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Note

The Imposition of an Age Restriction on Over-The-Counter Access to Plan B Emergency Contraception: Violating Constitutional Rights to Privacy and Exceeding Statutory Authority

*Sydney Kokjohn**

This note addresses whether the Food and Drug Administration (“FDA”) has a compelling or significant reason for limiting over-the-counter sale of Plan B emergency contraception, commonly known as the “morning after pill,” to women and men eighteen or older. The FDA approved Plan B for prescription use on July 28, 1999.¹ On February 14, 2001, more than sixty medical and consumer groups filed a citizen’s petition with the FDA to make emergency contraception available over-the-counter, arguing that Plan B’s two-pill regimen is safe, effective, and simple enough to be sold without a prescription.² In addition, Women’s Capital Corporation, the original distributor of Plan B, filed an application to change the availability of Plan B from prescription-only to over-the-counter for all age groups, and two FDA advisory committees voted 23-4 that Plan B should be made available without prescription to all age groups.³ After numerous delays, on August 23, 2006, the FDA approved the over-the-counter sale of Plan B for women and men over the age of eighteen; however, those under the age

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1. Julie Rovner, Timeline: The Debate Over Plan B, NPR, July 31, 2007, <http://www.npr.org/templates/story/story.php?storyId=5725514>.

2. *Id.*

3. *Id.* (noting that the FDA advisory committees also voted 27to 1 that Plan B is safe for all age groups).

of eighteen will still need a prescription to buy the pills.⁴

This Note will show that the FDA's age restriction on over-the-counter sale of Plan B emergency contraception is arbitrary and capricious, exceeds statutory authority, and violates privacy rights. It will discuss the constitutional and policy reasons why the FDA should not be able to place an age restriction on over-the-counter sale of Plan B without showing that the drug is unsafe for those under eighteen. Section I will describe the history of emergency contraception, the way in which Plan B prevents pregnancy, the FDA's procedure for changing a drug to nonprescription status, the problem of unplanned pregnancy for teens under the age of eighteen, and the constitutional issues behind reproductive rights. Sections II, III, and IV will analyze the medical, constitutional, and statutory reasons why the FDA should eliminate the age restriction on emergency contraception. Section V will lay out a solution to the restriction, and Section VI will discuss the policy reasons for allowing over-the-counter access of Plan B for women of all ages. This Note concludes that the age restriction for over-the-counter sale of Plan B is not motivated by medical and scientific safety concerns and violates constitutional rights to privacy.

I. THE ISSUES LEADING UP TO THE FDA'S DECISION TO IMPOSE AN AGE RESTRICTION ON OVER-THE-COUNTER ACCESS TO PLAN B

A. THE HISTORICAL DEVELOPMENT OF EMERGENCY CONTRACEPTION

Some form of emergency contraception has been available for almost half a century.⁵ Emergency contraception in the United States began in the 1960s as an "off-label" use of oral contraceptives, which involved prescribing a high dose of oral contraceptive pills.⁶ Not until 1998 did the FDA approve the

4. See Rovner, *supra* note 1; Rob Stein, *FDA Approves Plan B's Over-the-Counter Sale*, WASH. POST., Aug. 25, 2006, at A04.

5. Yuliya Fisher Schaper, *Emergency Contraception for Rape Victims: A New Face of the Old Battleground of Legal Issues in the Bi-Partisan Abortion Politics in the United States*, 29 RUTGERS L. REC. 1, 6 (2005).

6. *Id.*

first brand of emergency contraceptive, "PREVEN."⁷ Despite its availability, only a small percentage of women are currently aware of emergency contraception.⁸ In addition, many people incorrectly think emergency contraception is the same as RU-486, often called the abortion pill.⁹ RU-486 was discovered by a team of French scientists in 1980 as an alternative for surgical abortions.¹⁰ Unlike abortions (surgically or through use of RU-486), emergency contraception does not terminate pregnancy, but instead prevents pregnancy after sexual intercourse.¹¹

Today, emergency contraception is available in over one hundred countries¹² and an estimated forty-one countries allow emergency contraception without prescription, though not all countries have age restrictions.¹³ Chile has recently started giving free emergency contraception to females over the age of eighteen in order to make it equally available to women of all economic classes.¹⁴ In the United States, Plan B has been available over-the-counter to women over the age of eighteen since 2006.¹⁵

B. THE SCIENCE AND MEDICAL RESEARCH BEHIND PLAN B

Plan B is emergency contraception manufactured by Barr Pharmaceuticals, Inc.¹⁶ It consists of two levonorgestrel pills (0.75 mg in each pill) that are taken by mouth after unprotected sex or sex in which another method of birth control failed.¹⁷

7. *Id.*

8. *See id.* at 7 (noting that nearly nine out of ten women of reproductive age have not heard of or do not know information about emergency contraception); Am. Acad. of Pediatrics, *Emergency Contraception*, 116 PEDIATRICS 1038, 1040 (2005), available at <http://ec.princeton.edu/news/AAP-ECstatement.pdf> (noting that in a survey of mostly sexually active inner-city adolescents, only 30% had heard of emergency contraception).

9. *See* Schaper, *supra* note 5, at 5.

10. *Id.*

11. *Id.*

12. *Id.* at 6.

13. *Plan B Backers Vow to Fight Age Restrictions*, MSNBC, Aug. 25, 2006, <http://www.msnbc.msn.com/id/14512830/>.

14. *See* Jen Ross, *In Chile, Free Morning-After Pill to Teens*, CHRISTIAN SCI. MONITOR, Sept. 12, 2006, <http://www.csmonitor.com/2006/0912/p01s04-woam.html>.

15. *See* Barr Pharm., Learn About Plan B, <http://www.go2planb.com/ForPharmacists/AboutPlanB/faqs.aspx> (last visited Nov. 16, 2007).

16. *See id.*

17. U.S. Food and Drug Administration Center for Drug Evaluation and

The two pills act by stopping the release of an egg by the ovary.¹⁸ It may prevent the union of sperm and egg (fertilization), or if fertilization does occur, Plan B may prevent the fertilized egg from attaching to the womb (implantation).¹⁹ If used within seventy-two hours of unprotected sex, emergency contraception can prevent approximately seventy to eighty percent of pregnancies.²⁰ Another study summarized the effectiveness of emergency contraception as follows: if one hundred teenage women have unprotected sex in the middle of their menstrual cycles, estimates suggest that approximately eight will become pregnant each month.²¹ It went on to find that appropriate use of emergency contraception would reduce this number to approximately two pregnancies each month.²² The World Health Organization also performed a study finding that delaying the first dose by more than twelve hours increased the odds of pregnancy by almost fifty percent.²³

Although use of emergency contraception may come with side effects, they are usually minor. Common side effects associated with emergency contraception are nausea, abdominal pain, tiredness, headache, menstrual changes, dizziness, breast tenderness, and vomiting.²⁴ Progestin-only emergency contraception pills, such as Plan B, have significantly fewer side effects than progestin combination pills.²⁵ The reviewing

Research, FDA's Decision Regarding Plan B: Questions and Answers, <http://www.fda.gov/CDER/drug/infopage/planB/planBQandA20060824.htm> (last visited July 31, 2007).

18. *Id.*

19. *Id.*

20. Am. Acad. of Pediatrics, *supra* note 8, at 1040 (noting that these pregnancies are in teens and young women who are mid-cycle and, thus, at risk for pregnancy).

21. *Id.*

22. *Id.*

23. *Id.* See Soc'y for Adolescent Med., *Provision of Emergency Contraception to Adolescents*, 35 J. OF ADOLESCENT HEALTH 66, 66 (2004), available at http://www.adolescenthealth.org/PositionPaper_Emergency_Contraception.pdf.

24. Learn About Plan B, *supra* note 15.

25. See Soc'y for Adolescent Med., *supra* note 23, at 66–67 (noting that progestin-only emergency contraception pills reduce the side effects of nausea and vomiting from 51% to 23% and 19% to 6% respectively, compared to combination emergency contraception pills).

divisions of the FDA, the FDA advisory committee,²⁶ and multiple major medical organizations support nonprescription access for Plan B for all ages; however, the FDA only approved Plan B for over-the-counter sale to those over eighteen.²⁷ Recent studies have suggested that teenage women of all ages can use Plan B safely without instructions from health care providers,²⁸ indicating that Plan B will most likely satisfy the FDA standard for safe and effective use to switch a drug from prescription to over-the-counter status for women under the age of eighteen.²⁹

C. THE FDA PROCEDURE FOR APPROVING OVER-THE-COUNTER DRUGS

The Federal Food, Drug, and Cosmetic Act (“FDAC”) gives the FDA the statutory authority to regulate drugs.³⁰ The Commissioner of the FDA or an interested party, usually a drug manufacturer, may initiate a proposal to switch a prescription drug to over-the-counter status.³¹ 21 C.F.R. § 310.200(b) states:

Any drug limited to prescription use . . . shall be exempted from the 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.³²

26. See 21 C.F.R. § 14.5 (2007) (stating that advisory committees are utilized to conduct public hearings, to review issues of importance before the FDA, and to provide recommendations to the Commissioner of the FDA).

27. Answers to Frequently Asked Questions About . . . How to Get Emergency Contraception, <http://ec.princeton.edu/questions/what-fda-says.html> (last visited July 31, 2007) (stating that in addition to the reviewing divisions of the FDA and the FDA advisory committee, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the Society of Adolescent Medicine support nonprescription access to Plan B, without an age restriction).

28. See Am. Acad. of Pediatrics, *supra* note 8, at 1042.

29. See 21 C.F.R. § 310.200 (2007) (stating the standards a drug must meet in order for the FDA to switch the drug from prescription to over-the-counter status).

30. Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 301 (2007); Holly M. Spencer, Comment, *The Rx-to-OTC Switch of Claritin, Allegra, and Zyrtec: An Unprecedented FDA Response to Petitioners and the Protection of Public Health*, 51 AM. U. L. REV. 999, 1002 (2002).

31. 21 C.F.R. § 310.200 (2007); see Spencer, *supra* note 30, at 1003.

32. 21 C.F.R. § 310.200(b) (2007).

A report by the United States Government Accountability Office (“GAO”) notes that,

[i]n applying this standard, [the] 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.³³

In compliance with 21 C.F.R. § 310.200(b), more than sixty medical and consumer groups filed a citizen’s petition with the FDA on February 14, 2001 to make emergency contraception available over the counter.³⁴ They argued that the two-pill regimen was safe enough, effective enough, and simple enough to be sold without physician supervision, thus meeting the FDA requirements.³⁵ On April 16, 2003, the Woman’s Capital Corporation, the original manufacturer of Plan B, filed an application to change the status of Plan B from prescription-only to over-the-counter for all age groups.³⁶

The FDA took more than a year to respond to the Women’s Capital Corporation application and eventually rejected it pursuant to section 505(d) of the FDAC (21 U.S.C. § 355(d)) and 21 C.F.R. § 314.125(b).³⁷ The FDA stated that the company had

33. U.S. GOV’T ACCOUNTABILITY OFFICE, FOOD AND DRUG ADMINISTRATION DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF EMERGENCY CONTRACEPTION DRUG PLAN B WAS UNUSUAL 7 (Nov. 2005), *available at* <http://www.gao.gov/new.items/d06109.pdf> (footnotes omitted) [hereinafter GAO Report].

34. Rovner, *supra* note 1.

35. *Id.*

36. *Id.*

37. 21 U.S.C. § 355(d) (2006), states:

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are

not presented enough data to prove that girls under the age of sixteen could use Plan B safely without physician supervision,³⁸ specifically highlighting the fact that only 29 out of the 585 participants in the study were fourteen to sixteen years of age and none were under the age of fourteen.³⁹ The FDA also relied on 35 U.S.C. § 355a(b), which states that prior to the approval of an OTC application, if “the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies.”⁴⁰

In July 2004, Barr Pharmaceuticals, which purchased Women’s Capital Corporation before the FDA’s decision, submitted a revised application to allow over-the-counter sale of Plan B only to girls age sixteen and older in order to circumvent the FDA’s initial rejection.⁴¹ After missing its statutory deadline for ruling on the revised application,⁴² the FDA requested public comment about whether the agency should “initiate a rulemaking to codify [its] interpretation . . . regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an [over-the-

inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application[.]

see also 21 C.F.R § 314.125(b) (2007) (listing reasons for which the FDA may refuse to approve an application); Rovner, *supra* note 1.

38. *See* Rovner, *supra* note 1.

39. Letter from Steven Galson, M.D., M.P.H., Dir., Ctr. for Drug Evaluation Research, to Joseph A. Carrado, M.Sc., R.Ph., Vice President, Clinical Regulatory Affairs, Barr Research, Inc. (May 6, 2004), *available at* http://www.fda.gov/CDER/drug/infopage/planB/planB_NALetter.pdf [hereinafter Not Approvable Letter].

40. 21 U.S.C.A. § 355a(b) (2007).

41. *See* Rovner, *supra* note 1.

42. *Id.*

counter (“OTC”)] drug product.”⁴³ After receiving approximately 47,000 comments, the agency hired a contractor to review the submissions and determined that rulemaking was not necessary to resolve the issues raised by the Plan B application.⁴⁴

While the FDA considered Barr Pharmaceutical’s revised application, a group of women and women’s organizations sought judicial review under the Administrative Procedure Act (“APA”)⁴⁵ and the United States Constitution alleging that the delay of a final decision violated the right to privacy and equal protection because it exceeded the statutory authority of the FDA and was arbitrary and capricious.⁴⁶ The APA states that the reviewing court shall “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”⁴⁷ In addition, Democratic senators Patty Murray and Hillary Rodham Clinton announced that they would prevent the Senate from voting on Lester Crawford’s nomination to be the new Commissioner of the FDA until the

43. Letter from Lester M. Crawford, DVM, PhD, Comm’r of Food and Drugs, to Joseph A. Carrado, M.Sc., R.Ph., Senior Dir., Regulatory Affairs, Duramed Research, Inc. (Aug. 26, 2005), *available at* http://www.fda.gov/CDER/drug/infopage/planB/Plan_B_letter20050826.pdf [hereinafter Letter from Lester M. Crawford, Aug. 26, 2005].

44. Letter from Steven Galson, Dir., Ctr. for Drug Evaluation Research, to Joseph A. Carrado, Vice President, Clinical Regulatory Affairs, Duramed Research, Inc. (Aug. 24, 2006), *available at* <http://www.fda.gov/cder/foi/appletter/2006/021045s0111tr.pdf> [hereinafter Approval Letter]; *see also* Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product, 70 Fed. Reg. 52,050 (Sept. 1, 2005):

The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking to request comment on whether to initiate a rulemaking to codify its interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.), regarding when an active ingredient may be simultaneously marketed in both a prescription drug product and an over-the-counter (OTC) drug product.

45. *See* 5 U.S.C.A. § 706(2)(A) (2007).

46. *See* Tummino v. Von Eschenbach, 427 F.Supp.2d 212, 215–16 (E.D.N.Y. 2006) (holding that plaintiffs may conduct discovery beyond the administrative record and into communications and correspondence between individuals both within and outside the FDA to determine whether the motivations of the decision makers were appropriate).

47. 5 U.S.C. § 706(2)(A) (2000).

agency ruled on Plan B's pending application for over-the-counter status.⁴⁸

In a memorandum addressing Barr Pharmaceutical's request for over the counter status for Plan B, FDA Commissioner von Eschenbach stated that Barr Pharmaceuticals had not established the drug could be used safely and effectively by women age sixteen and under.⁴⁹ Therefore, the switch from prescription to OTC status could not be authorized pursuant to 21 U.S.C. 353(b)(3) for that cohort.⁵⁰ The FDA approved the over-the-counter sale of Plan B to those over eighteen on August 23, 2006,⁵¹ and it has been available to the public since the end of 2006.⁵² To ensure that it would not be sold to those under eighteen, the FDA required that the Plan B only be sold in pharmacies or other facilities staffed by a health care professional, and that it be kept behind the counter requiring proof of age to purchase.⁵³

D. MINORS AND UNPLANNED PREGNANCY

Teenage pregnancy is a significant problem in the United States. The federal government spends about seven billion dollars each year helping teenage mothers and their families.⁵⁴ Almost a million teenagers become pregnant each year.⁵⁵ Thirty percent of women become pregnant at least once before they turn twenty.⁵⁶ Seventy-eight percent of these teen pregnancies are unplanned and over twenty-five percent end in abortions.⁵⁷ Teen birth rates in the United States may be two

48. Rovner, *supra* note 1.

49. See Memorandum from Dr. Andrew C. von Eschenbach, Comm'r, Food and Drug Admin. (Aug. 23, 2006), available at <http://www.fda.gov/CDER/drug/infopage/planB/avememo.pdf>.

50. *Id.*; 21 U.S.C.A. § 353(b)(3) (2007) (providing that "[t]he Secretary may by regulation remove drugs subject to section 355 of this title from the [prescription requirements] when such requirements are not necessary for the protection of the public health.>").

51. Memorandum from Dr. Andrew C. von Eschenbach, *supra* note 49.

52. See Stein, *supra* note 4, at A04.

53. Rovner, *supra* note 1.

54. Teen Pregnancy Prevention: Information for Teens—Facts and Stats, <http://www.teenpregnancy.org/resources/teens/facts/fact1.asp> (last visited July 31, 2007).

55. Sex and Choices: Teen Pregnancy, <http://www.teencarecenter.com/index.php?s=factsheets&p=sheet12> (last visited July 31, 2007).

56. Teen Pregnancy Prevention, *supra* note 54.

57. See Am. Acad. of Pediatrics, *supra* note 8, at 1038 (stating that

to ten times higher than in other developed countries.⁵⁸ However, teen birth rates and teen abortion rates have decreased in the last decade.⁵⁹ Some studies suggest that increased use of emergency contraception has contributed substantially to the recent decrease in abortion rates.⁶⁰

Careless sex is not the only cause of teen pregnancy. Rape also contributes to a number of unwanted pregnancies. A 2000 Department of Justice report indicated that 302,091 women are forcibly raped each year in the United States, resulting in over 32,000 pregnancies with approximately fifty percent of these pregnancies ending in abortion.⁶¹ Women between the ages of sixteen and nineteen experience more rapes and sexual assaults than any other age group,⁶² and thus have a great need for easy-to-access emergency contraception.

Opponents of OTC access of Plan B for women under eighteen argue that easy access to emergency contraception will increase promiscuity.⁶³ This argument proves to be frivolous. Studies have shown no difference in the frequency of unprotected sex between females who received advanced provisions of emergency contraception and females who received education only.⁶⁴ The groups who received emergency contraception were two to three times more likely to use it than those who received education only.⁶⁵ The current administration, however, favors an “abstinence only” approach

approximately 28.5% of teenage pregnancies end in abortion); Sex and Choices, *supra* note 55 (noting that 264,000 of the almost one million teen pregnancies each year end in abortion).

58. Am. Acad. of Pediatrics, *supra* note 8, at 1038.

59. *Id.* (stating that the birth rate for fifteen- to seventeen-year-olds in the United States remains twice that of Canada and England and ten times higher than the rates in France and Sweden, however, birth rates for fifteen to nineteen-year-olds have declined by 28% and abortion rates have declined by 39% in the last decade).

60. *See id.* Cf. Soc’y for Adolescent Med., *supra* note 23, at 66 (“Timely use of emergency contraception could prevent up to 70% of abortions.”).

61. Schaper, *supra* note 5, at 1–2.

62. *See id.* at 12.

63. *See* Am. Acad. of Pediatrics, *supra* note 8, at 1043 (“The concern that widespread emergency-contraception use would encourage unprotected coitus in teens is not supported in the literature.”).

64. *See id.*

65. *Id.*

to sex education.⁶⁶ Thus, some young women may not even receive education on emergency contraception.

E. CONSTITUTIONAL ISSUES RELATING TO REPRODUCTIVE RIGHTS

Reproductive rights have been at the forefront of constitutional law since the 1960s. In 1965, the Supreme Court in *Griswold v. Connecticut*⁶⁷ struck down laws preventing married couples from obtaining contraception on fundamental right to privacy grounds.⁶⁸ In 1972, the Court also invalidated a statute prohibiting distribution of contraceptives to unmarried persons, holding that the right to control ones reproduction is a fundamental right.⁶⁹ The next year, *Roe v. Wade*⁷⁰ held that a woman's right to have an abortion was fundamental and interference with it could be justified only by a compelling state interest, such as protecting the life of a child after viability.⁷¹ The Court stated, "[w]ith respect to the State's important and legitimate interest in the health of the mother, the 'compelling' point, in the light of present medical knowledge, is at approximately the end of the first trimester."⁷² However, the Court restricted *Roe* in 1992 with *Planned Parenthood v. Casey*,⁷³ and held that states could impose regulations on a woman's right to an abortion as long as those regulations did not constitute an undue burden.⁷⁴ The Court defined an undue burden as a legal position of a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.⁷⁵ Two other Supreme Court cases, *Doe v. Bolton*⁷⁶ and *Webster v.*

66. Committee on Oversight and Government Reform—Politics & Science, The Effectiveness of Abstinence-Only Education, http://oversight.house.gov/features/politics_and_science/example_abstinence.htm (last visited Oct. 20, 2007).

67. 381 U.S. 479 (1965).

68. *See id.* at 485.

69. *See Eisenstadt v. Baird*, 405 U.S. 438, 453–55 (1972) (stating that allowing distribution of contraceptives to married couples, but not to unmarried persons, violates the Equal Protection Clause).

70. 410 U.S. 113 (1973).

71. *See id.* at 162–64.

72. *Id.* at 163.

73. 505 U.S. 833 (1992).

74. *See id.* at 901 (holding that a state regulation requiring a woman to notify her spouse prior to getting an abortion constituted an undue burden).

75. *Id.* at 877.

76. 410 U.S. 179 (1973).

Reproductive Health Services,⁷⁷ further restricted access to abortions by holding that physicians may refrain from performing them.⁷⁸

Some interpret these cases to also mean that pharmacists have the right to refrain from distributing emergency contraception if they feel emergency contraception is the same as abortion.⁷⁹ Nine states considered legislation allowing pharmacists to refuse to distribute emergency contraception in 2002.⁸⁰ The earliest report of a pharmacist's refusal to dispense emergency contraception was in 1991 and many instances have followed since.⁸¹ Currently, eight states allow pharmacists or other medical providers to refuse to distribute emergency contraception.⁸² In July 2007, pharmacists in Washington State filed a lawsuit, stating that a law requiring the sale of emergency contraception violates their civil rights by forcing them into "choosing between their livelihoods and their deeply held religious and moral beliefs."⁸³ Although some people believe emergency contraception is the same as abortion, most courts do not.⁸⁴

77. 492 U.S. 490 (1989).

78. *See id.* at 510 ("Nothing in the Constitution requires States to enter or remain in the business of performing abortions."); *Bolton*, 410 U.S. at 197–98 (stating that "the hospital is free not to admit a patient for an abortion" and that "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in an abortion procedure").

79. *Cf.* Tony J. Kriesel, *Recent Developments: Pharmacists and the "Morning-After Pill": Creating Room for Conscience Behind the Counter*, 7 MINN. J. L. SCI. & TECH. 337, 341–42 (2005) (noting that emergency contraception is similar to abortion because it may stop implantation of the fertilized egg).

80. Schaper, *supra* note 6, at 3.

81. *See* Jed Miller, Note, *The Unconscionability of Conscience Clauses: Pharmacists' Consciences and Women's Access to Contraception*, 16 HEALTH MATRIX 237, 238–39 (2006) (noting that some pharmacists go even further by refusing to refer the woman to another pharmacy or even berating her).

82. National Conference of State Legislatures, *Pharmacist Conscience Clauses: Laws and Legislation 2005–2007*, <http://www.ncsl.org/programs/health/conscienceclauses.htm> (last visited July 31, 2007).

83. Curt Woodward, *Plan B Rule Sparks Lawsuit from Pharmacists*, SEATTLE TIMES, July 27, 2007, http://seattletimes.nwsources.com/html/localnews/2003808220_pharmacists27m.html.

84. *See* Margaret S. v. Edwards, 488 F. Supp. 181, 191 (E.D. La. 1980) ("Abortion, as it is commonly understood, does not include the IUD, the 'morning-after' pill, or, for example, birth control pills."); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405, 413 (Cal. Ct. App. 1989) ("[T]he

In addition to constitutional right to privacy concerns, denying access to emergency contraception may prevent women from obtaining the medical care that they need. In *Brownfield v. Daniel Freeman Marina Hospital*,⁸⁵ the California Court of Appeals held that a rape victim has a cause of action for damages if a medical practitioner does not provide her with information on emergency contraception.⁸⁶ *Carey v. Population Services International*⁸⁷ struck down a New York law that made it a crime (1) for anyone to sell or distribute contraceptives to minors under the age of sixteen, (2) for anyone other than a licensed pharmacist to distribute contraceptives to persons over the age of sixteen, and (3) for anyone to advertise or display contraceptives.⁸⁸ *Carey* held that reproductive rights are fundamental rights.⁸⁹

F. REPRODUCTIVE RIGHTS FOR MINORS

This Note focuses on the area of constitutional law regarding reproductive rights as it affects the access of minors to abortions and emergency contraception. The Court in *Carey* stated, “[t]he right to privacy in connection with decisions affecting procreation extends to minors as well as to adults.”⁹⁰ The Court held that “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.”⁹¹ The plurality also noted that the government must have a significant interest to restrict the fundamental rights of minors and that the government cannot impose a blanket provision restricting the rights of minors.⁹²

For abortions, many states have parental notification laws requiring a minor wanting to have an abortion to either notify a

morning-after pill is a ‘pregnancy prevention’ treatment” and not a method of terminating pregnancy.). *But cf.* Kriesel, *supra* note 79, at 352–53 (arguing that pharmacists’ refusals to distribute emergency contraception would be constitutional).

85. 208 Cal. App. 3d 405 (Cal. Ct. App. 1989).

86. *See id.* at 414 (noting the right to control one’s medical treatment).

87. 431 U.S. 678 (1977).

88. *See id.* at 681.

89. *See id.* at 685.

90. *Id.* at 693 (plurality opinion).

91. *Id.* at 686 (majority opinion).

92. *See id.* at 692–95 (plurality opinion).

parent or obtain a judicial bypass. *Planned Parenthood of Central Missouri v. Danforth*⁹³ held that the state should not impose a blanket provision giving a third party, such as a parent, the right to override a minor's right to an abortion in the first trimester.⁹⁴ For a parental consent statute to be constitutional, it must

contain a bypass provision that meets four criteria: (i) allow the minor to bypass the consent requirement if she establishes that she is mature enough and well enough informed to make the abortion decision independently; (ii) allow the minor to bypass the consent requirement if she establishes that abortion would be in her best interests; (iii) ensure the minor's anonymity; and (iv) provide for expeditious bypass procedures.⁹⁵

Although no legal barriers explicitly prevent minors from accessing emergency contraception, some state and federal legislators strive to limit minors' access to reproductive services such as emergency contraception.⁹⁶ For example, the proposed Schoolchildren's Health Protection Act recommended prohibiting "federal education funding for elementary or secondary schools that provide access to emergency post-coital contraception."⁹⁷

Women have more reproductive rights than they did forty years ago; however, some of these fundamental rights, especially the those of minors, are being restricted without a compelling or significant state interest. For example, the FDA's age restriction on over-the-counter access to Plan B lacks a compelling or significant state interest. Although the scientific research of many reputable organizations supports over-the-counter access of Plan B for all ages,⁹⁸ the FDA has chosen to impose an age restriction, suggesting that it considered non-scientific factors, such as the interest in regulating the morality of minors, in its decision.

93. 428 U.S. 52 (1976).

94. *See id.* at 74.

95. *Lambert v. Wicklund*, 520 U.S. 292, 295 (1997); *see also* *Ohio v. Akron Ctr. for Reprod. Health*, 497 U.S. 502, 511–13 (1990) (restating the four criteria for parental notification laws).

96. *See* Schaper, *supra* note 5, at 12.

97. Schoolchildren's Health Protection Act, H.R. 926, 108th Cong. (2003) (unenacted); *see* Schaper, *supra* note 5, at 12.

98. Answers to Frequently Asked Questions About . . . How to Get Emergency Contraception, *supra* note 27.

II. THE IMPORTANCE OF OVER-THE-COUNTER AVAILABILITY OF EMERGENCY CONTRACEPTION TO MINORS

A. WITHOUT NON-PRESCRIPTION ACCESS, MINORS MAY NOT BE ABLE TO ACCESS PLAN B

As stated above, emergency contraception works most effectively when used within seventy-two hours (three days) after unprotected sex.⁹⁹ At least one study has shown that it is more effective the sooner it is used.¹⁰⁰ Many minors may not be able to see a doctor and get to a pharmacy in time to prevent pregnancy by emergency contraception. In addition, the rate of unprotected sex and the likelihood of teenage pregnancy are higher for minors who grow up in poor socioeconomic conditions.¹⁰¹ These minors are less likely to have access to medical care and thus less likely to be able to get a prescription for emergency contraception. Proponents of the age restriction argue that minors can get a prescription ahead of time or have an adult obtain emergency contraception for them.¹⁰² This proposal, however, would likely be ineffective for the same reasons that many underprivileged minors are unable to obtain last minute prescriptions: lack of access to doctors and pharmacies. In addition, some of these women do not have an adult figure to turn to for help.

Young women who do not get a prescription for regular oral contraception are unlikely to get a prescription for emergency contraception. Teen pregnancy is already an epidemic in the United States.¹⁰³ Oral contraceptives have been available by

99. Am. Acad. of Pediatrics, *supra* note 8, at 1040 (noting that these pregnancies are in teens and young women who are mid-cycle and, thus, at risk for pregnancy).

100. See Am. Acad. of Pediatrics, *supra* note 8, at 1041.

101. HEATHER BOONSTRA, THE GUTTMACHER REPORT ON PUBLIC POLICY, TEEN PREGNANCY: TRENDS AND LESSONS LEARNED 9 (Feb. 2002), <http://www.guttmacher.org/pubs/tgr/05/1/gr050107.pdf>.

102. *But cf. Study: Parental Notice Wouldn't Curb Teen Sex*, MSNBC, Jan. 18, 2005, <http://www.msnbc.msn.com/id/6839641/> (noting that many teens would avoid birth control or use less reliable methods if required to notify their parents in order to obtain birth control).

103. *Cf. Teen Pregnancy Prevention*, *supra* note 54 (noting that 750,000 teen girls get pregnant each year); *Sex and Choices*, *supra* note 55 (stating that each year 10% of all women aged fifteen to nineteen become pregnant and 78% of these pregnancies are unintended).

prescription for years, yet many young women choose not to use them,¹⁰⁴ possibly because they find it is too difficult or expensive to obtain a prescription. As Justice Stevens stated in *Carey*, “[i]t is almost unprecedented . . . for a State to require that an ill-advised act by a minor give rise to a greater risk of irreparable harm than a similar act by an adult.”¹⁰⁵ Restricting over-the-counter access of emergency contraception to adults would likely result in a greater chance of unwanted pregnancy for minors who do not properly use contraception than for adults who fail to do the same.

B. NON-PRESCRIPTION ACCESS TO EMERGENCY CONTRACEPTION WILL NOT ADVERSELY AFFECT WOMEN UNDER EIGHTEEN

The current administration stresses sexual abstinence amongst teenagers.¹⁰⁶ Instead of focusing on teaching teenagers how to prevent pregnancy and sexually transmitted diseases, the Bush administration insists on teaching “abstinence only” education.¹⁰⁷ Rather than tracking rates of pregnancy and sexually transmitted diseases, these programs measure success by attendance and attitudes at the end of the program.¹⁰⁸ Many of these programs also include misleading information, such as teaching teenagers that abortion leads to sterility and suicide.¹⁰⁹ However, no study has proved that abstinence only education decreases the number of people who have premarital sex, teen pregnancies, or sexually transmitted diseases.¹¹⁰ In addition, polls show that Americans prefer

104. See *Sex and Choices*, *supra* note 55 (stating that teens are less likely than older women to use contraception).

105. *Carey v. Population Services Int'l*, 431 U.S. 678, 714 (1977) (Stevens, J., concurring).

106. Schaper, *supra* note 5, at 14.

107. *Politics & Science*, *supra* note 66 (noting that over the past three years Congress has given over \$100 million in grants to organizations that support abstinence only education).

108. *Id.* (stating that one of the factors measured is “proportion of participants who indicate understanding of the social, psychological, and health gains to be realized by abstaining from premarital sexual activity”).

109. Ceci Connolly, *Some Abstinence Programs Mislead Teens, Report Says*, WASH. POST, Dec. 2, 2004, at A01 (stating that some abstinence only programs also mislead teenagers by teaching that half of gay male teenagers have tested positive for AIDS and that touching a person’s genitals can result in pregnancy).

110. See MARCELA HOWELL & AMMIE N. FEJOO, *ADVOCATES FOR YOUTH*,

prevention-based rather than abstinence-only sex education.¹¹¹

Opponents of over-the-counter access of Plan B for minors also argue that easy access to emergency contraception will increase promiscuity in teens.¹¹² As noted in Section I, this argument is unsubstantiated, as studies have shown that access to emergency contraception does not increase the rate of unprotected sex by teenagers.¹¹³ However, women who had easy access to emergency contraception were more likely to use it, thus decreasing their likelihood of unintended pregnancy.¹¹⁴ Proponents believe that over-the-counter access for all ages could reduce half of unwanted pregnancies.¹¹⁵ Thus, allowing easier to access to Plan B for all ages would reduce teenage pregnancies and meet one of the most important goals of any sex education program: preventing teenage pregnancies.

Opponents also feel that if Plan B is available over the counter, teenagers will obtain it without discussing it with their parents, thus creating a “wedge” between children and parents.¹¹⁶ Requiring teens to seek out an adult in order to obtain emergency contraception may reduce the number of teenagers who decide to use emergency contraception. In addition, one study found that eighteen percent of girls would use other less reliable methods of birth control if they were required to get parental notification to obtain prescription birth control.¹¹⁷ If young women are willing to engage in risky sexual habits rather than ask their parents for prescription birth control, it is unlikely that they will ask their parents to help

SCIENCE OR POLITICS? GEORGE W. BUSH AND THE FUTURE OF SEXUALITY EDUCATION IN THE UNITED STATES 1-2 (2001), available at <http://www.advocatesforyouth.org/publications/factsheet/fsbush.pdf> (noting that the American Medical Association, the Institute of Medicine, and the National Campaign to prevent teen pregnancy all think abstinence only education has not proved to be effective).

111. See Press Release, NARAL Pro-Choice America, *Bush Should Fulfill Promise of Uniting, Not Dividing, the Country* (Jan. 31, 2006) http://www.prochoiceamerica.org/news/press-releases/2006/pr01312006_bush.html (describing eight ways in which President Bush can reduce abortion in the United States; one of which is easier access to emergency contraception).

112. See Alexandra Marks, *How ‘Morning-After Pill’ Will Affect Sex Habits*, CHRISTIAN SCI. MONITOR, Dec. 18, 2003, <http://www.csmonitor.com/2003/1218/p02s01-ussc.html>.

113. See Am. Acad. of Pediatrics, *supra* note 8, at 1043.

114. See *id.*

115. See Marks, *supra* note 112.

116. See *id.*

117. *Study: Parental Notice Wouldn’t Curb Teen Sex*, *supra* note 102.

them obtain emergency contraception.

No data support the arguments against over-the-counter use of emergency contraception.¹¹⁸ Non-prescription access to Plan B will not increase promiscuity in teenage girls or create a wedge between parents and children. Instead, easier access to Plan B has the possibility of reducing teenage pregnancies and thus improving the lives of teens.

C. RESTRICTING ACCESS TO PLAN B IS ESPECIALLY DETRIMENTAL TO RAPE VICTIMS

Another important concern is the access of emergency contraception for rape victims. Although many opponents feel access to emergency contraception will increase premarital sex, rape can affect women who are adamantly against pre-marital sex.¹¹⁹ Because of the nature of rapes, victims are often hesitant to report the crime to the police or to tell anyone what happened to them.¹²⁰ This is an even greater concern for minors, who may be embarrassed and uncertain where to go for help. By requiring prescriptions for access to emergency contraception for women under eighteen, it is likely that many young rape victims will not obtain emergency contraception.

As noted in Section I, the court in *Brownfield v. Daniel Freeman Marina Hospital*¹²¹ found that the denial of information about emergency contraception to a rape victim violated her constitutional right of self-determination in medical treatment.¹²² The court stated that a patient's "right to control her treatment must prevail over [a medical provider's] moral and religious convictions."¹²³ In addition, the court reiterated that the morning-after pill is not the same as abortion.¹²⁴

Although the FDA's age restriction on over-the-counter access of Plan B does not prevent minor rape victims from obtaining emergency contraception, it does increase the

118. *See id.*; HOWELL & FEIJOO, *supra* note 110, at 1–2.

119. *See* Schaper, *supra* note 5, at 15.

120. *Id.*

121. 208 Cal. App. 3d 405 (Cal. Ct. App. 1989).

122. *See id.* at 412.

123. *Id.*

124. *See id.* at 413.

difficulty of obtaining it. Even though the courts do not feel emergency contraception is the same as abortion, many pharmacists feel differently.¹²⁵ Many states have “conscience clauses” or “refusal clauses” which give a pharmacist the legal right to refuse to dispense a drug that he or she feels is morally wrong.¹²⁶ Four states—Arkansas, Georgia, Mississippi, and South Dakota—have laws that allow pharmacists to refuse to fill emergency contraception prescriptions.¹²⁷ Thus, if a pharmacist in a state that has enacted such a conscience clause feels emergency contraception is morally wrong, he may legally refuse to fill the emergency contraception prescription of a rape victim. As stated in Section I, the earliest report of a pharmacist’s refusal to dispense emergency contraception was in 1991.¹²⁸ Although this was in violation of Texas state law and the pharmacist later lost his job,¹²⁹ his actions still prevented that rape victim from obtaining emergency contraception in a timely manner. Later that year, a New Hampshire pharmacist refused to fill an emergency contraception prescription for a young single mother.¹³⁰ In addition, he refused to refer her to another pharmacist, and he berated her.¹³¹ The American Pharmaceutical Association (“APhA”) has adopted its own conscience clause supporting the autonomy of pharmacists and pharmacy students in making ethical decisions.¹³² No court has invalidated a conscience clause on constitutional grounds.¹³³

Because of the legal availability of conscience clauses, rape victims may not be able to get emergency contraception in time, even if they do obtain a prescription. Many rural areas have

125. Kriesel, *supra* note 79, at 351–52.

126. *Id.*

127. National Conference of State Legislatures, *supra* note 82.

128. Miller, *supra* note 81, at 238.

129. See Marilyn Gardner, *Pharmacists’ Moral Beliefs vs. Women’s Legal Rights*, CHRISTIAN SCI. MONITOR, Apr. 26, 2004, at 11.

130. See Miller, *supra* note 81 at 239.

131. See *id.*

132. See C. Edwin Webb, *A Pharmacist’s Conscience & Quality Patient Care*, AM. C. CLINICAL PHARMACY, available at <http://www.accp.com/report/rpt0805/art05.php> (“APhA recognizes the individual pharmacist’s right to exercise conscientious refusal and supports the establishment of systems to ensure patient’s access to legally prescribed therapy without compromising the pharmacist’s right of conscientious refusal.”).

133. See Miller, *supra* note 81, at 259.

only one pharmacy,¹³⁴ thus, a young woman may have to drive miles in order to get to the next pharmacy in time for emergency contraception to work. For young women without access to transportation, getting to the next pharmacy may not be a feasible option. By requiring that minors obtain a prescription to access Plan B, the FDA is increasing the probability that young rape victims will not be able to prevent pregnancy.

III. THE AGE RESTRICTION ON OVER-THE-COUNTER ACCESS OF PLAN B VIOLATES MINORS' FUNDAMENTAL RIGHTS TO PRIVACY IN REPRODUCTIVE DECISIONS

A. THE RIGHT TO PRIVACY IN CONNECTION WITH DECISIONS AFFECTING PROCREATION EXTENDS TO MINORS AS WELL AS TO ADULTS

The Supreme Court has held for over forty years that the right to privacy in reproductive decision-making is a fundamental right.¹³⁵ As noted in Section I, *Carey v. Population Services International*¹³⁶ stated that this right to privacy in reproductive decision-making extends to minors as well as adults.¹³⁷ In *Carey*, sellers of contraceptives challenged a law that prohibited the sale of contraceptives to minors.¹³⁸ The Court noted that

minors are entitled to constitutional protection for freedom of speech, equal protection against racial discrimination, due process in civil contexts, and a variety of rights of defendants in criminal proceedings, including the requirement of proof beyond a reasonable doubt, the prohibition of double jeopardy, the rights to notice, counsel, confrontation, and cross-examination, and not to incriminate oneself,

134. See Gardner, *supra* note 129 (noting that Wal-mart, which is often located in rural areas, refuses to carry emergency contraception).

135. See *Roe v. Wade*, 410 U.S. 113, 154 (1973) (stating that the right to privacy also includes the abortion decision); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972) (noting that the right to privacy also protects from unwanted governmental intrusions into the reproductive decisions of unmarried people); *Griswold v. Conn.*, 381 U.S. 479, 485–86 (1965) (striking down a law that prohibited the use of contraceptives by married couples).

136. 431 U.S. 678 (1977).

137. See *id.* at 693 (plurality opinion).

138. See *id.* (majority opinion).

and the protection against coerced confessions.¹³⁹

In deciding to what extent a state can regulate the conduct of minors when it cannot regulate the same conduct in adults, the plurality found that the state must have a significant interest that is not present in the case of an adult.¹⁴⁰ The plurality went on to find that protecting the morality of minors was not a significant state interest.¹⁴¹ The Court also held that women, married or single, have the same fundamental interest in deciding when to bear children.¹⁴² The “significant state interest” test is less rigorous than the “compelling state interest” test applied when regulating the conduct of adults.¹⁴³ However, even under the significant interest test, the government still may not impose a blanket provision restricting the fundamental rights of minors.¹⁴⁴ Although the plurality in *Carey* indicated that the state could regulate the reproductive decisions of minors if it provided a significant interest,¹⁴⁵ this rule was not part of the majority holding.¹⁴⁶ The majority held that the government must provide a compelling state interest in order to regulate reproductive rights and the law must be narrowly tailored to express only that interest.¹⁴⁷ The majority does not indicate whether a lower standard should apply to minors, but does reaffirm the rule that the government needs a compelling interest to regulate reproductive rights.¹⁴⁸

Thus, the FDA’s blanket provision on over-the-counter access of emergency contraception for those under the age of

139. *Id.* at 692 (plurality opinion).

140. *See id.* at 692–93 (plurality opinion) (noting that the state does not have a constitutional right to impose a blanket provision).

141. *See id.* at 692–95 (plurality opinion).

142. *See id.* at 685; *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.”).

143. *See Carey*, 431 U.S. at 692–93 (plurality opinion); *see also Ginsberg v. New York*, 390 U.S. 629 (1968); *Prince v. Massachusetts*, 321 U.S. 158 (1944).

144. *See Carey*, 431 U.S. at 692–93 (plurality opinion); *Planned Parenthood of Central Mo. v. Danforth*, 428 U.S. 52, 74 (1976) (holding that a state may not impose a blanket provision requiring the consent of an unmarried minor’s parent as a condition for abortion).

145. *See Carey*, 431 U.S. at 693 (plurality opinion).

146. *See id.* at 681 (majority opinion).

147. *See id.* at 686; *Roe v. Wade*, 410 U.S. 113, 155–56 (1973).

148. *See Carey*, 431 U.S. at 686; *Roe*, 410 U.S. at 155–56.

eighteen is unconstitutional without a compelling or significant state interest. The FDA claims that there is not enough data that Plan B is safe for women under eighteen without a doctor's supervision,¹⁴⁹ however, multiple major medical organizations, including the American College of Obstetricians and Gynecologists,¹⁵⁰ the American Academy of Pediatrics,¹⁵¹ and the Society of Adolescent Medicine,¹⁵² support nonprescription access for Plan B without an age restriction,¹⁵³ suggesting that the government's interest is not a valid compelling or significant interest.

B. THE GOVERNMENT HAS FAILED TO PROVIDE A COMPELLING OR SIGNIFICANT STATE INTEREST FOR PREVENTING MINORS FROM ACCESSING PLAN B WITHOUT A PRESCRIPTION

Since the right of all women, married or unmarried, to make their own reproductive choices is a fundamental right, the government must provide a compelling state interest in order to restrict this right.¹⁵⁴ As noted in Section I, the law must be narrowly tailored to that compelling interest.¹⁵⁵

Although the plurality in *Carey* indicated the government's interest in regulating the conduct of minors must only be significant,¹⁵⁶ the Court has typically held that "[w]here certain 'fundamental rights' are involved . . . regulation limiting these rights may be justified only by a 'compelling state interest.'"¹⁵⁷

149. See Rovner, *supra* note 1.

150. See News Release, ACOG Office of Communications, Statement of The American College of Obstetricians and Gynecologists on the FDA's Approval of OTC Status for Plan B® (Aug. 24, 2006), http://www.acog.org/from_home/publications/press_releases/nr08-24-06.cfm.

151. See Am. Acad. of Pediatrics, *supra* note 8, at 1044 (noting that the American Academy of Pediatrics continues to support improved availability of emergency contraception, including over-the-counter access).

152. See Soc'y for Adolescent Med., *supra* note 23, at 69 ("To reduce barriers to accessing ECPs, SAM strongly supports efforts to change the status of ECP's from prescription-only to over-the-counter without an age restriction.").

153. Answers to Frequently Asked Questions About . . . How to Get Emergency Contraception, *supra* note 27.

154. See *Carey v. Population Services Int'l*, 431 U.S. at 686 (1977); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Roe v. Wade*, 410 U.S. 113, 155 (1973).

155. See *Carey*, 431 U.S. at 686; *Roe*, 410 U.S. at 155–56.

156. See *Carey*, 431 U.S. at 693 (plurality opinion).

157. *Roe*, 410 U.S. at 155.

The same cases that held there is a right to privacy in reproductive decision-making have also defined what is and is not a compelling state interest. In *Roe v. Wade*, the Court held that there was not a compelling state interest in regulating abortion during the first trimester but that the state's interests in the health of the mother and potential for human life became compelling in the second and third trimesters, respectively.¹⁵⁸ The Court noted that pregnancy places heavy burdens on women, possibly resulting in mental and physical harm, and that thus a woman should have control over her decision to have an abortion until the state's interest becomes compelling.¹⁵⁹ The Court in *Eisenstadt v. Baird*¹⁶⁰ found that the government's interests of deterring fornication, ensuring health, and promoting morality were not compelling enough to justify a ban on contraceptives for unmarried people.¹⁶¹ *Griswold v. Connecticut*¹⁶² upheld the principle that a "governmental purpose to control or prevent activities constitutionally subject to state regulation may not be achieved by means which sweep unnecessarily broadly and thereby invade the area of protected freedoms."¹⁶³

Other Courts have defined what should not be considered a significant state interest. The Court in *Carey* again rejected the idea that the government's interest in discouraging the sexual conduct of minors was a significant state interest.¹⁶⁴ *Planned Parenthood of Central Missouri v. Danforth* stated that the government's interest in "the safeguarding of the family unit and of parental authority" was not a significant interest to justify a blanket provision requiring an unmarried minor to obtain parental consent in order to get an abortion within the first twelve weeks of pregnancy.¹⁶⁵

Under either test, the FDA has not provided a governmental interest adequate to justify the blanket restriction on over-the-counter access of Plan B for women

158. *See id.* at 164–65.

159. *See id.* at 153–60.

160. 405 U.S. 438 (1972).

161. *See id.* at 452–53.

162. 381 U.S. 479 (1965).

163. *Id.* at 485 (citing *NAACP v. Alabama*, 377 U.S. 288, 307 (1964)).

164. *See Carey v. Population Services Int'l*, 431 U.S. 678, 694 (plurality opinion).

165. *See* 428 U.S. 52, 75.

under eighteen. The government's interest in protecting the health of minors is not compelling or significant when there is no proof that allowing pharmacies to sell emergency contraception to minors over-the-counter is unsafe. In addition, the Court has found that promoting morality is not a compelling or a significant state interest.¹⁶⁶ Since the FDA has not provided a compelling or significant interest that justifies the restriction of access to emergency contraception for minors, its decision should be reversed.

IV. THE FDA EXCEEDED ITS STATUTORY AUTHORITY BY PLACING AN AGE RESTRICTION ON OVER-THE-COUNTER ACCESS OF PLAN B

As noted in Section I, agency actions that are arbitrary, capricious, or abuse discretion are unlawful and should be overturned.¹⁶⁷ The court in *Natural Resources Defense Council, Inc. v. United States EPA*¹⁶⁸ defined an "arbitrary and capricious" decision as one displaying the absence of a rational connection between the facts found and the choice made.¹⁶⁹

In *Natural Resources*, an environmental action group challenged regulations made by the Environmental Protection Agency ("EPA").¹⁷⁰ The court noted that

an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.¹⁷¹

The court went on to find that the EPA investigated numerous options and considered comments from a range of viewpoints in arriving at its definition of "municipal separate storm sewer systems serving" a designated population, and thus found that there was a "rational connection between the facts found and the choices made."¹⁷²

166. *Eisenstadt v. Baird*, 405 U.S. 438, 452–53 (1972).

167. *See* 5 U.S.C. § 706(2)(A) (2000).

168. 966 F.2d 1292 (9th Cir. 1992).

169. *Id.* at 1297.

170. *See Natural Res.*, 966 F.2d at 1295.

171. *Id.* at 1303.

172. *Id.*

Unlike the situation in *Natural Resources*, however, the FDA's age restriction on over-the-counter access of Plan B to those under eighteen is arbitrary and capricious because the FDA did not make a rational connection between the facts and its choice. Multiple major medical organizations as well as two FDA advisory committees stated that Plan B is safe for nonprescription use by all ages.¹⁷³ Nevertheless, the FDA stated that Plan B was not acceptable for over-the-counter use by girls under the age of seventeen because they were not mentally mature enough to handle Plan B without physician supervision.¹⁷⁴ Acknowledging that using adolescent cognitive development for a not-approvable decision was unprecedented, the FDA relied on its increased focus on pediatric issues as the basis of its decision.¹⁷⁵

The FDA, however, did not make a rational connection between these facts and its choice and explained its decision in a way that ran counter of the evidence before the agency. As noted in Section I, Congress intended that any prescription drug shall be exempted from prescription 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.¹⁷⁶

Focusing on the "method of use" provision,¹⁷⁷ the FDA determined that there was not enough data demonstrating the safety and effectiveness of over-the-counter use of Plan B for women under the age of seventeen.¹⁷⁸

In order for the FDA to impose a restriction on over-the-

173. Answers to Frequently Asked Questions About . . . How to Get Emergency Contraception, *supra* note 27.

174. GAO Report, *supra* note 33, at 25.

175. 21 U.S.C. § 355a(b) (2000); GAO Report, *supra* note 33, at 25.

176. 21 C.F.R. § 310.200(b) (2007).

177. The FDA will grant a supplemental application to switch a drug from prescription to OTC when it finds that prescription 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. *Id.*

178. Memorandum from Steven Galson, MD, MPH, Director, Center for Drug Evaluation and Research 2, 3 (Aug. 24, 2006), *available at* <http://www.fda.gov/CDER/drug/infopage/planB/memo.pdf>.

counter access of a drug, it may only consider medical and scientific factors.¹⁷⁹ The FDA argued that Barr presented too little data about the safety of Plan B for women under the age of seventeen, and thus it was valid to require an age restriction.¹⁸⁰ However, many reputable medical organizations have found that Plan B is safe for women under eighteen, even without a doctor's supervision.¹⁸¹ These organizations have found that Plan B meets the FDA's criteria for determining drugs appropriate for over-the-counter use because "[i]t treats a condition that patients can diagnose themselves; it is safe and effective when used without direct prescriber supervision; and the drug's label adequately explains potential adverse effects and conditions of use."¹⁸² Moreover, while only twenty-nine of the 585 subjects tested were between the ages of fourteen and sixteen,¹⁸³ "the actual use study found that 82 percent of participants 16 years of age or under correctly took the second dose 12 hours later, compared to 78 percent of those 17 years and older."¹⁸⁴

While the FDA's reasoning behind the age restriction may be arguably within the law, some people felt that the FDA's initial denial of over-the-counter access to Plan B was to appease the Bush administration's pro-life allies.¹⁸⁵ Dr. Galson, the acting director of the Center for Drug Evaluation Research,

179. Cf. 21 U.S.C. § 353(b)(1)(A) (2000) (describing factors that would limit over-the-counter access to a drug).

180. See Memorandum from Steven Galson, *supra* note 178, at 3 (referencing Dr. Galson's previous memoranda dated May 6, 2004 and August 25, 2005, to describe why Plan B is not safe for OTC use for women under seventeen); Not Approvable Letter, *supra* note 39 ("Only 29 of the 585 subjects enrolled in the study were 14-16 years of age, and none was under 14 years of age."); see also 21 U.S.C. § 353(b)(1)(A) (2000); 21 C.F.R. § 310.200(b) (2007).

181. See Answers to Frequently Asked Questions About . . . How to Get Emergency Contraception, *supra* note 27 (stating that the reviewing divisions of the FDA, the FDA advisory committee, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the Society for Adolescent Medicine all support nonprescription access of Plan B without an age restriction); Ass'n of Reprod. Health Professionals, *EC OTC Sign-on Letter to the FDA*, Dec. 5, 2003, <http://www.arhp.org/healthcareproviders/resources/ecresources/ecotcfda.cfm>.

182. Ass'n of Reprod. Health Professionals, *supra* note 181.

183. GAO Report, *supra* note 33, at 24.

184. *Id.* at 27.

185. See Ronald Bailey, *Abort Plan B! The FDA's War on Promiscuity*, Jan. 12, 2005, <http://www.reason.com/news/show/34951.html>.

denied the first application for over-the-counter access based on the worry that easier access to emergency contraception would encourage risky sexual behavior among teens.¹⁸⁶ The FDA argued that women under the age of sixteen do not have the mental maturity to use Plan B without a doctor's supervision.¹⁸⁷ However, FDA review officials have noted "that the agency had not considered behavioral implications due to differences in cognitive development in prior OTC switch decisions, and that the agency had previously considered it scientifically appropriate to extrapolate data from older to younger adolescents."¹⁸⁸ In addition, cognitive development has never been a factor in the sale of other FDA-approved prescription or OTC contraceptives.¹⁸⁹ Moreover, the FDA has not required pediatric studies for any of the currently approved contraceptives, although it could have done so under 21 U.S.C. § 355a(b).¹⁹⁰ The GAO noted that for hormonal contraceptives, the FDA assumes that suppression of ovulation would be the same for any menstruating female. In addition, the GAO noted that the FDA did not identify any age-related restrictions in its review of the original application for prescription Plan B.¹⁹¹

Although Dr. Galson and the FDA review officials made these comments before the FDA's recent approval of over-the-counter access for those over eighteen, the rationale behind restricting access to minors is still the same. Dr. Galson's comments opined on over-the-counter emergency contraception effects on minors.¹⁹² The FDA review officials commented that the FDA process for considering whether to switch Plan B to nonprescription status did not comport with prior switches of drugs to over-the-counter status.¹⁹³ These comments, along with the fact that multiple major medical organizations feel

186. See Stephen Spotswood, *FDA Review Process On Plan B Unusual*, GAO Says, Dec. 2005, <http://www.usmedicine.com/article.cfm?articleID=1212&issueID=82> (noting that there were inconsistencies between the Plan B review process and previous review processes).

187. See GAO Report, *supra* note 33, at 3, 5.

188. Spotswood, *supra* note 186; accord GAO Report, *supra* note 33, at 22, 28.

189. GAO Report, *supra* note 33, at 6 (noting that explicitly considering differing levels of cognitive maturity between adolescents of different ages was novel and unprecedented for an OTC application).

190. 21 U.S.C. § 355a(b) (2000).

191. *Id.*

192. See Not Approvable Letter, *supra* note 39.

193. See GAO Report, *supra* note 33, at 25–29.

Plan B is safe for nonprescription use by minors,¹⁹⁴ indicate that the FDA was likely motivated by reasons other than medical and scientific data.

If the FDA's denial to grant over-the-counter access of Plan B to women of all ages was found to be arbitrary or capricious, according to federal law the decision is unlawful.¹⁹⁵ Because the FDA seemed to have been motivated by political pressures and moral values, neither of which are medical or scientific factors, it should modify its decision to allow over-the-counter access for women of all ages.

V. POLICY CONSIDERATIONS

Two competing policies exist when deciding whether to allow over-the-counter access of Plan B to minors: preventing teen pregnancies and abortions¹⁹⁶ and protecting the morality of teenagers by decreasing promiscuity.¹⁹⁷ Protecting the morality of teenagers may be a legitimate policy concern; however, proponents of this idea have not put forth credible evidence that allowing nonprescription access of Plan B will further this policy. On the other hand, pro-choice advocates have shown data that easier access to emergency contraception reduces unwanted pregnancies and abortions.¹⁹⁸ Both sides aim for the same goal, preventing teenage pregnancies, but are approaching that goal in different ways. Preventing teenage pregnancies is important from a social perspective and an economic perspective.¹⁹⁹ Most teenage fathers leave their pregnant girlfriends and many are minimally involved in the lives of their children.²⁰⁰ In addition, these teen fathers cannot

194. See Answers to Frequently Asked Questions About . . . How to Get Emergency Contraception, *supra* note 27.

195. See 5 U.S.C. § 706(2)(a) (2000).

196. See Am. Acad. of Pediatrics, *supra* note 8, at 1038; Ass'n of Reprod. Health Professionals, *supra* note 181.

197. See Am. Acad. of Pediatrics, *supra* note 8, at 1043 (noting that one concern about emergency contraception is that it would encourage unprotected sex in teens, however, this concern is unsupported).

198. See *id.* at 1038, 1043 (noting that in France, teens are given emergency contraception access by law and teen pregnancy rates are ten times lower than in the United States).

199. See Teen Pregnancy Prevention, *supra* note 54; Sex and Choices, *supra* note 55.

200. Sex and Choices, *supra* note 55.

make a meaningful contribution to the economic security of their children.²⁰¹ As noted in Section I, teen pregnancy costs the United States approximately seven billion dollars per year.²⁰²

Although the FDA argues that there is not enough data supporting the safety of Plan B without a prescription for minors, it instead seems to be following the current administration's unproven policy that "abstinence only" sex education is the best.²⁰³ The FDA should only be making decisions about switching drugs from prescription to nonprescription status based on medical and scientific factors.²⁰⁴ Even if the FDA could make decisions based on broader policy factors, allowing easier access to emergency contraception for all age groups is the best way to meet the widespread policy of preventing unwanted pregnancies and abortions.

VI. PROPOSAL FOR A SOLUTION TO THE FDA'S AGE RESTRICTION ON OVER-THE-COUNTER ACCESS OF PLAN B

The current FDA ruling on over-the-counter access of Plan B for women over eighteen is a step forward from prescription only access, but would be more effective if it allowed women of all ages to access Plan B without a prescription. Plan B is the type of drug that minors could safely use without the supervision of a doctor. In addition, allowing for easier access of emergency contraception will reduce unwanted pregnancies and abortions. Despite some groups' concerns that easier access of emergency contraception will increase promiscuity in teens and encourage risky sexual practices, no credible data have confirmed those concerns.

The FDA should modify its ruling and allow for over-the-counter access of Plan B for women (and men) of all ages. Many reputable medical organizations support nonprescription access

201. *Id.*

202. *See* Teen Pregnancy Prevention, *supra* note 54.

203. *See* Politics & Science, *supra* note 66.

204. *See* 21 C.F.R. § 310.200 (2007) (stating the standards that the FDA needs to find to switch a drug from prescription to over-the-counter status); *cf.* *FDA OKs Nonprescription 'Morning-After' Pill*, MSNBC, Aug. 24, 2006, <http://msnbc.msn.com/id/14497678/> (stating that critics of the FDA's initial handling of Plan B felt that political ideology had trumped science).

for minors because it would decrease unwanted teen pregnancies.²⁰⁵ By keeping Plan B at the pharmacy counter, rather than in the general store area, pharmacists will be available to answer any questions young women have about how to use it. This solution maintains minors' fundamental right to privacy in their reproductive choices, while still allowing for safe use of emergency contraception.

CONCLUSION

Unplanned pregnancy is a significant problem for women under the age of eighteen. Allowing over-the-counter access to emergency contraception for all ages would likely reduce the number of unplanned pregnancies. However, the FDA chose to restrict access to minors. The FDA's age restriction on over the counter access of Plan B was improperly motivated by factors other than science, thus it violates minors' fundamental right to privacy in reproductive decisions. Because many major medical organizations feel that Plan B is safe for nonprescription use by women of all ages, the real reason for the FDA's restriction seems to be regulating the morals of minors. The Court has never found the regulation of the morals of minors to be a compelling or significant state interest, as is needed to restrict reproductive rights.

Plan B should be available over the counter to women of all ages. Over-the-counter access of Plan B for women of all ages will reduce unwanted pregnancies and decrease the need for abortions. No studies have shown that easier access to emergency contraception increases promiscuity in young women. Studies have shown, however, that easier access will likely reduce the number of unwanted pregnancies and abortions, thus improving the lives of women of all ages.

205. See Ass'n of Reprod. Health Professionals, *supra* note 181.