The Constitutionality of the FDA’s Age-Based Plan B® Regulations:
Why the FDA Made the Wrong Decision

April 23, 2007
INTRODUCTION

After more than four years of denials and postponements, the resignation of the Food and Drug Administration’s (FDA) Assistant Commissioner for Women’s Health, numerous studies and recommendations, and a Government Accountability Office investigation, the FDA announced on August 24, 2006 that Plan B®, an emergency contraceptive (EC) drug, would be available over-the-counter (OTC) to individuals 18 and older.1 Plan B®, the only FDA-approved EC pill on the market in the United States today, had previously been available by prescription only to women of all ages.2

The right of individuals to make decisions concerning contraception was first recognized by the Supreme Court in its 1965 decision of Carey v. Population Services International.3 This paper argues that the FDA’s regulations concerning

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2 Matthew J. Seamon, Plan B or the FDA: A Need For a Third Class of Drug Regulation in the United States Involving a “Pharmacist-Only” Class of Drugs, 12 WM. & MARY J. WOMEN & L. 521, 529 (2006) (“In the United States, two drugs have been approved for EC to date, although only one is currently available. Preven® was the first drug approved in 1998 and is a combination product containing both an estrogen and a progestin. Plan B® was approved in 1999 and contains only a progestin. Interestingly, in May 2004, Barr Pharmaceuticals, Inc., the manufacturer of Plan B®, purchased the marketing rights to Preven® and has discontinued its sales.”).

3 Carey v. Population Services Int’l, 431 U.S. 678, 685 (1977) (citing Griswold v. Connecticut, 381 U.S. 479 (1965)) (The right to decide “whether or not to beget or bear a child” was first explicitly recognized in an opinion holding unconstitutional a statute prohibit the use of contraceptives, Griswold v. Connecticut.”).
Plan B® violate individuals’ rights concerning access to contraception in two ways: 1) requiring a prescription for females under 18 without medical evidence to justify the requirement is a bar to access for those under 18, and regulating the morality of minors is not a compelling state interest which justifies the infringement of their rights; and 2) requiring Plan B® to be kept behind the pharmacy counter and proof of age to purchase the drug OTC is a bar to access for those over 18, and enforcement of the age-restriction is not a compelling governmental interest which justifies the infringement.

Part I describes Emergency Contraception (EC) generally and Plan B® specifically, distinguishes contraception from abortion, outlines the FDA’s approval process for Plan B® and briefly describes a state’s role in drug regulation. Part I concludes with a summary of constitutionally recognized reproductive rights, including access to contraception and a case analysis of Carey. Part II discusses the constitutionality of the FDA’s regulations, explaining why the new FDA regulations impose undue burdens on both minors’ and adults’ fundamental rights to make decisions concerning procreation and why those burdens are not justified by any compelling governmental interests. This section applies the Supreme Court’s decision in Carey to the FDA’s regulations regarding Plan B®. Finally, Part III discusses the political and social influence surrounding the Plan B® OTC-switch decision and why the decision was incorrect, citing actions and comments by the Bush Administration and the FDA’s request for public comment on the decision surrounding Plan B®.
I. BACKGROUND

A. Emergency Contraception

1. An Overview of Emergency Contraception in the United States Today

Emergency contraception (EC) is a method of birth control that prevents pregnancy after sex (postcoitally), when another contraceptive method was not used or has failed.4 All forms of contraception, including EC, work prior to implantation of a fertilized egg, by delaying or inhibiting ovulation, blocking fertilization, or preventing implantation.5 EC does not interrupt or harm an established pregnancy.6

The FDA has approved two different types of EC pills: a combination pill containing progestin and estrogen, and a progestin-only pill.7 Evidence indicates that the progestin-only form of EC is more effective than the combination pills.8 Currently, Plan B®, which is a progestin-only pill containing the hormone

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6 Melanie A. Gold et al., Position Paper of the Society for Adolescent Medicine, Provision of Emergency Contraception to Adolescents, 35 JOURNAL OF ADOLESCENT HEALTH 66, 67 (2004). See also Jonathan D. Klein & Committee on Adolescence, Emergency Contraception, 116 PEDIATRICS 1038, 1042 (2005). (“A review of information suggests that there is no evidence demonstrating that any of the emergency-contraception methods are teratogenic.”)

7 Seamon, supra note 2, at 529.

8 Klein, supra note 6, at 1040.
levonorgestrel, is the only EC pill available in the United States.\textsuperscript{9} Levonorgestrel is a hormone that has been used in oral contraceptives (OCs) for 35 years,\textsuperscript{10} and its use as an EC “has been extensively studied worldwide” for more than three decades.\textsuperscript{11} The only contraindication for either type of pill, according to the World Health Organization (WHO), is a known pregnancy, “primarily because the treatment will not work if the patient is already pregnant.”\textsuperscript{12} Some other contraindications for progestin-only ECs may include hypersensitivity to an ingredient in the medication (rare), and undiagnosed abnormal vaginal bleeding.\textsuperscript{13}

Although the safety and effectiveness of EC pills has been well documented,\textsuperscript{14} some women may experience mild side effects. These side effects primarily include nausea and vomiting, but fatigue, breast tenderness, headaches, dizziness, and abdominal pain can also occur occasionally.\textsuperscript{15} Taking an anti-nausea medication one hour before taking an EC pill can easily minimize

\begin{footnotes}
\item[9] Seamon, \emph{supra} note 2, at 529.
\item[12] Klein, \emph{supra} note 6, at 1042.
\item[13] Gold et al., \emph{supra} note 6, at 67.
\item[15] Gold et al., \emph{supra} note 6, at 66-67.
\end{footnotes}
common gastrointestinal side effects.\textsuperscript{16} Also, progestin-only pills cause significantly less nausea and vomiting than the estrogen-progestin combination pills.\textsuperscript{17} Another possible side effect is a slight alteration in menstruation “depending on the timing of [EC’s] administration within the menstrual cycle.”\textsuperscript{18}

Overall, there is little concern about the safety of EC pills.

While Plan B\textsuperscript{®} is the only drug currently marketed as EC in the United States, certain OCs\textsuperscript{19} have been used off-label\textsuperscript{20} for postcoital prevention of pregnancy since 1974.\textsuperscript{21} Women are typically instructed to take two doses, of two to five regular birth control pills, 12 hours apart.\textsuperscript{22} The FDA “explicitly sanctioned” this off-label use, commonly referred to as the Yuzpe Regimen,\textsuperscript{23} in

\textsuperscript{16} Id. at 67.

\textsuperscript{17} Klein, supra note 6, at 1040.

\textsuperscript{18} Id. at 1043 (“If treatment is initiated before ovulation, the menses is often 3 to 7 days earlier than expected. Treatment initiated after ovulation usually results in menses at the expected time or in a slight delay. Patients who are 3 weeks post-treatment without menses should be evaluated for pregnancy.”).

\textsuperscript{19} OCs appropriate for off-label use as EC include: Alesse, Levlen, Levlite, Levora, Low-Ogestrel, Lo/Ovral, Nordette, Ogestrel, Ovral, Ovrette, Tri-Levlen, Triphasil, and Trivora. Id. at 1039 (Table 1).

\textsuperscript{20} “Off-label use” is the use of a FDA-approved drug to treat a condition that it has not been officially approved to treat by the FDA. MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY 861 (11th ed. 2004).

\textsuperscript{21} Seamon, supra note 2, at 525-526.

\textsuperscript{22} Id. at 526.

\textsuperscript{23} \textit{Emergency Contraception: A Guide to Over-the-Counter Availability}, supra note 11.
It published “a list of approved birth control pills that could be used as emergency contraception, and provided an accompanying chart showing the dosage conversion.” The Yuzpe Regimen is most often utilized “in hospitals, university health clinics, and, to a lesser extent, by physicians in private practice.” It may not be as effective as levonorgestrel alone, and has a greater likelihood of side effects.

2. Plan B®: What It Is and How It Works

Plan B® is the only EC pill available in the United States today. The FDA first approved it for prescription use in 1999. On August 24, 2006, the FDA announced that Plan B® would be available over-the-counter (OTC) to individuals (both men and women) eighteen years of age and older. However, the

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26 Seamon, supra note 2, at 525-526.


28 Seamon, supra note 2, at 529 (“In the United States, two drugs have been approved for EC to date, although only one is currently available. Preven® was the first drug approved in 1998 and is a combination product containing both an estrogen and a progestin. Plan B® was approved in 1999 and contains only a progestin. Interestingly, in May 2004, Barr Pharmaceuticals, Inc., the manufacturer of Plan B®, purchased the marketing rights to Preven® and has discontinued its sales.”).

29 Klein, supra note 6, at 1038.
drug remains available by prescription only to women under 18.\textsuperscript{30} Plan B\textsuperscript{®} is the first drug in the FDA’s history to be marketed as a prescription and an OTC medication, with the same dosage and instructions, simultaneously. Plan B\textsuperscript{®} is packaged as two pills, each containing 0.75 milligrams of levonorgestrel.\textsuperscript{31} The first pill should be taken within 72 hours after unprotected or underprotected sex, and the second should be taken 12 hours later.\textsuperscript{32} When taken correctly, Plan B\textsuperscript{®} reduces the occurrence of pregnancy by 89\%.\textsuperscript{33}

There is some indication that Plan B\textsuperscript{®} may still be effective, to some extent, if used after the initial 72 hour period has elapsed. The FDA has only approved use of Plan B\textsuperscript{®} within 72 hours after intercourse.\textsuperscript{34} However, it can take approximately six to seven days from the time of intercourse or ovulation for implantation to occur. Therefore, it makes sense that Plan B\textsuperscript{®} may still be effective if taken within 120 hours, or five days, after sex.\textsuperscript{35} Plan B\textsuperscript{®}’s success rate does diminish rather quickly, though: “The risk of pregnancy increases from 0.4 percent if contraception is initiated within 24 hours to 2.7 percent if it is

\begin{itemize}
\item \textsuperscript{30} FDA Approves Over-the-Counter Access for Plan B, supra note 1.
\item \textsuperscript{31} Plan B: FAQs, supra note 10.
\item \textsuperscript{32} Klein, supra note 6, at 1040.
\item \textsuperscript{33} Plan B: What is Plan B, http://www.go2planb.com/ForConsumers/AboutPlanB/WhatisPlanB.aspx.
\item \textsuperscript{34} FDA Approves Over-the-Counter Access for Plan B, supra note 1.
\item \textsuperscript{35} Gold et al., supra note 6, at 66.
\end{itemize}
initiated 24 to 72 hours after intercourse.”

Ultimately, the sooner the first dose can be taken, the greater the probability pregnancy will be avoided.

There is also evidence to suggest that separating the two doses of Plan B® by 12 hours is unnecessary. “Preliminary evidence suggests a single dose of two tablets of levonorgestrel is as effective as and possibly more effective than the standard two-dose regimen.” The FDA has not approved this use of Plan B®. However, taking the two doses together would be simpler, and could therefore increase the likelihood that the drug will be taken properly.

3. Emergency Contraception and Abortion Distinguished

There is often a misconception that Plan B®, and EC in general, causes abortions, but Plan B® is not an “abortion pill.” There is an abortion pill, mifepristone (Mifeprist®, or RU-486), that has been available by prescription in the United States since it was approved by the FDA in 2000, but it is not the same as Plan B®. It should be noted that mifepristone may be used in low doses

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36 Alastair J.J. Wood et al., A Sad Day for Science at the FDA, 353 NEW ENG. J. MED. 1197, 1197 (2005).

37 Klein, supra note 6, at 1040.


39 Id.

40 Id.


42 Seamon, supra note 2, at 534.
as EC.\footnote{Seamon, supra note 2, at 528.} However, the opposite is not true: high doses of Plan B\textsuperscript{®} will not cause an abortion.\footnote{Gold et al., supra note 6, at 67. See also Klein, supra note 6, at 1042 (“A review of information suggests that there is no evidence demonstrating that any of the emergency-contraception methods are teratogenic.”).}

It is important to understand how the medical community defines pregnancy, contraception, and abortion in order to understand how abortion and contraception differ. Pregnancy, medically speaking, is the implantation of a fertilized egg into the wall of the uterus.\footnote{Governments Worldwide, supra note 5.} Contraception occurs when a pregnancy is prevented, which can happen in a number of ways.\footnote{Id.} Delay or inhibition of ovulation, blocked fertilization, or prevented implantation of a fertilized egg, are all the results of contraception.\footnote{Id.} Therefore, any agent that prevents a pregnancy from occurring is classified as a contraceptive. An abortion occurs when a fertilized, implanted egg is disrupted from the uterus.\footnote{Seamon, supra note 2, at 527 (quoting Caroline Wellbery, \textit{Emergency Contraception: An Ongoing Debate}, 70 Am. Fam. Physician 655, 655 (2004)).} Agents that disrupt an already established pregnancy are classified as abortifacients.\footnote{An abortifacient is “an agent (as a drug) that induces abortion.” \textit{MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY} 3 (11th ed. 2004). Drugs that are classified as abortifacients include misprostol, methotrexate, and mifepristone. Seamon, supra note 2, at 534.}
Essentially, contraception occurs *before* a pregnancy has been established, and abortion occurs *after* a pregnancy has been established.

One reason confusion surrounding EC and abortifacients exists is because commonly accepted definitions of pregnancy are often inconsistent with its medical definition. Ten states recognize pregnancy as beginning at fertilization.\(^{50}\) This view actually has some merit because “a fertilized ovum has a full complement of DNA.”\(^{51}\) Eight other states recognize pregnancy as beginning at “conception,” which only creates more confusion because “conception” is sometimes used to describe implantation, and other times to describe fertilization.\(^{52}\) Being aware of these distinctions is important in understanding some of the political opposition surrounding EC.

Even if pregnancy could be defined as beginning at fertilization, it is likely that Plan B\(^{®}\) would still be classified as contraception. While Plan B\(^{®}\) has only been conclusively shown to prevent ovulation, there are two other possible mechanisms of Plan B\(^{®}\) which could prevent fertilization that are being examined further.\(^{53}\) Because sperm are viable in the vagina for up to five days, while an egg must be fertilized approximately one day after ovulation,\(^{54}\) there is speculation that Plan B\(^{®}\) could be keeping the sperm from getting to the egg in time to

\(^{50}\) Harper, *supra* note 24, at 245.

\(^{51}\) Seamon, *supra* note 2, at 528.

\(^{52}\) Harper, *supra* note 24, at 245.


\(^{54}\) Klein, *supra* note 6, at 1040 (2005).
fertilize it. Some studies suggest that Plan B® changes “the pH of the uterine cavity, which significantly decreases the number of viable sperm.”\textsuperscript{55} There is also speculation that Plan B® may “thicken cervical mucous, thus inhibiting sperm transport.”\textsuperscript{56} These speculated mechanisms still occur pre-fertilization, and thus would still qualify Plan B® as a contraceptive and not an abortifacient.

**B. Regulation of Prescription and Over-The-Counter Drugs**

1. Introduction to the Food & Drug Administration (FDA)

The Federal Food, Drug, and Cosmetic Act (FDCA) of 1906 created the FDA,\textsuperscript{57} which “is responsible for protecting the public health by assuring the safety, efficacy, and security of human . . . drugs.”\textsuperscript{58} The Prescription Drug Amendments (also known as the Durham Humphrey Amendments) were added to the FDCA in 1951, creating a formal distinction between prescription and nonprescription drugs for the first time.\textsuperscript{59} The Center for Drug Evaluation and Research (CDER) oversees all drug related issues that the FDA is in charge of, including those relating to prescriptions.\textsuperscript{60} The Office of Nonprescription Products, part of the CDER, is primarily responsible for handling nonprescription

\textsuperscript{55} Emergency Contraception: A Guide to Over-the-Counter Availability, supra note 11.

\textsuperscript{56} Id.

\textsuperscript{57} Harper, supra note 24, at 226.


\textsuperscript{59} Seamon, supra note 2, at 539.

\textsuperscript{60} Id. at 533.
drugs. Today, prescription drugs are those “that are safe for use only under the supervision of a health care practitioner.”

2. How a Prescription Drug Becomes an Over-The-Counter Drug

   a. Overview of Prescription to OTC Switch

      Only the FDA can switch a prescription drug to OTC status. This switch is called for when maintaining prescription status is no longer “necessary for the protection of the public health by reason of the drug’s toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use.” In short, the drug must be safe for self-medication, effective when self-administered, and the drug’s labeling must make it clear how self-administration should take place.

61 Id.


63 Harper, supra note 24, at 228.

64 21 C.F.R. § 310.200(b).

65 Id.
When a drug is determined to be safe\(^66\) and effective\(^67\) for self-medication, the Commissioner of the FDA is authorized to make the switch.\(^{68}\) When a product is being considered for OTC status, and it is the first product in its class undergoing such consideration, the FDA usually requires at least two types of studies before approving the switch. One study should be on the comprehensibility of the label, and the other on the “actual use” of the medication.\(^{69}\) If these two studies, in conjunction with other published materials on the drug, show that it is safe and effective for OTC use, then the application should be approved.

b. The Long Road Leading Up To Plan B®’s Partial Over-The-Counter Approval

A request for the FDA to consider a switch to OTC status can come from the Commissioner himself, or from any interested person, who wishes to file a petition, including the drug’s manufacturer.\(^{70}\) The request for Plan B®’s switch came from a citizens’ petition filed by the Center for Reproductive Law and

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\(^{66}\) “Safety means a low incidence of adverse reactions or significant side effects under adequate directions for use as well as low potential for harm which may result from abuse under conditions of widespread availability.” 21 C.F.R. § 330.10(a)(4)(i).

\(^{67}\) “Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed.” 21 C.F.R. § 330.10(a)(4)(ii).

\(^{68}\) 21 C.F.R. § 310.200(b).


\(^{70}\) 21 C.F.R. § 310.200(b).
Policy on February 14, 2001. The petition was signed by 66 organizations, including the American Public Health Association, the Association of Reproductive Health Professionals, and the American Academy of Pediatrics.

Women’s Capital Corporation (WCC), distributor of Plan B® prior to Barr Pharmaceuticals, Inc., submitted its supplemental New Drug Application (sNDA) to the FDA on April 6, 2003. Women’s Capital Corporation sponsored two studies relevant to their application for OTC availability of Plan B®. The first study evaluated the comprehensibility of the proposed OTC label. The study included 663 women in eight U.S. cities who were interviewed about their comprehension of a prototype of Plan B®’s OTC label. The second study was an “actual use” study, “designed to determine whether women would use the product appropriately and safely when it was dispensed using a simulated over-the-counter approach.” The studies concluded that there is no need for

71 Seamon, supra note 2, at 543.
73 Seamon, supra note 2, at 543.
75 Id.
76 Id.
77 Id.
providers to supervise women’s use of Plan B®, because women can use it safely and effectively on their own.\footnote{Id. at 23.} The studies thus supported OTC availability for Plan B®.\footnote{Id.}

On December 16, 2003, after examination of Plan B®’s sNDA, the FDA’s Nonprescription Drugs Advisory Committee and the Reproductive Health Drugs Advisory Committee both recommended that the FDA approve the switch of Plan B® from prescription to OTC status.\footnote{MINORITY STAFF COMMITTEE ON GOVERNMENT REFORM, U.S. HOUSE OF REP., FACT SHEET ON THE POLITICIZATION OF EMERGENCY CONTRACEPTION (2005), available at http://oversight.house.gov/Documents/20051013155450-84328.pdf (last visited Feb. 20, 2007) [hereinafter WAXMAN REPORT].} All members of the committees found Plan B® to be safe in a nonprescription setting and no evidence that OTC availability of Plan B® would lead to a decrease in regular contraceptive methods.\footnote{Id.} Despite these unanimous findings, 4 committee members voted to deny the switch, but conceded that their reasons were not related to safety or effectiveness.\footnote{Id. at 20 (“Dr. John K. Jenkins, the director of the Office of New Drugs at the FDA, wrote that ‘both divisions and offices responsible for review of this

\begin{enumerate}
\item Id. at 23.
\item Id.
\item Id.
\item Id.
\item Henry A. Waxman, Politics And Science: Reproductive Health, 16 HEALTH MATRIX 5, 19 (Winter 2006).
\item Id. at 20 (“Dr. John K. Jenkins, the director of the Office of New Drugs at the FDA, wrote that ‘both divisions and offices responsible for review of this
\end{enumerate}
The FDA disregarded its advisory committees’ recommendations and ultimately rejected the status change on May 7, 2004, because it was concerned “that there were inadequate data showing comprehension and proper use by young teens.”\(^{85}\) The FDA said it was concerned that young teenagers would forgo regular contraception in order to use the morning-after pill, even though the advisory committees had dismissed this concern\(^{86}\) and the FDA itself did not point to any actual data supporting its position.\(^{87}\) The FDA may “make decisions independent of its advisory committees,”\(^{88}\) but rarely, if ever, does so when advisory committee recommendations are also supported by the FDA’s review staff, which was the case with Plan B\(^\circ\) in 2004.\(^{89}\)

As a result of the FDA’s rejection of OTC Status for Plan B\(^\circ\), Senator Hillary Clinton, joined by 23 other U.S. senators, requested an investigation by the Senate and the Government Accountability Office (GAO) into the


\(^{86}\) WAXMAN REPORT, *supra* note 80.

\(^{87}\) Wood et al., *supra* note 36, at 1198.

\(^{88}\) Susan F. Wood, *supra* note 85, at 1651.

\(^{89}\) *Id.* See also Nadine Strossen, *Reproducing Women’s Rights: All Over Again*, 31 VT. L. REV. 1, 8 (Fall 2006) (“It is literally unheard-of for the FDA Commissioner to ignore recommendations by staff and scientific advisory panels. Yet in this situation, the commissioners took extraordinary action contrary to the health an welfare of many thousands of women.”).
inconsistencies of the decision. The GAO determined that the FDA’s review process of Plan B® was irregular in four ways. First, the director in the Office of Drug Evaluation, who is normally responsible for signing off on FDA action letters, did not sign the not-approvable letter, nor did the director of the Office of New Drugs. Second, the FDA review staff was “told early in the review process that the decision would be made by high-level management.” This kind of high-level involvement by management at the FDA is very uncommon for reviews of OTC switch applications, and had previously only been seen in decisions regarding the marketing of prescription drugs. Third, the GAO found some evidence that the decision to not approve Plan B® was made before the review process was even complete. The Director and Deputy Director of the Office of New Drugs reported that they were informed in December, 2003, by the Acting Deputy Commissioner for Operations and the Acting Director of CDER that Plan B® would not be approved. Lastly, the GAO determined that “the Acting Director of CDER’s decision was novel and did not follow FDA’s traditional

90 Seamon, supra note 2, at 549.
91 GAO Report, supra note 52.
92 Id.
93 Id.
94 Id.
95 Id.
96 Id.
97 Id.
practices." The FDA was concerned that OTC marketing of Plan B® might affect younger adolescents decisions to engage in “unsafe sexual behaviors because of their lack of cognitive maturity compared to older adolescents.” This concern was novel for the FDA, which had never before considered behavioral implications resulting from differences in cognitive development in an OTC switch decision. The Acting Director of CDER also asserted that extrapolating data from older to younger adolescents would not be appropriate for purposes of the FDA’s evaluation of Plan B®. However, the FDA has considered this technique scientifically appropriate in the past. Ultimately, the GAO categorized the FDA’s decision to reject the OTC-switch as “unusual.”

Following the initial refusal, the FDA recommended that Barr Pharmaceuticals, now the manufacturer of Plan B®, resubmit its application with an age distinction for OTC availability, suggesting that Plan B® remain prescription-only for females 16 and under. Barr submitted the revised application with the FDA’s recommendations, but the FDA commissioner then "belatedly discovered that the FDA has never before allowed two identical dosage

98 Id.
99 Id.
100 Id.
101 Id.
102 Id.
103 WAXMAN REPORT, supra note 80.
formulations to be sold simultaneously over the counter and by prescription.”\textsuperscript{104} This “belated discovery” delayed the FDA’s decision for almost another year.\textsuperscript{105}

The FDA’s treatment of Plan B\textsuperscript{®}’s OTC switch resulted in the resignation of two prominent figures at the FDA. On August 31, 2005, after the FDA rejected Barr’s second application for an OTC switch of Plan B\textsuperscript{®}, Susan F. Wood resigned her post as assistant commissioner for women’s health and director of the Office of Women’s Health at the FDA.\textsuperscript{106} She stated: “As a scientist, as a career FDA employee, and as the director of the Office of Women’s Health,\textsuperscript{107} whose mission is to be the champion for women’s health at the FDA, I could not sanction this action by remaining at the agency.”\textsuperscript{108} Wood believed that delaying approval of Plan B\textsuperscript{®} for OTC use indefinitely was the result of ignoring “scientific and clinical evidence and the established review process.” She also believed that the FDA’s actions were harmful to women’s health because they denied women “access to a product that can reduce the rate of unplanned pregnancies and the need for abortions.”\textsuperscript{109} Wood had also disagreed with the 2004 decision to consider dual-status of Plan B\textsuperscript{®} “because such dual status has never been required

\textsuperscript{104} Wood et al., \textit{supra} note 36, at 1198.

\textsuperscript{105} \textit{Waxman Report}, \textit{supra} note 80.

\textsuperscript{106} Susan F. Wood, \textit{supra} note 85, at 1650.

\textsuperscript{107} The Office of Women’s Health is “not in the usual decision-making chain for the approval of products at the FDA,” but “provide[s] consultation, serve[s] on working groups, or provide[s] a broad perspective on women’s health” to the review committees “particularly when a product under review has a clear link to women’s health.” \textit{Id.} at 1651.

\textsuperscript{108} \textit{Id.}

\textsuperscript{109} \textit{Id.} at 1650.
for other over-the-counter products sold to adolescents and because the proposal was not based on concerns about safety or efficacy.”110 The FDA’s decision also resulted in the resignation of Dr. Frank Davidoff from his post as consultant to the FDA’s Nonprescription Drugs Advisory Committee.111 Upon resignation he stated: “I can no longer associate myself with an organization that is capable of making such an important decision so flagrantly on the basis of political influence, rather than the scientific and clinical evidence.”112

c. The FDA Approves Plan B for OTC Use By Women 18 and Over, But Maintains Prescription Status for Women Under 18

The FDA finally approved Plan B® for OTC use by women 18 and over on August 24, 2006, while individuals under 18 still need a prescription to obtain the medication.113

Dr. Andrew C. Von Eschenbach, acting commissioner of the FDA at the time of Plan B®’s partial OTC approval, sent Barr a memo the day before the approval was announced which outlined the FDA’s decision to make the age distinction at 18.114 Dr. Von Eschenbach stated that CDER had found OTC

110 Id. at 1651.

111 WAXMAN REPORT, supra note 80.
112 Id. (quoting Plan B Casualties, Hartford Courant (Oct. 2, 2005) (internal quotation marks omitted)).

113 FDA Approves Over-the-Counter Access for Plan B, supra note 1.

availability appropriate for women 17 and older, but the FDA had ultimately decided to make the cutoff at age 18 because a “cutoff point” at that age would “best promote and protect the public health.”\textsuperscript{115} The reasons articulated seem to be only administrative in nature, so that the “well-established state and private-sector infrastructures” could be used to aide in restricting the sale of Plan B\textsuperscript{®} to those 18 and over.\textsuperscript{116} Dr. Von Eschenbach noted that pharmacies, and society in general, “are more familiar with 18 as a cutoff age,” and retail outlets are also familiar with “using 18 as the age restriction for the sale of certain products,” such as tobacco, OTC nicotine replacement therapy products, and OTC cough and cold products with pseudoephedrine.\textsuperscript{117} He also noted that 18 is the age of majority in every state,\textsuperscript{118} but neglected to mention that “the age of consent for sexual intercourse ranges from 12 to 18 under various state laws,” with 16 being the most common age.\textsuperscript{119} Essentially, Dr. Von Eschenbach cited no medical or scientific reason for setting an age distinction for OTC availability of Plan B\textsuperscript{®} at age 18.

\textsuperscript{115} Id.

\textsuperscript{116} Id.

\textsuperscript{117} Id.

\textsuperscript{118} Id.

\textsuperscript{119} Kate Sutherland, \textit{From Jailbird to Jailbait: Age of Consent Laws and The Construction of Teenage Sexualities}, 9 Wm. & Mary J. Women & L. 313, 314 (2003).
As a condition for the partial OTC switch, Barr Pharmaceuticals agreed to institute the CARE\textsuperscript{120} Program, a “rigorous labeling, packaging, education, distribution and monitoring program,”\textsuperscript{121} meant to help enforce the FDA’s new Plan B\textsuperscript{®} regulations. The CARE Program will ensure that Plan B\textsuperscript{®} is distributed only by licensed drug wholesalers, retail pharmacies, and clinics with licensed healthcare practitioners, and not at “convenience stores or other retail outlets where it could be made available to younger women without a prescription.”\textsuperscript{122} The Program will also ensure that Plan B\textsuperscript{®} will be kept behind pharmacy counters so it will not be accessible to individuals over 18 without proof of age.\textsuperscript{123}

2. How States are Handling Plan B\textsuperscript{®}

States are free to regulate drugs approved by the FDA more stringently than the FDA requires, but not less.\textsuperscript{124} Regulation of pharmacy and medical practice is retained by the states under their police powers, and states can therefore regulate how health care professionals administer FDA-approved prescription and nonprescription drugs.\textsuperscript{125} States generally set up pharmacy boards, which are charged with the “powers relating to the regulation, \textsuperscript{120}CARE stands for “Convenient Access, Responsible Education.” FDA Approves Over-the-Counter Access for Plan B, supra note 1.
\textsuperscript{121}FDA Approves Over-the-Counter Access for Plan B, supra note 1.
\textsuperscript{122}Id.
\textsuperscript{123}Id.
\textsuperscript{124}Harper, supra note 24, at 230.
\textsuperscript{125}Harper, supra note 24, at 229.
prescription, dispensation, and sale of prescription and nonprescription drugs”
within the state.\textsuperscript{126}

Some states, even prior to the FDA’s August 2006 decision regarding Plan
B\textsuperscript{®}, are moving toward increased access to EC by allowing pharmacists to
distribute EC without prescriptions. Nine states currently allow direct access to
EC from a pharmacist: Alaska, California, Hawaii, Maine, Massachusetts, New
Mexico, New Hampshire, Vermont, and Washington.\textsuperscript{127} These states have set up
collaborative drug therapy agreements between pharmacists and prescribers,
which “authorize pharmacists to provide emergency contraception directly to
women without having to make a prior visit or consult with a prescriber.”\textsuperscript{128} Drug
initiation, modification, monitoring, continuation and documentation
requirements are agreed upon by the authorizing prescriber and the pharmacist
and are defined in the written collaborative agreement.\textsuperscript{129} These states allow
pharmacists to dispense not only Plan B\textsuperscript{®}, but also other oral contraceptives,\textsuperscript{130}
“that the FDA has indicated are safe and effective for use as EC.”\textsuperscript{131}

\textsuperscript{126} Id.

\textsuperscript{127} Emergency Contraception: A Guide to Over-the-Counter Availability, supra
note 11.

\textsuperscript{128} Jacqueline S. Gardner et al., Increasing Access to Emergency Contraception
Through Community Pharmacies: Lessons from Washington State, 33 FAMILY
PLANNING PERSPECTIVES 172, 172 (2001), available at

\textsuperscript{129} Id.

\textsuperscript{130} See supra Part I.A.1.
C. The Fundamental Right of Individuals to Make Decisions Regarding Procreation

1. The Right to Privacy

The Supreme Court has stated that there is “a right to personal privacy, or a guarantee of certain areas or zones of privacy”132 that are part of the “liberty” protected by the Due Process Clause of the Fourteenth Amendment.133 “This right of personal privacy includes ‘the interest in independence in making certain kinds of important decisions,’”134 such as those concerning marriage,135 procreation,136 contraception,137 family relationships,138 and child rearing and education.139

Whenever the government attempts to restrict an individual’s right to privacy, including rights regarding procreation, the restriction must undergo a strict scrutiny analysis to ensure it does not amount to an undue burden on the

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134 Id. (quoting Whalen v. Roe, 429 U.S. 589, 599-600 (1977)).


individual. The restriction must be justified by a compelling state interest, and must be narrowly tailored to further only that compelling interest.

2. Access to Contraception as Part of Fundamental Right To Make Decisions Regarding Procreation

An individual’s right to make decisions regarding procreation was first explicitly recognized as part of an individual’s right to privacy in Griswold v. Connecticut, which found that a statute prohibiting the use of contraceptives is unconstitutional. The Supreme Court has recognized that “[t]he decision whether or not to beget or bear a child is at the very heart” of an individual’s right to privacy.

While there is not a fundamental “right of access to contraceptives,” access to contraception is essential for an individual to exercise his or her fundamental right to make decisions concerning procreation. All individuals

140 Harper, supra note 24, at 248.

141 Carey v. Population Services Int’l, 431 U.S. 678, 686 (1977) (“where a decision as fundamental as that whether to bear or beget a child is involved, regulations imposing a burden on it may be justified only by compelling state interests, and must be narrowly drawn to express only those interests.”).

142 Id. at 685.

143 Id. See also Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) (“If the right of privacy means anything, it is the right of the individual, married or single, to be free of unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.” (Emphasis omitted)).

144 Carey, 431 U.S. at 688-689 (“regulation ‘may be justified only by a “compelling state interest” . . . and . . . must be narrowly drawn to express only the legitimate state interests at stake.’ . . . This is so not because there is an independent fundamental ‘right of access to contraceptives,’ but because such access is essential to exercise of the constitutionally protected right of decision in
have the right to make decisions concerning procreation without “unwarranted
governmental intrusion.” Government restrictions on distribution and sale of
contraceptives are an intrusion on an individual’s rights to make decisions
concerning procreation because they “clearly burden the freedom to make such
decisions.” Any such restriction must therefore undergo a strict scrutiny
analysis.

The right to privacy is not limited to adults when it comes to decisions
regarding procreation. “Minors, as well as adults, are protected by the
Constitution and possess constitutional rights.” “Neither the Fourteenth
Amendment nor the Bill of Rights is for adults alone.” A state may only place
restrictions on a minor’s fundamental rights if the restrictions “serve any

matters of childbearing that is the underlying foundation of the holdings in

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145 *Eisenstadt*, 405 U.S. at 453.
147 *Carey*, 431 U.S. at 687.
148 Id. at 686 (“where a decision as fundamental as that whether to bear or beget a
child is involved, regulations imposing a burden on it may be justified only by
compelling state interests, and must be narrowly drawn to express only those
interests.”).
149 Id. at 693 ("[T]he right to privacy in connection with decisions affecting
procreation extends to minors as well as to adults.”) (citing *Planned Parenthood
of Central Missouri v. Danforth*, 428 U.S. 52, 74 (1976).).
*See also Prince v. Massachusetts*, 321 U.S. 158, 170 (1944) (“[T]he power of the
state to control the conduct of children reaches beyond the scope of its authority
over adults.”).
151 *In re Gault*, 387 U.S. 1, 13 (1967).
significant state interest . . . that is not present in the case of an adult.”152 The Court articulated its reason for this “unanimous rejection” in Eisenstadt v. Baird:

“It would be plainly unreasonable to assume that (the State) has prescribed pregnancy and the birth of an unwanted child (or the physical and psychological dangers of an abortion) as punishment for fornication.”153

In Carey v. Population Services International,154 the Supreme Court considered the validity of a New York Law making it a crime for anyone to distribute contraceptives to minors under age 16, and for anyone but pharmacists to distribute contraceptives to those over age 16.155

Because minors were still able to obtain contraceptives from physicians under the New York statute, and thus were not completely without access to them, the State argued that the statute did not place a significant burden on minors’ access to contraception.156 The Court disagreed, and held that less than complete

152 Carey, 431 U.S. at 693 (“State restrictions inhibiting privacy rights of minors are valid only if they serve 'any significant state interest . . . that is not present in the case of an adult.' [Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52, 75 (1976).]” (emphasis added) (internal quotations marks omitted)).

153 Id. at 695 (quoting Eisenstadt v. Baird, 405 U.S. 438, 448 (1972).) (internal quotation marks omitted).


155 Carey, 431 U.S. at 681 (“Under New York Ed. Law § 6811(8) . . . it is a crime (1) for any person to sell or distribute any contraceptive of any kind to a minor under the age of 16 years; (2) for anyone other than a licensed pharmacist to distribute contraceptives to persons 16 or over.”).

156 Id. at 697.
bars to access “must still pass constitutional scrutiny,” when, as in *Carey*, there is a significant burden placed on a decision involving procreation. Therefore, the statute still substantially burdened minors even though they were not completely banned from obtaining contraceptives.

New York also argued that the statute was “constitutionally permissible as a regulation of the morality of minors,” furthering the State’s policy of deterring minors from engaging in promiscuous sex. The State did not rely on any medical reasons for limiting “distribution of nonprescriptive contraceptives to minors.” Instead the State argued only that the restriction would serve “to emphasize to young people the seriousness with which the state views the decision to engage in sexual intercourse at an early stage.” The Court did not agree with the State’s arguments, holding that the State was unconstitutionally infringing upon a minor’s right to access contraception, and that regulating “the morality of minors” was not a significant state interest. The Court noted that there is no actual evidence that limiting minors’ access to contraceptives would “substantially discourage early sexual behavior,” and reaffirmed “the principle

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158 *Id.*

159 *Carey*, 431 U.S. at 692.

160 *Id.* at 697.

161 *Id.*

162 *Id.* at 694.
that when a State, as here, burdens the exercise of a fundamental right, its attempt to justify that burden as a rational means for the accomplishment of some significant state policy requires more than a bare assertion, based on a conceded complete absence of supporting evidence, that the burden is connected to such a policy.”164

Regarding access to those over 16, New York argued in Carey that limiting the sale of contraceptives to pharmacists was necessary to facilitate “enforcement of the other provisions of the statute.”165 The Court disagreed, holding that ease of enforcement was not a valid justification for burdening a fundamental right.166 The Court found that “[l]imiting the distribution of nonprescriptive contraceptives to licensed pharmacists clearly imposes a significant burden on the right of the individuals to use contraceptives if they choose to do so.”167 The Court recognized that the burden placed upon individuals was not as great as the burden that would result from a complete ban on distribution, but still found that “the restriction of distribution channels to a small fraction of the total number of possible retail outlets renders contraceptive devices considerably less accessible to the public, reduces the opportunity for privacy of selection and purchase, and lessens the possibility of price

163 Id. at 695.

164 Id. at 696.

165 Id. at 690.

166 Id. at 691 (“As to ease of enforcement, the prospect of additional administrative inconvenience has not been though to justify invasion of fundamental constitutional rights.”).

167 Id. at 689 (citing Eisenstadt v. Baird, 405 U.S. 438, 461-464 (1972).)
competition.”¹⁶⁸ The Court also recognize that the State has a valid interest in protecting an individual’s health,¹⁶⁹ but found that New York’s restriction would unduly “impair the exercise of a constitutional right,”¹⁷⁰ and did not bear any “relation to the State’s interest in protecting health.”¹⁷¹

Carey “remains illustrative of the scope of a minor’s procreative rights,”¹⁷² even though it was decided, as a plurality decision, three decades ago.¹⁷³ The Supreme Court stated in Planned Parenthood v. Casey that it did not doubt the correctness of the decisions in Griswold, Eisenstadt v. Baird, and Carey.¹⁷⁴

II. LEGAL ANALYSIS

A. The FDA’s New Plan B® Regulations Violate Minors’ Fundamental Right To Make Decisions Regarding Procreation

1. Requiring Minors’ to Obtain a Prescription for Plan B® is a Burden on Minors’ Access to Contraception


¹⁶⁹ Id. at 690.

¹⁷⁰ Id. (citing Eisenstadt, 405 U.S. at 464).

¹⁷¹ Carey, 431 U.S. at 690.

¹⁷² Beh & Diamond, supra note 157, at 52.


¹⁷⁴ Planned Parenthood v. Casey, 505 U.S. 833, 852-53 (1992) (“We have no doubt as to the correctness of [the Griswold, Eisenstadt, and Carey] decisions. They support the reasoning in Roe relating to the woman’s liberty because they involve personal decisions concerning not only the meaning of procreation but also human responsibility and respect for it.”).
The Supreme Court considers access to contraception part of an individual’s fundamental right to make decisions regarding procreation.\textsuperscript{175} Because access to contraception is essential to the practice of this right, a burden on the freedom to make decisions concerning procreation exists when the government restricts the distribution and sale of contraceptives.\textsuperscript{176}

The FDA’s regulations do not place a complete ban on access to Plan B\textsuperscript{®} for individuals under 18, because they can still obtain the medication through a prescription. However, a less than complete ban on access does not mean minors are not burdened by the regulation. The Supreme Court held in Carey that less than complete bars to access “must still pass constitutional scrutiny,”\textsuperscript{177} when there is a significant burden placed on a decision involving procreation,\textsuperscript{178} as there is here. Requiring a prescription from a doctor or other health care provider clearly limits access to Plan B\textsuperscript{®} because it could potentially delay taking the medication by anywhere from a few hours to more than a day.\textsuperscript{179} To obtain the medication, a minor would need to “in most cases contact a doctor’s office, schedule an appointment, go to the appointment and get a prescription, get to the

\textsuperscript{175} See supra Part I.C.2.

\textsuperscript{176} Harper, supra note 24, at 249.

\textsuperscript{177} Beh & Diamond, supra note 157, at 54 (citing Carey v. Population Services Int’l, 431 U.S. 678, 697-699 (1977)).

\textsuperscript{178} Id.

\textsuperscript{179} Harper, supra note 24, at 249.
pharmacy, and get the prescription filled\textsuperscript{180} all within the FDA’s recommended 72-hour time frame.\textsuperscript{181} An additional delay could exist in states where physicians have the right to refuse to prescribe EC and pharmacists have the right to refuse to fill a valid prescription for EC\textsuperscript{182} based on their religious beliefs concerning contraception.\textsuperscript{183} Undoubtedly, a burden exists concerning minors’ access to Plan B® because they must acquire a prescription prior to obtaining access to the medication.

2. No Compelling Governmental Interest Justifying Burden

As long as any significant burden is placed upon minors’ rights to obtain Plan B®, as is the case with requiring minors to obtain a prescription for the medication, the government must show a compelling state interest justifying the burden.\textsuperscript{184} The FDA points to two main reasons as to why OTC access of Plan


\textsuperscript{181} See supra Part I.A.2.

\textsuperscript{182} Harper, supra note 24, at 249-250.


\textsuperscript{184} \textit{Carey v. Population Services Int’l}, 431 U.S. 678, 686 (1977) (“where a decision as fundamental as that whether to bear or beget a child is involved,
B® should be limited to individuals 18 and older. The first is that Barr Pharmaceuticals, the manufacturer of Plan B®, failed to determine that the medication is safe and effective for use by adolescents under age 17 without a health care provider’s supervision.\textsuperscript{185} The second, similar to New York’s rationale in \textit{Carey}, is that the FDA is concerned that allowing OTC access to minors will increase sexual promiscuity among minors and that they will use Plan B® as their primary contraceptive method instead of other more common and reliable forms of contraception.\textsuperscript{186} The reasons given by the FDA can not be considered compelling interests for two reasons: 1) none of the FDA’s concerns have been substantiated by scientific evidence,\textsuperscript{187} and 2) the Supreme Court has consistently rejected the argument that regulating the morality of minors is a compelling governmental interest that justifies the infringement of a fundamental right.\textsuperscript{188}

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\textsuperscript{185} Eschenbach Memo, \textit{supra} note 114 (“CDER also determined, however, that Barr had not established that Plan B® could be used safely and effectively by young adolescents – girls 16 and younger – for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug.”).
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\textsuperscript{186} \textit{Waxman Report}, \textit{supra} note 80.
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\textsuperscript{187} \textit{See} discussion \textit{infra} Part II.A.2.a.
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\textsuperscript{188} \textit{Carey}, 431 U.S. at 694 (“The same argument, however, would support a ban on abortions for minors, or indeed support a prohibition on abortions, or access to contraceptives, for the unmarried, whose sexual activity is also against the public policy of many States. Yet, in each of these areas, the Court has rejected the argument, noting in \textit{Roe v. Wade}, that ‘no court or commentator has taken the argument seriously.’”).
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a. Safety and Effectiveness of Plan B®

There are several reasons why the FDA’s assertions regarding Plan B®’s safety and effectiveness in women under 18 are debatable. First, the FDA has never placed age-restrictions on an FDA-approved contraceptive prior to it’s Plan B® decision.189  Second, the FDA has never before required that specific data be provided on the safe and correct use by children and adolescents of other FDA-approved OTC medications.190  Third, professional medical groups dedicated to the study of adolescent health have rejected the idea that use of Plan B® requires a health care professional’s supervision.191  Finally, there is no medical evidence that minors would use Plan B® incorrectly if use of the medication were not supervised by a physician.192

The FDA’s decision to make Plan B® available OTC means that the FDA has found the medication to be safe and effective for self-administration.193  Additionally, the FDA has never before put any age-related restrictions for safety reasons on any FDA-approved contraceptive, whether available OTC or by prescription only.194  The agency, through labeling of oral contraceptives, has already conceded that age is not an issue for safety and effectiveness of any kind

189 See discussion infra Part II.A.2.a.
190 Steinbrook, supra note 69, at 2329.
191 See discussion infra Part II.A.2.a.
192 See discussion infra Part II.A.2.a.
193 See supra Part I.B.2.a.
194 GAO Report, supra note 52.
of oral contraceptive. All oral contraceptives, including EC, contain the following labeling: “Safety and effectiveness of [trade name] have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older.” 195 The FDA itself makes the assumption that ovulation will be suppressed by hormonal contraceptives the same way for any female who has begun menstruating, regardless of her age. 196 Also, results of a study examining adolescents aged 13 to 16 “showed that correct use of EC, the effect on the menses, and the adverse effects were consistent with data on adult women and that there was no reason to restrict access in this age group.” 197 Additionally, no inquiries were made regarding age-related effectiveness and safety before the FDA approved Plan B® for prescription use. 198 Consequently, the FDA did not place any age-restrictions on prescription availability of Plan B®, 199 and has no reason to do so for OTC availability.

195 Id.
196 Id.
198 GAO Report, supra note 52.
199 Id.
Similarly, the FDA has never required specific data on the safe and correct use of other medications for children and adolescents. Incorrect use of Plan B\textsuperscript{®} would not even come close to matching the potential dangers involved with incorrect use of other OTCs, such as acetaminophen, aspirin, and other nonsteroidal anti-inflammatories (NSAIDs). Incorrect use of acetaminophen could lead to serious liver damage, and regular use of NSAIDs could potentially lead to ulcers and bleeding in the stomach. Conversely, the risk of abuse or overdose of Plan B\textsuperscript{®} is unlikely, and if an overdose does occur the consequences are unlikely to be serious. Also, side effects are minor and well known, and interactions with other medications would not be fatal and would not alter Plan B\textsuperscript{®}'s effectiveness. Plan B\textsuperscript{®} is not toxic to women, or their embryos

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\item\footnote{Steinbrook, supra note 69, at 2329.}
\item\footnote{FDA, Use Caution With Pain Relievers (Sept. 2005), http://www.fda.gov/fdac/features/2003/103_pain.html (last visited Mar. 4, 2007) (“Acetaminophen can cause liver injury through the production of a toxic metabolite. The body eliminates acetaminophen by changing it into substances (metabolites) that the body can easily eliminate in the stool or urine. Under certain circumstances, particularly when more acetaminophen is ingested than is recommended on the label, more of the harmful metabolite is produced than the body can easily eliminate. This harmful metabolite can seriously damage the liver. . . . Serious cases of liver disease may lead to mental confusion, coma, and death.”).}
\item\footnote{Id. (“Consumers should also know that there is a potential for gastrointestinal bleeding associated with the use of aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen.”). See also The American College of Gastroenterology, The Dangers of Aspirin and NSAIDs (2006), http://gi.org/patients/women/asprin.asp (last visited April 23, 2007).}
\item\footnote{Citizen’s Petition, supra note 72.}
\item\footnote{Id.}
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if it is mistakenly taken while pregnant.\textsuperscript{205} Plan B\textsuperscript{®} is clearly safer than other more common products which are currently readily available OTC to minors.

The need for a physician’s supervision of an adolescent taking Plan B\textsuperscript{®} is also questionable. While Plan B\textsuperscript{®} was still only available by prescription to women of all ages, professional groups were encouraging physicians to prescribe EC without first meeting with their patients. The Society for Adolescent Medicine (SAM) asserts that calling in prescriptions over the phone without first examining a patient in need of EC is essential to ensuring timely access to the medication.\textsuperscript{206} Pregnancy tests, pelvic exams, Pap smears, and testing for sexually transmitted diseases are rarely indicated before prescribing EC,\textsuperscript{207} due to the fact that EC does not pose any harm to a woman, or a fetus if she is already pregnant and takes the medication accidentally.\textsuperscript{208} SAM also encouraged physicians to offer advance prescriptions of EC to adolescents, so that they would have more timely access to the drug if they needed it.\textsuperscript{209} Endorsements for advance provision of Plan B\textsuperscript{®} by a medical association dedicated to promoting the health of adolescents demonstrates that supervision by a health care professional is unnecessary.

\textsuperscript{205} \textit{Id.}

\textsuperscript{206} Gold et al., \textit{supra} note 6, at 67.

\textsuperscript{207} \textit{Id.}

\textsuperscript{208} Citizen’s Petition, \textit{supra} note 72.

\textsuperscript{209} Gold et al., \textit{supra} note 6, at 68.
The FDA’s fear that adolescents will take Plan B® incorrectly is also not supported by scientific evidence. Women’s Capital Corporation, the distributor of Plan B® before Barr, conducted an actual use study upon applying for OTC status with the FDA. 210 The study involved two subgroups, women 16 and under and women 17 and older. 211 The FDA was involved in designing the studies protocols. 212 The study showed that minors “were not substantially more likely than others to use the product in a contraindicated or incorrect manner and did not have notably higher risks of adverse events or pregnancy.” 213 The study concluded that there was no indication that women of any age group need a physician’s supervision in order to take EC correctly and safely. 214 Additionally, even if a woman takes EC contrary to the FDA’s recommendations, there is essentially no harm posed or reduction in effectiveness. Both tablets of Plan B® can be taken at the same time with no reduction in effectiveness or an increase in side effects. 215 It has actually been suggested that adolescents should be instructed to take both tablets at the same time because it is an easier regimen to comply with. 216

210 Raymond et al., supra note 74, at 18.

211 Id.

212 Id.

213 Id. at 21-22.

214 Id. at 23.

215 Gold et al., supra note 6, at 68.

216 Id.
The FDA does not point to any medical or scientific evidence of problems with safety and efficacy of Plan B® which justify the age-restriction it has set forth. Unsubstantiated claims are not enough to justify the burden the FDA has placed on minors’ access to Plan B® by requiring them to obtain prescriptions prior to use.217 The FDA’s own Nonprescription Drugs and Reproductive Health Drugs Committees found that Plan B® should be available OTC to women of all ages because safety and effectiveness are not an issue.218 Even the small minority of those on the committees who voted against the OTC switch stated that they did so for reasons other than safety or efficacy.219 Because safety and efficacy are the only factors the FDA can consider when deciding on an OTC switch application,220 and the FDA points to no medical or scientific evidence challenging either factor, the FDA’s rationale for its regulations serves no compelling interest which justifies the burden it has placed on minors access to Plan B®.

b. Access to Plan B® Will Not Increase Sexual Promiscuity Among Minors

217 Carey v. Population Services Int’l, 431 U.S. 678, 696 (1977) (“we again confirm the principle that when a State, as here, burdens the exercise of a fundamental right, its attempt to justify that burden as a rational means for the accomplishment of some significant state policy requires more than a bare assertion, based on a conceded complete absence of supporting evidence, that the burden is connected to such a policy.”).

218 Gold et al., supra note 6, at 68.

219 Wood et al., supra note 36, at 1197-1198.

220 21 C.F.R. § 310.200(b).
There are also two reasons why the FDA’s assertions regarding a change in minors’ sexual activity with OTC access of Plan B® are unfounded. First, there is no evidence in support of the FDA’s contention that OTC access to EC will increase unprotected sex among adolescents. Second, there is no evidence that OTC access to Plan B® will decrease minors’ use of more common and reliable forms of contraception, as the FDA claims. The FDA’s regulations concerning Plan B® are most likely an attempt by the FDA to limit the sexual activity of minors, which is not a compelling interest justifying the burden it has placed on minors access to EC.

There is no support for the FDA’s assertion that access to EC will increase unprotected sex among adolescents. Two studies of U.S. women ages 15 to 24 were conducted to examine whether or not advance provision of EC would increase the frequency of unprotected sex. One group of women received EC in advance, while the other only received education about EC. The studies concluded “[t]here were no differences in the frequency of unprotected sex between the groups.” The studies did show, however, that the group that received EC in advance was two to three times more likely to use it after

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221 See discussion infra Part II.A.2.b.

222 Id.

223 Klein, supra note 6, at 1043.

224 Id.

225 Id.
unprotected sex occurred, and that they were more likely to use it sooner, when it is more effective.\textsuperscript{226}

Another FDA concern is that if Plan B® is available to women under 18 OTC, they will stop using other regular methods of birth control, and instead use Plan B® as their primary method. However, “there is no evidence that [OTC] availability of Plan B® leads to substitution of emergency contraception for the regular use of other methods of contraception.”\textsuperscript{227} The two U.S. studies conducted by Women’s Capital Corporation, mentioned above, also showed that there was no decrease in consistent condom use among the group of women who were provided with advance EC\textsuperscript{228}. A similar study in the United Kingdom came to the same conclusions.\textsuperscript{229} There is some speculation that the cost of OTC Plan B® alone is enough of a deterrent from regular use, considering that one regimen of Plan B® costs between $30 and $40.\textsuperscript{230}

Another study, conducted in response to the FDA’s claim that there was a lack of data on young adolescents relating to Plan B®, concluded that “[y]oung adolescents with improved access to EC used the method more frequently when needed, but did not compromise their use of routine contraception nor increase

\textsuperscript{226} Id.

\textsuperscript{227} Steinbrook, \textit{supra} note 69, at 2327.

\textsuperscript{228} Klein, \textit{supra} note 6, at 1043.

\textsuperscript{229} Id. at 1044 (“A longitudinal study of teens and young women in the United Kingdom found that only 4% of emergency-contraception users reported taking emergency contraception more than twice within 1 year, suggesting that repeated use of emergency contraception within this group was not common.”).

\textsuperscript{230} Steinbrook, \textit{supra} note 69, at 2327.
their sexual risk behavior.”231 The study involved adolescents age 15 to 19.232 It showed that use among the youngest adolescents, those under 16, was the same, and in some instances slightly better, than those over 16.233 The study also found that 62% of adolescents only used EC once, which is similar to statistics regarding adult use.234 Additionally, 93% of all the adolescents who used EC in the study used it correctly, and the number increased to 97% for those under 16. Finally, those under 16 were significantly more likely to continue consistent condom use before and after they were provided with EC than were the older adolescents.235 “The high levels of correct use in the advance provision group in this study suggest that physician supervision does not 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.”236

231 Cynthia C. Harper et al., supra note 197, at 483 (“use among the youngest adolescents (38%) was the same as the middle group (38%), and slightly higher than the older adolescents aged 18-19 years (33%).”).

232 Id. at 486.

233 Id.

234 Id. (“Sixty-two percent of adolescents who used [EC] only used it once, similar to 65% in adults.”).

235 Id. at 488 (“the youngest age group was significantly more likely to report consistent condom use both at enrollment and follow-up (30%) than the middle and older adolescents (16% and 13%, respectively).”).

236 Id. at 490.
Again, unsubstantiated claims are not enough to justify the burden the FDA has placed on minors’ access to Plan B®. The FDA advisory committees were provided with studies demonstrating that women of all ages given ready access to EC “do not routinely use less effective regular contraception, do not engage more often in high-risk sexual behavior, do not become more promiscuous, and do not have increased rates of pregnancy or sexually transmitted diseases.” With an obvious lack of support for the FDA’s rationale for limiting minors’ access to Plan B®, one can only conclude that the FDA’s regulations are an attempt to restrict the sexual activity of minors. This attempt is nearly identical to the one made by the state of New York in Carey, which the Supreme Court held not to be a compelling state interest justifying the burden placed upon minors’ access to contraception.

c. FDA Decision to Make “Cutoff Age” 18 is Questionable

Even if the FDA could somehow justify their decision to restrict Plan B® OTC access to minors, that restriction should definitely not extend to those minors who are between the ages of 17 and 18. The Director of CDER at the FDA, Steven Galson, concluded that there was no need for prescription

237 Carey v. Population Services Int’l, 431 U.S. 678, 696 (1977) (“we again confirm the principle that when a State, as here, burdens the exercise of a fundamental right, its attempt to justify that burden as a rational means for the accomplishment of some significant state policy requires more than a bare assertion, based on a conceded complete absence of supporting evidence, that the burden is connected to such a policy.”).

238 Wood et al., supra note 36, at 1198.

239 Carey, 431 U.S. at 692.
dispensing of Plan B® for women 17 and over.\textsuperscript{240} Galson later retracted this finding, however, stating: “although I previously concluded that OTC use should be restricted to women 17 or older, I have now determined that for the reasons Dr. Von Eschenbach outlines, the approval of this application should reflect a restriction to OTC use for those 18 or older.”\textsuperscript{241} FDA commissioner, Dr. Von Eschenbach, stated that the only reasons the cutoff age should be 18, rather than 17, were that society is more familiar with 18 as a cutoff age and it is the age of majority in every state, thus making enforcement of the regulation easier.\textsuperscript{242} As previously discussed,\textsuperscript{243} administrative ease is not a compelling state interest that can justify the infringement of a fundamental right.\textsuperscript{244} Clearly, the reason asserted by the FDA for making the cutoff age 18 instead of 17 is for purposes of administrative ease, and the cutoff is therefore not a compelling state interest that justifies the infringement.

B. The FDA’s New Plan B® Regulations Are Violating The Fundamental Right of Individuals 18 and Over To Make Decisions Regarding Procreation

\textsuperscript{240} Eschenbach Memo, \textit{supra} note 114.


\textsuperscript{242} Eschenbach Memo, \textit{supra} note 114.

\textsuperscript{243} \textit{See supra} Part I.C.2.

\textsuperscript{244} \textit{Carey}, 431 U.S. at 691 (“As to ease of enforcement, the prospect of additional administrative inconvenience has not been thought to justify invasion of fundamental constitutional rights.”).
1. Requiring Individuals 18 and Over to Obtain Plan B® From A Pharmacist is a Burden on Access to Contraception

As previously discussed, access to contraception is essential to the exercise of an individual’s fundamental rights concerning decisions about procreation,\(^{245}\) and a burden on that right exists when the government restricts the distribution and sale of contraceptives.\(^{246}\)

Under Barr Pharmaceuticals CARE program, a program Barr agreed to implement as a condition for OTC availability for individuals 18 and over, Plan B® will only be available from “licensed drug wholesalers, retail operations with pharmacy services, and clinics with licensed healthcare practitioners.”\(^{247}\) Plan B® will not be sold at “convenience stores or other retail outlets where it could be made available to younger women without a prescription.”\(^{248}\) Retail Pharmacies must keep Plan B® behind-the-counter,\(^{249}\) and request proof of age when selling it without a prescription.\(^{250}\)

\(^{245}\) See supra Part I.C.2.

\(^{246}\) Harper, supra note 24, at 249.

\(^{247}\) FDA Approves Over-the-Counter Access for Plan B, supra note 1.

\(^{248}\) Id.


\(^{250}\) Although the FDA has not laid out specific procedures for verifying proof of age (Reproductive Health Technologies Project, Plan B OTC: What Will It Look Like? (Oct. 2006), http://www.rhtp.org/documents/PlanBOTC-
The FDA’s behind-the-counter requirement, nearly identical to the statute struck down by the Supreme Court in *Carey*, poses a significant burden to access for many individuals over 18 seeking to purchase Plan B®, legally, without a prescription. In *Carey*, the Supreme Court held that “[l]imiting the distribution of nonprescriptive contraceptives to licensed pharmacists clearly imposes a significant burden on the right of the individual to use contraceptives if they choose to do so.”251 The Court stated that even though the statute did not completely ban individuals 16 and over from purchasing OTC contraceptives, limiting where contraception could be sold made “contraceptive devices considerably less accessible to the public,” reducing “the opportunity for privacy of selection and purchase.”252 Making a woman go to the pharmacy counter to request Plan B®, and then present identification, would produce the same results: a woman may be intimidated and her privacy in purchasing the product will be invaded. A woman may be deterred from purchasing the product,253 which she is legally allowed to purchase, thus burdening her access.

Whatwillitlooklike.pdf (last visited Mar. 3, 2007)). Plan B® purchasers will have to provide some form of identification at the pharmacy counter proving that they are in fact at least 18. (FDA, *Plan B: Questions and Answers* (Dec. 14, 2006), http://www.fda.gov/cder/drug/infopage/planB/planBQandA20060824.htm (last visited Jan. 25, 2007)). The Drug Enforcement Administration (DEA) has guidelines for pharmacies to follow for checking identification when selling products containing pseudoephedrine, and pharmacies may ultimately decide to follow the same guidelines when selling Plan B®. (*Plan B OTC: What Will It Look Like?, supra* (Provides a complete list of DEA-acceptable forms of identification for purchasing pseudoephedrine.).)


252 *Id.* at 689.

253 Wood et al., *supra* note 36, at 1198.
2. No Compelling Governmental Interest Justifying Burden

While the Supreme Court has pointed out that regulations regarding contraception are not always invalid, the regulations must not infringe upon protected individual choices unless they serve a sufficiently compelling state interest.\(^{254}\) The FDA has stated that its main reason for keeping OTC Plan B® behind-the-counter is to enforce the restrictions on OTC sales to those 18 and older.\(^{255}\) Ease of enforcement of an age restriction is not enough to justify invasion of a fundamental constitutional right.\(^{256}\) The “compelling interest” cited by the FDA for allowing only pharmacists to sell nonprescription contraceptives to individuals 18 and over is nearly identical to the reason cited by New York in defense of its statute in Carey.\(^{257}\) The FDA’s desire to enforce its regulation

\(^{254}\) Carey, 431 U.S. at 685-686 ("That the constitutionally protected right of privacy extends to an individual’s liberty to make choices regarding contraception does not, however, automatically invalidate every state regulation in this area. The business of manufacturing and selling contraceptives may be regulated in ways that do not infringe protected individual choices. And even a burdensome regulation may be validated by a sufficiently compelling state interest.").

\(^{255}\) FDA Letter to Duramed, supra note 249 ("[W]e note and agree with the other elements of the CARE Program . . . which are designed to ensure compliance with the approved labeling, and particularly the restriction of OTC use to ages 18 and older. The program includes the following elements: The sponsor and third party distributors, wholesalers, and chain drug companies will only distribute Plan B® to licensed pharmacies or other licensed healthcare clinics. As a result, Plan B® will not be sold at gas stations or convenience stores. Given that Plan B® will have both Rx and OTC labeling, the pharmacies will keep Plan B® behind-the-counter.” (emphasis added).).

\(^{256}\) Carey, 431 U.S. at 691 ("As to ease of enforcement, the prospect of additional administrative inconvenience has not been thought to justify invasion of fundamental constitutional rights.").
allowing only those 18 and over to purchase Plan B® OTC should therefore be similarly dismissed as a compelling government interest.

III. PLAN B® DECISION INCORRECT: FDA IMPROPERLY INFLUENCED BY POLITICAL AND SOCIAL FACTORS

The decision regarding Plan B®’s OTC availability was noticeably and unduly influenced by political and social pressures rather than medical or scientific evidence. The Bush Administration’s actions, and comments by the President himself, have demonstrated social conservatives’ support for restrictions to access of Plan B®. Also, the FDA’s decision to open up the question regarding dual-status of the same drug at the same dosage to public comment suggests the agency was looking at considerations other than safety and efficacy of the drug when considering Plan B®’s OTC-switch application. The “FDA’s success depends on its decisionmaking [sic] not becoming politicized,” and “it goes without saying that the FDA’s decisions must be insulated from partisan

257 See supra Part I.C.2.

258 See discussion infra Part III.

259 Waxman, supra note 83, at 19 (“The agenda of social conservatives includes limiting access to the morning-after pill. In this area, the Administration has again disregarded science to make appointments and important regulatory decisions that further this agenda.”).


politics.”\textsuperscript{262} However, it is obvious that political and social pressure influenced the FDA’s decision,\textsuperscript{263} and as a result the restrictions the FDA’s regulations have placed on Plan B\textsuperscript{®} are clearly unreasonable and should be changed.

President Bush’s nomination of Dr. W. David Hager to serve as chairman of the FDA’s Reproductive Health Advisory Committee in October of 2002\textsuperscript{264} demonstrates the President’s support for restrictions on access to Plan B\textsuperscript{®}.\textsuperscript{265} The Reproductive Health Advisory Committee advises the FDA Commissioner on the safety and efficacy of drugs “for use in the practice of obstetrics, gynecology, and related specialties.”\textsuperscript{266} Dr. Hager is a conservative religious activist\textsuperscript{267} whose major publications include “writings on the use of prayer for the treatment of premenstrual disorder.”\textsuperscript{268} He has often expressed his strong religious views concerning abortion, and has been active in trying to have mifepristone removed

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\item \textit{Id.}
\item \textit{Waxman Report}, \textit{supra} note 80.
\item Seamon, \textit{supra} note 2, at 536 (“With his appointment of Dr. Hager, critics perceived President Bush as stacking the FDA with conservative cronies who obfuscate the issues surrounding EC.”).
\item \textit{Waxman Report}, \textit{supra} note 80.
\item Seamon, \textit{supra} note 2, at 536.
\end{enumerate}
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from the market. Dr. Hager was reported as saying the White House called him and asked him to join the committee “because ‘there are some issues coming up we feel are very critical, and we want you to be on the advisory board.’” Although Dr. Hager was “ultimately not appointed chair,” he was named as a member of the committee, and was one of four dissenting votes for approval of Plan B®’s OTC status for women of all ages. The Bush Administration has defended Dr. Hager’s appointment consistently, claiming Dr. Hager is “well qualified” and that concerns about his appointment at the FDA are “offensive and wrong.”

President Bush’s public statements regarding Plan B® are further evidence of his support of the FDA’s restrictions. Prior to the FDA’s announcement regarding approval of OTC status for women 18 and over, President Bush was quoted as saying, “I believe that Plan B® . . . ought to require

269 Id.

270 Marc Kaufman, Memo May Have Swayed Plan B Ruling, WASH. POST, May 12, 2005, at A02.

271 WAXMAN REPORT, supra note 80.

272 Waxman, supra note 83, at 22.

a prescription for minors.” President Bush has also publicly stated that he supports the FDA’s 2006 decision limiting access to minors.

The FDA’s request for public comment on Plan B®’s dual-status is another example of how factors other than safety and efficacy played a part in the FDA’s decision concerning OTC access of Plan B®. This request by the FDA was unprecedented. While the FDA wanted comments regarding the regulatory and policy issues surrounding marketing the same ingredient at the same dosage for OTC and prescription use, it received roughly 47,000 comments containing specific statements about Plan B®’s approval in general. It is hard to imagine that the FDA ignored all the comments simply

274 President George W. Bush, Press Conference by the President (Aug. 21, 2006) (transcript available at http://www.whitehouse.gov/news/releases/2006/08/print/20060821.html (last visited Mar. 4, 2007)) (responding to the question: “Mr. President, some pro-life groups are worried that your choice of FDA Commissioner will approve over the counter sales of Plan B, a pill that, they say, essentially can cause early-term abortions. Do you stand by this choice, and how do you feel about Plan B in general?”).

275 Id. (“I support Andy’s decision.”).

276 FDA Takes Action on Plan B, supra note 260. See also Harper, supra note 24, at 233-234 (“On August 26, 2005, FDA Commissioner Lester M. Crawford further delayed the approval of EC for OTC by publishing an advance notice of proposed rulemaking (NPRM). The NPRM asked the public to comment on whether the FDA has the authority to market a drug with the same active ingredients in a prescription and nonprescription form simultaneously.”).

277 Id.

278 Harper, supra note 24, at 234.
because they were not what the agency was looking for in its request to the public. Concerned Women for America, a group opposing the expansion of access to Plan B®, submitted 30 pages of comments, some of which contained societal issues related to the drug.280 “Societal issues” concerning Plan B®, and public opinions of Plan B®, should not have been considered at all by the FDA. The agency should be considering scientific data only, concerning safety and efficacy, when making decisions about drug regulations.

Based on the medical information available, the FDA’s decision to place an age restriction on the OTC availability of Plan B® is not in keeping with its responsibility to protect and promote public by monitoring the safety, efficacy and security of drugs.281 The FDA is charged with the power to make drugs that have been proven safe and effective for self-medication available to the public OTC,282 and the “FDA should not consider the social consequences potentially associated with the use of an FDA-approved product.”283 Plan B® should be available to women of all ages, without a prescription, as a true over-the-counter drug which would not require purchase directly from a pharmacist or the provision of


281 Taylor, supra note 261, at 805 (“FDA’s job is to protect and promote public health by regulating the safety, effectiveness and proper labeling of products within its jurisdiction, in accordance with standards established by law.”).

282 Steinbrook, supra note 69, at 2328.

283 Taylor, supra note 261, at 806.
identification. Safety and effectiveness should have been the only factors considered by the agency;\textsuperscript{284} politics and the morals of certain members of our society should never have entered into the FDA’s decision-making process.\textsuperscript{285}

**IV. CONCLUSION**

Plan B®’s availability as an over-the-counter medication has been intensely debated in the media, among government officials, and among society as a whole. The goal of this paper is to explain why the FDA’s new Plan B® regulations are a violation of an individual’s fundamental right to make decisions concerning procreation. Individuals have a right to make decisions about procreation, and thus contraception, without being unduly burdened by government regulation. The FDA’s regulations concerning Plan B® violate individuals’ rights concerning access to contraception in two ways: 1) requiring a prescription for females under 18 without medical evidence to justify the requirement is a bar to access for those under 18, and regulating the morality of minors is not a compelling state interest which justifies the infringement of their rights; and 2) requiring Plan B® to be kept behind the pharmacy counter and proof of age to purchase the drug OTC is a bar to access for those over 18, and

\textsuperscript{284} Steinbrook, *supra* note 69, at 2328.

\textsuperscript{285} See Taylor, *supra* note 261, at 805 (“the values and interests that are properly germane to FDA decisionmaking [sic] should be derived from law, not from the personal views and values of government officials, pressures brought to bear by outside parties, or the sometimes media-driven ‘issue of the day.’”).
enforcement of the age-restriction is not a compelling governmental interest which justifies the infringement.

The FDA is supposed to consider only safety and effectiveness when deciding whether or not to switch a drug from prescription to OTC status; the FDA should not be influenced by political or social pressures that run counter to scientific and medical evidence. However, in the case of Plan B® the FDA did not base its decision on any medical or scientific evidence regarding the safety and effectiveness of the drug. Instead, the FDA cited reasons very similar to those the Supreme Court has consistently rejected, concerning restrictions on access to contraceptives, for the past 30 years. In sum, the FDA made the wrong decision about Plan B®; Plan B® should be available to all women of all ages without a prescription because it has been proven safe and effective for over-the-counter use.