

PLAN B CONTRACEPTIVE AND THE ROLE OF POLITICS IN MEDICINE:  
A COMPARATIVE ANALYSIS OF THE “SWITCH” OF EMERGENCY  
CONTRACEPTION FROM PRESCRIPTION TO NON-PRESCRIPTION IN THE  
UNITED STATES, FRANCE, THE UNITED KINGDOM, AND CANADA

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*Abstract: Of the approximately 6 million pregnancies in the United States each year, almost half are unintended. Of these unintended pregnancies, approximately four in ten will end in abortion. Plan B emergency contraception is a drug that has the potential to reduce the number of abortions performed each year in half. Despite contentions from various religious and political sects, Plan B is not an abortifacient. It acts by preventing a pregnancy from starting rather than terminating a pregnancy that is already established. On December 16, 2003, a panel of medical and scientific experts gathered by the Food and Drug Administration (FDA), voted overwhelmingly to approve over-the-counter (OTC) status for Plan B emergency contraception for child-bearing women of all ages. In an unprecedented move, high level FDA officials rejected the panel's recommendation and issued a Not Approvable letter citing a lack of data concerning the safety of Plan B for younger adolescents. In a subsequent application for Plan B OTC status with age restrictions, the FDA again rejected OTC approval noting various marketing, enforcement, and labeling concerns. To illustrate the level of political interference in what should have been a medical and scientific decision, this manuscript compares the “switch” of Plan B from prescription to OTC status in the United States with the process in France, the United Kingdom, and Canada. The governmental, political, and social forces affecting the switch are analyzed. Examination of survey results from the studied countries reveal that non-prescription emergency contraception can be safely self-administered in reproductive females of all ages, and does not result in an increase of risky sexual practices among those women. Although, on August 24, 2006, the FDA finally granted approval for OTC access to Plan B for women aged eighteen years and older, adolescent women, arguably the group who could most benefit from OTC access, was once again denied. In the realm of female reproductive health, conservative politics continues to trump sound medical and scientific judgment.*

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## INTRODUCTION

There is a drug that has the capability of cutting the number of abortions performed each year in half. Imagine if women of all ages could better control their reproductive health through over-the-counter (OTC) access to that drug. In 2001, of the 6.4 million pregnancies in the United States (U.S.), almost half (3.1 million) were unintended.<sup>1</sup> Of these unintended pregnancies, approximately four in ten ended in abortion.<sup>2</sup> In fact, abortion is considered one of the most common surgical procedures in the U.S., estimated to affect twenty-one out of every 1000 American women aged fifteen to forty-four years.<sup>3</sup> Since 1980, the abortion rate has been declining, and the development of emergency contraception (EC) is thought to be one of the primary reasons behind this fall.<sup>4</sup> In fact, the Alan Guttmacher Institute estimated that EC may have averted as many as 51,000 abortions in the year 2000 alone.<sup>5</sup>

The timing of the administration of EC is critical to its success. Since efficacy is increased if the medication is started within the first twenty-four hours after unprotected intercourse,<sup>6</sup> ready access to EC is imperative. OTC availability of EC improves its accessibility. On December 16, 2003, the Independent Joint Advisory Committee of the Food and Drug Administration (FDA) voted overwhelmingly to “switch” the emergency contraception, Plan B, from prescription status to OTC status.<sup>7</sup> Less than five months later, in an unconventional move, the Acting Director of the FDA’s Center for Drug Evaluation and Research (CDER) issued a statement denying the OTC recommendation.<sup>8</sup> In explanation of this action, the director cited a lack of “adequate data to support a conclusion that Plan B can be used safely by young adolescent women for emergency contraception

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<sup>1</sup> Physicians for Reprod. Choice and Health® (PRCH) & Guttmacher Inst., *An Overview of Abortion in the United States*, May 2006, [http://www.guttmacher.org/presentations/abort\\_slides.pdf](http://www.guttmacher.org/presentations/abort_slides.pdf). The PRCH is a national physician-led organization committed to enhancing reproductive health and freedom. *Id.* The Alan Guttmacher Institute is a nonprofit organization that promotes sexual and reproductive health. *Id.*

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* In 2002, approximately 2% of all women in the U.S. aged fifteen to forty-four had an abortion. *Id.*

<sup>4</sup> *See id.*

<sup>5</sup> Rachel K. Jones et al, *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 PERSP. SEXUAL REPROD. HEALTH 294, 300 (2002), available at <http://www.guttmacher.org/pubs/journals/3429402.pdf>; see also American Academy of Pediatrics Policy Stmt., *infra* note 26, at 1038 (stating the decline in birth rates from 1994 to 2000, for teens aged fifteen to seventeen, reflected a higher rate of reported abstinence, more consistent use of standard forms of birth control, and use of EC).

<sup>6</sup> Barr Pharm, Inc., *Health Policy Issue Brief, Emergency Contraception Meets Significant Medical Need: Education and Access are Critical Issues*, [www.barrlabs.com/overview/government/RRL\\_pp-planb.pdf](http://www.barrlabs.com/overview/government/RRL_pp-planb.pdf) (last assessed July 22, 2006).

<sup>7</sup> Food & Drug Admin., Transcript of Meeting, *United States of America Food and Drug Administration Center for Drug Evaluation and Research, Nonprescription Drugs Advisory Committee (NDAC) in Joint Session with the Advisory Committee for Reproductive Health Drugs (ACRHD)*, (Dec. 16, 2003), <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.htm>.

<sup>8</sup> Letter from Steven Galson, Acting Dir., Ctr. for Drug Evaluation and Res., FDA, to Joseph A. Carrado, Senior Dir., Reg. Affairs, Barr Lab. (May 7, 2004), [http://www.fda.gov/cder/drug/infopage/planB/planB\\_NALetter.pdf](http://www.fda.gov/cder/drug/infopage/planB/planB_NALetter.pdf).

without the professional supervision of a practitioner . . . .”<sup>9</sup> Despite finding that the data was overwhelmingly supportive of the conclusion that Plan B is safe and effective for all women of child-bearing age when obtained without a prescription,<sup>10</sup> and that studies demonstrated that ready access to EC did not promote risky sexual behavior,<sup>11</sup> the FDA denied the OTC switch.

Responding to the FDA’s concerns regarding the effect of Plan B on adolescents, Barr Laboratories<sup>12</sup> (Barr) amended their application and requested a dual label for Plan B.<sup>13</sup> Under the dual label, Plan B would be sold to women OTC for ages sixteen and older and prescription-only for those under sixteen years.<sup>14</sup> However, the FDA again delayed making a decision on this proposal citing marketing and enforcement difficulties with the dual label, requesting a sixty day public comment phase to consider the need for initiating “rulemaking.”<sup>15</sup> These persistent delays angered both politicians and the public and lent credence to the charge that conservative politics had trumped medical and scientific decision-making.

This manuscript analyzes the governmental regulations, political forces, and public responses to the switch of Plan B, from prescription to OTC in the U.S. To enhance understanding of the political and societal forces at work in the U.S., a comparative analysis of the switch of EC from prescription to non-prescription in France, the United Kingdom (U.K.), and Canada is made. Part One of this article describes the composition of Plan B and reviews its mode of action. The modus operandi of Plan B is of particular importance since much of the political and social hostility surrounding the medication hinges on the perception of whether it is abortifacient or contraceptive. Part Two compares the regulatory processes and public reactions of the switch of EC from prescription to non-prescription in France, the U.K., and Canada. Part Three highlights the FDA regulatory body itself and explores the question of whether the FDA has been “politically stacked” by conservative appointees. Part Four describes the rocky road to OTC status for Plan B in the U.S. and whether conservative politics interfered with medical and scientific judgment. Part Five analyzes

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<sup>9</sup> *Id.*

<sup>10</sup> Food & Drug Admin., Transcript of Meeting, *supra* note 7.

<sup>11</sup> Jeffrey M. Drazen et al, *The FDA, Politics, and Plan B*, 350 NEW ENG. J. MED. 1561, 1561 (2004), available at [http://www.content.nejm.org/\(search"Plan B](http://www.content.nejm.org/(search)), then follow “The FDA, Politics, and Plan B” hyperlink); *see generally* Part V sec. C; *see also* Sue S.T. Lo et al, *Effect of Advanced Provision of Emergency Contraception on Women’s Contraceptive Behavior: A Randomized Controlled Trial*, 19 HUMAN REPROD. 2404, 2408-2409 (2004) (demonstrating that giving women an advance supply of EC pills does not lead to repeated use or affect their use of regular, more effective, birth control).

<sup>12</sup> The original manufacturer application for Plan B OTC status was submitted April 16, 2003 by Women’s Capital Corporation. U.S. Gov’t Accountability Office, *infra* note 165, at 15; *see* News Release, Barr Lab., Inc., *Barr Completes Acquisition of Women’s Capital Corporation and Plan B Emergency Contraception*, <http://www.go2ec.org/pdfs/BarrCompletesAcquisition.pdf> (last accessed July 30, 2006) (indicating Barr Pharmaceuticals acquired marketing rights for Plan B on February 26, 2004).

<sup>13</sup> Letter from Steven Galson to Joseph A. Carrado, *supra* note 8.

<sup>14</sup> *Id.*

<sup>15</sup> Letter from Lester M. Crawford, Comm’r of Food & Drugs, Food & Drug Admin., to Joseph A. Carrado, Senior Dir., Reg. Affairs, Duramed Research, Inc., NDA 21-045/S-011 (Aug. 26, 2005), [http://www.fda.gov/cder/drug/infopage/planB/Plan\\_B\\_letter20050826.pdf](http://www.fda.gov/cder/drug/infopage/planB/Plan_B_letter20050826.pdf); *see also* 21 C.F.R. Part 310, *infra* note 191. The FDA has interpreted the language of 503(b)(1) of the Federal Food, Drug, and Cosmetic Act to allow marketing of the same active ingredients in a prescription and an OTC product as long as a meaningful difference exists between the two that makes one product safe only by prescription. *Id.* Until Plan B, the FDA had not allowed marketing of the same active ingredient in a prescription product for one population and an OTC product for another. *Id.* A rulemaking would have codified the FDA’s interpretation of 503(b), but could have caused an indefinite delay on the Plan B decision. *Id.*

the survey results describing the pros and cons of non-prescription EC and the effects of EC on the sexual behaviors of women in the studied countries. In Part Six, the state and grassroot efforts that were used to by-pass the conservative stranglehold on OTC approval of Plan B are reviewed. Finally, in Part Seven, the current status of Plan B and the expectations for its future are examined.

## I. WHAT IS PLAN B?

In order to understand Plan B and the controversy that surrounds the drug, it is crucial to examine the mode of action of the medication and the significance that various religious and scientific factions place upon that mode. At the root of the controversy is the question of whether EC is contraceptive or abortifacient.<sup>16</sup>

The manufacturer of Plan B defines the medication as an emergency contraception that is used to prevent pregnancy after unprotected sex or contraceptive failure.<sup>17</sup> The manufacturer emphasizes that Plan B is intended for emergency contraceptive use only and is not to be used in lieu of routine birth control.<sup>18</sup> Plan B consists of two 0.75mg. pills of levonorgestrel, a synthetic progestin contained in many current birth control pills.<sup>19</sup> The first pill should be taken as soon as possible within the first seventy-two hours following unprotected intercourse.<sup>20</sup> The second pill should be taken twelve hours

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<sup>16</sup> Dorland's Illustrated Medical Dictionary 5 (30th ed. 2003) (defining abortifacient as causing abortion); *see also* Definition of Abortifacient, MedicineNet.com, <http://www.medterms.com/script/main/art.asp?articlekey=10912> (defining an abortifacient as a substance that causes pregnancy to end prematurely and causes an abortion) (last accessed July 30, 2006).

<sup>17</sup> Plan B official website, *What is Emergency Contraception?*, <http://www.go2planB.com/ForConsumers/AboutPlanB/AboutEmergencyContraception.aspx> (last accessed June 14, 2006). Unprotected sex is described as the act of using no birth control, using a method of birth control that did not work (such as a condom breaking), or the act of nonconsensual intercourse (rape). *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Food & Drug Admin. Ctr. for Drug Evaluation and Res., *FDA's Decision Regarding Plan B: Questions and Answers*, <http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm> (May 7, 2004). Prior to FDA approval of prescription Plan B, medical providers could prescribe elevated doses of routine birth control pills as a post-coital contraceptive. Grimes & Raymond, *infra* note 25, at 181 (listing levonorgestrel-containing EC options in U.S.).

<sup>20</sup> Plan B package labeling. The designation of Plan B as a "morning after pill" is actually a misnomer, for the first dose of Plan B should be taken within the first seventy-two hours after unprotected intercourse, not necessarily the "morning after." *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> Drazen et al, *supra* note 11, at 1561.

<sup>23</sup> *Id.*

<sup>24</sup> Alastair J.J. Wood et al, *A Sad Day for Science at the FDA*, 353 NEW ENG. J. MED 1197, 1197 (2005)

after the first.<sup>21</sup> If Plan B treatment is initiated within the first twenty-four hours after unprotected sex, the resultant pregnancy rate is as low as 0.4%.<sup>22</sup> If treatment is not started until forty-eight to seventy-two hours after unprotected sex, the pregnancy rate climbs to 2.7%.<sup>23</sup> Since EC is often needed on the evenings or weekends (times with limited access to physician supervised care) contraceptive efficacy could be increased by increasing accessibility of EC.<sup>24</sup> A prescription requirement for Plan B only creates delays.

According to the American College of Obstetricians and Gynecologists (ACOG), EC prevents a pregnancy from starting rather than interrupting an already established pregnancy.<sup>25</sup> Plan B's method of action is similar to that of other oral contraceptives in that it primarily inhibits ovulation, disrupts development of the ovarian follicle, and/or interferes with the maturation of the corpus luteum,<sup>26</sup> depending on the time in the menstrual cycle when the medication is taken.<sup>27</sup> In a study evaluating the effects of levonorgestrel on pre-ovulatory women, blood tests indicated that Plan B suppressed ovulation by suppressing luteinizing hormone.<sup>28</sup> However, several studies have shown a biochemical or tissue alteration in the uterine lining after treatment with EC, suggesting that it could impair the endometrium's receptivity to a fertilized egg.<sup>29</sup> Other studies have demonstrated no such changes.<sup>30</sup> Whether changes noted would be sufficient to impair implantation has not been established.<sup>31</sup> What is known is that Plan B, which is a progestin-only contraceptive, is supportive of pregnancy and will not terminate or negatively affect an already established pregnancy.<sup>32</sup>

Much of the controversy surrounding Plan B began when anti-abortion rights groups labeled the medication an abortifacient and not a contraceptive.<sup>33</sup> In contrast to the ideology of the scientific and medical community, which define conception as beginning at the moment of implantation of the

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<sup>25</sup> David A. Grimes & Elizabeth Raymond, *Emergency Contraception*, 137 ANNALS OF INTERNAL MED. 180, 182 (Aug. 6, 2002).

<sup>26</sup> Comm. on Adolescence, Pol'y Statement, *Emergency Contraception*, 116 PEDIATRICS 1038, 1040 (2005).

<sup>27</sup> Grimes & Raymond, *supra* note 25, at 181-182.

<sup>28</sup> Hapangama et al, *The Effects of Peri-Ovulatory Administration of Levonorgestrel on the Menstrual Cycle*, 63 CONTRACEPTION 123, 128 (2001). For further analysis, see Population Briefs, *Globilization is Transforming Adolescence in the Developing World*, 11 Rep. Population Council Res. (May 2005) (describing luteinizing hormone as the stimulus for the ovulatory process), available at <http://www.popcouncil.org/pdfs/popbriefs/pbmay05.pdf>.

<sup>29</sup> Yuzpe et al, *Post Coital Contraception – A Pilot Study*, 13 J. REPROD. MED. 53, 57 (Aug. 1974). For further discussion, see also Comm. on Adolescence, Pol'y Statement, *supra* note 26, at 1040; see also Hapangama, *supra* note 28, at 128 (where one study subject experienced slight vaginal bleeding possibly suggesting an endometrial change).

<sup>30</sup> Durand et al, *On the Mechanisms of Action of Short-Term Levonorgestrel Administration in Emergency Contraception*, 64 CONTRACEPTION 227, 233 (2001).

<sup>31</sup> *Id.*

<sup>32</sup> Planned Parenthood official website, *Emergency Contraception*, <http://www.plannedparenthood.org> (search "emergency contraception") (last accessed June 18, 2006).

<sup>33</sup> See transcript from CBS News, *The Debate Over Plan B*, Broadcast (June 11, 2006), available at <http://www.cbsnews.com/stories/2005/11/22/60minutes/printable106894.shtml>.

fertilized egg into the uterine lining,<sup>34</sup> the Roman Catholic Church defines conception as beginning at the moment of fertilization.<sup>35</sup> Therefore, according to the Church, a medication that has the potential to cause the uterine lining to become unreceptive toward the implantation of an embryo is abortifacient.<sup>36</sup>

Dr. David Hager, a conservative religious rights activist who served on the FDA advisory committee reviewing the application for the OTC switch, had previously classified Plan B as abortifacient despite inconclusive evidence that it could inhibit implantation of a fertilized egg into the endometrial lining.<sup>37</sup> However, when Dr. Hager argued against OTC approval for Plan B at the FDA advisory meeting, he did not voice an ethical opposition to the medication based on the abortion theory, but rather emphasized his concerns regarding Plan B and its effect on adolescents.<sup>38</sup> Dr. Hager stated, "I'm not in favor of promotion of a product that would increase sexual activity among teenagers."<sup>39</sup> Since that comment, fellow committee members have labeled Hager's concern a "political fig leaf"<sup>40</sup> used to cover the conservative Christian view that EC is abortifacient.

## II. THE SWITCH OF EMERGENCY CONTRACEPTION FROM PRESCRIPTION TO NONPRESCRIPTION IN FRANCE, THE UNITED KINGDOM, AND CANADA

Restrictions on dispensing EC are easing across the globe. EC is available worldwide in 102 countries.<sup>41</sup> Women in forty-two countries can obtain emergency contraception without a prescription.<sup>42</sup> In comparison, the U.S. has moved at a snail's pace in providing EC options to its

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<sup>34</sup> See Charles E. Rice, *Abortion, Euthanasia, and the Need to Build a New 'Culture of Life'*, 12 NOTRE DAM J.L. ETHICS & PUB. POL'Y 497, 511 (1998).

<sup>35</sup> See *Comments from Pro-Life Leaders, FDA Approval of the "Morning-After-Pill,"* Pro-Life Outreach Source, <http://www.cogforlife.org/morningafterpill.htm> (last accessed May 17, 2006); see also Elizabeth Spahn & Barbara Andrade, *Mis-Conceptions: The Moment of Conception in Religion, Science, and Law*, 32 U.S.F.LREV. 261, 264 (1998). Although it's a widely held belief that the Catholic Church has always maintained that human life began at the moment of fertilization, that assumption is incorrect. *Id.* Before 1869, the Church held the position that life began at the moment of "ensoulment" (when the soul entered the developing body), somewhere around the third to fourth month of gestation. *Id.* For further analysis, see JAFFE ET AL, *ABORTION POLITICS, THE CATHOLIC CONNECTION*, 73-85 (Robert A. Rosenbaum & Carolyn Nagy eds., Alan Guttmacher Inst., 1981) (discussing the political role of the Catholic Church dealing with abortion).

<sup>36</sup> *Comment from Pro-Life Leaders, FDA Approval of the "Morning-After-Pill," supra* note 35.

<sup>37</sup> Ayelish McGarvey, *Dr. Hager's Family Values*, THE NATION (May 30, 2005), available at <http://www.thenation.com/doc/20050530/mcgarvey>; see also Food & Drug Admin., Transcript of Meeting, *supra* note 7. Dr. Hager argued for a clear statement on the Plan B package label that would indicate that there is a potential effect on the endometrium lining from the medication. *Id.*

<sup>38</sup> Food & Drug Admin., Transcript of Meeting, *supra* note 7. The abortion argument would have carried little weight since abortion was made legal in the U.S. on January 22, 1973 in *Roe v. Wade*, 410 U.S. 113 (1973), and it is not the purpose of the FDA to dictate morality.

<sup>39</sup> Food & Drug Admin, Transcript of Meeting, *supra* note 7.

<sup>40</sup> McGarvey, *supra* note 37.

<sup>41</sup> PR Newswire, *Plan B® Emergency Contraceptive Granted Non-Prescription Status in Canada*, <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/04-20-2005/0003439714&EDATE=> (last accessed June 18, 2006).

<sup>42</sup> Planned Parenthood, *A Brief History of Emergency Hormonal Contraception* (2005), <http://www.ppfa.org/pp2/portal/files/portal/medicalinfo/ec/fact-emergency-contraception-history.xml>.

female residents. To better understand the FDA regulatory process and the consequences resulting from the agency's delay of action on Plan B, it is helpful to examine the experiences encountered in France, the U.K., and Canada during the process of making EC available non-prescription.

#### A. FRANCE

In June 1999, in response to a static abortion rate, the French government switched the status of Norlevo, the French EC drug, from "prescription" to "available on request from a pharmacist."<sup>43</sup> Although the French abortion rate is one-third that of the U.S., government officials were concerned because the numbers were remaining steady and not declining.<sup>44</sup> In order to reduce abortion numbers and revitalize contraceptive policies, France initiated an aggressive contraceptive education campaign called "La contraception, a vous de choisir la voire," or "Contraception: It's up to you to choose your own."<sup>45</sup> At the heart of this campaign was a media blitz which provided information about the myriad of contraceptive choices available for single women, couples who have completed childbearing, and adolescents.<sup>46</sup> Furthering this initiative, France announced a new policy which would allow school nurses to provide EC in junior and high schools, grades six through twelve.<sup>47</sup> In addition, financial incentives have been utilized to enhance EC access. In France, a woman can obtain a non-physician prescribed EC at full cost directly from a pharmacy, or at thirty-five percent of the cost with a prescription.<sup>48</sup> There is no cost for EC for females under the age of eighteen when the EC is obtained from a school nurse, pharmacist, or family planning clinic.<sup>49</sup>

This aggressive contraceptive campaign has enjoyed wide support from French citizens. Open about the concept of sexuality,<sup>50</sup> the French government's response to teenage pregnancy and abortion has focused on enhanced education and improved access to contraception.<sup>51</sup> In contrast, U.S. policymakers have tried to address high abortion and teenage pregnancy rates by promoting abstinence or by making abortions harder to get.<sup>52</sup> As lamented by Jacqueline Darroch, the vice president of research at The Alan Guttmacher Institute, "The gap between our countries' approaches to teen sexual behavior is reflected in a wide gap in our teen pregnancy and abortion rates. It is unfortunate that in the United States, we lag so far behind . . . We don't even come close to what's been achieved in

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<sup>43</sup> Heather Boonstra, *Promoting Contraceptive Use and Choice: France's Approach to Teen Pregnancy and Abortion*, 3 GUTTMACHER REP. ON PUB. POL'Y (June 2000), available at <http://www.guttmacher.org/pubs/tgr/03/3/gr030303.pdf>.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> Caroline Moreau et al, *The Impact of Pharmacy Access to Emergency Contraceptive Pills in France*, 73 CONTRACEPTION 602, 602 (2006). The decision to dispense EC in the schools was suspended by a court order between June 2000 and March 2001. *Id.* The Council of State (France's highest administrative court) overruled the decision to make EC available in the schools citing a 1967 law (the Contraception Law of 1967) stating that hormonal contraception could be distributed only under prescription by pharmacies. Planned Parenthood, *supra* note 42. In October 2000, the French Parliament amended the law allowing school nurses to once again dispense EC. *Id.*

<sup>48</sup> Heather Boonstra, *Emergency Contraception: Steps Being Taken to Improve Access*, 5 GUTTMACHER REP. ON PUB. POL'Y 10, 12 (Dec. 2002) available at <http://www.guttmacher.org/pubs/tgr/p5/5/gr050510.pdf>.

<sup>49</sup> *Id.*

<sup>50</sup> In 1974, the age for consensual sex in France was lowered from age twenty-one to eighteen. Nathalie Bajos & Sandrine Durand, *Teenage Sexual and Reproductive Behavior in Developed Countries: Country Report for France*, Alan Guttmacher Inst., [http://www.guttmacher.org/pubs/summaries/france\\_teen.pdf](http://www.guttmacher.org/pubs/summaries/france_teen.pdf).

<sup>51</sup> Boonstra, *supra* note 43.

<sup>52</sup> *Id.*

France.”<sup>53</sup>

However, the French contraceptive campaign was not without opposition. Activists affiliated with the “profamily” movement regarded the action of Norlevo as “tantamount to abortion,”<sup>54</sup> and were openly hostile to the campaign. The drive to distribute EC in schools faced opposition with parents fearful that the school policy would intensify an already liberal French attitude about sex, contraception, and abortion.<sup>55</sup> Other objections included the concern that the program did not encourage parental participation, that easier access to EC would increase sexually transmitted diseases (STD’s), and that EC would be used in lieu of regular birth control.<sup>56</sup> But despite being a Catholic dominated country, no organized opposition movement ever materialized.<sup>57</sup>

## B. THE UNITED KINGDOM

The U.K. was the second European country, following France, to make EC available directly from a pharmacist.<sup>58</sup> At twenty-four pregnancies per 1000 women aged fifteen to nineteen years, the U.K. has the highest teenage pregnancy rate in Europe – three times as high as that in France.<sup>59</sup>

The regulatory body for medicine in the U.K. is the Medicines and Healthcare Products Regulatory Agency.<sup>60</sup> Before a medicine can switch from “prescription only” to “pharmacy,” or “P” status,<sup>61</sup> the medication’s sponsor must demonstrate certain safety and efficacy standards.<sup>62</sup> In January 2001, Levonelle-2, a progestogen-only product, was granted “P” status in the U.K. and was made available for women over the age of sixteen years directly from a pharmacist without a prescription.<sup>63</sup> Women under the age of sixteen continued to require a health care provider’s prescription.<sup>64</sup> In order to differentiate the non-prescription product from the prescription product, Schering Health Care Ltd. (Schering) repackaged Levonelle-2 in a colorful pack with an enhanced information booklet and sold

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<sup>53</sup> *Id.*

<sup>54</sup> See Boonstra, *supra* note 48, at 12.

<sup>55</sup> Boonstra, *supra* note 43.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> Katie D. Schenek, *Emergency Contraception: Lessons Learned from the UK*, 29 J. FAM. PLAN. AND REPROD. HEALTH CARE 35, 35 (2003).

<sup>59</sup> *Id.*

<sup>60</sup> Alasdair Breckenridge & Kent Woods, *Medicine’s Regulations and the Pharmaceutical Industry*, 331 BRIT. MED. J. 834, 834 (2005), available at <http://bmj.bmjournals.com/cgi/reprint/331/7520/834?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=Medicines+regulation&searchid=1&FIRSTINDEX=0>. The duties of the agency are to protect public health, to provide adequate information on medicines to the public, and to refrain from imposing unnecessary restrictions that would prevent public access to innovative medicines. *Id.*

<sup>61</sup> Med. and Healthcare Products Reg. Agency, *Legal Status and Reclassification*, <http://www.mhra.gov.uk> (search “drug classification status,” then “Licensing of medicines: Legal status and reclassification of medicines” hyperlink). “P” status indicates that a medicine has met a safety standard which indicates it can be sold or supplied under the supervision of a pharmacist without a physician’s prescription. *Id.*

<sup>62</sup> *Id.* In order to switch to “P” status, the medicine’s sponsor must show that the medication can be used safely without the supervision of a doctor, the medicine is not a danger to human health, and it does not have a record of incorrect use. *Id.*

<sup>63</sup> S.R. Killick & G. Irving, *A National Study Examining the Effect of Making Emergency Hormonal Contraception Available Without a Prescription*, 19 HUMAN REPRODUCTION 553, 553 (2004).

<sup>64</sup> *Id.*



it non-prescription under the name Levonelle.<sup>65</sup> In 2005, the two-tablet Levonelle/Levonelle-2 was phased out to bring out a single tablet pack.<sup>66</sup> Again, the outer packaging and informational inserts differ between the prescription and non-prescription products.<sup>67</sup>

The move to introduce age restrictions for Levonelle was unusual as there were no age restrictions on the use of levonorgestrel-only EC's that were prescribed by licensed physicians, nor were there any age restrictions in the U.K. pilot studies.<sup>68</sup> Similar to the FDA's reasoning in the U.S., Schering explained the restriction by citing a lack of clinical data on adolescents and the need for appropriate counseling to meet an adolescent's ongoing sexual concerns.<sup>69</sup> The act of introducing age restrictions at an early stage in the licensing process may have represented an attempt by the pharmaceutical company to address the anticipated moral backlash, but age restrictions have been attacked as representing an unnecessary barrier to EC access.<sup>70</sup>

In the U.K., the switch of EC from prescription to non-prescription status was wrought with opposition. Pro-life groups vehemently opposed the switch maintaining levonorgestrel was abortifacient.<sup>71</sup> The Catholic Doctors Guild released a statement saying, "[w]hat is morally relevant is the deliberate attack upon life itself. That is clearly the intention, irrespective of the modus operandi of the means used."<sup>72</sup> In addition, in May 2001, the Society for the Protection of the Unborn Child brought a legal challenge before the High Court claiming the use of EC constituted an illegal abortion.<sup>73</sup> The case had potential to jeopardize all modern fertility control methods, but was eventually dismissed by the High Court in April 2002.<sup>74</sup>

Despite the controversies, the U.K. government continued to engage in an aggressive

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<sup>65</sup> Schenek, *supra* note 58, at 36.

<sup>66</sup> BBC News, *Morning After Pill Dose Changed*, December 1, 2003, <http://news.bbc.co.uk/2/hi/health/3253932.stm> (last accessed July 2, 2006). The World Health Organization conducted a large scale study which found a single dose was safe and effective. *Id.* See also World Health Org., Annual Technical Rep. 2000, Executive Summary, <http://www.who.int/mipfiles/2063/mipexsum.pdf> (reporting on the 1998 to 2000 multinational study involving nearly 1400 participants). The Department of Health hopes that a single dose will cut unintended pregnancies caused by women who forget to take the second dose. *Id.*

<sup>67</sup> E-mail from Andrea Solomon, Medimpex UK Ltd., (July 18, 2006, 09:23 CST) (on file with author); see also Schering Health Care Ltd., Levonelle® 1500 Microgram Tablet, <http://www.emc.medicines.org.uk/emc/assets/c/html/displaydoc.asp?documentid=17040> (informational booklet describing prescription-only Levonelle® 1500); see also Schering Health Care Ltd., Levonelle® One Step Tablet, <http://www.emc.medicines.org.uk/emc/assets/c/html/displaydoc.asp?documentid=15361> (informational booklet describing non-prescription Levonelle® One Step).

<sup>68</sup> Schenek, *supra* note 58, at 36-37. Prior to government approval for non-prescription access to EC, financially deprived areas with high teenage pregnancy rates were designated as Health Action Zones (HAZ). *Id.* at 36. Local health authorities in the HAZ bypassed legal restrictions and developed innovative pilot schemes to increase access to EC through a pharmacist at no cost to the consumer. *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 37.

<sup>71</sup> *Id.* at 38.

<sup>72</sup> Medical/Legal Critique, Catholic Doctors Guild, *A Challenge To the Legality of Supplying the 'Morning After Pill' (Levoneele-2) Without a Prescription*, available at <http://www.catholicdoctors.org.uk> (search "morning after pill;" then select "Morning After Pill – Critique" hyperlink) (last accessed June 14, 2006).

<sup>73</sup> Killick & Irving, *supra* note 63, at 556; see also Schenek, *supra* note 58, at 38 (noting that the plaintiffs claimed Levonelle was abortifacient and illegal under the 1861 Offences Against the Person Act (the Act)). Under the Act, it is illegal to supply any 'poison or other noxious thing' with intent to cause miscarriage. Offences Against the Person Act 1861 (Aug. 6, 1861), available at <http://members.aol.com/abtrbng/oatpa61.htm>.

<sup>74</sup> Schenek, *supra* note 58, at 38.

campaign to reduce the teenage pregnancy rate. In addition to making EC non-prescription, the community of Worcestershire made EC available to high school pupils without their parents' permission.<sup>75</sup> There is currently a proposal before Parliament to reduce the tax on condoms and EC from 17.5% to 5%, an estimated savings to consumers of \$88 million on condoms alone.<sup>76</sup> The cost of EC would drop from about \$44 per package to approximately \$39.<sup>77</sup> Financially deprived areas would offer Levonelle for free.<sup>78</sup> Since cost is a common barrier to EC access, a reduction in price could substantially increase access.

### C. CANADA

A 2004 survey revealed that 70% of Canadians agreed that Plan B should follow in the footsteps of France and the U.K. and be made available without prescription.<sup>79</sup> On April 19, 2005, Canada's national health agency, Health Canada, approved Plan B for use without a doctor's prescription.<sup>80</sup> The switch was from "Schedule F," sold only with a physician's prescription, to "Schedule II," available behind the counter from a pharmacy after consultation with a pharmacist.<sup>81</sup> Prior to the country-wide change to non-prescription status, Plan B was already sold without a prescription through pharmacists in the provinces of Quebec, British Columbia, and Saskatchewan.<sup>82</sup>

Although the Canadian federal government determines whether a drug should be prescription or non-prescription, each province establishes the condition for sale of non-prescription drugs.<sup>83</sup> Although previously reported that Plan B would be sold with age restrictions in French Canada,<sup>84</sup> Paladin Laboratories now reports that Plan B is sold without age restriction throughout the country.<sup>85</sup>

Public reaction to non-prescription access has been divided. Supporters of the OTC decision recognize that easier access to EC will reduce abortion numbers throughout the country, while opponents argue it will increase risky sexual behavior and become a substitute for routine birth

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<sup>75</sup> BBC News, *Pupils Given MAP: Pupils at High Schools Across Worcestershire Are to Be Offered the Morning After Pill*, <http://news.bbc.co.uk> (search "emergency contraception", then "Pupils Given Morning After Pill" hyperlink) (last accessed July 30, 2006).

<sup>76</sup> Henry Kaiser Fam. Found., *U.K. To Reduce Tax on Condoms, EC, Advocates Say* (March 3, 2006), [kaisernetwork.org](http://www.kaisernetwork.org), [http://www.kaisernetwork.org/daily\\_reports/print\\_report.cfm?DR\\_ID=35764&dr\\_cat=2](http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=35764&dr_cat=2).

<sup>77</sup> *Id.*

<sup>78</sup> Schenek, *supra* note 58, at 38.

<sup>79</sup> Canadian Women's Health Network, *Health Canada Gives Canadian Women a Plan B; Plan B "Morning After Pill" Now Available Without a Prescription*, <http://www.cwhn.ca/resources/cwhn/ec.html> (last accessed June 18, 2006).

<sup>80</sup> Med. News Today, *Health Canada Approves Emergency Contraceptive Plan B As OTC Drug* (Apr. 22, 2005), <http://www.medicalnewstoday.com/medicalnews.php?newsid=23275>. Health Canada's criteria for non-prescription medications include safety, self diagnosis, and narrow therapeutic range. *Nonprescription Status for Emergency Contraception*, *infra* note 225 at 861.

<sup>81</sup> Medical News Today, *supra* note 80. In accordance with Canada's regulatory process, the public was allowed a seventy-five day comment period before Health Canada gave final approval. *Go2ec.org.*, *infra* note 83.

<sup>82</sup> Women's Health Matters, *'Morning After Pill' Available Without Prescription* (Apr. 20, 2005), [http://www.womenshealthmatters.ca/news/news\\_show.cfm?number=429](http://www.womenshealthmatters.ca/news/news_show.cfm?number=429).

<sup>83</sup> *Go2ec.org.*, *Canada*, <http://www.go2ec.org/Canada.htm> (last accessed June 12, 2006).

<sup>84</sup> *Id.*

<sup>85</sup> Telephone interview with representative of Paladin Labs Marketing Division (conducted June 28, 2006), 1-888-376-7830.

control.<sup>86</sup> Catholic organizations label Plan B abortifacient,<sup>87</sup> while some women's health advocates feel the government's decision to switch Plan B to Schedule II did not go far enough.<sup>88</sup> Health Canada's decision to make Plan B available without a prescription was supported by the Canadian Pharmacists Association, the Royal College of Physicians and Surgeons, the Canadian Nurses Association, and the Planned Parenthood Federation of Canada.<sup>89</sup>

### III. THE FOOD & DRUG ADMINISTRATION: POLITICALLY STACKED?

The regulatory body for medications in the U.S. is the FDA.<sup>90</sup> The FDA is one of eleven Public Health agencies that falls within the jurisdiction of the Department of Health and Human Services (HHS).<sup>91</sup> The mission of the FDA is to protect public health "by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."<sup>92</sup>

From the humble beginnings of a single chemist in the U.S. Department of Agriculture in 1862, to a current staff of approximately 9,100 employees, the scope of the FDA is enormous.<sup>93</sup> The FDA oversees items accounting for approximately twenty-five cents of every dollar spent by consumers.<sup>94</sup> Annually, this totals approximately \$1.5 trillion, or 20% of all U.S. consumer expenditures.<sup>95</sup> The recently released FDA performance budget request for the year 2007 is \$1,947,282,000, which is \$70,798,000 higher than in 2006.<sup>96</sup>

The FDA consists of eight centers, including the CDER.<sup>97</sup> With the goal of assuring that safe and effective drugs are available to the American public,<sup>98</sup> the CDER regulates all matters relating to

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<sup>86</sup> Henry Kaiser Fam. Found., *Canadian Government Proposes Selling Emergency Contraception Without Doctor's Prescription* (May 20, 2004), Kaisernetwork.org,

[http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=239809](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=239809).

<sup>87</sup> Emergency Contraception Could Lower Abortion Rate, 170 CANADIAN MED. ASSOC. J. (2004); *see also* LifeSite, *Abortion-Causing Morning-After Pill Approved Across Canada Without Prescription*, <http://www.lifesite.net/1dn/2005/apr/05042002.html> (quoting Mary Ellen Douglas, National Organizer of Campaign Life Coalition, saying, "The government is telling our young people to act irresponsibly sexually and then run to the pharmacist who will provide them with a magic pill to solve their problems.").

<sup>88</sup> Henry Kaiser Fam. Found., *supra* note 86 (quoting the executive director of the Canadian Women's Health Network saying, "There is no compelling medical argument to require contact with a pharmacist to obtain [EC].").

<sup>89</sup> Med. News Today, *Health Canada Approves Emergency Contraception Plan B as OTC Drug*, <http://www.medicalnewstoday.com/medicalnews.php?newsid=23275> (last accessed July 30, 2006).

<sup>90</sup> Food & Drug Admin., FDA Organization, <http://www.fda.gov/opacom/7org.html> (last accessed June 19, 2006).

<sup>91</sup> *Id.*

<sup>92</sup> Food & Drug Admin., FDA's Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last accessed June 19, 2006); *see also* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 393 (d)(1) (2001) (stating the mission of the FDA is to promote public health by assuring foods, human drugs, and veterinary drugs are safe, and public is protected from product radiation).

<sup>93</sup> Food & Drug Admin., History of the FDA, <http://www.fda.gov/oc/history/historyoffda/default.htm> (last accessed June 19, 2006).

<sup>94</sup> Food & Drug Admin., Performance Budget Overview, <http://www.fda.gov/oc/oms/ofm/budget/2007/PDF/2ConsolidatedBIB.pdf> (last accessed June 19, 2006).

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> Food & Drug Admin., FDA Organization, *supra* note 90.

<sup>98</sup> Food & Drug Admin., *A Brief History of the Center for Drug Evaluation and Research*, <http://www.fda.gov/cder/about/history/Histext.htm> (last accessed June 19, 2006).

both prescription and non-prescription drugs and their generic counterparts.<sup>99</sup>

Under FDA rules and regulations, a drug shall be exempted from prescription dispensing requirements when it has been shown “that the drug is safe and effective for use in self-medication as directed by proposed labeling,”<sup>100</sup> and prescription requirements are not necessary for the protection of public health.<sup>101</sup> Regulations further state that the process of initiating a prescription status change may be started by the FDA Commissioner or by any interested person.<sup>102</sup>

On February 14, 2001, a group of seventy medical, public health, and other organizations filed a citizens’ request that the FDA exempt Plan B from prescription-dispensing requirements.<sup>103</sup> Despite Code regulations which require the FDA to respond within 180 days by either approving the petition, denying the petition, or providing a reason why a decision cannot be reached,<sup>104</sup> the FDA did not respond.<sup>105</sup> On April 21, 2003, Women’s Capital Corporation, the maker of Plan B, filed a supplemental new drug application (sNDA) requesting OTC status for the medication.<sup>106</sup> Their application contained approximately 15,000 pages of data bound in fifty-nine volumes and incorporated research from thirty-nine clinical studies.<sup>107</sup>

In recent years, the FDA has been plagued with accusations of politically conservative interference or stacking.<sup>108</sup> The President has the power to appoint the Commissioner of the FDA, subject to approval by the Senate.<sup>109</sup> Despite the theory that requiring Senate confirmation would make the FDA Commissioner’s role more powerful,<sup>110</sup> as of this date, only four FDA Commissioners have

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<sup>99</sup> Food & Drug Admin., *Center for Drug Evaluation and Research Fact Book 1997, Office of Pharmaceutical Science Generic Drug Review*, <http://www.fda.gov/cder/reports/cderfact.pdf> (last accessed June 19, 2006).

<sup>100</sup> New Drugs Exempted from Prescription-Dispensing Requirements, 21 C.F.R § 310.200(b) (2006).

<sup>101</sup> *Id.* See also Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and Not Misbranded, and for Establishing Monographs, 21 C. F. R. § 330.10 (2006) (stating a drug is suitable for OTC use when it demonstrates a safety and efficacy profile suitable for self administration and is labeled in a manner which can be understood by the ordinary individual).

<sup>102</sup> 21 C. F. R. § 310.200(b).

<sup>103</sup> Citizens petition to FDA requesting OTC status for Plan B (Feb. 14, 2001), Citizen Petition, 21 C.F.R. § 10.30(e)(2)(i)(ii)(iii) (2006), available at [www.crlp.org/pdf/EC\\_petition.pdf](http://www.crlp.org/pdf/EC_petition.pdf).

<sup>104</sup> Citizen Petition, 21 C.F.R. § 10.30(e)(2)(i)(ii)(iii) (2006).

<sup>105</sup> Ann Friedman, *Over the Counter Insurgency*, Mother Jones ( Aug. 1, 2006), [http://www.motherjones.com/news/update/2006/08/planb\\_timeline.html](http://www.motherjones.com/news/update/2006/08/planb_timeline.html).

<sup>106</sup> Planned Parenthood, *Milestones on Road to Over-the-Counter EC*, <http://www.plannedparenthood.org><http://www.plannedparenthood.org/pp2/portal/files/portal/media/media-050830-ec-timeline.xml> (last accessed July 30, 2006).

<sup>107</sup> *Id.* Included in the application was a labeling comprehension study and an actual use study. *Id.* The purpose of the one month label comprehension study was to test if consumers could understand the proposed label for Plan B. Food & Drug Admin., *Study #9728: Plan B OTC Label Comprehension Study*, available at [http://www.fda.gov/ohrms/dockets/AC/03/briefing/4015B1\\_06\\_FDA-Tab%202-2-Label%20Comprehension%20Study.doc](http://www.fda.gov/ohrms/dockets/AC/03/briefing/4015B1_06_FDA-Tab%202-2-Label%20Comprehension%20Study.doc) (last accessed July 30, 2006). Overall, test subjects could understand the indication for Plan B and recognize potential adverse reactions. *Id.* The purpose of the actual use study was to evaluate the subjects’ ability to select and administer Plan B in an OTC setting. Food & Drug Admin., *Executive Summary of Actual Use Study*, available at [http://www.fda.gov/ohrms/dockets/AC/03/briefing/4015B1\\_06\\_FDA-Tab%202-2-Label%20Comprehension%20Study.doc](http://www.fda.gov/ohrms/dockets/AC/03/briefing/4015B1_06_FDA-Tab%202-2-Label%20Comprehension%20Study.doc). The study results demonstrated the majority of subjects correctly selected and self administered Plan B. *Id.* Most incorrect use was due to not taking the second pill twelve hours after the first. *Id.*

<sup>108</sup> Feminist Majority Foundation, *Bush Stacks FDA Panel: Ideology Trumps Medicine and Science Again* (Dec. 26, 2002), <http://www.feminist.org/news/newsbyte/uswirestory.asp?id=7384>.

<sup>109</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 393(d)(1) (2001).

<sup>110</sup> Mark Kaufman, *FDA’s Reliance On Unconfirmed Chiefs is Faulted*, WASH. POST, Dec. 19, 2004, at A01.

been confirmed by the Senate.<sup>111</sup> President Bush nominated current acting Commissioner, Dr. Andrew C. von Eschenbach, for confirmation on March 15, 2006, but the final confirmation vote was delayed pending the FDA decision regarding OTC Plan B.<sup>112</sup> With the announcement on August 24, 2006, that the FDA had approved OTC access for Plan B for women eighteen years and older,<sup>113</sup> Senators Hillary Rodham Clinton and Patty Murray announced they would lift their hold on Dr. von Eschenbach's confirmation.<sup>114</sup>

Shortly after George Bush's inauguration, Dr. Jane Henney, the Commissioner of Food and Drugs (and a Clinton appointee), resigned<sup>115</sup> and was replaced by Dr. Mark McClellan,<sup>116</sup> the brother of former White House Press Secretary, Scott McClellan.<sup>117</sup> Dr. McClellan served as Commissioner of the FDA from November 2002 to March 2004 and is "widely regarded as one of the most effective of all Bush appointees."<sup>118</sup> Confirmed by a unanimous vote of the Senate to the position of Administrator of the Centers for Medicare & Medicaid Services on March 25, 2004, Dr. McClellan left the FDA and oversaw the massive task of implementing Medicare's new prescription drug plan.<sup>119</sup> After two years directing the nation's two largest public health insurance programs, Dr. McClellan announced his resignation on September 5, 2006.<sup>120</sup>

In place of Dr. McClellan, President Bush appointed Dr. Lester M. Crawford to serve as Acting Commissioner of the FDA.<sup>121</sup> With a Doctor of Veterinary Medicine degree and a Ph.D in

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<sup>111</sup> Food & Drug Admin., *Commissioners and Their Predecessors*, <http://www.fda.gov/oc/commissioners/> (last accessed June 20, 2006).

<sup>112</sup> Gardiner Harris, *Bush Picks F.D.A. Chief, But Vote Is Unlikely Soon*, NY TIMES, Mar. 16, 2006, at A18, available at 2006 WLNR 4369947. For further explanation, see discussion Part VII.

<sup>113</sup> Food & Drug Admin., Press Release, *FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older; Prescription Remains Required for Those 17 and Under*, <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html> (last accessed Aug. 28, 2006).

<sup>114</sup> Gardiner Harris, *F.D.A. Approves Broader Access to Next-Day Pill*, NY TIMES, Aug. 25, 2006, , available at <http://www.nytimes.com/2006/08/25/health/25fda.html?ei=5070&en=e61ea6b55f26fd92&ex=1158206400&pagewanted=print>.

<sup>115</sup> Alex Gordon, Comment, *The Delicate Dance of Immersion and Insulation: The Politicization of the FDA Commissioner*, course requirement Harv. L. School, available at <http://leda.law.harvard.edu/leda/data/536/Gordon.rtf>. Dr. Henney hoped she would be asked to remain in office, but Bush accepted her letter of resignation which had been filed as a routine matter before Bush's inauguration. *Id.*

<sup>116</sup> Biography of Mark B. McClellan., available at <http://www.cms.hhs.gov/CMSLeadership/Downloads/McClellanMarkBio.pdf> (last accessed June 20, 2006); see also Food & Drug Admin., Mark B. McClellan – Biography, <http://www.fda.gov/oc/commissioners/mcclellan.html> (last accessed June 19, 2006) (highlighting Dr. McClellan's work history in research and in the White House).

<sup>117</sup> Scott McClellan was White House Press Secretary for President George W. Bush from 2003 to 2006. Wikipedia, Scott McClellan – Biography, [http://en.wikipedia.org/wiki/Scott\\_McClellan](http://en.wikipedia.org/wiki/Scott_McClellan) (last accessed Aug. 6, 2006). He was replaced by Tony Snow on April 26, 2006. *Id.*

<sup>118</sup> Biography of Mark B. McClellan, *supra* note 116.

<sup>119</sup> *Id.*

<sup>120</sup> Christopher Lee, . . . and a Departure; McClellan to Step Down as Chief of Medicare After Overseeing Launch of Prescription Drug Plan, WASH. POST at A13, available at [http://www.washingtonpost.com/wp-dyn/content/article/2006/09/05/AR2006090500382\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2006/09/05/AR2006090500382_pf.html).

<sup>121</sup> Wikipedia, Lester Crawford – Biography, [http://en.wikipedia.org/wiki/Lester\\_Crawford](http://en.wikipedia.org/wiki/Lester_Crawford) (last accessed Aug. 6, 2006). Food & Drug Admin, Dr. Lester M. Crawford - Biography, <http://www.fda.gov/oc/crawford/bio.html> (last accessed June 19, 2006). Dr. Crawford had previously served as Deputy Commissioner of the FDA during a vacancy period from February 2002 to November 2002. *Id.*

pharmacology,<sup>122</sup> many lawmakers questioned Dr. Crawford's qualifications to lead an agency as powerful as the FDA. At the very least, Dr. Crawford's tenure at the FDA was considered "stormy."<sup>123</sup>

With the August 26, 2005 announcement that the FDA was delaying its decision on Plan B OTC status,<sup>124</sup> Dr. Crawford earned the ire of both politicians and the public.<sup>125</sup> Additionally, his controversial 2005 confirmation process for FDA Commissioner reeked of what has been labeled a "political double-cross."<sup>126</sup> Two months after his confirmation, on September 26, 2005, Dr. Crawford suddenly resigned amid allegations of financial improprieties.<sup>127</sup> In a court ordered deposition given May 24, 2006, Dr. Crawford denied that his resignation was in any way related to the FDA's handling of Plan B.<sup>128</sup>

Another colorful Bush appointee to the FDA was Dr. W. David Hager, who was appointed to the Reproductive Health Drugs Advisory Committee on December 24, 2002.<sup>129</sup> Although the move was publicly criticized,<sup>130</sup> Dr. Hager was asked to serve a second term in June 2004.<sup>131</sup> Opposition was voiced by the Planned Parenthood Federation of America Nation Medical Committee Chairman, Dr. Scott Spear, who stated, "Americans rely on the FDA as a trusted and objective safeguard. President Bush has betrayed the public trust by installing a biased ideologue in a key scientific role."<sup>132</sup>

Crawford was originally appointed by FDA Senior Associate Commissioner, Linda Arey Skladany, a former lobbyist with ties to the Bush family.<sup>133</sup> Skladany rejected at least two nominees that had been suggested by staff members of the FDA.<sup>134</sup> In a sly move to avoid a potential Congressional block of his appointment, Dr. Hager was appointed as a panel member of the Advisory Panel on Christmas Eve 2002.<sup>135</sup> This position, unlike a chairmanship, did not require Congressional

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<sup>122</sup> Food & Drug Admin., Lester M. Crawford – Biography, <http://www.fda.gov/oc/crawford/bio.html> (last accessed June 19, 2006).

<sup>123</sup> Henry Kaiser Fam. Found., *FDA Commissioner Crawford Resigns*, kaisernetwork.org (Sept. 26, 2005), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=32750](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=32750).

<sup>124</sup> Food & Drug Admin., *FDA Takes Action on Plan B - Statement by FDA Commissioner Lester M. Crawford*, <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01223.html> (last accessed June 5, 2006).

<sup>125</sup> Ayelish McGarvey, *Plan B for Plan B*, THE NATION (JULY 18, 2005), available at <http://www.thenation.com/doc/20050718/mcgarvey>.

<sup>126</sup> Harris, *supra* note 112, at A18.

<sup>127</sup> Henry Kaiser Fam. Found., *supra* note 123. Financial forms from the Department of Health and Human Services showed that in 2004, either Dr. Crawford or his wife, sold shares in companies regulated by the FDA when Dr. Crawford was Deputy or Acting Commissioner. Wikipedia, Lester Crawford – Biography, *supra* note 121. See also Letter from Waxman, *infra* note 161 (on "political double-cross").

<sup>128</sup> Transcript Deposition Lester M. Crawford 211:1- 216:3 (May 24, 2006).

<sup>129</sup> Int'l Women's Health Coal., *Bush's Other War: The Assault on Women's Sexual and Reproductive Health and Rights*, <http://www.iwhc.org/resources/bushsotherwar/othernominations.cfm> (last accessed June 20, 2006).

<sup>130</sup> See Press Release, Planned Parenthood website, *Re-Appointment of Dr. David Hager To FDA Committee Is Bad Medicine*, <http://www.plannedparenthood.org> (search "Dr. David Hager," then "Re-Appointment of Dr. David Hager To FDA Committee Is Bad Medicine" hyperlink) (June 28, 2004).

<sup>131</sup> Int'l Women's Health Coal., *supra* note 129.

<sup>132</sup> Planned Parenthood website, *supra* note 130.

<sup>133</sup> Karen Tumulty, *Jesus and the FDA*, TIME, Oct. 5, 2002, available at <http://www.time.com/time/nation/printout/0,8816,361521,00.html>.

<sup>134</sup> *Id.*

<sup>135</sup> See Heather Boonstra, *Critics Charge Bush Mix of Science and Politics is Unprecedented and Dangerous*, 6 Guttmacher Rep. Pub. Pol'y 1, 2 (May 2003), <http://www.guttmacher.org/pubs/tgr/06/2/gr060201.pdf>.

approval.<sup>136</sup>

Dr. Hager is a prominent obstetrician/gynecologist whose views on women and reproductive health are considered outside the mainstream of modern reproductive ideology.<sup>137</sup> Dr. Hager has refused to prescribe contraception to unmarried women,<sup>138</sup> has endorsed the concept that EC causes abortion,<sup>139</sup> and has counseled women to seek relief from premenstrual syndrome through prayer and scripture.<sup>140</sup> A former spokesman for the group that petitioned the FDA to rescind its approval of the abortion pill, RU-486,<sup>141</sup> Dr. Hager was also one of four members of the December 16, 2003, Advisory Committee that voted against the recommendation for OTC approval for Plan B.<sup>142</sup> Dr. Hager ended his term on June 30, 2005, when he chose not to be reappointed to the Reproductive Health Advisory Committee.<sup>143</sup>

#### IV. THE UPHILL BATTLE FOR OVER-THE-COUNTER PLAN B

On December 16, 2003, the FDA's Nonprescription Drugs Advisory Committee, in conjunction with the Advisory Committee For Reproductive Health Drugs, met to consider the application for Plan B's OTC status.<sup>144</sup> Following presentations from FDA officials, arguments from open public hearings, and analysis by the panel committee, the panel recommended the switch of Plan B from prescription to OTC.<sup>145</sup> The panel found the drug was safe to be administered without a physician's supervision, and there was no evidence of death, cardiovascular events, or increased risk of ectopic pregnancy associated with Plan B use.<sup>146</sup> All twenty-eight members of the committee found there was no evidence to support stated concerns that nonprescription availability of Plan B would cause women to stop using regular contraceptives.<sup>147</sup> The final vote was twenty-three to four in favor of switching Plan B to OTC status.<sup>148</sup> After the committee meeting, one of the dissenters, Dr. Hager, commented, "What we heard today was frequently about individuals who did not want to take responsibility for their actions and wanted a medication to relieve those consequences."<sup>149</sup>

Following the recommendation from the Advisory Committee, Dr. Hager, on request from an FDA official he has refused to identify,<sup>150</sup> wrote a minority opinion urging the FDA to reject OTC status for Plan B based on a lack of information regarding how the drug affects females under the age

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<sup>136</sup> E-mail Petition on Urban Legends and Folklore: About, *Petition Against Appointment of W. David Hager to the Reproductive Health Panel*, [http://www.urbanlegends.about.com/library/bl\\_w\\_david\\_hager.htm](http://www.urbanlegends.about.com/library/bl_w_david_hager.htm) (last accessed June 21, 2006).

<sup>137</sup> *Id.*

<sup>138</sup> Int'l Women's Health Coalition, *supra* note 129.

<sup>139</sup> *Id.*

<sup>140</sup> E-mail Petition on Urban Legends and Folklore, *supra* note 136.

<sup>141</sup> 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.

<sup>142</sup> Food & Drug Admin., Transcript of Meeting, *supra* note 7.

<sup>143</sup> Int'l Women's Health Coalition, *supra* note 129.

<sup>144</sup> Food & Drug Admin., Transcript of Meeting, *supra* note 7.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> Gina Kolata, *A Contraceptive Clears a Hurdle to Wider Access*, N.Y. TIMES, Dec. 17, 2003, at A1, available at 2003 WLNR 5684983 (quoting Dr. Hager's concern that OTC Plan B would encourage risky adolescent sexual behavior).

<sup>150</sup> FDA Week, *Clinton, Murray Ask Leavitt To Investigate Hager's Memo on Plan B* (May 13, 2005), available at 2005 WLNR 7566025.

of sixteen.<sup>151</sup> The Barr application for the OTC switch contained data on only twenty-nine patients aged fourteen to sixteen and no data on patients under the age of fourteen.<sup>152</sup> In response to this concern, on March 11, 2004, Barr amended their application for Plan B OTC status proposing a dual label.<sup>153</sup> Plan B would be available without a prescription for women aged sixteen years and older, while women under the age of sixteen would require a prescription.<sup>154</sup>

Despite recommendations by both the Advisory Committee and the Offices of Drug Evaluation, and the support of the American Medical Association, ACOG, and the American Academy of Pediatrics,<sup>155</sup> the FDA took the unprecedented action of rejecting the recommendations and denying Plan B OTC marketing status.<sup>156</sup> In a letter released May 6, 2004, Dr. Steve Galson, Acting Director of the CDER, denied Plan B OTC status asserting that Barr had “not provided adequate data to support a conclusion that Plan B can be used safely by young adolescent women for emergency contraception without the professional supervision of a practitioner . . . .”<sup>157</sup>

The letter further outlined the safety and labeling requirements necessary to obtain application approval. In particular, Dr. Galson requested further data that would support a conclusion that adolescent women, without the supervision of a licensed medical practitioner, could safely use Plan B.<sup>158</sup> Alternatively, Dr. Galson stated that Barr Laboratories could provide additional information in support of the proposed dual labeling amendment.<sup>159</sup> Specifically, Barr would have to provide details on the marketing strategy for implementing a simultaneous prescription and non-prescription program for Plan B.<sup>160</sup> In July 2004, Barr submitted an amended application with age restrictions.<sup>161</sup>

Criticism that the FDA had succumbed to political pressure rather than adhering to sound medical principles surfaced immediately following release of the Plan B Not-Approvable letter. Rooted in this criticism was the knowledge that on January 9, 2004, a group of forty-nine conservative Congressmen wrote President Bush requesting rejection of the FDA Joint Advisory panel recommendation for Plan B OTC availability.<sup>162</sup> The Congressmen specifically noted their concerns regarding unsupervised Plan B availability and the effect on female adolescent sexual behavior.<sup>163</sup>

Responding that Dr. Galson appeared to be setting a different standard for evaluating Plan B than had been applied to other contraceptives, John Jenkins, director of the FDA’s Office of New Drugs, stated, “[t]he agency has not [previously] distinguished the safety and efficacy of Plan B and

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<sup>151</sup> Letter from Galson, *supra* note 8.

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> Friedman, *supra* note 105.

<sup>156</sup> Letter from Galson, *supra* note 8.

<sup>157</sup> *Id.* *But see* U.S. GOV’T ACCOUNTABILITY OFFICE, *infra* note 165, at 18. On February 18, 2004, the review staff of the Offices of Drug Evaluation III and V presented their conclusion to high level FDA management that data provided evidence that there was neither an increase in risky behavior nor inappropriate use between younger adolescents and older populations in regard to EC. *Id.*

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> Letter from Henry A. Waxman, Ranking Minority Member, to Andrew C. von Eschenbach, Acting Comm’r Food & Drug Admin. (March 9, 2006), *available at* [www.democrats.reform.house.gov/Documents/20060309124932-06797.pdf](http://www.democrats.reform.house.gov/Documents/20060309124932-06797.pdf).

<sup>162</sup> Letter from forty-nine Congressmen to George W. Bush, Pres. of the U.S. (Jan. 9, 2004), *available at* <http://www.house.gov/pence/rsc/doc/weldon-morningafterpill.pdf>.

<sup>163</sup> *Id.*



other forms of hormonal contraception among different age groups of women of childbearing potential, and I am not aware of any compelling scientific reason for such a distinction in this case.”<sup>164</sup> In the past ten years, Plan B is the only drug which the FDA has rejected advisory committee recommendations and refused approval for OTC status.<sup>165</sup>

In an April 2006 deposition of Dr. Galson, the doctor acknowledged that although he had not yet made a firm decision, his inclination was to recommend OTC status for Barr’s amended application for Plan B OTC status.<sup>166</sup> Dr. Galson conceded that, “Dr. Crawford, who was the Acting Commissioner then, told me that he was concerned about where we were heading because he knew that I was heading towards this recommendation, and he told me that he was going to make the decision on what to do with the application.”<sup>167</sup> Essentially, Dr. Crawford removed Dr. Galson’s authority to make the application decision. Dr. Galson acknowledged that he had never had an application taken from him before on a comparable decision nor did he know of this happening to anyone else in his position.<sup>168</sup>

Responding to the FDA’s handling of the Plan B application, Senator Hillary Clinton wrote a letter, co-signed by twenty-three Senators, requesting a Senate investigation and General Accountability Office (GAO) inquiry into the FDA’s action.<sup>169</sup> In November 2005, the GAO released its findings that the process denying OTC marketing status for the initial manufacturer’s application of Plan B was “unusual” on four accounts.<sup>170</sup> First, the directors who would normally sign the Plan B decision letter disagreed with the conclusion and did not sign the disapproval letter.<sup>171</sup> Second, high level management was involved more than it had been in other OTC switches.<sup>172</sup> Third, there are conflicting reports as to when the decision to deny the application was made.<sup>173</sup> Finally, the rationale for rejection of the OTC switch was novel and nontraditional.<sup>174</sup>

On January 21, 2005, the Center for Reproductive Rights filed a lawsuit in federal court against Lester Crawford, Acting Director of the FDA, challenging the FDA denial for the Plan B switch.<sup>175</sup> In *Tummino v. Crawford*,<sup>176</sup> the plaintiffs claimed that the Plan B denial violated their privacy and equal protection rights under the Fifth Amendment, that it exceeded the statutory authority of the FDA, and that it is “arbitrary, capricious, [and] an abuse of discretion . . .”<sup>177</sup> In February 2006, the FDA failed

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<sup>164</sup> Marc Kaufman, *Staff Scientists Reject FDA’s Plan B Reasoning*, WASH. POST, June 18, 2004, at A02.

<sup>165</sup> 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, What GAO Found, GAO Highlights, *available at* <http://www.gao.gov/new.items/d06109.pdf>.

<sup>166</sup> Transcript Deposition Steven Galson, April 26, 2006, at 186:17-20, *available at* [http://www.crlp.org/pdf/crt\\_Galson1.TR.1.pdf](http://www.crlp.org/pdf/crt_Galson1.TR.1.pdf).

<sup>167</sup> *Id.* at 186:20-22 to 187:1-4.

<sup>168</sup> *Id.* at 187:8-13.

<sup>169</sup> Press Release, Senator Hillary Rodham Clinton, *Colleagues Call for “Plan B” Probe* (June 16, 2004), *available at* <http://clinton.senate.gov/~clinton/new/2004/2004618858.html>.

<sup>170</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 165, at 19.

<sup>171</sup> *Id.* at 19-20.

<sup>172</sup> *Id.* at 20-21.

<sup>173</sup> *Id.* at 21-22.

<sup>174</sup> *Id.* at 22-25. In addition, the report acknowledged that the FDA did not identify any issues that would call for age restrictions. *Id.* at 30 - 31. There are no age restrictions for any of the prescription or OTC contraceptives that have been approved by the FDA, and pediatric studies have not been required for any of them. *Id.*

<sup>175</sup> Complaint, *Tummino v. Crawford*, *available at* [http://www.crlp.org/pdf/crt\\_02105\\_fdacomplaint.pdf](http://www.crlp.org/pdf/crt_02105_fdacomplaint.pdf); *see also* *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212 (E.D.N.Y. 2006) (the lawsuit parties have changed as Dr. von Eschenbach is the current Acting Commissioner of the FDA).

<sup>176</sup> Complaint, *Tummino v. Crawford*, *supra* note 175.

<sup>177</sup> *Id.*

in its bid to quash plaintiffs' discovery requests,<sup>178</sup> and the case is currently awaiting trial.<sup>179</sup>

The FDA's denial of OTC status triggered a political sparring match between Democrats and Republicans. Angered by the FDA's delay on Plan B, Senators Hillary Clinton and Patty Murray threatened to place a hold on President Bush's nomination of Lester Crawford for FDA Commissioner until action was taken on the drug.<sup>180</sup> Pressed on the issue of Plan B in the confirmation hearings, Dr. Crawford responded that "[t]he science part is generally done. We're just now down to what the label will look [like]. This is going to be a very unusual sort of approval."<sup>181</sup>

Fearing that Dr. Crawford would not receive confirmation, Michael Leavitt, Secretary of HHS, wrote a letter to Senator Michael Enzi, Chairman of the Committee on Health, Education, Labor, and Pensions, stating that the FDA indicated they would act on the resubmitted Plan B application by September 1, 2005.<sup>182</sup> Assured of a date of action, the senators lifted their hold, and on July 18, 2005, Dr. Crawford was confirmed.<sup>183</sup>

Then, in what many consider a political double cross,<sup>184</sup> the FDA announced another delay. Although Dr. Crawford acknowledged the amended SNDA constituted a complete response to the May 6, 2004 Not Approvable action letter,<sup>185</sup> and the CDER had concluded data supported the safe use of Plan B as an OTC product for women seventeen years of age and older,<sup>186</sup> the FDA was unable to reach a decision regarding Plan B due to marketing and packaging issues.<sup>187</sup>

HHS Secretary, Mike Leavitt, defended the decision to defer action on Plan B stating that he promised the senators that the FDA would act by September 1, but that he had never guaranteed a "yes" or "no" decision.<sup>188</sup> Ranking Minority Member Henry A. Waxman wrote a series of scathing responses stating that the FDA mischaracterized its concerns of the regulatory issues at stake.<sup>189</sup> In the August

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<sup>178</sup> *Tummino v. von Eschenbach*, 427 F. Supp. 2d 212, 215 (E.D.N.Y. 2006).

<sup>179</sup> On March 14, 2006, the State of Wisconsin joined the lawsuit as an intervening plaintiff claiming the State had concrete and substantial interests in protecting the health and welfare of its citizens. Complaint of Intervening Plaintiff, State of Wisconsin, *Tummino v. Von Eschenbach*, 2006 WL 1019512. In a request for relief, Wisconsin asked that the Commissioner of the FDA switch Plan B to OTC status and declare unlawful the FDA's action of not having switched Plan B to OTC status. *Id.*

<sup>180</sup> Henry Kaiser Fam. Found, Democratic Senators to Block Vote on FDA Commissioner Nomination Over Agency's Delayed Decision on Emergency Contraception, [kaisernetwork.org](http://www.kaisernetwork.org) (Apr. 7, 2005), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=29182](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=29182).

<sup>181</sup> Marc Kaufman, *FDA Expects to Ease Plan B Availability*, WASH. POST, Mar. 18, 2005, at A10.

<sup>182</sup> Letter from Michael O. Leavitt, Sec'y of Health & Hum. Services, to Michael Enzi, Chairman, Comm. on Health, Educ., Labor & Pensions (July 13, 2005), <http://murray.senate.gov/healthcare/HHS-letter.pdf>.

<sup>183</sup> U.S. Senate, Vote Summary on the Nomination (Confirmation Lester M. Crawford, of Maryland, to Be Commissioner of Food and Drugs), [http://www.senate.gov/legislative/LIS/roll\\_call\\_lists/vote\\_menu\\_109\\_1htm](http://www.senate.gov/legislative/LIS/roll_call_lists/vote_menu_109_1htm) (last accessed June 22, 2006); see also Press Statement, *Senator Hillary Rodham Clinton, Murray, Clinton Declare Victory in Fight Over Plan B*, <http://clinton.senate.gov/news/statements/details.cfm?id=240700&&> (Senators Murray and Clinton declaring victory in their efforts to force a decision on Plan B).

<sup>184</sup> Letter from Waxman, *supra* note 161.

<sup>185</sup> Letter from Lester M. Crawford, Comm'r of Food & Drugs, Food & Drug Admin., to Joseph A. Carrado, Senior Dir., Reg. Affairs, Duramed Research Inc., NDA 210045/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).

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

<sup>188</sup> Henry Kaiser Fam. Found., *Leavitt Defends FDA's Decision to Delay Action on Nonprescription Sale of Plan B, Says 'Yes or No' Answer Not Guaranteed*, [kaisernetwork.org](http://www.kaisernetwork.org) (Aug. 30, 2005), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=2&DR\\_ID=32291](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=32291).

<sup>189</sup> Letter from Waxman, *supra* note 161.

2005 announcement of the delay, the FDA claimed “difficult and novel”<sup>190</sup> regulatory questions were responsible for the delay and initiated a sixty day public comment period on whether the FDA should initiate a rulemaking.<sup>191</sup> Congressman Waxman challenged the FDA’s assertions claiming that he had possession of previously undisclosed documents that demonstrate the FDA had been considering these “novel” issues for at least a year before the August 2005 decision to delay.<sup>192</sup> Senator Waxman’s documents are purported to show that the FDA policy staff analyzed and outlined potential solutions for the regulatory questions at least fifteen months prior to the FDA delay of action.<sup>193</sup> In addition, the documents indicate the FDA’s Chief Counsel had been notified of the potential regulatory issues, but had failed to submit a determinative legal analysis.<sup>194</sup>

In protest over the FDA’s indefinite delay on a decision on Plan B, Susan F. Wood, M.D., Assistant Commissioner for Women’s Health and Director of the Office of Women’s Health at the FDA, resigned her position on August 31, 2005.<sup>195</sup> Dr. Wood stated that in delaying a decision, the FDA was “disregarding the scientific and clinical evidence and the established review process and were taking an action that harms women’s health by denying them appropriate access to a product that can reduce the rate of unplanned pregnancies and the need for abortions.”<sup>196</sup> One month later, Dr. Frank Davidoff, former editor of the *Annals of Internal Medicine* and a consultant to the FDA, resigned for identical reasons.<sup>197</sup> As expressed by Dr. Wood, “[i]f the FDA is to continue to fulfill its important role in public health, both in the United States and internationally, its professional and scientific staff must maintain its independence and thus its scientific credibility.”<sup>198</sup> Although there was room for honest debate regarding the feasibility and enforceability of age restrictions and dual labeling, the FDA’s unprecedented actions sullied its reputation both at home and abroad.

## V. SURVEY RESULTS FROM FRANCE, THE UNITED KINGDOM, CANADA, AND THE UNITED STATES

### A. THE EFFECT OF EASILY ACCESSIBLE EMERGENCY CONTRACEPTION ON ABORTION AND UNINTENDED

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<sup>190</sup> Letter from Crawford, *supra* note 185. Crawford maintained that the application for dual marketing presented the FDA with three difficult and novel issues. *Id.* First, the Agency had never determined whether a drug could be both prescription and OTC based on the age of the individual using the drug. *Id.* Second, the FDA questioned how to enforce an age-based distinction for sale of Plan B. *Id.* Third, could the prescription and OTC versions of the same active ingredient be marketed in a single package? *Id.*

<sup>191</sup> Food & Drug Admin., Advance Notice of Proposed Rulemaking, 21 C.F.R. Part 310 [Docket No. 2005N-03450], *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* (Aug. 26, 2005), available at <http://www.fda.gov/bbs/topics/NEWS/2005/cd0584.pdf>.

<sup>192</sup> Letter from Waxman, *supra* note 161.

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> Perspective, Susan F. Wood, *Women’s Health and the FDA*, 353 *New Eng. J. Med.* 1650, 1650 (2005).

<sup>196</sup> *Id.*

<sup>197</sup> Janice Hopkins Tanne, *Another FDA Expert Resigns Over Emergency Contraception delay*, 331 *BRIT. MED. J.* 861, 861 (2005), available at <http://bmj.bmjournals.com/cgi/reprint/331/7521/861-a>.

<sup>198</sup> Wood, *supra* note 195, at 1651.

## PREGNANCY RATES

Despite various traditional health care options, unintended pregnancies are a major health care issue across the globe. Adolescents, in particular, face profound physical, psychological, financial, and social consequences from unplanned pregnancies.<sup>199</sup> In addition, the offspring of teenage mothers often face severe consequences from their adolescent parentage.<sup>200</sup> Children of teenage mothers suffer from a higher incidence of low birth weight and an increased mortality and morbidity rate.<sup>201</sup>

Proponents of the OTC status of Plan B claim that easier access to EC would result in a decline in the number of abortion services and would minimize the health and societal impact of unplanned pregnancies.<sup>202</sup> In support of this claim, the Alan Guttmacher Institute estimated that 43% of the decline in number of abortions in the U.S. between 1994 and 2000 could have been due to access to emergency contraception.<sup>203</sup> In addition (the state of Washington, where Plan B is available without a physician's prescription through physician collaborative agreements)<sup>204</sup> estimated that EC saved the state more than \$22 million in Medicaid costs that would have been earmarked for pregnancy and infant care costs.<sup>205</sup>

Although reducing the number of unplanned pregnancies and abortions is a primary goal of OTC EC,<sup>206</sup> there is a lack of worldwide data to support the theory that readily available EC reduces the number of abortions.<sup>207</sup> Although survey sample sizes have been limited, and there has probably been an under-reporting of abortion services, the quantitative difference in abortions performed before and after EC became available direct from the pharmacist in some countries is disappointingly small.<sup>208</sup> For example, in a U.K. study, pharmacy direct access to EC did not correlate with a statistically significant decrease in abortion numbers.<sup>209</sup> Despite a 28% increase in the proportion of women accessing EC within the first twenty-four hours of unprotected intercourse, direct pharmacy access to Levonelle prevented what roughly equated to only five additional pregnancies for every 10,000 uses

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<sup>199</sup> Adolescent Family Life Demonstration Projects, Findings and Purposes, 42 U.S.C § 300z(a)(5) (2001). Adolescent mothers demonstrated a higher percentage of complications during pregnancy and childbirth, an increased likelihood of not completing their education, a greater likelihood their marriage would end in divorce, and a higher risk of becoming dependent on unemployment and welfare. *Id.*

<sup>200</sup> 42 U.S.C. § 300z(a)(5), *supra* note 199.

<sup>201</sup> *Id.*

<sup>202</sup> Camp et al, *The Benefits and Risks of Over-the-Counter Availability of Levonorgestrel Emergency Contraception*, 68 *CONTRACEPTION* 309, 309 (2003).

<sup>203</sup> Emergency Contraception Education Act, H.R. 3326, 109<sup>th</sup> Congress (2005), *available at* <http://www.govtrack.us/data/us/bills.text/109/h3326.pdf> (referencing the Alan Guttmacher Institute Report estimating that 51,000 abortions were prevented in 2000 by the use of EC).

<sup>204</sup> Chinué Turner Richardson, *Advocates Again Look to States to Promote Eased Access to Emergency Contraception*, 9 *GUTTMACHER POL'Y REV.* 11,11 (2006), *available at* <http://www.guttmacher.org/pubs/gpr/09/2/gpr090211.pdf>; *see also* Center for Reprod. Rights, *infra* note 267 (noting a collaborative agreement allows a pharmacist to dispense medications through an established protocol developed with a collaborating physician); *see also* discussion Part VI.

<sup>205</sup> Barr Pharm., Inc., *supra* note 6.

<sup>206</sup> *See* Camp et al, *supra* note 202 at 310.

<sup>207</sup> Glasier et al, *Advanced Provision of Emergency Contraception Does Not Reduce Abortion Rates*, 69 *CONTRACEPTION* 361, 363-364 (2004).

<sup>208</sup> Killick & Irving, *supra* note 63, at 556.

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

of EC.<sup>210</sup> Possible reasons for the small abortion reduction are varied. A likely explanation is that many women don't actually use the EC due to a low sense of vulnerability towards pregnancy even though they knowingly have taken a risk.<sup>211</sup> Additionally, women may not even recognize the pregnancy risk.<sup>212</sup> In a number of studies of women having abortions, a lack of reproductive knowledge and the ensuing failure to recognize a risk of pregnancy were common reasons for not using EC.<sup>213</sup>

## B. PROS AND CONS OF PHARMACY DIRECT, NON-PRESCRIPTION ACCESS TO EMERGENCY CONTRACEPTION

It was suggested that a third class of drug regulation, a "pharmacist-only" class of drugs, would have been a viable solution to the Plan B crisis in the U.S.<sup>214</sup> However, in the studied countries which have access to EC direct through the pharmacist, unique issues have arisen.

Privacy issues were raised in all the studied countries. French survey results have shown a dissatisfaction with pharmacy direct EC that was focused around the loss of privacy in a pharmacy environment and the perception that the personal views of pharmacists were mixing with their professionalism.<sup>215</sup> Although many women felt that a pharmacy offered greater privacy than a physician's waiting room, others reported that they were embarrassed because there was no private counseling area.<sup>216</sup> In addition, because the pharmacist provided the contraceptive counseling, many women reported the pharmacist's personal views were evident in the counseling session.<sup>217</sup> In France, EC that is dispensed via the schools is subject to a policy which requires in-depth counseling by the school nurse.<sup>218</sup> Although not mandatory, parental involvement is encouraged and may be a deterrent to an adolescent seeking access to EC.<sup>219</sup>

In Canada, where counseling by the pharmacist is required, women have raised privacy issues in response to the collection of personal information by pharmacists before dispensing Plan B.<sup>220</sup>

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<sup>211</sup> Caroline Free, et al, *Young Women's Accounts of Factors Influencing Their Use and Non-Use of Emergency Contraception: In Depth Interview Study*, 325 BRIT. MED. J. 1393, 1394(2002); see also Jones et al, *supra* note 5, at 297 (noting the most common reason for contraceptive nonuse was the perception that the woman was at low risk for pregnancy).

<sup>212</sup> Jones et al, *supra* note 5, at 297.

<sup>213</sup> *Id.* See also Raine et al, *infra* note 264 at 54 (stating the public health impact of OTC EC may be minimal due to the high rate of unprotected intercourse and underutilization of EC).

<sup>214</sup> See e.g. Matthew J. Seamon, *Plan B for the FDA: A Need for a Third Class of Drug Regulation in the United States Involving a "Pharmacist-Only" Class of Drugs*, 12 WM. & MARY J. WOMEN & L 521, 522 (2006), available at 12 Wm. & Mary J. Women & L. 521 (Westlaw).

<sup>215</sup> Eric Gainer et al, *Bringing Emergency Contraception Over the Counter: Experiences of Nonprescription Users in France, Norway, Sweden and Portugal*, 68 CONTRACEPTION 117, 122 (2003).

<sup>216</sup> *Id.* at 121.

<sup>217</sup> *Id.*

<sup>218</sup> Boonstra, *supra* note 43.

<sup>219</sup> *Id.*

<sup>220</sup> Laura Eggertson & Barbara Sibbald, *Privacy Issues Raised Over Plan B: Women Asked for Names, Addresses, Sexual History*, 173 CAN. MED. ASS'N J. 1435, 1435 (2005); see also Henry Kaiser Fam. Found., *Canadian Medical Association Journal's Publisher Demands Deletion of Section of Report on Nonprescription Plan B Sales*, kaisernetwork.org (Dec. 15, 2005), www.kaisernetwork.org/daily\_reports/rep\_index.cfm?hint=2&DR\_ID=34335. The Canadian Medical Association, which owns the Canadian Medical Association Journal, demanded the deletion of a news report which questioned the request for private information when purchasing Plan B. *Id.* Personal information, including name and address, were being entered into a database, which is not standard practice for nonprescription drugs. *Id.* But

Mandatory counseling is seen by many as a barrier to access, and the Canadian Women's Health Network believes Plan B should be dispensed OTC without counseling.<sup>221</sup> In addition to the privacy issues, counseling by pharmacists can put the cost of Plan B out of the reach of many women. Canadian pharmacists are allowed to charge a counseling fee for Plan B, which, on average, runs around \$20.<sup>222</sup> Combined with the cost of the medication itself, a package of Plan B obtained directly from the pharmacist could cost over \$50 – a significant obstacle for many women.<sup>223</sup>

When a medication becomes non-prescription, often the benefit of a health plan or insurance coverage is lost. In France, EC can be obtained from a pharmacy without a physician's prescription for the full price of the medication, or it can be obtained under a physician's supervision for a reduced cost.<sup>224</sup> This different price structure can limit financially deprived women from pharmacy access and deprive them of the efficacy advantage of immediately accessible EC. Likewise, in the U.K., the \$37 to \$39 cost of Levonelle One Step represents a considerable cost barrier to students, low-income, and unemployed women.<sup>225</sup>

In Canada, as well as the U.S., pharmacists motivated by religious or moral scruples, may object to selling emergency contraception to their female customers.<sup>226</sup> In November 1999, the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA) adopted a model statement clarifying a pharmacist's rights and obligations.<sup>227</sup> Essentially, a pharmacist is permitted to object to certain pharmacy services if it conflicts with the pharmacist's view of morality or he believes his conscience will be harmed by the service.<sup>228</sup> The affected pharmacist must arrange an alternate source for the customer to obtain the needed service.<sup>229</sup>

Currently, U.S. consumers may face similar issues at the pharmacy, even when they present a valid prescription. Almost every state has a policy, a conscientious clause, which allows certain health care professionals or institutions to refuse to provide, or participate in abortion, contraceptive services, or sterilization services.<sup>230</sup> As of July 1, 2006, thirteen states had passed provisions that allow some

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*see* Letter, George Murray, *Privacy Issues and Plan B: The Canadian Pharmacists Association Responds*, 174 CAN. MED. J. 64, 64 (2006), available at <http://www.cmaj.ca/cgi/content/full/174/1/64> (defending the request for private information for health plan requirements).

<sup>221</sup> Eggertson & Sibbald, *supra* note 220, at 1435.

<sup>222</sup> *Id.*

<sup>223</sup> *Id.*

<sup>224</sup> Moreau, *supra* note 47, at 602.

<sup>225</sup> Schenek, *supra* note 58, at 37.

<sup>226</sup> Nonprescription Status for Emergency Contraception, 172 CANADIAN MED. ASSOC. J. 861, 861 (2005).

<sup>227</sup> Nat'l Ass'n of Pharm. Reg. Authorities, *Model Statement Regarding Pharmacists' Refusal to Provide Products or Services for Moral or Religious Reasons (NAPRA Statement)*, Nov. 1999, <http://www.napra.org/docs/0/95/157/165/179.asp>.

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> Alan Guttmacher Inst., *State Policies in Brief: Refusing to Provide Health Services*, [http://www.guttmacher.org/statecenter/spibs/spib\\_RPHS.pdf](http://www.guttmacher.org/statecenter/spibs/spib_RPHS.pdf) (July 1, 2006); *see also* Okla. H.B. 2884, available at [http://www2.lsb.state.ok.us/2005-06hb/hb2884\\_enr.rtf](http://www2.lsb.state.ok.us/2005-06hb/hb2884_enr.rtf). Oklahoma's conscientious clause passed the House of Representatives on March 14, 2006 and will become effective November 1, 2006. *Id.* The clause specifically allows a pharmacist to refuse to "refer to, dispense, or assist in the dispensing of any medication if there is reason to believe that the medication would be used to cause an abortion, destroy an unborn child . . . when said referral, dispensing, or assistance in dispensing would be contrary to the religious or moral convictions of the pharmacist . . ." *Id.*

<sup>231</sup> Alan Guttmacher Inst., *supra* note 230; *see also* Adam Sonfield, *Rights vs. Responsibilities: Professional Standards and Provider Refusals*, Alan Guttmacher Inst., <http://www.guttmacher.org/pubs/tgr/08/3/gr080307.pdf> (noting the American Medical Association has proposed legislation that will allow physicians to dispense medication if there is no

health care professionals to refuse to participate specifically in contraceptive related services.<sup>231</sup>

Further obstacles block EC access. Catholic hospitals have not only refused to dispense emergency contraception following cases of sexual assault, but even refused to educate the victim about the availability of EC.<sup>232</sup> In addition, certain pharmaceutical chains have opted out of stocking EC. On February 7, 2006, three women, who were unable to fill their Plan B prescriptions at Wal-Mart pharmacies,<sup>233</sup> filed a lawsuit claiming Wal-Mart violated a Massachusetts regulation requiring pharmacies to stock the medications that are routinely prescribed and are necessary to meet the needs of the community.<sup>234</sup> After a unanimous ruling by the Massachusetts Board of Registration in Pharmacy requiring Wal-Mart to stock Plan B in Massachusetts, the retailer announced it would stock the product in all stores.<sup>235</sup>

State regulators have stepped in to try to increase EC availability. For example, in 2003, New York City enacted a measure that prohibited city agencies from contracting with hospitals that did not dispense EC or provide counseling about the availability of EC to victims of rape.<sup>236</sup> Another measure was passed which required pharmacies to post a sign to inform the public if they did not carry emergency contraception.<sup>237</sup> The state's job of balancing a pharmacist's conscience with a woman's constitutional right to contraception has been a difficult act to perform.<sup>238</sup>

### C. THE EFFECT OF EMERGENCY CONTRACEPTION ON ADOLESCENT SEXUAL BEHAVIOR

Adolescents should be an important target group for emergency contraception based on their high rate of unintended pregnancy.<sup>239</sup> Seventy-four to ninety-five percent of teen pregnancies are

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consenting pharmacist within a thirty mile radius).

<sup>232</sup> See generally Yuliya Fisher Schaper, *Emergency Contraception for Rape Victims: A New Face of the Old Battleground of Legal Issues in the Bipartisan Abortion Politics in the United States*, 29 RUTGERS L. REC. 1, 10-11 (2005), available at 29 Rutgers L.Rec. 1 (Westlaw).

<sup>233</sup> Rebekah E. Gee, Perspective, *Plan B, Reproductive Rights, and Physician Activism*, 355 N. ENGL. J. MED. 4, 4 (July 6, 2006). 247 C.M.R. § 6.02(4); see also Allison Stevens, *Target at Center of Battle Over Plan B*, Women's e News (Jan. 15, 2006), <http://www.womensenews.org/article.cfm/dyn/aid/2602/context/archive>. Another retail giant, Target, maintains a policy that allows pharmacists to refuse to fill prescriptions for moral or religious reasons. *Id.* Pharmacists who take this option are required to refer the customer to another Target pharmacist or another pharmacy. *Id.* See also Med. News Today, *Planned Parenthood Denounces Retailer Target's Policy on Pharmacist Refusals to Fill Plan B Prescriptions, USA*, <http://www.medicalnewstoday.com/medicalnews.php?newsid=33594> (detailing Planned Parenthood's protest of Target's policy of allowing pharmacists to refuse to fill Plan B prescriptions and referring Plan B customers to other pharmacies).

<sup>234</sup> Registration, Mgmt. and Operation of a Pharmacy or Pharmacy Dept., 247 C.M.R. 6.02 (Current through July 28, 2006).

<sup>235</sup> Gee, *supra* note 233 at 4; see also Michael Barbaro, In Reversal, *Wal-Mart Will Sell Contraceptive*, N.Y. TIMES, March 4, 2006, at C4, available at 2006 WLNR 3661600 (quoting the vice president of Wal Mart's pharmacy business saying that they could no longer justify not selling Plan B).

<sup>236</sup> Richardson, *supra* note 204, at 14.

<sup>237</sup> *Id.*

<sup>238</sup> See generally Jed Miller, *The Unconscionability of Conscience Clauses: Pharmacists' Consciences and Women's Access to Contraception*, 16 HEALTH MATRIX 237, 250 (2006), available at 16 health Matrix 237 (Westlaw) (stating that courts have overwhelmingly adopted the medical definition of conception – that conception begins at implantation of the egg into the uterine lining – and that contraception is the prevention of fertilization or implantation).

<sup>239</sup> Planned Parenthood official website, *supra* note 32.

unintended, and in the year 2000, approximately 840,000 U.S. women, aged fifteen to nineteen, became pregnant.<sup>240</sup> Pregnancy rates and rates of STD's are higher for adolescent females in this age group in the U.S. than for those in the other studied countries.<sup>241</sup>

Although the FDA cited an absence of data on young adolescents to justify its Not Approvable decision for Plan B OTC status,<sup>242</sup> studies have shown that young adolescents behaved no differently in response to increased access to EC than other age groups.<sup>243</sup> In general, survey data in all four studied countries indicated that non-prescription availability of EC did not promote risky adolescent behavior at all. Evidence showed that women with easier access to EC did not abuse the method, did not abandon regular contraception in favor of EC, and did not engage in increased risk-taking activities.<sup>244</sup>

In France, survey results showed that EC use increased considerably during the five years following the introduction of Norlevo available directly from a pharmacist.<sup>245</sup> At the end of 1999 (six months after Norlevo became available non-prescription), 9.8% of women surveyed, aged fifteen to forty-four years, had used an EC.<sup>246</sup> This percentage rose to 16.9% five years later.<sup>247</sup> Women took advantage of the non-prescription availability of EC, for 85% of those in the survey who used EC in 2004 obtained it directly from the pharmacist.<sup>248</sup> Overall, while there has been no significant change in the use of regular contraception in France, the pattern of contraceptive use has changed.<sup>249</sup> The use of reversible methods of contraception (condoms, withdrawal, abstinence, and spermicides) have dropped, while the use of modern contraceptive methods (pill, IUD, and sterilization) have increased.<sup>250</sup> Rather than becoming a substitute for regular contraception, many women have reported an increased motivation to be more vigilant with regular contraceptive use and involve their partner in contraceptive decisions.<sup>251</sup>

In addition, there has been no indication that sexual risk taking has increased.<sup>252</sup> An increase in access to EC did not result in a decrease in the age of first intercourse, an increase in the proportion of women who had ever had intercourse, or a significant increase in those at-risk for unintended pregnancies.<sup>253</sup>

Although the proportion of U.K. women using EC has not changed since Levonelle was made available directly from pharmacies in January 2001, the location where women obtain EC has changed

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<sup>240</sup> *Id.*

<sup>241</sup> Susheela Sing & Jacqueline E. Darroch, *Adolescent Pregnancy and Childbearing: Levels and Trends in Developed Countries*, 32 *FAM. PLAN. PERSP.* 14, 16 (2000); *see also* Christine Panchaud et al, *Sexually Transmitted Diseases Among Adolescents in Developed Countries*, 2 *FAM. PLAN. PERSP.* 24, 30-32 (2000) (noting STD's disproportionately affect adolescents in comparison to other age groups).

<sup>242</sup> Letter from Galson, *supra* note 8.

<sup>243</sup> Cynthia C. Harper et al, *The Effect of Increased Access to Emergency Contraception Among Young Adolescents*, 106 *OBSTETRICS & GYNECOLOGY* 483, 483 (2005).

<sup>244</sup> S.L. Camp et al, *The Benefits and Risks of Over the Counter Availability of Levonorgestrel Emergency Contraception*, 68 *CONTRACEPTION* 309, 311-312 (2003).

<sup>245</sup> Moreau, *supra* note 47, at 604.

<sup>246</sup> *Id.*

<sup>247</sup> *Id.*

<sup>248</sup> *Id.* at 606.

<sup>249</sup> *Id.*

<sup>250</sup> *Id.*

<sup>251</sup> Gainer et al, *supra* note 215, at 120-121.

<sup>252</sup> Moreau, *supra* note 47, at 606 (defining "risk taking" as the proportion of women having intercourse, the age at first intercourse, and the number at risk for unintended pregnancy).

<sup>253</sup> *Id.*



markedly.<sup>254</sup> The proportion of women reporting that they obtained EC from a pharmacist rather than a health care provider increased to from 19.7% in 2001 to 32.6% in 2002.<sup>255</sup> Furthermore, studies did not demonstrate that women discarded regular, more effective, methods of birth control in favor of EC.<sup>256</sup> In fact, in a study comparing EC users in the U.S. to those in the U.K., the U.K. participants were more likely to be using regular contraception than their American counterparts.<sup>257</sup> In addition, studies have concluded that repeat use of EC is rare.<sup>258</sup>

As in France, Canadian research has shown that the number of EC prescriptions sought by women has dramatically increased since the medication became available directly through the pharmacy.<sup>259</sup> In a British Columbia survey, EC prescriptions increased by 102% in a five year period in comparison to the pre-policy mean.<sup>260</sup> Furthermore, repeat use of EC was infrequent.<sup>261</sup> Only 2.1% of EC users required EC three or more times during the study period.<sup>262</sup> This finding was consistent with a British study in which only 4% of the women studied used EC's more than twice per year.<sup>263</sup>

Comparable with the French, U.K., and Canadian studies, U.S. studies have demonstrated that EC use is not associated with increased risk taking behaviors among adolescent women.<sup>264</sup> Studies have verified that increased access to EC does not result in a substitute of EC for routine contraception, an increase in number of sexual partners or unprotected intercourse, or an increase in the frequency of STD's.<sup>265</sup> Studies have also demonstrated that adolescents were equally capable as adults in taking EC correctly.<sup>266</sup> In fact, in one study, adolescents under the age of sixteen years showed the highest comprehension in an age-based comprehension comparison.<sup>267</sup> Likewise, in a previous observational study which examined the understanding of thirteen to sixteen year olds on correct use of EC, how EC affected the menses, and common adverse side effects, the comprehension of the adolescent group was consistent with that of the adult women.<sup>268</sup> These survey results suggest that adolescents should not

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<sup>254</sup> Cicely Marston et al, *Impact on Contraceptive Practice of Making Emergency Hormonal Contraception Available Over the Counter in Great Britain: Repeated Cross Sectional Surveys*, 331 BRIT. MED. J. 271, 272 (2005).

<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> Kelly Blanchard et al, *Differences Between Emergency Contraception Users in the United States and the United Kingdom*, 57 JOURNAL OF AM. MED. WOMEN'S ASS'N 200, 2003 (2002).

<sup>258</sup> Judith Roizen et al, *Repeat Use of Emergency Contraception: How Frequent is It?* 27 J. FAM. PLANNING REPROD. HEALTH CARE, 197, 200 (2001); *see also* Rowlands, *infra* note 263, at 142.(reporting only 4% of EC users received it more than twice in one year); *see also* Anna Glasier & David Baird, *The Effects of Self-Administering Emergency Contraception*, 339 NEW ENG. J. MED. 1, 4 (1998) (noting few women in the study's treatment group used EC more than once).

<sup>259</sup> Judith A. Soon et al, *Effects of Making Emergency Contraception Available Without A Physician's Prescription: A Population-Based Study*, 172 CANADIAN MED. ASS'N J. 878, 879 (2005)

<sup>260</sup> *Id.* *But see* Roizen et al, *supra* note 258, at 201 (showing a high level of repeat use of EC across all age groups).

<sup>261</sup> Soon et al, *supra* note 259, at 879.

<sup>262</sup> *Id.*

<sup>263</sup> S. Rowlands et al, *Repeated Use of Hormonal Emergency Contraception By Younger Women in the UK*, 26 BRIT. J. FAM. PLAN. 138, (2000).

<sup>264</sup> Tina R. Raine et al, *Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs: A Randomized Controlled Trial*, 293 JAMA 54, 58-59 (2005).

<sup>265</sup> *Id.*

<sup>266</sup> Harper et al, *supra* note 243, at 490.

<sup>267</sup> *Id.*

<sup>268</sup> Cynthia C. Harper et al, *Tolerability of Levonorgestrel Emergency Contraception in Adolescents*, 191 AM. J. OBSTETRICS & GYNECOLOGY 1158, 1160 (2004).

be restricted from OTC Plan B use due to fears about their inability to use the product correctly or concerns about unknown side effects.<sup>269</sup>

## VI. ALTERNATIVES TO FEDERAL REGULATION OF PLAN B

Although scientific studies and medical evidence showed that Plan B was effective, safe, and did not contribute to risky sexual behavior, the FDA blocked every attempt at OTC approval. As a result, advocates of OTC status doubled their efforts at the state level to try to circumvent federal regulations and provide timely access to EC. At the heart of the effort was the state collaborative practice law.<sup>270</sup> Collaborative practice laws allow pharmacists to prescribe certain medications directly in the pharmacy setting via an agreement with a collaborating physician.<sup>271</sup>

Washington State was the first to act by launching the Emergency Contraception Collaborative Agreement Pilot Project in an effort to increase women's awareness of EC and make it available directly from a pharmacist.<sup>272</sup> Under the agreement, pharmacists were able to dispense EC to women who met the screening criteria established through collaborative physician protocol.<sup>273</sup> The pilot project was highly successful and pharmacy direct EC access continues today. The Washington program has served as a model to other states.<sup>274</sup> To date, nine states (Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington) have policies in force that specifically allow a pharmacist to dispense EC to reproductive women of all ages without a physician's prescription.<sup>275</sup> More states have considered similar legislation,<sup>276</sup> but only time will tell the effect that the recent passage of age-restricted OTC Plan B will have on these plans.

Because of the political make-up of some states, the likelihood of enacting a collaborative practice agreement for Plan B is slim, and advocates look at different avenues. Grassroot campaigns have sprung up across the country to raise public awareness of emergency contraception and to ensure physicians are prescribing the drug and pharmacies are stocking it.<sup>277</sup>

The "Back Up Your Birth Control" campaign was begun five years ago to "raise awareness and position emergency contraception as a commonsense back-up method . . .".<sup>278</sup> Activists promote EC by distributing educational materials to pharmacists in training and promote public education through information packs printed in both English and Spanish.<sup>279</sup> Similarly, the "Pharmacy Access Partnership" is an organization aimed at improving women's access to EC by "promoting communication, leveraging resources, and building an understanding of options for change at the state

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<sup>269</sup> *Id.* at 1162.

<sup>270</sup> Richardson, *supra* note 204, at 11.

<sup>271</sup> *Id.*

<sup>272</sup> PATH, *Collaborative Drug Therapy Agreements to Promote Public Health*, [http://www.path.org/files/ECT\\_agrment\\_pubhlth.pdf](http://www.path.org/files/ECT_agrment_pubhlth.pdf) (last accessed July 23, 2006).

<sup>273</sup> Center for Reprod. Rights, *State Trends in Emergency Contraception Legislation*, [http://www.crlp.org/tools/pring\\_page.jsp](http://www.crlp.org/tools/pring_page.jsp) (last accessed July 24, 2006).

<sup>274</sup> PATH, *supra* note 272.

<sup>275</sup> GO2EC.ORG, *Models for EC Pharmacies*, <http://go2ec.org/ModelsForECPharmacies.htm> (last accessed July 3, 2006).

<sup>276</sup> Center for Reprod. Rights, *supra* note 273.

<sup>277</sup> Heather Boonstra, *Emergency Contraception: Increasing Public Awareness*, 5 GUTTMACHER REP. 3, 6 (Oct. 2002), available at [http://www.guttmacher.org/pubs/ib\\_2-03.pdf](http://www.guttmacher.org/pubs/ib_2-03.pdf) (describing grassroot and legislative efforts to increase public and provider awareness of EC).

<sup>278</sup> *Id.*

<sup>279</sup> Richardson, *supra* note 204, at 13.

and national level.”<sup>280</sup> The Pharmacy Access Partnership created the website, [www.GO2EC.org](http://www.GO2EC.org), that provides a forum for pharmacists and health care advocates to share resources and ideas for improving EC access.<sup>281</sup>

The most recent grassroots campaign aimed at improving EC awareness is the ACOG program called “Ask Me.”<sup>282</sup> The campaign is directed at educating the public about EC and encouraging women to get an advanced prescription for Plan B from their health care provider.<sup>283</sup> Campaign materials describing Plan B are provided for viewing in physician examination and waiting rooms, and the “Ask Me” button, worn by the physician, is supplied to promote dialogue about EC between the patient and her health care provider.<sup>284</sup>

The internet has also provided a new avenue for EC access. Princeton University launched a website entitled [Not-2-Late.com](http://Not-2-Late.com) that allows women to search for Plan B providers via zip code, area code, or city and state.<sup>285</sup> In addition, for a \$24.95 fee, [Getthepill.com](http://Getthepill.com) will provide prescriptions for Plan B to be submitted to a pharmacy of one’s choice.<sup>286</sup>

Easier access to Plan B whether by physician, pharmacist, or OTC will not be effective in reducing unintended pregnancies if the public is not aware of the availability of the product. Many women have never heard of emergency contraception, and many health care providers do not prescribe it<sup>287</sup>. Even if women have heard of Plan B, they often confuse it with the abortion pill, RU-486 (mifepristone).<sup>288</sup>

Once people understand what emergency contraceptive is, and its mode of action, the majority are overwhelmingly supportive.<sup>289</sup> In a 2002 survey, two-thirds of those surveyed felt government involvement in order to reduce unintended pregnancies was a good idea.<sup>290</sup> Furthermore, three-fourths supported legislation aimed at improving public health knowledge.<sup>291</sup> On July 18, 2005, Representative Louise Slaughter introduced the “Emergency Contraception Education Act” proposing a ten million dollar yearly budget to develop and distribute information to the public regarding emergency

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<sup>280</sup> Pharmacy Access Partnership, *National EC Pharmacy Access Efforts*, <http://www.pharmacyaccess.org/NatECPharmAccEfforts.htm> (last accessed July 24, 2006).

<sup>281</sup> *Id.*

<sup>282</sup> News Release, The American College of Obstetricians and Gynecologists, *ACOG Steps Up Efforts to Get Emergency Contraception to Women*, available at [http://www.acog.org/from\\_home/publications/press\\_releases/nr05-08-06-1.cfm](http://www.acog.org/from_home/publications/press_releases/nr05-08-06-1.cfm) (May 8, 2006).

<sup>283</sup> *Id.*

<sup>284</sup> Richardson, *supra* note 204, at 14.

<sup>285</sup> Official website, NOT-2-LATE.com, <http://cc.princeton.edu> (access “Getting EC in the U.S. and Canada” hyperlink, then search by zip code, area code, or city and state) (last accessed Aug. 9, 2006).

<sup>286</sup> [Getthepill.com](http://www.getthepill.com), Online Prescriptions for Emergency Contraception, <http://www.getthepill.com> (last accessed July 26, 2006). [Getthepill.com](http://www.getthepill.com)’s service is limited in that it sells prescriptions in only nineteen states. Richardson, *supra* note 204, at 14.

<sup>287</sup> Grimes & Raymond, *supra* note 25, at 180.

<sup>288</sup> Henry Kaiser Fam. Found., *The Difference Between Medical Abortion and Emergency Contraception Pills*, [http://www.arhp.org/files/mifepristone\\_ecfactsheet.pdf](http://www.arhp.org/files/mifepristone_ecfactsheet.pdf) (last accessed July 26, 2006). Mifepristone ends pregnancy by blocking those hormones necessary to sustain pregnancy. *Id.*

<sup>289</sup> Boonstra, *supra* note 277, at 6.

<sup>290</sup> *Id.*

<sup>291</sup> *Id.*

contraception.<sup>292</sup> The bill has been referred to the House Subcommittee on Health on July 29, 2005.<sup>293</sup> As of this date, no action has been taken.

## VII. CURRENT STATUS OF PLAN B

While the lawsuit, *Tummino*, awaits trial, the political/scientific sparring over Plan B has continued. On July 31, 2006, one day before Dr. von Eschenbach's Senate confirmation hearings for FDA Commissioner, the FDA announced that it was proceeding to resolve the Plan B issue<sup>294</sup> (five years after the initial application). In a July 31, 2006, letter to Duramed Research, Inc. (a subsidiary of Barr), Dr. von Eschenbach requested a prompt meeting to discuss the sNDA for Plan B.<sup>295</sup> Dr. von Eschenbach wrote that in order to obtain FDA approval, the sNDA would need to be amended to seek Plan B OTC status for women ages eighteen and over (in lieu of ages sixteen and over as in the previous amended application).<sup>296</sup> In addition, new packaging proposals and information regarding Barr's proposed marketing, education, distribution, and monitoring of OTC Plan B would be required.<sup>297</sup>

The Senate reacted skeptically to Dr. von Eschenbach's Plan B proposal although the doctor maintained that the decision to revive consideration of Plan B was made "not on a political ideology, but on a medical ideology."<sup>298</sup> Senators Clinton and Murray vowed to block his nomination until a final decision was made on Plan B.<sup>299</sup>

On August 24, 2006, the FDA announced approval for OTC access for Plan B for women eighteen years of age and older.<sup>300</sup> Plan B will remain a prescription medication for those seventeen years and younger.<sup>301</sup> Senators Clinton and Murray announced they would lift their hold on Dr. von

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<sup>292</sup> Emergency Contraception Education Act, H.R. 3326, available at <http://www.govtrack.us/data/us/bills.text/109/h/h3326.pdf>. A similar bill was proposed by Rep. Slaughter and S. Patty Murray in 2002, but was not acted on. Boonstra, *supra* note 277, at 6.

<sup>293</sup> GovTrack.us, H.R. 3326: Emergency Contraception Education Act, <http://www.govtrack.us/congress/bill.xpd?bill=h109-3326> (last accessed July 27, 2006). This bill is in the first step of the legislative process – the majority of bills never make it out of committee. *Id.*

<sup>294</sup> Food & Drug Admin., FDA Statement, *FDA Announces Framework for Moving Emergency Contraception Medication to Over-the-Counter Status*, <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01421.html> (last accessed Aug. 1, 2006).

<sup>295</sup> Food & Drug Admin., letter from Andrew von Eschenbach, Acting Commissioner Food & Drug Admin., to Joseph A. Carrado, Senior Dir. (July 31, 2006), Reg. Affairs of Duramed Research, Inc., available at <http://www.fda.gov/oc/planb/duramed073106.html>.

<sup>296</sup> *Id.*

<sup>297</sup> *Id.* Dr. von Eschenbach specifically requested information on Barr's proposal to restrict distribution of Plan B to those pharmacies agreeing to keep the OTC version behind the pharmacy counter. *Id.* In addition, pharmacies permitted to dispense the medication must check valid identification to verify the age of the consumer. *Id.*

<sup>298</sup> MSNBC, *Morning-After Pill Entangles FDA Nominee* (Aug. 1, 2006), available at <http://www.msnbc.msn.com/id/14137422/> (quoting Dr. von Eschenbach about the timing of the announcement reviving the Plan B application process).

<sup>299</sup> *Id.* Senator Murray, referring to the previous tactics during Commissioner Crawford's confirmation hearings, stated, "Fool me once. We are not going to go there again. We will hold this nomination until we have a decision on Plan B." *Id.* Senator Murray called the timing of Dr. von Eschenbach's announcement regarding the Plan B application as "highly suspicious behavior." *Id.*

<sup>300</sup> Food & Drug Admin., Press Release, *supra* note 113.

<sup>301</sup> *Id.*

## CONCLUSION

It is naive to think the FDA can operate in a vacuum. After all, it is housed in the nation's capitol in the midst of the political forces which shape this country. Congress has approved regulations that give the President the power to appoint those who agree with his political, religious, and philosophical ideology. Therefore, it has fallen upon the people and the states to enact policies which can keep this kind of Presidential power in check.

The FDA has a stated mission to protect and advance public health for all its citizens, but in regard to Plan B, it has fallen far short of this mission. On December 16, 2003, a joint committee of medical and scientific experts voted twenty-three to four to approve OTC status for Plan B. The committee found Plan B to be safe, effective, and suitable for woman of all ages. In an unprecedented move, FDA executives discarded the recommendation and issued a Not Approvable letter for Plan B, citing concerns about its affect on young adolescents. Amending the sNDA to address these concerns, Barr resubmitted the application and requested a dual label with age restrictions for Plan B OTC access. The FDA again rejected the application citing difficulties in marketing, labeling, and enforcement.

Survey results from countries such as France, the U.K., and Canada have confirmed that EC can be administered safely without a physician's supervision, and that readily accessible EC does not promote risky or promiscuous behavior. Although the FDA Advisory Committee experts agreed that Plan B was safe for women of all ages, and OTC status for Plan B is supported by the American Academy of Pediatrics, the FDA held fast to the idea of age restrictions. In fact, in his latest letter to Barr Laboratories, Dr. von Eschenbach demanded a higher age restriction than had ever been previously proposed. This new age restriction will restrict access to those who need it most – our nation's adolescents.

It was not coincidence that the Plan B application sat dormant until Senate confirmation hearings for the FDA Commissioner began in July 2006. Political games continued to be played as the Senate vowed to block a confirmation vote on Dr. von Eschenbach until a decision was reached on Plan B. The hold on Dr. von Eschenbach's confirmation was released as soon as the FDA released their decision. Unfortunately, the losers of this game have been the women of this country whose rights to reproductive health and choice have been jeopardized, and the unborn children whose very lives have likely been affected. It has never been the responsibility of the FDA to dictate the moral fiber of the citizens of the U.S. It is time for the religious philosophy of government and FDA officials to defer to sound medical and scientific judgment. Although the recent FDA approval for Plan B for ages eighteen and older is a step in the right direction, OTC approval for Plan B for women of all ages is long over-due.

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<sup>302</sup> Harris, *supra* note 114.