THE FDA'S RECENT ABOUT-FACE: PLAN B AGE RESTRICTION IS UNLAWFUL RULEMAKING AND VIOLATES MINORS' DUE PROCESS RIGHTS

I. INTRODUCTION

Nearly half of all fifteen- to nineteen-year-olds in the United States are sexually active.[1] A sexually active teen who does not use contraception has a ninety percent chance of becoming pregnant within a year.[2] Together, these statistics signal an alarming public health crisis: rising rates of unwanted teenage pregnancies in the United States.[3]

Rather than fulfilling its congressional mandate to protect public health, Food and Drug Administration ("FDA") decision making, fueled by a shifting political climate, has been aimed at appeasing social and political groups. In August 2006, following years of controversy, the FDA issued a decision approving Plan B as emergency contraception for over-the-counter use.[4] It provided that Plan B should be used within seventy-two hours of intercourse if regular contraception failed or was not used.[5] The FDA determined that Plan B is safe and effective,[6] has only minor side effects,[7] and will not terminate a pregnancy if a fertilized egg is already attached to the uterus.[8] In short, Plan B is a backup method of contraception for use in emergency situations. Though the FDA's decision is a step in the right direction, it falls short of a complete success. While the decision granted over-the-counter access to Plan B, it included an age restriction: those under eighteen must have a prescription for the drug.[9]

In light of the Supreme Court's recognition of a fundamental due process right to access contraception,[10] the FDA's decision should be overturned on two

1. GUTTMACHER INST., IN BRIEF: FACTS ON AMERICAN TEENS' SEXUAL AND REPRODUCTIVE HEALTH 1 (2006), *available at* http://www.guttmacher.org/pubs/fb_ATSRH.pdf.

2. *Id.*

3. Steven Reinberg, *Teen Birth Rates Up for First Time in 14 Years, U.S. Reports*, USNEWS.COM, Dec. 5, 2007, http://health.usnews.com/usnews/health/healthday/071205/teen-birth-rates-up-for-first-time-in-14-years-us-reports.htm. See *infra* notes 258-60 and accompanying text for statistics about unintended pregnancies and abortions among teenagers.

4. See *infra* Part II.B.2.c for a detailed discussion of the FDA's August 2006 decision.

5. See *infra* Part II.B.1 for a medical description of Plan B.

6. See *infra* note 81 and accompanying text for a discussion of the results of the FDA's research, which caused the FDA to conclude that Plan B is safe and effective.

7. See *infra* notes 78-80 and accompanying text for a discussion of Plan B's side effects.

8. See *infra* notes 70-72 and accompanying text for a discussion of Plan B's effect on fertilization.

9. See *infra* Part II.B.2.c for a discussion of the FDA's August 2006 decision imposing the age restriction.

10. See *infra* Part II.C.2.b for a discussion of the due process right to access contraception generally and Part II.C.2.c for a discussion of minors' due process rights to access contraception.

grounds. First, the decision constitutes unlawful rulemaking, and a federal court should overturn it under the Administrative Procedure Act ("APA").[11] Second, the age restriction is functionally equivalent to a parental notification law and must be found unconstitutional because it fails even a minimal rational basis review.[12] In light of overwhelming scientific data,[13] the age restriction should be removed and minors should have unrestricted access to Plan B.[14]

Part II.A of this Comment provides general background about the FDA, how prescriptions drugs may be switched to over-the-counter status, and standards for judicial review of executive agencies. Part II.B then provides Plan B's medical description as well as a detailed history of the FDA's treatment of Plan B from 1997 through August 2006. Part II.C explains the FDA's asserted rationale for the age restriction, provides a general description of parental notification laws, and, more specifically, discusses minors' due process rights under the Constitution. It also includes a brief description of examples of federal and state attempts to legislate access to contraceptives for minors. Part III.A argues that the FDA's decision constitutes unlawful rulemaking because it is arbitrary and capricious and, therefore, should be overturned. Part III.B then argues that the age restriction on access to Plan B is unconstitutional because it is a contraceptive, and minors have a due process right to access contraceptives. Finally, Part III.C concludes by analyzing the ramifications of the FDA's decision and suggests eliminating the age restriction so that Plan B is widely available in the United States.

II. OVERVIEW

As an executive agency, the FDA derives its authority from the Federal Food, Drug, and Cosmetic Act ("FDCA").[15] Pursuant to its mandate, the FDA has authority to switch a prescription drug to over-the-counter status.[16] The actions of the FDA, however, may be subject to judicial review.[17] The FDA's treatment of Plan B, a method of emergency contraception, has varied from 1997 through 2006.[18] In 2006, the FDA chose to make Plan B available over-the-

11. See *infra* Part III.A for a discussion of why a court should overturn the FDA's August 2006 decision based on the APA's arbitrary and capricious standard.

12. See *infra* Part III.B for a discussion of the age restriction's unconstitutionality.

13. *See* Ctr. for Drug Evaluation & Research, FDA, Nonprescription Drugs Advisory Committee (NDAC) in Joint Session with the Advisory Committee for Reproductive Health Drugs (ACRHD) Meeting, at 40 (Dec. 16, 2003), *available at* http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.doc [hereinafter Joint Committee Meeting] (discussing safety profile supported by data from clinical trials). See *infra* notes 78-80 and 92-94 and accompanying text for a further discussion of the scientific data supporting removal of Plan B's age restriction.

14. See *infra* Part III.C for a discussion of proposed solutions.

15. 21 U.S.C. § 393(a) (2006).

16. *Id.* § 353(b)(3). See *infra* Part II.A.2 for a discussion of the process to switch a prescription drug to over-the-counter status.

17. *See* 5 U.S.C. § 706 (providing for judicial review over decisions of federal agencies). See *infra* Part II.A.3 for a discussion of when a court may review an executive agency's actions.

18. See *infra* Parts II.B.1-2 for a medical description of Plan B and a discussion of the FDA's

counter, but it limited this decision to those over eighteen years of age.[19] In spite of this FDA limitation, the Supreme Court has recognized that minors have a fundamental due process right to access contraceptives.[20] Finally, both federal and state legislatures have acted to broaden minors' rights to access contraception.[21]

A. The FDA

As an executive agency, the FDA's mandate is to protect the public health.[22] Pursuant to this mandate, the FDA determines when prescription drugs are safe enough for over-the-counter use.[23] This authority, however, is not unchecked.[24] Instead, under the APA,[25] a court may judicially review the FDA's actions.[26]

1. General Background

The FDA is an executive agency that derives its authority and jurisdiction from various congressional acts, particularly the FDCA.[27] The FDA's mandate is to protect public health by assuring the "safety, efficacy, and security of . . . drugs."[28] The FDA affects the lives of American consumers because it regulates over one trillion dollars in products annually.[29]

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treatment of Plan B from 1997 through 2006.

19. See *infra* Part II.B.2.c for a description of the FDA's August 2006 decision and Part II.C.1 for a discussion of the FDA's rationale for setting the age restriction at eighteen.

20. *See, e.g.*, Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 852-53 (1992) (plurality opinion) (reiterating agreement with previous decisions affording constitutional protection to women's use of contraceptives); Carey v. Population Servs. Int'l, 431 U.S. 678, 693-94 (1977) (finding prohibitions on minors' access to contraception unconstitutional). See *infra* Part II.C.2 for a discussion of the evolution of Supreme Court jurisprudence concerning the fundamental right to access contraception.

21. See *infra* Parts II.C.2.d-e for a discussion of how federal and state legislatures have broadened minors' rights to access contraception.

22. *See* U.S. Food and Drug Administration, FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Nov. 28, 2008) (setting forth FDA's responsibilities, which include protection of public health).

23. 21 U.S.C. § 353(b)(3) (2006).

24. See *infra* Part II.A.3 for a discussion of when a court can review FDA actions.

25. 5 U.S.C. §§ 551-559, 701-706.

26. *Id.* §§ 701-706. See *infra* Part II.A.3 for a description of the APA's arbitrary and capricious standard of review.

27. 21 U.S.C. § 393(a).

28. FDA's Mission Statement, *supra* note 22. The FDA's stated mission is:

> [P]rotecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Id.

29. FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., FDA: THE NATION'S PREMIER CONSUMER

The President appoints the FDA commissioner, who is then confirmed by the Senate.[30] In recent years, however, some have criticized the FDA's failure to appoint permanent, settled leadership because of political considerations.[31]

When President George W. Bush began his first term, he appointed Dr. Mark McClellan as Commissioner of the FDA.[32] McClellan, the White House press secretary's brother, served as Commissioner for seventeen months.[33] Although this was a seemingly controversial appointment, McClellan was qualified for the position.[34] He served until March 2004.[35] Thereafter, President Bush nominated Dr. Lester Crawford as a replacement in February 2005.[36] Prior to being appointed as Commissioner, Crawford served as both Acting and Deputy Commissioner of the FDA.[37] Before Crawford's Senate confirmation, Senators Hillary Clinton of New York and Patty Murray of Washington placed a legislative hold on his nomination to force the FDA to make a decision about Plan B.[38] As a result of a promise from the Health and Human Services Secretary that a decision would be made by September 1, 2005, they lifted the hold.[39] After Crawford's confirmation, the FDA again delayed its decision regarding Plan B.[40] Just weeks after his appointment, Crawford resigned,

PROTECTION AND HEALTH AGENCY, DHHS PUBLICATION NO. (FDA) 01-1316, at 2 (2001), *available at* http://www.fda.gov/oc/opacom/brochure/healthbro.pdf; FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., FREQUENTLY ASKED QUESTIONS (FAQS), *available at* http://www.fda.gov/opacom/faqs/faqs.html (last visited Nov. 28, 2008).

30. 21 U.S.C. § 393(d)(1).

31. Marc Kaufman, *FDA's Reliance on Unconfirmed Chiefs Is Faulted*, WASH. POST, Dec. 19, 2004, at A1.

32. *Id.*

33. *Id.*

34. Centers for Medicare & Medicaid Services, Agency Administrators: Tenure, http://www.cms.hhs.gov/History/Downloads/CMSAdministratorsTenure.pdf (last visited Nov. 28, 2008); s*ee also* Press Release, AEI-Brookings Joint Center for Regulatory Studies, Mark McClellan to Join AEI-Brookings Joint Center (Oct. 16, 2006), *available at* http://www.aei-brookings.org/pdf/McClellan_announcement.pdf (discussing McClellan's government service since 2001).

35. 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, 535-36 (2006); Leila Abboud, *FDA Official Criticized Agency for Scrutiny of Contraceptive: Rejected 'Plan B' Pill Faced Unique Hurdles, Reviewer's Memo Says*, WALL ST. J., June 18, 2004, at B4.

36. Gardiner Harris & Robert Pear, *After Lengthy Wait, Acting Head of F.D.A. Is Picked to Be Leader*, N.Y. TIMES, Feb. 15, 2005, at A1; *see also* Food and Drug Administration, Biography of Dr. Lester M. Crawford, http://www.fda.gov/oc/crawford/bio.html (last visited Nov. 28, 2008) (noting that Senate confirmed Crawford as FDA Commissioner on July 18, 2005).

37. Biography of Dr. Lester M. Crawford, *supra* note 36.

38. Gardiner Harris, *F.D.A. Approves Broader Access to Next-Day Pill*, N.Y. TIMES, Aug. 25, 2006, at A1. Plan B, the focus of this Comment, is commonly referred to as the "morning-after" pill. Food and Drug Administration, Plan B: Questions and Answers, http://www.fda.gov/cder/drug/infopage/planB/planBQandA20060824.htm (last visited Nov. 28, 2008). It is emergency contraception that should be used primarily when regular contraception fails or was not used. *Id*. Containing ingredients identical to regular birth control pills, Plan B prevents fertilization; it does not terminate an existing pregnancy. *Id.*

39. Harris, *supra* note 38.

40. *Id.*

"causing further upheaval at an agency [already] in turmoil."[41]

President Bush then appointed a family friend, Dr. Andrew C. von Eschenbach, as Commissioner of the FDA.[42] A nationally renowned urologic surgeon and oncologist, von Eschenbach resigned as Director of the National Cancer Institute upon appointment.[43] Senators Clinton and Murray[44] promised to block von Eschenbach's nomination to pressure the FDA to make a decision about permitting over-the-counter sales of Plan B, just as they had done with Crawford.[45]

2. Switching Prescription Drugs to Over-the-Counter Status

Whereas financial concerns often fuel the decision to switch a drug from prescription status to over-the-counter status, in the case of emergency contraception, social and political forces provided the momentum.[46] Under the FDCA, the FDA has authority to switch a drug from prescription to over-the-counter status in three ways.[47] First, if the FDA determines that a drug is safe and effective, and its labeling provides clear, comprehensible, and adequate directions and warnings, the FDA Commissioner can initiate a proposal to make the drug available over the counter.[48] Second, any interested party, including a private citizen, can file a petition to switch a drug from prescription to over-the-counter status.[49] Finally, any interested person can file a supplement to an approved new drug application to switch a drug from prescription status.[50] Because the manufacturer developed the drug for prescription use and knows the most about it, the manufacturer is in the best position to determine whether,

41. Robert Pear & Andrew Pollack, *Leader of the F.D.A. Steps Down After a Short, Turbulent Tenure*, N.Y. TIMES, Sept. 24, 2005, at A1.

42. Gardiner Harris, *Bush Picks F.D.A. Chief, but Vote Is Unlikely Soon*, N.Y. TIMES, Mar. 16, 2006, at A18.

43. Food and Drug Administration, Biography of Andrew C. von Eschenbach, M.D., http://www.fda.gov/oc/voneschenbach/bio.html (last visited Nov. 28, 2008).

44. Both senators are Democrats and support the Plan B application for over-the-counter sales. Harris, *supra* note 42.

45. *Id.*

46. Seamon, *supra* note 35, at 542.

47. *See* 21 U.S.C. § 353(b)(3) (2006) (allowing FDA Secretary to remove, by regulation, prescription drugs from prescription status when restrictions are not needed to protect public health).

48. *See* 21 C.F.R. § 330.10 (2006) (outlining procedures, including labeling, for classifying over-the-counter drugs as safe and effective and not misbranded). The FDA once attempted to switch a drug's status on its own initiative, but this effort was ultimately unsuccessful. Consumer Healthcare Products Association, FAQs About Rx-to-OTC Switch, http://www.chpa-info.org/scienceregulatory/FAQs_Switch.aspx (last visited Nov. 28, 2008). In 1982, the FDA attempted to switch an asthma drug to over-the-counter status. *Id.* Following negative comments, the FDA quickly rescinded its decision. *Id.* If the FDA were to make a recommendation to switch a product, it would have to follow a resource-intensive, complex process. *Id.* Many questions exist with respect to this approach, including those concerning the FDA's authority to initiate this process and the lack of regulations about such an approval. *Id.*

49. 21 C.F.R. § 310.200(b) (2006).

50. *Id.*

and under what circumstances, it would be appropriate to require a switch.[51]

The Nonprescription Drug Manufacturers Association estimates that more than 200 over-the-counter drug products on the market today were once available only by prescription,[52] including "Rogaine for hair loss," "Aleve for pain," and "Monistat for vaginal yeast infections."[53] Over-the-counter drug products contain ingredients in dosage strengths that the FDA has deemed safe enough for self-use.[54] By reclassifying these drugs, as well as others, the FDA has demonstrated a growing acceptance that certain drugs can be safely used without a doctor's prescription.[55]

3. Judicial Review

Under the APA, actions of an agency such as the FDA are generally not judicially reviewable, though there are exceptions.[56] For example, an agency's actions may be reversed by a court if they were arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law.[57] A court must determine whether the agency action was based on a consideration of relevant factors and whether the action constituted a clear judgment error.[58] Courts have held an agency's action is arbitrary and capricious when

51. See *supra* note 48 for an example of how the FDA once attempted to switch a drug's status but failed.

52. Tom Reynolds, *Switching from Prescription to Over the Counter*, 136 ANNALS INTERNAL MED., Jan. 15, 2002, at 177, 177, *available at* http://www.annals.org/cgi/reprint/136/2/177.pdf.

53. Sheryl Gay Stolberg, *F.D.A. Considers Switching Some Prescription Drugs to Over-the-Counter Status*, N.Y. TIMES, June 28, 2000, at A18.

54. Reynolds, *supra* note 52, at 177.

55. Seamon, *supra* note 35, at 541-42.

56. 5 U.S.C. § 706 (2006). According to the APA, there are six instances in which courts may hold agency action unlawful and set it aside. *Id.* Section 706 states:

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—
>
> (1) compel agency action unlawfully withheld or unreasonably delayed; and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
>
> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.
>
> In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

Id.

57. 5 U.S.C. § 706(2)(A).

58. *See* Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971) (noting that proper standard of review is one of deference), *abrogated by* Califano v. Sanders, 430 U.S. 99, 105 (1977).

> 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.[59]

Nevertheless, courts apply the standard deferentially and, therefore, uphold agency decisions that have a reasonable basis.[60]

B. Plan B and the FDA: Background and Description

Plan B is a progestin-only contraceptive with only minor side effects.[61] Since 1997, the FDA has regarded Plan B as a safe and effective method of emergency contraception.[62] In 2004, contrary to overwhelming scientific evidence and pursuant to an unusual review process, the FDA rejected Barr Pharmaceutical's proposal to market Plan B as a nonprescription product for women over sixteen years of age.[63] In 2006, the FDA approved Plan B for over-the-counter use but restricted access for those under eighteen.[64]

1. Medical Description of Plan B

Commonly referred to as the "morning-after" pill, Plan B is emergency contraception.[65] To be effective, emergency contraception should be used within seventy-two hours of intercourse[66] when regular contraception failed or was not used.[67] Plan B is nearly ninety percent effective[68] if taken orally in the form of

59. Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see also* Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 286 (1974) (stating court will uphold agency's decision even if it is not ideally clear so long as agency's reasoning can be discerned).

60. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

61. See *infra* notes 73 and 78-80 and accompanying text for a description of Plan B's ingredients and side effects.

62. *See* Prescription Drug Products, Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610, 8610-11 (Feb. 25, 1997) [hereinafter Prescription Drug Products] (declaring certain types of oral emergency contraception "safe and effective").

63. U.S. GOV'T ACCOUNTABILITY OFFICE, FOOD AND DRUG ADMINISTRATION: DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 2-3, 42 (2005), *available at* http://www.gao.gov/new.items/d06109.pdf [hereinafter GAO REPORT]. See *infra* Part II.B.2.b for a detailed analysis of the FDA's 2004 decision.

64. Letter from Steven Galson, Dir., Ctr. Drug Evaluation & Research, FDA, to Joseph A. Carrado, Vice President Clinical Regulatory Affairs, Duramed Research, Inc. (Aug. 26, 2006), *available at* http://www.fda.gov/CDER/foi/nda/2006/021045s011_Plan_B_APPROV.pdf [hereinafter Approval Letter]. See *infra* Part II.B.2.c for a detailed discussion of the FDA's August 2006 decision denying minors over-the-counter access to Plan B.

65. Plan B: Questions and Answers, *supra* note 38.

66. *Id.* The pills, however, may be effective up to 120 hours after intercourse. *See* Suk Wai Ngai et al., *A Randomized Trial to Compare 24h Versus 12h Double Dose Regimen of Levonorgestrel for Emergency Contraception*, 20 HUM. REPROD. 307, 307, 311 (2005) (concluding that two doses of levonorgestrel are effective up to 120 hours after intercourse).

67. Plan B: Questions and Answers, *supra* note 38.

two pills, each containing .75 milligrams of levonorgestrel, a synthetic hormone that has been used in birth control pills for more than thirty years.[69] Ideally, a woman would take a second pill twelve hours after the first pill to prevent pregnancy, as such dosages halt the egg's release from the ovary.[70] Even if an egg has been released, the pill prevents fertilization or attachment to the uterine wall.[71] If a fertilized egg is already attached to the uterus, the pill will not terminate the pregnancy.[72]

Unlike combination pills, which contain both estrogen and progestin, Plan B contains only progestin.[73] Progestin works to prevent pregnancy in three ways.[74] First, the progestin-only pill signals to the woman's body that she is pregnant and prevents the ovaries from releasing an egg.[75] Second, it causes changes to the uterus that make fertilization less likely even if an egg has been released.[76] Finally, because the pill thickens the mucus between the uterus and the vagina, it makes it more difficult for sperm to penetrate the mucus and reach the egg.[77]

Plan B is safe for most women and has only minor side effects.[78] For example, it may cause nausea, abdominal pain, fatigue, headache, dizziness, or breast tenderness.[79] In addition, it may cause spotting or bleeding before the next menstrual period.[80]

2. Political History of Plan B

a. Early Treatment

In 1997, the FDA released results of its research announcing that morning-after pills were safe and effective contraception.[81] In this notice, the FDA

68. Barr Pharmaceuticals, Inc., What is Plan B?, http://www.go2planb.com/ForConsumers/AboutPlanB/WhatisPlanB.aspx (last visited Nov. 28, 2008).

69. Plan B: Questions and Answers, *supra* note 38.

70. *Id.*

71. *Id.*

72. *Id.*

73. Food and Drug Administration, FDA's Decision Regarding Plan B: Questions and Answers, http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm (last visited Nov. 28, 2008).

74. Familydoctor.org, Progestin-only Contraceptives, http://familydoctor.org/632.xml (last visited Nov. 28, 2008).

75. *Id.*

76. *Id.*

77. *Id.*

78. Barr Pharmaceuticals, Inc., Plan B: FAQs, http://www.go2planb.com/ForConsumers/TakingPlanB/faqs.aspx (last visited Nov. 28, 2008); Plan B: Questions and Answers, *supra* note 38.

79. Plan B: FAQs, *supra* note 78.

80. *Id.*

81. *See* Prescription Drug Products, *supra* note 62, at 8610-11 (noting "combined oral contraceptives are now accepted as remarkably safe and effective when used as directed"). The FDA also noted that emergency contraception has been used in the United Kingdom since 1984, with over four million recorded prescriptions. *Id.* at 8610.

indicated that it hoped the test results would "encourage manufacturers to make this additional contraceptive option available."[82]

The FDA approved Plan B in 1999, and the manufacturer began marketing it as a safe and effective emergency contraceptive.[83] In 2001, the Center for Reproductive Law and Policy, acting on behalf of sixty-six organizations, filed a citizen's petition requesting that the FDA make emergency contraception available without a prescription.[84] The petition argued that the FDA should switch emergency contraception to over-the-counter use for several reasons: it is safe for self-medication, administration is simple, it treats a condition readily diagnosable by a woman, it includes clear labeling, and it will promote public health.[85]

In 2003, Women's Capital Corporation, later acquired by Barr Pharmaceuticals, Inc.,[86] submitted a supplemental new drug application that sought to approve Plan B for over-the-counter use.[87] The application discussed how Plan B satisfied the requirements for over-the-counter use.[88] First, clinical trials showed that out of 7000 women, Plan B was eighty-nine percent effective in preventing pregnancy if taken within the first seventy-two hours after intercourse.[89] Side effects during these trials were minimal, limited to common effects such as nausea, abdominal pain, and fatigue.[90] Second, label comprehension studies indicated the vast majority of women could understand the main communication objectives of the Plan B label.[91] Finally, the manufacturer performed actual-use studies in nearly 600 women between the ages of fourteen to forty-four (focusing on the seventeen to twenty-five age group) to determine if women could self-select themselves as proper candidates for Plan B.[92] Ninety-nine percent of the women were proper candidates for use, ninety-eight percent took the first pill within the required seventy-two hours, and seventy-four percent took the required second pill within twelve hours.[93] In short, studies simulating the over-the-counter setting indicated that Plan B was equally safe and effective when used as an over-the-counter and prescription drug.[94] Therefore, the application seemed to meet the requirements for a

82. *Id.*

83. AM. PHARM. ASS'N, EMERGENCY CONTRACEPTION: THE PHARMACIST'S ROLE 1, 2 (2000).

84. Letter from Daniel Yuhas, Ctr. for Reprod. Law & Policy, to FDA, Citizen's Petition 2 (Feb. 14, 2001), *available at* http://www.fda.gov/ohrms/dockets/dailys/01/Feb01/021401/cp00001.pdf.

85. *Id.*

86. Bloomberg News, *Barr Labs Agrees to Buy Assets of Women's Capital*, N.Y. TIMES, Oct. 3, 2003, at C4.

87. GAO REPORT, *supra* note 63, at 2-3, 42.

88. Joint Committee Meeting, *supra* note 13, at 39-40.

89. *Id.* at 40.

90. *Id.* at 41. In addition, there was no increase in the frequency of ectopic pregnancies and no deaths occurred during the clinical trials. *Id.* at 41-42.

91. *Id.* at 43-44.

92. Joint Committee Meeting, *supra* note 13, at 51-52.

93. *Id.* at 53-54.

94. *Id.* at 56.

prescription to over-the-counter switch.

Typically, in a prescription to over-the-counter switch, the FDA seeks the "recommendation of a joint advisory committee made up of members of the [FDA's] Nonprescription Drugs Advisory Committee and another advisory committee with expertise in the type of drug being considered."[95] On December 16, 2003, a joint panel of the Nonprescription Drugs Advisory Committee and the FDA's Reproductive Health Drugs Advisory Committee met and voted twenty-three to four to recommend Plan B for over-the-counter use.[96] The panel found that the drug was safe and effective for use without a prescription. Individual members noted it was "extraordinarily safe," "with a wide safety margin," safe "with statistical certainty," and the "safest produc[t]" before the panel in four years.[97] Overall, twenty-two committee members found plans for the introduction of Plan B into the nonprescription setting adequate with respect to consumer access and safe use, while five opposed the switch and one abstained.[98] At the conclusion of the meeting, the committee voted twenty-three to four to recommend approval of Plan B without a prescription.[99]

95. Tamar Nordenberg, *Now Available Without a Prescription*, FDA CONSUMER, Nov. 1996, *available at* http://www.fda.gov/FDAC/features/996_otc.html.

96. Joint Committee Meeting, *supra* note 13, at 6, 395.

97. *Id.* at 344-49.

98. *Id.* at 381. In addressing the question, the chairman asked committee members to state their views on age restrictions. *Id.* at 351. One member, Dr. Sandra Kweder, noted because Plan B currently has no age restriction in prescription form, there was no reason to limit in over-the-counter access based on age. *Id.* at 351-52. Further, Kweder noted that all oral contraceptives historically have not had age restrictions because women of reproductive age are "capable of reproduction as one group." Joint Committee Meeting, *supra* note 13, at 352.

Some committee members indicated that the actual-use study failed to give them enough information about the younger adolescent population to reach a decision. *Id.* at 354-55. One proposal was to conduct more studies of Plan B's effects on younger users. *Id.* at 370. Kweder also stated the most common method of preventing use by certain age groups would be to include an insert that says "under age X see a doctor." *Id.* at 357. Another member, Dr. Larry Lipshultz, noted that the ideal solution would be to place the drug behind the counter, thereby forcing the consumer to speak with the pharmacist. *Id.* at 358. Dr. Julie Johnson suggested that the educational focus for health care professionals should be directed to pharmacists, because they will be interfacing with consumers who wish to purchase the product. Joint Committee Meeting, *supra* note 13, at 359. Johnson also reasoned that having no age restrictions is better because ten- or eleven-year-old children would not become pregnant due to restrictions imposed to prevent a hypothetical risk that they might be taking the product. *Id.*

Some committee members were concerned about the appeal of the Convenient Access Responsible Education ("CARE") program, a program designed to increase access to and awareness of Plan B's availability, to women ages seventeen to forty-four and questioned future plans to address a younger age group. *Id.* at 369. Dr. Geri Hewitt, a pediatric analyst and gynecologist, noted that while adolescents are different medically, psychologically, and behaviorally, progestin is safe for them to use. *Id.* at 371. Furthermore, Hewitt felt the drug should be widely available without the need to ask a pharmacist. *Id.* at 372. Another member quipped that only when adolescent women are required show proof of age prior to engaging in sexual intercourse should they be required to show proof of age to obtain Plan B. Joint Committee Meeting, *supra* note 13, at 373-74. An adolescent gynecologist with over fifteen years of experience noted that barriers to accessing contraception should be decreased because adolescent females are embarrassed about their sexuality. *Id.* at 378.

99. *Id.* at 382, 395.

b. 2004 Decision Denying Over-the-Counter Use

In March, 2004, Barr Pharmaceuticals submitted a preliminary proposal which indicated its intention to market Plan B as a prescription-only product for women under sixteen years of age and a nonprescription product for women over sixteen.[100] While the FDA's scientific staff favored approval, a senior agency official disagreed and denied the application, noting he was concerned that teenagers would use the pill.[101] Although the FDA considered the Plan B application according to its normal protocols, the review process was marked by four abnormalities.[102] First, the letter rejecting Barr's preliminary proposal was signed by the Center for Drug Evaluation and Research ("CDER") Acting Director because the directors who typically bear responsibility for signing disagreed with the decision.[103] Second, upper management of the FDA participated in the review process for the Plan B application significantly more than it normally did in evaluations of over-the-counter switch applications.[104] Third, while FDA officials have insisted that scientific and regulatory concerns drove their decision to disapprove or delay Plan B, the Government Accountability Office found last year that top agency officials rejected the application before the agency staff completed their scientific review.[105] Finally, von Eschenbach's novel rationale for his decision, focusing on administrative ease, did not conform to traditional FDA practices.[106]

Of the sixty-seven proposed prescription to over-the-counter switches the FDA has decided between 1994 and 2004, the Plan B decision was unique in several ways.[107] First, only the Plan B decision disregarded the advisory committee's suggestion.[108] Second, the FDA has never implemented age-related marketing restrictions or required pediatric studies for any approved over-the-counter or prescription contraceptives.[109] Finally, when it initially reviewed Plan B as a prescription drug, the FDA identified no issues that would warrant age-related restrictions.[110]

In July 2004, Barr submitted a complete amended application to propose selling Plan B over the counter for women over sixteen years of age.[111] One month later, the FDA announced that it completed its review of the Plan B application and determined that scientific data supported Plan B's safe over-the-

100. Letter from Steven Galson, Acting Dir., Ctr. for Drug Evaluation & Research, to Joseph A. Carrado, Senior Dir., Regulatory Affairs, Barr Research, Inc. (May 6, 2004), *available at* http://www.fda.gov/cder/drug/infopage/planB/planB_NALetter.pdf.

101. Harris, *supra* note 42.

102. GAO REPORT, *supra* note 63, at 5.

103. *Id.* The Director of the Office of New Drugs also disagreed and refused to sign the letter. *Id.*

104. *Id.*

105. *Id.*

106. GAO REPORT, *supra* note 63, at 5.

107. *Id.*

108. *Id.*

109. *Id.* at 6.

110. Harris, *supra* note 42.

111. GAO REPORT, *supra* note 63, at 3.

counter use for women seventeen and older.[112] Rather than approving the drug, the FDA sought public comment on marketing issues implicated by the amended application,[113] known as an Advanced Notice of Proposed Rulemaking ("ANPRM"). In particular, the FDA pointed out three concerns: "the [FDA] ha[d] never determined whether a drug may be [prescription and over the counter] based on the age of the individual using the drug"; enforcing age-based distinctions could be problematic; and the FDA had never determined whether a manufacturer could market prescription and over-the-counter versions of the same active ingredient in a single package.[114] By the time the comment period closed on November 1, 2005, the FDA received approximately 47,000 comments.[115] At the close of the comment period, the FDA engaged a contractor to review the comments.[116] Following the contractor's final reports on May 19, 2006, the FDA agreed with the "overwhelming majority" of comments, which said rulemaking was an unnecessary delay tactic, and "chose not to engage in rulemaking to resolve the novel regulatory issues" the application raised.[117] Instead, in a letter to Duramed, a Barr Pharmaceuticals subsidiary, dated July 31, 2006, the FDA indicated it would "proceed[] with further evaluation" of the supplemental new drug application and meet with the manufacturer to discuss necessary application amendments,[118] including a framework for distributing the drug as a nonprescription product for women over eighteen.[119] In response to this letter, Duramed submitted a proposal on August 17, 2006, indicating it would market Plan B as an over-the-counter product with a "prescription-only requirement" for those under seventeen.[120] Duramed's proposal received mixed

112. *Id.* at 3 n.11.

113. *Id.*; *see also* Statement by Lester M. Crawford, Comm'r, FDA, FDA Takes Action on Plan B (Aug. 26, 2005), *available at* http://www.fda.gov/bbs/topics/NEWS/2005/NEW01223.html (noting that, because regulatory and policy issues were "too profound and cut across too many different products," there should be open process to solicit public comment).

114. Letter from Lester M. Crawford, Comm'r of Food & Drugs, FDA, to Joseph A. Carrado, 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 Not Approvable Letter].

115. Letter from Andrew von Eschenbach, Acting Comm'r of Food & Drugs, FDA, to Joseph A. Carrado, Senior Dir., Regulatory Affairs, Duramed Research, Inc. (July 31, 2006), *available at* http://www.fda.gov/oc/planb/duramed073106.html [hereinafter Approvable Letter].

116. *Id.*

117. *Id.*

118. *Id.* For example, in the letter to Duramed, a subsidiary of Barr Pharmaceuticals, von Eschenbach indicated scientific data did not support distributing Plan B over the counter to those over sixteen. *Id.* Instead, the Agency considered eighteen the appropriate age for over-the-counter access. Approvable Letter, *supra* note 115. In the letter, the acting commissioner inquired of Barr's plans to monitor pharmacies' drug distribution to determine compliance with the CARE program. *Id.* Finally, the FDA expressed an interest in Barr's plan to enforce restrictions if pharmacies failed to comply with them. *Id.*

119. *Id.*

120. Memorandum from Julie Beitz, Acting Dir., Office of Drug Evaluation, FDA (Aug. 22, 2006), *in* CTR. FOR DRUG EVALUATION & RESEARCH, APPLICATION NUMBER 21-045/S011: MEDICAL REVIEW 2, *available at* http://www.fda.gov/CDER/foi/nda/2006/021045s011_Plan_B__MedR.pdf.

opinions. For example, Dr. Julie Beitz, the acting office director of the CDER, concluded that Plan B could be approved for over-the-counter sales absent an age registration because scientific data suggested the drug was safe and effective.[121] Similarly, Dr. Charles Ganley, director of the Office of Nonprescription Products, indicated that the data did not suggest the need for an age-based restriction.[122]

c. August 2006 Decision Denying Minors Over-the-Counter Access to Plan B

On August 26, 2006, the FDA approved Plan B for over-the-counter use by consumers over eighteen but noted that women seventeen years old or younger would still need to obtain a prescription from a doctor to access the drug.[123] The manufacturer, Barr Pharmaceuticals, had to assure the FDA that the drug would not be sold to those under eighteen.[124] To fulfill that assurance and comply with FDA restrictions, the company developed the Convenient Access Responsible Education program ("CARE"), which would prohibit Plan B sales at convenience stores and gasoline stations that have pharmacies.[125] In addition, the contraceptive would be behind a pharmacy counter instead of on drugstore shelves.[126] Finally, women purchasing the drug would have to show photo identification to prove their age.[127]

In addition, Barr would evaluate the effectiveness of the CARE program by conducting marketing surveys and research to track the trends in the use of emergency contraception.[128] Similarly, the FDA required Barr to establish a Point-of-Purchase Monitoring Program to evaluate sales of Plan B at the moment of purchase, including consumer comprehension levels of the

121. *Id.* Beitz further noted that, "[i]n the absence of new data to support an age restriction," her conclusions discussed in previous memos "remain unchanged." *Id.*

122. Memorandum from Charles J. Ganley, Dir., Office of Nonprescription Prods., FDA (Aug. 22, 2006), *in* CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 120, at 4. John Jenkins, director of the Office of New Drugs, also agreed that an age restriction was not necessary. Memorandum from John K. Jenkins, Dir., Office of New Drugs (Aug. 22, 2006), *in* CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 120, at 6. Nevertheless, Steven Galson, who rejected the drug's approval in 2004, stated women age seventeen and older can use the product safely. Memorandum from Steven Galson, Dir., Ctr. for Drug Evaluation & Research (Aug. 26, 2005), *in* CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 120, at 13. Soon after the drug's approval for over-the-counter use in August 2006, however, Galson issued a memo that indicated he had changed his mind and now agreed with von Eschenbach that eighteen is the appropriate age cutoff. Memorandum from Steven Galson, Dir., Ctr. for Drug Evaluation & Research 3 (Aug. 24, 2006), *available at* http://www.fda.gov/CDER/drug/infopage/planB/memo.pdf.

123. Approval Letter, *supra* note 64.

124. Stephanie Saul, *F.D.A. Shifts View on Next-Day Pill*, N.Y. TIMES, Aug. 1, 2006, at A1; *see also* Approvable Letter, *supra* note 115 (noting that Barr must develop program "sufficiently rigorous" to prevent underage girls from obtaining over-the-counter version of drug).

125. Approval Letter, *supra* note 64.

126. *Id.*

127. Approvable Letter, *supra* note 115.

128. Approval Letter, *supra* note 64.

prescription age requirement.[129]

C. Constitutional Rights and the Age Limitation on Over-the-Counter Access to Plan B Contraception

The FDA rationalized its decision to restrict minors' access to Plan B by stressing the administrative ease of enforcing an age restriction of eighteen years. Unlike laws requiring minors to notify their parents before having an abortion, minors do not need parental consent to access emergency contraception.[130] In fact, since 1965, the Supreme Court has recognized that there is a privacy right to access contraceptives.[131] Over ten years later, the Supreme Court recognized that this right extended to minors.[132] Finally, both Congress and many states have passed legislation broadening minors' rights to access contraceptives.[133]

1. FDA's Rationale for Setting Age Restriction at Eighteen

In a memo, von Eschenbach, Acting FDA Commissioner, explained why setting the age restriction at eighteen best promotes and protects the public health.[134] Referring to the August 2005 memo from Dr. Steven Galson, Director of the CDER, von Eschenbach agreed with the CDER's conclusion that Barr did not conclusively establish that Plan B could be used by women sixteen and under without the professional supervision of a licensed practitioner.[135] The Director noted state-regulated pharmacies and society as a whole are "more familiar" with age eighteen rather than seventeen as a cutoff.[136] For example, eighteen is the minimum age to purchase "FDA approved non-prescription nicotine replacement therapy products," tobacco products, and "nonprescription cough-cold products."[137] In addition, he noted that in all fifty states, eighteen is the age of majority.[138] He concluded that "[t]his approach builds on well-established

129. *Id.*

130. See *infra* Part II.C.2.a for a general description of parental notification laws, which only apply to abortions.

131. *See* Eisenstadt v. Baird, 405 U.S. 438, 453-54 (1972) (finding that equal protection required similar treatment of married and unmarried persons with respect to access to contraception); Griswold v. Connecticut, 381 U.S. 479, 485-86 (1965) (recognizing "zone of privacy," which included marital relationship, fundamentally guaranteed by Constitution).

132. Carey v. Population Servs. Int'l, 431 U.S. 678, 688-89 (1977) (holding unconstitutional statute barring sales of contraceptives to minors without prescription). See *infra* Part II.C.2.c for a discussion of the Supreme Court's jurisprudence recognizing minors' rights to access contraceptives.

133. See *infra* Parts II.C.2.d-e for a description of legislation dealing with minors' access to contraceptives, as well as state-enacted regulations.

134. Memorandum from Andrew C. von Eschenbach, Acting Comm'r, FDA (Aug. 23, 2006), *available at* http://www.fda.gov/CDER/drug/infopage/planB/avememo.pdf [hereinafter August 2006 Memorandum].

135. *Id.* at 1.

136. *Id.*

137. *Id.*

138. *Id.* Von Eschenbach defined majority as "the legal delineation between minor and adult." August 2006 Memorandum, *supra* note 134, at 1.

state and private-sector [legal] infrastructures to restrict certain products to consumers 18 and older."[139]

2. Minors' Rights to Access Contraception

a. Parental Notification Laws Regarding Abortion

Parental notification laws have a tremendous impact on minors' reproductive rights and decisions. Of the twenty-one percent of women in the United States who had an abortion in 2002,[140] many of them were teenagers.[141] Parental notification laws stand in the way of many minors, because such laws "prohibit minors from acting without consulting a parent" in two broad ways.[142] First, one form of such a law requires "'clinics to give advance notice to one or both parents.'"[143] Second, parental consent laws "require the minor to obtain the written consent of one of her parents before she can have an abortion."[144]

These laws vary from state to state.[145] Pennsylvania law, for example, allows a minor "to consent to all medical, dental and other health services, except abortion, if the minor has: (1) graduated from high school; or (2) been married; or (3) been pregnant."[146] Because emergency contraception does not induce abortion, the parental consent requirement for minors receiving abortions in Pennsylvania does not extend to the provision of emergency contraception. Indeed, "Pennsylvania law has been interpreted to permit clinicians to provide confidential contraceptive care to minors upon their own consent."[147] Because

139. *Id.* at 2.

140. GUTTMACHER INST., *supra* note 1, at 2.

141. *See* GUTTMACHER INST., IN BRIEF: FACTS ON INDUCED ABORTION IN THE UNITED STATES 1 (2006), *available at* http://www.guttmacher.org/pubs/fb_induced_abortion.pdf (noting that seventeen percent of women seeking abortions are teenagers).

142. Amanda C. Scuder, Comment, *The Inapplicability of Parental Involvement Laws to the Distribution of Mifepristone (RU-486) to Minors*, 10 AM. U. J. GENDER SOC. POL'Y & L. 711, 720 (2002).

143. *Id.* (quoting Angela Bonavoglia, *Kathy's Day in Court*, *in* FROM ABORTION TO REPRODUCTIVE FREEDOM: TRANSFORMING A MOVEMENT 161, 168 (Marlene Gerber Fried ed., 1990)); *see also, e.g.*, MD. CODE ANN., HEALTH-GEN. § 20-103 (LexisNexis 2005) (providing that physicians may not perform abortions on unmarried minors unless physician first gives notice to minor's parent or guardian).

144. Scuder, *supra* note 142, at 720 (citing Robin Abcarian, *How a Law that Sounds OK on Paper Killed a Girl*, L.A. TIMES, Apr. 14, 1996, at E1); *see also, e.g.*, IND. CODE ANN. § 16-34-2-4 (West 2007) (providing that physicians may not perform abortions on minors without written consent of minor's parent or guardian).

145. Scuder, *supra* note 142, at 720. *Compare* FLA. STAT. ANN. § 390.01114 (West 2007) (requiring parental notification but providing for doctor-authorized waiver where medical emergency exists), *with* KY. REV. STAT. ANN. § 311.732 (West 2006) (requiring parental consent and providing for judicial-bypass procedure).

146. AM. CIVIL LIBERTIES UNION OF PA., REFERENCE CARD: MINORS' ACCESS TO CONFIDENTIAL HEALTHCARE FOR REPRODUCTIVE HEALTH, MENTAL HEALTH AND SUBSTANCE ABUSE IN PENNSYLVANIA (2005), *available at* http://www.aclupa.org/downloads/PAminorscard2005.pdf.

147. *Id.*

Plan B is emergency contraception, minors do not need parental consent to obtain it under Pennsylvania law.[148]

b. Due Process Rights to Access Contraception Under the United States Constitution

The Supreme Court began to address reproductive privacy issues and due process rights to access contraception over forty years ago in the landmark 1965 case *Griswold v. Connecticut*.[149] The Court in *Griswold* recognized that the Bill of Rights creates "zones of privacy" that protect against governmental invasions[150] "'of the sanctity of a man's home and the privacies of life.'"[151] Because of such constitutional guarantees of privacy, the Court found it was unconstitutional for states to intrude into the marital relationship by prohibiting contraceptive use or limiting physicians' abilities to help married couples obtain contraceptives.[152]

A few years later, in 1972, the Court in *Eisenstadt v. Baird*[153] concluded that there was no rational explanation for treating married and unmarried couples differently with respect to rights to access contraceptives.[154] The Court agreed with the court of appeals, which reasoned that "'[i]f . . . the same physician who can prescribe for married patients does not have sufficient skill to protect the health of patients who lack a marriage certificate, or who may be currently divorced, it is illogical to the point of irrationality.'"[155] The Court concluded that the right of privacy is "the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[156]

In 1976, in *Planned Parenthood of Central Missouri v. Danforth*,[157] the Court determined that minors have a similar due process right to privacy, but "the State has somewhat broader authority to regulate the activities of children than of adults."[158] The Court held there must be a "significant state interest . . . not present in the case of an adult" to justify state burdens on minors' privacy rights.[159]

148. *Id.*

149. 381 U.S. 479, 485 (1965).

150. *See Griswold*, 381 U.S. at 484-85 (holding that law forbidding use of contraceptives by married couples violates area of protected freedoms).

151. *Id.* at 484 (quoting Boyd v. United States, 116 U.S. 616, 630 (1886)).

152. *Id.* at 485-86.

153. 405 U.S. 438 (1972).

154. *Eisenstadt*, 405 U.S. at 447.

155. *Id.* at 451 (quoting Baird v. Eisenstadt, 429 F.2d 1398, 1401 (1st Cir. 1970)).

156. *Id.* at 453.

157. 428 U.S. 52 (1976).

158. *Danforth*, 428 U.S. at 74.

159. *Id.* at 75.

c. Minors' Due Process Rights to Access Contraception

The Supreme Court addressed minors' due process rights to access contraception in the 1977 case, *Carey v. Population Services International*,[160] in which the plaintiffs challenged a New York law prohibiting over-the-counter sales of contraceptives to anyone under sixteen.[161] The Court recognized that access to contraception is a constitutionally protected decision in matters of childrearing and that the right underlies the Supreme Court's reasoning in *Roe v. Wade*,[162] *Griswold*, and *Eisenstadt*.[163]

Citing *Eisenstadt*, the Court noted that limiting distribution of contraceptives to licensed pharmacists significantly burdens individuals' rights to choose whether to use contraceptives.[164] The Court also observed that restricting distribution of contraceptives to a small percentage of potential retail outlets limits public access, reduces privacy of selection and purchase, and hampers price competition.[165]

Addressing minors' due process rights under the Constitution, a plurality of the Court found the "significant state interest" standard laid out in *Danforth* was applicable.[166] The Court reasoned that deciding to have an abortion implicates the State's interest in protecting potential life and pregnant minors' health more than deciding to use a nonhazardous contraceptive.[167] That an absolute prohibition on the distribution of contraceptives to minors is "*a fortiori* foreclosed" follows from the Court's determination of the unconstitutionality of both a blanket prohibition on abortion for minors and a blanket parental consent requirement for minors.[168]

Since *Carey*, the Supreme Court has afforded constitutional acceptance to more stringent parental consent requirements for minors seeking abortions,[169] although no decision has permitted parental notification requirements with

160. 431 U.S. 678 (1977).

161. *Carey*, 431 U.S. at 694.

162. 410 U.S. 113 (1973).

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

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

165. *Id.*

166. *Id.* at 693 (internal quotation marks omitted) (quoting Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 75 (1976)).

167. *Id.* at 694.

168. *Carey*, 431 U.S. at 694.

169. *See* Ayotte v. Planned Parenthood of N. New England, 126 S. Ct. 961, 966-67 (2006) (noting that parental notification poses no undue burden where there is exception for health of mother); Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 899 (1992) (plurality opinion) (providing for judicial-bypass option but requiring unemancipated minor seeking abortion to give her own informed consent and to obtain informed consent of one parent or guardian); Ohio v. Akron Ctr. for Reprod. Health, 497 U.S. 502, 506-08 (1990) (upholding significantly burdensome judicial-bypass procedure for minors seeking abortions without parental consent, which requires them to file complaint in juvenile court, obtain guardian ad litem, and hire attorney for proceedings); Bellotti v. Baird, 443 U.S. 622, 643-44, 647-48 (1979) (recognizing parental consent requirement for abortion would be permissible if state provided judicial-bypass option where minor could have abortion without notifying her parents by proving she is mature enough to make her own decision or abortion is in her best interests).

respect to minors' access to contraceptives. In fact, many cases have affirmed the liberty principles in *Carey* and have stressed that minors have a due process right to access contraception.[170] These cases have emphasized that the "law affords constitutional protection to personal decisions relating to . . . contraception."[171]

d. Legislating Access to Contraception for Minors

Congress has taken action to broaden minors' rights to access contraceptives. In 1970, Congress passed Title X of the Public Health Services Act,[172] which created a "comprehensive federal program devoted entirely to the provision of family planning services on a national basis."[173] Nearly ten years later, Congress amended Title X to ensure that recipients of the statute's family planning funds were required to provide services to adolescents.[174] In 1981, Congress again amended the statute to require providers to "encourage family participation" for minors seeking access to contraceptives.[175] Later, the House of Representatives passed the Parental Notification Act of 1998, an amendment to Title X.[176] If passed in the Senate, the bill would have required public clinics to notify parents before providing their teenage children with contraception.[177] This bill would have required clinics to give parents written notification unless the minor obtained judicial permission to bypass parental notification.[178] Before the bill went to the Senate, the sponsors feared a presidential veto and tabled it.[179] One year later, the sponsors of the 1998 Act again proposed an identical amendment.[180] Ultimately, they dropped the proposal in exchange for fifty million dollars of funding for abstinence education.[181] In June 2005, Congress attempted to reenact the "Parent's Right to Know" laws, which would have required that federally funded health clinics notify parents at least five days before providing contraceptives to their child.[182]

170. *See, e.g.*, *Casey*, 505 U.S. at 852-53 (reiterating agreement with previous decisions supporting women's liberty and respecting procreation choices).

171. *Id.* at 851 (citing *Carey*, 431 U.S. at 685); *see also* Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) (noting that constitutional right to privacy encompasses "decision whether to bear or beget a child"); Griswold v. Connecticut, 381 U.S. 479, 485 (1965) (recognizing that married couples' decisions to use contraception falls within "zone of privacy created by several fundamental constitutional guarantees").

172. 42 U.S.C. §§ 300 to 300a-6 (2006).

173. ALAN GUTTMACHER INST., FACTS IN BRIEF: TITLE X AND THE U.S. FAMILY PLANNING EFFORT (1997), *available at* http://www.guttmacher.org/pubs/ib16.html.

174. J. Shoshanna Ehrlich, *From Age of Consent Laws to the "Silver Ring Thing": The Regulation of Adolescent Female Sexuality*, 16 HEALTH MATRIX 151, 163 (2006).

175. *Id.* at 165.

176. Stephanie Bornstein, *The Undue Burden: Parental Notification Requirements for Publicly Funded Contraception*, 15 BERKELEY WOMEN'S L.J. 40, 40 (2000).

177. *Id.*

178. *Id.*

179. *Id.* at 40-41.

180. *Id.* at 41.

181. Bornstein, *supra* note 176, at 41.

182. Parent's Right to Know Act of 2005, S. 1279, 109th Cong. § 2(a)(1) (2005); Parent's Right to

e. State Laws

Many states have enacted their own laws regulating distribution of emergency contraception.[183] For example, nine states have passed legislation or regulations that permits "specially trained pharmacists to provide Plan B to women without a doctor's prescription."[184] In addition, under Pennsylvania law, minors have a right to obtain Plan B because the state has determined it is nothing more than contraception.[185]

Similarly, specific pharmacy practices are regulated from state to state.[186] In pharmacy-access states, women under the age of eighteen will still be able to obtain Plan B without a doctor's prescription through specially trained and licensed pharmacists.[187] The FDA ruling will not change these existing pharmacy-access programs unless those states pass new legislation to change them.[188]

III. DISCUSSION

A federal court should overturn the FDA's August 2006 decision restricting minors' over-the-counter access to Plan B because it constitutes unlawful rulemaking and violates the Due Process Clause of the Constitution. Part III.A of this Comment argues that a federal court should hold that the FDA's August 2006 decision is unlawful rulemaking and set it aside. Part III.B.1 then argues the FDA's rationale for the age restriction is unconvincing; instead, the decision creates the functional equivalent of a parental notification law. Part III.B.2 asserts Plan B is a contraceptive, not an abortifacient. Part III.B.3 concludes that restricting minors' access to contraceptives is unconstitutional and violates their due process rights. Finally, Part III.C discusses the consequences of the FDA's decision and proposes solutions to alleviate the problems it creates.

Know Act of 2005, H.R. 3011, 109th Cong. § 2(a)(1) (2005).

183. These states are California, Washington, Alaska, Hawaii, New Mexico, Maine, New Hampshire, Massachusetts, and Vermont. Office of Population Research & Association of Reproductive Health Professionals, Answers to Frequently Asked Questions About How to Get Emergency Contraception, http://ec.princeton.edu/questions/what-fda-says.html (last visited Nov. 28, 2008) [hereinafter The Emergency Contraception Web Site].

184. The Emergency Contraception Web Site, *supra* note 183. For the legislation of these nine states, see CAL. BUS. & PROF. CODE § 4052.3 (West Supp. 2007); HAW. REV. STAT. ANN. § 461-1 (LexisNexis 2005); ME. REV. STAT. ANN. tit. 32, §§ 13821-13825 (Supp. 2006); MASS. GEN. LAWS ANN. ch. 94C, § 19A (West 2006); N.H. REV. STAT. ANN. § 318:47-e (Supp. 2006); VT. STAT. ANN. tit. 26, §§ 2078-2079 (2006); WASH. REV. CODE ANN. § 18.64.011 (West 1999); ALASKA ADMIN. CODE tit. 12, § 52.240 (West, Westlaw through April 2007 Register 181); N.M. Code R. tit. 16, § 16.19.26.10 (West, Westlaw through May 1, 2007 rules, amendments, and repeals).

185. See *supra* notes 146-48 and accompanying text for a discussion of Pennsylvania law.

186. The Emergency Contraception Web Site, *supra* note 183.

187. *Id.*

188. *Id.*

A. FDA's August 2006 Decision Is Arbitrary and Capricious and Should Be Overturned

When the FDA decided in August 2006 to require that minors obtain prescriptions to access emergency contraception, the agency exceeded its congressional mandate under the FDCA to protect the public health.[189] Because the FDA's actions were arbitrary and capricious, a federal court should hold the FDA's actions unconstitutional and set them aside pursuant to APA guidelines allowing judicial review.[190]

> Courts have found agency action 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.[191]

The FDA's decision restricting minors' over-the-counter access to Plan B satisfies several of these factors. First, the FDA failed to consider important aspects of the problem. For example, minors currently have access to other types of contraceptives and Congress has, through Title X, specifically ensured that recipients of family-planning funds provide services to adolescents.[192] In addition, the agency did not recognize that Plan B is merely a larger dose of regular birth control pills, which are also accessible to minors.[193] Similarly, the FDA failed to give weight to the overwhelming recommendation of the joint advisory committee (a group of experts from the Nonprescription Drugs Advisory Committee and the Reproductive Health Drugs Advisory Committee) to approve access to Plan B without a prescription.[194] Therefore, because the FDA did not consider important aspects of the problem, a court should find its action was arbitrary and capricious.

Second, the FDA's explanation for its decision contradicts overwhelming scientific evidence. Plan B's side effects are minor.[195] As early as 1997, following research, the FDA announced Plan B was a safe and effective method of contraception.[196] Furthermore, Barr Pharmaceuticals' 2003 application seeking

189. See *supra* notes 22-28 and accompanying text for a discussion of the FDA's stated mission and mandate under the FDCA.

190. See *supra* Part II.A.3 for a discussion of when an administrative agency's actions are reviewable under the APA.

191. Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see also* Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 127 S. Ct. 2518, 2529 (2007) (quoting *Motor Vehicles Mfrs. Ass'n* for deferential review under "arbitrary and capricious" standard); Arkansas v. Oklahoma, 503 U.S. 91, 113 (1992) (applying test from *Motor Vehicles Mfrs. Ass'n*).

192. 42 U.S.C. §§ 300 to 300a-6 (2006). See *supra* Part II.C.2.d for a discussion of Congress's legislation affecting minors' access to contraception.

193. See *supra* Part II.B.1 for a medical description of Plan B.

194. See s*upra* notes 95-99 and accompanying text for a detailed discussion of the joint advisory committee meeting.

195. See *supra* notes 78-80 and accompanying text for a description of Plan B's minor side effects.

196. Prescription Drug Products, s*upra* note 62, at 8610-11.

approval of Plan B for over-the-counter use satisfied the requirements of a prescription to over-the-counter switch.[197] The application successfully established that Plan B was safe and effective, that its labeling was clear and comprehensible, and that women older than fourteen could properly self-select themselves as candidates for use.[198] This information is sufficient to approve a complete prescription to over-the-counter switch under the FDCA's clear guidelines.[199] Therefore, this factor strongly suggests the FDA's actions restricting access to Plan B were arbitrary and capricious.

Finally, the FDA's stated rationale for its action is implausible, because the FDA failed to assert a compelling governmental interest and failed to illustrate how its decision achieves public health goals. While protecting the public health is a compelling state interest, it is not one implicated in the FDA's August 2006 decision. As discussed earlier, effects of Plan B are minor[200] and scientific studies involving women over fourteen have shown it is safe.[201] Furthermore, restrictions based on age are not narrowly tailored to promote public health. Plan B is the first drug for which the FDA has decided to implement age-related marketing restrictions and pediatric studies.[202] This approach is particularly illogical because, when the FDA initially reviewed Plan B, it did not identify any issues requiring age-related restrictions.[203] Furthermore, the FDA's asserted rationale for setting the cutoff at eighteen is that it facilitates administrability by relying on state and private-sector infrastructure.[204] Administrability is not a sufficient state interest to allow the FDA to take away young women's fundamental liberty interests involving intimate decisions. The implausible rationale for the FDA's action supports a finding that its action was arbitrary and capricious. In sum, the FDA's decision constituted unlawful rulemaking, and a federal court should overturn it under the APA's arbitrary and capricious standard.

B. FDA's August 2006 Decision Fails Strict Scrutiny and Violates Minors' Due Process Rights

Based on uncontroverted evidence and the FDA's own characterizations of Plan B as emergency contraception, the proper analysis is under the *Griswold v. Connecticut*[205] line of cases recognizing fundamental liberty interests pursuant to

197. See *supra* notes 86-94 and accompanying text for a discussion of Barr Pharmaceutical's 2003 application.

198. See *supra* notes 89-92 and accompanying text for a discussion of the studies used to establish the effectiveness and clarity of Plan B's label.

199. See *supra* Part II.A.2 for a discussion of the FDCA's procedures to reclassify a prescription drug as an over-the-counter drug.

200. *See* Plan B: FAQs, s*upra* note 78 (noting that Plan B does not have any serious or lasting side effects).

201. See s*upra* notes 88-94 and accompanying text for a discussion of actual-use studies performed by the manufacturer.

202. Harris, *supra* note 42.

203. *Id.*

204. August 2006 Memorandum, *supra* note 134, at 2.

205. 381 U.S. 479 (1965).

the Due Process Clause. Were Plan B an abortifacient, it would be analyzed under *Planned Parenthood of Southeastern Pennsylvania v. Casey*.[206] Minors' rights to access contraceptives, however, should be analyzed as fundamental rights that may not be infringed unless the government satisfies strict scrutiny analysis.

1. FDA's Rationale for Eighteen-Year Age Restriction Is Unconvincing: The Age Restriction Is Functionally a Parental Notification Law

The recent FDA decision allowing Plan B to be sold over-the-counter is limited to those eighteen and over.[207] Minors must get a prescription from a doctor before they can access Plan B.[208] This distinction leaves minors with few practical options. First, minors can get a prescription from a licensed practitioner. Alternatively, a minor can turn to an older person to purchase the contraceptive for her.[209] Nevertheless, many minors unable to obtain the pill through these means would have to turn to their parents. Parents would have to accompany minors to the pharmacy and purchase Plan B for them. Therefore, for minors who cannot access Plan B by prescription or through an older purchaser, the eighteen-year age limit requires minors to notify their parents, who must then accompany the minors to the pharmacy or purchase Plan B for them. Thus, the FDA's decision is the functional equivalent of a parental notification law.

While acting FDA Commissioner von Eschenbach indicated that an eighteen-year age restriction would best protect public health, his reasoning focused on political and economic ramifications.[210] Von Eschenbach noted that Barr failed to establish that those under sixteen could use the drug without the professional supervision of a licensed practitioner. [211] Nevertheless, von Eschenbach was more concerned with the age restriction's administrability and barely touched on the health consequences of an alternate decision.[212] In particular, he stressed that a cutoff at age eighteen would be easier for state-regulated pharmacies and society to enforce.[213] Finally, von Eschenbach analogized the age restriction for contraceptives to age restrictions for nonprescription nicotine-replacement therapy, nonprescription cough-cold products, and tobacco products.[214] This reasoning falls drastically short of the compelling state interest required under strict scrutiny to allow a fundamental right to be infringed.[215] Unlike the right to access tobacco products, which pose

206. 505 U.S. 833 (1992).

207. See *supra* Part II.B.2.c for a discussion of the FDA's August 2006 decision.

208. Approval Letter, *supra* note 64.

209. *See id.* (providing that anyone over eighteen can obtain Plan B).

210. See *supra* Part II.C.1 for a discussion of the FDA's rationale for the age restriction.

211. August 2006 Memorandum, *supra* note 134, at 1.

212. *See id.* (highlighting administrative difficulties with enforcement of age-based restrictions).

213. *Id.*

214. *Id.*

215. See *infra* note 249 for a brief discussion of strict scrutiny analysis.

significant health risks, the right to access contraceptives is an intimate bodily decision with minimal side effects.[216] Furthermore, even granting that promoting the public health may be an important government interest, the FDA's decision is not narrowly tailored to achieve this purpose because it is overinclusive.[217] Instead, the decision may cause more harm than good to minors by increasing unwanted pregnancies.[218]

While the FDA's proffered rationale for limiting access to Plan B is that it harms the health of minors,[219] the FDA's decision to limit access has caused greater harm to minors' health. In an attempt to protect minors, the FDA has left them with fewer contraceptive choices and reduced access to recourse for failed contraception. If fewer choices harm minors' health, as the Supreme Court has pointed out,[220] the FDA's own decision leads to results that contravene the policies of promoting minors' health.

In fact, several major medical organizations, including the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the Society for Adolescent Medicine, have undermined the FDA's reasoning by supporting nonprescription access to Plan B absent an age restriction.[221] Similarly, the FDA's own joint advisory committee overwhelmingly voted to approve sales of Plan B without age restrictions.[222] Finally, multiple people involved in the FDA decision have outwardly indicated their disdain for the age restrictions.[223] This opposition further indicates that the FDA's rationale is implausible and contrary to broad scientific opinion.

In practice, the age restriction is effectively equivalent to a parental notification law that requires a minor to obtain at least one parent's consent before she can have access to contraceptives.[224] While parental notification laws merely require advance notice or written consent,[225] minors will have to bring their parents with them to the pharmacy to purchase Plan B. This obstacle prohibits many minors from acting without their parents' direct involvement. In

216. See *supra* notes 78-80 and accompanying text for a discussion of Plan B's minor side effects.

217. See *supra* Part II.B.2.c for a discussion of the FDA's August 2006 decision to restrict access to contraception.

218. *See* Press Release, Planned Parenthood, Emergency Contraception OTC (Aug. 22, 2006), *available at* http://www.plannedparenthood.org/about-us/newsroom/press-releases/emergency-contraception-otc.htm (suggesting that restricting over-the-counter use of Plan B to women over eighteen "'makes it harder for teenagers to avoid unintended pregnancy'" (quoting statement of Planned Parenthood Federation of America President Cecile Richards)).

219. *See generally* August 2006 Memorandum, *supra* note 134 (explaining rationale for restricting access to contraceptives).

220. See generally *Carey v. Population Servs., Int'l*, 431 U.S. 678 (1977), for a discussion of the Supreme Court's decision regarding minors' due process rights to access contraceptives.

221. The Emergency Contraception Web Site, *supra* note 183.

222. See *supra* notes 96-99 and accompanying text for a discussion of the joint advisory committee's suggestions.

223. See *supra* notes 121-22 and accompanying text for a discussion of opinions contradicting the FDA's decision.

224. See *supra* Part II.C.2.a for a discussion of the two types of parental notification laws.

225. See *supra* notes 142-46 and accompanying text for a discussion of parental notification laws.

sum, the FDA fails to assert a compelling government interest for infringing on minors' due process rights to access contraceptives and proposes a decision that is not narrowly tailored to achieve its purpose.

2. Plan B Is a Contraceptive, Not an Abortifacient

Plan B is a form of emergency contraception, not an abortifacient. *Oxford English Dictionary* defines an abortifacient as something that produces or causes an abortion.[226] Medically, however, Plan B does not induce abortions. Instead, it prevents pregnancies.[227] Unlike other combination pills with estrogen and progestin, Plan B is a "progestin-only" drug.[228] If a fertilized egg is already attached to the uterus, Plan B does not terminate the pregnancy.[229] Rather, the pill is a contraceptive that prevents fertilization, as it contains greater quantities of the same ingredients used in regular contraceptive devices.[230]

Furthermore, the FDA has always referred to the morning-after pill as emergency contraception.[231] As early as 1997, the FDA released results of research on the morning-after pill, recognizing it as a safe and effective method of emergency contraception.[232] In that press release, the FDA indicated that it hoped manufacturers would begin to make this "additional contraceptive option" more widely available.[233] Never did the FDA refer to Plan B as a drug that induces abortion.[234] In addition, when the FDA approved the drug for prescription use, it allowed manufacturers to market it as emergency contraception that is safe and effective.[235] Furthermore, von Eschenbach referred to Plan B as an "oral hormonal contraceptive" in his 2006 memo discussing the rationale for the age restriction.[236] Finally, even the FDA Web site refers to Plan B as an emergency contraceptive.[237] In sum, both the FDA and

226. THE OXFORD ENGLISH DICTIONARY 36 (2d ed. 1989).

227. Planned Parenthood, The Difference Between Emergency Contraception and Medical Abortion, http://www.plannedparenthood.org/issues-action/abortion/anti-choice-activity/reports/difference-between-emergency-contraception-medication-abortion-6138.htm (last visited Nov. 28, 2008).

228. Food and Drug Administration, FDA's Decision Regarding Plan B: Questions and Answers, http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm (last visited Nov. 28, 2008); Planned Parenthood, Emergency Contraception, http://www.plannedparenthood.org/health-topics/emergency-contraception-morning-after-pill-4363.htm (last visited Nov. 28, 2008).

229. See *supra* notes 74-77 and accompanying text for a discussion of Plan B's effect on fertilization.

230. What is Plan B?, *supra* note 68; *see also* Plan B: FAQs, *supra* note 78 (indicating that Plan B contains synthetic hormone used in birth control for over thirty years).

231. Plan B: Questions and Answers, *supra* note 38.

232. Prescription Drug Products, *supra* note 62, at 8610-11.

233. *Id.*

234. *Id.*

235. See *supra* notes 81-83 and accompanying text for a description of Plan B's approval as a prescription drug.

236. August 2006 Memorandum, *supra* note 134, at 1.

237. *See* U.S. Food and Drug Administration, Plan B (0.75mg levonorgestrel) Tablets Information, http://www.fda.gov/cder/drug/infopage/planB/default.htm (last visited Nov. 28, 2008)

Barr Pharmaceuticals, Plan B's manufacturer, have labeled the drug as a backup method of emergency contraception.

3. Restricting Minors' Access to Contraceptives Violates Their Due Process Rights

For over forty years, the Supreme Court has recognized that the decision "to bear or beget a child"[238] is a fundamentally private, constitutionally protected individual choice.[239] In *Griswold*, the Court recognized a married couple's right of privacy in the intimate decision to use contraception.[240] This right was extended to unmarried couples in *Eisenstadt v. Baird*.[241] In *Carey v. Population Services International*,[242] the Court extended the right of privacy to minors, stressing the unconstitutionality of a blanket prohibition on the distribution of contraceptives to minors.[243] No Supreme Court decision has overturned the principles in *Carey*.[244] In fact, these principles were reaffirmed by *Casey*.[245]

Similarly, Congress's intent is clear in the provisions of Title X.[246] These provisions require public health clinics and other recipients of family planning funds to provide contraceptives and additional services to adolescents.[247] Therefore, the FDA decision directly contradicts clear congressional intent to broaden access to contraceptives for minors. In addition, while there have been numerous attempts to pass laws requiring parental notification before providing minors with contraception, no such laws have passed.[248] Both of these factors indicate the legislature has chosen to uphold minors' unrestricted rights to access contraception.

In addition, pursuant to the *Griswold* line of cases, minors have a constitutional due process right to privacy, which includes a right to access

(recognizing Plan B as emergency contraception).

238. Eisenstadt v. Baird, 405 U.S. 438, 453 (1972).

239. See *supra* Part II.C.2.b for a discussion of the Supreme Court's jurisprudence recognizing a fundamental right to privacy.

240. Griswold v. Connecticut, 381 U.S. 479, 485-86 (1965). See *supra* notes 149-52 and accompanying text for a discussion of the Court's analysis in *Griswold*.

241. 405 U.S. at 453. See *supra* notes 153-56 and accompanying text for a discussion of the Court's analysis in *Eisenstadt*.

242. 431 U.S. 678 (1977).

243. *Carey*, 431 U.S. at 692-93. See *supra* notes 160-68 and accompanying text for a detailed explanation of the Court's rationale in *Carey*.

244. *See* Lawrence v. Texas, 539 U.S. 558, 566 (2003) (discussing with approval *Carey*'s extension of right to privacy to minors). See *supra* note 169-71 and accompanying text for a discussion of cases that have reaffirmed *Carey*'s principles.

245. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 852-53 (1992) (plurality opinion).

246. See *supra* Part II.C.2.d for a discussion of Title X of the Public Health and Services Act, 42 U.S.C. §§ 300 to 300a-6 (2006).

247. *See* 42 U.S.C. § 300(a) (authorizing federal funds for family planning services, including adolescent services); Bornstein, *supra* note 176, at 47 (discussing congressional intent to serve adolescents under Title X).

248. Ehrlich, *supra* note 174, at 164-65.

contraceptives.[249] Requiring minors to notify their parents before they can obtain contraceptives violates their rights under the Fifth and Fourteenth Amendments. As the *Carey* and *Eisenstadt* courts have pointed out, individuals face a significant burden on their liberty rights to choose a contraceptive method when licensed pharmacists control distribution of contraceptives.[250] *Carey* emphasized that "a blanket prohibition of the distribution of contraceptives to minors is *a fortiori* foreclosed."[251] Thus, because the FDA's action results in a broad restriction of access to contraceptives by minors, it is an impermissible burden on this right and a federal court should overturn its action.

While *Carey* does not make any limitation to access unconstitutional, but rather only a blanket limitation to all contraceptives, the Court's underlying rationale clearly indicates minors have a fundamental right to access contraceptives.[252] The Court specifically stated the "right to privacy in connection with decisions affecting procreation extends to minors."[253] The Court then stressed that restrictions inhibiting minors' privacy rights are permitted "only if they serve 'any significant state interest that is not present in the case of an adult.'"[254] Finally, the Court dismissed the state's proffered interests and pointed out that limiting access to contraception is an impermissible burden on minors' due process rights.[255] Similarly, though minors have access to other contraceptives, that is not a reason to limit access to Plan B, which is a backup method of emergency contraception intended as recourse for failed contraception following intercourse.

C. Consequences of the FDA Decision and Proposed Solutions

Given that the age restrictions established by the FDA have no scientific basis[256] and violate due process, they should be removed and Plan B should be readily available for minors and adults. Not only would this alternative enable the use of a safe and effective contraceptive method, but it would lower the

249. See *supra* Part II.C.2.b for a discussion of the Supreme Court's jurisprudence regarding a constitutional due process right to privacy, which encompasses a right to access contraceptives. While outside the scope of this Comment, an argument can also be made that the FDA's decision violates the Equal Protection Clause under the Fifth Amendment. Under equal protection analysis, a court would give deference to the FDA's decision and evaluate it under rational basis review. Age is not analyzed under strict scrutiny because it is not a suspect category as defined by *United States v. Carolene Prods. Co*., 304 U.S. 144 (1938). *See id.* at 152 n.4 (recognizing that "more searching judicial inquiry" is required where discrete and insular minorities are adversely affected).

250. See *supra* notes 153-56, 160-68 and accompanying text for a discussion of the Court's analysis in *Carey* and *Eisenstadt*.

251. Carey v. Population Servs. Int'l, 431 U.S. 678, 694 (1977).

252. *Cf. id.* at 693 (stating right to privacy with respect to procreation extends to minors and adults).

253. *Id.*

254. *Id.* (quoting Planned Parenthoood of Cent. Missouri v. Danforth, 428 U.S. 52, 69 (1976)).

255. *Id.* at 694-95.

256. See *supra* Part II.B.2 for general political history of Plan B, including the joint advisory committee's findings that the drug is safe and should be available for over-the-counter use without age restrictions.

numbers of unintended pregnancies in teenagers.[257]

Experts estimate that, every year, as many as 1.7 million unintended pregnancies as well as 800,000 abortions could be avoided through greater access to emergency contraception.[258] In fact, research demonstrates that over-the-counter access to emergency contraceptives does not promote sexual activity among teens.[259] Instead, increased access to established pregnancy prevention methods, such as sex education and emergency contraception, is the most effective way to minimize the rate of unwanted pregnancies among teens in the United States.[260]

In particular, Barr's CARE program restricts distribution to a small percentage of retail outlets, which makes contraceptives considerably less accessible to the public and reduces consumer choice.[261] Distribution of Plan B has become even more limited because some pharmacies have refused to keep emergency contraception in stock.[262] Because all other forms of contraceptives are sold in pharmacies, retail outlets, gas stations, and so on, there is no reason to limit sales of Plan B to select locations. It should be widely available, just like other methods of contraception.

The FDA's proffered reason for limiting Plan B sales to pharmacies is to allow pharmacists to enforce age restrictions by checking photo identification. This proffered reason depends on the validity of the age restriction. As shown in the above section, however, the age restriction itself is not legitimate. Even if this were a legitimate concern, there is no reason to think pharmacists would be any more successful at preventing teens from obtaining Plan B than they have been in limiting minors' use of other age-restricted over-the-counter products.[263] In short, in light of Plan B's safety and effectiveness,[264] there is no scientific basis to limit Plan B over-the-counter use to those eighteen and over.

IV. CONCLUSION

The Supreme Court has determined that married and unmarried couples alike have a right to access contraceptives.[265] Furthermore, addressing minors' due process rights, the Supreme Court has reiterated that the right to

257. *See* Press Release, Planned Parenthood, *supra* note 218 (noting that experts expect that unintended teenage pregnancies could be greatly reduced with universal over-the-counter access to emergency contraceptives).

258. *Id.*

259. *Id.*

260. *Id.*

261. See *supra* Part II.B.2.c and accompanying text for a description of the CARE program.

262. Laura Lambert, *EC over the Counter*, PLANNEDPARENTHOOD.ORG, http://www.plannedparenthood.org/issues-action/birth-control/emergency-contraception/articles/ec-otc-6698.htm (last visited Nov. 28, 2008).

263. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 160-61 (2000) (holding FDA does not have jurisdiction to regulate cigarettes under FDCA).

264. Prescription Drug Products, *supra* note 62, at 8610-11.

265. See *supra* Part II.C.2.b for a discussion of the *Griswold* line of cases upholding the fundamental right to access contraception.

nonhazardous contraceptives is a constitutionally protected due process right that underlies the Supreme Court's reasoning for over fifty years.[266]

In August 2006, the FDA made a decision that not only exceeded its congressional authority as an executive agency[267] but also significantly eroded every minor's fundamental due process rights to access contraceptives. The FDA's decision is scientifically baseless and contradicts its own joint committee's technical expertise.[268] The narrow issue of minors' rights to contraceptives is rooted in our nation's history and tradition as the right of each individual to make decisions concerning her own body, intimate conduct in the home, and similar personal liberties. A scared sixteen-year-old girl who walks into a pharmacy should not have to live through an unwanted pregnancy and raise a child because it may be administratively easier for the pharmacy to verify whether someone is eighteen. Despite the FDA's mandate to protect the public health, its recent decision regarding Plan B is contrary to public policy, impairs minors' medical health and well being, and should be overturned.

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266. See *supra* Part II.C.2.c for a discussion of constitutional decisions regarding minors' due process rights to access contraception.

267. See *supra* Part II.A.3 for a discussion of judicial review of an executive agency under the APA.

268. See *supra* Part II.B for a medical description of Plan B and a history of its treatment by the FDA.

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