THE CONSTITUTIONALITY OF THE FDA'S AGE-BASED PLAN B® REGULATIONS:

WHY THE FDA MADE THE WRONG DECISION

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I. 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,[1] numerous studies and recommendations, and a Government Accountability Office investigation,[2] 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.[3] 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.[4]

The right of individuals to make decisions concerning contraception was first recognized by the Supreme Court in 1965 with its decision in *Griswold v. Connecticut*.[5] This paper argues that the FDA's regulations concerning Plan B®

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1. *See* discussion *infra* Part II.B.2.b.

2. *Id.*

3. 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 (Aug. 24, 2006), http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html [hereinafter FDA Approves Over-the-Counter Access for Plan B].

4. Matthew J. Seamon, *Plan B for 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.").

5. Carey v. Population Serv. Int'l, 431 U.S. 678, 685 (1977) (recognizing that the right to decide "whether or not to beget or bear a child" was first explicitly recognized in

violate individuals' rights concerning access to contraception in two ways: (1) requiring a prescription for females under eighteen, without medical evidence justifying the requirement, constitutes an impermissible barrier to access for those under eighteen, and regulating the morality of minors is not a sufficient state interest to justify the infringement of their rights; and (2) requiring Plan B® to be kept behind the pharmacy counter and requiring proof of age to purchase the drug OTC is a barrier to access for those over eighteen, and enforcement of the age-restriction is not a compelling governmental interest which justifies the infringement.

Part II 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 II concludes with a summary of constitutionally recognized reproductive rights, including access to contraception and a case analysis of *Carey v. Population Services International*, the landmark Supreme Court case which held unconstitutional a statute prohibiting the sale of contraception to minors.[6]

Part III discusses the constitutionality of the FDA's regulations, and explains 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 compelling governmental interests. This section applies the Supreme Court's decision in *Carey* to the FDA's regulations regarding Plan B®.

Finally, the Conclusion discusses the political and social influence surrounding the FDA's decision to make an age distinction for OTC availability of Plan B® 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®.

II. 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 sexual intercourse (post-coitally), when another contraceptive method was not used or has failed.[7] All forms of contraception, including EC, work prior to implantation of a fertilized egg, by delaying or inhibiting

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Griswold v. Connecticut, 381 U.S. 479 (1965), which held unconstitutional a statute prohibiting the use of contraceptives).

6. *Id.* at 678.

7. Int'l Consortium for Emergency Contraception, What is Emergency Contraception?, http://www.cecinfo.org/what/index.htm (last visited Mar. 1, 2007).

ovulation, blocking fertilization, or preventing implantation.[8] EC does not interrupt or harm an established pregnancy.[9]

The FDA has approved two different types of EC pills: a combination pill containing progestin and estrogen, and a progestin-only pill.[10] Evidence indicates that the progestin-only form of EC is more effective than the combination pills.[11] Plan B®, a progestin-only pill containing the hormone levonorgestrel, is the only EC pill currently available in the United States.[12] Levonorgestrel is a hormone that has been used in oral contraceptives (OCs) for 35 years,[13] and its use as an EC "has been extensively studied worldwide" for more than three decades.[14] 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."[15] Some other contraindications for progestin-only ECs may include rare hypersensitivity to an ingredient in the medication, and undiagnosed abnormal vaginal bleeding.[16]

Although the safety and effectiveness of EC pills has been well-documented,[17] some women may experience mild side effects. These side effects primarily include nausea and vomiting, and, occasionally, fatigue, breast tenderness, headaches, dizziness, and abdominal pain can also occur.[18] Taking an anti-nausea medication one hour before taking an EC pill can easily minimize common gastrointestinal side effects.[19] Also, progestin-only pills cause significantly less nausea and vomiting than the estrogen-progestin combination pills.[20] Another possible side effect is a slight alteration in

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8. Briefing Paper, *Governments Worldwide Put Emergency Contraception into Women's Hands,* Center for Reproductive Rights, Sept. 2004, at 2, *available at* http://www.reproductiverights.org/pdf/pub_bp_govtswwec.pdf.

9. Melanie A. Gold, Gina S. Sucato, Lee Ann E. Conard & Paula J. Adams Hillard, Position Paper of the Soc'y for Adolescent Med., *Provision of Emergency Contraception to Adolescents*, 35 J. OF ADOLESCENT HEALTH 66, 67 (2004); *see also* Jonathan D. Klein & Comm. on Adolescence, *Emergency Contraception*, 116 PEDIATRICS 1026, 1030 (2005). ("A review of information suggests that there is no evidence demonstrating that any of the emergency-contraception methods are teratogenic.").

10. Seamon, *supra* note 4, at 529.

11. Klein, *supra* note 9, at 1032.

12. Seamon, *supra* note 4, at 529.

13. Duramed (subsidiary of Barr Pharmaceuticals, Inc.), Frequently Asked Questions, How does Plan B® work?, http://www.go2planB.com/ForConsumers/TakingPlanB/faqs.aspx (last visited Nov. 26, 2007).

14. Kathleen H. Besinque & Donald F. Downing, *Emergency Contraception: A Guide to Over-the-Counter Availability*, U.S. PHARMACIST, Dec. 2006, http://www.uspharmacist.com/index.asp?page=ce/105394/default.htm (last visited Nov. 26, 2007.).

15. Klein, *supra* note 9, at 1030.

16. Gold et al., *supra* note 9, at 67.

17. Besinque & Downing, *supra* note 14.

18. Gold et al., *supra* note 9, at 66.

19. *Id*. at 67.

20. *Id*.

menstruation "depending on the timing of [EC's] administration within the menstrual cycle."[21] Overall, there is little concern about the safety of EC pills.[22]

While Plan B® is the only drug currently marketed as EC in the United States, certain OCs[23] had been used off-label[24] for post-coital prevention of pregnancy since 1974.[25] "Women were typically instructed to take two doses, of two to five of their regular birth control pills, 12 hours apart."[26] In 1997, the FDA "explicitly sanctioned" this off-label use, commonly referred to as the "Yuzpe Regimen."[27] It published "a list of approved birth control pills that could be used as [EC], and provided an accompanying chart showing the dosage conversion."[28] The Yuzpe Regimen is most often utilized "in hospitals, university health clinics, and, to a lesser extent, by physicians in private practice."[29] It may not be as effective as levonorgestrel alone, and has a greater likelihood of side effects.[30]

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

Plan B® is the only EC pill available in the United States today.[31] The FDA first approved it for prescription use in 1999.[32] On August 24, 2006, the FDA announced that Plan B® would be available over-the-counter (OTC) to

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21. Klein, *supra* note 9, at 1031 ("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.").

22. *See, e.g.,* The Emergency Contraception Website, *Answers to Frequently Asked Questions About…," available at* http://ec.princeton.edu/questions/ecsideeffects.html (last visited Dec. 3, 2007) ("Emergency contraceptive pills have no long-term or serious side effects, and emergency contraception is safe for almost every woman to use.").

23. OCs appropriate for off-label use as EC include: Alesse, Aviane, Levlen, Levlite, Levora, Low-Ogestrel, Lo/Ovral, Nordette, Ogestrel, Ovral, Ovrette, Tri-Levlen, Triphasil, and Trivora. *Id*. at 1027 (Table 1).

24. "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).

25. Seamon, *supra* note 4, at 525.

26. *Id*. at 526.

27. Samantha Harper, Note, *"The Morning After": How Far Can States Go To Restrict Access to Emergency Contraception?*, 38 COLUM. HUM. RTS. L. REV. 221, 224 (2006); *see also* Besinque & Downing, *supra* note 14.

28. Harper, *supra* note 27, at n.12 (citing Prescription Drug Products: Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610-01, 8611 (Feb. 25, 1997)).

29. Seamon, *supra* note 4, at 525-26. This paper is not focused on the Yuzpe Regimen and is not referring to it when discussing access to EC.

30. Besinque & Downing, *supra* note 14.

31. Seamon, *supra* note 4, at 529.

32. Klein, *supra* note 9, at 1026.

individuals (both men and women) eighteen years of age and older.[33] However, the drug remains available by prescription only to females under 18.[34] Plan B® 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.[35] Plan B® is packaged as two pills, each containing 0.75 milligrams of levonorgestrel.[36] The first pill should be taken within 72 hours after unprotected or underprotected sex, and the second should be taken 12 hours later.[37] When taken correctly, Plan B® reduces the occurrence of pregnancy by 89%.[38]

There is some indication that Plan B® may still be effective if used after the initial 72-hour period has elapsed.[39] The FDA has only approved use of Plan B® within 72 hours after intercourse.[40] However, it can take approximately six to seven days from the time of intercourse or ovulation for implantation to occur.[41] Therefore, it makes sense that Plan B® may still be effective if taken within 120 hours, or five days, after sex.[42] Plan B®'s success rate diminishes rather quickly, however: "The risk of pregnancy increases from 0.4 percent if contraception is initiated within 24 hours to 2.7 percent if it is initiated 48 to 72 hours after intercourse."[43] 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.[44] "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."[45] The FDA has not approved this use of Plan B®.[46] However, taking the two doses together would be simpler, and could therefore increase the likelihood that the drug will be taken properly.[47]

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33. FDA, Plan B: Questions & Answers, http://www.fda.gov/cder/drug/infopage/planB/planBQandA20060824.htm (last visited Nov. 16, 2007).

34. FDA Approves Over-the-Counter Access for Plan B, *supra* note 3.

35. Besinque & Downing, *supra* note 14.

36. FDA, *supra* note 33.

37. Klein, *supra* note 9, at 1028.

38. Duramed (subsidiary of Barr Pharmaceuticals, Inc.), What is Plan B®?, http://www.go2planb.com/ForConsumers/AboutPlanB/WhatisPlanB.aspx (last visited Nov. 25, 2007).

39. Gold et al., *supra* note 9, at 66 ("Though FDA-approved for use up to 72 hours after unprotected intercourse, ECPs have been shown to reduce the risk of pregnancy if taken up to 120 hours after intercourse.").

40. Besinque & Downing, *supra* note 14.

41. *Id*.

42. Gold et al., *supra* note 9, at 66.

43. Alastair J.J. Wood, Jeffrey M. Drazen & Michael F. Greene, *A Sad Day for Science at the FDA*, 353 NEW ENG. J. MED. 1997, 1997 (2005).

44. Klein, *supra* note 9, at 1028.

45. Besinque & Downing, *supra* note 14.

46. *Id.*

47. *Id.*

3. Emergency Contraception and Abortion Distinguished

There is often a misconception that Plan B®, and EC in general, causes abortions.[48] But Plan B® is not an "abortion pill."[49] There is an abortion pill, mifepristone (Mifeprix®, commonly referred to as RU-486), that has been available by prescription in the United States since it was approved by the FDA in 2000,[50] but it is not the same as Plan B®.[51] It should be noted that mifepristone may be used in low doses as EC.[52] However, the opposite is not true: even high doses of Plan B® will not cause an abortion.[53]

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.[54] Contraception occurs when a pregnancy is prevented by delaying or inhibiting ovulation, blocking fertilization, or preventing implantation of a fertilized egg.[55] Therefore, any agent that prevents a pregnancy from occurring is classified as a contraceptive.[56] An abortion occurs when a fertilized, implanted egg is disrupted from the uterus.[57] Agents that disrupt an already established pregnancy are classified as abortifacients.[58] Essentially, contraception occurs

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48. *See e.g.,* CBS NEWS, *The Debate Over Plan B: Did Relgion Play a Role in An FDA Decision?*, *available at* http://www.cbsnews.com/stories/2005/11/22/60minutes/main1068924.shtml (last visited Dec. 3, 2007) ("The Catholic Church opposes Plan B not just because it's birth control, but because it considers use of Plan B to be, in Cardinal Egan of New York's words, 'a chemical abortion.'"); Robert Bazell, *Plan B Highlights Abortion Debate*, MSNBC.COM, *available at* http://www.msnbc.msn.com/id/12692188/ (last visited Dec. 3, 2007) ("The argument is that Plan B prevents a fertilized egg from implanting in the womb. Dr. Charmaine Youst of the conservative Family Research Council says women should be told that is an abortion."); Gardiner Harris, *'Morning After' Pill Is Cleared for Wider Sales*, NYTIMES.COM, Aug. 24, 2006, *available at* http://www.nytimes.com/2006/08/24/health/24cnd-pill.html (last visited Dec. 3, 2007) ("Anti-abortion groups strongly opposed Barr's application for over-the-counter sales, saying [Plan B] is an abortion pill . . . .").

49. Int'l Consortium for Emergency Contraception, EC and Mifepristone: What is the Difference?, http://www.cecinfo.org/what/mifepristone.htm (last visited Nov. 26, 2007).

50. Seamon, *supra* note 4, at 534.

51. Int'l Consortium for Emergency Contraception, *supra* note 49.

52. Seamon, *supra* note 4, at 528.

53. Gold et al., *supra* note 9, at 66*; see also* Klein, *supra* note 9, at 1030.

54. *Governments Worldwide Put Emergency Contraception into Women's Hands*, *supra* note 8, at 2.

55. *Id*.

56. *Id*.

57. Seamon, *supra* note 4, at 527 (quoting Caroline Wellbery, *Emergency Contraception: An Ongoing Debate*, 70 AM. FAM. PHYSICIAN 655, 655 (2004)).

58. An abortifacient is "an agent (as a drug) that induces abortion." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 3 (10th ed. 2004). Drugs that are classified as abortifacients include misprostol, methotrexate, and mifepristone. Seamon, *supra* note 4, at 528.

before a pregnancy has been established, and abortion occurs *after* a pregnancy has been established.

Confusion surrounding EC and abortifacients exists because commonly accepted definitions of pregnancy are often inconsistent with the medical definition of pregnancy. Ten states recognize pregnancy as beginning at fertilization.[59] This view has some merit as "a fertilized ovum has a full complement of DNA."[60] 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.[61] Awareness of these distinctions is important to understanding the political opposition to EC.

Plan B® has only been conclusively shown to prevent ovulation, but three other possible mechanisms of Plan B®, which could prevent fertilization, are being examined further.[62] There is speculation that Plan B® can prevent sperm from getting to an egg in time to fertilize it, because sperm are viable in the vagina for up to five days, while an egg must be fertilized within approximately one day after ovulation for pregnancy to result.[63] Research also suggests that Plan B® may change "the pH of the uterine cavity, which significantly decreases the number of viable sperm."[64] Finally, researchers are examining the possibility that Plan B® "thicken[s] cervical mucous, thus inhibiting sperm transport."[65] These speculated mechanisms still occur pre-fertilization, and thus would still qualify Plan B® as a contraceptive and not an abortifacient.[66] Therefore, even if pregnancy could be defined as beginning at fertilization, it is likely that Plan B® would still be classified as contraception.

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,[67] which "is responsible for protecting the public health by assuring the safety, efficacy, and security of human . . . drugs."[68] 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

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59. Harper, *supra* note 27, at 245.
60. Seamon, *supra* note 4, at 528.
61. Harper, *supra* note 27, at 245.
62. Besinque & Downing, *supra* note 14.
63. Klein, *supra* note 9, at 1028.
64. Besinque & Downing, *supra* note 14.
65. *Id.*
66. *See* discussion *supra* Part II.A.3.
67. 21 U.S.C. §§ 301-399 (2007); Harper, *supra* note 27, at 226.
68. FDA, FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Feb. 26, 2007).

nonprescription drugs for the first time.[69] The Center for Drug Evaluation and Research (CDER) oversees all of the FDA's drug-related issues, including those relating to prescription drugs.[70] The Office of Nonprescription Products, part of the CDER, is primarily responsible for handling nonprescription drugs.[71] Today, prescription drugs are, generally, those "that are safe for use only under the supervision of a health care practitioner."[72]

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

a. Overview of Prescription to Over-the-Counter Switch

Only the FDA can change a prescription drug to OTC status.[73] This change, more commonly called a "switch,"[74] 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."[75] 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.[76]

When a drug is determined to be safe[77] and effective[78] for self-medication, the Commissioner of the FDA is authorized to make the switch.[79] When a

69. Seamon, *supra* note 4, at 539.

70. *Id*. at 533.

71. *Id*.

72. U.S. GOV'T ACCOUNTABILITY OFFICE, FOOD AND DRUG ADMINISTRATION: DECISION PROCESS TO DENY INITIAL OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 7 (2005), *available at* http://oversight.house.gov/Documents/20051116110800-24167.pdf [hereinafter GAO REPORT].

73. Harper, *supra* note 27, at 228.

74. FDA, Frequently Asked Questions on the Regulatory Process of Over-the-Counter (OTC) Drugs, http://www.fda.gov/cder/about/smallbiz/OTC_FAQ.htm (last visited Nov. 26, 2007) ("Prescription to OTC switch refers to over-the-counter marketing of a product that was once a prescription drug product for the same indication, strength, dose, duration of use, dosage form, population, and route of administration.").

75. 21 C.F.R. § 310.200(b).

76. *Id.*

77. "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).

78. "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).

79. 21 C.F.R. § 310.200(b); *see also* FDA, Questions & Answers: Over-the-Counter Drug Products Public Hearing, June 28 and 29, 2000, http://www.fda.gov/cder/meeting/otcqa-600.htm.

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. [80] One study should be on the comprehensibility of the label (whether an average consumer can read and understand the instructions), and the other on the "actual use" of the medication.[81] 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.[82]

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

A request for the FDA to consider a switch from prescription to OTC status can come from the Commissioner himself/herself, or from any interested

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> In allowing . . . drugs to be sold over the counter, the agency consider[s] the safety and effectiveness criteria, . . . the benefit-to-risk ratio, and whether clear and understandable labeling could be written to enable consumers to safely self-medicate without the intervention of a health professional . . . . In general, the Agency has permitted OTC marketing of drugs when there is sufficient information to establish that they are effective and acceptably safe for OTC use.

Id.; Memorandum from Steven Galson, Dir., Ctr. for Drug Evaluation and Research on Plan B® to NDA 21-045, S-011 (Aug. 24, 2006), *available at* http://www.fda.gov/cder/drug/infopage/planB/memo.pdf.

> FDA will grant a supplemental application to 'switch' when it finds that Rx dispensing is: 'not 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, and . . . the drug is safe and effective for use in self-medication as directed in proposed labeling.' (citing 21 C.F.R. § 310.200(b))

Id.; GAO REPORT, *supra* note 72, at 7.

> FDA will authorize a prescription-to-OTC switch only after it is determined that the drug in question has met the following FDA criteria: (1) it has an acceptable safety profile based on prescription use and experience; (2) it has a low potential to be abused; (3) it has an appropriate safety and therapeutic index; (4) it has a positive benefit-risk assessment; and (5) it is needed for a condition or illness that is self-recognizable, self-limiting, and requires minimal intervention by a health care practitioner for treatment.

Id.

80. Robert Steinbrook, *Waiting for Plan B — The FDA and Nonprescription Use of Emergency Contraception*, 350 NEW ENG. J. MED. 2327, 2328 (2004).

81. *Id.*

82. 21 C.F.R. § 310.200(b).

> Any drug limited to prescription use . . . shall be exempted from prescription dispensing requirements when the Commissioner finds such requirements are not 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, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling.

person who wishes to file a petition, including the drug's manufacturer.[83] The request for Plan B®'s switch came from a citizens' petition filed by the Center for Reproductive Law and Policy on February 14, 2001.[84] 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.[85]

Women's Capital Corporation (WCC), distributor of Plan B® prior to Barr Pharmaceuticals, Inc., submitted a supplemental New Drug Application (sNDA) to the FDA on April 16, 2003.[86] WCC sponsored two studies relevant to their application for OTC availability of Plan B®.[87] The first study evaluated the comprehensibility of the proposed OTC label.[88] 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.[89] 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."[90] The studies concluded that there is no need for providers to supervise the use of Plan B®, because women can use it safely and effectively on their own.[91] The studies thus supported OTC availability for Plan B®.[92]

On December 16, 2003, after examination of Plan B®'s safety, effectiveness and labeling, the FDA's Over-the-Counter Committee and the Reproductive Health Drugs Advisory Committee both recommended that the FDA approve the switch of Plan B® from prescription to OTC status.[93] All members of the committees found Plan B® to be safe in a non-prescription

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83. 21 C.F.R. §310.200(b).

> A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(B) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, which petition may be pursuant to part 10 of this chapter, or in the form of a supplement to an approved new drug application.

Id.

84. Seamon, *supra* note 4, at 543.

85. Ctr. for Reprod. Rights, Citizen's Petition to FDA (Feb. 14, 2001), *available at* http://www.crlp.org/pdf/EC_petition.pdf [hereinafter Citizen's Petition].

86. Seamon, *supra* note 4, at 543.

87. Elizabeth G. Raymond, Pai-Lien Chen & Sandra M. Dalebout, *"Actual Use" Study of Emergency Contraceptive Pills Provided in a Simulated Over-the-Counter Manner*, 102 OBSTETRICS & GYNECOLOGY 17, 17 (2003).

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.* at 23.

92. *Id.*

93. MINORITY STAFF COMM. ON GOV'T REFORM, U.S. HOUSE OF REP., FACT SHEET: THE POLITICIZATION OF EMERGENCY CONTRACEPTION 2-3 (2005), *available at* http://oversight.house.gov/Documents/20051013155450-84328.pdf [hereinafter WAXMAN REPORT].

setting and that there was no evidence that OTC availability of Plan B® would lead to a decrease in regular contraceptive methods.[94] Despite these unanimous findings, four out of twenty-seven committee members voted to deny the switch, but conceded that their reasons were not related to safety or effectiveness.[95] "[S]enior scientists at the FDA in charge of reviewing" Plan B®'s application concurred with the committees' recommendation for approval.[96]

However, the FDA's Acting Director of CDER, Steven Galson, disregarded the advisory committees' recommendations and ultimately rejected the status change on May 6, 2004,[97] citing concern that young teenagers would

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94. *Id.*

95. *Meeting of Nonprescription Drugs Advisory Committee In Joint Session With Advisory Committee on Reproductive Health Drugs*, FDA Center for Drug Evaluation and Research, (Dec. 16, 2003) *available at* http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.htm.

> DR. STANFORD: I . . . have concerns about the labeling . . . . I'm not convinced enough that the labeling is addressing the actual best effectiveness data and adequately addressing informed consent . . . .
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> DR. CROCKETT: . . . as an OB-GYN I'm going to go down kicking and screaming before I allow somebody to break that relationship between myself and my patients because I value the education component so much in that relationship I have with my patients . . . . I would like to see a better designed actual use trial that more accurately reflects what's going to happen over the counter, i.e., people would be able to get more than one pack at a time, as was restricted in the actual use study without reenrollment. I would like to see more data on teen use . . . and people with low or no literacy levels. And I would like for some data to be gathered on how many times it's used in a nonindicated [sic] manner if that's possible. Also, if this does go to a pure over-the-counter status, I think we would be doing a disservice to our patients to not include a larger section on education of alternate methods of contraception, including a very strong statement from the company about abstinence and use of condoms to prevent STDs, and this could be a necessary and required portion of the labeling; and that it should be very clear that Plan B is only to be used actually after abstinence and condoms or another primary form of birth control are not used . . . .
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> CHAIRMAN CANTILENA: . . . The label comprehensive study was, I think, an overall failure . . . . my concern with the actual use is it doesn't accurately reflect what will likely be the most common setting for this product based on what we've heard. So the actual use was not as close as possible to what we think will actually happen with the drug.

Id.

96. Henry A. Waxman, *Politics and Science: Reproductive Health*, 16 HEALTH MATRIX 5, 20 (2006).

> 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 application have recommended approval.' He added that 'the data from the studies submitted by the sponsor are sufficient and adequate on which to base a regulatory approval.

Id.

97. Memorandum from Steven Galson, *supra* note 79.

not use the product safely.[98] The specific fear was that young teenagers would use EC in lieu of more common and reliable forms of contraception, even though the advisory committees had dismissed this concern[99] and no actual data was provided by anyone at the FDA in support of this position.[100] The Director of CDER may "make decisions independent of [the FDA's] advisory committees,"[101] 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® in 2004.[102]

As a result of the FDA's rejection of OTC Status for Plan B®, Senator Hillary Clinton, joined by twenty-three other U.S. senators, requested an investigation by the Government Accountability Office (GAO) and the Senate into the inconsistencies of the decision.[103] The GAO determined that the FDA's review process of Plan B® was irregular in four ways.[104] 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.[105] Second, the FDA review staff was "told early in the review process that the decision would be made by high-level management."[106] This kind of high-level involvement by management at the FDA is uncommon for reviews of OTC-switch applications,[107] and had previously only been seen in decisions regarding the marketing of prescription drugs.[108] Third, the GAO found some evidence that the decision not to approve Plan B® was made before the review process was even complete.[109] For example, in December 2003, the Acting Deputy Commissioner for Operations and the Acting Director of CDER informed the Director and Deputy Director of the Office of New Drugs that Plan B® would not be approved for over the counter sales.[110] Lastly, the GAO determined that "the Acting Director of

98. WAXMAN REPORT, *supra* note 93, at 3.

99. *Id.* at n.17 ("The advisory committee, including Dr. Hager voted unanimously that the 'data demonstrate[s] that Plan B is safe for use in the nonprescription setting.'").

100. Wood et al., *supra* note 43, at 1198.

101. Susan F. Wood, *Women's Health and the FDA*, 353 NEW ENG. J. MED., 1650, 1651 (2005).

102. *Id. See also* Nadine Strossen, *Reproducing Women's Rights: All Over Again*, 31 VT. L. REV. 1, 8 (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 and welfare of many thousands of women.").

103. Seamon, *supra* note 4, at 549.

104. GAO REPORT, *supra* note 72, at 5.

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id*. at 6.

109. *Id.* at 5.

110. *Id.* at 21.

CDER's decision was novel and did not follow the FDA's traditional practices."[111]

The Acting Director of CDER 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."[112] The FDA has never before considered behavioral implications resulting from differences in cognitive development in an OTC switch decision.[113] 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®,[114] even though the FDA has considered this technique scientifically appropriate in the past.[115] Ultimately, the GAO categorized the FDA's decision-making process, which resulted in the rejection of switching Plan B® from prescription to OTC, as "unusual."[116]

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 sixteen and under.[117] 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 formulations to be sold simultaneously over the counter and by prescription."[118] This "belated discovery" delayed the FDA's decision for almost another year.[119]

The FDA's treatment of Plan B®'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®, 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.[120] She stated: "As a scientist, as a career FDA employee, and as the director of the Office of Women's Health,[121] 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."[122] Wood believed that delaying approval of Plan B® for OTC use indefinitely was the

111. *Id.* at 5.
112. *Id.*
113. *Id.*
114. *Id.*
115. *Id.*
116. *Id.*
117. WAXMAN REPORT, *supra* note 93, at 4.
118. Wood et al., *supra* note 43, at 1198.
119. WAXMAN REPORT, *supra* note 93, at 4.
120. Susan F. Wood, *supra* note 101, at 1650.
121. 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 needs." *Id.* at 1651.
122. *Id.*

result of ignoring "scientific and clinical evidence and the established review process . . . ."[123] 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."[124] Wood had also disagreed with the 2004 decision to consider dual-status of Plan B® "because such dual status has never been required for other over-the-counter products sold to adolescents and because the proposal was not based on concerns about safety or efficacy."[125]

The FDA's actions also resulted in the resignation of Dr. Frank Davidoff from his post as consultant to the FDA's Nonprescription Drugs Advisory Committee.[126] 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."[127]

c. The FDA Approves Plan B® for Over-the-Counter Use By Women Eighteen and Over, But Maintains Prescription Status for Women Under Eighteen

The FDA finally approved Plan B® for OTC use by women 18 and over on August 24, 2006, while females under eighteen still need a prescription to obtain the medication.[128]

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.[129] Dr. von Eschenbach stated that CDER had found OTC availability appropriate for women seventeen and older, but the FDA had ultimately decided to make the cutoff at age eighteen because a "cutoff point" at that age would "best promote and protect the public health."[130] The reasons articulated seem to be only administrative in nature.[131] Essentially, Dr. von

123. *Id*. at 1650.

124. *Id.*

125. *Id.* at 1651.

126. WAXMAN REPORT, *supra* note 93, at 5 (citing *FDA Advisor Resigns Over Plan B Handling*, ASSOCIATED PRESS (Oct. 6, 2005)).

127. *Id.*

128. FDA Approves Over-the-Counter Access for Plan B, *supra* note 3.

129. Memorandum from Dr. Andrew C. von Eschenbach, Acting Comm'r, FDA, to NDA 21-045, S-011 (Aug. 23, 2006), *available at* http://www.fda.gov/cder/drug/infopage/planB/avememo.pdf [hereinafter Eschenbach Memo].

130. *Id.*

131. Dr. Andrew C. von Eschenbach, Acting Commissioner of the FDA stated that the "well-established state and private-sector infrastructures" could be used to aid in restricting the sale of Plan B® to those 18 and over. Eschenbach Memo, *supra* note 129. He also stated that "pharmacies that will be dispensing Plan B® . . . (as well as society as a whole) are more familiar with 18 as a cutoff age . . . . [I]n all 50 states, 18 is the age of majority, . . . and retail outlets, including pharmacies, are familiar with using 18 as the age restriction for the sale of

Eschenbach cited no medical or scientific reason for setting an age distinction for OTC availability of Plan B® at age eighteen.

As a condition for the partial OTC switch, Barr Pharmaceuticals agreed to institute the Convenient Access, Responsible Education (CARE) Program, a "rigorous labeling, packaging, education, distribution and monitoring program," meant to help enforce the FDA's new Plan B® regulations.[132] The CARE Program will ensure that Plan B® 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."[133] The Program will also ensure that Plan B® will be kept behind pharmacy counters so it will not be accessible to individuals over eighteen without proof of age.[134]

3. How States are Handling Plan B®

States are free to regulate drugs approved by the FDA more stringently than the FDA requires, but not less.[135] 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 non-prescription drugs.[136] States generally set up pharmacy boards, which are charged with the "powers relating to the regulation, prescription, dispensation, and sale of prescription and nonprescription drugs" within the state.[137]

Some states, even prior to the FDA's August 2006 decision regarding Plan B®, have moved toward increased access to EC by allowing pharmacists to distribute EC to females of any age without a prescription.[138] Nine states

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certain products," such as tobacco, OTC nicotine replacement therapy products, and OTC cough and cold products with pseudoephedrine. *Id.* However, Dr. Eschenbach neglected to mention that "[t]he age of consent for sexual intercourse ranges from 12 to 18 under various state laws, the most common age of consent being 16." Kate Sutherland, *From Jailbird to Jailbait: Age of Consent Laws and The Construction of Teenage Sexualities*, 9 WM. & MARY J. WOMEN & L. 313, 314 (2003).

132. FDA Approves Over-the-Counter Access for Plan B, *supra* note 3.

133. *Id.*

134. *Id.*

135. Harper, *supra* note 27, at 230.

136. *Id.* at 229.

137. *Id.*

138. Sarah Zarbock, *Plan B OTC: Not a Total Solution*, 13 PHARMACY TODAY 23, 23 (2007), *available at* http://www.pharmacyaccess.org/pdfs/PharmacyToday0507.pdf.

> Before FDA's decision last August, Washington was one of nine states that had taken steps to make Plan B more easily accessible to their residents. The others were Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, and Vermont. Each enabled pharmacists to provide EC to patients without having them first see a physician. Now in these states, patients younger than 18 who need a prescription for EC can obtain Plan B simply by speaking directly with a pharmacist authorized to initiate an EC prescription under protocol.

currently allow direct access to EC from a pharmacist: Alaska, California, Hawaii, Maine, Massachusetts, New Mexico, New Hampshire, Vermont, and Washington.[139] These states have set up collaborative drug therapy agreements between pharmacists and prescribers, which "authorize pharmacists to provide emergency contraception directly to women without their having to make a prior visit or consult with a prescriber."[140] 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.[141] These states allow pharmacists to dispense not only Plan B®, but also other oral contraceptives,[142] "that the FDA has indicated are safe and effective for use as EC."[143]

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"[144] that are part of the "liberty" protected by the Due Process Clause of the Fourteenth Amendment.[145] "This right of personal privacy includes 'the interest in independence in making certain kinds of important decisions,'"[146] such as those concerning marriage,[147] procreation,[148] contraception,[149] family relationships,[150] child rearing and education.[151]

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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Id.

139. Besinque & Downing, *supra* note 14.

140. Jacqueline S. Gardner, Jane Hutchings, Timothy S. Fuller & Don Downing, *Increasing Access to Emergency Contraception Through Community Pharmacies: Lessons from Washington State*, 33 FAM. PLAN. PERSP. 172, 172 (2001), *available at* http://www.guttmacher.org/pubs/journals/3317201.pdf.

141. *Id.*

142. *See supra* Part II.A.1.

143. Besinque & Downing, *supra* note 14.

144. Roe v. Wade, 410 U.S. 113, 152 (1973).

145. Carey v. Population Serv. Int'l, 431 U.S. 678, 684 (1977).

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

147. Loving v. Virginia, 388 U.S. 1, 12 (1967).

148. Skinner v. Oklahoma ex rel. Williamson, 316 U.S. 535, 541-42 (1942).

149. Eisenstadt v. Baird, 405 U.S. 438, 453-54 (1972).

150. Prince v. Massachusetts, 321 U.S. 158, 166 (1944).

151. Pierce v. Society of Sisters, 268 U.S. 510, 535 (1925); *see also* Meyer v. Nebraska, 262 U.S. 390, 399 (1923).

individual.[152] The restriction must be justified by a compelling state interest, and must be narrowly tailored to further only that compelling interest.[153]

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*.[154] 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.[155]

All individuals have the right to make decisions concerning procreation without "unwarranted governmental intrusion."[156] 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.[157] Government restrictions on distribution and sale of contraceptives have been found to be an intrusion on an individual's rights to make decisions concerning procreation[158] because they "clearly burden the freedom to make such decisions."[159] Any such restriction must therefore undergo a strict scrutiny analysis.[160]

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152. Harper, *supra* note 27, at 248.

153. Carey v. Population Serv. Int'l, 431 U.S. 678, 686 (1977) ("[W]here 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.").

154. *Id.* at 685 ("holding unconstitutional a statute prohibiting the use of contraceptives.").

155. *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)).

156. *Eisenstadt*, 405 U.S. at 453.

157. *Carey*, 431 U.S. at 688-89.

> [R]egulation '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 matters of childbearing that is the underlying foundation of the holdings in *Griswold*, *Eisenstadt v. Baird*, and *Roe v. Wade*.

Id.

158. Harper, *supra* note 27, at 249.

159. *Carey*, 431 U.S. at 687.

160. *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.").

"[T]he right to privacy in connection with decisions affecting procreation extends to minors as well as to adults."[161] However, "the power of the state to control the conduct of children reaches beyond the scope of its authority over adults."[162] Consequently, the Supreme Court has ruled that a state may place restrictions on a minor's fundamental rights if the restrictions "serve any significant state interest . . . that is not present in the case of an adult."[163]

3. *Carey v. Population Services International*

In *Carey*, the Supreme Court considered the validity of a New York law making it a crime for anyone to distribute contraceptives to minors under age sixteen, and for anyone but pharmacists to distribute contraceptives to those over age sixteen.[164] 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 could not "be held unconstitutional."[165] The Court, however, determined that even though minors were not completely banned from obtaining contraceptives under the New York statute, "[r]estrictions on the distribution of contraceptives clearly burden" decisions regarding procreation.[166] Consequently, the Court held that less than complete barriers to access "must also pass constitutional scrutiny,"[167] when, as in *Carey*, there is a significant burden placed on a decision involving procreation.[168]

New York further argued that any burden placed on minors by 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.[169] The State did not rely on any medical reasons for limiting "distribution of nonprescription contraceptives to minors,"[170] but instead argued only that the

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161. *Id.* at 693 (citing Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52, 74 (1976)); *see also id*. ("Minors, as well as adults, are protected by the Constitution and possess constitutional rights."); In re Gault, 387 U.S. 1, 13 (1967) ("[N]either the Fourteenth Amendment nor the Bill of Rights is for adults alone.").

162. Prince v. Massachusetts, 321 U.S. 158, 170 (1944).

163. *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.'" (citing *Planned Parenthood of Central Missouri,* 428 U.S. at 75.)).

164. *Id*. at 681 ("Under New York Educ. 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.").

165. *Id.* at 697.

166. *Id.* at 687 ("[T]he Constitution protects individual decisions in matters of childbearing from unjustified intrusion by the State. Restrictions on the distribution of contraceptives clearly burden the freedom to make such decisions.").

167. *Id.* at 697.

168. Hazel Glenn Beh & Milton Diamond, *The Failure of Abstinence-Only Education: Minors Have a Right to Honest Talk About Sex*, 15 COLUM. J. GENDER & L. 12, 54 (2006).

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

170. *Id.* at 697.

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."[171]

The Court did not agree with the State's arguments, and it held that the State's position unconstitutionally infringed upon a minor's right to access contraception.[172] The Court also held that regulating "the morality of minors" was not a significant state interest.[173] The Court noted that there is no actual evidence that limiting minors' access to contraceptives would "substantially discourage early sexual behavior,"[174] and reaffirmed:

> . . . 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.[175]

Regarding access to those over sixteen, New York argued that limiting the sale of contraceptives to pharmacists was necessary to facilitate "enforcement of the other provisions of the statute."[176] The Court disagreed, holding that ease of enforcement was not a valid justification for burdening a fundamental right.[177] The Court found that "[l]imiting the distribution of nonprescription contraceptives to licensed pharmacists clearly imposes a significant burden on the right of the individuals to use contraceptives if they choose to do so."[178] 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 competition."[179] The Court also recognized that the State has a valid interest in protecting an individual's health,[180] but found that New York's restriction would unduly "impair the

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171. *Id.*

172. *Id.* at 697-99.

173. *Id.* at 692.

174. *Id.* at 695.

175. *Id.* at 696.

176. *Id.* at 690.

177. *Id.* at 691 ("As to ease of enforcement, the prospect of additional administrative inconvenience has not been thought to justify invasion of fundamental constitutional rights.").

178. *Id.* at 689 (citing Eisenstadt v. Baird, 405 U.S. 438, 461-64 (1972)).

179. *Carey*, 431 U.S. at 689.

180. *Id.* at 690.

exercise of a constitutional right,"[181] and did not bear any "relation to the State's interest in protecting health."[182]

Carey "remains illustrative of the scope of a minor's procreative rights,"[183] even though it was decided, as a plurality decision, three decades ago.[184] The Supreme Court stated in *Planned Parenthood v. Casey* that it did not doubt the correctness of the decisions in *Griswold, Eisenstadt*, and *Carey*.[185]

III. 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

The Supreme Court considers access to contraception part of an individual's fundamental right to make decisions regarding procreation.[186] 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.[187]

The FDA's regulations do not place a complete ban on access to Plan B® for individuals seventeen and under, because they can still obtain the medication through a prescription.[188] However, a less than complete ban on access does not mean minors are not burdened by the regulation.[189] The Supreme Court held in *Carey* that less than complete barriers to access "must also pass constitutional scrutiny,"[190] when there is a significant burden placed on a decision involving procreation,[191] as there is here. Requiring a prescription from a doctor or other health care provider clearly limits access to Plan B®

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

182. *Id*.

183. Beh & Diamond, *supra* note 168, at 52.

184. Jessica R. Arons, *Misconceived Laws: The Irrationality of Parental Involvement Requirements for Contraception*, 41 WM. & MARY L. REV. 1093, 1096 (2000).

185. 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.").

186. *See supra* Part II.C.2.

187. Harper, *supra* note 27, at 249.

188. FDA Approves Over-the-Counter Access for Plan B, *supra* note 3.

189. Beh & Diamond, *supra* note 168, at 54 (citing Carey v. Population Serv. Int'l, 431 U.S. 678, 697-99 (1977)).

190. *Carey*, 431 U.S. at 697.

191. *Id.*

because it could potentially delay taking the medication by anywhere from a few hours to more than a day.[192] 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 a pharmacy, and get the prescription filled"[193] all within the FDA's recommended 72-hour time frame.[194]

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[195] based on their religious beliefs concerning contraception.[196] 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

When the government significantly burdens 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.[197] The FDA cites two main reasons why OTC access of Plan B® should be limited to individuals eighteen 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 seventeen without a health care provider's supervision.[198] The second, similar to the State's rationale in *Carey*, is that the FDA is concerned that allowing OTC access to minors will increase sexual promiscuity among minors and that they

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192. Harper, *supra* note 27, at 249.

193. Dr. Carolyn Westhoff, *Emergency Contraception: A NextGen Focus on Your Health*, 2 NEXT GENERATION 3 (2006), *available at* http://www.nextgenmd.org/vol2-3/westhoff.html.

194. *See supra* Part II.A.2.

195. Harper, *supra* note 27, at 249-50.

196. *See*, *e.g.*, Jed Miller, Note, *The Unconscionability of Conscience Clauses: Pharmacists' Consciences And Women's Access to Contraception*, 16 HEALTH MATRIX 237, 238 (2006); Melissa Duvall, *Pharmacy Conscience Clause Statutes: Constitutional Religious "Accommodations" or Unconstitutional "Substantial Burdens" on Women?*, 55 AM. U. L. REV. 1485, 1487 (2006); Claire A. Smearman, *Drawing The Line: The Legal, Ethical and Public Policy Implications of Refusal Clauses for Pharmacists*, 48 ARIZ. L. REV. 469, 472-73 (2006); Minh N. Nguyen, *Refusal Clauses & Pro-Life Pharmacists: How Can We Protect Ourselves From Them?*, 8 SCHOLAR 251, 252-53 (2006).

197. Carey v. Population Serv. Int'l, 431 U.S. 678, 686 (1977) ("[W]here 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."); *Id.* at 697 ("As we have held above as to limitations upon distribution to adults, less than total restrictions on access to contraceptives that significantly burden the right to decide whether to bear children must also pass constitutional scrutiny.").

198. Eschenbach Memo, *supra* note 129 ("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.").

will use Plan B® as their primary contraceptive method instead of other more common and reliable forms of contraception.[199]

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,[200] and (2) the Supreme Court has consistently rejected the argument that regulating the morality of minors is a compelling governmental interest justifying the infringement of a fundamental right.[201]

a. Safety and Effectiveness of Plan B®

There are several reasons why the FDA's assertions regarding Plan B®'s safety and effectiveness in females under eighteen are questionable. First, the FDA has never placed age-restrictions on an FDA-approved contraceptive prior to its Plan B® decision.[202] 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.[203] 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.[204] Finally, there is no medical evidence that minors would use Plan B® incorrectly if use of the medication were not supervised by a physician.[205]

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.[206] The agency, through labeling of oral contraceptives, has already conceded that age is not an issue for safety and effectiveness of any kind of oral contraceptive.[207] All oral contraceptives, including EC, contain the following labeling: "Safety and effectiveness of [trade name] have been established in women of reproductive age.[208] Safety and efficacy are expected to be the same for post-pubertal adolescents under the age of 16 and for users 16 years and older."[209] The FDA itself makes the assumption that ovulation will be suppressed by

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199. WAXMAN REPORT, *supra* note 93, at 3.

200. *See* discussion *infra* Part III.A.2.a.

201. *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 *Roe v. Wade*, that 'no court or commentator has taken the argument seriously.

Id.

202. *See* discussion *infra* Part III.A.2.a.

203. Steinbrook, *supra* note 80, at 2329.

204. *See* discussion *infra* Part III.A.2.a.

205. *See* discussion *infra* Part III.A.2.a.

206. *See supra* Part II.B.2.a.

207. GAO REPORT, *supra* note 72, at 30.

208. *Id.*

209. *Id.*

hormonal contraceptives the same way for any female who has begun menstruating, regardless of her age.[210] Also, results of a study that examined adolescents aged thirteen to sixteen "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."[211] Additionally, no inquiries were made regarding age-related effectiveness and safety before the FDA approved Plan B® for prescription use.[212] Consequently, the FDA did not place any age-restrictions on prescription availability of Plan B®,[213] and has no reason to do so for OTC availability.

Similarly, the FDA has never required specific data on the safe and correct use of other medications for children and adolescents.[214] Incorrect use of Plan B® 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,[215] and regular use of NSAIDs could potentially lead to ulcers and bleeding in the stomach.[216] Conversely, the risk of abuse or overdose of Plan B® is unlikely, and if an overdose does occur the consequences are unlikely to be serious.[217] Also, side effects are minor and well known, and interactions with other medications would not be fatal and would not alter Plan B®'s effectiveness.[218] Plan B® is not toxic to women, or their embryos if it is mistakenly taken while pregnant.[219] Plan B® is arguably safer

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210. *Id.*

211. Cynthia C. Harper et al., *The Effect of Increased Access to Emergency Contraception Among Young Adolescents*, 106 OBSTETRICS & GYNECOLOGY 483, 490 (2005) (citing Cynthia C. Harper et al., *Tolerability of Levonorgestrel Emergency Contraception in Adolescents*, 191 AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY 1158 (2004)).

212. GAO REPORT, *supra* note 72, at 31.

213. *Id.*

214. Steinbrook, *supra* note 80, at 2329.

215. FDA, Use Caution With Pain Relievers (2005), http://www.fda.gov/fdac/features/2003/103_pain.html (last visited Nov. 25, 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.

Id.

216. *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 Nov. 25, 2007).

217. Citizen's Petition, *supra* note 85.

218. *Id.*

219. *Id.*

than other more common products which are currently accessible to minors OTC.

The need for physician supervision of an adolescent taking Plan B® is also questionable. While Plan B® was still only available by prescription to females 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.[220] Pregnancy tests, pelvic exams, Pap smears, and testing for sexually transmitted diseases are rarely conducted before prescribing EC,[221] because EC does not pose any harm to a woman, or a fetus if she is already pregnant and takes the medication accidentally.[222] SAM also encouraged physicians to offer advance prescriptions of EC to adolescents, so that they would have more timely access to the drug if needed.[223]

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.[224] The study involved a total of six subgroups, two of which included females sixteen and under and females seventeen and older.[225] The FDA was involved in designing the study's protocols.[226] 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."[227] The study concluded that there was no indication that females of any age group need a physician's supervision in order to take EC correctly and safely.[228] Additionally, even if a female 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.[229] 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.[230]

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. 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

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220. Gold et al., *supra* note 9, at 68.
221. *Id*. at 67.
222. Citizen's Petition, *supra* note 85.
223. Gold et al., *supra* note 9, at 68.
224. Raymond et al., *supra* note 87, at 17.
225. *Id.* at 19.
226. *Id.* at 18.
227. *Id.* at 21-22.
228. *Id.* at 23.
229. Gold et al., *supra* note 9, at 68.
230. *Id.*

use.[231] The FDA's own Nonprescription Drugs and Reproductive Health Drugs Committees found that Plan B® should be available OTC to females of all ages because safety and effectiveness are not issues.[232] 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.[233] Because safety and efficacy are the only factors the FDA can consider when deciding on an OTC switch application,[234] 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

There are 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.[235] 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.[236] The FDA's regulations concerning Plan B® are most likely an attempt by the FDA to limit the sexual activity of minors,[237] which is not a compelling interest justifying the burden it has placed on minors' access to EC.[238]

Two studies of U.S. women ages fifteen to twenty-four were conducted to examine whether or not advance provision of EC would increase the frequency of unprotected sex.[239] One group of women received EC in advance, while the other only received education about EC.[240] The studies concluded "[t]here were no differences in the frequency of unprotected sex between the groups."[241] The studies did show, however, that the group that received EC in advance was two

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231. Carey v. Population Serv. Int'l, 431 U.S. 678, 696 (1977).

> [W]e 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.

Id.

232. Gold et al., *supra* note 9, at 68.
233. Wood et al., *supra* note 43, at 1197.
234. 21 C.F.R. § 310.200(b).
235. *See* discussion *infra* Part III.A.2.b.
236. *Id.*
237. *Id.*
238. *Id.*
239. Klein, *supra* note 9, at 1031.
240. *Id.*
241. *Id.*

to three times more likely to use it after unprotected sex occurred, and that they were more likely to use it sooner, when it is most effective.[242]

The FDA is also concerned that if Plan B® is available OTC to females under 18, they will stop using other more common and reliable methods of birth control, and instead use Plan B® as their primary method of contraception.[243] 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."[244] The two U.S. studies conducted by Women's Capital Corporation, mentioned above, demonstrated that there was no decrease in consistent condom use among the group of women who were provided with advance EC.[245] A similar study in the United Kingdom came to the same conclusions.[246] 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 thirty and forty dollars..[247]

Another study, conducted in response to the FDA's claim that there was a lack of data on adolescents, aged fifteen to nineteen, relating to their use of 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 their sexual risk behavior."[248] It showed that use among the youngest adolescents, those under sixteen, was the same, and in some instances slightly better, than those over sixteen.[249] The study also found that 62% of adolescents only used EC once, which is similar to statistics for adult use.[250] 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.[251] Finally, those under sixteen were significantly more likely to continue consistent condom use before and after they were provided with EC than were the older adolescents.[252] "The high levels of correct use in the advance provision group in this study suggest that physician supervision does not

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242. *Id.*

243. WAXMAN REPORT, *supra* note 93, at 3.

244. Steinbrook, *supra* note 80, at 2327.

245. Klein, *supra* note 9, at 1031.

246. *Id.* at 1032 ("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.").

247. Steinbrook, *supra* note 80, at 2328.

248. Harper et al., *supra* note 211, at 483.

249. *Id.*

250. *Id.* at 486 ("[U]se 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%) . . . Sixty-two percent of adolescents who used [EC] only used it once, similar to 65% in adults.").

251. *Id.* at 487.

252. *Id.* at 489 ("[T]he 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).").

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."[253]

Again, unsubstantiated claims are not enough to justify the burden the FDA has placed on minors' access to Plan B®.[254] The FDA advisory committees were provided with studies which show females of all ages who have 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."[255] 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*,[256] which the Supreme Court held not to be a compelling state interest justifying the burden placed upon minors' access to contraception.[257]

c. FDA Decision to Make "Cutoff Age" Eighteen is Questionable

Even if the FDA could somehow justify their decision to restrict Plan B® OTC access to minors, that restriction should not extend to those minors who are between the ages of seventeen and eighteen. The Director of CDER at the FDA, Steven Galson, concluded that there was no need for prescription dispensing of Plan B® for females seventeen and over.[258] 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 and older."[259] FDA commissioner, Dr. von Eschenbach, stated that the only reasons the cutoff age should be eighteen, rather than seventeen, 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.[260] As previously discussed,[261] administrative ease is not a compelling state interest that can justify the infringement of a fundamental

253. *Id.* at 490.

254. Carey v. Population Serv. Int'l, 431 U.S. 678, 696 (1977).

255. Wood et al., *supra* note 43, at 1198.

256. *Carey*, 431 U.S. at 681 ("Under New York Educ. Law § 6811(8) (McKinney 1972) 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.").

257. *Id.* at 692.

258. Eschenbach Memo, *supra* note 129.

259. Memorandum from Steven Galson, *supra* note 79.

260. Eschenbach Memo, *supra* note 129.

261. *See supra* Part II.C.2.

right.[262] It is apparent that the reason asserted by the FDA for making the cutoff age eighteen instead of seventeen 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 Rights of Individuals Eighteen and Over To Make Decisions Regarding Procreation

1. Requiring Individuals Eighteen 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,[263] and a burden on that right exists when the government restricts the distribution and sale of contraceptives.[264]

Under Barr Pharmaceuticals CARE program, a program Barr agreed to implement as a condition for OTC availability for individuals eighteen and over, Plan B® will only be available from "licensed drug wholesalers, retail operations with pharmacy services, and clinics with licensed healthcare practitioners."[265] 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."[266] Retail Pharmacies must keep Plan B® behind the counter,[267] and request proof of age when selling it without a prescription.[268]

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 eighteen seeking to purchase Plan B®, legally, without a prescription. In *Carey*, the Supreme Court held that "[l]imiting the

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262. Carey v. Population Serv. Int'l, 431 U.S. 678, 691 (1977) ("As to ease of enforcement, the prospect of additional administrative inconvenience has not been thought to justify invasion of fundamental constitutional rights.").

263. *See supra* Part II.C.2.

264. Harper, *supra* note 27, at 249.

265. FDA Approves Over-the-Counter Access for Plan B, *supra* note 3.

266. *Id.*

267. Letter from FDA on Approval of Over-the-Counter Plan B® to Duramed Research, Inc. (Sept. 15, 2006), *available at* http://www.fda.gov/cder/foi/appletter/2006/021045s011ltr.pdf [hereinafter FDA Letter to Duramed].

268. FDA, *supra* note 33. Although the FDA has not laid out specific procedures for verifying proof of age, Plan B® purchasers will have to provide some form of identification at the pharmacy counter proving that they are in fact at least 18. Reproductive Health Technologies Project, *Plan B OTC: What Will It Look Like?* (2006), *available at* http://www.rhtp.org/documents/PlanBOTC-Whatwillitlooklike.pdf. 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®. *Id.* (providing a complete list of DEA-acceptable forms of identification for purchasing pseudoephedrine).

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."[269] The Court stated that even though the statute did not completely ban individuals sixteen 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."[270] Forcing a woman to the pharmacy counter to request Plan B®, and then requiring her to 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,[271] which she is legally allowed to purchase, thus burdening her access.

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.[272] The FDA has stated that its main reason for keeping OTC Plan B® behind the pharmacy counter is to enforce the restrictions on OTC sales to those eighteen and older.[273] Ease of enforcement of an age restriction is not enough to justify invasion of a fundamental constitutional right.[274] The justification cited by the FDA for allowing only pharmacists to sell

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269. Carey v. Population Serv. Int'l, 431 U.S. 678, 689 (1977).

270. *Id.*

271. Wood et al., *supra* note 43, at 1198.

272. *Carey*, 431 U.S. at 685-86.

> 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.

Id.

273. FDA Letter to Duramed, *supra* note 267.

> [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.

Id (emphasis added).

274. *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.").

nonprescription contraceptives to individuals 18 and over is nearly identical to the reason cited by New York in *Carey* in defense of its statute.[275] The FDA's desire to enforce its regulation allowing only those eighteen and over to purchase Plan B® OTC is not a compelling government interest.

IV. CONCLUSION

Plan B®'s availability as an over-the-counter medication has been the subject of intense debate in the media, between government officials, and among society as a whole. Individuals have the right to make decisions about procreation, including contraception, without being unduly burdened by government regulation.[276] The FDA's Plan B® regulations violate that right by requiring females under eighteen to obtain a prescription without medical evidence to justify the requirement,[277] and by requiring OTC Plan B® to be kept behind the pharmacy counter and those over eighteen to provide proof of age to purchase the drug OTC.[278] Regulating the morality of minors and enforcement of the age-restriction are not compelling governmental interests which justify the infringement on an individual's right of access to contraception.

The decision to restrict Plan B®'s OTC availability was noticeably and unduly influenced by political and social pressures rather than medical or scientific evidence.[279] The Bush Administration's actions,[280] and comments by

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275. *See supra* Part II.C.2.

276. *Carey,* 431 U.S. at 691.

277. *See* discussion *supra* Part III.A.1.

278. *See* discussion *supra* Part III.B.1.

279. *See* discussion *infra* Part IV.

280. WAXMAN REPORT, *supra* note 93.

> The administration nominates Dr. W. David Hager, a conservative religious activist, to chair the FDA's Reproductive Health Drugs Advisory Committee. . . . Dr. Hager's major publications are medical books imbued with religious themes, such as the advice that women who suffer from premenstrual syndrome should pray and read the bible. Although ultimately not appointed chair, Dr. Hager is named a member of the committee. He later takes part in the committee's deliberations on emergency contraception.

Id.; Seamon, *supra* note 4, at 536.

> Dr. Hager is considered an eccentric physician because of his strong religious views on abortion, his public protests to remove Mifeprex® from the market, and his writings on the use of prayer for the treatment of premenstrual disorder. With the appointment of Dr. Hager, critics perceived President Bush as stacking the FDA with conservative cronies who obfuscate the issues surrounding EC.

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

> In his October sermon, Hager said that White House officials called him in June 2001 and asked him to serve in some capacity -- initially as a candidate for surgeon general and later as a member of two advisory boards. After one month, Hager said, he was called by the White House and asked to resign from those committees and join the FDA's reproductive drugs panel instead because 'there

the President himself,[281] have demonstrated social conservatives' support for restrictions to access of Plan B®.[282] Also, the FDA's decision to open up the question regarding dual-status of the same drug at the same dosage to public comment[283] 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,"[284] and "it goes without saying that the FDA's decisions must be

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> are some issues coming up we feel are very critical, and we want you to be on that advisory board.'

Id.

281. KaiserNetwork.org, *Bush Says He Supports Plan B Prescription-Only Access for Minors, von Eschenbach's Consideration of Nonprescription Application* (2006), http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=39349 (last visited Nov. 25, 2007). 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 a prescription for minors." President George W. Bush, Press Conference by the President (2006) (transcript available at http://www.whitehouse.gov/news/releases/2006/08/print/20060821.html) (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?"). President Bush has also publicly stated that he supports the FDA's 2006 decision limiting access to minors. *Id.* ("I support Andy's decision.").

282. Waxman, *supra* note 96, 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.").

283. FDA, *FDA Takes Action on Plan B* (Aug. 26, 2005), http://www.fda.gov/bbs/topics/news/2005/NEW01223.html (last visited Mar. 4, 2007); *see also* Harper, *supra* note 27, at 233-34.

> 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.

Id.

This 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. *Id.* 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. FDA, Comment Summary, Plan B (May 19, 2006), http://www.fda.gov/oc/planb/summary051906.html#_Toc135813791 (last visited Nov. 25, 2007); Harper, *supra* note 27, at 234. It is hard to imagine that the FDA ignored all the comments simply 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. Marc Kaufman, *FDA Comment Period on 'Morning-After Pill' Ends*, WASH. POST, Nov. 2, 2005, at A14.

284. Michael R. Taylor, *Protecting FDA's Ability to Protect Public Health*, 61 FOOD & DRUG L.J. 805, 805 (2006).

insulated from partisan politics."[285] However, it is obvious that political and social pressure influenced the FDA's decision,[286] and as a result the restrictions the FDA's regulations have placed on Plan B® are an unreasonable infringement on individuals' rights and should be changed.

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 line with its responsibility to protect and promote public health by monitoring the safety, efficacy and security of drugs.[287] 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,[288] and the "FDA should not consider the social consequences potentially associated with the use of an FDA-approved product."[289] Safety and effectiveness should have been the only factors considered by the agency;[290] politics and the morals of certain members of society should never have entered into the FDA's decision-making process.[291] In making its decision, the FDA cited reasons such as concern for increased sexual promiscuity among minors[292], and ease of enforceability of the age restriction.[293] These reasons are strikingly similar to those the Supreme Court has consistently rejected, for the past thirty years.[294]

In sum, the FDA made the wrong decision about Plan B®. Given that the Supreme Court has repeatedly held that individuals have liberty and privacy interests in decisions involving procreation, Plan B® should be available to individuals 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 identification.

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285. *Id.*

286. Jeffrey M. Drazen, Michael F. Greene & Alastair J.J. Wood, Editorial, *The FDA, Politics, and Plan B*, 350 NEW ENG. J. MED. 1561, 1562 (2004).

287. Taylor, *supra* note 284, 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.").

288. Steinbrook, *supra* note 80, at 2328.

289. Taylor, *supra* note 284, at 806.

290. Steinbrook, *supra* note 80, at 2328.

291. *See* Taylor, *supra* note 284, at 805 ("[T]he 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.'").

292. *See* discussion *supra* Part III.A.2.

293. *See* discussion *supra* Part III.B.2.

294. *See* discussion *supra* Part II.C.3.