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

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INTRODUCTION

On May 6, 2004, the Food and Drug Administration (FDA) rejected an application to market and sell Plan B® emergency contraception (EC) without a prescription,1 despite an overwhelming recommendation from a joint advisory committee.2 This decision triggered the most heated political debate involving the FDA since their refusal to approve thalidomide in 1962.3 Proponents of the FDA’s decision describe it as a well-reasoned ruling by an elected administration, a pro-life victory, and justice in public welfare.4 Opponents characterize this decision as a dangerous furtherance of

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3. In 1960, the FDA delayed approval of thalidomide by requesting more clinical data regarding its safety, despite tremendous political pressure from the manufacturer. David M. Keifer, How an Iron-Willed FDA Officer Averted a Birth Defect Disaster, 6 TODAY'S CHEMIST WORK 92 passim (1997) [hereinafter Thalidomide]. Thalidomide was widely available throughout the world without a prescription to treat morning sickness, as a sleeping aid, and was even coined West Germany’s favorite “baby-sitter.” Id. at 92. While thalidomide was pending approval in the United States, worldwide surveillance revealed the drug was extremely teratogenic causing a number of children to be born with phocomelia (Greek for seal limb) and the drug was not approved. Id. at 93, 96.

social conservatism, propaganda “trumping” science, and political ideology run amuck.5

Clearly this situation is complex. The issues that surround EC are emotionally charged and involve a sharp split among the American public.6 For example, a number of states have established their own regulatory system allowing EC to be available without a prescription, undermining the authority of the FDA.7 On the other hand, pharmacists may conscientiously object to selling it, undermining public health.8

At the epicenter of this debate lies the FDA, an agency compelled to make a decision that lost the confidence of many of the people they were trying to protect.9 An alternate solution may have been overlooked. Congress should establish a “pharmacist-only” class of drugs in this country allowing the sale of EC without a physician's prescription under required consultation with a pharmacist.10

Part I of this article reviews the historical, scientific, political, legal, and bioethical issues surrounding EC in the United States. It also introduces the focus of this discussion and the only EC product


6. The issue that surrounds emergency contraception is, essentially, abortion. Pro-choice advocates view EC as an important option, while pro-life advocates view it as abortion and essentially murder.


8. See AM. PHARMACISTS ASS'N, HOUSE OF DELEGATES, 2004 REPORT OF THE POLICY REVIEW COMMITTEE: PHARMACISTS CONSCIENCE CLAUSE 10 (2004), available at http://www.aphanet.org/AM/Template.cfm?Section=Search&section=About_APhA1&template=/CM/ContentDisplay.cfm&ContentFileID=224 [hereinafter APhA CONSCIENCE CLAUSE]. The 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 as compromising the pharmacist's right of conscientious refusal.” Id.


10. A pharmacist-only class of drugs includes drugs that are available without a prescription, but can be obtained only in a pharmacy and sometimes dispensed only by a pharmacist. U.S. GEN. ACCOUNTING OFFICE, REPORT TO THE RANKING MINORITY MEMBER, COMMITTEE ON COMMERCE, HOUSE OF REPRESENTATIVES, NONPRESCRIPTION DRUGS: VALUE OF A PHARMACIST CONTROLLED CLASS HAS YET TO BE DEMONSTRATED 11, GAO/PEMID-95-12 (1995), available at http://www.gao.gov/archive/1995/pe95012.pdf [hereinafter GAO REPORT].
currently available in this country, Plan B®. Part II discusses the regulatory framework surrounding prescription and nonprescription medications and how a drug undergoes an "Rx to OTC Switch." Part III explores the issues surrounding Barr Pharmaceuticals, Inc.’s application for Plan B® nonprescription use and the FDA’s controversial decision to reject it. It also presents a discussion of statewide protocols and collaborative practice agreements currently in place to allow EC, such as Plan B®, without a prescription in select states. Part IV of this article describes the establishment of a third class of drug regulation in this country: a pharmacist-only class of drugs. Part V examines the practical limitations to a pharmacist-only class of drug regulation for EC and the future of Plan B® in the United States.

I. EMERGENCY CONTRACEPTION

A. Background

Emergency contraception (EC) is defined as the targeted use of hormone therapy, or use of an intrauterine device, specifically designed to prevent pregnancy following unprotected intercourse or contraceptive failure. EC is also indicated for victims of sexual assault and women exposed to known teratogens. EC works by preventing ovulation or inhibiting implantation of a fertilized ovum, both of which are necessary for pregnancy to occur.

The first widely recognized reference to birth control involved the withdrawal method mentioned in the Bible’s book of Genesis.
Other, more novel approaches, have been documented since 1850 B.C. when women in Egypt used a combination of crocodile dung, honey, and sodium carbonate to make vaginal suppositories, called pessaries, to prevent pregnancy. In the 1700s, Giacomo Casanova, the Venetian seducer, noted the use of half a lemon rind as a cervical cap and used condoms as a form of contraception. He was believed to prefer condoms made of lamb intestine. References relating to post-coital contraception date back to at least 1500 B.C. when women tried sneezing, hopping, dancing, and jumping after intercourse to prevent pregnancy. Although these practices were not effective, similarly amusing variations have continued through this century, with reports from the 1930s through the 1960s of women using Lysol® and Coca-Cola® as post-coital douches.

EC is under a great transformation in this country. Over the past fifty years, with the advent of synthetic estrogens and progestins, women have had an increasing number of options to prevent unwanted pregnancies. Birth control pills, patches, vaginal rings, and injections are available, even a chewable tablet in spearmint flavor. Furthermore, the use of EC has been increasing and physicians are now writing “advance prescriptions” for women to keep on hand.  

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19. Id.
20. Id.
22. LaValleur, supra note 21, at 818; DeNoon, supra note 18.
A number of renowned national healthcare organizations have publicly advocated EC without a prescription, including the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the American Academy of Family Physicians. An influential segment of our culture, however, is strongly opposed to EC. Pro-life organizations such as the Family Research Council, Concerned Women for America, and sects of the Catholic Church have strongly opposed the attempted switch. This dissension is readily apparent with the latest Department of Justice Guidelines for treating sexual assault victims, where mention of EC is conspicuously absent. Media reports indicate that EC was included in earlier versions of the protocol and purposefully omitted from the final one. One New York congresswoman was even denied the opportunity to comment on this glaring omission at a public hearing on the subject.

Although EC is generally considered a recent phenomenon, oral contraception has been used "off label" since 1974 as EC. This use is seen primarily in hospitals, university health clinics, and, to a


28. See OFFICE OF VIOLENCE AGAINST WOMEN, U.S. DEPT OF JUSTICE, A NATIONAL PROTOCOL FOR SEXUAL ASSAULT MEDICAL FORENSIC EXAMINATIONS, ADULTS/ ADOLESCENTS, NCJ 206554 (2004), available at http://www.ncjrs.org/pdffilesl/ovw/206554.pdf. This protocol "provides detailed guidelines for criminal justice and health care practitioners in responding to the immediate needs of sexual assault victims." Id. at iii. It emphasizes that "[c]ombining cutting edge response techniques with collaboration among service providers will greatly enhance our ability to treat and support victims." Id. There is no mention, however, of Plan B or EC in the protocol.


lesser extent, by physicians in private practice.\textsuperscript{32} Women were typically instructed to take two to five of their regular birth control pills for two doses, 12 hours apart, following unprotected intercourse.\textsuperscript{33}

In 1997, the FDA declared this form of EC safe and effective for women.\textsuperscript{34} EC has been formally available in this country since 1998 with a prescription,\textsuperscript{35} and is widely available throughout the world without a prescription.\textsuperscript{36} Overall, there is a mounting trend toward acceptance of EC.\textsuperscript{37} Furthermore, research in this area has grown exponentially over the last decade,\textsuperscript{38} providing further evidence that EC is safe and effective and poses no increased risk of sexually transmitted diseases or pregnancy.\textsuperscript{39}

The rate of unintended pregnancies is reaching epidemic proportions, and the need for a reliable and widely accessible redress is growing.\textsuperscript{40} An estimated 3.5 million unintended pregnancies occur annually in this country, with one-third involving teenagers.\textsuperscript{41} In fact, about twenty percent of all teenage girls who have sexual intercourse become pregnant each year.\textsuperscript{42} Further estimates are that fifty percent of unwanted pregnancies could be averted with EC,\textsuperscript{43} thus greatly reducing the number of abortions performed. Moreover, fewer than one-quarter of teenagers know anything about EC or other options following unprotected intercourse.\textsuperscript{44} Two-thirds of the teenage girls who were informed of the option said they would be likely to use EC.\textsuperscript{45}

\begin{footnotes}
\textsuperscript{32} FDA Notice, \textit{supra} note 31, at 8610.
\textsuperscript{33} See Grimes & Raymond, \textit{supra} note 14, at 181 tbl.2.
\textsuperscript{34} FDA Notice, \textit{supra} note 31; see also LaValleur \textit{supra} note 21, at 818.
\textsuperscript{35} FDA Notice, \textit{supra} note 31. For more information, see NOT-2-LATE.com, a website operated by the Office of Population Research at Princeton Health Professionals. NOT-2-LATE.com Home Page, http://ec.princeton.edu (last visited Mar. 22, 2006). This website serves as an evidence-based resource for information on emergency contraception. \textit{Id.} It is a great source of information with references, educational and promotional materials, and a local directory of providers available to prescribe EC. \textit{Id.}
\textsuperscript{36} \textit{See} Field, \textit{supra} note 7, at 151.
\textsuperscript{38} A simple MEDLINE search using PubMed and the keywords "Emergency Contraception" reveals that from 1980-1990 there is one article, from 1990-2000 there are 321 articles, and from 2000-2004 there are 433 articles.
\textsuperscript{39} See, e.g., Raine et al., \textit{supra} note 7, at 58-62.
\textsuperscript{40} David A. Grimes et al., \textit{Emergency Contraception Over-the-Counter: The Medical and Legal Imperatives}, 98 OBSTETRICS \& GYNECOLOGY 151, 151 (2001).
\textsuperscript{41} Litt, \textit{supra} note 23, at 98.
\textsuperscript{42} Suzanne F. Delbanco et al., \textit{Missed Opportunities: Teenagers and Emergency Contraception}, 152 ARCHIVES PEDIATRICS \& ADOLESCENT MED. 727, 727 (1998).
\textsuperscript{43} Raine et al., \textit{supra} note 7, at 54.
\textsuperscript{44} \textit{See} Delbanco et al., \textit{supra} note 42, at 729.
\textsuperscript{45} \textit{Id.} at 730.
\end{footnotes}
The difference between EC and abortion is a nebulous, yet important, distinction for many people and is based on highly technical terminology. The consensus among the scientific and medical communities is that EC is not abortifacient. The FDA, the National Institutes of Health (NIH), and the American College of Obstetricians and Gynecologists define abortion "only as disruption of an implanted fertilized ovum." Accordingly, pregnancy occurs only after implantation of the fertilized egg to the uterine wall.

Ovum (egg) and sperm each have twenty-three chromosomes. Upon ovulation, the ovum is released from the ovaries and travels down the fallopian tube. Fertilization occurs when the sperm attaches to a receptor on the ovum called the zona pellucida. At this stage, a zygote is created, having a complete set of maternal and paternal DNA (i.e., forty-six chromosomes). It is not until the fertilized ovum (i.e., zygote) actually implants in the uterine wall that pregnancy is considered to occur.

The zygote then continues down the fallopian tube toward the uterus where it divides into a ball of cells at around day two. The zygote then organizes itself into the morula around day three or four while continuing to divide. At approximately day six, the morula enters the uterine cavity and develops into a blastocyst, a sphere-shaped structure with both inner and outer cells. The inner cells of the blastocyst, called the embryoblast, develop into the embryo while the outer layer of cells, called the trophoblast, ultimately form part of the placenta. The embryo then implants in the uterine wall

46. This distinction is the basis for the debate between pro-life and pro-choice advocates. Grimes, supra note 37, at 847.
48. Id. (emphasis added); see also 45 C.F.R. § 46.202(f) (2005) (defining pregnancy as "the period of time from implantation until delivery").
51. See William Byrd, Fertilization, Embryogenesis, and Implantation, in Textbook of Reproductive Medicine, supra note 49, at 1, 5-6.
52. Stradtman, supra note 49, at 58.
53. See Fetal Development, supra note 50.
54. Id.
56. Id.
at approximately day seven, and at that point pregnancy occurs.\textsuperscript{57} It is important to note that not all fertilized ovum fully develop or implant in the uterine wall.\textsuperscript{58}

Whereas EC \textit{prevents} pregnancy, abortion disrupts an already established pregnancy.\textsuperscript{59} Thus, EC differs from other “morning after” pills such as misoprostol, methotrexate, or mifepristone (Mifeprex\textsuperscript{®}, RU-486) in that these agents disrupt an already established pregnancy and are considered abortifacients.\textsuperscript{60} To complicate this controversy, morning after pills like mifepristone may also be used in low doses to prevent pregnancy.\textsuperscript{61}

Although this matter may be resolved with mere semantics, the issue remains substantially more complex. Critics of the implantation distinction note that ‘life’ begins at conception.\textsuperscript{62} Under this doctrine, EC is an abortifacient.\textsuperscript{63} Scientifically speaking, this argument has merit, as a fertilized ovum has a full complement of DNA.\textsuperscript{64} Suffice it to say, the distinction between abortion and

\begin{itemize}
\item \textsuperscript{57} Id.; see also Wellbery, supra note 47, at 655.
\item \textsuperscript{58} See WILLIAMS OBSTETRICS 580-82 (F. Gary Cunningham et al. eds., Appleton & Lange, 20th ed. 1999) (1930). Williams presents a theoretical discussion of reproductive success and failure in healthy, young women. Approximately 5% of ovarian cycles fail to produce an ovum, and an additional 7% produce an ovum that is not fertilizable. Id. at 580. Moreover, approximately 23% of fertilized ovum will fail to implant or are lost to early pregnancy wastage. See \textit{id.} at 582. Of the remaining clinical pregnancies, approximately 10% will spontaneously abort with additional perinatal mortality of 1%. \textit{Id.} at 581. Ectopic pregnancy is another complication involving early loss. This is where a fertilized ovum implants outside of the uterus, usually within the fallopian tube and fails to develop. See Medline Plus Medical Encyclopedia, Ectopic Pregnancy, http://www.nlm.nih.gov/medlineplus/ency/article/000895.htm (last visited Mar. 22, 2006). In summary, it may be overly simplistic to consider fertilization as the sole prerequisite for pregnancy to occur.
\item \textsuperscript{59} See Grimes, supra note 37, at 847.
\item \textsuperscript{60} Renee C. Wyser-Pratte, \textit{Protection of RU-486 as Contraception, Emergency Contraception and as an Abortifacient Under the Law of Contraception}, 79 OR. L. REV. 1121, 1121 (2000).
\item \textsuperscript{61} \textit{Id.} at 1132.
\item \textsuperscript{62} For example, the Roman Catholic Church teaches that “life” begins at fertilization (i.e., conception), even if “ensoulment” occurs at a later time. See Herbe, supra note 27, at 86-87; see also THE SACRED CONGREGATION FOR THE DOCTRINE OF THE FAITH, \textit{DECLARATION ON PROCURED ABORTION} (1974), available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19741118_declaration-abortion_en.html (stating the Catholic Church’s stance on abortion); Hazel J. Markwell & Barry F. Brown, \textit{Bioethics for Clinicians: 27. Catholic Bioethics}, 165 CAN. MED. ASS’N J. 189, 190 (2001).
\item \textsuperscript{63} See POPE PAUL VI, \textit{HUMANA VITAE, ENCYCLICAL OF POPE PAUL VI ON THE REGULATION OF BIRTH} (1968), available at http://www.vatican.va/holy_father/paul_vi/encyclicals/documents/hf_p-vi_enc_25071968_humanae-vitae_en.html (describing contraception as unlawful and possibly a mortal sin).
\item \textsuperscript{64} Once a human egg and sperm fuse, the ensuing zygote has forty-six chromosomes, the same genetic makeup as an adult human. See Stradtman, supra note 49, at 58.
\end{itemize}
contraception is not easily resolved, and the line appears to be arbitrarily drawn.

In the United States, two drugs have been approved for EC to date, although only one is currently available. Preven® was the first drug approved in 1998 and is a combination product containing both an estrogen and a progestin. Plan B® was approved in 1999 and contains only a progestin. Interestingly, in May 2004, Barr Pharmaceuticals, Inc., the manufacturer of Plan B®, purchased the marketing rights to Preven® and has discontinued its sales. Plan B® is a preferential product since it has a lower incidence of nausea and vomiting than Preven® and has enhanced packaging. Preven® was packaged with a pregnancy test, which increased its size and cost and reaffirmed a notion that it was an abortifacient.

B. Plan B®

Plan B®, also called levonorgestrel, is a synthetic progestin used for EC. Plan B® requires a prescription in this country. Plan B® is marketed as two doses (i.e., two tablets of 0.75 mg levonorgestrel) which should be initiated as soon as possible following unprotected sexual intercourse or contraceptive failure.

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65. See generally CTR. FOR DRUG EVALUATION & RES., FOOD & DRUG ADMIN., ELECTRONIC ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2005), http://www.fda.gov/cder/ob/default.htm (containing approval dates, patent expiration dates, and application numbers for all brand and generic drugs approved by the FDA) [hereinafter ELECTRONIC ORANGE BOOK].

66. Id.


68. Plan B Prescribing Information, supra note 11, at 1.


70. Carolyn Westhoff, Emergency Contraception, 349 NEW ENG. J. MED. 1830, 1832 (2003). Studies show the incidence of vomiting with Preven® is 22% compared to 8% with Plan B®. Id. at 1831.


72. Plan B Prescribing Information, supra note 11, at 1. The active component in Plan B® is also widely available in combination oral birth controls such as Climara®, Levlite®, Seasonale® and others. ELECTRONIC ORANGE BOOK, supra note 65, at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

preferably within seventy-two hours. The first dose is followed by a second dose, twelve hours later. Plan B® is highly effective, decreasing the risk of pregnancy by approximately 75% when used within seventy-two hours. Although EC is considered extremely time sensitive, there is some evidence that Plan B® can be given successfully up to 120 hours after unprotected intercourse. There are also data that both tablets can be taken in a single dose with no loss of efficacy. The main side effect of Plan B® is nausea, which occurs in almost one quarter of patients. As a result, many practitioners recommend anti-emetic therapy with treatment.

The prescribing information for Plan B® describes the mechanism of action as preventing ovulation or fertilization and, alternatively, as inhibiting implantation. It explicitly states that Plan B® is not effective once the process of implantation has begun, and is not effective if the woman is already pregnant. Accordingly, Plan B® generally is not considered an abortifacient.

C. Legal Basis

Contraception, EC, medical abortion involving drugs, and surgical abortion are all lawful in this country. These practices, however, have not always been legal. In 1873, Anthony Comstock tried to legislate morality by introducing legislation (the Comstock

74. Plan B Prescribing Information, supra note 11, at 3.
75. Id.
76. Id. at 5.
77. 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).
79. See Plan B Prescribing Information, supra note 11, at 8.
81. See Plan B Prescribing Information, supra note 11, at 1.
82. Id.
83. Medical abortion involves administering an agent orally or by injection to induce an abortion. T.A. Weitz et al., "Medical" and "Surgical" Abortion: Rethinking the Modifiers, 69 CONTRACEPTION 77, 77 (2004).
84. Surgical abortion mainly involves vacuum aspiration, also referred to as suction curettage, under local anesthesia, whereas medical abortion involves drugs such as mifepristone, methotrexate, or misoprostol taken in combination or in sequence. Weitz et al., supra note 83, at 78.
85. The rights to contraception and to abortion have been considered fundamental by the Supreme Court in Griswold v. Connecticut, 381 U.S. 479, 485 (1965), and Roe v. Wade, 410 U.S. 113, 153 (1973).
Act) banning the mailing of obscene and immoral materials, including contraceptive agents.\textsuperscript{86} Section 1 of the Act outlawed the sale or distribution of "any drug or medicine, or any article whatever, for the prevention of contraception . . . \textsuperscript{87} Section 2 prohibited the mailing of "any article or thing designed or intended for the prevention of contraception . . . \textsuperscript{88} State variations of this law were enacted and enforced until 1936, when the Court of Appeals for the Second Circuit held that the use of contraception under medical supervision is not immoral and should be excluded from Comstockery.\textsuperscript{89}

Setting the stage for this decision was a general culture shift in the early twentieth century. This shift was exemplified by Margaret Sanger, a pioneering nurse, who advocated contraception from the streets of Brooklyn, New York, to the steps of the United States Supreme Court, and in the interim established the first birth control clinic.\textsuperscript{90}

Modern day jurisprudence involving contraception developed from the Supreme Court decision in \textit{Griswold v. Connecticut}, which first held that women have a constitutional right to contraception.\textsuperscript{91} This right was extended to all similarly situated persons, including single women, in \textit{Eisenstadt v. Baird}.\textsuperscript{92} In \textit{Eisenstadt}, the Supreme Court relied on the Equal Protection Clause of the Fourteenth Amendment in recognizing a constitutional right to contraception.\textsuperscript{93} The Supreme Court later held in \textit{Carey v. Population Services International} that the right to contraception is a fundamental right, subject to strict scrutiny, and even extends to minors, to a certain degree.\textsuperscript{94} Furthermore, the Court held in \textit{Roe v. Wade} that there is a constitutional right to abortion\textsuperscript{95} and in \textit{Planned Parenthood v. Casey} that no state may impose an undue burden on this right.\textsuperscript{96} Moreover, medical abortion has been legal in the United States

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\item \textsuperscript{86} An Act for the Suppression of Trade in, and Circulation of, Obscene Literature and Articles of Immoral Use, ch. 258, § 2, 17 Stat. 598, 598 (1873).
\item \textsuperscript{87} Id. § 1.
\item \textsuperscript{88} Id. § 2.
\item \textsuperscript{89} United States v. One Package, 86 F.2d 737, 739 (2d Cir. 1936).
\item \textsuperscript{90} See William N. Eskridge, Jr., \textit{Some Effects of Identity-Based Social Movements on Constitutional Law in the Twentieth Century}, 100 Mich. L. Rev. 2062, 2118-19 (2002). This article also discusses Sanger's birth control clinic, named the American Birth Control League, which she founded in 1922 and was renamed the Planned Parenthood Federation of America in 1942. Id. at 2120-21.
\item \textsuperscript{91} 381 U.S. 479, 485-86 (1965).
\item \textsuperscript{92} 405 U.S. 498, 463 (1972).
\item \textsuperscript{93} Id. at 443.
\item \textsuperscript{94} 431 U.S. 678, 693-94 (1977).
\item \textsuperscript{95} 410 U.S. 113, 153 (1973).
\item \textsuperscript{96} 505 U.S. 833, 851 (1992).
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since Mifeprex® was approved in 2000. Thus, women have a constitutionally protected right in the United States to receive contraception and abortion without an undue burden by the state. The issue that remains, however, is whether these rights extend to women without a prescription. That decision, at least initially, lies with the FDA.

II. REGULATION OF DRUGS

A. FDA

The FDA is an executive agency, created by Congress, whose mission, in part, is to provide safe, effective, and properly labeled drugs to U.S. consumers. In addition to regulating human drugs, the FDA also regulates veterinary drugs, medical devices (e.g., pacemakers), radiation emitting devices (e.g., cell phones and airport metal detectors), cosmetics, and food, including biological products. The responsibility of the FDA to the U.S. consumer is enormous, and its reach is tremendous in scope, regulating over

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97. Letter from the Ctr. for Drug Evaluation & Res. to Sandra P. Arnold, Population Council (Sept. 28, 2000), available at http://www.fda.gov/cder/foi/appletter/2000/20687applt.htm. Also known as the French abortion pill, Mifeprex® ("RU-486") was approved in 2000 for early abortion, defined as forty-nine days or less. See id. Mifeprex® is dosed as three 200 mg tablets on day one under the supervision of a physician. Mifeprex (mifepristone) Tablets Label, http://www.fda.gov/cder/foi/label/2000/20687lbl.htm (last visited Mar. 22, 2006). On day three, if abortion has not yet occurred, the patient takes two 200 mg tablets of Cytotec® (misoprostol). Id. The patient returns on day fourteen for a post-treatment examination. Id.


99. See Food & Drug Admin., FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission. html (last visited Mar. 22, 2006). The FDA's mission is to: Protect[] the public health by assuring the safety, efficacy, and security of human . . . drugs . . . [and] 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.


101. Id. § 360c.

102. Id. §§ 360hh-360ss.

103. Id. §§ 361-363.

one trillion dollars in products annually.\textsuperscript{105} In fact, products regulated by the FDA account for more than twenty cents of every dollar spent by U.S. consumers.\textsuperscript{106}

The FDA is one of eleven Public Health Agencies under the Department of Health and Human Services.\textsuperscript{107} The FDA has eight centers (offices), including the Center for Drug Evaluation and Research (CDER), which handles all matters relating to drugs including prescription drugs.\textsuperscript{108} Within the CDER is the Office of Nonprescription Products that primarily handles nonprescription drugs.\textsuperscript{109}

The Commissioner of the FDA is appointed by the President and confirmed by the Senate.\textsuperscript{110} The President also has the authority to appoint a myriad of other members to the FDA, including advisory committee members.\textsuperscript{111} The Commissioner of the FDA has

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\item[106.] FDA PREMIER CONSUMER PROTECTION AND HEALTH AGENCY, supra note 105. Yet the FDA costs less than two cents per person per day to operate. \textit{Id.}
\item[107.] U.S. Dep't Health \& Hum. Services, About HHS, http://www.hhs.gov/about/index.html (last visited Mar. 22, 2006). The other agencies are the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, Program Support Center, and Substance Abuse and Mental Health Services Administration. \textit{Id.}
\item[108.] Food & Drug Admin., FDA Organization, http://www.fda.gov/opacom/7org.html (last visited Mar. 22, 2006). The other centers are the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, National Center for Toxicological Research, Office of the Commissioner, and Office of Regulatory Affairs. \textit{Id.}
\item[110.] Emergency contraception is not one of these classes.
\end{footnotes}
been subject to Senate confirmation since 1988 in an attempt to give the job more authority. To date, the FDA has only had four Commissioners confirmed by the U.S. Senate.

The FDA has had a seemingly long and gloried history, although it has been under increasing scrutiny following the removal of Vioxx® and ephedra in 2004, Bextra®, in 2005, and the Plan B® fiasco. A closer analysis, however, shows that the political pressure surrounding the FDA has been escalating for some time.

The FDA approved Mifeprex®, the French abortion pill, under intense dispute in September 2000, the waning days of the Clinton Administration, despite numerous protests from conservative and pro-life activists. Immediately upon President George W. Bush’s

113. Food & Drug Admin., Commissioners and Their Predecessors, http://www.fda.gov/oc/commissioners (last visited Mar. 22, 2006). David Kessler was confirmed in November 1990, Jane Henney was confirmed in January 1999, Mark McClellan was confirmed in November 2002, and Lesley Crawford was confirmed in July 2005. Id. The current acting commissioner of the FDA, Andrew C. von Eschenbach, has not yet been confirmed by the Senate. See infra notes 129-132.
114. Vioxx®, generic name rofecoxib, is a non-steroidal anti-inflammatory, cyclo-oxygenase 2 selective (COX-2) inhibitor used mainly for arthritis pain that was withdrawn from the U.S. market by Merck Pharmaceuticals in 2004. Marc Kaufman, Merck Found Liable in Vioxx Case; Texas Jury Awards Widow $253 Million, WASH. POST, Aug. 20, 2005, at A1. Estimates are that twenty million Americans used Vioxx® since it was first approved in 1999. Id. The drug was shown to increase the risk of heart attack and stroke. Further estimates suggest that 89,000-139,000 Vioxx® users suffered a heart attack or stroke, and of these approximately thirty to forty percent died. David J. Graham, M.D., M.P.H., Testimony Before the United States Senate Committee on Finance (Nov. 18, 2004), http://finance.senate.gov/hearings/testimony/2004test/111804dgtest.pdf; see also David J. Graham et al., Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with Cyclo-oxygenase 2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs: Nested Case-Control Study, 365 LANCET 475 passim (2005).
inauguration, Dr. Jane Henney, the Commissioner of Food and Drugs, was fired\textsuperscript{119} and replaced with Dr. Mark McClellan, the brother of White House Press Secretary Scott McClellan.\textsuperscript{120} Although the appointment of Dr. McClellan might have been somewhat contentious, few people could dispute his impressive credentials, and he was appointed by unanimous consent.\textsuperscript{121} Dr. McClellan served as the FDA Commissioner until March 2004, and by most accounts did an outstanding job.\textsuperscript{122} Dr. McClellan resigned from the FDA in March 2004 to become the Administrator for the Centers for Medicare and Medicaid Services.\textsuperscript{123}

In his place, President Bush appointed Dr. Lester Crawford to head the FDA.\textsuperscript{124} Dr. Crawford is a veterinarian with a Doctorate in Pharmacology.\textsuperscript{125} Dr. Crawford previously served as acting\textsuperscript{126} and deputy commissioner of the FDA before being appointed, and subsequently confirmed, as commissioner.\textsuperscript{127} Dr. Crawford's overall tenure at the post was highly tumultuous, and he resigned suddenly and unexpectedly amidst great controversy.\textsuperscript{128} The current acting commissioner of the FDA is Dr. Andrew C. von Eschenbach, the third Bush appointee to the position.\textsuperscript{129} Before arriving at the FDA, Dr. von Eschenbach served as the Director of the National Cancer Institute of the National Institutes of Health.\textsuperscript{130}

\begin{itemize}
\item \textsuperscript{120} Kaufman, supra note 112.
\item \textsuperscript{121} Biography — CMS Leadership, Mark B. McClellan, M.D., Ph.D., available at http://www.cms.hhs.gov/CMSLeadership/Downloads/McClellanMarkBio.pdf (last visited Mar. 22, 2006). Dr. McClellan earned his M.D. from Harvard and his Ph.D. in Economics from the Massachusetts Institute of Technology. \textit{Id.}
\item \textsuperscript{122} \textit{Id.}
\item \textsuperscript{125} \textit{Id.} Dr. Crawford earned his Doctor of Veterinary Medicine from Auburn University, his Ph.D. in pharmacology from the University of Georgia, and was granted an Honorary Doctorate (M.D.V.) from Budapest University. \textit{Id.}
\item \textsuperscript{126} 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.
\item \textsuperscript{127} Dr. Lester M. Crawford — Biography, supra note 124. Dr. Crawford served as Acting Commissioner from 1999-2002. Dr. Crawford has also served as the Administrator of the Food Safety and Inspection Service of the USDA and as Deputy Commissioner of the FDA. \textit{Id.}
\item \textsuperscript{128} Pear & Pollack, supra note 126.
\item \textsuperscript{130} \textit{Id.}
\end{itemize}
has been nominated to the full time position by the President, but has received strong opposition because of Plan B®, and his future as a confirmed appointee is uncertain.

Another notable appointee to the FDA is Dr. W. David Hager, who was appointed to serve on the FDA's Advisory Committee for Reproductive Health Drugs. Dr. Hager was appointed by Linda Skladany, the FDA Senior Associate Commissioner in charge of the Office of External Relations at the time. The Senior Associate position reports directly to the FDA Commissioner, who is appointed by the President. Dr. Hager was appointed as part of an entire re-staffing in December 2002. Dr. Hager is considered an eccentric physician because of his strong religious views on abortion, his public protests to remove Mifeprex® from the market, and his writings on the use of prayer for the treatment of premenstrual disorder. With the appointment of Dr. Hager, critics perceived President Bush as stacking the FDA with conservative cronies who obfuscate the issues surrounding EC. Overall, the number of recent changes and instability in the agency have

133. Marc Kaufman, Abortion Foe to be Reappointed to FDA Panel; Four Lawmakers Tell Bush That Doctor Has Allowed His Personal Views to Overshadow His Duty, WASH. POST, June 29, 2004, at A6.
137. Kaufman, supra note 133.
138. Id.
139. Published books authored or co-authored by Dr. Hager include: AS JESUS CARED FOR WOMEN: RESTORING WOMEN THEN AND NOW (1998); STRESS AND THE WOMAN'S BODY (1996); WOMEN AT RISK: THE REAL TRUTH ABOUT SEXUALLY TRANSMITTED DISEASES (1993).
140. Press Release, Feminist Majority Foundation, Bush Stacks FDA Panel: Ideology Trumps Medicine and Science Again (Dec. 26, 2005), http://www.feminist.org/news/newsbyte/uswirestory.asp?id=7384; see also Kaufman, supra note 133; Joint Committee Report, supra note 2 passim (expressing Dr. Hager's concerns about the long-term effects of Plan B® utilization, the contradiction of stating that Plan B® does not cause abortion but may effect the endometrium, the unknown effect of Plan B® utilization upon younger adolescent women, and the risk that the pricing of Plan B® will restrict access to the drug). The Nation reports that Dr. Hager was asked to write a minority opinion for the FDA commissioner outlining why Plan B® application for nonprescription use be rejected. Ayelish McGarvey, Dr. Hager's Family Values, 21 NATION 11, 18 (2005).
clearly weakened the FDA's authority and complicated the issues surrounding EC.

B. Legal Foundation

In the United States, drugs are regulated as either prescription or nonprescription products. To understand the complex regulatory framework involving drugs, it is important to examine some of the relevant legislation and historical milestones.

The first major law regulating drugs was the Pure Food and Drugs Act in 1906. This law was established to ensure the safety and purity of food and drugs by prohibiting the "interstate commerce" of adulterated and misbranded products. Accordingly, drugs that differed from the standard on the label regarding their strength, quality, or purity (i.e., adulterated), or drugs that were mislabeled (i.e., misbranded) could not be sold. Otherwise, all drugs could be lawfully sold, even if they were unsafe or advertised with outlandish therapeutic claims. In 1912, the Sherley Amendment was passed to strengthen the Food and Drugs Act by prohibiting false and fraudulent claims. In 1914, Congress enacted the

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141. See Kaufman, supra note 112.
144. Pure Food and Drugs Act of 1906 § 2, ch. 3195, 34 Stat. 768 (1906) (repealed 1938). Because Congress has no enumerated police powers, its authority to regulate drugs is derived from Interstate Commerce. U.S. CONST. art I, § 8, cl. 3. As long as legislation is rationally related to interstate commerce it will be ruled constitutional. See Gonzales v. Raich, 125 S. Ct. 2195, 2205-06 (2005).
146. See Huang, supra note 145, at 573.
147. Sherley Amendment, Pub. L. No. 62-301, 37 Stat. 416, 21 U.S.C. § 10 (1912) (amended by 37 Stat. 732 (1913)). This amendment was passed in response to U.S. v. Johnson, 221 U.S. 488 (1911), which held that the 1906 Pure Food and Drugs Act had no regulatory authority over false claims made by drug manufacturers. Id. at 498. Johnson Remedy Company marketed a product that knowingly made false claims of its
Harrison Narcotic Act, requiring certain habit-forming drugs to be sold only by licensed doctors and pharmacies, creating the first legislative distinction between drug classes.\(^{146}\)

In 1937, the infamous sulfanilamide incident sparked an important change in drug regulation.\(^{149}\) Until that time, drugs did not have to be proven safe for marketing.\(^{150}\) However, in 1937, over 100 people died, many of whom were children, after ingesting an antibiotic (sulfanilamide) dissolved in a toxic vehicle (diethylene glycol).\(^{151}\) In response to that catastrophe, Congress passed the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).\(^{152}\) This legislation, for the first time, required that drugs be proven safe

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\(^{149}\) Prior to 1937, drugs were essentially non-regulated. As long as they were not mislabeled or adulterated they could be marketed or sold, even if they were completely ineffective or dangerous. See Huang, supra note 145, at 573.

\(^{150}\) Id.

\(^{151}\) See Donna Young, Documentary Examines Sulfanilamide Deaths of 1937, AM. SOCY HEALTH-SYS. PHARMACISTS, Dec. 5, 2003, http://www.ashp.org/news/showarticle.cfm?id=3659. In 1937, the Massengill Company used diethylene glycol (DEG) with raspberry flavoring to dissolve a new antibiotic (sulfanilamide) for administration to children. Id. However, DEG is an industrial solvent and close relative to antifreeze that can cause renal failure and death when consumed orally. Id. Amazingly enough, a similar tragedy occurred almost sixty years later, in 1996, when eighty-five of eighty-seven children admitted to a hospital in Haiti died after ingesting acetaminophen mixed with DEG. See Katherine L. O’Brien et al., Epidemic of Pediatric Deaths from Acute Renal Failure Caused by Diethylene Glycol Poisoning, 279 JAMA 1175, 1177 (1998).

before marketing.\textsuperscript{153} In addition, it established the requirement of a New Drug Application (NDA) for each drug prior to entry into interstate commerce.\textsuperscript{154} It also expanded previous drug-labeling requirements, authorized factory inspections of drug manufacturers, and added the remedy of court injunctions to the established penalties of seizures and prosecutions.\textsuperscript{155} This act is the basis of our current drug laws.

The distinction between prescription and non-prescription drugs was formally established in 1951 when Congress enacted the Prescription Drug Amendments to the FDCA, also know as the Durham Humphrey Amendments.\textsuperscript{156} The purpose of this legislation was to mandate certain drugs be used only under the supervision of a physician,\textsuperscript{157} creating a separation of prescription and non-prescription drug classes. Under this law, any drug with the potential for addiction, or unsafe for use except under supervision, or applied for under a prescription drug application, requires a prescription.\textsuperscript{158} All other drugs are considered nonprescription. Thus, the Durham Humphrey Amendments establish a bright-line rule for differentiating prescription and nonprescription drugs.\textsuperscript{159} Prior to this act, drug manufacturers were allowed to determine by which means they would market their products, whereas now the FDA makes this

\textsuperscript{153} See McGuire, \textit{supra} note 152, at 993. Prior to the enactment of the Food, Drug, and Cosmetic Act, drugs were not required to undergo any testing or proof of safety. \textit{See} Huang, \textit{supra} note 145.


\textsuperscript{156} Durham-Humphrey Drug Prescriptions Act, Pub. L. No. 82-215, 65 Stat. 648 (1951) (codified as amended in scattered sections of 21 U.S.C.). These amendments were named after Democratic Senator Hubert Humphrey from Minnesota, who was later Vice President to Lyndon B. Johnson, and Democratic Congressman Carl Durham from North Carolina, both pharmacists.


\textsuperscript{159} Under the Durham Humphrey Amendments, drugs that can be used safely and effectively without requiring the supervision of a physician will be regulated as non-prescription. Drugs that require the supervision of a physician, or are used to treat a condition that requires the care of a physician, will be prescription-only. \textit{See} Jacobs, \textit{supra} note 158, at 2209.
determination. Table 1 includes a list of criteria used by the FDA to decide the suitability of a drug for nonprescription use.

Following the enactment of the Durham Humphrey Amendments, drug regulation in this country remained static until the thalidomide tragedy. In 1961, a number of worldwide reports found horrific fetal abnormalities in children born to mothers who took thalidomide. Although the drug was not approved for use in this country, in reverberation Congress passed the 1962 Kefauver Harris Drug Reform Amendments to the 1938 Food, Drug, and Cosmetic Act. This law gave the FDA increased authority in its decision making power and has since set it among the most reputable regulatory agencies in the world. An important inclusion in this act was the requirement that drugs be proven safe and effective by “substantial evidence” before they could be marketed in this country. The act also established and required compliance with “current good manufacturing practice” to better protect consumers.

Thus, prior to 1938, drugs required no proof of safety and, prior to 1962, needed no proof of efficacy before marketing. Accordingly, after these amendments, there were a large number of drugs on the market in violation of the current law. Drugs marketed before 1938 were never proven safe or effective. Drugs approved between 1938 and 1962 were proven safe, but not effective. In response to these limitations, the FDA “grandfathered” all pre-1938 drugs, allowing them to remain on the market, and required certain procedures to evaluate drugs approved between 1938 and 1962 for

161. See infra tbl.1. Note that the FDA has never formally published these criteria and the precise influence of each factor in the decision-making process is uncertain. The FDA likely considers the totality of the circumstances when considering whether a drug is suitable for nonprescription use instead of any rigid mathematical formula.
162. During the period between 1951 and 1961, not a single major federal drug law was enacted.
163. See supra note 3 and accompanying text.
164. See Keifer, supra note 3, at 93, 96.
168. Griffin, supra note 165, at 375.
169. Id. § 102 (codified at 21 U.S.C. § 355(d) (2005)).
170. Id. § 101 (codified at 21 U.S.C. § 360(f) (2005)).
171. See McGuire, supra note 152, at 993.
their efficacy. These procedures included having the National Research Council of the National Academy of Sciences evaluate the drugs and remove the drugs lacking evidence of efficacy through the Drug Efficacy Study Implementation (DESI) review program. The procedures also included the 1972 Over-the-Counter Drug Review for nonprescription drugs. All nonprescription drugs available today are subject to approval under a New Drug Application (NDA) or a monograph recognizing the drug as generally safe and effective before marketing.

C. Rx to OTC Switch

A drug approved as requiring a prescription can "switch" to over-the-counter status by submitting a supplemental New Drug Application (sNDA) and demonstrating it meets one of the exceptions to the Durham Humphrey Amendments or "such requirements [of prescription-only status that] are not necessary for the protection of the public health." This switch may be initiated by the FDA, the drug manufacturer, or any interested person through a citizen's petition.

In the United States, there is an increasing trend toward Rx to OTC switches. It is estimated that in the past thirty years, more than 700 drug products have made the transition. It is almost nostalgic to consider products such as Children's Motrin®, hydrocortisone cream, nicotine patches, and Rogaine® as drugs once requiring a

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172. See Stringer, supra note 160, at 633. The Drug Efficacy Study Implementation (DESI) review program called for the National Research Council of the National Academy of Sciences to evaluate more than 16,000 claims for approximately 4000 drugs approved between 1938 and 1962 for efficacy. Joseph L. Fink, III, Jesse C. Vivian & Kim K. Reid, Facts and Comparisons, PHARMACY LAW DIGEST 33 (37th ed. 2003) (1965) [hereinafter PHARMACY LAW DIGEST]. The review program established eighty-six drug categories, performed reviews, accepted public comments, and issued final monographs. Id. During this review period all drugs were permitted to remain on the market. See Stringer, supra note 160, at 635-36. The review, which has taken more than 40 years to complete, found "14.7% of the drugs ineffective, 34.9% possibly effective, 7.3% probably effective, 19.1% effective and 24% to be effective, but . . . ." PHARMACY LAW DIGEST, supra, at 33.

173. PHARMACY LAW DIGEST, supra note 172, at 33.


175. Id. at 106; see 21 C.F.R. § 330.10 (providing procedures "for classifying drugs as generally recognized as safe and effective, and not misbranded, and for establishing monographs").


177. Grimes et al., supra note 40, at 154.

178. Grimes, supra note 37, at 846.
prescription. Most recently, Prilosec® and Claritin® have been reclassified as nonprescription products, demonstrating a growing acceptance by the FDA that certain drugs can be safely used without the supervision of a physician.

The mounting trend toward nonprescription use of prescription drugs mostly is motivated by financial concerns. For example, the nonsedating antihistamine, Claritin®, was recently available by prescription only, despite strong protests from consumer protection groups and insurance companies. However, once Claritin® came off patent, the manufacturer determined the drug would be more profitable if available without a prescription and applied for, and received, nonprescription status. Nevertheless, the importance of this issue for EC is unique. The demand for nonprescription access to EC is driven by social and political, rather than financial, concerns.

III. PLAN B® FOR NONPRESCRIPTION USE

A. FDA Evaluation

The FDA approved Plan B® as a prescription drug on July 28, 1999, pursuant to an NDA. Plan B® was deemed safe and

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179. Other common drugs that have undergone Rx to OTC switch since 1990 include Gyne-Lotrimin® for vaginal yeast infections; IvyBlock® for Poison Ivy protection; Monistat 7® for vaginal yeast infections; Aleve® for pain, fever, and inflammation; Pepcid AC® for acid reflux disease; and Lamisil AT® for Athlete's Foot. CONSUMER HEALTHCARE PRODUCTS ASS’N, INGREDIENTS & DOSAGES TRANSFERRED FROM RX-TO-OTC STATUS (OR NEW OTC APPROVALS) BY THE FOOD AND DRUG ADMINISTRATION SINCE 1975 (Jan. 26, 2006), available at http://www.chpa-info.org/web/advocacy/general_issues/switch/switch_list.pdf.


183. See ANGELI, supra note 143, at 186-87.

184. Id. at 187. The original patent on Claritin was due to expire in 1998, id. at 186; however, after extensive maneuvering by its manufacturer, Schering-Plough, and an estimated $5 million in legal costs, the patent was extended through 2002. Id. at 186-87.

185. See Joint Committee Report, supra note 2, at 20, 21. During the drug approval process, the FDA can issue an "Approval" letter, a "Not Approvable" letter, or an "Approvable" letter. See Food & Drug Admin., Ctr. for Drug Evaluation & Research, CDER Data Standards Manual, http://origin.www.fda.gov/cder/dsm/GEN/gen10306.htm (last visited Mar. 22, 2006). Approved drugs have met all statutory requirements and are considered safe and effective for their intended use and can be sold and marketed in this
effective for the prevention of pregnancy in women of all reproductive ages. On February 14, 2001, a citizens' petition was filed by the Center for Reproductive Law and Policy on behalf of sixty-six organizations requesting the availability of EC without a prescription. The petition asserted that EC met all of the regulatory requirements for nonprescription use and should be available without a prescription. However, the petition was not formally decided by the FDA at that time.

On April 16, 2003, Women’s Capital Corporation (WCC), now Barr Pharmaceuticals, Inc., submitted a sNDA to the FDA to market Plan B® without a prescription based on its ability to be used appropriately without the supervision of a physician. The application contained extensive support including clinical and behavioral data, label comprehension information, proof of actual use, and safety information.

This labeling comprehension study was designed to assess understanding of various aspects of a prototype label such as indications, contraindications, dosing, possible side effects, and

country. Food & Drug Admin., Ctr. for Drug Evaluation & Res., New Drug Application (NDA) Process, http://www.fda.gov/cder/regulatory/applications/nda.htm (last visited Mar. 22, 2006). Not Approvable drugs fail to meet such requirements and are not permitted for sale or marketing. Id. Approvable drugs have substantially met requirements for approval but must submit additional data in areas of deficiency before they can be sold and marketed. Id.

186. See Plan B Prescribing Information, supra note 11. Note that the product labeling does not include any age restrictions, suggesting that Plan B® has been deemed by the FDA as safe and effective for woman of all reproductive ages.


188. Id. at 3-4. The petition claimed that EC is safe and effective for self-medication, its labeling is tailored to self-administration, and it is used to treat a condition which is self-diagnosable. Id. at 3.


190. See GAO UNUSUAL DECISION REPORT, supra note 1, at 42; see also Joint Committee Report, supra note 2. The application involved the CARE (Convenient Access, Responsible Education) Program. See Newsletter, FDA Advisory Comm., Barr Plan B Emergency Contraceptive OTC CARE Program Adequate, Cmte. Says (Dec. 16, 2003) (on file with author). CARE is designed to enhance the safe use of Plan B® without a prescription. See Joint Committee Report, supra note 2, at 69-70. The four “core” elements of the CARE program include a consumer toll-free hotline staffed by healthcare professionals, an educational program with distribution of published materials, limited distribution of the product only to retail operations with pharmacy services or clinics, and a system to monitor and update the program accordingly. Id. at 73-77.

management of serious complications. The study found that 93% of women recognized proper indications and 97% understood initiation of the product must be within seventy-two hours. Additionally, 98% of women understood not to use the product if they were already pregnant and 94% recognized that the drug does not prevent HIV or AIDS.

The actual use study was designed to evaluate anticipated use under simulated over-the-counter conditions. The investigators of this study followed up with patients one and four weeks after providing them with EC. The study evaluated the patients’ self-selection and timing of doses. The results showed that all of the reasons given for using EC were consistent with the labeled indication for use with 95% taking the first dose within seventy-two hours as directed, and 74% taking the second dose exactly twelve hours later (93% took the second pill within sixteen hours after the first pill), indicating that “women do not need provider intervention to use the levonorgestrel regimen of emergency contraception pills safely and effectively.” Overall, it appears that the application (sNDA) met all of the requirements for the switch.

As a routine part of the drug approval process, relevant independent FDA advisory committees met to discuss the application and make a recommendation to the deciding body. On December 16, 2003, a joint panel of the FDA’s Reproductive Health Drugs Advisory Committee and Nonprescription Drugs Advisory Committee voted twenty-three to four to recommend approval of Plan B® without a prescription. The panel found the drug safe for use without a

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193. Id. at 342-43.
194. Id. at 346 tbl.3.
195. Id.
197. Id. at 18.
198. Id. at 17-18.
199. Id. at 23. The predominant reasons that patients provided for using EC were that a condom broke (45%) or that the intercourse was unprotected (40%). Id. at 20.
201. See Joint Committee Report, supra note 2, at 395.
prescription with no reports of death or cardiovascular events. Furthermore, the potential for misuse and abuse was minimal and the risk of ectopic pregnancy was low. The only concerns noted were from a small minority of members and involved the low number of young adolescents included in the studies, as the application contained data on only twenty-nine patients aged fourteen to sixteen and no data on patients under age fourteen.

In response to these concerns, on March 11, 2004, Barr amended their application proposing Plan B® without a prescription for women sixteen years of age and older, while requiring a prescription for women under sixteen years of age. As part of this proviso, Barr outlined the CARE program to address many of the concerns noted. Although the advisory committee had already shown overwhelming support for Plan B® nonprescription use, Barr wanted to assure a favorable decision.

B. FDA Decision

In an unexpected turn of events, on May 6, 2004, the FDA issued a “Non-Approvable” letter to Barr, signed by the Director of the CDER. The FDA deemed the application incomplete and inadequate for a full review, citing the lack of data that Plan B® could be “used safely by young adolescent women . . . without the professional supervision of a [physician].” Moreover, the FDA expressed concerns regarding how Barr would comply with both the prescription and nonprescription requirements in the same packaging.

202. Id. at 344-45, 349.
204. See Joint Committee Report, supra note 2, at 354-57.
206. Id. The FDA was unable to complete a full review of this amendment because it was “preliminary and incomplete.” Id.
207. See supra note 190 and accompanying text.
208. Joint Committee Report, supra note 2.
209. Id. The Director of the CDER does not usually sign decision letters. Gardiner Harris, Morning-After Pill Ruling Defies Norm, N.Y. TIMES, May 8, 2004, at A13. However, Dr. Steven Galson, the Acting Director, chose to sign this letter because his opinion differed from that of the review staff on the adequacy of data in young adolescents. Id. He believed that additional data were needed. Id.
211. Id.
The FDA letter provided instructions for Barr to follow before its application could be approved.\textsuperscript{212} Ironically, in the same response letter, the FDA conceded that the "[w]ide availability of safe and effective contraceptives is important to public health."\textsuperscript{213} Critics were quick to characterize the FDA's decision as political because of the overwhelming support by the advisory committee and the extensive data submitted.\textsuperscript{214} Although the FDA is not required to follow advisory recommendations, there is usually sufficient logic and reasoning to do so.\textsuperscript{215}

In response to this rejection, on July 22, 2004, Barr submitted data to the FDA, which had six months to make another decision.\textsuperscript{216} Barr developed an innovative approach to the FDA's recommendations and proposed bifurcated, single package labeling, allowing Plan B\textsuperscript{®} to be sold with and without a prescription in the same packaging.\textsuperscript{217} Nevertheless, on January 21, 2005, as the six-month deadline passed, the FDA announced a delay, citing their inability to complete the review in time.\textsuperscript{218} Once again, this decision outraged many people and was seen as filibustering by the FDA.\textsuperscript{219} Ironically, this announcement came one day after President Bush's second inauguration.\textsuperscript{220}

\begin{itemize}
\item \textsuperscript{212} Id. The FDA recommended that Barr supply additional evidence that Plan B\textsuperscript{®} could be used safely for women under age sixteen or that it could be packaged for both prescription and nonprescription use while meeting the necessary legal requirements. Id.
\item \textsuperscript{213} Id.
\item \textsuperscript{214} See Marc Kaufman, \textit{Staff Scientists Reject FDA's Plan B Reasoning}, \textit{WASH. POST}, June 18, 2005, at A02. Top agency reviewers at three different levels in the FDA dismissed Dr. Galson's reasoning for refusing to accept Barr's Application. Id.
\item \textsuperscript{215} It is believed that this is the second time in the last five decades that the FDA has refused to follow the advisory committee's recommendation. See Senator Hillary Rodham Clinton, \textit{Floor Statement (As Prepared), The Bush Administration's Repeated Attempts to Put Politics and Ideology over Science} (June 15, 2005), \textit{available} at http://clinton.senate.gov/~clinton/speeches/2005616647.html.
\item \textsuperscript{217} See Barr Response, supra note 216.
\item \textsuperscript{218} See Plan B Status Delayed, supra note 216.
\item \textsuperscript{219} See Press Release, Ctr. for Repro. Rights, supra note 189.
\item \textsuperscript{220} U.S. Dep't of State, President Bush Inauguration http://usinfo.state.gov/special/inauguration.html (last visited Mar. 22, 2006).
\end{itemize}
This delay also triggered a threatened block of Dr. Crawford's confirmation hearings by prominent Democratic Senate Committee members until a decision was made by the FDA. In response to escalating fears that Dr. Crawford would not be confirmed, Michael Leavitt, the Secretary of Health and Human Services, wrote a letter to Senator Michael Enzi, the Chairman of the Committee on Health, Education, Labor and Pensions, asserting that he had spoken with the FDA and that a decision would be made by September 1, 2005. Assured of an action date, the senators lifted their block and, on July 18, 2005, Dr. Crawford was confirmed by a vote of seventy-eight to sixteen, with six members not voting.

Then, on Friday, August 26, 2005, as Hurricane Katrina had ripped across South Florida and was approaching New Orleans, the FDA announced a further delay. This time, the FDA expressed uncertainty of whether or not the same active ingredient "may be simultaneously marketed in both a prescription drug product and an OTC drug product," although a number of currently marketed products had previously been approved under this system.

226. Id.
227. 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. 52050 (proposed Sept. 1, 2005) (to be codified at 40 C.F.R. pt. 310) [hereinafter Drug Approvals]. The FDA has "allow[ed] marketing of the same active ingredient in products that are both prescription and OTC, assuming some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner." Id. Examples of drugs simultaneously marketed as both prescription (Rx) and nonprescription (OTC) products include Meclizine (Rx for vertigo, OTC for motion sickness), Clotrimazole (Rx for candidiasis, OTC for athlete's foot), Loperamide (Rx for chronic diarrhea, OTC for acute diarrhea), nicotine products (Rx for inhaler, OTC for gums and patches), and Ibuprofen (Rx for > 400 mg for arthritis, OTC for ≤ 400 mg for aches and pains). Id.
Interestingly, the FDA did concede that Plan B® is safe and effective for women seventeen years of age and older and could be available without a prescription in those patients; however, their current decision was to the contrary.\(^2\)

The FDA also issued an advance notice of proposed rulemaking, requesting a sixty-day public comment period on the issue of simultaneous marketing ending November 1, 2005.\(^2\)\(^2\)\(^9\) The FDA did not commit to any timetable for ruling on this matter and many critics viewed this act as simply another stall technique.\(^2\)\(^3\) In fact, on March 9, 2006, Congressman Waxman wrote a letter to the FDA's Acting Commissioner describing a number of “undisclosed documents” that raised this same regulatory issue at least fifteen months prior to the delay.\(^2\)\(^3\)\(^1\) Although the question at hand is valid, and the FDA's concerns are relevant, the manner in which these concerns have been raised undermined the FDA's credibility. Now the FDA is left to mull over some 10,000 responses that have been received and still must establish a clear course of action,\(^2\)\(^3\)\(^2\) something the FDA has been unable to accomplish to date.

The FDA's inability to resolve this matter is a clear breach of the promise that government health executives made to U.S. Senators and has caused political backlash. First, the Assistant Commissioner for Women's Health and Director of the Office of Women's Health at the FDA, Dr. Susan Wood, promptly resigned from office, citing the agency's complete disregard for science and harmful actions towards women's health.\(^2\)\(^3\)\(^3\) Then, the Commissioner of Food and Drugs, Dr. Lester Crawford, suddenly and mysteriously resigned, with no public explanation whatsoever, just sixty days after being confirmed.\(^2\)\(^3\)\(^4\)

Proponents of the FDA's decision not to approve Plan B® for nonprescription use to date declare rectitude in public welfare and the protection of our youth by elected officials.\(^2\)\(^3\)\(^5\) They cite a letter to President Bush, signed in January 2004 by forty-nine conservative members of Congress, requesting the rejection of the Plan B®

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228. See Sponsor Letter, \(\text{supra} \) note 225.
229. See Drug Approvals, \(\text{supra} \) note 227.
234. See Pear & Pollack, \(\text{supra} \) note 126.
235. See Grimes, \(\text{supra} \) note 37, at 847-48.
Opponents of the FDA's decision fear a slippery slope. They view the decision as election year politics by an executive agency plagued with a conservative agenda. More importantly, they fear a growing public health crisis in this country involving unintended pregnancy.

Following the initial refusal to approve Plan B® without a prescription, Senator Clinton from New York wrote a letter, co-signed by twenty-three other senators, requesting a Senate investigation and a Government Accountability Office inquiry into the inconsistencies of the FDA's decision. The GAO released the requested report in November 2005, which contained a number of "unusual" findings. The report concluded that the Plan B® application was handled differently from other applications because it was the first time the FDA went against an advisory recommendation; it was signed by an FDA official who does not normally sign such letters; high-level FDA management was particularly involved in the decision; the FDA gave conflicting accounts on why the application was rejected; and the rationale for rejecting the application was novel and varied.

It seems clear that the battle to approve Plan B® is predominantly political and minimally scientific. It is important to remember that Congress funds the FDA, the President appoints the Commissioner, and the current administration and legislature are conservative. A further analysis of the situation illustrates more subtle and pressing issues. For example, there may be certain practical considerations for approving a drug without a prescription for one age group and requiring a prescription for another age group. For instance, this distinction creates the need to define

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236. See Kaufman, supra note 214.


238. See, e.g., Grimes, supra note 5, at 221.


240. GAO UNUSUAL REPORT, supra note 1.

241. Id. at 5-7.


243. The proposed application for Plan B® requires a prescription for women under the age of sixteen, but not for women sixteen years of age and older. See Plan B Letter, supra note 205. It would be very easy to circumvent this prescription requirement for
acceptable identification for proof of age. This would also create financial consequences because insurance plans do not cover non-prescription drugs, including EC, as part of their routine practice. There may be the social consequences to increasing access to EC. These issues are of great relevance and are not easily addressed.

The possible advantages to having EC available without a prescription include increased awareness of the product, improved access to the product, a decrease in unwanted pregnancies, a decrease in abortions, and provision of an important option for victims of sexual assault. Possible disadvantages include promotion of promiscuous and unprotected intercourse, spread of sexually transmitted diseases, fear of excessive and inappropriate use, and erosion of our overall respect for life. Both sides have compelling arguments; however, suffice it to say, they are nonscientific arguments.

C. Statewide Protocols and Collaborative Agreements

Although EC currently requires a prescription from a physician in this country, eight states — Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, and Washington — have passed laws bypassing this requirement by allowing pharmacists to dispense EC without a prescription under statewide protocols and collaborative practice agreements. New York received initial approval from the State Assembly to make EC available without a prescription, but the bill was vetoed by the

244. Many people do not have state-issued photo identification and this may cause problems for pharmacists. EC is very time sensitive and the pharmacist may be reluctant to deny sales to women for such an important drug in cases without proper age identification. Also, issues of “proper” identification and fake identification will force pharmacists into policing roles and away from counseling roles.

245. If Plan B® becomes available without a prescription, consumers will have to bear the cost directly as insurance will not cover it. See Spencer, supra note 182, at 1001-02; see also Lance W. Rook, Listening to Zantac: The Role of Non-Prescription Drugs in Health Care Reform and the Federal Tax System, 62 TENN. L. REV. 107, 109 (1994).

246. Many believe that increasing access to EC will have negative social consequences because young women will have a diminished valuation of pregnancy and intercourse. See Grimes, supra note 37, at 847. Others see increased access as a necessity to protect against unwanted pregnancy and ensure free choice. Id.

247. See, e.g., id. at 846-48.


249. See, e.g., Grimes, supra note 37, at 846-47.

250. See Raine et al., supra note 7, at 54; see also Grimes, supra note 5, at 221.
Governor. In brief, these protocols allow pharmacists with approved training who work with an "authorized prescriber" (i.e., physician), to prescribe and dispense EC without a prescription. A total of sixteen states have either passed, attempted to pass, or are in the process of proposing legislation to provide EC through pharmacists without a prescription.

It appears, therefore, that a number of states are undermining the regulations of the Food Drug and Cosmetic Act by enacting legislation to provide EC without a prescription while other states are lagging behind. This disparity may lead to Equal Protection, Equal Rights, and Equal Privileges arguments between citizens of different states. The legal and political ramifications of these statewide protocols and collaborative practice agreements have not been fully elucidated, and their future remains clouded. Still, a better solution may be readily available: the establishment of a pharmacist-only class of drugs.

IV. PHARMACIST-ONLY DRUG REGULATION

In the United States, drugs are classified either as "legend only," which requires a medical prescription, or available without a

252. See Field, supra note 7, at 159-61 (describing in detail the dependent pharmacist prescribing model).
254. The United States Constitution guarantees that "[n]o state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; . . . nor deny to any person within its jurisdiction the equal protection of the laws." U.S. CONST. amend. XIV, § 1. Statewide protocols and collaborative practice agreements that undermine the intent of federal legislation may be unconstitutional under field preemption. However, one commentator describes the ambiguities of 21 U.S.C. § 353(b)(1)(B)(I), which grants prescribing authority to "a practitioner licensed by law to administer such drug," as the justification for states to determine who has prescribing authority under Amendment X. See Field, supra note 7, at 224 n.317 (quoting 21 U.S.C. § 353(b)(1) (1994) and indicating that the language quoted above replaces a list of professionals authorized to prescribe drugs); see also Phyllis Coleman & Ronald A. Shellow, Extending Physician’s Standard of Care to Non-Physician Prescribers: The Rx for Protecting Patients, 35 IDAHO L. REV. 37, 63-67 (1998) (presenting arguments for and against extending prescribing authority to pharmacists and other healthcare providers).
255. See GAO REPORT, supra note 10, at 11 (naming such a third category of drugs, "pharmacist-only" drugs, as distinct from the current and existing two categories of prescription and over-the-counter drugs).
However, in many countries there is a third classification of drugs, those that are available without a prescription but only through a pharmacist. A pharmacist-only drug class allows access to certain medications without a prescription, but requires consultation with a pharmacist. The State of Florida has a similar, de facto, system on the books; however, due to practical considerations, it is almost never utilized. Table 2 provides a suggested list of determinative criteria for the inclusion of drugs in a pharmacist-only class.

Pharmacists in the United States have been advocating for a third class of federal drug regulation for some time, with no avail. Recently, the American Pharmacist Association (APhA) has made a strong push for such a third class. The APhA convened a task force in August 2004 to develop recommendations for a "Pharmacy


257. See GAO REPORT, supra note 10, at 24 tbl.2.1 (listing countries that have a pharmacist-only class of drugs, including Australia, Ontario, Denmark, France, Germany, Italy, the Netherlands, Switzerland, and the United Kingdom). Examples of drugs included in this class are; orlistat (Xenical®) for weight loss, Australia; acetaminophen (Tylenol®) with small quantities of codeine, Canada; lovastatin (Mevacor®) for high cholesterol, England; fluticasone (Flonase®) for allergic rhinitis, New Zealand. In the United States these drugs are prescription-only. Id.

258. See GAO REPORT, supra note 10, at 45-47 (describing the counseling requirements in countries with a pharmacist-only class of drugs).

259. See FLA. ADMIN. CODE ANN. r. § 64B16-27.220 (2005). This list of drugs is highly outdated and includes a number of products already available without a prescription. Naturally, pharmacists fear additional liability under this law.

260. These criteria should allow a regulatory agency, such as the FDA, to reasonably evaluate a drug for inclusion in a "pharmacist-only" class of drugs based upon the totality of the circumstances. These criteria take into account the strengths and limitations of the pharmacist, the disease to be treated, and the attributes of the drug under investigation. This is the first time these criteria have been delineated in literature and the author looks forward to receiving comments and feedback on their utility.

261. See Joseph A. Woelfel, Pharmacy Care OTC Status Supported but OTC Status of Statins Denied, Detail Doc. #210201, 21 PHARMACIST'S LETTER/PRESCRIBER'S LETTER 1 (Feb. 2005). In a recent undclared vote involving the establishment of a third drug class for statins, members of an FDA advisory committee favored the idea. Id.

Care OTC\textsuperscript{263} category of drugs.\textsuperscript{263} These products would be regulated similarly to traditional nonprescription drugs; however, they would only be available in areas with pharmacists present for consultation.\textsuperscript{264} Pharmaceutical manufacturers and insurance companies are likely to be in favor of this system, as sales would be expected to increase and insurance coverage to desist, as non-prescription drugs are not covered.\textsuperscript{265}

Lobbying groups, including the Consumer Healthcare Products Association and the American Medical Association, have strongly opposed this idea. The Consumer Healthcare Products Association is concerned that a pharmacist-only class of drugs would restrict consumer access through higher drug costs to consumers.\textsuperscript{266} The American Medical Association opposes such a move,\textsuperscript{267} perhaps because of a perceived shift in responsibility from the medical to the pharmacy profession. Others claim that a pharmacist-only class of drugs would provide no additional benefit over the current system.\textsuperscript{268}

The establishment of a third class of drugs has genuine benefits beyond consumer access. One such benefit is the ability to limit and track the sale of certain pharmaceuticals.\textsuperscript{269} For example, an increasing number of pharmacies are restricting the sale of pseudoephedrine, a common decongestant, because of the potential for it to be converted into methamphetamine (crank) in makeshift clandestine laboratories.\textsuperscript{270} A number of states have already passed legislation limiting pseudoephedrine sales,\textsuperscript{271} and Congress had been working to classify

\begin{footnotesize}
\begin{enumerate}
\item[263.] Id.
\item[264.] Id.
\item[265.] See Spencer, supra note 182, at 1001-02.
\item[267.] Id.
\item[268.] See Field, supra note 7, at 206.
\item[269.] This benefit would be particularly helpful to address concerns about the potential for the abuse of products. See Food & Drug Admin., FDA Talk Paper: FDA Warns Against Abuse of Dextromethorphan (DMX) (May 20, 2005), available at http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01360.html (describing the serious and potentially deadly consequences of abusing DMX, available OTC as a cough suppressant). Some pharmacies are limiting the sale of DMX. Id. DMX is chemically related to codeine and at high doses, has mild hallucinogenic actions. Id. DMX has been reported to cause a number of deaths among teenagers and young adults when abused. Id.
\item[271.] See, e.g., H.B. 1347, 2005 Leg. (Fla. 2005) (limiting the amount of sole active ingredient pseudoephedrine sales to three packages or nine base grams per customer and requiring retailers to restrict customer access by displaying the product behind the pharmacy counter); see also H.D. 2485, 73d Leg. Assemb., Reg. Sess. (Or. 2005) (classifying ephedrine or pseudoephedrine as a Schedule III Controlled Substance).
\end{enumerate}
\end{footnotesize}
it as a Controlled Substance. Furthermore, on March 9, 2006, President Bush signed the USA PATRIOT Improvement and Reauthorization Act of 2005, which contained the Combat Methamphetamine Epidemic Act of 2005. This act includes a number of strict anti-methamphetamine provisions, restricting the sale of ingredients necessary to make methamphetamine. Another potential benefit of a third drug class is a reduction in healthcare costs, achieved by decreasing unnecessary physician visits, as pharmacy consultations are not routinely billed. It may be beyond the FDA's authority to create such a drug class through regulation. The establishment of a new class of drugs may require an act of Congress acting under constitutional authority. Interestingly, Congress has requested information on this subject and studied this topic in some depth. In 1995, the U.S. General Accounting Office, the investigative arm of Congress, issued

272. See The Combat Meth Act 2005, H.R. 314, 109th Cong. § 104 (2005) (a federal attempt to restrict consumer access to pseudoephedrine by classifying it as a Schedule V Controlled Substance). The Drug Enforcement Agency (DEA) schedules drugs based on medical use and potential for abuse. Schedules for Controlled Substances, 21 U.S.C. § 812 (2002). Schedule I drugs have no approved medical use, a high potential for abuse, and a lack of accepted safety. Id. § 812(b)(1). Schedule II drugs have an accepted medical use but a high potential for abuse, which may lead to severe psychological dependence. Id. § 812(b)(2). Schedule III and IV drugs have moderate to limited potential for abuse. Id. § 812(b)(3)-(4). Schedule V drugs have a low potential for abuse and generally include antitussives (i.e., cough preparations) and antidiarrheals. Id. § 812(b)(5). Some Schedule V drugs are available for nonprescription use. Id. These drugs must be dispensed by a pharmacist and purchased by an adult eighteen years of age or older and are restricted in quantity. See PHARMACY LAW DIGEST, supra note 172, at 130-32; see also Controlled Substances Act, 21 U.S.C. §§ 881-966 (2005) (providing a complete list of controlled substances and schedules); U.S. Drug Enforcement Agency, Drug Scheduling, www.dea.gov/pubs/scheduling.html (last visited Mar. 22, 2006). Schedule changes can be initiated by the DEA, the Department of Health and Human Services, or through a petition by any interested party. See Tara Christine Brady, Comment, The Argument for the Legalization of Industrial Hemp, 13 SAN JOAQUIN AGRIC. L. REV. 85, 99 (2003); see also U.S. Drug Enforcement Agency, Controlled Substances Act, http://www.usdoj.gov/dea/agency/csa.htm (last visited Mar. 22, 2006).


275. See GAO REPORT, supra note 10, at 30 (citing a study finding a decrease in physician visits following a switch to OTC status).

276. Although traditional pharmacy services are not routinely billed, there is a trend toward pharmacists seeking reimbursement for their services. See generally, J.M. Ganther, Third Party Reimbursement for Pharmacist Services: Why Has It Been So Difficult to Obtain and Is It Really the Answer for Pharmacy?, 42 J. AM. PHAR. ASS´N 875 (2002).

277. See GAO REPORT, supra note 10, at 83.

278. See id.

279. U.S. CONST. art. I, § 8, cl. 3.
a report on the value of a “Pharmacist-Controlled Class.” This report, however, found no compelling data to support the creation of this class and the establishment of a pharmacist-only class of drugs has not been implemented.

Today is far different from 1995. Since then, several drugs, such as Zantac®, Claritin®, and Prilosec®, have become available without a prescription, and their impact has been tremendous. Furthermore, there has been an increasing push for the availability of certain drugs, such as statins and the diet drug orlistat, to be available without a prescription, but the FDA has grappled with their risks.

There appears to be great utility for a third class of drug regulation and minimal reasons opposing it. Pharmacists publicly support such a class and the time appears right. Pharmacists have the experience and knowledge to address the multitude of concerns regarding proper and reliable use, and pharmacists are widely accessible. Furthermore, the establishment of a pharmacist-only class of drugs could serve as a reasonable compromise between two completely dichotomous views.

280. See GAO REPORT, supra note 10.
281. Id. at 3.
283. Statins are used for high cholesterol and have proven to reduce cardiovascular mortality in diverse populations. G. De Angelis, The Influence of Statin Characteristics on Their Safety and Tolerability, 58 INT’L J. CLINICAL PRAC. 945 passim (2004). Statins include Crestor®, Lescol®, Lipitor®, Mevacor®, Pravachol®, and Zocor®. There are, however, serious adverse drug reactions associated with statins including muscle toxicity, liver toxicity, and numerous drug-drug interactions. Id. at 949-52. These drugs have also been associated with a number of birth defects and are generally contraindicated in pregnancy.
285. During a joint meeting, two FDA advisory committees voted twenty to three against selling Mevacor®, a statin, over the counter. Hilda F. Scharen, Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee 2, 5-6 (Jan. 13-14, 2005) (summary minutes), available at http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4086Ml.pdf. Some members expressed a desire for an “in-between option” of prescription and non-prescription drug regulation, whereby the product could be purchased without a prescription, but only after speaking to a pharmacist. Id. at 6; see also Anna Wilde Mathews, Glaxo Gets Tough FDA Questions over Bid for OTC Sale of Diet Drug, WALL ST. J., Jan. 21, 2006, at A6 (identifying concerns regarding drug-drug interactions with Orlistat).
286. See PHARMACY REPORT, supra note 262.
287. Rita Rubin, Rx out of the Box, USA TODAY, Feb. 8, 2005, at 1D.
V. PLAN B® AND PHARMACIST-ONLY REGULATION

A. Practical Considerations

The complex regulatory framework surrounding EC poses many obstacles and a tremendous opportunity for this country. Pharmacists have been looking to expand their role past “pill counters” for many years, and EC appears to provide an ideal opportunity to launch a pharmacist-only class of drugs.288

The Plan B® application is nonprescription for adolescents sixteen years of age and older and prescription for patients younger than sixteen.289 The distinction is pragmatically inconsequential; anybody who wants to purchase the product will be able to do so, because the system can be easily circumvented. Moreover, this system forces pharmacists into an adversarial role because they must refuse to sell the product to underage girls. Additionally, the question of whether supermarkets, convenience stores, and even gas stations could litigate to sell Plan B® remains unanswered, as there is no legal precedent or legislation addressing this issue.

EC is an ideal candidate for a pharmacist-only class of drugs based on the controversial issues at hand. EC is extremely safe and effective and is important for public health.290 Furthermore, worldwide experience with EC is significant since more than thirty countries allow its sale without a prescription.291 Pharmacists in this country are in an ideal position to address the critical time constraints of EC since they are accessible twenty-four hours a day, seven days a week in many markets. Additionally, since statins and their associated risks have been increasingly mentioned for non-prescription use, both classes could be launched simultaneously, shifting some of the media coverage.292

288. Id.
289. See Plan B Status Delayed, supra note 216.
290. See Grimes, supra note 37.
292. See Woelfel, supra note 261. Despite safety concerns associated with statin use, simvastatin (Zocor® Heart Pro) has recently become available in England without a
B. Conscientious Objection

There are important obstacles to establishing a pharmacist-only class of drugs for EC. Ironically, one of these barriers is the pharmacist himself. Over the past few years, a growing number of pharmacists have relied on conscientious objection when refusing to dispense birth control and EC. In 1998, the APhA issued a committee report recognizing the right to conscientious objection for pharmacists.

Conscientious objection is the moral or religious justification for refusing to act against one’s own belief. For example, a pharmacist may refuse to sell EC based on his “conscientious objection” if he feels it is wrong or against his religious beliefs. Currently, forty-seven states have passed conscientious objection legislation, commonly referred to as refusal laws, supporting healthcare providers. Most of these laws, however, were not intended for pharmacists and deal with abortion. Still, several states permit healthcare providers to conscientiously refuse to provide contraception, and further legislation is pending in ten other states.

Amazingly Wal-Mart, the nation’s leading retailer, even had a corporate policy to refuse to sell Plan B® since 1999. Under increasing pressure to dispense emergency contraception, however, they reversed that decision on March 3, 2006. Nevertheless, Wal-Mart and its warehouse division, Sam’s Club, maintain a conscientious objection policy permitting its pharmacists to refer prescription and many are advocating its sale in the U.S. without a prescription if a similar behind-the-counter system is available. Id.

294. See APhA CONSCIENCE CLAUSE, supra note 8, at 10.
295. See Cantor & Baum, supra note 293, at 2009.
296. See Herbe, supra note 27, at 86 (providing a synopsis of the teachings of the Roman Catholic Church).
298. Id.
patients with prescriptions for Plan B® to another pharmacy.\textsuperscript{302} Thus, even if Plan B® became available without a prescription, its unimpeded access may remain a problem for some.\textsuperscript{303} One pharmacist recently made news after refusing to fill, transfer, or return a prescription for birth control for a University of Wisconsin student at a K-Mart pharmacy.\textsuperscript{304} In another matter, four pharmacists in the state of Illinois sued Walgreen after being placed on unpaid leave and offered jobs in another state for failing to sign a statement ensuring that they would dispense EC under a valid prescription, citing protection under the state right of refusal law.\textsuperscript{305} The plaintiffs in this case were being represented by the American Center for Law and Justice, founded by Yale Law School graduate and evangelist, Pat Robertson.\textsuperscript{306} Moreover, in Hellinger v. Eckerd Corp., the court held that the plaintiff established a prima facie case of religious discrimination under Title VII of the Civil Rights Act of 1964 when an employer fired a pharmacist for refusing to sell contraception (e.g., condoms) because of his religious beliefs.\textsuperscript{307} Even if a pharmacist-only class of drugs came to fruition, legal issues remain about the ability to require pharmacists to participate and dispense drugs against their moral or religious beliefs.

Alternatively, the Governor of Illinois has recently filed a rule requiring pharmacists in that state to dispense EC without question.\textsuperscript{308} Federal lawmakers have unveiled a bill in Congress permitting a pharmacist to refuse to dispense this medication

\begin{footnotes}
\footnotetext[302]{Id.}
\footnotetext[303]{See The Council of the City of N.Y., Emergency Contraception: Available at Your Pharmacy Yet? (2004), available at http://www.nyc.gov/html/records/pdf/govpub/872emergpills.pdf. This report shows that more than twenty-five percent of the city's pharmacies were not stocking EC and some boroughs were less likely to stock it than others. Id. at 8-9. The pharmacies not stocking EC were in violation of a local law requiring pharmacies to post notice that they do not stock EC. Id. at 14.}
\footnotetext[304]{Pharmacist Neil Noesen was ordered by an administrative law judge to take a six-hour course in pharmacy ethics, had his license restricted for two years, and had to pay legal fees of approximately $20,000 for "unprofessional conduct." See Press Release, Planned Parenthood Advocates of Wisconsin, Pharmacist Punished for Denying Patient Access to Birth Control (Apr. 13, 2005), available at http://www.ppawi.org/media/PPAWI/News/NoesenReprimanded.4-13-05.htm. The pharmacist could have likely avoided these penalties if he had simply returned the prescription citing his conscientious objection and referred her elsewhere.}
\footnotetext[307]{67 F. Supp. 2d 1359, 1360-61 (S.D. Fla. 1999) (denying defendant's motion for summary judgment).}
\footnotetext[308]{Monica Davey, Illinois Pharmacies Ordered to Provide Birth Control, N.Y. Times, Apr. 2, 2005, at A10.}
\end{footnotes}
provided another pharmacist is available to fill these types of prescriptions.\textsuperscript{309}

Another concern regarding a pharmacist-only class of drugs for EC is a potential conflict of interest. Pharmacists would be selling controversial products for which they may have a vested financial interest. Imagine opening your Sunday newspaper and seeing a coupon for Plan B\textsuperscript{®} — buy one, get one free.\textsuperscript{310} Or, worse yet, buy a six-pack of beer and get Plan B\textsuperscript{®} for free. Also, requiring consultation with a pharmacist may heighten concerns of embarrassment, shame, or fear among women, which would otherwise be absent if they could purchase it directly without the pharmacist. Moreover, with increased responsibility, pharmacists may be subject to increased liability, which may prevent them from actively participating in such a program. Additionally, certain states may repudiate a federal class by implementing more stringent drug laws or specifically prohibiting EC without a prescription.\textsuperscript{311} Finally, critics argue that EC encourages unprotected sexual intercourse and thus increases the spread of sexually transmitted disease, although the available data suggest otherwise.\textsuperscript{312}

\textbf{CONCLUSION}

Plan B\textsuperscript{®} is safe and effective for OTC use.\textsuperscript{313} Furthermore, the data suggests that it can be used appropriately in a nonprescription setting.

\begin{itemize}
  \item \textsuperscript{309} This bill, called the Workplace Religious Freedom Act, is supported by a bipartisan group of senators and representatives. \textit{See} Rick Santorum & John Kerry, \textit{Religion in the Pharmacy}, N.Y. TIMES, Apr. 12, 2005, at A20.
  \item \textsuperscript{310} Barr Pharmaceuticals, however, has indicated that if Plan B\textsuperscript{®} is approved for nonprescription use, they will not offer any coupons, samples, rebates, or trial offers. \textit{See} Joint Committee Report, \textit{supra} note 2, at 92-93. Advertising of nonprescription drugs is regulated very differently than advertising of prescription drugs. Advertising of nonprescription drugs and dietary supplements (i.e., herbs) is regulated by the Federal Trade Commission, whereas prescription drug advertising is regulated by the FDA. Fred Sheftell et al., \textit{Direct-to-Consumer Advertising of OTC Agents Under Current FTC Regulations: Concerns and Comment}, 41 HEADACHE 534, 534 (2001) (expressing concern for consumer safety due to the FTC & regulation of OTC advertising).
  \item \textsuperscript{311} If a state law is more stringent than the federal law, it will be enforceable as long as there is no conflict between the two (conflict preemption), or the federal law is not so pervasive to leave no room for state regulatory control (field preemption). \textit{See} Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 74 n.6, 74-75 (1st Cir. 2001).
  \item \textsuperscript{312} \textit{See} Raine et al., \textit{supra} note 7, at 55, 58-62 (presenting clinical data suggesting that pharmacy access and advanced provision of emergency contraception have no significant effect on unprotected intercourse or the risk of sexually transmitted diseases).
  \item \textsuperscript{313} Anna Glasier & David Baird, \textit{The Effects of Self-Administering Emergency Contraception}, 339 NEW ENG. J. MED. 1, 4 (1998) (presenting research finding that Plan B\textsuperscript{®} is safe and may prevent unwanted pregnancies).
\end{itemize}
setting. However, Plan B® symbolizes something else — a growing schism in our social system. Pro-life activists view EC as an abortifacient and its use as the killing of an unborn child. They believe that increasing access to EC will condone its use and diminish social responsibility. Meanwhile, pro-choice activists view EC as an integral part of a woman's choice and a necessary option to prevent unwanted pregnancy. Nevertheless, the FDA has already approved EC in this country.

The current regulatory framework seems unable to deal with the subtle nuances involving EC and the escalating push to have it available without a prescription. It is becoming increasingly apparent that the two-class distinction (prescription and nonprescription) is incomplete and fails in this situation. The public outcry regarding EC has been remarkable, with strong advocates on both sides. Furthermore, a growing number of states have ventured into their own regulatory systems, which undermine the current federal system.

Approval of EC under a third class of drug regulation, a pharmacist-only class, is an appropriate and viable solution. Moreover, it is greatly preferable to the evolving statewide protocols and collaborative practice agreements currently in place. Women in this country cannot rely on the states for such an important matter regarding privacy rights. We have already seen states like Texas enforce sodomy laws while even more “liberal” states, such as Oregon, outlaw gay marriage. The FDA decided long ago that EC is safe, reliable, and effective, and now it should have full faith and credit in their decision. A growing segment of the public is in need of EC and the best way to ensure its access is through the pharmacist.

314. See id.; see also Raymond et al., supra note 196, at 21.
315. See supra notes 62-63, 249 and accompanying text.
316. See Grimes, supra note 37, at 846-47.
317. See id. at 847.
319. See supra Part III.C.
320. See Lawrence v. Texas, 539 U.S. 558, 562-63, 579 (2003) (reversing, six to three, the Texas Court of Appeals, which had upheld the enforcement of a Texas statute making engaging in homosexual conduct illegal).
Table 1. Over-the-Counter Drug Criteria

<table>
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<th>Criteria</th>
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<tr>
<td>Drug is safe for self-treatment</td>
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<td>Drug is effective with self-treatment</td>
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<tr>
<td>Potential for misuse and abuse is low</td>
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<tr>
<td>Potential for drug-drug interactions is low</td>
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<tr>
<td>Condition is self-diagnosable (i.e., symptomatic)</td>
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<tr>
<td>Condition is self-treatable</td>
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<tr>
<td>Condition is self-limiting</td>
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<tr>
<td>Product labeling can provide adequate directions for use</td>
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<tr>
<td>Drug has widespread experience, domestic or international</td>
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<tr>
<td>Condition should be non-life threatening</td>
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<tr>
<td>Condition is short-lived</td>
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<tr>
<td>Condition should not mask a more serious underlying disorder</td>
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<td>Drug has an acceptable safety margin</td>
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Table 2. Pharmacist-Only Drug Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
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<tbody>
<tr>
<td>Drug is generally safe if taken as directed but has the potential for serious adverse effects and harm</td>
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<tr>
<td>Drug is effective for treatment</td>
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<tr>
<td>Drug has the potential for abuse and misuse if sold or used unregulated</td>
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<tr>
<td>Drug has the potential for clinically significant drug interactions</td>
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<tr>
<td>Condition may or may not be self-diagnosable (i.e., symptomatic)</td>
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<tr>
<td>Condition is self-treatable</td>
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<tr>
<td>Condition may or may not be self-limiting</td>
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<tr>
<td>Drug treats a condition that could be dangerous or life-threatening if not managed</td>
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<tr>
<td>Product labeling may be somewhat complicated for the typical user to understand or comply with</td>
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<tr>
<td>Drug has widespread experience, domestic or international</td>
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<tr>
<td>Pharmacist is able to identify appropriate indications for therapy</td>
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<tr>
<td>Drug has important contraindications the pharmacist is able to assess</td>
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<tr>
<td>Pharmacist can recognize or ascertain patients who meet criteria for use</td>
</tr>
<tr>
<td>Pharmacist can recognize or ascertain patients who fail to meet criteria for use</td>
</tr>
<tr>
<td>Pharmacist is able to monitor or recommend appropriate monitoring to the patient</td>
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<tr>
<td>Pharmacist can identify the need for referral to a physician</td>
</tr>
<tr>
<td>Drug has the potential for inappropriate use which may be harmful to society or the individual</td>
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<tr>
<td>Drug has few or no “off-label” uses</td>
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<tr>
<td>Drug has been deemed socially important</td>
</tr>
<tr>
<td>Drug has an acceptable safety margin</td>
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</tbody>
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