

GETTING TO PLAN B: A HISTORY OF CONTRACEPTIVE RIGHTS IN THE UNITED STATES AND AN ARGUMENT FOR A PRIVATE RIGHT OF ACTION AGAINST THE FDA

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INTRODUCTION

[I]nstead of improving and advancing women’s health, the FDA leadership is ignoring its process and not relying on science and medical evidence. Americans need a strong and independent FDA.¹

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¹ Press Release, Dr. Susan Wood, Former Ass’t Comm’r for Women’s Health & Former Dir. of the Office of Women’s Health, FDA, Comments on GAO Findings on Plan B (Nov. 14, 2005), available at <http://www.go2ec.org/pdfs/SusanWoodonGAOReport.pdf>.

For years, the Food and Drug Administration (FDA) rejected the widespread availability of Plan B, a drug designed to safely prevent unwanted pregnancies among women of all ages.² This drug has an eighty-nine percent effectiveness rate,³ but it is one hundred percent controversial. Currently, women and men aged eighteen and older can purchase Plan B without a prescription in pharmacies nationwide, but just as cashiers card purchasers of alcohol or tobacco products, purchasers of Plan B must present identification to prove their age to the pharmacists who dispense the drug.⁴ Many individuals, including former FDA insiders, consider this method of dispensation unacceptable because it unnecessarily erects barriers to public health goals.⁵

This Note will examine the constitutional rights associated with the availability and distribution of emergency contraceptives in the United States, particularly Plan B, the “morning after pill,” as a case study to show how the FDA approval process is flawed and why consumers should be able to challenge this administrative process in limited circumstances.

The first part of the Note will review Supreme Court decisions that interpret the right of privacy and provide background on the history of contraceptives in the United States.⁶ The second part of the Note will explore the FDA approval process,⁷ emphasizing specific approval procedure discrepancies related to Plan B’s proposed prescription-to-over-the-counter switch.⁸ This section will suggest that the FDA chose not to approve a safe and effective product and that non-scientific reasons unduly influenced this choice.⁹ This section will also examine the FDA’s August 2006 decision to permit Plan B sales *behind* the counter.¹⁰

The third part of this Note will question whether the American public has a constitutional right to challenge the validity of the FDA’s drug approval process, or whether the government, through the FDA’s administrative powers, should always decide unilaterally which products are placed in the stream of commerce.¹¹ This Note will argue that the process is flawed and that individuals should have the right to challenge it in order to maintain the integrity of the FDA. Finally, this section will

² Duramed Pharm., Inc., What is Plan B?, <http://www.go2planb.com/ForConsumers/AboutPlanB/WhatisPlanB.aspx> (last visited Feb. 18, 2006).

³ *Id.*

⁴ Press Release, U.S. Food & Drug Admin., FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older: Prescription Remains Required for Those 17 and Under (Aug. 24, 2006), <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html>; NPR.org, “Plan B” Pill to Be Sold Over the Counter, <http://www.npr.org/templates/story/story.php?storyId=5703349> (last visited Feb. 18, 2006).

⁵ See Wood, *supra* note 1. Indeed, two FDA officials resigned because of the FDA’s handling of the Plan B application and its denial of OTC status to Plan B. Tummino v. Von Eschenbach, 427 F. Supp. 2d 212, 227–28 (E.D.N.Y. 2006).

⁶ See *infra* Part I.

⁷ See *infra* Part II.A.

⁸ See *infra* Part II.B.

⁹ See *id.*

¹⁰ See *infra* Part II.C.

¹¹ See *infra* Part III.

describe the circumstances in which individuals should be able to challenge the FDA approval process in court.¹²

I. THE HISTORY OF CONTRACEPTION IN THE UNITED STATES

A. *Contraceptive Rights, the Constitutional Right of Privacy, and the Supreme Court*

A string of Supreme Court cases starting in the 1960s reveals a legal history of contraceptive rights in the United States,¹³ but contraceptive use started earlier.¹⁴ In his work, Peter Irons states that the distribution of contraceptives was originally a spinoff of the eugenics movement that was popular among nativists in the early twentieth century.¹⁵ The rise of Nazi Germany, with its stomach-turning sterilization of “unfit” Germans gave supporters pause.¹⁶ The women’s movement later distributed contraceptives as part of feminist ideals.¹⁷

The controversy over contraceptives became intimately tied with the constitutional right of privacy in the landmark case *Griswold v. Connecticut*.¹⁸ An 1879 Connecticut law titled “An Act to Amend an Act Concerning Offences Against Decency, Morality, and Humanity” carried distinctly moral overtones and prohibited contraceptives.¹⁹ Despite the prohibition, or perhaps because of it,²⁰ Estelle Griswold, the Executive Director of the Planned Parenthood League of Connecticut, and Dr. C. Lee Buxton, the Medical Director for the Planned Parenthood League in New Haven, provided contraceptives to a married couple and were arrested.²¹ They challenged their criminal

¹² *See id.*

¹³ *See, e.g.*, *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992); *Webster v. Reprod. Health Servs.*, 492 U.S. 490 (1989); *Carey v. Population Servs. Int’l*, 431 U.S. 678 (1977); *Roe v. Wade*, 410 U.S. 113 (1973); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479 (1965).

¹⁴ “Contraception” is the “[p]revention of conception or impregnation.” *STEDMAN’S MEDICAL DICTIONARY* 404 (27th ed. 2000). Contraceptives are the actual methods, devices, or drugs employed to prevent conception, including oral, intrauterine, and barrier contraceptives. *Id.*

¹⁵ PETER IRONS, *CASES AND CONTROVERSIES: CIVIL RIGHTS AND LIBERTIES IN CONTEXT* 407 (2005).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ 381 U.S. at 485–86.

¹⁹ JOHN W. JOHNSON, *GRISWOLD V. CONNECTICUT: BIRTH CONTROL AND THE CONSTITUTIONAL RIGHT OF PRIVACY* 8 (2005). Johnson mentions that the Connecticut law mirrored, to a large extent, the Comstock Act, which was passed by Congress in 1873. The Comstock Act, which was designed to prevent the circulation of obscene literature, strengthened federal law against the practice of sending obscene materials through the mail. Anthony Comstock, a religious man, considered both literature and pictures about preventing conception obscene materials. In his inspections as a postal agent, he seized over 60,000 condoms and diaphragms and arrested fifty-five people for violating the law in 1873. *Id.* at 7–8.

²⁰ Some argue that *Griswold v. Connecticut* was a legal test case specifically designed to lift the prohibition against contraceptives. *See id.* at 6.

²¹ *Griswold*, 381 U.S. at 480.

conviction.²² Though the conviction was reversed, Justice Douglas did not base his holding on the Due Process Clause of the Fourteenth Amendment;²³ instead, he used the “penumbras” of the amendments in the Bill of Rights to suggest that there are “zones of privacy” in which the government dare not interfere.²⁴

Seven years after *Griswold*, the Supreme Court struck down a Massachusetts statute allowing the distribution of contraceptives to married couples to prevent pregnancy but denying their distribution to single individuals because the statute violated the Equal Protection Clause.²⁵ The Equal Protection Clause of the Fourteenth Amendment calls for the equal treatment of similarly situated individuals.²⁶ Justice Brennan’s ruling expanded the right of privacy under the Equal Protection Clause; without this ruling, only married persons—but not unmarried persons—would have the right to control their reproductive health through the use of contraceptives.²⁷ Unless unmarried and married persons are “dislike” one another, the government is not allowed to treat them differently.²⁸ In essence, Justice Brennan expanded the idea of privacy as a fundamental constitutional right.²⁹

²² *Id.*

²³ *Id.* at 481–82; U.S. CONST. amend. XIV, § 1.

All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Id.

²⁴ *Id.* at 484–85. Justice Douglas relied on the First, Third, Fourth, Fifth, Ninth, and Fourteenth Amendments. *Id.*

²⁵ *Eisenstadt v. Baird*, 405 U.S. 438, 447–48 (1972).

²⁶ U.S. CONST. amend. XIV, § 1; *see, e.g.*, *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 439 (1985) (holding that animus is not a legitimate basis for unequal treatment and that requiring special permits for a group home for the mentally retarded violated the Equal Protection Clause because the differences between the mentally retarded and the occupants of other facilities in the zoning area were irrelevant to the housing needs of each group).

²⁷ *Eisenstadt*, 405 U.S. at 453.

²⁸ *Id.* Clarifying his opinion, Justice Brennan stated:

If under *Griswold* the distribution of contraceptives to married persons cannot be prohibited, a ban on distribution to unmarried persons would be equally impermissible. It is true that in *Griswold* the right of privacy in question inhered in the marital relationship. Yet the marital couple is not an independent entity with a mind and heart of its own, but an association of two individuals each with a separate intellectual and emotional makeup. If the right of privacy means anything, it is the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.

Id.

²⁹ *See* JOHNSON, *supra* note 19, at 200.

Roe v. Wade made waves in 1973 when the Supreme Court recognized a woman's absolute right to an abortion during the first trimester of pregnancy with a qualified right thereafter.³⁰ In *Roe*, the Supreme Court expanded the fundamental right of privacy and held that reproductive rights fall into this category of personal privacy rights.³¹ Building on the fundamental right of privacy enunciated in *Roe*, *Carey v. Population Services International*, decided four years later in 1977, challenged New York statutes limiting the distribution of contraceptives.³² In Justice Brennan's opinion, the Supreme Court made four distinct holdings. First, the Court held that a third party, namely, the distributor of contraceptives, has a right to challenge a New York statute on behalf of its customers.³³ Second, the Court held that the decision whether to bear children is so fundamental a choice that regulations affecting this right must be subject to strict scrutiny.³⁴ Third, the Court held that individuals over sixteen would be unduly burdened if they were allowed to receive non-medical contraceptives only from licensed pharmacists.³⁵ Finally, the Court held that it was unconstitutional to outlaw the advertisement or display of contraceptives.³⁶ In addition to reaffirming the existence of a fundamental right of privacy with respect to reproductive choices, the Court enunciated its opinion that "[t]he business of manufacturing and selling contraceptives may be regulated in ways that do not infringe protected individual choices. And even a burdensome regulation may be validated by a sufficiently compelling state interest."³⁷

Planned Parenthood of Southeastern Pennsylvania v. Casey is one of the more recent Supreme Court decisions discussing reproductive rights.³⁸ In *Casey*, a physician and a Planned Parenthood organization challenged the constitutionality of amendments to a Pennsylvania abortion statute that imposed consent, notice, and time restrictions on abortions.³⁹ Using the principle of stare decisis,⁴⁰ *Casey* reaffirmed *Roe*'s holding that a woman has a right to choose whether to have an abortion before viability of the fetus, but it discarded *Roe*'s trimester test.⁴¹ *Casey* also relied heavily on the Due Process Clause of the Fourteenth Amendment and emphasized a personal right of

³⁰ 410 U.S. 113, 163 (1973).

³¹ *Id.* at 152–53. In the majority opinion, Justice Blackmun stated, “[w]e, therefore, conclude that the right of personal privacy includes the abortion decision, but that this right is not unqualified and must be considered against important state interests in regulation.” *Id.* at 154.

³² See *Carey v. Population Servs. Int’l*, 431 U.S. 678, 683 (1977); JOHNSON, *supra* note 19, at 201.

³³ *Carey*, 431 U.S. at 683.

³⁴ *Id.* at 686.

³⁵ *Id.* at 689.

³⁶ *Id.* at 700–01.

³⁷ *Id.* at 685–86.

³⁸ 505 U.S. 833 (1992).

³⁹ *Id.*

⁴⁰ *Id.* at 854.

⁴¹ *Id.* at 872.

privacy.⁴² The Court stated that “[n]either the Bill of Rights nor the specific practices of States at the time of the adoption of the Fourteenth Amendment marks the outer limits of the substantive sphere of liberty which the Fourteenth Amendment protects.”⁴³ In the fifteen years since *Casey*, women have relied on the existence of this right of privacy and personal liberty when making decisions regarding their reproductive health.

B. The Specific History of Emergency Contraceptives

The phrase “emergency contraception” refers to drugs consisting of estrogen and progestin, either singly or in combination, which are used to prevent pregnancy after some form of unprotected intercourse including rape, failure of ordinary contraceptives, or lack of planning.⁴⁴ Emergency contraception is colloquially referred to as the “morning after pill.”⁴⁵ A woman’s ability to access emergency contraception has been questioned by state legislatures and challenged in the courts. In recent years, citizen petition groups and drug manufacturers have fought back. The history of emergency contraception use in the United States is instructive in understanding today’s debates.

The FDA approved the use of ordinary oral contraceptives in the 1960s.⁴⁶ Since that time, physicians, emergency room hospitals, reproductive health clinics, and university health centers prescribed combinations of oral contraceptive pills or dosages as a form of emergency contraception.⁴⁷ The FDA, however, never officially sanctioned the emergency use of oral contraceptives at that time.⁴⁸ The Center for Reproductive Law and Policy filed a citizen petition in 1994 with the FDA requesting that the FDA label certain oral contraceptives for use as emergency contraception.⁴⁹ The FDA denied this petition but left to its Advisory Committee the issue of deciding the safety and efficacy of oral contraceptives.⁵⁰ In 1997, the FDA stated that emergency contraception “substantially reduces the chances of becoming pregnant after unprotected sexual intercourse.”⁵¹ Furthermore, the FDA acknowledged that the risks associated with emergency contraception were similar to the risks associated with ordinary oral

⁴² *Id.* at 846–47.

⁴³ *Id.* at 848.

⁴⁴ Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610 (proposed Feb. 25, 1997) (codified at 21 C.F.R. pt. 314) [hereinafter Prescription Drug Products].

⁴⁵ U.S. Dep’t of Health & Human Servs., *Emergency Contraception*, WOMEN’S HEALTH (2006), <http://www.4woman.gov/faq/econtracep.htm> [hereinafter *Emergency Contraception*].

⁴⁶ FDA, *FDA Calls for Applications for Emergency Use of Oral Contraceptives*, 27 FDA MEDICAL BULLETIN (March 1997), available at <http://www.fda.gov/medbull/mar97/notices.htm> [hereinafter *Applications for Emergency Use*].

⁴⁷ See Prescription Drug Products, *supra* note 44, at 8610.

⁴⁸ See *Applications for Emergency Use*, *supra* note 48.

⁴⁹ See Prescription Drug Products, *supra* note 44, at 8610.

⁵⁰ *Id.*

⁵¹ See *Applications for Emergency Use*, *supra* note 48.

contraceptives.⁵² The FDA's statement affirmed the results of a 1970s study that showed that high doses of the conventional birth control pill could prevent pregnancy when taken within seventy-two hours of sexual intercourse.⁵³ The statement also reinforced the findings of an FDA-hosted panel of experts who unanimously concluded such high doses were "both safe and effective."⁵⁴ As a result, the FDA solicited drug manufacturers for supplemental new drug applications (sNDAs) for the use of oral contraceptives as a form of emergency contraception starting in 1997.⁵⁵

The FDA approved the first oral contraceptive for emergency use within one year of soliciting sNDAs.⁵⁶ In September 1998, the FDA officially approved Preven, which contained both estrogen and progestin,⁵⁷ for prescription use as an emergency contraceptive pill.⁵⁸ In July 1999 the FDA also approved Plan B, a progestin-only drug, as an emergency contraceptive pill for prescription use only.⁵⁹ Individuals who believed that Plan B and any other form of morning after pill were abortifacients objected to the decision.⁶⁰

The controversy over pharmacists' rights emerged as a backlash from this approval.⁶¹ Some pharmacists chose not to fill Preven or Plan B prescriptions or even to stock emergency contraception in their pharmacies.⁶² For example, in April 1999, prior to the approval of Plan B for prescription use, Wal-Mart announced that it would not stock emergency contraception in any of its pharmacies based on a "variety of

⁵² *Id.*

⁵³ Sheldon Segal, *Contraceptive Update*, 23 N.Y.U. REV. L. & SOC. CHANGE 457, 463–64 (1997).

⁵⁴ *Id.* at 464.

⁵⁵ See *Applications for Emergency Use*, *supra* note 48.

⁵⁶ CenterWatch, *Drugs Approved by the FDA*, <http://www.centerwatch.com/patient/drugs/dru476.html> (last visited Oct. 15, 2006).

⁵⁷ Monica J. Smith, *New Contraception Options*, DIABETES SELF-MGMT., Sept.–Oct. 2004, available at <http://www.diabetesselfmanagement.com/article.cfm?sid=2&tid=96&stid=142&aid=1908>.

⁵⁸ CenterWatch, *supra* note 58; FDA, Talk Paper T98-49, *FDA Approves Application for Preven Emergency Contraceptive Kit* (Sept. 2, 1998), <http://www.fda.gov/bbs/topics/ANSWERS/ANS00892.html> [hereinafter *Preven*].

⁵⁹ See Duramed Pharm., Inc., *About Plan B*, <http://www.go2planb.com/ForPharmacists/aboutPlanB/Default.aspx> (last visited Oct. 15, 2006) [hereinafter *About Plan B*]; Ann Friedman, *Over-the-Counter Insurgency*, MOTHER JONES, Aug. 2006, available at http://www.motherjones.com/news/update/2006/08/planb_timeline.html; Prescription Drug Products, *supra* note 44, at 8610; Smith, *supra* note 59.

⁶⁰ See, e.g., Suzanne Alexander, *Plan B: Russian Roulette, Anyone?*, CHRISTIAN MED. & DENTAL ASS'NS, Oct. 5, 2005, <http://www.cmdahome.org/index.cgi?CONTEXT=rt&cat=100111&art=3105&BISKIT=3857217411&CONTEXT=art> (last visited July 13, 2007).

⁶¹ See, e.g., Nate Anderson, *Pharmacists with No Plan B*, CHRISTIANITY TODAY, Aug. 2006, available at <http://www.christianitytoday.com/ct/2006/august/31.44.html>; Rob Stein, *Pharmacists' Rights at the Front of New Debate*, WASH. POST, Mar. 28, 2005, at A1.

⁶² Stein, *supra* note 63, at A1.

business considerations.”⁶³ Wal-Mart announced that it would refer women requesting EC to an alternate pharmacy instead.⁶⁴ In March 2006, however, Wal-Mart reversed its position, stating that it *would* stock Plan B.⁶⁵ The reversal occurred after three women in Massachusetts filed a lawsuit against the company.⁶⁶ In Illinois, a state directive achieved the same result.⁶⁷ Wal-Mart then decided to sell emergency contraception in its pharmacies nationwide.⁶⁸

On the opposite end of the spectrum, other organizations and groups pushed for over-the-counter (OTC) use of Plan B by releasing statements and petitioning the FDA directly. In 2000, the American Medical Association (AMA) stated that it would support an sNDA asking the FDA to switch Plan B from prescription-only use to OTC use.⁶⁹ A trustee for the AMA confirmed that it would support wider access to emergency contraception if the FDA found that OTC distribution was safe.⁷⁰ However, the trustee also cautioned that the AMA would continue to respect the right of physicians to abstain from conduct that conflicted with their moral principles.⁷¹ In February 2001, the American College of Obstetricians and Gynecologists (ACOG) encouraged the approval of emergency contraception for OTC status.⁷² ACOG cited the FDA’s findings that emergency contraception was safe and effective in preventing pregnancy in support of its position, and it also stated that increased availability of emergency contraception could substantially reduce the abortion rate in America.⁷³

Groups also petitioned the FDA directly. A consortium of over seventy reproductive and medical health organizations formally filed a citizen petition in February 2001 asking the FDA to switch Preven⁷⁴ and Plan B from prescription-only to OTC status.⁷⁵ The Center for Reproductive Law and Policy (now known as the Center for

⁶³ See Friedman, *supra* note 61.

⁶⁴ B.A. Robinson, *Wal-Mart’s Initial Refusal to Stock EC—the “Morning-After” Pill*, RELIGIOUS TOLERANCE, http://www.religioustolerance.org/abo_walm.htm (last visited Nov. 8, 2007).

⁶⁵ Press Release, Nat’l Org. for Women, Decision by Wal-Mart to Stock Emergency Contraception “Long Overdue” (Mar. 3, 2006), *available at* <http://www.now.org/press/03-06/03-03.html>. This change in policy was unexpected, so it is not surprising to learn that Wal-Mart did not change its position willingly. *Id.*

⁶⁶ *Id.*

⁶⁷ Robinson, *supra* note 66.

⁶⁸ *Id.*

⁶⁹ Jane Cys, *AMA Eyes Over-the-Counter Access for Emergency Contraception*, AMNEWS, Dec. 25, 2000, http://www.go2ec.org/pdfs/Endorsement_AMA_OTC.pdf.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Friedman, *supra* note 61.

⁷³ Press Release, ACOG, Statement of the American College of Obstetricians and Gynecologists Supporting the Availability of Over-the-Counter Emergency Contraception (Feb. 14, 2001), *available at* http://www.go2ec.org/pdfs/Endorsement_ACOG_OTC.pdf.

⁷⁴ Preven was on the market until 2004. See Friedman, *supra* note 61.

⁷⁵ Ctr. for Reprod. Law & Policy, *Citizen’s Petition* (Feb. 14, 2001), *available at*

Reproductive Rights) served as common counsel for the petitioners.⁷⁶ Five years later, the FDA denied the citizen petition on June 9, 2006, stating that the petitioners did not have standing to file a request and that their petition lacked supporting scientific data.⁷⁷

In April 2003 the manufacturer of Plan B, Women's Capital Corporation, submitted an application to the FDA to switch Plan B from prescription to OTC status for women of all ages.⁷⁸ The application contained information from thirty-nine clinical studies and included over 15,000 pages of data.⁷⁹ On February 13, 2004, the FDA extended the decision deadline until May 21, 2004.⁸⁰ Barr Pharmaceuticals acquired Women's Capital Corporation approximately two weeks later, on February 26, 2004.⁸¹ In March 2004 Barr amended the original application and proposed that Plan B be made available over the counter for women sixteen and older and by prescription for those under sixteen.⁸² On May 5, 2004, the Acting Director of the FDA's Center for Drug Evaluation and Research (CDER) denied the application because Barr did not adequately address the effects of Plan B on young adolescents.⁸³ Dr. Galson stated that the CDER also did not review the amendment because Barr did not sufficiently explain how Plan B would be labeled for both prescription and OTC use.⁸⁴ In response, Barr Pharmaceuticals submitted a new application that addressed the labeling issues.⁸⁵ On August 26, 2005, the FDA announced that it would not rule on Barr Pharmaceutical's new proposal by the September 1, 2005, deadline but would instead allow sixty days for public comment.⁸⁶ On July 31, 2006, the FDA proposed selling Plan B over the counter to women aged eighteen and older.⁸⁷ Abruptly, the FDA formally approved the sale of Plan B *behind* the counter to women and men aged eighteen and older on

http://www.crlp.org/pdf/EC_petition.pdf.

⁷⁶ *Id.* at 5.

⁷⁷ Letter from Randall W. Lutter, Assoc. Comm'r for Policy & Planning, Dep't of Health & Human Servs., to Bonnie Scott Jones, Esq., & Simon Heller, Esq., Ctr. for Reprod. Rts (June 9, 2006), *available at* <http://www.fda.gov/ohrms/dockets/dockets/01p0075/01p-0075-pdn001-vol348.pdf>; *see* Friedman, *supra* note 61.

⁷⁸ *See* Friedman, *supra* note 61.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ Press Release, Barr Pharm., Inc., Barr Completes Acquisition of Women's Capital Corporation and Plan B Emergency Contraception (Feb. 26, 2004), *available at* <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/02-26-2004/002117446&EDATE>.

⁸² Letter from Steven Galson, Acting Dir., Ctr. for Drug Evaluation & Research, to Joseph A. Carrado, Senior Dir., Regulatory Affairs, Barr Research, Inc. (May 6, 2004), *available at* http://www.fda.gov/cder/drug/infopage/planB/planB_NALetter.pdf (reciting a brief history of Barr's application and amendments).

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *See* Friedman, *supra* note 61.

⁸⁶ *Id.*

⁸⁷ *Id.*

August 24, 2006.⁸⁸ The FDA did not specify when behind-the-counter sales of Plan B would begin,⁸⁹ but some pharmacies and student health centers began selling Plan B behind-the-counter in November 2006.⁹⁰

In addition to petitions, lawsuits were filed against the FDA. Before the FDA issued any decision on Plan B, the Center for Reproductive Rights filed a lawsuit against Lester Crawford, the then-Acting Commissioner of the FDA, in the United States District Court for the Eastern District of New York.⁹¹ The complaint claimed that the FDA's refusal to issue a decision constituted a constructive denial of the application,⁹² which effectively violated a woman's right of privacy and equal protection under the Fifth Amendment.⁹³ Individual women and members of the Morning-After-Pill Conspiracy (on behalf of all women who need emergency contraception), the Association for Reproductive Health Professionals (ARHP), and the National Latina Institute for Reproductive Health filed the lawsuit.⁹⁴

Finally, the states responded differently to the idea of prescription and OTC emergency contraception. Between 1997 and 2005, well before the 2006 FDA approval of Plan B for behind-the-counter sales, legislation in eight states allowed pharmacists to dispense emergency contraception without a prescription.⁹⁵ Conversely, Republican John Stahl introduced a bill to the Michigan legislature in 2005 proposing to ban all nonprescription sales of emergency contraception.⁹⁶ Later that year, the Missouri

⁸⁸ Marc Kaufman & Rob Stein, *Plan B Approval Said to Be Near*, WASH. POST, Aug. 24, 2006, at A1; Rob Stein, *FDA Approves Plan B's Over-the-Counter Sale*, WASH. POST, Aug. 25, 2006, at A4.

⁸⁹ See Stein, *supra* note 90, at A4.

⁹⁰ E.g., College of William & Mary, Student Health Center, <http://www.wm.edu/health/> (last visited Feb. 15, 2007).

⁹¹ Complaint at 10, *Tummino v. Crawford*, No. 1:05cv00366 (E.D.N.Y. Jan. 21, 2005).

⁹² *Id.*

⁹³ *Id.* at 15.

⁹⁴ Press Release, Ctr. for Reprod. Rights, State of Wisconsin Seeks to Join Center's Lawsuit Against the FDA Over the "Morning-After Pill" (Mar. 15, 2006), available at http://www.crlp.org/pr_06_0315WisconsinFDA.html. The State of Wisconsin also sought to intervene in that suit as a plaintiff. Press Release, State of Wis. Dep't of Justice, Lawsuit Against FDA over Delay in "Plan B" Emergency Contraception (Mar. 15, 2006), available at http://www.doj.state.wi.us/news/2006/nr031506_PL.asp.

⁹⁵ See Friedman, *supra* note 61. The eight states that allowed a physician to dispense emergency contraception without a prescription before the FDA approval were, in reverse chronological order, Massachusetts, New Hampshire, Maine, Hawaii, New Mexico, Alaska, California, and Washington, which had legislation on this point pre-dating 1997. *Id.*

⁹⁶ *Michigan Lawmaker Introduces Bill that Would Ban Nonprescription Sales of EC in State*, MED. NEWS TODAY, Nov. 30, 2005, available at <http://www.medicalnewstoday.com/medicalnews.php?newsid=34305>. Representative Stahl introduced the following bill in the Michigan House of Representatives on October 18, 2005:

(1) Emergency contraception shall only be dispensed as a prescription drug and under the control of a licensed pharmacist or prescriber. The

Senate also introduced a bill proposing that emergency contraception be limited to prescription-use only.⁹⁷ As of July 2007, multiple states have legislation restricting access to emergency contraception.⁹⁸ These restrictions take various forms, from the exclusion of emergency contraception from Medicaid Family Planning Expansion and the Contraceptive Coverage Mandate to state laws that allow either the pharmacist or the pharmacy to refuse to dispense emergency contraception.⁹⁹

II. AN EYE INTO THE FDA APPROVAL PROCESS

A. *The FDA Approval Process Generally*

The Federal Food, Drug, and Cosmetic Act (FDCA) outlines the powers given to the FDA by Congress to regulate food and drug use in the United States.¹⁰⁰ Section 355 of the FDCA describes the procedure for regulating new drugs.¹⁰¹ The FDCA prohibits new drugs from entering the stream of interstate commerce unless an application for the new drug has been filed with and approved by the FDA.¹⁰²

The FDCA emphasizes safety and efficacy. A petitioner who submits a new drug application (NDA) must also submit investigation reports to prove that the drug is

licensed pharmacist or prescriber who dispenses the emergency contraception shall maintain the same records for the dispensing of the emergency contraception as required for the dispensing of prescription drugs. (2) As used in this section, "emergency contraception" means a medication or combination of medications approved by the federal Food and Drug Administration taken or used after sexual intercourse for the prevention of pregnancy by preventing ovulation, fertilization of an egg, or implantation of an egg in a uterus.

H.R. 5311, 93d Leg., Reg. Sess. (Mich. 2005).

⁹⁷ On December 1, 2005, Senators Crowell, Engler, Mayer, and Nodler introduced the following bill:

1. For purposes of this section, "emergency contraceptive" means any drug approved by the Food and Drug Administration that prevents pregnancy after intercourse and which contains the hormones estrogen and progestin, either separately or in combination.
2. Emergency contraceptives shall be dispensed only upon prescription by an authorized health care professional.

S.B. 608, 93d Gen. Assem., 2d Reg. Sess. (Mo. 2006).

⁹⁸ *Emergency Contraception*, STATE POLICIES IN BRIEF (Guttmacher Inst., New York, N.Y.), Aug. 1, 2007, available at http://www.guttmacher.org/statecenter/spibs/spib_EC.pdf. Arkansas, Georgia, Mississippi, North Carolina, and South Dakota had explicit restrictions concerning EC. *Id.*

⁹⁹ *Id.*

¹⁰⁰ 21 U.S.C. §§ 301-397 (2000).

¹⁰¹ 21 U.S.C.A. § 355 (West Supp. 2007).

¹⁰² 21 U.S.C. § 355(a).

“safe for use and . . . effective in use.”¹⁰³ The Act also dictates that all of the individuals who review the applications should have “technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards.”¹⁰⁴

The timeline for review is quite short; the FDCA states that within 180 days of the petitioner’s filing of an NDA, the Secretary of Health and Human Services (HHS) must either approve the application or give the petitioner notice of an opportunity for a hearing to discuss the scientific issues involved and determine whether the application is approvable.¹⁰⁵ This deadline can be extended only if the HHS Secretary and the petitioner agree to an extension.¹⁰⁶

Finally, the FDCA enumerates the acceptable grounds for refusing a new drug application. The HHS Secretary can reject a new drug application if (1) the investigations submitted by the petitioner do not include tests that are adequate to determine the safety of the drug;¹⁰⁷ (2) the tests show that the drug is not safe;¹⁰⁸ (3) the manufacturing, processing, and packing processes for the drug are not adequate;¹⁰⁹ (4) other information in the application or other information about the drug is insufficient to show the drug’s safety;¹¹⁰ (5) there is a lack of substantial evidence to show the effectiveness of the drug from the application and other information available about the drug;¹¹¹ (6) patent information for the drug was not provided with the application;¹¹² or, finally, if (7) the labeling was false or misleading.¹¹³

The FDA is divided into specialized departments and divisions, each armed with procedures to carry out the approval process in accordance with the FDCA’s guidelines. The process for approval of an OTC switch application is similar to the new drug application and approval process. Instead of an NDA, the petitioner submits an sNDA for an approved NDA.¹¹⁴ Typically, the drug manufacturer or sponsor submits the data, and the CDER reviews the data.¹¹⁵ Two of the CDER’s six drug evaluation

¹⁰³ 21 U.S.C. § 355(b)(1)(A) (Supp. IV 2004).

¹⁰⁴ *Id.* § 355(b)(5)(A).

¹⁰⁵ 21 U.S.C. § 355(c)(1) (2000).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* § 355(d)(1).

¹⁰⁸ *Id.* § 355(d)(2).

¹⁰⁹ *Id.* § 355(d)(3).

¹¹⁰ *Id.* § 355(d)(4).

¹¹¹ *Id.* § 355(d)(5).

¹¹² *Id.* § 355(d)(6).

¹¹³ *Id.* § 355(d)(7).

¹¹⁴ U.S. GOV’T ACCOUNTABILITY OFFICE, FOOD AND DRUG ADMINISTRATION, DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 8 (Nov. 2005), available at www.gao.gov/cgi-bin/getrpt?GAO-06-109 [hereinafter GAO] (reviewing the FDA’s approval process and the peculiar chain of events surrounding the OTC application for Plan B).

¹¹⁵ FDA, *OTC Drug Monograph Review Process*, CDER HANDBOOK, <http://www.fda.gov/cder/handbook/otc.htm> [hereinafter *OTC Drug Monograph Review Process*] (diagraming the

offices review the data for drugs that are the first within a particular class of drugs to be reviewed by the FDA for an OTC switch.¹¹⁶ The Office of Drug Evaluation V reviews all OTC switch applications; it is automatically one of the two reviewing offices.¹¹⁷ The second office reviewing the data is the one with expertise relevant to the drug.¹¹⁸ A joint advisory committee of outside experts also may provide scientific advice, if requested.¹¹⁹ Together, the two offices of the CDER review the OTC switch application and the advice from the joint advisory committee.¹²⁰ If the offices agree, they sign and issue an action letter that the FDA sends to the sponsor.¹²¹ Three outcomes are possible. First, an application can receive “approval,” in which case the drug gains OTC status.¹²² If it does not, the application is marked as either “approvable” or “not-approvable.”¹²³ In the latter two cases, the issue letter states the application’s deficiencies, and the petitioner may address them and file again.¹²⁴

If the two offices of the CDER cannot reach a consensus, the OTC switch application is forwarded to a superior office for further review.¹²⁵ The Director of the Office of New Drugs within the CDER or the CDER Director makes the decision and signs the action letter.¹²⁶ Opportunity for the applicant to revise and amend the application is built into this procedure.¹²⁷ Sometimes a sixty to ninety day comment period allowing the public to voice its opinion on the proposal may occur after the proposal is published in the Federal Register.¹²⁸

The Offices of Drug Evaluation V¹²⁹ and III¹³⁰ reviewed the Plan B OTC application submitted in April 2003.¹³¹ The sNDA contained both an actual use study for Plan B and a label comprehension study to evaluate whether consumers would understand how to use the product.¹³² The two offices relied on the advice of a joint advisory

internal process for OTC drug application and review).

¹¹⁶ See GAO, *supra* note 116, at 1.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.* at 1–2.

¹²⁰ *Id.* at 2.

¹²¹ *Id.*; *OTC Drug Monograph Review Process*, *supra* note 117.

¹²² See GAO, *supra* note 116, at 9.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ See *OTC Drug Monograph Review Process*, *supra* note 117.

¹²⁸ *Id.*

¹²⁹ The Division of Over-the-Counter Products is part of the Office of Drug Evaluation V. See GAO, *supra* note 116, at 2.

¹³⁰ The Division of Reproductive and Urologic Projects is part of the Office of Drug Evaluation III. *Id.*

¹³¹ *Id.*

¹³² *Id.* at 14.

committee comprised of the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs during the review process.¹³³ The advisory committee overwhelmingly recommended the approval of the Plan B OTC switch application.¹³⁴ FDA review personnel agreed that Plan B should be approved.¹³⁵ Nonetheless, the Acting Director of the CDER instead issued a not-approvable letter on the initial Plan B OTC switch application in May 2004.¹³⁶

B. The FDA's Reasons for Delaying a Decision on the Plan B OTC Switch Application

In November 2005, the United States Government Accountability Office (GAO) issued a report on the FDA's decisionmaking process for the initial Plan B OTC switch application and concluded that the procedure was "unusual."¹³⁷ The GAO discovered that the FDA did not follow its prescription-to-OTC switch application review procedures in four ways. First, the individuals who are usually responsible for issuing the action letter, the directors of the Offices of Drug Evaluation III and V, did not sign the not-approvable action letter for the Plan B application.¹³⁸ They told the GAO that they approved the Plan B prescription-to-OTC switch.¹³⁹ The Director of the Office of New Drugs was next in line to sign and issue the action letter.¹⁴⁰ Like the directors of the evaluating offices, he did not agree with the Acting Director of the CDER's decision to issue a not-approvable letter and did not sign it.¹⁴¹ The Acting Director of the CDER signed and issued the not-approvable letter instead.¹⁴² The FDA maintains that the reason the directors for the Offices of Drug Evaluation and the Office of New Drugs did not sign the not-approvable letter is because the Acting Director of the CDER did not actually *ask* any of them for their signature.¹⁴³ This explanation is both circuitous and unsatisfying—the Acting Director of the CDER did not ask these directors to sign the not-approvable letter because he knew that they did not agree with the decision and would refuse to sign.¹⁴⁴

¹³³ *Id.* at 2.

¹³⁴ *Id.* The vote by the joint advisory committees was twenty-three in favor of approval and four against approval of the application. *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.* at 5.

¹³⁷ *Id.*

¹³⁸ *Id.* at 5.

¹³⁹ *Id.* at 19.

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 5.

¹⁴² *Id.*

¹⁴³ *Id.* at 20.

¹⁴⁴ *Id.*

That the Director of the Office of New Drugs was asked to review the staff's decision at all is unusual in itself.¹⁴⁵ Under the FDA's standard operating procedures, the Director of the Office of New Drugs makes a decision on the prescription-to-OTC switch application *only* if there is a disagreement between the two reviewing offices—in the case of Plan B, there was no such disagreement because both reviewing offices approved the OTC switch.¹⁴⁶

Second, high-level FDA management participated in the review and decision-making process for the Plan B application to an unusual degree.¹⁴⁷ Staff at the Offices of Drug Evaluation III and V stated that at a January 2004 meeting the Acting Director of the CDER told them that high-level management would act on the Plan B switch application.¹⁴⁸ The Director for the Office of New Drugs informed the GAO that this was not the usual procedure for approval decisionmaking, but other FDA officials stated that high-level management involvement is always possible in any visible, sensitive, and controversial case.¹⁴⁹ These officials declared that such involvement occurred in the past.¹⁵⁰

Third, the GAO found evidence that the decision to issue a not-approvable action letter may have been made before the reviews even were completed.¹⁵¹ The Offices of Drug Evaluation III and V completed their reviews of the Plan B OTC switch application in April 2004.¹⁵² Personnel from both those offices, however, stated that high-level management told them that the Plan B application would receive a not-approvable letter.¹⁵³ High-level management made the decision on Plan B before the Offices of Drug Evaluation completed their evaluations. The Director and Deputy Director of the Office of New Drugs confirmed that the Acting Director of the CDER told them

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 20–21.

¹⁵⁰ *Id.* The FDA gave two examples of previous high-level involvement in review decisions. Both examples involved NDAs, not OTC switch applications. First, the Director of the CDER approved thalidomide, a drug for leprosy, despite the review staff's concerns about off-label usage. *Id.* at 21 n.41. The Deputy Center Director of the CDER signed the approval letter. Letter from Murray M. Lumpkin, Deputy Ctr. Dir., Ctr. for Drug Evaluation & Research, to Steve Thomas, Celgene Corp. (July 16, 1998), *available at* <http://www.fda.gov/cder/foi/appltr/1998/20785ltr.pdf>. Second, the Commissioner signed the approval letter for mifepristone. GAO, *supra* note 116, at 21 n.42. The Commissioner and the review staff both agreed that mifepristone should be approved, but the Commissioner signed the letter to protect the identities of the review staff. *Id.* A copy of the approval letter can be found on the FDA's website. Letter from the Ctr. for Drug Evaluation & Research to Sandra P. Arnold, Vice President of Corporate Affairs, Population Council (Sept. 28, 2000), *available at* <http://www.fda.gov/cder/foi/appltr/2000/20687appltr.pdf> [hereinafter RU-486 Approval Letter].

¹⁵¹ *See* GAO, *supra* note 116, at 5.

¹⁵² *Id.* at 21.

¹⁵³ *Id.*

that the Plan B application would receive a not-approvable letter in December 2003, five months before he announced the decision.¹⁵⁴ High-level management denied making such statements; the Acting Director of the CDER stated that he may have merely indicated after the December 2003 meeting that the agency was *leaning toward* a not-approvable decision.¹⁵⁵ Although review staff claim that they were told during a January 14, 2004, meeting that Plan B would receive a not-approvable decision, the minutes from the meeting show that the Acting Director only recommended a not-approvable decision.¹⁵⁶ Furthermore, the Acting Director of the CDER claimed he did not make his final decision until a few weeks before the action letter was issued in May 2004.¹⁵⁷

Finally, the GAO concluded that the Acting Director of the CDER's rationale for issuing the not-approvable action letter was abnormal.¹⁵⁸ The GAO learned that the Acting Director of the CDER was concerned that younger adolescents would be more likely to engage in unsafe sex if Plan B were available over the counter, and this concern partially motivated his decision.¹⁵⁹ The Acting Director of the CDER found the petitioner's actual use and label comprehension studies to be inadequate because the studies did not evaluate enough adolescents under the age of sixteen to gauge the effect that OTC Plan B would have on their behavior.¹⁶⁰ The Acting Director of the CDER refused to extrapolate the data from adolescents over sixteen to younger adolescents.¹⁶¹ He claimed that the differences in cognitive maturity between younger and older adolescents argued against extrapolating the results.¹⁶² However, the CDER did not consider differences in cognitive maturity among adolescents or the influence these differences have on behavior in any OTC-switch application prior to the Plan B switch application.¹⁶³

The departures from standard operating procedures and from the advice of the professional evaluation staff suggest that the Acting Director of the CDER made his decision on Plan B for non-scientific reasons. Though the FDA considered both scientific and non-scientific evidence when deciding whether to approve Plan B for OTC status, it ultimately deferred to non-scientific reasoning when issuing its decision.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at 21–22.

¹⁵⁶ *Id.* at 21.

¹⁵⁷ *Id.* at 21–22.

¹⁵⁸ *Id.* at 5.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 5, 24.

¹⁶¹ *Id.*

¹⁶² *Id.* at 22. The Acting Director of the CDER believed that because cognitive maturity is less developed in younger adolescents, they would be less able to control impulsive behavior, including impulses to engage in risky sexual conduct, if Plan B were available over the counter. *Id.* at 23.

¹⁶³ *Id.* at 22.

C. The FDA's Decision to Allow Plan B Sales Behind-the-Counter

After the FDA denied the initial Plan B prescription-to-OTC switch application, Barr Pharmaceuticals submitted an amended sNDA that addressed both the Acting Director of the CDER's and the FDA's labeling recommendations.¹⁶⁴ The amended sNDA recommended the sale of Plan B over the counter for women aged sixteen and older.¹⁶⁵ After meeting with the FDA, Barr Pharmaceuticals agreed to resubmit the Plan B application using eighteen-and-older guidelines.¹⁶⁶ On August 24, 2006, less than two weeks after Barr Pharmaceuticals agreed to resubmit the application, the FDA approved sales of Plan B to women and men aged eighteen and above without a prescription.¹⁶⁷ The FDA approved Plan B for behind-the-counter sales instead of OTC sales,¹⁶⁸ however, and currently women under eighteen still must have a prescription to purchase the drug.¹⁶⁹

The FDA's approval is not satisfactorily explained by scientific advances, because no reported changes or new discoveries in the safety or efficacy of Plan B prefaced the FDA's reversal.¹⁷⁰ Indeed, the data had not changed. The FDA review staff had already concluded that Plan B was safe and effective for women and young girls.¹⁷¹ Other relevant studies to date showed that access to emergency contraceptives did not increase risky sexual behavior among adolescents.¹⁷² In fact, the FDA chose eighteen as the cut-off age for Plan B because this age is used as the cut-off age for sales of nicotine and cold medicine products.¹⁷³

¹⁶⁴ Aaron Lorenzo, *Plan B Progress Seen as Aid to Von Eschenbach*, BIOWORLD TODAY, Aug. 14, 2006, available at http://www.bioworld.com/servlet/com.accumedia.web.Dispatcher?next=bioworldHeadlines_article&forceid=40421.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ Gardiner Harris, *FDA Approves Broader Access to Next-Day Pill*, N.Y. TIMES, Aug. 25, 2006, at A1.

¹⁶⁸ In July 2006, the FDA told Barr Pharmaceuticals that it might consider approval of Plan B over the counter if the age limit were increased. Jonathan D. Rockoff, *Morning-After Pill Could Be over Counter*, BALTIMORE SUN, Aug. 1, 2006, at A1. After years of delay, the FDA approved Plan B with dual status and the new age limit less than one month later. John Davidson, *Morning-After Pill Gets OTC Approval*, TIMES LEADER (Wilkes-Barre, Pa.), Aug. 25, 2006, at A1.

¹⁶⁹ Davidson, *supra* note 171, at A1.

¹⁷⁰ Articles reporting the FDA's decision did not cite any new scientific data as the reason why OTC availability of Plan B was more acceptable in August 2006 than in May 2004 when the FDA issued the not-approvable letter. *See, e.g.*, Stein, *supra* note 90, at A4.

¹⁷¹ Judith Graham, *Plan B Pill Gets OK for Direct Sale*, DAILY PRESS (Newport News, Va.), Aug. 25, 2005, at A1.

¹⁷² *Id.*

¹⁷³ *Finally, on to Plan B: Controversial "Morning-After" Pill Helps Prevent Unwanted Pregnancies*, LAS VEGAS SUN, Aug. 28, 2006, at A4 [hereinafter *Finally, on to Plan B*].

The FDA may have changed its position because it was satisfied that Plan B was safe and effective for OTC use for women eighteen and older, but there are skeptics.¹⁷⁴ Some allege that the FDA bowed to political pressure from the White House when originally deciding to issue the not-approvable action letter on the initial and subsequent Plan B prescription-to-OTC switch applications.¹⁷⁵ Others state that the FDA's reversal in the summer of 2006 was also politically motivated. Senators Hillary Rodham Clinton and Patty Murray from New York and Washington, respectively, threatened to stall President Bush's nomination of Andrew von Eschenbach for the position of FDA Commissioner.¹⁷⁶ The Senators dropped the hold when the FDA issued its approvable decision on Barr Pharmaceutical's most recent sNDA for a Plan B OTC switch for women aged eighteen and older.¹⁷⁷

Political factors similar to those that influenced the FDA approval process for RU-486 also directed the approval process for the Plan B prescription-to-OTC switch application. The two drugs *are* different: Plan B works by preventing an unplanned pregnancy, while RU-486 contains mifepristone, which induces abortions by interrupting and terminating an established pregnancy.¹⁷⁸ RU-486's success rate exceeds ninety-five percent when it is used with a second drug that induces contractions.¹⁷⁹ One writer stated that "[p]olitical opposition to RU 486 in the United States has prevented its availability as a medical abortifacient in this country."¹⁸⁰ Another author suggested that the FDA would not approve clinical trials for RU-486 because the first Bush administration objected to abortion.¹⁸¹ Consequently, pharmaceutical companies declined to begin the approval process.¹⁸² Similarly, yet another author stated that the major concern with RU-486 was the drug's potential to erode the power of pro-life groups to control access to abortions.¹⁸³ The FDA ultimately approved RU-486 for prescription-use in 2000.¹⁸⁴

¹⁷⁴ See, e.g., Editorial, *FDA Chokes on "Plan B" Pill: Morning-After Pill Becomes Political Football*, PHILA. DAILY NEWS, Aug. 3, 2006, at 15; Stephanie Saul, *F.D.A. Shifts View on Next-Day Pill*, N.Y. TIMES, Aug. 1, 2006, at A1.

¹⁷⁵ See *Finally, on to Plan B*, *supra* note 176, at A4.

¹⁷⁶ See Graham, *supra* note 174, at A1; see also Lorenzo, *supra* note 167.

¹⁷⁷ *Conservative Group Hunts Senators to Thwart Vote for FDA Head*, FDA WEEKLY, Sept. 1, 2006 (on file with the *William & Mary Bill of Rights Journal*).

¹⁷⁸ See Segal, *supra* note 55, at 464; see also *60 Minutes: The Debate over Plan B* (CBS television broadcast June 11, 2006) (transcript available at <http://www.cbsnews.com/stories/2005/11/22/60minutes/main1068924.shtml>).

¹⁷⁹ See Segal, *supra* note 55, at 464.

¹⁸⁰ *Id.*

¹⁸¹ Mark A. Hernandez, *RU-486; Safe? Effective? Banned! Why Would the Food and Drug Administration Ban a Drug with Such Potential?*, 11 DICK. J. INT'L L. 653, 668 (1993).

¹⁸² *Id.*

¹⁸³ Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 573 (2001).

¹⁸⁴ See RU-486 Approval Letter, *supra* note 152.

Prior to 2000, the FDA did not approve RU-486 for use as an abortifacient, but it did allow the drug to be used as treatment for another medical condition. One author noted that the FDA denied “a twenty-nine year-old woman a ninety-six percent proven effective means of nonsurgical abortion while allowing a middle age man access to the drug [RU-486] for a use that is essentially speculative [battling brain tumors].”¹⁸⁵ This example illustrates that the FDA approval process can become inconsistent when it is subject to external pressure that restricts its ability to approve safe and effective products. So what can the American public do? The next part of this Note will explain in more detail the proposition that individuals should be able to challenge the FDA approval process, and it will suggest the types of limited situations in which they can exercise this right.

III. CHALLENGING THE FDA

A. *The Role of the Administrative Agency*

Moral judgment is a legitimate reason for the government to ban products or outlaw certain behavior.¹⁸⁶ Moral judgments are a method of constitutional decision-making, and many of our past and present federal and state laws are based on moral and religious values.¹⁸⁷ However, moral judgment should not play any role in the FDA’s decisionmaking process.

The role of the FDA is not to legislate, but to evaluate and approve products that meet the standards of safety and efficacy.¹⁸⁸ Recently, the FDA disregarded moral issues in the face of controversial concerns over enhancement biotechnologies. For example, in 2002 Eli Lilly submitted an NDA for Humatrope, a human growth hormone (HGH) drug that could be used on abnormally short children.¹⁸⁹ These children were not deficient in HGH, but the FDA only considered whether the drug was safe and effective for non-growth hormone deficiency.¹⁹⁰ Even though there were ethical concerns with enhancement biotechnologies, excerpts from the clinical review and advisory committee deliberations showed that “it [was] not possible for the Agency to incorporate [moral] thinking into its final decision-making [sic] process, for there

¹⁸⁵ Claire L. Ahren, Note, *Drug Approval in the United States and England: A Question of Medical Safety or Moral Persuasion?—The RU-486 Example*, 17 SUFFOLK TRANSNAT’L L. REV. 93, 109 (1994).

¹⁸⁶ Marriage laws, obscenity laws, and abortion laws are examples of the numerous types of moral legislation in the United States. See 1 U.S.C. § 7 (2000); 18 U.S.C. §§ 1460–70 (2000); 18 U.S.C. § 1531 (Supp. IV 2004).

¹⁸⁷ See sources cited note 186.

¹⁸⁸ 21 U.S.C. § 355(b)(1) (Supp. IV 2004).

¹⁸⁹ See Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135, 1180–81 (2005).

¹⁹⁰ *Id.* at 1180.

is no system or precedent which would allow it.”¹⁹¹ In contrast, the FDA discounted scientific evidence of safety and efficacy in consideration of ethical or moral concerns with Plan B, thus abrogating its delegated authority.¹⁹²

American citizens should be able to challenge the FDA when non-scientific influences dominate the approval process. First, because high-level FDA officials are appointed and insulated from the political process, they should be held legally accountable for exceeding the scope of their authority. Second, affected citizens should have the opportunity to challenge the validity of suspect decisions, such as the Plan B decision. The goal of allowing challenges is to prevent history from repeating itself with other scientifically proven but ethically controversial drugs that have yet to come before the FDA.

B. The Standing Problem: The Gateway to Challenging the FDA

The law provides private individuals with little recourse to the courts if the FDA disapproves or withholds approval of a drug. The FDCA allows an applicant to appeal the FDA’s order on a new drug application to the United States Court of Appeals for the district of the applicant’s residence or principal place of business within sixty days.¹⁹³ The HHS Secretary must provide the court with the administrative record of the decision.¹⁹⁴ The court then has exclusive jurisdiction to affirm or set aside the order.¹⁹⁵ The FDCA implies that applicants must exhaust internal administrative remedies before appealing to the court.¹⁹⁶ The FDCA also places the burden of persuasion on the plaintiff-applicant; the text states that the HHS Secretary’s findings are conclusive if they are supported by substantial evidence.¹⁹⁷

The general tendency is to foreclose judicial review for private individuals because they lack standing. The FDCA makes no reference to a private cause of action for private individuals—that is, potential *consumers*—who would be affected by the FDA’s approval or disapproval of the drug.¹⁹⁸ Therefore, consumers must satisfy standing requirements to challenge the FDA.

For example, in *Duncan v. United States*, the United States District Court for the Western District of Oklahoma held that private individuals who sued the HHS Secretary for prohibiting the use of a drug that would ostensibly treat their daughter’s

¹⁹¹ *Id.* at 1181.

¹⁹² *See supra* text accompanying note 161.

¹⁹³ 21 U.S.C. § 355(h) (2000).

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.* The exact text of the statute reads as follows: “No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure to do so.” *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *See id.*

Down Syndrome did so without standing.¹⁹⁹ The court said that the FDCA allowed anyone, even private individuals, to file an NDA with the FDA for the approval of a new drug.²⁰⁰ The court said that the plaintiffs had not exhausted their administrative remedies because the plaintiffs had not shown a good faith attempt to comply with the administrative procedures.²⁰¹ The court said that the plaintiffs could have submitted an NDA, which they had not done, and then, if the FDA rejected their NDA, they could have filed an appeal against the FDA if the FDA rejected their NDA.²⁰² The fact that an average individual is exceedingly unlikely to be in a position—financial or otherwise—to either conceive of the product or to submit an NDA with the FDA was not lost on the *Duncan* court, but the court felt constrained in its ability to alter what it considered to be a constitutionally valid procedure.²⁰³

Thus, as *Duncan* suggests, standing via administrative exhaustion is the critical issue in any suit against the FDA.²⁰⁴ Administrative exhaustion is not an inflexible command, however, and it may be circumvented in certain situations. Though section 355(h) of the FDCA requires exhaustion,²⁰⁵ courts recognize multiple exceptions to the exhaustion doctrine. In his concurring opinion in *Woodford v. Ngo*, Justice Breyer noted that constitutional claims, futility, hardship, and inadequate or unavailable remedies are exceptions to exhaustion.²⁰⁶ The *McCarthy v. Madigan* court also recognized three broad categories of exceptions to the exhaustion doctrine, namely when (1) exhaustion would result in undue prejudice to subsequent court action, including when there is an unreasonable or indefinite timetable for agency action; (2) the agency does not have the power to grant the relief requested; and, (3) the agency is biased or has predetermined the issue.²⁰⁷

¹⁹⁹ 590 F. Supp. 39, 42 (W.D. Okla. 1984).

²⁰⁰ *Id.* at 41–42 (citing the FDCA).

²⁰¹ *Id.* at 43. The court specifically stated that “[t]he fact that compliance might be expensive and burdensome is not unfairness in the procedure.” *Id.* (quoting *Rutherford v. Am. Med. Assoc.*, 379 F.2d 641, 643 (7th Cir. 1967)).

²⁰² *Id.* at 42.

²⁰³ *Id.* at 44. The *Duncan* court revealed its position when it stated:

The court is concerned that the statutory scheme involved in gaining approval for a new drug application may involve costs which are so substantial as to cause plaintiff and persons similarly situated to forego compliance with 21 U.S.C. § 355(b). However, that scheme is constitutional as an exercise of Congress’ power to set standards in order to protect the public from unsafe drugs

Id. (quoting *Gadler v. United States*, 425 F. Supp. 244, 248 (D. Minn. 1977)).

²⁰⁴ To be sure, administrative exhaustion has many virtues, including preserving administrative autonomy, see *McCarthy v. Madigan*, 503 U.S. 140, 145 (1992), and aiding judicial efficiency, example given, *Woodford v. Ngo*, 126 S. Ct. 2378, 2385 (2006).

²⁰⁵ The text states that “[n]o objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure to do so.” 21 U.S.C. § 355(h) (2000).

²⁰⁶ *Woodford*, 126 S. Ct. at 2393 (Breyer, J., concurring).

²⁰⁷ *McCarthy*, 503 U.S. at 146–48. 42 U.S.C. § 1997(e) superseded *McCarthy* with respect

Finally, consumers have standing and can bypass some of the requirements of administrative exhaustion when the FDA delays acting on a citizen petition within the requisite timeframe. The Code of Federal Regulations allows private individuals to challenge the FDA through a citizen petition.²⁰⁸ Moreover, the FDA specifically authorizes interested individuals to file a citizen petition or sNDA to request an OTC switch for an approved prescription drug.²⁰⁹ When the citizen petition is filed, the FDA Commissioner must respond to each petitioner within 180 days.²¹⁰ The FDA must approve or deny the petition, or it must issue a tentative response.²¹¹ For example, the FDA can state that the agency has not yet made a decision, explain the reasons why it has not done so, and provide the probable response.²¹² In *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach (Abigail I)*, a non-profit agency representing terminally ill patients filed a citizen petition challenging an FDA policy that prohibited the sale of investigational new drugs deemed safe for expanded human testing.²¹³ The court did not question the petitioner's standing to challenge the FDA.²¹⁴ The FDA had failed to respond to the citizen petition within the 180 days prescribed by regulation, entitling the non-profit to seek judicial review of the challenged policy because they had effectively exhausted administrative remedies.²¹⁵ Consumers may be able to apply any one of these exceptions to gain standing and bypass exhaustion in a suit against FDA officials for failure to issue a decision on Plan B or any similar drug.

However, besides exhausting administrative remedies or meeting one of the recognized exceptions to exhaustion, courts have found that *consumers* have constitutional and prudential standing to challenge agency actions in federal court.²¹⁶ Constitutional standing under Article III has three elements.²¹⁷ First, the plaintiff must show injury or the threat of injury.²¹⁸ Second, the agency must have caused the injury or threat of injury.²¹⁹ Third, the court has to be able to remedy the injury.²²⁰ In addition to constitutional standing, plaintiffs challenging FDA decisionmaking must meet the requirements for prudential standing.²²¹ A prospective plaintiff meets these requirements

to federal prisoners. Section 1997(e) expressly mandates that federal prisoners must exhaust their administrative remedies. 42 U.S.C. § 1997(e) (2000).

²⁰⁸ 21 C.F.R. § 10.30(a) (2007).

²⁰⁹ *Id.* § 310.200(b).

²¹⁰ *Id.* § 10.30(e)(2).

²¹¹ *Id.*

²¹² *Id.*

²¹³ 445 F.3d 470, 471–73, (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007) (holding that terminally ill individuals have no fundamental right to access investigational drugs).

²¹⁴ *See id.* at 473.

²¹⁵ *Id.*

²¹⁶ *See Barnes v. Shalala*, 865 F. Supp. 550 (W.D. Wis. 1994).

²¹⁷ *Id.* at 558.

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.*

by showing that he or she is an individual to whom the relevant statute applies.²²² In *Barnes*, the court found that consumers had both constitutional and prudential standing to challenge the FDA's approval of bovine growth hormone because they met the three aforementioned factors.²²³

C. A Constitutional Claim: The Fundamental Right of Privacy

According to Justice Breyer's concurrence in *Woodford*, consumers with a constitutional claim could circumvent the exhaustion problem posed in *Duncan*.²²⁴ Potentially, consumers could base a constitutional claim on the fundamental right of privacy,²²⁵ but consumers may still find it hard to petition the court for review of an FDA decision on the approval process based on this right.²²⁶

In *Carnohan v. United States*, the Ninth Circuit held that a cancer patient had to exhaust his administrative remedies by filing an NDA before the court would entertain his constitutional claim.²²⁷ The plaintiff was a cancer patient who petitioned the court for a declaratory judgment that laetrile was not a new drug so that he would not have to go through the approval process.²²⁸ The FDA Commissioner decided previously that laetrile was a new drug.²²⁹ The plaintiff argued that the administrative process of filing a new drug application would create a substantial burden that would infringe upon his constitutional rights.²³⁰ The court noted that "[c]onstitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of government police power."²³¹ The Ninth Circuit affirmed the district court's dismissal of the plaintiff's motion for declaratory judgment, noting that individuals must exhaust their administrative remedies first.²³²

The D.C. Circuit continued this reasoning recently in *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach (Abigail II)*.²³³ The court affirmed

²²² 5 U.S.C. § 702 (2000) states that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof."

²²³ *Barnes*, 865 F. Supp. at 560–61.

²²⁴ *Woodford v. Ngo*, 126 S. Ct. 2378, 2393 (2006) (Breyer, J., concurring).

²²⁵ *See supra* Part I.A.

²²⁶ *See, e.g., Duncan v. United States*, 590 F. Supp. 39, 42 (W.D. Okla. 1984) (denying petitioners standing under the exhaustion requirement without considering standing under any constitutional rights).

²²⁷ 616 F.2d 1120, 1122 (9th Cir. 1980).

²²⁸ *Id.* at 1121–22.

²²⁹ *Id.* at 1121.

²³⁰ *Id.* at 1122.

²³¹ *Id.*

²³² *Id.*

²³³ No. 04-5350, 2007 WL 2238914, at *13 (D.C. Cir. Aug. 7, 2007) (Ginsburg, J., dissenting). The appellants in *Abigail II* filed suit on behalf of terminally ill patients for the right to access potentially life-saving drugs still in the investigational phase. *Id.* at *1.

the district court's dismissal of the plaintiffs' claim, stating that access to investigational new drugs is not a fundamental right under the Fifth Amendment.²³⁴ In making this determination, the court concluded that access to new drugs was not rooted in the nation's history and traditions.²³⁵ The right that would be asserted in any Plan B challenge would be fundamentally different than the rights asserted in both *Carnohan* and *Abigail II*, however. Plan B plaintiffs would likely argue for access based on the fundamental right of privacy. *Griswold v. Connecticut* and its progeny firmly established this fundamental right.²³⁶ Therefore, because of the robust history behind the constitutional right of privacy concerning the decision whether to bear children,²³⁷ it is likely that a constitutional claim could be found in any case analogous to the Plan B decision.

Consumers challenging the FDA's decision to deny unrestricted OTC sales of emergency contraceptives are as equally well-positioned as the dairy consumers in *Barnes* to have standing to challenge FDA actions. Consumers of Plan B have convincing evidence of injury or the threat of injury. First, consumers who could have purchased Plan B over the counter during the time of the FDA's delay and used it to prevent unwanted pregnancies would satisfy the injury or threat of injury requirement for constitutional standing. Second, these consumers would be able to show that the FDA's constructive denial of OTC Plan B caused the risk of physical or mental injury brought on by an unplanned or unwanted pregnancy. Finally, though a court is not able to order that the FDA approve a drug,²³⁸ a court can compel an agency official to perform his or her duty.²³⁹ In other words, a court could order an FDA official to follow the regulations that prescribe a timeline for decisionmaking and to definitively rule on a drug application.

The FDA's decision to approve Plan B for restricted OTC use—that is, behind-the-counter use—*is* forward progress in Americans' rights to contraceptive freedom and freedom from government intrusion in the bedroom. However, plaintiffs should be able to base a private right of action against the FDA on the fundamental right of privacy because of the FDA's unreasonable delay in issuing a decision and the FDA's decision to allow only *behind*-the-counter sales of Plan B, which requires the purchaser to show proof of identity. As litigants, potential consumers would fight to extend the

²³⁴ *Id.* at *11.

²³⁵ *Id.* Despite its holding, the *Abigail II* court did not answer the “broader question of whether access to medicine might *ever* implicate fundamental rights.” *Id.* at *4 (emphasis added).

²³⁶ *See supra* Part I.A.

²³⁷ *See, e.g.,* *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) (reviewing the cases upholding the right to bear children as a Due Process liberty interest and holding that physician-assisted suicide is not a fundamental right under the Due Process Clause); *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942) (applying strict scrutiny to Oklahoma's sterilization laws and reversing the Supreme Court of Oklahoma's order that the defendant undergo a vasectomy).

²³⁸ *Hanson v. United States*, 417 F. Supp. 30, 37 (D. Minn. 1976).

²³⁹ 28 U.S.C. § 1361 (2000).

right of privacy in the bedroom into the public arena for the purposes of access to and purchase of Plan B and similar drugs.

Thirty-two years ago, the Supreme Court decided *Griswold v. Connecticut*, championing a married couple's right to access contraceptives based on an enhanced version of the fundamental right of privacy.²⁴⁰ *Griswold* relied on several different constitutional amendments, including the First, Third, Fourth, Fifth, Ninth, and Fourteenth Amendments.²⁴¹ Therefore, potential consumers of OTC emergency contraceptives should base their claims on the Due Process Clause of the Fifth Amendment²⁴² in suits against the FDA when the FDA improperly rules against the approval of a new drug or against the prescription-to-OTC switch of an already approved drug, provided the drug is safe and effective for use as evidenced by adequate clinical trials and studies.

D. Administrative Law Requirements

As a preliminary issue, not all drug products are covered by the umbrella of a constitutional claim like Plan B is, but other methods to challenge the FDA, such as exhaustion, could be used to bypass administrative law requirements.

As mentioned by Justice Breyer in *Woodford*, futility is an exception to the need to exhaust administrative remedies.²⁴³ The *McCarthy* court also excused the failure to exhaust on account of bias.²⁴⁴ In fact, bias and futility work together to create an alternative for an effective exhaustion of administrative remedies. The existence of bias creates an exemption from the exhaustion of administrative remedies, for it would be futile for an individual to petition a biased entity. Two cases are instructive here, although they deal with state administrative proceedings.²⁴⁵ In *Gibson v. Berryhill*, the Court affirmed that a state administrative agency was biased when it acted as a judge and prosecutor in the revocation proceedings for multiple optometrist licenses.²⁴⁶ Similarly, in *Kelly v. Board of Education*, the court declined to require the plaintiffs

²⁴⁰ 381 U.S. 479, 485–86 (1965). For a brief summary of *Griswold* and its place in the evolution of contraceptive rights in America, see *supra* text accompanying notes 18–25.

²⁴¹ *Griswold*, 381 U.S. at 484–85.

²⁴² U.S. CONST. amend. V. The Fifth Amendment states that “[n]o person shall . . . be deprived of life, liberty, or property, without due process of law.” *Id.*

²⁴³ *Woodford v. Ngo*, 126 S. Ct. 2378, 2393 (2006) (Breyer, J., concurring).

²⁴⁴ *McCarthy v. Madigan*, 503 U.S. 140, 148–49 (1992).

²⁴⁵ *Gibson v. Berryhill*, 411 U.S. 564 (1973); *Kelly v. Bd. of Educ.*, 159 F. Supp. 272 (M.D. Tenn. 1958).

²⁴⁶ The *Gibson* Court affirmed the district court's conclusion that the Alabama Board of Optometry was biased because it previously filed a complaint in state court against the plaintiffs on charges substantially similar to the charges pending in the administrative proceeding. 411 U.S. at 578. First, the Court concluded that the administrative agency prejudged the issue. *Id.* Second, the Court found that the administrative agency had a personal interest in the outcome of the proceeding because the members of the Alabama Board of Optometry were optometrists working in private practice who could benefit from revoking the licenses of all optometrists working for business corporations in Alabama. *Id.*

to exhaust administrative remedies because the administrative remedy, failing a petition with a biased school board for admission or transfer, would be futile.²⁴⁷

Despite the fact that these cases are concerned specifically with state actions, they demonstrate that Plan B plaintiffs could be exempt from the need to exhaust administrative remedies because the FDA effectively foreclosed non-scientific decisionmaking. The same could apply to any plaintiffs in an analogous situation. Ergo, the Plan B plaintiffs or their corollaries in an analogous lawsuit would be better served by filing suit in district court for injunctive relief. When impartial decisionmaking is stonewalled, attempting to exhaust administrative procedures is an inefficient use of resources and ultimately futile.

Plaintiffs do not need to exhaust their administrative remedies if there is unreasonable delay.²⁴⁸ The Supreme Court noted that unreasonable delay can constitute a violation of due process.²⁴⁹ In *Smith v. Illinois Bell Telephone Co.*, Illinois Bell filed suit against the Illinois Commerce Commission and the Illinois Attorney General, seeking an injunction against the enforcement of the current rate schedule after Illinois Bell submitted a higher rate schedule.²⁵⁰ When the district court granted the injunction, the Illinois Commerce Commission and the Illinois Attorney General appealed,²⁵¹ claiming that Illinois Bell did not exhaust its legislative remedies.²⁵² The Supreme Court found that the Illinois Commerce Commission delayed issuing a decision on the proposed rate increases for two years.²⁵³ Therefore, the Supreme Court allowed Illinois Bell

²⁴⁷ 159 F. Supp. at 276. In *Kelly*, African American children and their parents filed a class action against the Nashville Board of Education, asserting the children's constitutional right to attend public schools. *Id.* at 273. The Nashville Board of Education's desegregation plan allowed for a gradual integration beginning with first-grade students only. *Id.* at 274. The plan also allowed parents to transfer students and called for further studies to determine the next steps for integration. *Id.* The court stated that the proposed administrative remedies were inadequate and refused to grant the defendant's motion to dismiss for the plaintiff's failure to exhaust administrative remedies. *Id.* at 276. However, though the court found the defendant's plan unconstitutional, it gave the defendant time to devise a new desegregation plan. *Id.* at 278-79.

²⁴⁸ *E.g.*, *Gibson*, 411 U.S. at 574-75 (recognizing that unreasonable delay, bias, and the inability to grant effective relief are three exceptions to exhaustion, and affirming that the plaintiffs did not have to wait until the Alabama Board of Optometry exhausted its administrative remedies before filing suit in federal court for an injunction against the revocation of their optometrist licenses); *Smith v. Ill. Bell Tel. Co.*, 270 U.S. 587, 590-92 (1926) (finding that unreasonable delay can constitute a violation of due process).

²⁴⁹ *Smith*, 270 U.S. at 590-92.

²⁵⁰ *Id.* at 588.

²⁵¹ *Id.*

²⁵² *Id.* at 590.

²⁵³ *Id.* at 589. The Supreme Court remarked upon the Illinois Commerce Commission's delay in approving or rejecting the proposed rate increase:

It thus appears that . . . the commission, for a period of two years, remained practically dormant; and nothing in the circumstances suggests that it had any intention of going further with the matter. For this

to seek judicial review for an injunction that would allow it to use the proposed rate schedule despite the Illinois Commerce Commission Company's failure to act.²⁵⁴

Each of the examples listed above provides consumers with another method of circumventing the standing and exhaustion requirements in *Duncan*, should the FDA stonewall a controversial drug—including Plan B, but not limited to Plan B or even to emergency contraceptives generally.

E. Objections to Administrative and Constitutionally-Based Private Rights of Action

Some of the cases mentioned in the preceding section, especially *Duncan*, illustrate situations in which the courts denied an individual's right to a private cause of action against the FDA.²⁵⁵ One of the main objections by the *Duncan* court was the individual plaintiff's lack of standing to challenge the FDA.²⁵⁶ However, as suggested earlier in this Note, individual plaintiffs should be able to circumvent the standing requirement to challenge the FDA approval process in one of several ways.²⁵⁷ First, private individuals join with others to finance and submit an NDA with the FDA.²⁵⁸ Second, private individuals could join a citizen petition to request a switch for an approved prescription drug product, and the FDA would be obliged to respond.²⁵⁹ Lastly, private individuals could get around the exhaustion requirement by seeking an exception to exhaustion, including the constitutional claim exception, the futility and bias exceptions, and the unreasonable delay exception.²⁶⁰

Opponents of a broad standard of judicial review will argue against allowing private individuals standing and exemptions from exhaustion under any of the foregoing scenarios. First, opponents of a private right of action will argue that allowing judicial review of agency actions in those scenarios would be too broad.²⁶¹ What

apparent neglect on the part of the commission, no reason or excuse has been given . . . Property may be as effectively taken by long-continued and unreasonable delay . . . as by an express affirmance . . . and where, in that respect, such a state of facts is disclosed as we have here, the injured public service company is not required indefinitely to await a decision of the rate-making tribunal before applying to a federal court for equitable relief.

Id. at 591–92.

²⁵⁴ *Id.*

²⁵⁵ *See supra* Part III.B.

²⁵⁶ *Duncan v. United States*, 590 F. Supp. 39, 42 (W.D. Okla. 1984).

²⁵⁷ *See supra* text accompanying notes 209–10.

²⁵⁸ *See supra* text accompanying note 203.

²⁵⁹ *See supra* text accompanying notes 211–14.

²⁶⁰ *See supra* Part III.B.

²⁶¹ *See, e.g.*, Frank B. Cross, *Shattering the Fragile Case for Judicial Review of Rulemaking*, 85 VA. L. REV. 1243, 1244–45 (1999) (arguing that judicial review of administrative decisions is an illegitimate power grab by the courts).

this objection fails to consider, however, is that judicial review would be tailored and limited to situations in which both the safety and effectiveness of the drug *and* the consumer's good faith effort to comply with the administrative procedure or valid exemption are shown. Opponents cannot argue that *all* drugs meet these two threshold requirements. First, showing a product's safety and effectiveness is a high bar to meet because reliable studies, clinical trials, and data must support these conclusions. Second, it is complicated for consumers to show a good faith effort to comply with administrative procedure because it implies that the consumers have the foresight to submit an NDA, join a citizen petition, or document a valid exemption. Therefore, the existence of these two thresholds limits litigation to the type of drug this individual right of action is designed to protect—namely, to drugs like Plan B that are proven to be safe and effective but that are also highly controversial.

A second objection opponents might raise is that a private right of action unnecessarily challenges agency authority. However, this could be refuted by requiring the consumer to demonstrate evidence of the agency's bad faith. Consumers should be able to create an implication of the agency's bad faith by presenting evidence of the product's safety and effectiveness.²⁶² Departures from an agency's standard operating procedures in the approval process could provide evidence of the agency's bad faith as well.²⁶³ In either case, the challenge to agency authority would be appropriate, and it would allow reviewing courts to check the power of administrative agencies that exceed their statutory authority.

Opponents might object to allowing private causes of action because of the delays it would cause in the agency's decisionmaking process. However, this objection would not always be applicable. In the case of Plan B, the agency itself created the delay; the lawsuit did not.²⁶⁴ Rather, filing a lawsuit is an appropriate means of compelling an agency decision, so the courts would be providing a remedy for existing delay.²⁶⁵ Opponents might counter that any delay on the agency's part is justifiable because of the number of applicants or the need to thoroughly review the complex clinical trials and studies. If that is the case, there will be no conflict; a court will conclude that such a delay would not be *unreasonable*, and it would dismiss the consumer's lawsuit.

Lastly, opponents might object to a private right of action because it would require courts to serve as scientific arbiters.²⁶⁶ In general, judges are not scientific and technical experts, but agencies like the FDA hire expert staff to specifically evaluate drugs and recommend decisions. Opponents would argue that courts should defer to the agency

²⁶² See, e.g., J. Roland Pennock, *Judicial Control of Administrative Decisions*, 221 ANNALS AM. ACAD. POL. & SOC. SCI. 183, 188 (1942) (building on the theory of fair procedure).

²⁶³ See *id.*

²⁶⁴ See *supra* Part II.B.

²⁶⁵ See generally Steven Goldman, *Administrative Delay and Judicial Relief*, 66 MICH. L. REV. 1423 (1968) (promoting judicial review as a remedy for administrative delays that is removed from the influence of wealth and political power).

²⁶⁶ See, e.g., Thomas O. McGarity, *Judicial Review of Scientific Rulemaking*, 9 SCI. TECH. & HUM. VALUES 97, 97–98 (1984).

and its specific expertise for this reason alone. Although it is true that most judges do not have particularized scientific expertise, they *are* experts at making legal and factual conclusions based on the evidence presented. And in most cases, judges would not evaluate the effectiveness of a product by examining the drug's composition and its supporting trials and studies. Instead, as in the case of Plan B, the court would determine whether the agency's conduct was appropriate by looking at the procedural process.²⁶⁷ If the deviations from standard operating procedure are significant, the courts may remand an agency's decision. Likewise, if individual constitutional rights are unduly trampled, the courts may remand an agency's decision. Courts are well-equipped to make these types of decisions.

F. Looking Forward: The Tummino Case

*Tummino v. Von Eschenbach*²⁶⁸ is a recent example of the struggle for the right to challenge administrative agency action in court. *Tummino* began when individual women and reproductive rights organizations filed a lawsuit asking for judicial review of the FDA's actions concerning Plan B OTC switch applications against the Acting Commissioner of the FDA.²⁶⁹ Originally, the plaintiffs wanted several forms of relief:

- (1) an injunction requiring the FDA to approve OTC access to Plan B, (2) a judgment declaring that the FDA's denial of OTC access to persons of all ages violates the APA and the United States Constitution, and (3) if the court finds the FDA has not taken final action, a judgment declaring that the FDA has unlawfully withheld or unreasonably delayed issuing such a final decision, in violation of the APA and the United States Constitution, and an order requiring the FDA to issue a final decision on OTC access to Plan B.²⁷⁰

In response, the FDA submitted a motion for a protective order and a motion for judgment on the pleadings.²⁷¹ The judge denied the FDA's motion for judgment on the pleadings with respect to the plaintiffs' unreasonable delay claim and reserved decision as to the remainder of the plaintiffs' claims.²⁷² The court did not decide whether OTC access for Plan B was appropriate.²⁷³ At the time of this Note's publication, the court had responded to the FDA's motion for a protective order against the plaintiffs' discovery requests and planned depositions of present and former FDA

²⁶⁷ See, e.g., Donald W. Crowley, *Judicial Review of Administrative Agencies: Does the Type of Agency Matter?*, 40 W. POL. Q. 265, 265 (1987).

²⁶⁸ 427 F. Supp. 2d 212 (E.D.N.Y. 2006) (order denying defendant's motion for a protective order and granting discovery).

²⁶⁹ *Id.* at 215.

²⁷⁰ *Id.* at 216.

²⁷¹ *Id.*

²⁷² *Id.*

²⁷³ *Id.* at 232.

officials²⁷⁴ by denying the FDA's motion for a protective order.²⁷⁵ It found that the plaintiffs were entitled to discovery that was broader than the administrative record compiled by the FDA and that due to the nature of the claim—the fact that the FDA was accused of unreasonable delay in rendering a decision on the Plan B OTC switch application—the court needed to look at evidence outside the record to determine whether the delay was reasonable.²⁷⁶ The plaintiffs' suggestion that the FDA acted in bad faith with respect to the Plan B applications elicited the court's order.²⁷⁷

The plaintiffs based their original claims on two sources: the Administrative Procedure Act (APA) and the Constitution.²⁷⁸

1. *Tummino's* Unreasonable Delay Claim²⁷⁹

The APA provides guidelines for judicial review of administrative agencies.²⁸⁰ Under the APA, a reviewing court has the authority to “compel agency action

²⁷⁴ *Id.* at 216.

²⁷⁵ *Id.* at 235.

²⁷⁶ *Id.* at 230–31.

²⁷⁷ *Id.*

²⁷⁸ *Id.* at 215.

²⁷⁹ The *Tummino* plaintiffs amended their complaint after the February 2006 discovery order. Compare 3d Amended Complaint at ¶ 1, *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212 (E.D.N.Y. 2006) (No. CV-05-0366) with 5th Amended Complaint at ¶ 1, *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212 (E.D.N.Y. 2006) (No. CV-05-0366). In its most recent form from October 2006, the complaint reiterates the *Tummino* plaintiffs' standing to challenge the FDA based on the FDA regulation that authorizes interested individuals to file citizen petitions to request OTC switches for prescription drugs. 5th Amended Complaint at ¶ 35, *Tummino*, 427 F. Supp. 2d 212 (No. CV-05-0366) (citing 21 C.F.R. §§ 310.200(b) & 10.30(e)(2)). The *Tummino* plaintiffs continue to argue that the FDA violated the APA and the Constitution by denying OTC access to Plan B for all ages and by approving Plan B behind-the-counter sales. *Id.* at ¶ 1. They assert that the FDA violated the constitutional rights of privacy and equal protection under the Fifth Amendment. *Id.* at ¶¶ 167, 169. Furthermore, they also state that the FDA's actions were arbitrary, capricious, an abuse of discretion, and that the FDA exceeded its statutory authority. *Id.* at ¶¶ 153, 165. The *Tummino* plaintiffs adjusted their prayer for relief, however, to reflect the removal of the unreasonable delay cause of action. Instead, the *Tummino* plaintiffs request injunctive relief in the form of Plan B OTC approval for women of all ages, a declaratory judgment that the FDA's denial of OTC access to Plan B violated the APA and the Constitution, and other equitable relief. *Id.* at ¶ 1. The *Tummino* plaintiffs do cite the FDA's unreasonable delay as evidence of bad faith and improper agency action. *Id.* at ¶¶ 148–57, 160.

²⁸⁰ 5 U.S.C. § 706 (2000). Under the APA, unreasonable delay is one foundation for a cause of action against a government organization or its employees. *See id.* § 706(1). Other possible foundations under the APA include arbitrary or capricious findings, *id.* § 706(2)(A), decisions that violate constitutional rights or privileges, *id.* § 706(2)(B), decisions outside the scope of the agency's authority, *id.* § 706(2)(C), decisions made without regard to statutorily-prescribed procedure, *id.* § 706(2)(D), decisions unsupported by substantial evidence, *id.* § 706(2)(E), and factually unwarranted findings, *id.* § 706(2)(F). Given *Tummino*, potential plaintiffs who are part of a citizen petition may also have standing. *See supra* Parts III.B, III.E (discussing the use of a citizen petition as evidence of plaintiffs' good faith efforts).

unlawfully withheld or unreasonably delayed.”²⁸¹ The court echoed the plaintiffs’ suggestion of unreasonable delay when it remarked:

On January 21, 2005, the FDA announced that a decision on Barr’s amended application would be delayed beyond the 180-day period in which it is ordinarily required to act on such an application. Nevertheless, in the ensuing months up through August of 2005, the FDA apparently did nothing to advance the decision-making process, adding but two documents to the administrative record during that entire period.²⁸²

After noting that the plaintiffs’ evidence supported the claim of unreasonable delay, the court reprimanded the FDA for stalling in order to prevent review of its decision.²⁸³ Specifically, the court said that “the actions of the FDA in dealing with the SNDA and the amended SNDA, strongly suggest that the delay is a calculated ‘filibuster’ designed to avoid making a decision subject to judicial review.”²⁸⁴

Unreasonable delay can be an exception to the exhaustion of administrative remedies.²⁸⁵ A situation in which the preliminary evidence points toward approval and where the FDA continually withholds a decision based on non-scientific reasoning could be sufficient for a finding of unreasonable delay.

The *Tummino* plaintiffs originally sought an injunction to compel the FDA to issue a decision on the Plan B application.²⁸⁶ As a practical matter, the plaintiffs’ request for the court to order the FDA to issue a definitive decision on the Plan B application became null when the FDA issued a decision in August 2006 to allow behind-the-counter sales of Plan B without a prescription to women and men aged eighteen and over.²⁸⁷ Now even if the court does find that the FDA unreasonably delayed the decision, it is unable to order specific performance because the requested performance has been performed. This is a less than satisfactory result for two reasons. First, for those who would have preferred an all-or-nothing result, the FDA’s abrupt decision in 2006 created an awkward compromise: *behind*-the-counter sales, not OTC sales,

²⁸¹ 5 U.S.C. § 706(1).

²⁸² *Tummino*, 427 F. Supp. 2d at 225 (citations omitted).

²⁸³ *Id.* at 232.

²⁸⁴ *Id.*

²⁸⁵ *See supra* Part III.D.

²⁸⁶ *Tummino*, 427 F. Supp. 2d at 216.

²⁸⁷ The plaintiffs’ requested remedies included an injunction requiring the FDA to approve Plan B for OTC availability, and, if the court found unreasonable delay, an order requiring the FDA to issue a final decision on OTC availability of Plan B. *See id.* Although the plaintiffs could still receive a judgment stating that the FDA’s actions violated the APA and the Constitution, it would be essentially a symbolic victory, because the practical effect of the judgment—the injunction—would already have been satisfied by the August 2006 decision. *Id.*

for a certain group of women, but not for all women. Second, on a more general level, the FDA's decision was anticlimactic in that it underscored the reality that the FDA, when challenged, can short-circuit accountability by limiting a drug's proposed scope of access. Assuming the FDA had not already issued a decision on Plan B, however, the text of the court's opinion suggests that, given the evidence presented in favor of the plaintiffs' unreasonable delay claim and provided that discovery would later yield no evidence to the contrary, the court would be inclined to require the FDA to issue a final decision on the Plan B OTC switch applications.²⁸⁸

2. *Tummino*'s Constitutional Claim

The *Tummino* plaintiffs presented two constitutional claims in their lawsuit against the FDA.²⁸⁹ The plaintiffs established a link between their claims and the Fifth Amendment of the Constitution, which prohibits an individual's deprivation of liberty without due process of law.²⁹⁰ The plaintiffs claimed that the FDA's delay over Plan B OTC availability infringed on women's right of privacy because the right to contraceptives falls within the scope of privacy rights.²⁹¹ As mentioned earlier, *Eisenstadt* established the idea that an individual's right to contraceptives is based on the fundamental right of privacy.²⁹² Similarly, the APA also permits a cause of action for private individuals whose constitutional rights have been violated.²⁹³ The *Tummino* plaintiffs have a stronger basis from which to argue for a constitutional claim than the plaintiffs in *Carnohan*, *Abigail II*, or *Duncan*.²⁹⁴

3. *Tummino* Summary

Tummino contains significant factual differences from *Duncan*. The *Duncan* court quickly dispatched with the plaintiffs' equal protection claim.²⁹⁵ The *Duncan* plaintiffs were persons with Down Syndrome and their parents or guardians.²⁹⁶ The court stated that this was not a protected class and that there was no discriminatory treatment.²⁹⁷ In *Tummino*, however, the plaintiffs are women or women's organizations advocating

²⁸⁸ The court found a strong preliminary showing of bad faith. *See id.* at 232–33.

²⁸⁹ *Id.* at 215–16.

²⁹⁰ *Id.*; U.S. CONST. amend. V.

²⁹¹ *Tummino*, 427 F. Supp. 2d at 215–16.

²⁹² *See supra* text accompanying notes 26–31.

²⁹³ 5 U.S.C. § 706(2) (2000). The text of the act states that a reviewing court must “hold unlawful and set aside agency action, findings, and conclusions found to be . . . contrary to constitutional right, power, privilege, or immunity.” *Id.*

²⁹⁴ *See supra* Part III.C.

²⁹⁵ *Duncan v. United States*, 590 F. Supp. 39, 41 (W.D. Okla. 1984).

²⁹⁶ *Id.*

²⁹⁷ *Id.*

the approval of a drug designed for use by women only.²⁹⁸ As such, the *Tummino* plaintiffs have a stronger argument that the FDA discriminated based on sex, which is a recognized protected class.²⁹⁹ As it stands, however, the plaintiffs in *Tummino* are unlikely to succeed even if they base their claim on equal protection. Remedies for the plaintiffs' suit include equitable relief, such as an order to compel the FDA to make a decision.³⁰⁰ The equal protection argument based on the plaintiffs' status as women became less compelling when the FDA approved Plan B in August 2006, because now some women *do* have access to Plan B. The *Tummino* plaintiffs continue to challenge the FDA for discrimination based on the FDA's denial of unrestricted OTC access.³⁰¹ The government may still be challenged for discriminating against the young, but in general the State has a stronger interest in protecting and regulating minors.³⁰²

The *Tummino* court did not decide the issue of OTC access to Plan B, and thus it did not confirm the plaintiffs' right to challenge the FDA approval process based on the right of privacy or equal protection. However, the court did validate the plaintiffs' right to challenge the FDA based on a theory of the FDA's unreasonable delay.³⁰³ The *Tummino* plaintiffs dropped this cause of action in their fifth amended complaint.³⁰⁴ Had the FDA continued to delay making a decision on Plan B OTC access, the court may have entered judgment for the plaintiffs on this claim, thereby encouraging a cause of action based on the constitutional right of privacy.

Tummino creates an opening for consumers to challenge the FDA approval process. First, the potential plaintiffs must have standing and evidence of exhaustion or an exception to exhaustion.³⁰⁵ In general, the applicant is allowed to challenge the FDA because he or she is the only one to go through the administrative remedies of filing an NDA and appealing the decision.³⁰⁶ A special exception to standing applies to prescription-to-OTC switch applications by virtue of section 310.200 of the Code of Federal Regulations.³⁰⁷ This statute allows private individuals, including consumers,

²⁹⁸ *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 215 (E.D.N.Y. 2006).

²⁹⁹ See *United States v. Virginia*, 518 U.S. 515, 531–32 (1996); *Reed v. Reed*, 404 U.S. 71, 77 (1971) (holding that an Idaho statute that favored males over females in the administration of estates was unconstitutional).

³⁰⁰ There is a difference between a court that orders the FDA to make a decision and a court that tells the FDA how to decide. Because Congress delegated power to the FDA to determine the safety and efficacy of drugs, the district courts have no role in determining whether the FDA should approve a particular drug. *Hanson v. United States*, 417 F. Supp. 30, 37 (D. Minn. 1976).

³⁰¹ 5th Amended Complaint, *supra* note 282, at ¶¶ 158–59, 170.

³⁰² *E.g.*, *Ayotte v. Planned Parenthood of N. New England*, 126 S. Ct. 961, 966 (2006).

³⁰³ Judge Korman denied the FDA's motion for a judgment on the pleadings insofar as it attacked the plaintiffs' unreasonable delay claim. Judge Korman also expressly authorized discovery with respect to the unreasonable delay claim. *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 216 (E.D.N.Y. 2006).

³⁰⁴ See 5th Amended Complaint, *supra* note 282, at ¶ 1.

³⁰⁵ See *supra* Part III.B.

³⁰⁶ See *id.*

³⁰⁷ 21 C.F.R. § 310.200(b) (2007).

to petition the FDA.³⁰⁸ These petitioners have standing to challenge FDA action or inaction based on the citizen petition.³⁰⁹ Furthermore, applicants are allowed to bypass exhaustion before seeking administrative review in certain situations, and non-applicants should be able to use some of these exceptions, too.³¹⁰ Unreasonable delay, constitutional claims, hardship, futility, and bias are five exceptions to exhaustion.³¹¹

Second, *Tummino* suggests that consumers who want to challenge an FDA decision or lack thereof should base their claims directly on constitutional rights if the FDA's denial or unreasonable delay would deprive them of those rights.³¹² In that situation, a plaintiff would have recourse to the courts to satisfy the due process requirement. Potential plaintiffs' best chances of maintaining a private cause of action against the FDA increase when access to the drug falls under the scope of some recognized right or privilege.³¹³ For example, a potential plaintiff would have a better chance challenging the FDA approval process for a reproductive drug or contraceptive, such as a drug that safely and effectively prevents or even terminates pregnancy, than a drug that safely and effectively hastens death in terminally ill patients, simply because there is no constitutionally recognized right to die or take one's own life.³¹⁴ In fact, it is theoretically possible that manufacturers or even potential consumers of RU-486 could use the Plan B OTC switch application process in support of increased access to RU-486 in the United States.

Finally, a consumer has a better chance of success when the facts are similar to the facts in the Plan B OTC switch application approval process. The *Tummino* plaintiffs have compelling facts, including sound scientific studies showing the safety and efficacy of the drug that are endorsed by a majority of the FDA's review staff and joint advisory committee; repeated delay or denial of the application by the FDA; and, convincing evidence of bad faith on the part of FDA officials making the decision.³¹⁵ "Bad faith" can take several forms, as it did in the Plan B case, including political, moral, or religious reasoning used to deny the application and pressure or influence by high-level management or outside politicians for a specific outcome;³¹⁶ statements by FDA decisionmakers intimating that a decision for the approval of the drug was made before the completion of the review;³¹⁷ resignations of FDA personnel in protest

³⁰⁸ *Id.*

³⁰⁹ *Id.* at § 10.30(e)(2) (explaining the deadline for an agency response and the form required of the response).

³¹⁰ *See supra* Parts III.B–D.

³¹¹ 5 U.S.C. § 706 (2000).

³¹² *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 216 (E.D.N.Y. 2006).

³¹³ *See, e.g., Eisenstadt v. Baird*, 405 U.S. 438, 443 (1972).

³¹⁴ *Washington v. Glucksberg*, 521 U.S. 702, 722–23 (1997) (explaining that the right to assistance in committing suicide is not a fundamental right).

³¹⁵ *See* GAO, *supra* note 116 (examining the FDA's decision process in evaluating Plan B and concluding it was unusual).

³¹⁶ *See, e.g., Stein, supra* note 90, at A4.

³¹⁷ *See* GAO, *supra* note 116, at 21.

over the final decision;³¹⁸ and an abrupt reversal of the FDA's decision from rejection to approval.³¹⁹

CONCLUSION

This Note began by exploring the progress toward increased access to ordinary and emergency contraceptives in the United States.³²⁰ Over the years, challenges based on a constitutional right of privacy allowed individuals to assert their right to contraceptives in a gradual fashion. Securing the right to behind-the-counter access of emergency contraceptives in August 2006 was not easy. Discrepancies emerged early in the FDA approval process for Plan B prescription-to-OTC switch applications.³²¹ Evidence suggests that the FDA chose not to approve a safe and effective product for OTC use by American women, a move which surpassed its statutory delegation of authority.³²²

This Note posited that the American public has a right to challenge the FDA's drug approval process. It also suggested that the FDA improperly violated its duty and obligation to the American public by unreasonably delaying its decision to approve Plan B for OTC use *and* by allowing moral judgments to influence its decisionmaking process. Building on the example of *Tummino v. Von Eschenbach*, this Note outlined a way in which consumers could challenge analogous infringements on their fundamental rights in limited circumstances.³²³

In conclusion, the FDA's recent delay and denial of unrestricted OTC access for Plan B threatens the fundamental right of privacy. The evidence suggests that the FDA based its decisions on the moral judgments and religious convictions held by high-level officials and the high-powered politicians who influenced them. However, *Tummino v. Von Eschenbach* illustrates that the public has the right to challenge the FDA approval process. Consumers should be willing to exercise this right. Not only may challenging the FDA lead to relief on an individual and national scale, it may also, somewhat ironically, restore the integrity of the FDA and public faith in that agency at the same time.

³¹⁸ See, e.g., Marc Kaufman, *FDA Official Quits over Delay on Plan B*, WASH. POST, Sept. 1, 2005, at A8.

³¹⁹ See Stein, *supra* note 90, at A4.

³²⁰ See *supra* Part I.

³²¹ See *supra* Part II.B.

³²² See *id.*

³²³ See *supra* Part III.F.