takes effect on October 1 2007.<sup>72</sup> Emergency rooms must provide information about emergency contraceptives in 10 states: Arkansas, California, Colorado, Illinois, Massachusetts, New Jersey, New Mexico, New York, Texas, and Washington. A similar policy in Ohio does not have an enforcement mechanism.

Several states have enacted laws regarding pharmacists who refuse to dispense birth control and emergency contraception.<sup>73</sup> These laws vary widely from state to state. Four states (Arkansas, Georgia, Mississippi, and South Dakota) explicitly allow pharmacists to refuse to dispense contraceptives, including emergency contraceptives. In five states (Colorado, Florida, Illinois,

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<sup>67</sup> No. 07-668, p. 10, 25, 31, 38, 41 (defendant's motion to dismiss filed June 29, 2007).

<sup>68</sup> Except for the Medicaid coverage discussion at the end of this section, the information contained in this section was largely found in the following publication: Guttmacher Institute, "States Policies in Brief—Emergency Contraception," July 1, 2007 [http://www.guttmacher.org/statecenter/spibs/spib\\_EC.pdf](http://www.guttmacher.org/statecenter/spibs/spib_EC.pdf).

<sup>69</sup> Although FDA has the authority to determine the status for medications (OTC or prescription), states have the authority to determine who may prescribe prescription medications. Pharmacy access laws reflect the current prescription status for Plan B, as determined by the FDA <http://www.pharmacyaccess.org/pdfs/PharmacistFAQsOTC.pdf>.

<sup>70</sup> According to Steven Galson, Director of the FDA Center for Drug Evaluation and Research, the Plan B OTC decision will not effect these state regulations that allow the drug to be dispensed without prescription to people of all ages. Rita Rubin, "FDA Approves Over-The-Counter Sales of Plan B," *USA Today*, August 25, 2006, p. A2.

<sup>71</sup> In addition, a few pharmacists in Montana provide Plan B under collaborative agreement with physicians. NOT-2-LATE.com, the Emergency Contraception Website <http://ec.princeton.edu/questions/what-fda-says.html>.

<sup>72</sup> Hilary Waldman, "Rell Signs Plan B Law; Changes Still Possible," *The Hartford Courant*, May 17, 2007.

<sup>73</sup> For further information, see CRS Report RS22293, *Federal and State Laws Regarding Pharmacists Who Refuse to Distribute Contraceptives*, by (name redacted).

Maine, and Tennessee), a broadly worded refusal policy may apply to pharmacists or pharmacies, but does not specifically include them. In Illinois, however, pharmacies that stock contraceptives must also dispense emergency contraceptives. In the state of Washington, a recent rulemaking by the state's Board of Pharmacy requires pharmacy owners to ensure that if one pharmacist refuses to fill a prescription, another pharmacist will deliver the lawfully prescribed drug or device to the patient.<sup>74</sup> If a prescription drug or device is out-of-stock, the new rule provides several options to the patient, including transmitting the patient's prescription to another pharmacy, chosen by the patient, that will fill the prescription.<sup>75</sup> The Washington State regulations are being challenged in federal district court by the parent corporation of two grocery stores, including one that has a pharmacy, and two pharmacists who are the sole pharmacists on duty at pharmacies that allegedly could not hire another pharmacist to dispense drugs such as Plan B.<sup>76</sup>

On March 20, 2006, all Wal-Mart pharmacies began stocking and filling prescriptions for Plan B. Prior to that date, the company only stocked and filled prescriptions for the drug at its pharmacies in Massachusetts and Illinois where it was required by law. The company decided to change its policy because Wal-Mart expects more states to require Plan B to be available for sale. "Because of this, and the fact that [Plan B] is an FDA-approved product, we feel it is difficult to justify being the country's only major pharmacy chain not selling it."<sup>77</sup> The company intends to keep its "conscientious objection" policy, which allows pharmacists to refuse to fill prescriptions and refer patients to another pharmacy or pharmacist. There are more than 3,700 Wal-Mart pharmacies nationwide.

Connecticut Attorney General Richard Blumenthal announced on March 4, 2006, that state health plans would not cover prescriptions from pharmacies that do not stock Plan B. Attorney General Blumenthal said that his decision to remove pharmacies from the state's health plan coverage would remain until he is certain "every pharmacy will dispense [Plan B] wherever it is medically prescribed."<sup>78</sup>

There is great variation among the states regarding emergency contraception coverage for Medicaid beneficiaries.<sup>79</sup> Following the August 2006 FDA decision, 16 states have implemented written policies to address coverage of emergency contraception as an OTC drug. Most of the remaining states had policies on emergency contraception coverage prior to August 2006, and those policies remain in effect. Because the billing procedures of most state Medicaid programs require the pharmacist to submit a prescription in order to be reimbursed for OTC drugs, low-income women must either obtain a prescription or pay the \$40 out-of-pocket cost. In nine states (Alabama, Arizona, Idaho, Indiana, Kentucky, Maryland, Nevada, North Carolina, Rhode Island) prior authorization is required for emergency contraception reimbursement. The dual status of

<sup>74</sup> See Wash. Admin. Code 246-869-010, 246-863-095; News Release, Washington State Department of Health, *Pharmacy Dispensing Rules go into Effect July 26* (July 17, 2007) [http://www.doh.wa.gov/Publicat/2007\\_news/07-116.htm](http://www.doh.wa.gov/Publicat/2007_news/07-116.htm).

<sup>75</sup> Wash. Admin. Code 246-869-010.

<sup>76</sup> *Stormans, Inc. v. Seleck*, No. 07-5374, p. 10, 12 (W.D.Wash. filed July 25, 2007). The plaintiffs allege violations of the equal protection and supremacy clauses of the U.S. Constitution, as well as violations of their rights to free exercise of religion and procedural due process. *Id.* at 15-17.

<sup>77</sup> Reuters, Wal-Mart Pharmacies to Carry Morning-After Pill, March 3, 2001.

<sup>78</sup> Michael Barbaro, "In Reversal, Wal-Mart Will Sell Contraceptives," *New York Times*, March 4, 2006.

<sup>79</sup> Information in this paragraph was found in the following publication: National Health Law Program, "Over the Counter or Out of Reach? A Report on Evolving State Medicaid Policies for Covering Emergency Contraception," June 2007, <http://www.healthlaw.org/>.

Plan B (OTC for women 18 and over, prescription-only for women under 18) is creating coverage disparities.

For example, the Georgia Medicaid program, which allows very limited coverage for OTC drugs, has revised its provider manual to exclude coverage of Plan B for women 18 and older while covering the drug for women 17 and under who have a doctor's prescription. Arkansas will cover two tablets per prescription. In other states, such as North Carolina, Medicaid will cover [emergency contraception] for women only if they have a doctor's prescription for the drug, regardless of their age.<sup>80</sup>

In Hawaii, Illinois, Maryland, New Jersey, New York, Oklahoma, Oregon, and Washington, Medicaid will cover Plan B as an OTC drug for women over age 18 without the need for a prescription.<sup>81</sup> Mississippi, however, has decided to exclude emergency contraception from Medicaid coverage.<sup>82</sup>

## Justice Department Guidelines for Sexual Assault Victims

The National Violence Against Women Survey, which was conducted in 1996 and 1997, found that an estimated 300,000 women were raped in a single year.<sup>83</sup> Based on an estimated 333,000 rapes occurring in 1998, as many as 25,000 pregnancies resulted due to rape in that year; potentially 22,000 of such pregnancies could have been prevented if women had been provided with emergency contraceptive treatment.<sup>84</sup>

The Office of Violence Against Women within the Department of Justice (DOJ) developed guidelines for the treatment of sexual assault victims pursuant to Section 1405 of the Violence against Women Act of 2000 (P.L. 106-386). The guidelines serve as an informational resource to communities as they develop or revise their own procedures and do not invalidate any

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<sup>80</sup> Ibid., p. 5-6.

<sup>81</sup> National Institute for Reproductive Health, "Expanding Medicaid Coverage for EC on the State Level," <http://www.prochoice.org/assets/files/ecreport.pdf>.

<sup>82</sup> National Health Law Program, "Over the Counter or Out of Reach? A Report on Evolving State Medicaid Policies for Covering Emergency Contraception," June 2007, <http://www.healthlaw.org/>. Additional information on Medicaid coverage of emergency contraception can be found in the following document, Institute for Reproductive Health Access, National Health Law Program, National Latina Institute for Reproductive Health, and Ibis Reproductive Health, "Emergency Contraception & Medicaid: A State-by-State Analysis and Advocate's Toolkit," November 2005 <http://www.ibisreproductivehealth.org/pub/downloads/ECMedicaidAnalysisToolkit.pdf>.

<sup>83</sup> Patricia Tjaden and Nancy Thoennes, "Extent, Nature, and Consequences of Rape Victimization: Findings From the National Violence Against Women Survey," U.S. Department of Justice, National Institute of Justice, January 2006 <http://www.ncjrs.gov/pdffiles1/nij/210346.pdf>. The National Crime Victimization Survey estimates that there were 209,880 rapes or sexual assaults in 2004 and 191,670 in 2005. Shannan M. Catalano, "Criminal Victimization, 2005," U.S. Department of Justice, Bureau of Justice Statistics, September 2006 <http://www.ojp.usdoj.gov/bjs/pub/pdf/cv05.pdf>. The Uniform Crime Reporting Program, of the U.S. Department of Justice, Federal Bureau of Investigation, states in the annual report "Crime in the United States" that there were an estimated 93,934 forcible rapes reported to law enforcement in 2005, a 1.2 percent decrease compared with 2004 [http://www.fbi.gov/ucr/05cius/offenses/violent\\_crime/forcible\\_rape.html](http://www.fbi.gov/ucr/05cius/offenses/violent_crime/forcible_rape.html). Victim surveys indicate a larger number of rapes per year because less than 50 percent of rapes are reported to the police.

<sup>84</sup> Felicia H. Stewart and James Trussell, "Prevention of Pregnancy Resulting from Rape: A Neglected Preventive Health Measure," *American Journal of Preventive Health Medicine*, v. 19, November 2000, pp. 228-229.

jurisdictional protocols, policies or practices. Released in September 2004, the 141 page document, *A National Protocol for Sexual Assault Medical Forensic Examination*,<sup>85</sup> has been criticized by numerous organizations because it does not mention offering emergency contraception to female rape victims.

The DOJ *Protocol* states on page 111: “Patients of different ages, social, cultural, and religious/spiritual backgrounds may have varying feelings regarding acceptable treatment options. Examiners and other involved health care personnel must be careful not to influence patients’ choices of treatment.” The DOJ *Protocol* recommends that health care providers: discuss the probability of pregnancy with female patients; conduct a pregnancy test for all patients with reproductive capability (with their consent); and discuss treatment options with patients. A footnote directs the reader to the National Sexual Violence Resource Center (877-739-3895 or 717-909-0710 or <http://www.nsvrc.org>.) for more detailed information about sexual assault and pregnancy. An early draft of the document did include mention of emergency contraception.<sup>86</sup> In contrast to the half page of information on pregnancy, the *Protocol* offers several pages of information on treatment of sexually transmitted diseases.

The American College of Obstetricians and Gynecologists and the American Public Health Association recommend that emergency contraception should be offered to female rape victims who are at risk of pregnancy.<sup>87</sup> The American Medical Association, the American Nurses Association, the American College of Emergency Physicians, the American Academy of Pediatrics, and the Society for Adolescent Medicine also support advising rape victims about emergency contraception and providing the drug when appropriate.<sup>88</sup>

A letter signed by 277 national, state, and local organizations and individuals was sent to the Department of Justice on January 6, 2005, strongly urging that the *Protocol* be amended to include the routine offering of emergency contraception to sexual assault victims who are at risk of pregnancy.<sup>89</sup> According to the letter, hospitals often do not provide this service: only 6% of hospitals in Louisiana, 8% of hospitals in Idaho and 20% of hospitals in Montana provide emergency contraception on-site to rape victims.

On January 13, 2005, a letter signed by 97 Members of Congress was sent to the Director of the Office on Violence Against Women expressing concern over the failure to mention emergency contraception and urging that the *Protocol* be changed to include such information.<sup>90</sup>

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<sup>85</sup> The DOJ guidelines are available at <http://www.ncjrs.org/pdffiles1/ovw/206554.pdf>.

<sup>86</sup> Marie McCullough, Guidelines for Treating Rape Victims Omit Emergency Contraception, *The Philadelphia Inquirer*, December 31, 2004, p. A1.

<sup>87</sup> ACOG Educational Bulletin, Sexual Assault, *International Journal of Gynecology and Obstetrics*, v. 60, 1998, pp. 297-304; American College of Obstetricians and Gynecologists, Violence Against Women: Acute Care of Sexual Assault Victims (2004), available at [http://www.acog.org/departments/dept\\_notice.cfm?recno=17&bulletin=1625](http://www.acog.org/departments/dept_notice.cfm?recno=17&bulletin=1625); and American Public Health Association, 2003 Policy Statements, “2003-16 Providing Access to Emergency Contraception for Survivors of Sexual Assault,” available at [http://www.gotoec.org/pdfs/Endorsement\\_APHA\\_SexualAssault.pdf](http://www.gotoec.org/pdfs/Endorsement_APHA_SexualAssault.pdf).

<sup>88</sup> Center for Policy Alternatives, “Emergency Contraception for Sexual Assault Victims,” found at <http://www.stateaction.org/issues/issue.cfm/issue/EC-SexualAssault.xml>; and Melanie A. Gold et al., Society for Adolescent Medicine, “Provision of Emergency Contraception to Adolescents,” *Journal of Adolescent Health*, v. 35, July 2004 pp. 66-70.

<sup>89</sup> The letter is available online at <http://www.aclu.org/reproductiverights/gen/12743res20050106.html>.

<sup>90</sup> The letter is available at <http://www.maloney.house.gov/documents/olddocs/choice/011305DOJ.pdf>.

## Federal Legislation

S. 21 (Reid), the Prevention First Act, was introduced on January 4, 2007. The bill would expand access to preventive health care services that help reduce unintended pregnancy, reduce abortions, and improve access to women's health care. It directs the Secretary of Health and Human Services (HHS) to develop and disseminate information on emergency contraception to the public and to health care providers. S. 21 would require hospitals, as a condition of receiving federal funds, to offer and to provide, upon request, emergency contraception to victims of sexual assault. S. 21 was referred to the Senate Health, Education, Labor, and Pensions Committee. S. 21 is similar to S. 20 (Reid), which was introduced in the 109<sup>th</sup> Congress. A companion bill, H.R. 819 (Slaughter), was introduced in the House on February 5, 2007.

H.R. 464 (Rothman), the Compassionate Assistance for Rape Emergencies Act of 2007, was introduced on January 12, 2007. H.R. 464 is similar to H.R. 2928 (Rothman), which was introduced in the 109<sup>th</sup> Congress. The bill would prohibit any federal funds from being provided to a hospital under Medicare or to a state, with respect to hospital services, under Medicaid, unless certain conditions are met. A woman who is a victim of sexual assault must be provided with (1) accurate and unbiased information about emergency contraception, (2) an offer of emergency contraception, (3) emergency contraception must be provided to the woman upon her request, and (4) such services cannot be denied because of the inability to pay. H.R. 464 was referred to the Committee on Energy and Commerce and the Committee on Ways and Means. S. 1240 (Clinton), introduced on April 26, 2007, has the same language and title as H.R. 464, but it would also provide a woman with risk assessment, counseling, and treatment for certain sexually transmitted infections. S. 1240 was referred to the Committee on Finance.

H.R. 2064 (Michaud), the Compassionate Care for Servicewomen Act, was introduced on April 26, 2007. The bill would require emergency contraception to be included on the basic core formulary of the uniform formulary of pharmaceutical agents for the pharmacy benefits program of the Department of Defense. Under the bill, prior authorization would not be required for emergency contraception. H.R. 2064 was referred to the Subcommittee on Military Personnel. A companion bill, S. 1800 (Clinton), was introduced on July 17, 2007. S. 1800 was referred to the Committee on Armed Services.

H.R. 2503 (DeLauro), the FDA Scientific Fairness for Women Act, was introduced on May 24, 2007. Among other things, the bill would provide for a scientific workshop to review and evaluate current scientific data on the use of emergency contraceptives by women under the age of 18. The bill was referred to the House Committee on Energy and Commerce.

H.R. 2596 (Maloney)/S. 1555 (Lautenberg), the Access to Birth Control Act, was introduced on June 6, 2007. The bill would amend Title II of the Public Health Service Act establishing certain duties for pharmacies to ensure the provision of an FDA-approved contraceptive, including an emergency contraceptive, to a customer requesting such a product. The bill would provide a civil penalty for a violation of up to \$5,000 per day, not to exceed \$500,000 for all violations adjudicated in a single proceeding. H.R. 2596 was referred to the House Committee on Energy and Commerce; S. 1555 was referred to the Committee on Health, Education, Labor, and Pensions.

## Impact of the FDA OTC Decision

The Plan B OTC application was mired in controversy over the three year period from when it was filed with FDA in April 2003 to its August 2006 approval. Individuals who criticize the delayed FDA decision believe that Bush Administration policy and FDA actions were based on political and ideological considerations rather than on sound science. FDA is required by law to make decisions exclusively on substantial scientific evidence regarding the safety and efficacy of a drug. These critics believe the FDA decision was delayed to appease conservative religious and pro-life groups that are long time supporters of President Bush.

President Bush indicated his support for the then-imminent Plan B decision during a news conference on August 21, 2006.<sup>91</sup> The FDA decision and the President's support of the decision have greatly angered conservative religious and pro-life groups. One such organization, Concerned Women of America, asked that Dr. Andrew von Eschenbach's nomination as FDA commissioner be withdrawn and recommended that consumers stop doing business with drug stores that sell OTC Plan B.<sup>92</sup> The Family Research Council, a Christian conservative non-profit think tank and lobbying organization, states that it is "pursuing legal and legislative options" to overturn the FDA's decision.<sup>93</sup> Such groups are unhappy because they believe Plan B should only be used with the supervision of a healthcare professional; they also believe Plan B use may lead to an increase in unsafe sexual activity.

A recent review of the medical literature, published in April 2007, found that having emergency contraception on hand "did not lead to increased rates of sexually transmitted infections, increased frequency of unprotected intercourse, nor changes in contraceptive methods."<sup>94</sup> A U.S. study also found that easier access to emergency contraception did not decrease the use of condoms or oral contraceptives or lead to an increase in sexually transmitted infections or unprotected sex.<sup>95</sup> A followup study found that adolescents younger than 16 years of age behaved no differently in response to increased access to emergency contraception compared with older age groups.<sup>96</sup> Their behaviors did not become riskier: no increased incidence of unprotected sex, sexually transmitted disease, or pregnancy, nor did they become more vulnerable to unwanted sexual activity, including the very youngest participants in the study. Moreover, "the adolescents were equally capable as adults in taking EC correctly, with the youngest adolescents, under 16 years, showing the best results. These results are consistent with findings from [a] previous study that specifically examined young adolescents ... there was no reason to restrict access in this age group. The high levels of correct use ... in this study suggest that physician supervision does not

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<sup>91</sup> The White House, Office of the Press Secretary, Press Conference by the President, August 21, 2006 <http://www.whitehouse.gov/news/releases/2006/08/20060821.html>.

<sup>92</sup> Diedtra Henderson, "FDA Approves Sale of Morning-After Pill," *Boston Globe*, August 25, 2006.

<sup>93</sup> Joyce Howard Price, "Plan B Allowed Over The Counter," *The Washington Times*, August 25, 2006.

<sup>94</sup> C.B. Polis et al., "Advance Provision of Emergency Contraception for Pregnancy Prevention," *Cochrane Database of Systematic Reviews*, April 18, 2007, at <http://www.cochrane.org/reviews/en/ab005497.html>.

<sup>95</sup> Tina R. Raine et al., "Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs," *Journal of the American Medical Association*, v. 293, January 5, 2005, pp. 54-62.

<sup>96</sup> Cynthia Harper et al., "The Effect of Increased Access to Emergency Contraception Among Young Adolescents," *Obstetrics and Gynecology*, v. 106, September 2005, pp. 483-491.

improve adherence to the regimen and that young adolescents should not be singled out due to concerns about their inability to follow the regimen correctly.”<sup>97</sup>

The Society for Adolescent Medicine does not place an age limit on access to emergency contraception.<sup>98</sup> The American College of Obstetricians and Gynecologists (ACOG) believes that Plan B can be safely used without supervision by a physician, and that the age restriction imposed by FDA is medically unnecessary. In a statement released on the same day as the FDA approval of OTC status for Plan B, ACOG stated:

By restricting its OTC availability to women age 18 and older, the FDA has missed an unparalleled opportunity to prevent teenage pregnancies. Each year there are more than 800,000 teen pregnancies in the US, with many ending in abortion. Pregnancy itself is not without risk, especially for a young woman. There is no scientific or medical reason to impose an age restriction and to withhold emergency contraception from this population. Emergency contraception is safe for over-the-counter use by women of all ages.<sup>99</sup>

As stated above, studies of Plan B have shown that women, even young adolescents, can follow the directions on the package and use the product correctly without an increase in high risk behaviors.<sup>100</sup> One member of the FDA advisory panel, a pharmacist, noted that for even the youngest women, the morning-after pill poses less of a health risk than pregnancy: “In terms of age, I’m not an OB-GYN, but I can’t imagine that I would prefer a ten or 11 year old to be pregnant over some hypothetical risk that there might be with a ten or 11 year old taking this product. So I guess I would feel pretty strongly about not having any age restrictions.”<sup>101</sup> The side effects of Plan B would probably influence most women to find another method of regular birth control. For rape victims who don’t immediately seek medical care, OTC availability would be expected to be beneficial. Under the FDA approval agreement with Barr, the drug will only be sold in pharmacies or health clinics where consumers can obtain advice from a pharmacist or other health care professional. Plan B will not be available at gas stations, convenience stores, online pharmacies, or other places where other nonprescription drugs are sold.

The primary concern of conservative religious and pro-life groups with Plan B, however, is that it may prevent the implantation of the embryo in the uterus. Pro-life groups believe that prevention of embryo implantation in the uterus is an abortion. According to the Catholic pro-life group Human Life International, “President Bush’s implied support for the abortion-causing drug Plan B is completely inconsistent with his recent veto of the embryonic stem cell research (ESCR) funding bill. What the president apparently fails to realize is that Plan B kills the same innocent

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<sup>97</sup> Ibid.

<sup>98</sup> Melanie A. Gold et al., Society for Adolescent Medicine, “Provision of Emergency Contraception to Adolescents,” *Journal of Adolescent Health*, v. 35, July 2004 pp. 66-70.

<sup>99</sup> News Release, Statement of The American College of Obstetricians and Gynecologists, On the FDA’s Approval of OTC Status for Plan B, August 24, 2006. Available at [http://www.acog.org/from\\_home/publications/press\\_releases/nr08-24-06.cfm](http://www.acog.org/from_home/publications/press_releases/nr08-24-06.cfm).

<sup>100</sup> Cynthia C. Harper et al., “Tolerability of Levonorgestrel Emergency Contraception in Adolescents,” *American Journal of Obstetrics and Gynecology*, v. 191, 2004, pp. 1158-1163; Raine, “Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs,” *Journal of the American Medical Association*, v. 293, January 5, 2005, pp. 54-62; Harper, “The Effect of Increased Access to Emergency Contraception Among Young Adolescents,” *Obstetrics and Gynecology*, v. 106, September 2005, pp. 483-491.

<sup>101</sup> Comment made by Dr. Julie A. Johnson, University of Florida Colleges of Pharmacy and Medicine, at the December 16, 2003 FDA Advisory Committee Meeting, page 225 of a 248-page transcript found at <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.htm>.

unborn children that the ESCR process does.”<sup>102</sup> The medical community, however, does not consider prevention of implantation to be an abortion. “Pregnancy begins with implantation, not fertilization. Medical organizations and the federal government concur on this point. Fertilization is a necessary but insufficient step toward pregnancy.... Any method of regulation of fertility that acts before implantation is not an abortifacient.”<sup>103</sup> FDA does not classify Plan B as an abortion drug.

Research has found that the use of emergency contraception rises when it is made available without a prescription. In France, sales of a nonprescription emergency contraceptive, introduced in 1999, rose 72% over five years.<sup>104</sup> In British Columbia, use of emergency contraception increased 102% after a new policy allowed pharmacists to dispense without a prescription.<sup>105</sup> Some experts have estimated that use of emergency contraception in the United States could prevent 1 million abortions and more than 2 million unintended pregnancies that result in childbirth each year.<sup>106</sup> However, a report in the January 2007 issue of *Obstetrics & Gynecology*, which looked at 23 studies of emergency contraception use, found that “increased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates.”<sup>107</sup> This same conclusion was reached in a separate review of the medical literature published in April 2007.<sup>108</sup> The authors of this second study found that “advance provision of emergency contraception did not reduce pregnancy rates when compared to conventional provision.... The interventions tested thus far have not reduced overall pregnancy rates in the populations studied.”<sup>109</sup>

Pro-choice groups believe OTC status for Plan B will reduce the number of unintended pregnancies and reduce the number of abortions performed in the United States. Although pro-choice groups believe the FDA decision is a step in the right direction, they would have preferred that OTC status for Plan B would have been approved for all women, not just those 18 and older. They believe that the age restriction might keep the drug from women who need it the most. An estimated 3.5 million unwanted pregnancies occur annually, one third of which involve teenagers.<sup>110</sup> In the United States, four in ten girls become pregnant at least once before turning 20.<sup>111</sup>

<sup>102</sup> Press Release, Human Life International, “President Bush Files for Divorce with Catholic Base,” August 21, 2006 [http://www.hli.org/press\\_releases\\_divorcing\\_catholic\\_base.html](http://www.hli.org/press_releases_divorcing_catholic_base.html).

<sup>103</sup> David A. Grimes, “Emergency Contraception—Expanding Opportunities for Primary Prevention,” *The New England Journal Of Medicine*, v. 337, October 9, 1997, pp. 1078-1079.

<sup>104</sup> Barbara Martinez and Anna Wilde Mathews, “Easier Access to Contraceptives May Boost Costs,” *The Wall Street Journal*, August 25, 2006, p. A8.

<sup>105</sup> Ibid.

<sup>106</sup> James Trussell et al., “Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies,” *Family Planning Perspectives*, v. 24, November-December 1992, pp. 269-273.

<sup>107</sup> Elizabeth G. Raymond, et al., “Population Effect of Increased Access to Emergency Contraceptive Pills—A Systematic Review,” *Obstetrics and Gynecology*, v. 109, January 2007, pp. 181-188.

<sup>108</sup> C.B. Polis et al., “Advance Provision of Emergency Contraception for Pregnancy Prevention,” *Cochrane Database of Systematic Reviews*, April 18, 2007, at <http://www.cochrane.org/reviews/en/ab005497.html>.

<sup>109</sup> Ibid.

<sup>110</sup> Centers for Disease Control and Prevention, “National and State-Specific Pregnancy Rates Among States, 1995-1997,” *MMWR Morbidity and Mortality Weekly Report*, v. 49, 2000, pp. 605-611.

<sup>111</sup> National Campaign to Prevent Teen Pregnancy, Not Just Another Single Issue: Teen Pregnancy Prevention’s Link to Other Critical Social Issues, February 2002. Available at <http://www.teenpregnancy.org/resources/data/pdf/notjust.pdf>.

Prescriptions of Plan B have been covered by most state Medicaid programs and many private health insurers.<sup>112</sup> Drugs that are switched to OTC typically lose insurance coverage and therefore the OTC switch for Plan B may result in increased cost to insured consumers who buy the drug without a prescription. Prior to the change to OTC status, Plan B was prescribed about 1.5 million times per year in the United States; about half are filled in clinics such as Planned Parenthood or on college campuses.<sup>113</sup> During its first month as an OTC drug, Plan B was available in in one state, Pennsylvania for \$20 through Planned Parenthood clinics and for \$39.99 to \$44.99 at various retail pharmacies.<sup>114</sup> According to Barr Pharmaceuticals, sales of Plan B in the United States have doubled since August 2006, “rising from about \$40 million a year to what will probably be close to \$80 million for 2007.”<sup>115</sup>

## Author Contact Information

(name redacted)  
Specialist in Biomedical Policy  
[redacted]@crs.loc.gov, 7-....

(name redacted)  
Legislative Attorney  
[redacted]@crs.loc.gov, 7-....

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<sup>112</sup> Barbara Martinez and Anna Wilde Mathews, “Easier Access to Contraceptives May Boost Costs, *The Wall Street Journal*, August 25, 2006, p. A8.

<sup>113</sup> Ibid.

<sup>114</sup> Jill Daly, “OTC Plan B Marks First Month,” *Pittsburgh Post-Gazette*, December 13, 2006, p. F1.

<sup>115</sup> Rob Stein, “Plan B Use Surges, And So Does Controversy,” *The Washington Post*, July 13, 2007, p. A1.

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