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# 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

MATTHEW J. SEAMON\*

## 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,<sup>1</sup> despite an overwhelming recommendation from a joint advisory committee.<sup>2</sup> This decision triggered the most heated political debate involving the FDA since their refusal to approve thalidomide in 1962.<sup>3</sup> 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.<sup>4</sup> Opponents characterize this decision as a dangerous furtherance of

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1. U.S. GOV'T ACCOUNTABILITY OFFICE, FOOD & DRUG ADMIN.; DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 2-3 (2005), *available at* <http://www.gao.gov/new.items/d06109.pdf> [hereinafter GAO UNUSUAL DECISION REPORT].

2. Food & Drug Admin., Ctr. for Drug Evaluation & Res., Nonprescription Drugs Advisory Committee (NDAC) in Joint Session with the Advisory Committee for Reproductive Health Drugs (ACRHD) Meeting (Dec. 16, 2003) (unpublished manuscript), *available at* <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.doc> [hereinafter Joint Committee Report]. The Joint Advisory Committee voted twenty-three to four to approve Plan B® for use without a prescription. *Id.* at 395.

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.

4. See, e.g., Jenni Parker, *Pro-Lifers, Pro-Family Groups Hail FDA Decision Rejecting OTC Morning-After Pill*, AGAPEPRESS.ORG, May 7, 2004, *available at* <http://headlines.agapepress.org/archive/5/72004b.asp>.

social conservatism, propaganda “trumping” science, and political ideology run amuck.<sup>5</sup>

Clearly this situation is complex. The issues that surround EC are emotionally charged and involve a sharp split among the American public.<sup>6</sup> 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.<sup>7</sup> On the other hand, pharmacists may conscientiously object to selling it, undermining public health.<sup>8</sup>

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.<sup>9</sup> 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.<sup>10</sup>

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

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5. See, e.g., David A. Grimes, *Emergency Contraception: Politics Trumps Science at the U.S. Food and Drug Administration*, 104 AM. C. OBSTETRICIANS & GYNECOLOGISTS 220, 220 (2004).

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.

7. See Heather M. Field, *Increasing Access to Emergency Contraceptive Pills Through State Law Enabled Dependent Pharmacist Prescribers*, 11 UCLA WOMEN’S L.J. 141, 229-31 (2000); Tina R. Raine et al., *Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs*, 293 JAMA 54, 54 (2005). See also Grimes, *supra* note 5, at 221 (“Women in California and . . . other states can buy emergency contraception at pharmacies without first seeing a physician for a prescription.”); *Morning After Pill: OTC?*, CBSNEWS.COM, Aug. 9, 2005, <http://www.cbsnews.com/stories/2005/08/09/health/main767140.shtml>.

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](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.*

9. See Jeffrey M. Drazen et al., *The FDA, Politics, and Plan B*, Editorial, 350 NEW ENG. J. MED. 1561, 1561-62 (2004).

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®.<sup>11</sup> Part II discusses the regulatory framework surrounding prescription and nonprescription medications and how a drug undergoes an "Rx to OTC Switch."<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup> EC is also indicated for victims of sexual assault and women exposed to known teratogens.<sup>15</sup> EC works by preventing ovulation or inhibiting implantation of a fertilized ovum, both of which are necessary for pregnancy to occur.<sup>16</sup>

The first widely recognized reference to birth control involved the withdrawal method mentioned in the Bible's book of Genesis.<sup>17</sup>

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11. Plan B® has been available since 1999 and has been the only drug available for emergency contraception since 2004. National Family Planning & Reproductive Health Ass'n, Emergency Contraception and Plan B®, <http://www.nfprha.org/pac/factsheets/planb.asp> (last visited Mar. 11, 2006). For information concerning how Plan B® is prescribed, see Barr Pharmaceuticals, Inc., Plan B® (levonorgestrel) U.S. Prescribing Information (Feb. 2004), available at <http://www.go2planb.com/PDF/PlanBPI.pdf> [hereinafter Plan B Prescribing Information]. See also *infra* notes 67-68 and accompanying text.

12. "Rx to OTC Switch" refers to the regulatory process for changing a prescription (Rx) drug to nonprescription (OTC). See Leland L. Price, Sweetening the Bitter Pill: Rx to OTC Switches Via a Third Class of Drugs 7-9 (unpublished manuscript, available at Harvard Law School Legal Electronic Document Archive, <http://leda.law.harvard.edu/leda/data/115/lprice.pdf> (last visited Mar. 22, 2006)).

13. See *infra* Part III.C.

14. David A. Grimes & Elizabeth G. Raymond, *Emergency Contraception*, 137 ANNALS INTERNAL MED. 180, 180 (2002).

15. *Id.* at 180 tbl.1.

16. *Id.* at 182.

17. See *Genesis* 38:9 (Holman Christian Standard) ("But Onan knew that the offspring would not be his; so whenever he slept with his brother's wife, he released his

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.<sup>18</sup> 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.<sup>19</sup> He was believed to prefer condoms made of lamb intestine.<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup>

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.<sup>23</sup> Birth control pills, patches, vaginal rings, and injections are available, even a chewable tablet in spearmint flavor.<sup>24</sup> Furthermore, the use of EC has been increasing and physicians are now writing "advance prescriptions" for women to keep on hand.<sup>25</sup>

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semen on the ground so that he would not produce offspring for his brother."'). See also *Genesis* 38:10, which continues "What he did was evil in the Lord's sight, so He put him to death also." *Id.*

18. Daniel DeNoon, *Birth Control Timeline*, WEBMD.COM, May 4, 2004, <http://www.webmd.com/content/article/71/81244.htm?printing=true>.

19. *Id.*

20. *Id.*

21. June LaValleur, *Emergency Contraception*, 27 OBSTETRICS & GYNECOLOGY CLINICS N. AM. 817, 818 (2000).

22. LaValleur, *supra* note 21, at 818; DeNoon, *supra* note 18.

23. Iris F. Litt, *Placing Emergency Contraception in the Hands of Women*, 293 JAMA 98, 98 (2005).

24. The following are examples of these birth control devices. Ortho Evra® is a weekly contraceptive patch marketed by Ortho-McNeil Pharmaceutical, Inc. Ortho Evra Home Page, <http://www.orthoevra.com> (last visited Mar. 22, 2006). NuvaRing® is a monthly contraceptive vaginal ring manufactured by Organon. NuvaRing Home Page, [http://www.nuvaring.com/consumer/whatIsNuvaRing/index\\_flash.asp](http://www.nuvaring.com/consumer/whatIsNuvaRing/index_flash.asp) (last visited Mar. 22, 2006). Depo-Provera® is a contraceptive injection administered every 11 to 13 weeks manufactured by Pfizer. Depo-Provera Home Page, <http://www.depo-provera.com/howitworks.asp> (last visited Mar. 22, 2006). Ovcon 35® is a spearmint flavored chewable oral contraceptive marketed by Warner Chilcott Pharmaceuticals. Ovcon 35, <http://www.warnerchilcott.com/products/ovcon.php> (last visited Mar. 22, 2006).

25. Certain doctors and chapters of Planned Parenthood provide patients with prescriptions for emergency contraception at routine visits. They are instructed to take these prescriptions to a pharmacy in case of an emergency. See Ann Carms, *U.S. Web Sites Let Women Obtain Emergency Contraceptive Pills — Reproductive Rights Advocates Applaud Service — Elimination of Visits with Doctor Concerns Opponents*, WALL ST. J. (Eur.), May 6, 2001, at 24.

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.<sup>26</sup> 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.<sup>27</sup> This dissension is readily apparent with the latest Department of Justice Guidelines for treating sexual assault victims, where mention of EC is conspicuously absent.<sup>28</sup> Media reports indicate that EC was included in earlier versions of the protocol and purposefully omitted from the final one.<sup>29</sup> One New York congresswoman was even denied the opportunity to comment on this glaring omission at a public hearing on the subject.<sup>30</sup>

Although EC is generally considered a recent phenomenon, oral contraception has been used "off label" since 1974 as EC.<sup>31</sup> This use is seen primarily in hospitals, university health clinics, and, to a

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26. Victoria S. Elliott, *Doctors Assess Impact of Morning-After Pill Going OTC*, AMEDNEWS.COM, Jan. 19, 2004, <http://www.ama-assn.org/amednews/2004/01/19/hll10119.htm>. See also AMA Policy, HR-75.985 Access to Emergency Contraception, available at [http://www.ama-assn.org/apps/pf\\_new/pf\\_online?f\\_n=resultLink&doc=policyfiles/HnE/H-75.985.HTM&S-t=75-985&catg=AMA/HnE&catg=AMA/BnGnC&catg=AMA/DIR&&nth=1&&st\\_p=o&nth=1&](http://www.ama-assn.org/apps/pf_new/pf_online?f_n=resultLink&doc=policyfiles/HnE/H-75.985.HTM&S-t=75-985&catg=AMA/HnE&catg=AMA/BnGnC&catg=AMA/DIR&&nth=1&&st_p=o&nth=1&) (last visited Mar. 22, 2006).

27. Gina Kolata, *Debate on Selling Morning-After Pill over the Counter*, N.Y. TIMES, Dec. 12, 2003, at A1. See also Donald W. Herbe, Note, *The Right to Refuse: A Call for Adequate Protection of a Pharmacist's Right to Refuse Facilitation of Abortion and Emergency Contraception*, 17 J. L. & HEALTH 77, 87 (2002).

28. See OFFICE OF VIOLENCE AGAINST WOMEN, U.S. DEP'T OF JUSTICE, A NATIONAL PROTOCOL FOR SEXUAL ASSAULT MEDICAL FORENSIC EXAMINATIONS, ADULTS/ADOLESCENTS, NCJ 206554 (2004), available at <http://www.ncjrs.org/pdffiles1/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.

29. See American Civil Liberties Union, Take Action: Urge Congress to Support Pregnancy Prevention Information for Rape Victims, <https://secure.aclu.org/site/Advocacy?pagename=homepage&page=UserAction&id=153> (last visited Mar. 22, 2006).

30. See Press Release, Congresswoman Carolyn B. Maloney, Justice Department Denies Member of Congress Ability to Speak or Submit Testimony at Public Hearing on Health Treatment Protocol for Victims of Sexual Assault (Feb. 10, 2005), available at [http://maloney.house.gov/index.php?option=com\\_content&task=view&id=144&Itemid=61](http://maloney.house.gov/index.php?option=com_content&task=view&id=144&Itemid=61).

31. The Yuzpe method of birth control is named after the Canadian professor who first identified its use, Albert Yuzpe. Food & Drug Admin. Notice, Prescription Drug Products: Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610 (Feb. 25, 1997) [hereinafter FDA Notice]. The Yuzpe method consists of two doses separated by twelve hours and initiated within seventy-two hours of unprotected intercourse. *Id.*; Litt, *supra* note 23, at 98.

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

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

The rate of unintended pregnancies is reaching epidemic proportions, and the need for a reliable and widely accessible redress is growing.<sup>40</sup> An estimated 3.5 million unintended pregnancies occur annually in this country, with one-third involving teenagers.<sup>41</sup> In fact, about twenty percent of all teenage girls who have sexual intercourse become pregnant each year.<sup>42</sup> Further estimates are that fifty percent of unwanted pregnancies could be averted with EC,<sup>43</sup> 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.<sup>44</sup> Two-thirds of the teenage girls who were informed of the option said they would be likely to use EC.<sup>45</sup>

32. FDA Notice, *supra* note 31, at 8610.

33. See Grimes & Raymond, *supra* note 14, at 181 tbl.2.

34. FDA Notice, *supra* note 31; see also LaValleur *supra* note 21, at 818.

35. FDA Notice, *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. *Id.* It is a great source of information with references, educational and promotional materials, and a local directory of providers available to prescribe EC. *Id.*

36. See Field, *supra* note 7, at 151.

37. See David A. Grimes, *Switching Emergency Contraception to Over-the-Counter Status*, 347 NEW ENG. J. MED. 846, 848 (2002).

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.

39. See, e.g., Raine et al., *supra* note 7, at 58-62.

40. David A. Grimes et al., *Emergency Contraception Over-the-Counter: The Medical and Legal Imperatives*, 98 OBSTETRICS & GYNECOLOGY 151, 151 (2001).

41. Litt, *supra* note 23, at 98.

42. Suzanne F. Delbanco et al., *Missed Opportunities: Teenagers and Emergency Contraception*, 152 ARCHIVES PEDIATRICS & ADOLESCENT MED. 727, 727 (1998).

43. Raine et al., *supra* note 7, at 54.

44. See Delbanco et al., *supra* note 42, at 729.

45. *Id.* at 730.

The difference between EC and abortion is a nebulous, yet important, distinction for many people and is based on highly technical terminology.<sup>46</sup> The consensus among the scientific and medical communities is that EC is not abortifacient.<sup>47</sup> 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.”<sup>48</sup> Accordingly, pregnancy occurs only *after* implantation of the fertilized egg to the uterine wall.

Ovum (egg) and sperm each have twenty-three chromosomes.<sup>49</sup> Upon ovulation, the ovum is released from the ovaries and travels down the fallopian tube.<sup>50</sup> Fertilization occurs when the sperm attaches to a receptor on the ovum called the zona pellucida.<sup>51</sup> At this stage, a zygote is created, having a complete set of maternal and paternal DNA (i.e., forty-six chromosomes).<sup>52</sup> 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.<sup>53</sup> The zygote then organizes itself into the morula around day three or four while continuing to divide.<sup>54</sup> 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.<sup>55</sup> 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.<sup>56</sup> The embryo then implants in the uterine wall

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46. This distinction is the basis for the debate between pro-life and pro-choice advocates. Grimes, *supra* note 37, at 847.

47. Caroline Wellbery, *Emergency Contraception: An Ongoing Debate*, 70 AM. FAM. PHYSICIAN 655, 655 (2004).

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”).

49. See Earl W. Stradtman, Jr., *Genetics in Reproduction*, in TEXTBOOK OF REPRODUCTIVE MEDICINE 57, 57 (Bruce R. Carr & Richard E. Blackwell eds., Appleton & Lange, 2d ed. 1998) (1993).

50. See Medline Plus Medical Encyclopedia, Fetal Development, <http://www.nlm.nih.gov/medlineplus/ency/article/002398.htm> (last visited Mar. 22, 2006) [hereinafter Fetal Development].

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.*

55. See Press Release, Nat’l Inst. of Health, Researchers Discover How Embryo Attaches to the Uterus (Jan. 16, 2003), available at <http://www.nichd.nih.gov/new/releases/embryo.cfm>.

56. *Id.*



at approximately day seven, and at that point pregnancy occurs.<sup>57</sup> It is important to note that not all fertilized ovum fully develop or implant in the uterine wall.<sup>58</sup>

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

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.<sup>62</sup> Under this doctrine, EC is an abortifacient.<sup>63</sup> Scientifically speaking, this argument has merit, as a fertilized ovum has a full complement of DNA.<sup>64</sup> Suffice it to say, the distinction between abortion and

57. *Id.*; see also Wellbery, *supra* note 47, at 655.

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 *id.* at 582. Of the remaining clinical pregnancies, approximately 10% will spontaneously abort with additional perinatal mortality of 1%. *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.

59. See Grimes, *supra* note 37, at 847.

60. Renee C. Wyser-Pratte, *Protection of RU-486 as Contraception, Emergency Contraception and as an Abortifacient Under the Law of Contraception*, 79 OR. L. REV. 1121, 1121 (2000).

61. *Id.* at 1132.

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, 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](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, *Bioethics for Clinicians: 27. Catholic Bioethics*, 165 CAN. MED. ASS'N J. 189, 190 (2001).

63. See POPE PAUL VI, 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](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).

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.

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.<sup>65</sup> Preven® was the first drug approved in 1998 and is a combination product containing both an estrogen and a progestin.<sup>66</sup> Plan B® was approved in 1999<sup>67</sup> and contains only a progestin.<sup>68</sup> Interestingly, in May 2004, Barr Pharmaceuticals, Inc., the manufacturer of Plan B®, purchased the marketing rights to Preven® and has discontinued its sales.<sup>69</sup> Plan B® is a preferential product since it has a lower incidence of nausea and vomiting than Preven® and has enhanced packaging.<sup>70</sup> Preven® was packaged with a pregnancy test,<sup>71</sup> 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.<sup>72</sup> Plan B® requires a prescription in this country.<sup>73</sup> 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.*

67. ELECTRONIC ORANGE BOOK, *supra* note 65, at [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?select=p](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?select=p&BrowsebyDrugName=PlanB) under "Browse by Drug Name"; then follow "Plan B" hyperlink on page 2) (last visited Mar. 22, 2006).

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

69. The Electronic Orange Book lists Preven® as discontinued. ELECTRONIC ORANGE BOOK, *supra* note 65, at [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?select=p](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?select=p&BrowsebyDrugName=Preven) under "Browse by Drug Name"; then follow "Preven" hyperlink on page 5).

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.

71. Press Release, Gynetics Inc., Preven™ Emergency Contraceptive Kit — The First and Only Emergency Contraceptive Product — Approved by the FDA (Sept. 2, 1998), available at <http://ec.princeton.edu/news/preven.html>.

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>.

73. ELECTRONIC ORANGE BOOK, *supra* note 65, at [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?select=p](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?select=p&BrowsebyDrugName=PlanB) under "Browse by Drug Name"; then follow "Plan B" hyperlink on page 2) (last visited Mar. 22, 2006).

preferably within seventy-two hours.<sup>74</sup> The first dose is followed by a second dose, twelve hours later.<sup>75</sup> Plan B® is highly effective, decreasing the risk of pregnancy by approximately 75% when used within seventy-two hours.<sup>76</sup> 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.<sup>77</sup> There are also data that both tablets can be taken in a single dose with no loss of efficacy.<sup>78</sup> The main side effect of Plan B® is nausea, which occurs in almost one quarter of patients.<sup>79</sup> As a result, many practitioners recommend anti-emetic therapy with treatment.<sup>80</sup>

The prescribing information for Plan B® describes the mechanism of action as preventing ovulation or fertilization and, alternatively, as inhibiting implantation.<sup>81</sup> 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.<sup>82</sup> Accordingly, Plan B® generally is not considered an abortifacient.

### C. Legal Basis

Contraception, EC, medical abortion involving drugs,<sup>83</sup> and surgical abortion<sup>84</sup> are all lawful in this country.<sup>85</sup> These practices, however, have not always been legal. In 1873, Anthony Comstock tried to legislate morality by introducing legislation (the Comstock

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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).

78. Helena von Hertzen et al., *Low Dose Mifepristone and Two Regimens of Levonorgestrel for Emergency Contraception: A WHO Multicentre Randomised Trial*, 360 LANCET 1803, 1803 (2002).

79. See Plan B Prescribing Information, *supra* note 11, at 8.

80. Ass'n of Reprod. Health Prof., *Emergency Contraception — Information for Providers of Family Planning Services*, <http://www.arhp.org/healthcareproviders/resources/ecresources/ecppprotocol.cfm> (last visited Mar. 22, 2006).

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.<sup>86</sup> Section 1 of the Act outlawed the sale or distribution of "any drug or medicine, or any article whatever, for the prevention of contraception . . . ."<sup>87</sup> Section 2 prohibited the mailing of "any article or thing designed or intended for the prevention of contraception . . . ."<sup>88</sup> 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.<sup>89</sup>

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.<sup>90</sup>

Modern day jurisprudence involving contraception developed from the Supreme Court decision in *Griswold v. Connecticut*, which first held that women have a constitutional right to contraception.<sup>91</sup> This right was extended to all similarly situated persons, including single women, in *Eisenstadt v. Baird*.<sup>92</sup> In *Eisenstadt*, the Supreme Court relied on the Equal Protection Clause of the Fourteenth Amendment in recognizing a constitutional right to contraception.<sup>93</sup> The Supreme Court later held in *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.<sup>94</sup> Furthermore, the Court held in *Roe v. Wade* that there is a constitutional right to abortion<sup>95</sup> and in *Planned Parenthood v. Casey* that no state may impose an undue burden on this right.<sup>96</sup> Moreover, medical abortion has been legal in the United States

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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).

87. *Id.* § 1.

88. *Id.* § 2.

89. *United States v. One Package*, 86 F.2d 737, 739 (2d Cir. 1936).

90. See William N. Eskridge, Jr., *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.

91. 381 U.S. 479, 485-86 (1965).

92. 405 U.S. 438, 453 (1972).

93. *Id.* at 443.

94. 431 U.S. 678, 693-94 (1977).

95. 410 U.S. 113, 153 (1973).

96. 505 U.S. 833, 851 (1992).

since Mifeprex® was approved in 2000.<sup>97</sup> 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.<sup>98</sup>

## 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.<sup>99</sup> In addition to regulating human drugs, the FDA also regulates veterinary drugs,<sup>100</sup> medical devices (e.g., pacemakers),<sup>101</sup> radiation emitting devices (e.g., cell phones and airport metal detectors),<sup>102</sup> cosmetics,<sup>103</sup> and food, including biological products.<sup>104</sup> 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/appltr/2000/20687appltr.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.*

98. *See* 21 C.F.R. § 310.200 (2006); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (2005) (indicating the criteria by which the FDA decides the status of prescription and nonprescription drugs).

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.*

100. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b (2005).

101. *Id.* § 360c.

102. *Id.* §§ 360hh-360ss.

103. *Id.* §§ 361-363.

104. *Id.* §§ 341-350. The only foods not regulated by the FDA are meat, poultry, and egg products, which are regulated by the Food Safety and Inspection Service (FSIS) of U.S. Department of Agriculture. U.S. Dep't of Agric., About FSIS, [http://www.fsis.usda.gov/About\\_FSIS/index.asp](http://www.fsis.usda.gov/About_FSIS/index.asp) (last visited Mar. 22, 2006).

one trillion dollars in products annually.<sup>105</sup> In fact, products regulated by the FDA account for more than twenty cents of every dollar spent by U.S. consumers.<sup>106</sup>

The FDA is one of eleven Public Health Agencies under the Department of Health and Human Services.<sup>107</sup> 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.<sup>108</sup> Within the CDER is the Office of Nonprescription Products that primarily handles nonprescription drugs.<sup>109</sup>

The Commissioner of the FDA is appointed by the President and confirmed by the Senate.<sup>110</sup> The President also has the authority to appoint a myriad of other members to the FDA, including advisory committee members.<sup>111</sup> The Commissioner of the FDA has

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105. FOOD & DRUG ADMIN., DEPT OF HEALTH AND HUMAN SERVS., PUBL'N NO. 01-1316, THE NATION'S PREMIER CONSUMER PROTECTION AND HEALTH AGENCY (2006), available at <http://www.fda.gov/oc/opacom/brochure/healthbro.pdf> (last visited Mar. 22, 2006) [hereinafter FDA PREMIER CONSUMER PROTECTION AND HEALTH AGENCY]. As drugs, radiation emitting devices, and biotechnology become increasingly complex, the impact of the FDA will become increasingly important. Interestingly, the FDA was not officially established by statute until 1988. Food & Drug Admin., Milestones in U.S. Food and Drug Law History, <http://www.fda.gov/opacom/backgrounders/miles.html> (last visited Mar. 22, 2006). Before that time, its authority was derived from administrative and legislative actions. *Id.*

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. *Id.*

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. *Id.*

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. *Id.*

109. Food & Drug Admin., Ctr. for Drug Evaluation & Res., Nonprescription Products: What We Do, <http://www.fda.gov/cder/Offices/OTC/whatwedo.htm> (last visited Mar. 22, 2006). The Office of Nonprescription Drug Products regulates "more than 80 classes (therapeutic categories) of OTC drugs, ranging from acne drug products to weight control drug products." *Id.* Emergency contraception is not one of these classes.

110. 21 U.S.C. § 393(d)(1) (2005).

111. Federal Advisory Committee Act, Pub. L. No. 92-463, § 1, 86 Stat. 770 (1972) (codified at 42 U.S.C. §§ 7403 note, 7409 note, 7417 note, 7607 note, 7614 note), amended by Pub. L. No. 94-409, 90 Stat. 1247 (1976) (codified at 5 U.S.C. §§ 552b note, 552b, 552, 554, 552a, prec. 500, 557); Pub. L. No. 96-523, 94 Stat. 3040 (1980) (codified at 5 U.S.C. §§ app., 8332, 28 U.S.C. § 640(a)(16)(A), 29 U.S.C. § 3102, 39 U.S.C. § 410(b)(1)); Pub. L. No. 97-375, 96 Stat. 1822 (1982) (codified at 33 U.S.C. § 1703); Pub. L. No. 105-153, 111 Stat. 2689 (1997) (codified at 5 U.S.C. §§ 1 note, 3, 15, 16).

been subject to Senate confirmation since 1988 in an attempt to give the job more authority.<sup>112</sup> To date, the FDA has only had four Commissioners confirmed by the U.S. Senate.<sup>113</sup>

The FDA has had a seemingly long and gloried history, although it has been under increasing scrutiny following the removal of Vioxx®<sup>114</sup> and ephedra<sup>115</sup> in 2004, Bextra®<sup>116</sup> 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,<sup>117</sup> despite numerous protests from conservative and pro-life activists.<sup>118</sup> Immediately upon President George W. Bush's

112. Marc Kaufman, *FDA's Reliance on Unconfirmed Chiefs is Faulted*, WASH. POST, Dec. 19, 2004, at A1, available at <http://www.washingtonpost.com/ac2/wp-dyn/A10775-2004Dec18?html>.

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, cyclooxygenase 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/111804dgttest.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).

115. Ephedra is a dietary supplement that was removed from the market in April 2004 due to serious health risks. See FDA Statement, Food & Drug Admin., FDA Announces Rule Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids Effective April 12 (Apr. 12, 2004), available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01050.html>.

116. Bextra®, generic name valdecoxib, is a non-steroidal anti-inflammatory COX-2 inhibitor marketed by Pfizer Pharmaceuticals since 2001. Bextra® was withdrawn from the U.S. market in April 2005 due to its risk of heart attack and life-threatening skin reactions. FDA Alert, Food & Drug Admin., Alert for Healthcare Professionals: Valdecoxib (Marketed as Bextra®) (Apr. 7, 2005), available at <http://www.fda.gov/cder/drug/infosheets/hcp/valdecoxibhcp.htm>.

117. See Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 571-72 (2001).

118. Am. Ass'n of ProLife Obstetricians & Gynecologists, AAPLOG Statement on Mifeprex (mifepristone) and the Protection of Women's Health (Jan. 25, 2001), available at <http://www.aaplog.org/newsru486.htm>.

inauguration, Dr. Jane Henney, the Commissioner of Food and Drugs, was fired<sup>119</sup> and replaced with Dr. Mark McClellan, the brother of White House Press Secretary Scott McClellan.<sup>120</sup> 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.<sup>121</sup> Dr. McClellan served as the FDA Commissioner until March 2004, and by most accounts did an outstanding job.<sup>122</sup> Dr. McClellan resigned from the FDA in March 2004 to become the Administrator for the Centers for Medicare and Medicaid Services.<sup>123</sup>

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

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119. Robert Pear, *Transition in Washington: Health and Human Services: Thompson Says He Will Order a New Review of Abortion Drug*, N.Y. TIMES, Jan. 20, 2001, at A17.

120. Kaufman, *supra* note 112.

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. *Id.*

122. *Id.*

123. Leila Abboud, *FDA Official Criticized Agency for Scrutiny of Contraceptive: Rejected 'Plan B' Pill Faced Unique Hurdles, Reviewer's Memo Says*, WALL ST. J., June 18, 2004, at B4.

124. See Food & Drug Admin., Dr. Lester M. Crawford — Biography, <http://www.fda.gov/oc/crawford/bio.html> (last visited Mar. 22, 2006).

125. *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. *Id.*

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.

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. *Id.*

128. Pear & Pollack, *supra* note 126.

129. Nat'l Cancer Inst., U.S. Nat'l Inst. of Health, About the Director, <http://www.cancer.gov/directorscorner/about-the-director> (last visited Mar. 22, 2006).

130. *Id.*



has been nominated to the full time position by the President,<sup>131</sup> but has received strong opposition because of Plan B®, and his future as a confirmed appointee is uncertain.<sup>132</sup>

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.<sup>133</sup> Dr. Hager was appointed by Linda Skladany,<sup>134</sup> the FDA Senior Associate Commissioner in charge of the Office of External Relations at the time.<sup>135</sup> The Senior Associate position reports directly to the FDA Commissioner,<sup>136</sup> who is appointed by the President. Dr. Hager was appointed as part of an entire re-staffing in December 2002.<sup>137</sup> Dr. Hager is considered an eccentric physician because of his strong religious views on abortion,<sup>138</sup> his public protests to remove Mifeprex® from the market, and his writings on the use of prayer for the treatment of premenstrual disorder.<sup>139</sup> With the appointment of Dr. Hager, critics perceived President Bush as stacking the FDA with conservative cronies who obfuscate the issues surrounding EC.<sup>140</sup> Overall, the number of recent changes and instability in the agency have

131. Press Release, The White House, Nominations Sent to the Senate (Mar. 15, 2006), available at <http://www.whitehouse.gov/news/releases/2006/03/20060315-3.html>.

132. Gardiner Harris, *Bush Picks FDA Chief, but Vote Is Unlikely Soon*, N.Y. TIMES, Mar. 16, 2006, at A18.

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.

134. See Karen Tumulty, *Jesus and the FDA*, TIME, Oct. 14, 2002, at 26.

135. Press Release, Food & Drug Admin., Linda Arey Skladany Appointed to Direct FDA's Office of External Relations (July 9, 2002), available at <http://www.fda.gov/bbs/topics/news/2002/NEW00820.html>.

136. Food & Drug Admin., Organizational Chart, <http://www.fda.gov/oc/orgcharts/fda.pdf> (last visited Mar. 22, 2006).

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's® application for nonprescription use be rejected. Ayelish McGarvey, *Dr. Hager's Family Values*, 21 NATION 11, 18 (2005).

clearly weakened the FDA's authority<sup>141</sup> and complicated the issues surrounding EC.

### *B. Legal Foundation*

In the United States, drugs are regulated as either prescription or nonprescription products.<sup>142</sup> 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.<sup>143</sup> This law was established to ensure the safety and purity of food and drugs by prohibiting the "interstate commerce" of adulterated and misbranded products.<sup>144</sup> 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.<sup>145</sup> Otherwise, all drugs could be lawfully sold, even if they were unsafe or advertised with outlandish therapeutic claims.<sup>146</sup> In 1912, the Sherley Amendment was passed to strengthen the Food and Drugs Act by prohibiting false and fraudulent claims.<sup>147</sup> In 1914, Congress enacted the

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141. See Kaufman, *supra* note 112.

142. See 21 C.F.R. § 310.200 (2006). Herbal remedies are considered "dietary supplements" by the FDA and are not regulated as drugs in this country. Dietary Supplement Health and Education Act of 1994 § 2(14), Pub. L. No. 103-417, 108 Stat. 4325-26 (1994) (codified as amended in 21 U.S.C. § 321 (2006)).

143. Pure Food and Drugs Act of 1906, ch. 3195, 34 Stat. 768 (1906) (repealed 1938). This law was passed in response to an excessive number of cure-all claims by unregulated and potentially dangerous products and the increasing use of harmful preservatives and dyes. Food & Drug Admin., *The Long Struggle for the 1906 Law*, FDA CONSUMER (1981), available at <http://www.cfsan.fda.gov/~lrd/history2.html>. Upton Sinclair's novel, *The Jungle*, which publicized the unsanitary conditions of Chicago's meatpacking plants, played a role in the establishment of this act. MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES*, 33 (2004).

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).

145. Pure Food and Drugs Act of 1906 § 2, ch. 3195, 34 Stat. 768 (1906) (repealed 1938). However, the Act did not require a manufacturer to disclose ingredients. Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 FOOD & DRUG L.J. 555, 573 (1998).

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.<sup>148</sup>

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

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ability to cure cancer. *Id.* at 494. The Supreme Court ruled Johnson was not in violation of any law at the time because the drug was not misbranded under the current statute. *Id.* at 498. In response, President Taft called on Congress to enact the Sherley Amendment and to close this loophole. See Arthur H. Hayes, Jr., *Food and Drug Regulation After 75 Years*, 246 JAMA 1223, 1223 (1981). This Amendment was not very successful, as the government now held the burden to pursue and prove false and fraudulent claims, a difficult task. *Id.*

148. Harrison Narcotic Act, Pub. L. No. 63-223, 38 Stat. 785 (1914). Interestingly, licensure under this Act was by the Internal Revenue Bureau of the Treasury Department. The Harrison Narcotic Act was established in response to the International Agreement of the 1912 Hague Convention, which "Determined to bring about the gradual suppression of the abuse of opium, morphine, and cocaine." See International Opium Convention, January 23, 1912, <http://www.cicad.oas.org/EN/treaties/mj1.htm> (last visited Mar. 22, 2006). Today all habit-forming and controlled substances are regulated under the Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 881-966 (2006)). For a history of drug control and enforcement legislation, see U.S. Dep't of Justice, Drug Enforcement Admin., The Diversion of Drugs and Chemicals, <http://www.deadiversion.usdoj.gov/pubs/program/activities/background.htm> (last visited Mar. 22, 2006).

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. SOC'Y 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).

152. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 321 (2006)). The Food Drug and Cosmetic Act was signed by President Franklin D. Roosevelt on June 25, 1938 and completely revamped the 1906 Pure Food and Drug Act. See Thomas F. McGuire, *Food, Drug or Both? Dual Classification Under the Federal Food, Drug, and Cosmetic Act*, 1984 U. ILL. L. REV. 987, 992-93 (1984).

before marketing.<sup>153</sup> In addition, it established the requirement of a New Drug Application (NDA) for each drug prior to entry into interstate commerce.<sup>154</sup> 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.<sup>155</sup> 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 known as the Durham Humphrey Amendments.<sup>156</sup> The purpose of this legislation was to mandate certain drugs be used only under the supervision of a physician,<sup>157</sup> creating a separation of prescription and nonprescription 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.<sup>158</sup> All other drugs are considered nonprescription. Thus, the Durham Humphrey Amendments establish a bright-line rule for differentiating prescription and nonprescription drugs.<sup>159</sup> Prior to this act, drug manufacturers were allowed to determine by which means they would market their products, whereas now the FDA makes this

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153. See McGuire, *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. See Huang, *supra* note 145.

154. 21 U.S.C. § 355(a) (2006).

155. John P. Swann, *History of the FDA*, in THE HISTORICAL GUIDE TO AMERICAN GOVERNMENT (George Kurian ed., 1998), available at <http://www.fda.gov/oc/history/historyoffda/fulltext.html>. This new court remedy was necessary for the FDA to accomplish its new responsibilities. See Kepten D. Carmichael, *Strict Criminal Liability for Environmental Violations: A Need for Judicial Restraint*, 71 IND. L.J. 729, 738 n.62 (1996).

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.

157. *Id.* 21 U.S.C. §§ 321, 331-32, 348, 351-3, 355, 357-60, 372, 374, 381 (2005).

158. *Id.* The original requirement of a prescription for all potentially addictive drugs, 21 U.S.C. § 352 d), was repealed by Pub. L. No. 105-115 on Nov. 21, 1997. See also Lori R. Jacobs, *Prescription-to-over the Counter Drug Reclassification*, 57 AM. FAM. PHYSICIAN 2209, 2209 (1998).

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. See Jacobs, *supra* note 158, at 2209.

determination.<sup>160</sup> Table 1 includes a list of criteria used by the FDA to decide the suitability of a drug for nonprescription use.<sup>161</sup>

Following the enactment of the Durham Humphrey Amendments, drug regulation in this country remained static<sup>162</sup> until the thalidomide tragedy. In 1961, a number of worldwide reports found horrific fetal abnormalities in children born to mothers who took thalidomide.<sup>163</sup> Although the drug was not approved for use in this country,<sup>164</sup> in reverberation<sup>165</sup> Congress passed the 1962 Kefauver Harris Drug Reform Amendments to the 1938 Food, Drug, and Cosmetic Act.<sup>166</sup> This law gave the FDA increased authority in its decision making power<sup>167</sup> and has since set it among the most reputable regulatory agencies in the world.<sup>168</sup> 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.<sup>169</sup> The act also established and required compliance with "current good manufacturing practice" to better protect consumers.<sup>170</sup>

Thus, prior to 1938, drugs required no proof of safety<sup>171</sup> 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

160. See Stan Stringer, *What Has Been Happening with over the Counter Drug Regulation*, 53 FOOD & DRUG L.J. 633 *passim* (1998).

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.

165. See Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 377 (1991).

166. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. §§ 321, 331-2, 348, 351-3, 357-60, 372, 374, 381). See also Jacobs, *supra* note 158, at 2209.

167. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. §§ 321, 331-2, 348, 351-3, 357-60, 372, 374, 381).

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.<sup>172</sup> 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.<sup>173</sup> The procedures also included the 1972 Over-the-Counter Drug Review for nonprescription drugs.<sup>174</sup> 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.<sup>175</sup>

### 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.”<sup>176</sup> This switch may be initiated by the FDA, the drug manufacturer, or any interested person through a citizen’s petition.<sup>177</sup>

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.<sup>178</sup> 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.

174. See Robert G. Pinco, *Implications of FDA’s Proposal to Include Foreign Marketing Experience in the Over-the-Counter Drug Review Process*, 53 FOOD & DRUG L.J. 105, 105 (1998).

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”).

176. 21 U.S.C. § 353(b)(3) (2005).

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

178. Grimes, *supra* note 37, at 846.

prescription.<sup>179</sup> Most recently, Prilosec®<sup>180</sup> and Claritin®<sup>181</sup> 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.<sup>182</sup> For example, the nonsedating antihistamine, Claritin®, was recently available by prescription only, despite strong protests from consumer protection groups and insurance companies.<sup>183</sup> 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.<sup>184</sup> 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.<sup>185</sup> Plan B® was deemed safe and

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](http://www.chpa-info.org/web/advocacy/general_issues/switch/switch_list.pdf).

180. See Food & Drug Admin., Drug Information: Questions and Answers on Prilosec OTC (omeprazole), <http://www.fda.gov/cder/drug/infopage/prilosecOTC/prilosecotcQ&A.htm> (last visited Mar. 22, 2006).

181. *Updates: FDA Approves OTC Claritin*, 37 FDA CONSUMER 3, 3 (Jan.-Feb. 2003), available at [http://www.fda.gov/fdac/departs/2003/103\\_upd.htm](http://www.fda.gov/fdac/departs/2003/103_upd.htm).

182. See Holly M. Spencer, Note, *The Rx-to-OTC Switch of Claritin, Allegra, and Zyrtec: An Unprecedented FDA Response to Petitioners and the Protection of Public Health*, 51 AM. U. L. REV. 999, 1001-02 (2002).

183. See ANGELL, *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.<sup>186</sup> 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.<sup>187</sup> The petition asserted that EC met all of the regulatory requirements for nonprescription use and should be available without a prescription.<sup>188</sup> However, the petition was not formally decided by the FDA at that time.<sup>189</sup>

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.<sup>190</sup> The application contained extensive support including clinical and behavioral data, label comprehension information, proof of actual use, and safety information.<sup>191</sup>

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

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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.

187. See Letter from the Ctr. for Reprod. Law & Pol'y, Citizen's Petition to FDA (Feb. 14, 2001), available at <http://www.fda.gov/ohrms/dockets/dailys/01/Feb01/021401/cp00001.pdf>.

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.

189. See Press Release, Ctr. for Repro. Rights, Center Sues FDA for Denying Women Over-the-Counter Access to Emergency Contraception (Jan. 21, 2005), available at [http://www.crlp.org/pr\\_05\\_0121planb.html](http://www.crlp.org/pr_05_0121planb.html). The Center for Reproductive Law and Policy filed suit against the FDA for its failure to act. *Id.*

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.

191. Joint Committee Report, *supra* note 2, at 39-56.



management of serious complications.<sup>192</sup> Patients were recruited at shopping malls and family planning clinics in eight U.S. states.<sup>193</sup> The study found that 93% of women recognized proper indications and 97% understood initiation of the product must be within seventy-two hours.<sup>194</sup> 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.<sup>195</sup>

The actual use study was designed to evaluate anticipated use under simulated over-the-counter conditions.<sup>196</sup> The investigators of this study followed up with patients one and four weeks after providing them with EC.<sup>197</sup> The study evaluated the patients' self-selection and timing of doses.<sup>198</sup> 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."<sup>199</sup> 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.<sup>200</sup> 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.<sup>201</sup> The panel found the drug safe for use without a

192. Elizabeth G. Raymond et al., *Comprehension of a Prototype Over-the-Counter Label for an Emergency Contraceptive Pill Product*, 100 OBSTETRICS & GYNECOLOGY 342, 342 (2002).

193. *Id.* at 342-43.

194. *Id.* at 346 tbl.3.

195. *Id.*

196. Elizabeth G. Raymond et al., *"Actual Use" Study of Emergency Contraceptive Pills Provided in a Simulated Over-the-Counter Manner*, 102 OBSTETRICS & GYNECOLOGY 17 *passim* (2003).

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.

200. See Joint Committee Report, *supra* note 2. Advisory committees have been required under the Federal Advisory Committee Act since 1972. For the FDA's provisions concerning "Public Hearing Before a Public Advisory Committee," see 21 C.F.R. §§ 14.1-14.174 (2006).

201. See Joint Committee Report, *supra* note 2, at 395.

prescription with no reports of death or cardiovascular events.<sup>202</sup> Furthermore, the potential for misuse and abuse was minimal and the risk of ectopic pregnancy was low.<sup>203</sup> The only concerns noted were from a small minority of members and involved the low number of young adolescents included in the studies,<sup>204</sup> as the application contained data on only twenty-nine patients aged fourteen to sixteen and no data on patients under age fourteen.<sup>205</sup>

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.<sup>206</sup> As part of this proviso, Barr outlined the CARE program to address many of the concerns noted.<sup>207</sup> Although the advisory committee had already shown overwhelming support for Plan B® nonprescription use, Barr wanted to assure a favorable decision.<sup>208</sup>

### 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.<sup>209</sup> 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]."<sup>210</sup> Moreover, the FDA expressed concerns regarding how Barr would comply with both the prescription and nonprescription requirements in the same packaging.<sup>211</sup>

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202. *Id.* at 344-45, 349.

203. Daniel Davis, *Medical Officer Safety Review* (Nov. 15, 2003), at 4, [http://www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1\\_12\\_FDA-Tab%205-1-Medical%20Officer%20Review.doc](http://www.fda.gov/ohrms/dockets/ac/03/briefing/4015B1_12_FDA-Tab%205-1-Medical%20Officer%20Review.doc) (reviewing the safety of Plan B®).

204. See Joint Committee Report, *supra* note 2, at 354-57.

205. See Letter from Steven Galson, Acting Dir., Ctr. for Drug Evaluation & Research, to Joseph A. Carrado, Senior Dir., Regulatory Affairs, Barr Research Inc. (May 6, 2004), Plan B NA letter NDA 21-045/S-011, available at [http://www.fda.gov/cder/drug/infopage/planB/planB\\_NALetter.pdf](http://www.fda.gov/cder/drug/infopage/planB/planB_NALetter.pdf) [hereinafter Plan B Letter].

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.*

210. Plan B Letter, *supra* note 205.

211. *Id.*

The FDA letter provided instructions for Barr to follow before its application could be approved.<sup>212</sup> Ironically, in the same response letter, the FDA conceded that the "[w]ide availability of safe and effective contraceptives is important to public health."<sup>213</sup> 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.<sup>214</sup> Although the FDA is not required to follow advisory recommendations, there is usually sufficient logic and reasoning to do so.<sup>215</sup>

In response to this rejection, on July 22, 2004, Barr submitted data to the FDA, which had six months to make another decision.<sup>216</sup> Barr developed an innovative approach to the FDA's recommendations and proposed bifurcated, single package labeling, allowing Plan B® to be sold with and without a prescription in the same packaging.<sup>217</sup> 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.<sup>218</sup> Once again, this decision outraged many people and was seen as filibustering by the FDA.<sup>219</sup> Ironically, this announcement came one day after President Bush's second inauguration.<sup>220</sup>

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212. *Id.* The FDA recommended that Barr supply additional evidence that Plan B® 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.*

213. *Id.*

214. See Marc Kaufman, *Staff Scientists Reject FDA's Plan B Reasoning*, 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.*

215. It is believed that this is only 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, Floor Statement (As Prepared), *The Bush Administration's Repeated Attempts to Put Politics and Ideology over Science* (June 15, 2005), available at <http://clinton.senate.gov/~clinton/speeches/2005616647.html>.

216. See Press Release, Barr Pharmaceuticals, Inc., Barr Submits Response to FDA in Support of Over-the-Counter Status for Plan B® Emergency Contraceptive (July 22, 2004), available at <http://www.barrlabs.com/pages/nprpr.html> [hereinafter Barr Response]. According to the Prescription Drug User Fee Act, the FDA must make regulatory decisions such as this within six months. Prescription Drug User Fee Act of 1992 § 106(c), Pub. L. No. 102-571, 106 Stat. 4491 (1992) (codified at 21 U.S.C. §§ 301 note, 379g note, prec. 379g, 379g, 379h); see also Press Release, Barr Pharmaceuticals, Inc., FDA Decision on Plan B® OTC Status Delayed (Jan. 21, 2005), available at <http://ec.princeton.edu/news/PlanB-OTC.html> [hereinafter Plan B Status Delayed].

217. See Barr Response, *supra* note 216.

218. See Plan B Status Delayed, *supra* note 216.

219. See Press Release, Ctr. for Repro. Rights, *supra* note 189.

220. U.S. Dep't of State, President Bush Inauguration <http://usinfo.state.gov/special/inauguration.html> (last visited Mar. 22, 2006).

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.<sup>221</sup> 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.<sup>222</sup> 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.<sup>223</sup>

Then, on Friday, August 26, 2005, as Hurricane Katrina<sup>224</sup> had ripped across South Florida and was approaching New Orleans, the FDA announced a further delay.<sup>225</sup> 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,"<sup>226</sup> although a number of currently marketed products had previously been approved under this system.<sup>227</sup>

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221. Gardiner Harris, *3 Senators Plan to Bar Vote on F.D.A. Head*, N.Y. TIMES, June 10, 2005, at A13.

222. Letter from Michael O. Leavitt, Sec'y of Health & Hum. Services, to Michael Enzi, Chairman, Comm. on Health, Educ., Labor & Pensions (July 13, 2005), available at <http://murray.senate.gov/healthcare/HHS-letter.pdf>.

223. U.S. Senate, Vote Summary on the Nomination (Confirmation Lester M. Crawford, of Maryland, to Be Commissioner of Food and Drugs), available at [http://www.senate.gov/legislative/LIS/roll\\_call\\_lists/roll\\_call\\_vote\\_cfm.cfm?congress=109&session=1&vote=00190#top](http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=109&session=1&vote=00190#top).

224. Hurricane Katrina is believed to be the costliest hurricane in history with total losses estimated at \$140 billion. See *After the Hurricanes: Impact on the Fiscal Year 2007 Budget: Hearing Before the H. Budget Comm.*, 109th Cong. (2005) (statement of Douglas Holtz-Eakin, Dir. Of the Cong. Budget Office), available at <http://www.cbo.gov/ftpdocs/66xx/doc6684/10-06-Hurricanes.pdf>.

225. Letter from Lester M. Crawford, Comm'r of Food & Drugs, Food & Drug Admin., to Joseph A. Carrado, Senior Dir., Regulatory Affairs, Duramed Research, Inc., NDA 21-045/S-011, available at [http://www.fda.gov/bbs/topics/news/2005/duramed\\_ltr.html](http://www.fda.gov/bbs/topics/news/2005/duramed_ltr.html) (last visited Mar. 16, 2006) [hereinafter Sponsor Letter].

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.<sup>228</sup>

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.<sup>229</sup> The FDA did not commit to any timetable for ruling on this matter and many critics viewed this act as simply another stall technique.<sup>230</sup> 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.<sup>231</sup> 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,<sup>232</sup> 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.<sup>233</sup> 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.<sup>234</sup>

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.<sup>235</sup> 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®

228. See Sponsor Letter, *supra* note 225.

229. See Drug Approvals, *supra* note 227.

230. See John J. Lumpkin, *FDA Passed on Morning-After Pill*, CBSNEWS.COM, Nov. 1, 2005, <http://www.cbsnews.com/stories/2005/11/01/health/main1001547.shtml>.

231. See Letter of Representative Henry Waxman to the FDA (Mar. 9, 2006), available at <http://www.democrats.reform.house.gov/Documents/20060309124932-06797.pdf>.

232. Marc Kaufman, *FDA Comment Period on 'Morning-After Pill' Ends*, WASH. POST, Nov. 2, 2005, at A14.

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

234. See Pear & Pollack, *supra* note 126.

235. See Grimes, *supra* note 37, at 847-48.

application.<sup>236</sup> 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.<sup>237</sup> More importantly, they fear a growing public health crisis in this country involving unintended pregnancy.<sup>238</sup>

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.<sup>239</sup> The GAO released the requested report in November 2005, which contained a number of "unusual" findings.<sup>240</sup> 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.<sup>241</sup>

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,<sup>242</sup> 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.<sup>243</sup> For instance, this distinction creates the need to define

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236. See Kaufman, *supra* note 214.

237. Jill Wechsler, *Politics Versus Science in Biomedical Research and Development: Decisions to Accelerate the Approval of AIDS Combination Drugs, Reject Over-the-Counter Status for the Morning After Pill, and Limit Support for Stem Cell Research Reflect Mounting Political Pressures*, 28 PHARMACEUTICAL TECH. 24, 24 (2004).

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

239. See Kaufman, *supra* note 214; see also Press Release, Senator Hillary Rodham Clinton, Colleagues Call for "Plan B" Probe (June 16, 2004), available at <http://clinton.senate.gov/~clinton/news/2004/2004618858.html>.

240. GAO UNUSUAL REPORT, *supra* note 1.

241. *Id.* at 5-7.

242. The FDA's proposed budget for 2006 is approximately \$1.9 billion. Press Release, Lester M. Crawford, Acting Comm'r, Food & Drug Admin., Message from the Acting Commissioner (Feb. 9, 2005), available at <http://www.fda.gov/oc/oms/ofm/budget/2006/commissioner.htm>.

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.<sup>244</sup> This would also create financial consequences because insurance plans do not cover non-prescription drugs, including EC, as part of their routine practice.<sup>245</sup> There may be the social consequences to increasing access to EC.<sup>246</sup> 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,<sup>247</sup> and provision of an important option for victims of sexual assault.<sup>248</sup> 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.<sup>249</sup> 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.<sup>250</sup> New York received initial approval from the State Assembly to make EC available without a prescription, but the bill was vetoed by the

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most women less than sixteen years of age by simply asking a relative or friend to make the purchase.

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.

248. Yuliya F. Schaper, *Emergency Contraception for Rape Victims: A New Face of the Old Battleground of Legal Issues in the Bi-Partisan Abortion Politics in the United States*, 29 RUTGERS L. REC. 1, 15-16 (2005).

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.<sup>251</sup> 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.<sup>252</sup> 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.<sup>253</sup>

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.<sup>254</sup> 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.<sup>255</sup>

#### 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

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251. Al Baker, *Pataki Vetoes Bill That Would Ease the Availability of the Morning-After Pill*, N.Y. TIMES, Aug. 5, 2005, at B3.

252. See Field, *supra* note 7, at 159-61 (describing in detail the dependent pharmacist prescribing model).

253. The Pharmacy Access Partnership was established in 1999 to promote knowledge about contraceptives among pharmacists. Their website provides a current and thorough list of legislative actions involving emergency contraception. The Pharmacy Access Partnership, Legislation, <http://www.go2ec.org/Legislation.htm> (last visited Mar. 22, 2006). For a summary of legislation on pharmacy access to EC, see Pharmacy Access Partnership, Current Pharmacy Access to EC (Aug. 15, 2005), <http://www.go2ec.org/pdfs/LegislationSummary081505.doc>.

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).



prescription.<sup>256</sup> However, in many countries there is a third classification of drugs, those that are available without a prescription but only through a pharmacist.<sup>257</sup> A pharmacist-only drug class allows access to certain medications without a prescription, but requires consultation with a pharmacist.<sup>258</sup> The State of Florida has a similar, *de facto*, system on the books,<sup>259</sup> 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.<sup>260</sup>

Pharmacists in the United States have been advocating for a third class of federal drug regulation for some time, with no avail.<sup>261</sup> Recently, the American Pharmacist Association (APhA) has made a strong push for such a third class.<sup>262</sup> The APhA convened a task force in August 2004 to develop recommendations for a "Pharmacy

256. The term "legend drug" is synonymous for prescription drug. *See, e.g.*, Field, *supra* note 7, at 224 n.317 (discussing the Durham-Humphrey Amendments to the FDCA, specifically their modification regarding who may prescribe legend drugs). After 1951, all prescription drugs required the statement: "Caution: Federal Law prohibits dispensing without a prescription." Pub. L. No. 82-215, 65 Stat. 648, 649 (1951) (prior to 1997 amendment). This phrase was subsequently changed to "Rx Only." FDA Modernization Act of 1997, Pub. L. No. 105-115, § 126, 111 Stat. 2296, 2327 (1997) (current version codified at 21 U.S.C. § 353(b)(4)(a) (2005)).

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 undeclared vote involving the establishment of a third drug class for statins, members of an FDA advisory committee favored the idea. *Id.*

262. *See* Am. Pharmacists Ass'n, APhA Pharmacy Care OTC Task Force Report of Opening Meeting 1 (Jan. 12, 2005), available at <http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=2810&TEMPLATE=/CM/ContentDisplay.cfm> [hereinafter PHARMACY REPORT].

Care OTC" category of drugs.<sup>263</sup> These products would be regulated similarly to traditional nonprescription drugs; however, they would only be available in areas with pharmacists present for consultation.<sup>264</sup> 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.<sup>265</sup>

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.<sup>266</sup> The American Medical Association opposes such a move,<sup>267</sup> 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.<sup>268</sup>

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.<sup>269</sup> 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.<sup>270</sup> A number of states have already passed legislation limiting pseudoephedrine sales,<sup>271</sup> and Congress had been working to classify

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263. *Id.*

264. *Id.*

265. See Spencer, *supra* note 182, at 1001-02.

266. Consumer Healthcare Prod. Ass'n, Third Class of Drugs, available at [http://www.chpa-info.org/web/press\\_room/news\\_releases/2003/05\\_27\\_03\\_Third\\_Class\\_of\\_Drugs.pdf](http://www.chpa-info.org/web/press_room/news_releases/2003/05_27_03_Third_Class_of_Drugs.pdf) (last visited Mar. 22, 2006).

267. *Id.*

268. See Field, *supra* note 7, at 206.

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.*

270. See Leslie Earnest & Rong-Gong Lin II, *Target Moves Sale of Cold Medications to Pharmacy*, L.A. TIMES, Apr. 20, 2005, at C1, available at <http://www.latimes.com/business/la-fi-target19apr19,1,53115,print.story?coll=la-headlines-business>.

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).

it as a Controlled Substance.<sup>272</sup> Furthermore, on March 9, 2006, President Bush signed the USA PATRIOT Improvement and Reauthorization Act of 2005,<sup>273</sup> 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.<sup>274</sup> Another potential benefit of a third drug class is a reduction in healthcare costs, achieved by decreasing unnecessary physician visits,<sup>275</sup> as pharmacy consultations are not routinely billed.<sup>276</sup>

It may be beyond the FDA's authority to create such a drug class through regulation.<sup>277</sup> The establishment of a new class of drugs may require an act of Congress<sup>278</sup> acting under constitutional authority.<sup>279</sup> 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

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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](http://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).

273. Pub. L. No. 109-177, 120 Stat. 192 (2006).

274. *Id.*; see also Press Release, U.S. Drug Enforcement Agency (Mar. 9, 2006), available at <http://www.dea.gov/pubs/pressrel/pr030906.html> (listing the key anti-methamphetamine provisions).

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.”<sup>280</sup> This report, however, found no compelling data to support the creation of this class,<sup>281</sup> 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.<sup>282</sup> Furthermore, there has been an increasing push for the availability of certain drugs, such as statins<sup>283</sup> and the diet drug orlistat,<sup>284</sup> to be available without a prescription, but the FDA has grappled with their risks.<sup>285</sup>

There appears to be great utility for a third class of drug regulation and minimal reasons opposing it. Pharmacists publicly support such a class,<sup>286</sup> and the time appears right.<sup>287</sup> 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.

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280. See GAO REPORT, *supra* note 10.

281. *Id.* at 3.

282. Patrick W. Sullivan & Michael B. Nichol, *The Economic Impact of Payer Policies After the Rx-to-OTC Switch of Second-Generation Antihistamines*, 7 VALUE IN HEALTH 402 *passim* (2004).

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.

284. Anna Wilde Mathews, *Glaxo Diet Drug Is Backed by Panel; FDA Advisory Committee Supports Bid to Sell Orlistat Without a Prescription*, WALL ST. J., Jan. 24, 2006, at D6.

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/2005-4086M1.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.<sup>288</sup>

The Plan B® application is nonprescription for adolescents sixteen years of age and older and prescription for patients younger than sixteen.<sup>289</sup> 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.<sup>290</sup> Furthermore, worldwide experience with EC is significant since more than thirty countries allow its sale without a prescription.<sup>291</sup> 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.<sup>292</sup>

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288. *Id.*

289. See Plan B Status Delayed, *supra* note 216.

290. See Grimes, *supra* note 37.

291. *Health Canada Gives Canadian Women a Plan B*, CANADA NEWS WIRE, Apr. 20, 2005, available at <http://www.newswire.ca/en/releases/archive/April2005/20/c7796.html> (reporting that Health Canada approved Plan B for use without a prescription). Emergency contraception was first available without a prescription in 1999 when France approved Norlevo (0.75 mg levonorgestrel). See *The Dedicated Product NorLevo Is Now Available over the Counter in France*, NOT-2-LATE.COM, <http://ec.princeton.edu/news/newsnorlevo.html>. Emergency contraception is also available without a prescription in Australia, New Zealand, Norway, and the United Kingdom, among other countries. See Wikipedia, Emergency Contraception, [http://en.wikipedia.org/wiki/Emergency\\_contraception](http://en.wikipedia.org/wiki/Emergency_contraception). Canada was the most recent country to approve emergency contraception without a prescription when Health Canada approved Plan B® on April 20, 2005. See *Health Canada Gives Canadian Women a Plan B*, *supra*.

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.<sup>293</sup> In 1998, the APhA issued a committee report recognizing the right to conscientious objection for pharmacists.<sup>294</sup>

Conscientious objection is the moral or religious justification for refusing to act against one's own belief.<sup>295</sup> 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.<sup>296</sup> Currently, forty-seven states have passed conscientious objection legislation, commonly referred to as refusal laws, supporting healthcare providers.<sup>297</sup> Most of these laws, however, were not intended for pharmacists and deal with abortion.<sup>298</sup> Still, several states permit healthcare providers to conscientiously refuse to provide contraception, and further legislation is pending in ten other states.<sup>299</sup>

Amazingly Wal-Mart, the nation's leading retailer, even had a corporate policy to refuse to sell Plan B® since 1999.<sup>300</sup> Under increasing pressure to dispense emergency contraception, however, they reversed that decision on March 3, 2006.<sup>301</sup> Nevertheless, Wal-Mart and its warehouse division, Sam's Club, maintain a conscientious objection policy permitting its pharmacists to refer

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prescription and many are advocating its sale in the U.S. without a prescription if a similar behind-the-counter system is available. *Id.*

293. See generally Julie Cantor & Ken Baum, *The Limits of Conscientious Objection — May Pharmacists Refuse to Fill Prescriptions for Emergency Contraception?*, 351 NEW ENG. J. MED. 2008 (2004).

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).

297. Andis Robeznieks, *Battle of the Conscience Clause: When Practitioners Say No*, AM. MED. NEWS, Apr. 11, 2005, available at <http://www.ama-assn.org/amednews/2005/04/11/prsa0411.htm>.

298. *Id.*

299. Editorial, *Moralists at the Pharmacy*, N.Y. TIMES, Apr. 3, 2005, § 4, at 12, available at <http://query.nytimes.com/gst/abstract.html?res=F50E16FB3A5B0C708CDDAD0894DD404482&incamp=archive:search>.

300. Dana Canedy, *Wal-Mart Decides Against Selling a Contraceptive*, N.Y. TIMES, May 14, 1999, at C1.

301. See Press Release, Wal-Mart, Wal-Mart to Carry Plan B Contraception, <http://walmartstores.com/GlobalWMStoresWeb/navigate.do?catg=512&contId=6074> (last visited Mar. 22, 2006). State laws in Illinois and Massachusetts require pharmacies in the state to sell Plan B®, and New York and Connecticut are working on similar laws. *Id.*

patients with prescriptions for Plan B® to another pharmacy.<sup>302</sup> Thus, even if Plan B® became available without a prescription, its unimpeded access may remain a problem for some.<sup>303</sup> 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.<sup>304</sup> 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.<sup>305</sup> 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.<sup>306</sup> 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.<sup>307</sup> 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.<sup>308</sup> Federal lawmakers have unveiled a bill in Congress permitting a pharmacist to refuse to dispense this medication

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302. *Id.*

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.

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/Media/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.

305. See Julie Ingwersen, *US Pharmacists Sue Walgreen over Contraceptive*, REUTERS HEALTH INFO., Jan. 30, 2006, available at <http://www.medscape.com/viewarticle/522604>.

306. See American Center for Law & Justice, History of ACLJ, <http://www.aclj.org/About/default.aspx?Section=10> (last visited Mar. 22, 2006).

307. 67 F. Supp. 2d 1359, 1360-61 (S.D. Fla. 1999) (denying defendant's motion for summary judgment).

308. Monica Davey, *Illinois Pharmacies Ordered to Provide Birth Control*, N.Y. TIMES, Apr. 2, 2005, at A10.

provided another pharmacist is available to fill these types of prescriptions.<sup>309</sup>

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® — buy one, get one free.<sup>310</sup> Or, worse yet, buy a six-pack of beer and get Plan B® 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.<sup>311</sup> Finally, critics argue that EC encourages unprotected sexual intercourse and thus increases the spread of sexually transmitted disease, although the available data suggest otherwise.<sup>312</sup>

## CONCLUSION

Plan B® is safe and effective for OTC use.<sup>313</sup> Furthermore, the data suggests that it can be used appropriately in a nonprescription

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309. This bill, called the Workplace Religious Freedom Act, is supported by a bipartisan group of senators and representatives. See Rick Santorum & John Kerry, *Religion in the Pharmacy*, N.Y. TIMES, Apr. 12, 2005, at A20.

310. Barr Pharmaceuticals, however, has indicated that if Plan B® is approved for nonprescription use, they will not offer any coupons, samples, rebates, or trial offers. See Joint Committee Report, *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., *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).

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). See *Pharm. Research & Mfrs. of Am. v. Concanon*, 249 F.3d 66, 74 n.6, 74-75 (1st Cir. 2001).

312. See Raine et al., *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).

313. Anna Glasier & David Baird, *The Effects of Self-Administering Emergency Contraception*, 339 NEW ENG. J. MED. 1, 4 (1998) (presenting research finding that Plan B® is safe and may prevent unwanted pregnancies).



setting.<sup>314</sup> 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.<sup>315</sup> They believe that increasing access to EC will condone its use and diminish social responsibility.<sup>316</sup> Meanwhile, pro-choice activists view EC as an integral part of a woman's choice and a necessary option to prevent unwanted pregnancy.<sup>317</sup> Nevertheless, the FDA has already approved EC in this country.<sup>318</sup>

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,<sup>319</sup> 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<sup>320</sup> while even more "liberal" states, such as Oregon, outlaw gay marriage.<sup>321</sup> 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.

318. See Notice, 62 Fed. Reg. 8610 (Feb. 25, 1997); ELECTRONIC ORANGE BOOK, *supra* note 65, at <http://www.fda.gov/cder/orange/obannual.pdf> (last visited Mar. 22, 2006); Plan B Prescribing Information, *supra* note 11.

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).

321. Kate Zernike, *Groups Vow Not to Let Losses Dash Gay Rights*, N.Y. TIMES, Nov. 14, 2004, at A13 (noting that Oregon's marriage amendment ballot measure passed with fifty-seven percent of the vote).

Table 1. Over-the-Counter Drug Criteria

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

Table 2. Pharmacist-Only Drug Criteria

Drug is generally safe if taken as directed but has the potential for serious adverse effects and harm
Drug is effective for treatment
Drug has the potential for abuse and misuse if sold or used unregulated
Drug has the potential for clinically significant drug interactions
Condition may or may not be self-diagnosable (i.e., symptomatic)
Condition is self-treatable
Condition may or may not be self-limiting
Drug treats a condition that could be dangerous or life-threatening if not managed
Product labeling may be somewhat complicated for the typical user to understand or comply with
Drug has widespread experience, domestic or international
Pharmacist is able to identify appropriate indications for therapy
Drug has important contraindications the pharmacist is able to assess
Pharmacist can recognize or ascertain patients who meet criteria for use
Pharmacist can recognize or ascertain patients who fail to meet criteria for use
Pharmacist is able to monitor or recommend appropriate monitoring to the patient
Pharmacist can identify the need for referral to a physician

Drug has the potential for inappropriate use which may be harmful to society or the individual
Drug has few or no "off-label" uses
Drug has been deemed socially important
Drug has an acceptable safety margin