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LOOKING BEYOND JUDICIAL DEFERENCE
TO AGENCY DISCRETION:
A FUNDAMENTAL RIGHT OF ACCESS TO RU 486?

INTRODUCTION

At New York City's John F. Kennedy International Airport on July 1, 1992, Leona Benten walked off an international flight into a public maelstrom. Six and one-half weeks pregnant, unemployed and single, she carried a small amount of an unapproved French abortifacient known as RU 486.¹ Ms. Benten hoped to use the drug, as prescribed by her physician,² to terminate her pregnancy in the privacy of her home. She sought to use an existing exception to statutory bans on unapproved drugs that allows an individual to import a small amount of an unapproved drug for her personal use while under the supervision of a physician. Nevertheless, upon notifying an agent of the United States Customs Service that she possessed the drug, Ms. Benten was detained by Customs and Food and Drug Administration ("FDA") agents and the drug was seized. Although she sued the Commissioners of the FDA and the Bureau of Customs and, although she prevailed in the District Court for the Eastern District of New York, the United

¹ The name "RU 486" is the manufacturer's internal designation for mifepristone. Different spellings include "RU-486" and "RU486;" this Note employs the spelling used by the inventors. See Michael Klitsch, *Antiprogestins and the Abortion Controversy: A Progress Report*, 23 FAM. PLAN. PERSP. 275 (1991). See generally Rebecca J. Cook, *Antiprogesterin Drugs: Medical and Legal Issues*, 42 MERCER L. REV. 971 (1991); Sarah Ricks, *The New French Abortion Pill: The Moral Property of Women*, 1 YALE J.L. & FEMINISM 75 (1989). See also Martha Minow, *Breaking the Law: Lawyers and Clients in Struggles for Social Change*, 52 U. PITT. L. REV. 723 (1991) (considering ethical issues confronting lawyers interested in challenging existing law using RU 486 hypothetical).

² Dr. Louise Tyrer, Ms. Benten's physician, is a prominent obstetrician/gynecologist licensed to practice medicine in California and Nevada. She was well-qualified to examine Ms. Benten and to recommend, prescribe and supervise Ms. Benten's use of RU 486. Under the FDA's regulations, unapproved drugs may be imported for personal use with the advice and supervision of a physician. See *infra* notes 97-105 and accompanying text.

States Court of Appeals for the Second Circuit granted a stay of the district court decision, and the United States Supreme Court refused to vacate the stay.³ Ultimately, Ms. Benten was unable to use RU 486 and underwent a surgical abortion.

RU 486 had already been recognized by members of Congress,⁴ state and city governments,⁵ physicians,⁶ pro-choice

³ See *infra* notes 115-33 and accompanying text.

⁴ In February 1991, Representative Robert Dornan (R-Cal.) introduced legislation to forbid "federal financial assistance in any form" to research medical uses of RU 486. During the same month, Representative Ron Wyden of Oregon submitted a bill that would have overturned the FDA import ban on the drug. *THE PINK SHEET*, Feb. 11, 1991 (FDC Reports). In 1992, similar bills were introduced in both the House, by Representative Ron Wyden, and the Senate, by Senator Alan Cranston of California. The House bill had sixty co-sponsors. Sylvia Bennett, *102nd Congress' Attention to Cancer Remains Significant*, 84 J. NAT'L CANCER INST. 841-42 (1992). Legislation to permit research on RU 486 by the National Institutes of Health was also submitted to the House in 1993 and co-sponsored by Representatives Wyden, Henry Waxman (D-Cal.), Pat Schroeder (D-Colo.) and Peter DeFazio (D-Ore.). *NIH Reauthorization Hearing Tentatively Planned for Jan. 21; Wyden Introduces RU 486 Research Bill*, *THE BLUE SHEET*, Jan. 6, 1993, at 2-3 (FDC Reports). Despite some legislators' interest in RU 486, Congress has not acted to alter the FDA's import ban or to facilitate research on the drug.

Representative Wyden, Chairman of the Subcommittee on Regulation, Business Opportunities and Energy of the House of Representative's Committee on Small Business, has held three public hearings on RU 486. Through these hearings, he has attempted to encourage the manufacturer to submit evidence of RU 486's safety and efficacy to the FDA for its approval. See *RU 486: The Import Ban and its Effect on Medical Research: Hearings Before the Subcomm. on Regulation, Business Opportunities, and Energy of House of Rep. Comm. on Small Business*, 101st Cong., 2d Sess. 53 (1990) [hereinafter *Hearing 1*]; *The Safety and Effectiveness of the Abortifacient RU 486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization: Hearing Before the Subcomm. on Regulation, Business Opportunities, and Energy of the House of Rep. Comm. on Small Business*, 102d Cong., 1st Sess. 65-66 (1991) [hereinafter *Hearing 2*]; *The Effect of the Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers, Hearings Before the Subcomm. on Regulation, Business Opportunities, and Energy of the House of Rep. Comm. on Small Business*, 102d Cong., 1st Sess. (1992) [hereinafter *Hearing 3*].

⁵ The former Mayor of New York City, David Dinkins, organized a petition-writing campaign to encourage Roussel-Uclaf, a French subsidiary of a large German multinational, Hoechst Corporation, to submit RU 486 to the FDA for approval and garnered signatures from many of the mayors of the largest cities. Klitch, *supra* note 1, at 280. The presence of these signatories is significant because women in large urban centers probably would be the first to use RU 486. Since the present medical protocol calls for two visits to a physician for the administration of the drug, urban women have greater access than rural women to a network of clinics that would provide follow-up care.

In addition to efforts by city officials, the state legislatures of California, Oregon and New Hampshire have passed resolutions urging Roussel to initiate the approval process. *Id.*

and pro-life activists⁷ and Administration officials⁸ as a drug with the potential to alter fundamentally the highly contentious and politicized debate on the topic of abortion. Although pro-choice activist groups had attempted to encourage the manufacturer, Roussel-Uclaf, to begin the standard, new-drug application process in the United States,⁹ the French company hesitated under threats of boycotts by pro-life groups.¹⁰ In a

Efforts such as these by city and state officials do not have any direct influence on whether a drug is approved by the FDA. Rather they are intended to demonstrate to the manufacturer and the FDA that there is public interest in the drug and a desire among many for its approval and availability.

⁶ Eighty-five percent of obstetricians and gynecologists polled at a medical conference said they would prescribe the drug. *See Around the U.S.*, DALLAS MORNING NEWS, May 18, 1993, at 8A.

⁷ "Pro-choice" and "pro-life" are labels adopted by the activists involved in the abortion debate. As the President of the National Right to Life Committee, the well-known pro-life group, Richard Glasow, stated, "We [the National Right to Life Committee] have been following the results of tests of RU 486 closely since 1985." *Hearing 2*, *supra* note 4. Other pro-life advocates, like the American Life League, have also vowed their opposition to "the birth control pill, RU-486, Norplant and Depo-Provera, each of which also act to abort tiny babies after their lives begin at fertilization." Judie Brown, *Opposition Clear*, CHI. TRIB., Apr. 3, 1993, at N24 (President of League's letter to the editor)

⁸ Dr. Jocelyn Elders, the Surgeon-General, has "vowed . . . to make the abortion pill RU 486 'available in this country.'" *See* Elizabeth Neuffer, *View on Teen-Age Pregnancy May Spark Fiery Hearings on Surgeon-General Pick*, BOSTON GLOBE, July 15, 1993, at 1; *see also* Robin Toner, *Settling In: Easing Abortion Policy; Clinton Orders Reversal of Abortion Restrictions Left by Reagan and Bush*, N.Y. TIMES, Jan. 23, 1993, at 1 ("[President Clinton] also called for a review of the ban on the importation of the French abortion drug, RU-486, for personal use."). President Clinton's action did not lift the import ban on RU 486. Rather, he signed an executive order directing that the Secretary of the Department of Health and Human Services, Donna Shalala, "promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU 486 from the list of drugs that qualify" for the personal use exemption to the ban on importation. *Safeguards for Fetal Tissue Transplantation Research Featured in NIH Reauthorization Bill*, THE BLUE SHEET, Jan. 27, 1993, at 3-4 (FDC Reports) (numerous news stories); *see* Ron Wyden, *Let the Pill Into the U.S.*, N.Y. TIMES, Apr. 10, 1991, at A25 (former President Bush concerned about funding of World Health Organization research efforts involving RU 486).

⁹ If a drug manufacturer wants to distribute an unapproved drug in the United States, it must submit a New Drug Application ("NDA") to the FDA. 21 C.F.R. § 314 (1993); *see* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUIREMENTS OF LAWS AND REGULATIONS ENFORCED BY THE U.S. FOOD AND DRUG ADMINISTRATION 39-41 (1989). The manufacturer's NDA must include safety and efficacy data from adequate and well-controlled scientific studies.

¹⁰ *See generally* LAWRENCE LADER, RU 486—THE PILL THAT COULD END THE ABORTION WARS AND WHY AMERICAN WOMEN DO NOT HAVE IT 41 (1991). Roussel is the foremost producer of steroids in the world and engages in business in over

preemptive strike, however, the FDA acted against the drug. It issued an order to its import enforcement and Customs agents requiring them automatically to seize RU 486 under all circumstances.

This action and the FDA's subsequent refusals to lift the import ban appear to have violated both the agency's own regulations and federal law governing agency rulemaking. When an agency, such as the FDA, does not follow proper rulemaking procedures, it acts outside the scope of its statutory authority. In so doing, the agency improperly extends the scope of its discretion. The possibility that an administrative agency could independently broaden its discretion threatens the existing system of administrative rulemaking, which provides for public involvement. Since agency officials are not elected, substantive regulations issued by administrative agencies must be reviewed by courts. In the absence of meaningful

90 countries. Roussel was partially nationalized in 1982 when the French government bought 36.25% of its stock. Hoechst retains 54.5% of Roussel stock, and the remaining shares are publicly held. *Id.* This division of company assets affected the conflict over RU 486's development and subsequent debates about its availability in European countries and the United States. The French foreign ministry was supportive of its development and distribution. *Id.* at 49. Hoechst, on the other hand, was reticent to encourage production for several reasons. First, its President, Wolfgang Hilger, is Roman Catholic and strongly pro-life. Second, Hoechst's corporate forerunner, I.G. Farben, had manufactured the poison gas used in World War II death camps, and Hoechst was sensitive to any negative publicity engendered by historical association. Finally, Hoechst was concerned about jeopardizing \$6 billion in annual profits in the United States market if RU 486 became available and anti-abortion groups organized a successful boycott. *Id.* at 49-50. Roussel decided to manufacture RU 486 for French distribution and on September 23, 1988, the French government announced its availability. *Id.* at 50. One month later, on October 26, after protests led by Catholic priests and doctors, Roussel announced that it would not produce RU 486. *Id.* The French health ministry swiftly responded two days later in a strongly worded statement, asserting RU 486 was the "moral property of women" and ordering Roussel to continue distribution. *Id.* at 51; see also *Hearing 2*, *supra* note 4, at 12 (testimony of Dilys Cossey, Chairwoman, British Family Planning Association, England). Since Roussel was partially nationalized and since the French government has the power to strip a company of its license and award it to a competitor, the French government was suitably situated to exert such influence. LADER, *supra*, at 51-52. There is some evidence to suggest that Roussel never intended to stop production, but rather announced that it would to secure a greater base of political support. No matter what its motivation, Roussel's action generated tremendous publicity for RU 486, contributed to a higher level of consumer education about the drug and encouraged physicians who might have remained silent to declare their support for its availability. *Id.* at 50-51.

judicial review, those affected are left without a legal remedy.

In addition to raising issues of administrative rulemaking, examining Ms. Benten's situation also provides an opportunity to consider women's role in determining health care policy and the importance of participatory decisionmaking processes for traditionally absent classes of persons. In addition, her case warrants special attention for it is the first in a line of cases that will challenge the existing contours of constitutional doctrine defining the rights to birth control and abortion.

This Note explores the FDA's use of import bans as a form of administrative rulemaking and asserts that by imposing the ban, the FDA violated procedural requirements for issuing regulations and acted arbitrarily and capriciously. This Note also asserts that RU 486 as a new reproductive health technology may challenge the Supreme Court to reconsider its classification of a woman's constitutional right to choose birth control as greater than her right to choose abortion. Ultimately, the Court may ratify, once again, a woman's fundamental right to choose abortion at the onset of pregnancy, unimpeded by state restrictions.

Part I describes the drug, RU 486, at which the import ban was directed and surveys the scientific data on its safety and efficacy. The Note then recounts the history of drug regulation in the United States and considers the nature of administrative rulemaking generally, and the appropriate standard of judicial review of agency regulations. Part I also considers the enforcement efforts of the FDA with particular emphasis on a regulation entitled the "personal use exception," which permits individuals to import unapproved drugs. Part II of this Note then analyzes the FDA's import ban on RU 486 and Ms. Benten's arguments in her suit against the FDA. Finally, the Note considers in Part III the involvement of women in forming women's health care policy and the import ban's negative effect on participation. The Note concludes with an analysis of how RU 486 will impact significantly existing Supreme Court interpretations of the right to privacy, birth control and abortion.

I. BACKGROUND

A. RU 486

RU 486, a steroid hormone, appears to be a safe and effective way to terminate pregnancy.¹¹ To date, over 120,000 European women have taken the drug.¹² It is approved for use as an abortifacient and widely available to women in France, Great Britain and Sweden.¹³

Its efficacy has been proven in a number of large-scale clinical trials conducted by the developer, and in independent analyses by researchers reviewing the drug's use in France, England and Scotland.¹⁴ The efficacy rate ranges from ninety-six percent¹⁵ to ninety-nine percent, depending on the drug protocol followed.¹⁶ RU 486 may be used up to the ninth week of pregnancy without diminishing its effectiveness.¹⁷

The drug continues to be the focus of intense interest among medical researchers around the world. Chinese scientists are testing RU 486 as an abortifacient.¹⁸ Studies in Canada and the Netherlands are evaluating the drug's potential as

¹¹ See *Mifepristone*, Micromedex, 1993, available in LEXIS, Genmed Library, Medex File (a comprehensive medical analysis of RU 486 intended for health professionals).

¹² Telephone Interview with Graydon Forrer, Counsel to the Subcommittee on Regulation, Business Opportunities, and Energy of the House of Representatives Committee on Small Business (Nov. 19, 1992).

¹³ Philip J. Hilts, *Abortion Pill's Sale Unlikely Soon Despite Change of Administration*, N.Y. TIMES, Nov. 13, 1992, at 38.

¹⁴ Klitsch, *supra* note 1, at 275 n.6; see also David A. Grimes, *Mifepristone (RU 486) for Early Abortion*, in 2 OBSTETRICS/GYNECOLOGY REP. 91 (1990); Louise Silvestre et al., *Voluntary Interruption of Pregnancy with Mifepristone (RU 486) and a Prostaglandin Analogue: A Large Scale French Experience*, 322 NEW ENG. J. MED. 645 (1990); André Ulmann et al., *RU 486*, 262 SCI. AM. 42 (1990).

¹⁵ Klitsch, *supra* note 1, at 275.

¹⁶ When given with oral prostaglandin, see *infra* notes 38-39 and accompanying text, the administration of RU 486 will terminate pregnancies in ninety-nine percent of its users. See Elyse Tanouye, *Abortion Procedure Is Found to be 99% Effective*, WALL ST. J., May 27, 1993, at B6 (reviewing research published in the *New England Journal of Medicine*).

¹⁷ Klitsch, *supra* note 1, at 276 n.12.

¹⁸ Fox Butterfield, *In New Hampshire, A Move to Test Abortion Pill*, N.Y. TIMES, May 5, 1991, at 28. A pro-choice group has begun testing a Chinese version of RU 486 on animals in the United States in an effort to encourage Roussel-Uclaf to seek FDA approval for RU 486. See Philip J. Hilts, *Abortion Rights Group Uses Chinese Pill to Goad French*, N.Y. TIMES, Feb. 18, 1993, at B9.

an anti-cancer agent, particularly for breast¹⁹ and brain cancers.²⁰ In Scotland, RU 486 is being studied as a morning-after pill, contraceptive and an abortifacient.²¹ Other promising applications include its use as a cure for disfiguring hormonal disorders such as Cushing's Syndrome.²² RU 486 also has been used effectively to encourage labor induction,²³ treat ectopic pregnancies²⁴ and diminish the effects of endometriosis.²⁵

In the United States, clinical trials testing RU 486 as an abortifacient were to have begun during the summer of 1993 in Oregon. The trials were to have been directed by the Population Council, a non-profit research group that was negotiating a licensing agreement with Roussel-Uclaf.²⁶ As of January 1,

¹⁹ Telephone Interview with Graydon Forrer, *supra* note 12; see Susan Jenks, *RU 486 Enters Limited Clinical Trials*, 84 J. NAT'L CANCER INST. 563 (1992).

²⁰ See S.W.J. Lamberts et al., *Mifepristone (RU 486) Treatment of Meningiomas*, abstraction reprinted in *International Abstracts*, 268 JAMA 3428 (1992) (RU 486 limited tumor growth in majority of patients).

²¹ The "morning-after pill" has typically been a high-dose birth control pill administered after unprotected intercourse to prevent pregnancy. See Klitsch, *supra* note 1, at 277; Gina Kolata, *New Use is Found for Abortion Pill*, N.Y. TIMES, Oct. 8, 1992, § 6 (Magazine), at A1 ("Both treatments [RU 486 and birth control pills] prevented pregnancy in women who had had unprotected sexual intercourse in the preceding 72 hours . . . but RU 486 caused far less nausea and vomiting."); see also Anna Glasier et al., *Mifepristone (RU 486) Compared With High-Dose Estrogen and Progestogen for Emergency Postcoital Contraception*, 327 NEW ENG. J. MED. 1041-44 (1991); Jan Hoffman, *The Morning-After Pill: A Well-Kept Secret*, N.Y. TIMES, Jan. 10, 1993, § 6 (Magazine), at 12, 14 ("The side effects of RU 486, when used as a morning-after pill, are considerably less unpleasant than those of birth-control pills used for the same purpose.").

²² See *Mifepristone*, *supra* note 11.

²³ R. Frydman et al., *Labor Induction in Women at Term with Mifepristone (RU 486): A Double-blind, Randomized, Placeto-controlled Study*, 80 OBSTETRICS/GYNECOLOGY REP. 972 (1992), as abstracted by LEXIS, Genmed library, Medline file ("[W]e have found mifepristone to be a safe, efficient, and suitable induction agent for initiation of labor in women at term.").

²⁴ Daniel J. Garry et al., *Are There Really Alternatives to the Use of Fetal Tissue From Elective Abortions in Transplantation Research*, 327 NEW ENGL. J. MED. 1592 nn.8 & 14 (1992).

²⁵ See Klitsch, *supra* note 1, at 277; see also Philip J. Hilts, *Study Set on Abortion Pill's Use in Breast Cancer*, N.Y. TIMES, Dec. 5, 1991, at 22; Sharyn Thylan, *RU 486 May Also Help Alleviate Endometriosis*, N.Y. TIMES, Oct. 30, 1992, at A30 (letter to the editor from President of Endometriosis Alliance of Greater New York reviewing study by University of California scientists that explored the use of RU 486 for treatment of endometriosis).

²⁶ See Warren E. Leary, *Maker of Abortion Pill Reaches Licensing Pact with U.S. Group*, N.Y. TIMES, Apr. 21, 1993, at A18; Associated Press, *Controversial Abortion Pill to Get First U.S. Clinical Trials in Oregon*, L.A. TIMES, May 1, 1993,

1994, it was unclear when clinical trials would actually begin.²⁷ The researcher who developed RU 486 has reached a preliminary agreement with the manufacturer to distribute the drug in the U.S. as soon as the drug has received FDA approval.²⁸ Once there are small-scale trials and a reliable production source, FDA approval of the drug as an abortifacient appears likely.²⁹ Already, an expert panel appointed by the National Academy of Sciences' Institute of Medicine has hailed the class of drugs to which RU 486 belongs, the antiprogestins, as showing significant promise in a variety of medical applications.³⁰ Indeed, the FDA has approved a clinical trial of RU 486 for the treatment of breast cancer.³¹

Part of RU 486's appeal is its potential to alter a woman's

at A8. Roussel-Uclaf's negotiations concerning a licensing agreement with the Population Council is a political saga with a soap-opera-like plot twists and turns. Since the late 1980s, Roussel-Uclaf and its parent company, Hoescht, had been repeatedly contacted by the drug's American proponents and foes. Since the election of a pro-choice President, additional pressure encouraging Roussel-Uclaf either to market the drug in the U.S. or to select a licensing partner has been exerted by Administration, agency and congressional officials. For a chronology of these developments, see *News Capsules*, THE BLUE SHEET, Feb. 10, 1993 (FDC Reports) (HHS Secretary directs FDA to review agency import ban on RU 486 through published notice in *Federal Register*); *RU 486 Review by FDA Could Be Completed Six Months Following an NDA Submission*, Agency Tells Wyden, THE BLUE SHEET, Dec. 30, 1992 (FDC Reports); *Three Firms Express Interest in Marketing RU 486 in U.S.*; *Wyden Asks Roussel-Uclaf to Seek U.S. Partner*, THE BLUE SHEET, Dec. 9, 1992, at 14 (FDC Reports); Associated Press, *French Abortion Pill Will Be Tested in U.S.*, N.Y. TIMES, Mar. 18, 1993, at A18 (Roussel-Uclaf identifying research partners in response to official request from President Clinton's administration; clinical trials to begin in two months); Philip J. Hilts, *Door May Be Open for Abortion Pill to be Sold in U.S.*, N.Y. TIMES, Feb. 25, 1993, at A1 (President of Roussel-Uclaf and FDA Commissioner meet to discuss RU 486 approval and marketing in U.S.); Leary, *supra*, at A18.

²⁷ Tamar Lewin, *Plans For Abortion Pill Stalled in U.S.*, N.Y. TIMES, Oct. 13, 1993, at A17; Elyse Tanouye, *Legal Import of Abortion Pill Appears Near*, WALL ST. J., Jan. 24, 1994, at B1.

²⁸ Reuters, *Deal Seen on Abortion Pill*, N.Y. TIMES, Nov. 15, 1993, at A12.

²⁹ *Large Phase III Trials of RU 486 in U.S. Should Not Be Required for FDA Approval*, Institute of Medicine Report Concludes, THE BLUE SHEET, Sept. 15, 1993 (FDC Reports); *RU 486 Timetable Will Depend on Establishment of Manufacturing Capacity by U.S. Marketer*, THE BLUE SHEET 8, May 26, 1993 (FDC Reports).

³⁰ Warren E. Leary, *Broader Uses Seen for Abortion Pill*, N.Y. TIMES, Sept. 9, 1993, at A17.

³¹ Associated Press, *Abortion Pill Approved for Breast Cancer Test*, N.Y. TIMES, Nov. 19, 1993, at A20. California researchers are also evaluating RU 486 as a treatment for prostate and brain cancer. See Patricia Anstett, *Brain Tumor Research Called Hopeful*, DETROIT FREE PRESS, Apr. 5, 1993, at 1G.

experience of terminating a pregnancy. RU 486 also allows a woman to be a substantially more active participant in the abortion. She ingests the pills and experiences a heavy period rather than being partially or fully anesthetized and having medical personnel perform an invasive surgical procedure on her.³² At least one, small-scale study has examined women's reactions and determined that ninety-four percent of the users found the procedure satisfactory because the process seemed more natural or empowering than a surgical abortion.³³

RU 486 also provides women with the opportunity to have a non-surgical abortion in the privacy of their homes, thus avoiding pro-life activists at abortion clinics.³⁴ As tactics used by some pro-life activists have become more violent, the efforts of local law enforcement have been unable to ensure access to

³² Contrast the non-surgical abortion method to a description of the surgical technique:

Before dilating the uterus, the size and location of the uterus is determined by clinical examination. The vagina, vulva and cervix are scrubbed. . . . Dilation of the cervix is next accomplished using Hegar's or Pratt dilators, cylindrical instruments employed to probe and dilate the cervix. . . . Once the cervix is dilated adequately, the uterus is evacuated. . . . [A] suction curette aspirator will be introduced into the uterus after cervical dilation. When the tube is inserted into the uterus, it is drawn back and forth from the fundus or upper portion of the uterus to the cervix or lower portion and rotated in all directions. . . . If parts of the placenta or fetal parts remain in the body, they may be removed with a sharp curet. Complete removal of the fetus is always mandatory . . . to avoid continued bleeding and infection.

Benten v. Kessler, 799 F. Supp. 281, 284 n.3 (E.D.N.Y. 1992) (citing ROSCOE N. GRAY, ATTORNEY'S TEXTBOOK OF MEDICINE § 311.84(1) (3d ed. 1991)), *stay granted*, (2d Cir.), *application to vacate denied*, 112 S. Ct. 2929 (1992).

³³ Klitsch, *supra* note 1, at 277; see also JANICE G. RAYMOND ET AL., RU 486 MISCONCEPTIONS, MYTHS AND MORALS (1991) (arguing that women should not accept medical abortion techniques without evaluating risks of ingesting relatively new chemical technologies when there is a relatively simple and safe surgical alternative).

³⁴ A number of pro-life groups, including "Operation Rescue," have blocked or sought to limit patient access to health care clinics that provide abortion services. See Associated Press, *Court Allows Challenge to Clinic Blockades*, N.Y. TIMES, Oct. 31, 1993, at A22. Operation Rescue's leader, Randall Terry, a colorful character, was found guilty of criminal contempt for violating an injunction when he confronted then-Governor Bill Clinton with a fetus during the 1992 Democratic National Convention. *Randall Terry Receives Jail Sentence*, REPROD. FREEDOM NEWS, July 2, 1993, at 7 (Ctr. for Reproductive Law and Policy, New York, N.Y.). For a discussion of the propriety of issuing injunctions against pro-life blockades of abortion clinics, see Carolyn Grose, Note, "Put Your Body on the Line:" Civil Disobedience and Injunctions, 59 BROOK. L. REV. 1497 (1994).

clinics for patients and staff.³⁵ And while pro-life demonstrators physically block access to clinics, other factors, including restrictive state abortion laws,³⁶ a shortage of physicians providing abortion services and remoteness of clinics, also may make it difficult for women to obtain surgical abortions.³⁷

A woman may use the medical abortion technique as soon as she realizes she is pregnant rather than waiting until she is seven weeks pregnant, the earliest time at which she could obtain a surgical abortion. She ingests 600 milligrams of RU 486 in pill form. Since RU 486 inhibits progesterone, the hormone necessary for the development of a uterine lining to sustain a fertilized egg, the uterus will begin to shed its lining.³⁸ Thirty-six to forty-eight hours later, the woman receives an oral form of a prostaglandin, a synthetic hormone, which speeds up the flushing of the uterine lining.³⁹ The medical

³⁵ Recently, in *National Org. for Women v. Scheidler*, 114 S. Ct. 798 (1994), the Supreme Court held that clinic operators and prosecutors could use racketeering laws (RICO) to punish pro-life demonstrators who conspire to close or damage health care clinics that provide abortion services. Violators charged with conspiring to violate RICO may be liable for treble damages.

Among federal law enforcement officials there is a growing consensus that federal legislation is necessary in order to protect clinics adequately, particularly in light of the murder of a Florida physician, Dr. David Gunn. Attorney General Janet Reno has stated that the "passage of this legislation is a priority." See Michael Isikoff, *Administration Will Attempt to Make Obstructing Abortion Clinics a Felony*, WASH. POST, Mar. 24, 1993, at A13; see also Associated Press, *Reno Vows Inquiries into Abortion Violence*, N.Y. TIMES, Oct. 31, 1993, at A22.

³⁶ As locating a clinic at which to receive a surgical abortion has become more difficult, women have sought "at-home" alternatives including a procedure called "menstrual extraction." See *Women Turn to Self-Help Groups for Abortions, Despite the Risks*, N.Y. TIMES, Sept. 9, 1992, at C13.

³⁷ Eighty-three percent of American counties have no abortion provider, a figure that will surely increase as most medical schools no longer train medical students in surgical abortion techniques. Since states may pass restrictions on abortion services ranging from parental consent for minors to waiting periods and counseling directives, these restrictions in combination with a decreasing number of providers will make it even more difficult for women to seek surgical abortions at clinics. For a comprehensive account of legal restrictions on abortion and practical considerations that continue to reduce women's access to surgical abortion services, see Janet Benshoof, *Planned Parenthood v. Casey: The Impact of the New Undue Burden Standard on Reproductive Health Care*, 269 JAMA 2249 (1993). See also Sara Rimer, *Abortion Clinics Seek Doctors But Find Few*, N.Y. TIMES, Mar. 31, 1993, at A14; Joannie M. Schrof, *Reproduction Showdown: Advocates Predict the Abortion Pill Will Revolutionize Women's Health*, U.S. NEWS & WORLD REP., Mar. 22, 1993, at 32.

³⁸ Grimes, *supra* note 14, at 91.

³⁹ See Klitsch, *supra* note 1, at 276; Tanouye, *supra* note 16, at B1.

abortion technique enables women to avoid risks associated with surgical abortion including infections, serious physical injury to the uterus or the cervix and complications arising from anaesthesia.⁴⁰

The side effects associated with RU 486 include bleeding, nausea, and uterine cramping. One study characterizes the average blood loss as "clinically unimportant," "like a heavy period" which does "not disrupt[] [women's] usual activities."⁴¹ In addition, studies suggest that only one percent of users experience excessive menstrual bleeding requiring either vacuum aspiration or curettage.⁴² The most serious side effects are associated not with RU 486 but with a class of drugs called prostaglandins. One of these, Cytotec, would have been administered with RU 486 to Ms. Benten. Cytotec is FDA-approved and readily available in the United States.⁴³ There have been three cases of prostaglandin-related cardiovascular complications and one fatality resulting from the medical abortion technique.⁴⁴ These complications, however, arose in association with the use of another prostaglandin, not Cytotec.⁴⁵ Nevertheless, if the patient is over thirty-five-years-old or smokes, the RU 486 protocol may not be appropriate.⁴⁶

B. *The Food and Drug Administration*

Had RU 486 been developed in the nineteenth century there would have been no effort to regulate it. Federal regulation of the pharmaceutical industry began in 1906 when Congress passed the Pure Food and Drug Act.⁴⁷ The Act required that drugs sold in interstate commerce must not be mislabelled

⁴⁰ See Schrof, *supra* note 37, at 32.

⁴¹ Grimes, *supra* note 14, at 94.

⁴² Klitsch, *supra* note 1, at 275-76.

⁴³ Cytotec, a hormone-like fatty acid also known as misoprostal, has been approved by the FDA for the prevention of ulcers. *Trade & Gov't Memos*, THE PINK SHEET, May 31, 1993 (FDC Reports). Once the FDA approves a drug for one use, a physician may prescribe it for other purposes. Jane E. Henney, *The Changing Approval Process*, 47 FOOD DRUG COSM. L.J. 505, 507 (1992) ("[P]hysicians, of course, may prescribe approved drugs for uses they find appropriate.").

⁴⁴ *Trade & Gov't Memos*, *supra* note 43.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ HENRY G. GRABOWSKI & JOHN M. VERNON, *THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS* 1 (1983).

or adulterated. It did not, however, require that the safety or efficacy of drugs be substantiated before the drugs were sold to consumers.⁴⁸ A public health crisis involving numerous poisoning deaths from the drug sulfanilamide dramatized this dangerous flaw in the legislation.⁴⁹ In response to the tragedy, Congress repealed the 1906 Act and passed the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), a more comprehensive regulatory scheme.⁵⁰ Under the new legislation a manufacturer was required to submit a new drug application ("NDA")⁵¹ before its drug could be introduced into interstate commerce.⁵² The NDA directed a drug company to specify the purpose of the new drug and demonstrate its safety.⁵³ The manufacturer, however, did not have to establish the efficacy of a new drug and NDAs were automatically approved within sixty days of filing, unless regulators undertook specific action against a drug.⁵⁴

Uncomfortable with an automatic approval process that did not require a manufacturer to prove the effectiveness of a new drug, Congress acted to amend the FDCA to include an efficacy requirement. In 1962 it passed the Kefauver-Harris amendments to the FDCA.⁵⁵ The amendments required com-

⁴⁸ *Id.* at 1-2.

⁴⁹ More than 100 children died upon ingesting a new liquid form of a popular sulfa drug, sulfanilamide. The manufacturer, Massengill Company, combined the sulfanilamide with a poisonous chemical solvent, diethylene glycol, without performing toxicity studies to ensure the chemical's safety. *Id.* at 2.

⁵⁰ Federal Food, Drug, and Cosmetic Act ("FDCA"), ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-31 (1988)). The FDA is a division of the Public Health Service of the Department of Health and Human Services. The Secretary of Health and Human Services, who is a member of the Cabinet, directs the Department's programs and goals. A Commissioner, appointed by the President with consent of the Senate, oversees the day to day activities of the FDA. UNITED STATES GOVERNMENT MANUAL 301-14 (1993).

⁵¹ 21 U.S.C. § 355 (1988 & Supp. IV 1992).

⁵² U.S. CONST., art. I, § 8, cl. 3. The "commerce clause" is the source of the federal government's power to regulate interstate commercial activity.

⁵³ GRABOWSKI & VERNON, *supra* note 47, at 2.

⁵⁴ *Id.*

⁵⁵ *Id.* at 3. The amendments were spurred by a widely reported tragedy involving the drug thalidomide. When thousands of pregnant women in Europe took Thalidomide, a sleeping aid with anti-nausea effects, their children were born with serious birth defects. The disaster spurred Americans to consider the risks of new drugs. Fortunately, thalidomide had been introduced in the United States only for investigational use and had not been approved for widespread distribution. Max Sherman & Steven Strauss, *Thalidomide: A Twenty-Five Year Perspective*, 41

panies to submit evidence from adequate and well-controlled clinical trials that a new drug was safe and effective.⁵⁶ With this change, pharmaceutical companies were required to take affirmative steps to gain FDA approval before a drug could enter the stream of interstate commerce.⁵⁷ Through the Kefauver-Harris amendments, the federal government was no longer simply an "evaluator of evidence and research findings," but had become an "active participant" in the development of safe, effective drugs.⁵⁸

C. Rulemaking by Administrative Agencies

1. A Period of Public Notice and Comment

Administrative agencies, such as the FDA, are governmental hybrids with both regulatory and enforcement powers. When Congress grants rulemaking authority to administrative agencies through enabling statutes, Congress delegates its constitutional power to legislate.⁵⁹ Specific enabling statutes define the role of each agency, its ability to write and enforce regulations and the scope of its discretion. Congress relies on an agency's expertise and enhanced ability to generate detailed policies and appropriately precise regulations.⁶⁰

FOOD, DRUG COSM. L.J. 458 (1986); see also Mindy J. Lees, Note, *I Want a New Drug: RU-486 and the Right to Choose*, 63 S. CAL. L. REV. 1113, 1134 n.175 (1990).

⁵⁶ GRABOWSKI, *supra* note 47, at 3.

⁵⁷ *Id.* at 3-4.

⁵⁸ *Id.* at 4.

⁵⁹ U.S. CONST., art. I, § 8.

⁶⁰ See generally Sidney A. Shapiro & Robert L. Glicksman, *Congress, The Supreme Court, and the Quiet Revolution in Administrative Law*, 1988 DUKE L.J. 819. Most enabling statutes, until recently, have been broadly written delegations of authority to regulate. When enabling legislation is general in scope, proponents may more easily build consensus around its passage. *Id.* Congress may increase its own efficiency by delegating its regulatory authority. Since agencies have greater expertise in their specific topic area and larger staffs to develop and implement policy, Congress finds it useful to delegate the task of drafting detailed regulations to agencies. Of course, in doing so, Congress also delegates legislative power and control, which implicates the balance of power between the different branches of government. See *infra* note 61.

The independence of agencies may also be curtailed by Congress. For example, in the area of environmental law Congress has sought to limit the Environmental Protection Agency's power in order to regain control of environmental is-

In an effort to standardize proper procedures for agency action, Congress passed the Administrative Procedure Act ("APA" or "Act"). The Act outlined the rulemaking authority of administrative agencies and described what formal procedures an agency must follow to promulgate binding regulations.⁶¹ The statutory scheme mandates that when issuing a binding regulation that either exceeds the express scope of congressional legislation or may impact substantive rights, an agency first must provide for a period of notice by publication in the Federal Register and then solicit public comment.⁶² Such reg-

sues. *Id.* Congress could enact similar legislation to control more tightly FDA activities such as the agency's use of import alerts like RU 486. *See infra* notes 192-93 and accompanying text.

⁶¹ 5 U.S.C. §§ 551, 553 (1988). The APA was passed in 1946 to control and standardize administrative procedures. KENNETH F. WARREN, *ADMINISTRATIVE LAW IN THE POLITICAL SYSTEM* 267 (1988). The growth of administrative agencies and the influence of agency officials has significant constitutional implications for the separation of powers. *Id.* at 265-66. For example, as the size of administrative agencies increases and as agencies, instead of Congress, set policy and draft regulations, the executive branch assumes some of the rulemaking authority traditionally exercised by Congress. The language of 5 U.S.C. § 551 defines "agency," "rule" and "rulemaking" as follows:

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include—(A) the Congress; (B) the courts of the United States; (C) the governments of the territories or possessions of the United States; (D) the government of the District of Columbia. . . .

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency. . . .

(5) "rule making" means agency process for formulating, amending, or repealing a rule.

Section 553 sets forth the rulemaking scheme incorporating a requirement of public notice:

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—(1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

⁶² 5 U.S.C. § 553 (1982):

(b) . . . Except when notice or hearing is required by statute, this subsection does not apply—(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or (B) when

ulations are regarded as "legislative" or "substantive" rules. Thus, the APA both ensures that individuals have notice of and an opportunity to comment on proposed rules that may impact their substantive rights and permits citizens to petition for the implementation, change or revocation of rules.⁶³

No notice and comment procedure is required, however, if an agency issues an "interpretative" rule, clarifying its own policies or regulations. Presumably an interpretative rule impacts only the agency's internal operations or is a statement of policy which will not affect the substantive rights of those regulated. In contrast, a "legislative" rule is more similar to a new law, the effects of which will extend to persons outside of the agency.⁶⁴ When an agency's regulatory action is best characterized as a "legislative" rule, the APA notice and comment procedure is necessary. If an agency does not follow the notice and comment requirements of the APA when issuing regulations, a court may invalidate the regulation on procedural grounds.⁶⁵

2. Scope and Standard of Judicial Review

In addition to setting forth procedural guidelines for agencies generating regulations, the APA codified Congress's presumption that final agency action would be reviewable by the

the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. . . .

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—(1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ See *infra* notes 155-171 and accompanying text (discussing scope of judicial review of agency action).

courts.⁶⁶ Generally, agency determinations are accorded considerable deference by courts.⁶⁷ When a court must evaluate a factual determination by an agency, agency administrators must provide a sufficiently detailed evidentiary record for the court to evaluate whether agency action was supported by substantial evidence.⁶⁸ At the same time, a court may not require agencies to follow procedures not contemplated by the APA when the agency generates regulations.⁶⁹ If the agency record is insufficient, the reviewing court should not attempt to rationalize some basis for agency action⁷⁰ and may find the

⁶⁶ See 5 U.S.C. §§ 551-59, 701-06 (1982). Section 706 provides:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—(1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute. . . .

Id. § 706. The requirement of final agency action ensures that agencies have sufficient autonomy to make decisions, independently develop a factual record and determine how to allocate resources. *Public Citizen v. Commissioner, Food and Drug Admin.*, 740 F.2d 21, 29 (D.C. Cir. 1984) (FDA rulemaking on issue of labeling of aspirin was ongoing and, thus, not suitable for review); see also *Cutler v. Hayes*, 818 F.2d 879, 896 (D.C. Cir. 1987) ("An agency has broad discretion to set its agenda and to first apply its limited resources to the regulatory tasks it deems most pressing.").

⁶⁷ *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984) (considerable deference is accorded administrative interpretations of enabling statute); *Fidelity Fed. Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 169-70 (1982) (administrator's actions should be subject to judicial review only if arbitrary or if actions exceed statutory authority).

⁶⁸ 5 U.S.C. § 706(2)(E) (1982); see *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 454, 477 (1986) (finding that the court must accept the Commission's findings of fact if supported by such relevant evidence as a reasonable mind might accept as adequate); see also *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 700-01 (2d Cir.), *cert denied*, 423 U.S. 827 (1979) (substantial evidence test applied to proceedings which are the subject of hearing provisions of 5 U.S.C. § 556 or 557).

⁶⁹ *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 545-48 (1978) (finding that a court must be careful not to invade the domain which Congress has set aside for an administrative agency).

⁷⁰ *Bowen v. American Hosp. Ass'n*, 476 U.S. 610, 627 (1986).

agency action arbitrary and capricious.⁷¹

Although most agency decisions are subject to judicial review using the arbitrary and capricious standard, the APA created two limited exceptions. Judicial review of an agency's determination is not appropriate when an enabling statute expressly precludes it⁷² or if the administrative decision at issue is "committed to agency discretion by law."⁷³ Accordingly, in *Citizens to Preserve Overton Park v. Volpe*,⁷⁴ the Court determined that the scope of agency immunity as set forth in these exceptions is "very narrow"⁷⁵ and limited to statutes "drawn in such broad terms that in a given case there is no law to apply."⁷⁶ In this instance, the *Volpe* Court considered whether the court could review the Secretary of Transportation's decision to approve the use of federal funds for highway construction where a highway would traverse and bisect parkland. The Court first concluded that the Secretary should be accorded some discretion.⁷⁷ The *Volpe* Court then determined that it nevertheless could review the Secretary's decision to determine whether the "decision was based on a consideration of the relevant factors."⁷⁸ Through the review process, the court could ensure that the Secretary had adequately considered existing federal laws protecting public parkland.⁷⁹ Thus, as long as there is a judicially cognizable standard embodied in the statute that circumscribes agency action, agency decisionmaking remains subject to review by courts.⁸⁰

⁷¹ *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971); see *infra* notes 74-79 and accompanying text.

⁷² 5 U.S.C. § 701(a)(1) (1982).

⁷³ *Id.* § 701(a)(2).

⁷⁴ 401 U.S. 402 (1971).

⁷⁵ *Id.* at 410.

⁷⁶ *Id.* at 410 (quoting S. REP. NO. 752, 79th Cong., 1st Sess. 26 (1945)).

⁷⁷ *Id.* at 415-16.

⁷⁸ *Id.* at 416.

⁷⁹ *Id.* at 412-14.

⁸⁰ *Heckler v. Chaney*, 470 U.S. 821, 834-35 (1985) (holding no judicial review of FDA's refusal to take enforcement action under the FDCA where prisoners sought to force the FDA to challenge the state's use of certain drugs for lethal injections). *Heckler's* implications for judicial review of agency discretion has been comprehensively reviewed by commentators. See Elizabeth L. Crittenden, *Heckler v. Chaney: The Presumption of Unreviewability in Administrative Nonenforcement Cases*, 89 W. VA. L. REV. 363 (1987) (presumption against judicial review in cases of agency nonfeasance is major shift in administrative law and deprives citizens of opportu-

Guaranteeing the availability of judicial review is an essential part of ensuring procedural due process for persons affected by agency rulemaking.⁸¹ Whether drafting enabling legislation like the FDCA for specific agencies or sweeping legislation, such as the APA, Congress has assumed that judicial review will temper agency discretion.⁸² In the absence of judicial review, administrative agencies would exist almost as an autonomous "fourth branch" of government, independently carrying out the policies of the President through extensive drafting of substantive legislation in the form of regulations, rather than as an enforcement arm of the Executive branch regulated by Congress.⁸³ The constitutional doctrine of separation of powers guarantees that each branch of government will be able to carry out its constitutionally defined role and provide a check on the other branches of government. If one could not bring a legal challenge to the actions of administrative agencies or the scope of an agency's discretion, the necessary balance of power between the three branches of government would be disrupted.

Additionally, our democratic system of government assumes that the public will influence federal policy primarily through electing representatives to the Congress, although citizens also vote for the chief executive. Yet, in the twentieth

nity to challenge agency discretion); Shapiro & Glicksman, *supra* note 60, at 854-58; Cass R. Sunstein, *Reviewing Agency Inaction after Heckler v. Chaney*, 52 U. CHI. L. REV. 653 (1985) (judicial review of agency inaction should be available if enforcement decision violates statutory constraints); Sharon Werner, *The Impact of Heckler v. Chaney on Judicial Review of Agency Decisions*, 86 COLUM. L. REV. 1247 (1986) (agency decisionmaking is reviewable under *Heckler v. Chaney* if judicially manageable standards exist).

⁸¹ Cynthia R. Farina, *Statutory Interpretation and the Balance of Power in the Administrative State*, 89 COLUM. L. REV. 452, 482 (1989) (an active judicial branch ensures a functioning system of checks and balances in a tripartite government). At least one commentator has remarked that judicial review is an integral part of the APA's regulatory scheme. KENNETH DAVIS, *ADMINISTRATIVE LAW OF THE EIGHTIES* §§ 7:8-12 (Supp. 1989).

⁸² *Abbott Labs. v. Gardner*, 387 U.S. 136, 142 (1967) ("There is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law. . . ." (quoting H.R. REP. NO. 2755, 74th Cong., 2d Sess. 8 (1936))).

⁸³ Peter L. Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV. 573 (1984) (examining the relationship of congressional authority to executive authority in the control of administrative agencies).

century, the role of administrative agencies and their size and complexity have greatly increased as agencies have become more involved in quasi-legislative activities of regulation and policy development. Since administrative agencies have become an essential feature of the federal government and because agency officials are not elected, a citizen's right to vote is no longer a sufficiently direct means of influencing policy. Thus, judicial review ensures the accountability of agency officials, who are political appointees and, unlike congressional representatives, do not face re-election.⁸⁴ Judicial review also guarantees that agencies remain participatory in character and that citizens may still play a role in policy definition.

3. FDA Regulatory Authority

The procedural requirements of the FDA's enabling statute, the FDCA, parallel the APA's standards for rulemaking and judicial review.⁸⁵ The Commissioner of the FDA may promulgate necessary and appropriate regulations to fulfill FDA's health and safety mandate.⁸⁶ Proposed agency regulations are first subject to notice and comment procedures like those of the APA, including publication in the Federal Register and a period of public comment.⁸⁷ The FDCA also provides for judicial review of agency rulemaking using the standards adopted by the APA.⁸⁸ Since the FDA's enabling statute has parallel procedural requirements to the APA, and since Congress passed the APA specifically to standardize administrative procedures,⁸⁹ the APA's procedural requirements and standard of judicial review provide the appropriate analytical framework to

⁸⁴ Thomas McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 1992 DUKE L.J. 1385 (regulatory vehicles for policymaking should be participatory).

⁸⁵ The FDA's regulatory scheme predates the APA but has been revised to conform with the APA. The regulations articulating the FDA's procedures appear in the Code of Federal Regulations. 21 C.F.R. §§ 10.25, 10.30 & 10.40 (1992).

⁸⁶ 21 C.F.R. § 10.40 (1992).

⁸⁷ *Id.*

⁸⁸ Specific provisions outlined in 21 U.S.C. § 371(f)(1)-(6) (1982) indicate that a court may review agency decisions to determine if the actions of administrators are based on substantial evidence. These provisions supplemented existing channels of judicial review and predated the APA by eight years. *Abbott Labs. v. Gardner*, 387 U.S. 136, 142 (1967).

⁸⁹ See *supra* notes 59-65 and accompanying text (explaining administrative procedures).

evaluate FDA's enforcement policies and rulemaking.

D. *The FDA's Enforcement Efforts*

To introduce a new drug into the United States market, a manufacturer must undertake the FDA's drug approval procedure. The FDCA prohibits any pharmaceutical company from bypassing the regulatory process.⁹⁰ A company or individual may not import a new, "unapproved" drug,⁹¹ defined as any drug that is "forbidden or restricted in sale in the country in which it was produced" or "is adulterated [or] misbranded."⁹² The United States Customs Service enforces the import regulations of the FDA. All shipments of goods subject to FDA control—drugs, food, medical devices and cosmetics—may be inspected as they are cleared through customs.⁹³ To ensure that dangerous substances do not enter the United States, two special FDA procedures have been implemented. First, the FDA may issue an import alert concerning a specific drug. The import alert is an internal memorandum issued by FDA administrators through the Office of Import Operations to field agents in district offices. The alert advises field personnel and Customs agents of "new or unusual problems affecting imports."⁹⁴ It provides identifying information about a product,

⁹⁰ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (1982).

⁹¹ 21 U.S.C. § 355 (1982).

⁹² *Id.* § 381(a)(2)-(3).

⁹³ See DEPARTMENT OF HEALTH AND HUMAN SVCS., FOOD AND DRUG ADMINISTRATION, FDA'S IMPORT COVERAGE APPROACHES (1982) (HHS Pub. No. (FDA) 82-1085) [hereinafter, FDA'S IMPORT COVERAGE APPROACHES]; DEPARTMENT OF HEALTH AND HUMAN SVCS., FOOD AND DRUG ADMINISTRATION, FDA'S IMPORT ENFORCEMENT OPERATIONS (1982) (HHS Pub. No. (FDA) 81-1086) [hereinafter, FDA'S IMPORT ENFORCEMENT OPERATIONS]; see also John R. Fleder, *The Role of the Department of Justice in Enforcement Matters Relating to the Food and Drug Administration*, 46 FOOD DRUG COSM. L.J. 781-92 (1991) (Director of Office of Consumer Litigation, Civil Division, U.S. Dep't of Justice's explanation of efforts to ensure compliance through civil and criminal enforcement actions); Paul M. Hyman, *Legal Overview of FDA Authority Over Imports and Exports*, 42 FOOD DRUG COSM. L.J. 203-12 (1987) (outlining FDA's authority in import cases); Marie A. Urban, *The FDA's Policy on Seizures, Injunctions, Civil Fines, and Recalls*, 47 FOOD DRUG COSM. L.J. 411-19 (1992) (Director of Compliance Management and Operations, FDA's Office of Enforcement/Regulatory Affairs' description of enforcement policies).

⁹⁴ FDA'S IMPORT COVERAGE APPROACHES, *supra* note 93, at 3. The FDA has issued import alerts to notify Customs agents to intercept a wide variety of drugs of dubious value. The character of drugs named in import alerts ranges from the

the reasons for the alert and instructions for responding to an entry application.

The second procedural mechanism is to issue an automatic detention order. The FDA will automatically retain or deny entry to products under such detention orders without examining products individually.⁹⁵ Detention orders are based on a history of violations by a shipper or based on a product's country of origin.⁹⁶ Import alerts may be used in the announcement of automatic detention orders. The purpose of both these administrative tools is to ensure an efficient regulatory response by the agency.

1. The Personal Use Exception

While drugs that have not gone through the FDA approval process may not be sold in the United States, the FDA has a longstanding policy of allowing individuals to import for their

unusual and medically useless to the extremely dangerous. A recent survey of import alerts includes the following drugs: abortafacients, European diet drugs, evening primrose oil, ginseng, herbal medicines, anabolic steroids and adrenal cortex extract. 1531 Food Drug Cosm. L. Rep. (CCH) 7244-45 (1992).

The difference between the average drug alert and the drug alert for abortafacients is notable. In almost all cases, the FDA has included in its alert a specific reason suggesting why the import of the drugs must be scrutinized more carefully. *Id.* at 7244. For abortafacients, however, there is no proffered scientific rationale, only a reference to the import alert number. *Id.* ("All shipments of unapproved abortifacient drugs should be automatically detained.").

⁹⁵ See generally DEPARTMENT OF HEALTH AND HUMAN SERVICES, FDA IMPORT OPERATIONS BRANCH: FISCAL YEAR 1991—WORLD WIDE IMPORT DETENTION SUMMARY (1991) (comprehensive summary of all import alerts issued worldwide organized by region and substance).

⁹⁶ *Id.*; see also Telephone Interview with John Brown, Consumer Safety Officer, Import Operations Branch, Food and Drug Administration (Sept. 18, 1992) (notes on file with the *Brooklyn Law Review*). Examples of drugs that are subject to automatic detention include L-Tryptophan, Dr. Johnson's and Dr. Sister Complement for Weight Loss, Interferon, "714x" Cancer/AIDS serum, anabolic steroids, Laetrile, Oil of Evening Primrose, homeopathic drugs, Woodward's Gripe Water, "Tatex" Tattoo Remover, Eagle Brand Medicated Oil, Mexican folk remedies, "P2P" (an ingredient used in the manufacture of amphetamines), Dimethyl Sulfoxide, Trichosanthin (Compound Q) and anti-aging cream. FOOD AND DRUG ADMINISTRATION, IMPORT ALERT INDEX (Aug. 31, 1992) (Pub No. #92-11). Each of these examples is either a remedy with little, if any, recognized medical benefit or is a drug that poses a known and substantial health risk to the user. In contrast, research on RU 486 has generated substantial evidence of the drug's safety and efficacy. See *supra* notes 11-31 and accompanying text (discussing safety and efficacy of RU 486).

personal use small quantities of unapproved drugs that do not appear to pose a significant threat to a user's health or safety. This policy was first outlined in a 1954 directive from the FDA's Division of Field Operations to all district offices.⁹⁷ In 1977, the FDA Regulatory Procedures Manual provided for importation of unapproved drugs through mail shipments as long as an importer's physician requested the release of the detained drugs, and the drugs were shipped in personal baggage.⁹⁸

The policies set forth in the Regulatory Procedures Manual were updated in 1988 through an import alert entitled "Pilot Guidance for Release of Mail Importations."⁹⁹ This alert allowed unapproved drugs that had been purchased for personal use, in non-commercial quantities, to avoid detention altogether.¹⁰⁰ The alert set forth only a few situations when the ship-

⁹⁷ *Hearing 1*, *supra* note 4, at 175-77 (Letter from Acting Commissioner of the FDA to Assistant Secretary for Health (Nov. 19, 1990)).

⁹⁸ *Id.* at 176.

⁹⁹ *Id.* at 162-63 (July 20, 1988 import alert issued by the Director of Regional Operations).

¹⁰⁰ *Id.* at 163. The updated 1988 mail import policy has been viewed as an attempt to be particularly responsive to individuals suffering from terminal illnesses such as AIDS. AIDS activists have criticized the FDA's regulation of new drugs, arguing that the existing drug approval process keeps life-prolonging treatments from patients, and they have sought to speed drug trials to provide quicker access. While patients with HIV have been permitted to bring in unapproved drugs of questionable safety and efficacy under the 1988 mail import policy, women seeking to import RU 486 have been thwarted by the import ban. *See infra* notes 97-114 and accompanying text (discussing FDA's mail import policy). *See generally* Margaret Salmon Rivas, *The California AIDS Initiative and the Food and Drug Administration: Working at Odds With Each Other?*, 46 *FOOD DRUG COSM. L.J.* 107 (1991) (criticizing the federal government's lack of a national AIDS policy); Gene P. Schultz & Charles A. Parmenter, *Medical Necessity, AIDS, and the Law*, 9 *ST. LOUIS U. PUB. L. REV.* 379 (1990) (discussing state's obligation to provide medical services to patients with AIDS); Jon S. Batterman, Note, *Brother Can You Spare a Drug: Should the Experimental Drug Distribution Standards be Modified in Response to the Needs of Persons With AIDS?*, 19 *HOFSTRA L. REV.* 191 (1990) (criticizing lack of FDA approved drugs for treatment of AIDS); John Patrick Dillman, Note, *Prescription Drug Approval and Terminal Diseases: Desperate Times Require Desperate Measures*, 44 *VAND. L. REV.* 925 (1991) (criticizing FDA's conservative stance with respect to new AIDS drugs); Bret L. Lansdale, Note, *A Procedural Due Process Attack on FDA Regulations: Getting New Drugs to People With AIDS*, 18 *HASTINGS CONST. L.Q.* 417 (1991) (arguing that the FDA deprives people with AIDS of their interests in life and liberty by precluding them from obtaining life extending drugs); Beth E. Myers, Note, *The Food and Drug Administration's Experimental Drug Approval System: Is it Good for Your Health?*, 28 *HOUS. L. REV.* 309 (1991) (recognizing that FDA "red tape" prevents critically ill patients from

ment should be detained: for fraudulent promotion or misrepresentation or if the unapproved drug presents an "unreasonable health risk due to toxicity or possible contamination," or if the size of the shipment suggests it will be distributed commercially.¹⁰¹ While the alert indicated that the FDA conceived of this policy as discretionary, the alert is an authoritative policy statement by the FDA that allows individuals to import unapproved drugs for personal use under the supervision of a physician on a case-by-case basis.¹⁰²

The FDA formally incorporated the provisions of the 1988 mail import alert into the Regulatory Procedures Manual in December 1989 without changing or expanding the mail import policy.¹⁰³ The Manual designates two situations when unap-

choosing "risky" drugs).

¹⁰¹ *Hearing 1*, *supra* note 4, at 163.

¹⁰² *Id.*

¹⁰³ *Id.* at 167 (citing FOOD AND DRUG ADMINISTRATION REGULATORY PROCEDURES MANUAL, PUB. NO. 90-02, pt. 9-71 (Dec. 11, 1989)). The FDA's Division of Field Investigations issued the following information to its enforcement officers to update the chapter of the Manual on Coverage of Importations Contained in Personal Baggage and Pilot Guidance for Release of Mail Importations:

BACKGROUND: There has always been a market in the United States for some foreign made products that are not available domestically. . . . Individuals seek medical treatments that are not available in this country. . . . With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds, or may be otherwise not legal for sale in the United States. . . . [T]reatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions such as AIDS or cancer. Because some countries do not regulate or restrict the commercial exportation of unapproved products, people who mail order from these businesses may not be afforded the protection of either foreign or U.S. laws. In view of the potential scale of such commercial operations, FDA has focused its enforcement resources more on products that are shipped commercially. . . .

GENERAL GUIDANCE: Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the products before making a final decision. . . .

DRUGS, BIOLOGICS, AND DEVICES: When personal shipments of drugs and devices that appear violative are brought to FDA's attention by Customs, FDA personnel will have to use their discretion to decide on a case by case basis whether to sample or detain. Generally, drugs . . . subject to Import Alerts are not amenable to this guidance. . . . In deciding whether to exercise discretion to allow personal shipments of drug(sic) . . . , FDA personnel should consider a more permissive policy in the following situations:

- when the intended use is appropriately identified, such use is

proved drugs may be imported under the personal use exception. In the first scenario, an unapproved drug may be allowed to enter the United States when the intended use is identified and the product is not known to represent a significant health risk regardless of whether or not the importer suffers from a serious illness.¹⁰⁴ The second category provides that importation is permissible if the importer has a serious condition, there is no reasonable alternative treatment and the drug does not pose an unreasonable health risk. In addition, the importer of the drug must provide the name and address of the supervising physician and must not attempt to commercialize the drug.¹⁰⁵

2. The Automatic Detention of RU 486

With the incorporation of the "Policy Guidance" provisions into the Regulatory Procedures Manual, RU 486 seemed to be a proper candidate for importation under either scenario of the personal use exception.¹⁰⁶ Following the first scenario, one could import RU 486 as long as one specified the intended use since the drug does not present a serious health risk.¹⁰⁷ The second set of circumstances would permit the importation of RU 486 if pregnancy constitutes a serious condition. To meet the latter importation requirements, an individual seeking to

not for treatment of a serious condition, and the product is not known to represent a significant health risk; or

- when 1) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; 2) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; 3) the product is considered not to represent an unreasonable risk; and 4) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment began in a foreign country.

Id. at 168-72.

¹⁰⁴ *Id.* at 171.

¹⁰⁵ *Id.* at 171-72.

¹⁰⁶ See *supra* notes 11-31 and accompanying text (explaining safety and effectiveness of RU 486).

¹⁰⁷ *Id.*

import the drug would demonstrate that the existing surgical abortion technique would not be "effective,"¹⁰⁸ that the importer will not try to promote or market the drug and that the product does not present an "unreasonable risk."¹⁰⁹ This analysis of the personal use exception suggests that an individual would be allowed to import RU 486 under the FDA's policy for unapproved drugs. Nevertheless on September 26, 1988, FDA Director of Field Operations, Burton Love, issued an import alert blocking importation of RU 486 and directing all enforcement personnel to prohibit individuals from importing RU 486 under the 1988 mail import alert.¹¹⁰ It remains unclear what precipitated the imposition of this alert.

Once the mail import policy permitting individuals to import unapproved drugs was publicized, however, a number of conservative Senators and Representatives, unaware of the Love import alert, corresponded with the Commissioner of the FDA regarding RU 486.¹¹¹ Their major concern was to ensure

¹⁰⁸ What constitutes an "effective" medical procedure is unclear. For example, does the availability of a surgical alternative for some women but not others disqualify the "others" from obtaining a medical abortion under the second scenario? While American women have a constitutional right to choose abortion before a fetus is viable, a woman's ability to exercise choice may be hampered by many factors, singly or in combination, that may make a surgical abortion impossible to obtain. There are constitutionally permitted restrictions on access to surgical abortions which make it difficult if not impossible for some women, particularly low-income women and women from rural areas, to obtain abortions. These include twenty-four to forty-eight-hour waiting periods which require at least two visits to a clinic, raising financial barriers like the cost of lodging, travel expenses, transportation and child care. For minors, the requirement of one or both parents' consent may be an insurmountable obstacle. See Benshoof, *supra* note 37, at 2249-51 (discussing the Supreme Court's decision in *Planned Parenthood v. Casey* allowing states to impose placing constitutionally permissible restrictions on access to surgical abortions); see also *Planned Parenthood v. Casey*, 112 S. Ct. 2791 (1992) (holding state-imposed 24-hour waiting period and parental consent provisions constitutionally permissible); Stanley K. Henshaw, *The Accessibility of Abortion Services in the United States*, 23 FAM. PLAN. PERSP. 246 (1991).

¹⁰⁹ See *supra* notes 11-13 and accompanying text (explaining safety and effectiveness of RU 486).

¹¹⁰ The import alert read as follows:

Type of Alert: Automatic Detention; Product: RU 486 or "Mifepristone." . . . Charge: "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug without an effective new drug application (NDA) as required by Section 505(a). . . . The intended use of such drugs could pose a risk to the safety of the user.

FOOD AND DRUG ADMINISTRATION IMPORT ALERT NO. 66-47 (Sept. 26, 1988).

¹¹¹ *Hearing 1, supra* note 4, at 180-81 (Letter from Frank E. Young, Commis-

that RU 486 could not enter the country under the personal use exception.¹¹² One month following this exchange of correspondence, the FDA issued a revised import alert and enlarged the exception to the personal import policy to require that all abortifacients, including RU 486, automatically be detained.¹¹³ Presumably this alert would prohibit someone from

sioner, Food and Drug Administration, to Senator Jesse Helms (undated response to Senator Helms's letter of February 23, 1989, stating that "We do not believe that this [personal importation] policy can be appropriately applied to the importation of RU-486 in that use of the product could present an unreasonable safety risk.")). *Id.* at 181; *Id.* at 183 (Letter from ten Representatives to Commissioner Young (May 5, 1989)). The Representatives' letter to Commissioner Young asserted that

[t]he U.S. government should not be involved in abetting abortion. This includes regulations that would allow the use of abortifacients such as RU 486. . . . We would greatly appreciate a clarification on your policy. Does your policy directive allow the importation of RU-486 or similar non-approved abortifacient drugs? If it does, have abortifacients . . . been imported under your directive? Finally, are there regulations currently being drafted that would add abortifacients, and specifically RU 486, to the list of prohibited drugs?

Id.; see also *id.* at 259-60 (Letter from Otis R. Bowen, Secretary of Health and Human Services, to Senator Gordon J. Humphrey (April 10, 1986)). Mr. Brown responded,

Thank you for your recent letters . . . regarding the use of Federal funds for research on the compound RU 486. Following my meeting with representatives of the pro-life movement . . . I investigated the use by the National Institutes of Health ("NIH") of HHS funds to support research . . . The NIH . . . has neither supported nor conducted abortifacient research involving RU 486 . . . due to the considerable concern about the potential use of RU 486 as an abortifacient, I have asked the Director of the National Institutes of Health to continue monitoring closely this biomedical research to assure that no support will be provided to RU 486 as an abortifacient.

¹¹² The personal use exception was widely discussed in the media and scholarly journals as a compassionate stance taken by the agency to assist AIDS victims and other seriously ill patients. See *supra* note 100 (articles discussing personal use exception). Health activists had roundly criticized the snaillike pace of the drug approval process and many FDA critics heralded the reviving of the thirty-year-old personal use exception. See *Hearing 1, supra* note 4, at 183 (Letter from ten Representatives to Commissioner Young ("[T]he December 1988 issue of *American Health* . . . asserts that you have approved a policy that would allow American citizens to mail order non-approved drugs from overseas . . . [how] . . . could the FDA possibly allow [RU 486] to be purchased through mail order?")); see also *id.* at 175 (Letter from Acting Commissioner of Food and Drugs to Assistant Secretary for Health (Mar. 10, 1990)) (RU 486 import alert was subject of a Washington Post editorial).

¹¹³ *Hearing 1, supra* note 4, at 185 (citing FOOD AND DRUG ADMINISTRATION IMPORT ALERT NO. 66-47 (June 6, 1989):

CHARGE: The article is subject to refusal of admission pursuant to Sec-

importing RU 486 or any other antiprogesterone drug even if the intended use was as something other than an abortifacient. This revised import alert was updated further on April 17, 1990, by listing the chemical names for RU 486 to enable customs agents to identify and seize the compound more easily.¹¹⁴ The history behind the different versions of the import ban suggest that it was an FDA action borne out of politics not scientific analysis or health and safety concerns.

II. ANALYSIS: *BENTEN V. KESSLER* AND THE IMPACT OF ADMINISTRATIVE RULEMAKING

A. *The Legal Proceedings*

The courts' decisions in *Benten v. Kessler*¹¹⁵ and Ms. Benten's plight reflect how an agency's rulemaking may significantly impact the lives and substantive rights of individuals.

tion 801(a)(3) in that it appears to be a new drug without an effective new drug application (NDA) as required by Section 505(a).

REASON FOR ALERT: Questions have been raised about a new abortifacient product, RU 486 . . . and whether the agency should use its discretion, pursuant to the Pilot Guidance for Release of Mail Importations . . . or otherwise, to allow its importation for personal use. FDA has concluded that unapproved products of this kind would be inappropriate for release under the personal importation policy. The intended use could pose a risk to the safety of the user.

INSTRUCTIONS: Automatically detain all shipments of unapproved abortifacient drugs.

¹¹⁴ FOOD AND DRUG ADMINISTRATION, REGULATORY PROCEDURES MANUAL, NO. 66-47 ch. 9-79, Apr. 17, 1990 (revised version).

Type of Alert: Automatic Detention; Product: Abortifacient Drugs; Manufacturer: All Unapproved; Reason for Alert: . . . FDA has concluded that unapproved products of this kind would be inappropriate for release under the personal importation policy. The intended use of such drugs could pose a risk to the safety of the user. . . .

Instructions: Automatically detain all shipments of unapproved abortifacient drugs.

As of January 1, 1994, FDA had not issued any further alerts concerning RU 486. Instead, in the first days of his administration President Clinton ordered a review of the reasons for the alert in anticipation of lifting the import ban. See *supra* note 8 (discussing Clinton's order for determination of whether import ban should be lifted).

¹¹⁵ 799 F. Supp. 281 (E.D.N.Y. 1992), *stay granted*, (2d Cir.), *application to vacate stay denied*, 112 S. Ct. 2929 (1992). Upon the Supreme Court's refusal to vacate the stay granted by the Second Circuit, and after Ms. Benten had obtained a surgical abortion, the case was dismissed.

These decisions further highlight the need for participatory rulemaking. In papers filed in the District Court of the Eastern District of New York seeking a preliminary injunction granting her access to the RU 486 that she had sought to import, Ms. Benten argued that regardless of RU 486's status as an unapproved drug, she could import it for her personal use upon the advice of a physician.¹¹⁶ Her view was in accordance with the FDA regulatory manual's import regulations, which permit the importation of small quantities of unapproved drugs under certain circumstances.¹¹⁷ Ms. Benten asserted that since there had been no notice to the public or opportunity to comment on the import ban as required by the APA,¹¹⁸ the ban was invalid.¹¹⁹ But, even if the district court were to find that no notice and comment were required, Ms. Benten argued, the import ban was improper because it was arbitrary and capricious.¹²⁰ By contending that the import ban should be enjoined, Ms. Benten attempted to assert the rights of individuals, as defined under the APA, to take an active role in agency decisionmaking and, in her case, to gain access to a useful drug. Her arguments demonstrated how the public had been excluded from the agency's deliberations on the availability of an extremely safe and effective drug—a drug that promised a substantially different and desirable treatment for women seeking abortions.¹²¹

The government's response to Ms. Benten's claims relied on the Supreme Court's broad protection of agency discretion articulated in *Heckler v. Chaney*.¹²² Arguing that the import ban was simply an enforcement decision, the government contended that the FDA's action was committed to agency discre-

¹¹⁶ Plaintiffs Memorandum of Law in Support of Plaintiffs Motion for a Temporary Restraining Order and Preliminary Injunction at 3-4, *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992), (No. CV-92-3161) [hereinafter Plaintiffs Memorandum].

¹¹⁷ See *supra* notes 97-105 and accompanying text (discussing circumstances under which importation of unapproved drugs is permissible).

¹¹⁸ See *supra* notes 59-65 and accompanying text (discussing notice and hearing provisions required under APA).

¹¹⁹ Plaintiffs Memorandum, *supra* note 116, at 8-10.

¹²⁰ *Id.* at 13-15.

¹²¹ *Id.*

¹²² 470 U.S. 821 (1985); see *supra* note 80 and accompanying text (discussing broad protection given to agency discretion).

tion as a matter of law and, thus, was not subject to judicial review under the APA.¹²³ Moreover, the government replied that if the ban was not subject to judicial review, there was no judicially cognizable standard against which it could be judged arbitrary and capricious.¹²⁴

The district court agreed with Ms. Benten's argument that the APA compelled the FDA to provide the public with notice and an opportunity to comment on the import ban before taking action to prohibit the importation of RU 486 for personal use. The court issued an order granting Ms. Benten access to the RU 486 that she had attempted to import.¹²⁵ In addition, the court urged the FDA to act quickly to adhere to the APA's procedural requirements: "The still larger question, whether RU 486 should be available to women in this country, generally, is not before this Court for decision but should promptly be addressed by the agency assigned the task of resolving it according to the legal procedures mandated by Congress for resolving such issues."¹²⁶ The court further chided the FDA stating that, "the defendants would be well advised to put their administrative house in order" even if the process of soliciting public comment "will be raucous and emotional," for "in a democracy the best results over the long run flow from adhering to the democratic procedures set forth in the country's laws."¹²⁷ In concluding, the district court indicated that while the court did not need to reach the question whether or not the import ban was arbitrary and capricious, Ms. Benten had demonstrated a substantial likelihood that the import ban could be struck down on those grounds as well.¹²⁸

Although the district court refused to stay the order granting Ms. Benten access to RU 486, on appeal to the Second Circuit, the government was able to secure a stay on the preliminary injunction.¹²⁹ The court of appeals heard oral argument on the defendant's motion to stay the lower court's deci-

¹²³ Defendant's Memorandum in Opposition to Plaintiff's Motion for Preliminary Relief at 15, *Benten* (No. CV-92-3161).

¹²⁴ *Id.* at 15-17.

¹²⁵ *Benten*, 799 F. Supp. at 291-92.

¹²⁶ *Id.*

¹²⁷ *Id.* at 291.

¹²⁸ *Id.* at 290.

¹²⁹ Defendant's Notice of Appeal at 2, *Benten* (No. CV-92-3161).

sion on the grounds that Ms. Benten was not entitled to equitable relief because she could not demonstrate irreparable injury. The Second Circuit agreed, and Ms. Benten immediately appealed to Supreme Court Justice Clarence Thomas to vacate the stay.¹³⁰ Justice Thomas, in turn, asked the entire court to consider Ms. Benten's application. In a *per curiam* opinion, a majority of seven Justices refused to vacate the stay, stating only that Ms. Benten had not demonstrated a substantial likelihood of success on the merits.¹³¹ An eloquent dissent authored by Justice Stevens however, asserted that "on the specific facts of the case, the Government's purported interest [in safety and health] actually supports the applicant's position . . . I am persuaded that the relevant legitimate federal interest is not sufficient to justify the burdensome consequence of this seizure."¹³² Justice Stevens also suggested that the import ban did not appear to be based on scientific proof and, therefore, was an "undue burden" on Ms. Benten's ability to exercise her constitutional right to obtain an abortion.¹³³

B. Import Bans as Legislative Rules

The legality of the import ban on RU 486 depends first upon whether the FDA was required to follow the APA's requirements for notice and comment. If the import ban may be characterized as a legislative rule under the APA, then the FDA was required to satisfy notice and comment procedures.¹³⁴ A legislative rule is a "substantive regulation" which . . . 'grants rights, imposes obligations, or produces other significant effects on private interests,'" whereas an interpre-

¹³⁰ Appellant's Memorandum of Law in Support of an Application to Vacate the Stay Pending Appeal at 1-2, *Benten* (No. A-40). Each Justice is assigned to one or more Circuits to hear emergency appeals for relief. Justice Thomas is the designee for the Second Circuit.

¹³¹ 112 S. Ct. 2929 (1992) (Stevens, J., dissenting).

¹³² *Id.* at 2931.

¹³³ *Id.*; see also *Planned Parenthood v. Casey*, 112 S. Ct. 2791 (1992). For a discussion regarding whether woman have a fundamental constitutional right to RU 486, rather than a more limited right that merely may not be unduly burdened, see *infra* Part III.

¹³⁴ For a discussion of two other FDA "policies"—an alert list and fraud policy, that critics characterize as substantive regulations which should have been subject to notice and comment regulations, see Richard S. Morey, *Legal and Practical Concerns with the FDA's Fraud Policy*, 47 FOOD DRUG COSM. L.J. 431-435 (1992).

tative rule reflects an agency's "intended course of action, its tentative view of the meaning of a particular statutory term, or internal house-keeping measures organizing agency activit[y]."¹³⁵ Those few courts that have had the opportunity to consider an FDA import alert correctly characterize it as a legislative rule within the meaning of the APA.¹³⁶

The district court in *Bellarno International Limited v. FDA*,¹³⁷ for example, had considered whether an import alert is a legislative rule in the context of a pharmaceutical company's attempt to reimport drug products manufactured in the United States. The drugs had been exported for sale and, upon being shipped back to the United States, had been detained by the FDA pursuant to an import alert.¹³⁸ Like the import alert on RU 486, the import alert considered in *Bellarno* was issued by the FDA without prior notice and com-

¹³⁵ *Perales v. Sullivan*, 948 F.2d 1348, 1354 (2d Cir. 1991) (Department of Health and Human Services assurance requirement under which patents must document a disability, was found to be a substantive regulation); see also *National Family Planning and Reprod. Health Ass'n v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992) (abortion counseling regulation forbidding medical personnel from discussing abortion, promulgated with notice and comment procedure, cannot be substantively altered by a presidential directive permitting doctors to provide abortion counseling without following APA notice and comment procedure), *supra* notes 59-65 and accompanying text. The problem of an agency attempting to perform its rulemaking mandate through its enforcement powers is not unique to the FDA. See generally ROBERTA S. KARMEI, REGULATION BY PROSECUTION (1982) (where former SEC Commissioner Karmel attributed her numerous dissents from the institution of enforcement proceedings by the SEC to the SEC's apparent policy of performing its mandate of regulating the securities industry by enforcement actions instead of through its rulemaking authority); cf. *New York City Employees Retirement Sys. v. SEC*, 843 F. Supp. 858 (S.D.N.Y. 1994) (SEC improperly reversed its policy concerning shareholder proposals in proxy statements through no-action letter instead of through statutorily mandated notice and comment procedures).

¹³⁶ The FDA's use of an import ban has rarely been challenged. See *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992) (import alert is a substantive rule and FDA should have followed notice and comment procedures), *stay granted*, (2d Cir.), *application to vacate stay denied*, 112 S. Ct. 2929 (1992) (refusing to vacate stay because no substantial likelihood of success on the merits) (*Blackmun & Stevens, JJ.*, dissenting); *Bellarno Int'l v. FDA*, 678 F. Supp. 410 (E.D.N.Y. 1988) (holding FDA import alert providing for detention and re-exportation of over-the-counter drugs is substantive regulation and invalid due to lack of notice and comment); *United States v. Articles of Drug, Consisting of: 203 paper bags, more or less, Nos. 84C7677, 85C1879 & 85C6020*, 1986 WL 3104 (N.D. Ill. Mar. 18, 1986) (memorandum opinion) (stating that import alert is substantive rule subject to notice and comment procedures).

¹³⁷ 678 F. Supp. 410 (E.D.N.Y. 1988).

¹³⁸ *Id.* at 411.

ment procedures.¹³⁹ The *Bellarno* court enumerated four interrelated factors to be considered in determining whether or not an FDA order is substantive: "the binding effect of the pronouncement[;] . . . the degree of discretion accorded the agency . . . in [applying] the pronouncement[;] . . . deference to the agency's . . . characterization[; and the] language [of] the [pronouncement] itself."¹⁴⁰ By issuing a formal directive to all field offices instructing FDA personnel to seize and detain abortifacient drugs automatically, the FDA brought its policy on RU 486 within the ambit of the notice and comment requirements of the APA.¹⁴¹

Under *Bellarno*, the RU 486 import ban is a substantive rule because: it is binding on both the agency and the importer; it does not permit FDA agents to use their discretion in its application; it is characterized by the agency itself as a rule and not a general statement of policy; and it uses language more akin to a mandate. The import ban is absolute, as was the case in *Bellarno*, instructing that all field offices "automatically detain all shipments."¹⁴² Thus, the ban constrains FDA agents from using their discretion to determine whether to allow personal importation of abortifacients and RU 486 on a case-by-case basis.¹⁴³ Moreover, the FDA itself has consistent-

¹³⁹ *Id.* at 412.

¹⁴⁰ *Id.* at 413.

¹⁴¹ See IMPORT BULLETIN NO. 66-B13 (Sept. 26, 1988); IMPORT ALERT NO. 66-47 (June 6, 1989); see also *National Family Planning and Reprod. Health Assoc. v. Sullivan*, 979 F.2d 227, 229 (D.C. Cir. 1992) ("directives are legislative rules").

¹⁴² IMPORT ALERT NO. 66-47 (June 6, 1989). The earlier order also explicitly stated, "this drug [RU 486] will not be allowed entry. . . ." IMPORT BULLETIN NO. 66-B13 (Sept. 26, 1988) (emphasis added); see also Letter from FDA Commissioner Frank Young to Representative Robert Dornan (June 9, 1989) ("the import alert . . . instructs our field personnel to prevent the importation of unapproved abortifacient drugs, such as RU 486."). Therefore, the FDA's internal and external correspondence suggests that the ban was unequivocal.

¹⁴³ An interpretative rule does not bind an agency. *Public Citizen, Inc. v. United States Nuclear Reg. Comm'n*, 940 F.2d 679, 682 (D.C. Cir. 1991) (Nuclear Regulatory Commission regulation on exemptions from prohibitions on exposure to radiation was an interpretive rule as the NRC did not intend to be bound by such regulation). It "genuinely leaves the agency . . . free to exercise discretion." *Alaska v. United States Dep't of Transp.*, 868 F.2d 441, 445 (D.C. Cir. 1989) (quoting *Community Nutrition Inst. v. Young*, 818 F.2d 943, 945-46 (D.C. Cir. 1987)) (mandatory language, department practice of granting exemptions and publication in CFR support finding that Department of Transportation orders regarding airline advertising are substantive rules.); see also *Huberman v. Perales*, 884 F.2d 62, 67 (2d Cir. 1989) (stating that substantive rules derive from Health and Human Ser-

ly characterized the import ban as an absolute rule.¹⁴⁴ Despite the FDA description of the ban as an interpretative rule or non-binding policy statement, such representations are not dispositive.¹⁴⁵ As Justice Scalia has noted in another context, "[t]here is deference and there is deference . . . [O]f far greater importance is the language used in the statement itself."¹⁴⁶ The language and tone of the import ban also suggest the ban is a directive.¹⁴⁷

In addition, the import ban is a legislative rule if it significantly impacts the rights of the regulated parties.¹⁴⁸ The personal use exception codified in the FDA's Regulatory Procedures Manual granted a woman the right to a case-by-case

vices Secretary's rulemaking authority).

¹⁴⁴ *Hearing 1, supra* note 4, at 151 (Statement of Ronald Chesemore, FDA Associate Commissioner for Regulatory Affairs) ("[I]f [RU 486] is observed coming into the country either through the mail or with individual persons, it *will be* detained by FDA field personnel and U.S. Customs Service officials.") (emphasis supplied); see also Kevin W. Saunders, *Agency Interpretations and Judicial Review: A Search for Limitations in the Controlling Effect Given Agency Statutory Constructions*, 30 ARIZ. L. REV. 769 (1988) (discussing impact of legislative-interpretative distinction).

¹⁴⁵ The FDA's description is accorded only limited deference. The *Bellarno* court, for instance adopted the plaintiff's assertion that the FDA import alert was a substantive rule. *Bellarno Int'l v. FDA*, 678 F. Supp. 410, 415 (1988); see also *San Diego Air Sports Center, Inc. v. Federal Aviation Administration*, 887 F.2d 966, 970 (9th Cir. 1989) (holding that FAA letter forbidding parachuting within Air Terminal Control Area was binding substantive rule and invalid due to FAA's neglect of required notice and comment procedure).

¹⁴⁶ *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538 (D.C. Cir. 1986) (voluntary language in Secretary of Labor's published enforcement policy supports a finding that it is an interpretive rule).

¹⁴⁷ If the ban were simply a policy statement providing guidance for FDA agents to assist them as they exercise their discretion as representatives of the FDA, the language would sound more like the example of "guidance" provided by *Bellarno*: "We [the FDA] *suggest* that all entries . . . be given serious consideration. . . ." *Bellarno*, 678 F. Supp. at 415 n.6 (emphasis added).

The import ban readily may be distinguished from a general statement of policy. The latter provides guidelines for future action and does not "have a substantial impact on those regulated." *United States v. Articles of Drug*, Consisting of: 203 paper bags, more or less, Nos. 84C7677, 85C1879 & 85C6020, 1986 WL 3104, at *12 (N.D. Ill. Mar. 18, 1986) (quoting *Aiken v. Obledo*, 442 F. Supp. 628, 649 (E.D. Cal. 1977)); see also *Panhandle Producers and Royalty Owners Assoc. v. Economic Regulatory Administration*, 822 F.2d 1105, 1110 (D.C. Cir. 1987) (a "policy statement cannot create a norm binding the promulgating agency or its delegate[s]").

¹⁴⁸ *New York v. Lyng*, 829 F.2d 346, 354 (2d Cir. 1987) (stating that interpretative rule does not change existing rules and obligations); *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975) (notice and comment required if regulations have "substantial impact on those regulated").

determination concerning importing a small quantity of RU 486 for her personal use.¹⁴⁹ The import alert extinguished this right.¹⁵⁰ Therefore, applying the *Bellarino* court's reasoning, it is apparent that the FDA promulgated a legislative regulation when it issued the RU 486 import ban under the guise of its enforcement power. Since the FDA failed to provide notice to the public by publishing the proposed alert in the Federal Register and neglected to provide an opportunity for the public to comment and participate in the rulemaking process, it violated the procedural requirements of the APA.¹⁵¹

¹⁴⁹ *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992). Judge Sifton held that the FDA had taken away an existing right by imposing the import ban:

The government . . . argues that no obligation was created by the alert as (1) the plaintiff never had any right to import RU 486 for personal use, and (2) the alert did not create new duties. As to the first, the government focuses on the wrong right. It argues that, since there was never a statutory right to import RU 486, the alert took nothing away. The right at issue, however, was that created . . . by the revision of the R[egulatory] P[rocedures] M[anual]. Under the RPM, plaintiff had a right to a case-by-case discretionary decision by the FDA on her personal importation of RU 486. After the ban this right no longer existed.

Id. at 289 (emphasis added); see also *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 412 (7th Cir. 1987) ("when an agency gets out the Dictionary of Newspeak and pronounces that for purposes of its regulation war is peace, it has made a substantive change for which the APA may require procedures").

¹⁵⁰ One commentator writes on the danger of permitting agencies to rewrite their own rules without following the APA requirements:

[If an agency issues] legislative regulation . . . directly affecting conduct of agency personnel and members of the public . . . it may not subsequently repudiate that announced meaning and substitute for it a totally different meaning without proceeding through notice and comment rulemaking normally required for amendments of a rule. To sanction any other course would render the requirements of § 553 basically superfluous in legislative rulemaking by permitting agencies to alter their requirements for affected public members at will through the ingenious device of "reinterpreting" their own rule.

Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 396.

¹⁵¹ Nor can the FDA avoid the notice and comment process and sustain the import ban by invoking the "good cause" exception. 5 U.S.C. § 553(b)(B) (1986). There is nothing in the administrative record to indicate that the required notice and comment procedure was "impracticable, unnecessary, or contrary to the public interest." *Id.* 553(b)(A). The FDA has not demonstrated that there is a compelling public interest justifying an immediate import ban on RU 486. Conversely, the public had expressed an interest in the drug, forwarding numerous inquiries about the medical applications of the drug to the FDA, and it should have had an opportunity to comment on any proposed ban. Yet the FDA dismissed the public's right to comment on proposed rules before those rules were enacted without show-

The district court, therefore, correctly characterized the FDA's actions as "illegal."¹⁵²

C. *An Arbitrary and Capricious Regulation*

Even if the import ban on RU 486 was an interpretative rule not subject to notice and comment procedures, a court nevertheless could properly invalidate it as arbitrary and capricious. Since there was no administrative record on which to base a decision to ban the import of RU 486, the FDA's action was ill-considered. Moreover, the FDA treated RU 486 differently under the personal use policy depending on how the drug was to be used. A brain cancer patient was able to obtain RU 486 less than four weeks after Ms. Benten was denied access to the drug, even though the import ban remained in force.¹⁵³ Also, the agency allowed the importation of a number of unapproved drugs that posed a known health risk to users.¹⁵⁴

ing that urgent circumstance required the agency to "eliminate a valuable procedure." *Williams v. Pierce*, 708 F.2d 57, 62 (2d Cir. 1983) (Mansfield, J., dissenting), cert. denied, 464 U.S. 1046 (1984); see *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1978) ("notions of fairness and informed administrative decision making require that agency decisions be made only after affording interested persons notice and an opportunity to comment."). The prescribed notice and comment process was not impracticable because no one had promoted RU 486 in the United States such that the imposition of an immediate import alert would be necessary. Letter from Acting FDA Commissioner James Benson to Representative Ron Wyden (June 29, 1990). Additionally, Americans, especially American women, have a strong (public) interest in RU 486 as an alternative to surgical abortion. For instance, French officials have recognized the importance of the drug by referring to it as the "moral property" of women. See *supra* notes 1 & 10.

¹⁵² *Benten*, 799 F. Supp. at 283.

¹⁵³ Associated Press, *Cancer Patient Can Get Unapproved Abortion Pill*, N.Y. TIMES, July 30, 1992, at A22. The medical condition of the patient in this case does not legitimize the agency's disparate treatment of RU 486 based on the specified medical use. The FDA appropriately used its regulatory discretion in accordance with the personal use exception to benefit this critically ill patient. It considered the facts of an individual's predicament to determine whether access to the drug should be granted. Ms. Benten sought the exact same determination, but in her case the FDA refused to evaluate the facts of her situation and rested its decision on the existence of the import alert.

¹⁵⁴ See *infra* notes 184-86 and accompanying text.

1. Scope of Judicial Review of Agency Action

The district court correctly held that the FDA's action imposing the import ban is subject to review by the courts¹⁵⁵ because it had not been committed to agency discretion by law.¹⁵⁶ The FDA's action may be criticized as "arbitrary, capricious, [and] an abuse of discretion."¹⁵⁷ This test, set forth in the APA, defines the limits of the FDA's discretion by providing a standard of review for courts evaluating the FDA's policies and rulemaking. The scope of review under the "arbitrary and capricious" analysis, however, is quite narrow.¹⁵⁸ The court must show deference to agency determinations and actions, and it should not "substitute its judgment for that of the agency."¹⁵⁹ Nevertheless, if an agency acts, it must be able to provide concrete reasons for why it did so, and the actions must be logically consistent.¹⁶⁰ Courts are free to examine the record for errors of procedure,¹⁶¹ to identify whether the agency has followed its own guidelines¹⁶² and to en-

¹⁵⁵ The FDA argued in *Benten v. Kessler* that the import alert is not subject to judicial review as enforcement action, that public health and safety concerns legitimize the import ban and that the district court usurped the role of the FDA by substituting its judgment for that of the agency. Notice of Appeal, Civ. No. 92-3161, U.S. Attorney E.D.N.Y., Summary of Argument, July 14, 1992 (on file with the *Brooklyn Law Review*). The government relied upon *Heckler v. Chaney*, 470 U.S. 821 (1980), and interpreted it broadly. See *supra* note 122 and accompanying text. Even if an agency action creates no direct obligation, is informational and does not involve enforcement or a formal effect, it is nevertheless subject to judicial review. *Citizens Communication Ctr. v. FCC*, 447 F.2d 1201 (D.C. Cir. 1971) (court applied a test examining the fitness for judicial review and the hardship to the parties attendant to withholding judicial consideration in determining if an FCC policy statement was ripe for review).

¹⁵⁶ *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 410 (1971); see *supra* notes 71-77 and accompanying text.

¹⁵⁷ 5 U.S.C. § 706(2)(A) (1986).

¹⁵⁸ *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 30 (1983) (National Highway Traffic Safety Administration's decision to rescind a prior regulation remains subject to the arbitrary and capricious test).

¹⁵⁹ *Id.*; see also *Chevron, U.S.A. v. National Resource Defense Council*, 467 U.S. 837 (1984) (stating that agency interpretation of statute must be logical).

¹⁶⁰ *Motor Vehicle*, 463 U.S. at 42; see also *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1240 (D.D.C. 1987) (Department of Health and Human Services refusal to issue regulations banning the interstate sale of unpasteurized milk arbitrarily ignored record demonstrating existence of serious health risk).

¹⁶¹ *Id.*

¹⁶² *Heckler v. Chaney*, 470 U.S. 821, 831 (1985); *Williams v. Pierce*, 708 F.2d 57, 64 (2d Cir. 1983) ("[I]t is well settled that regulations promulgated under stat-

sure that the agency can provide factual grounds for its decisionmaking.¹⁶³ "If the agency cannot articulate a policy that justifies its action or demonstrate the consistency of its action with existing agency policy, Congress has not authorized the action. . . . Denying the appropriateness of a court's role . . . [in requiring such a response would] result in 'an impoverished judicial role indeed.'"¹⁶⁴

Courts have commented upon the need for a sufficient administrative record upon which to base administrative agency regulations and decisions.¹⁶⁵ For example, in *Ethicon, Inc. v. Food and Drug Administration*, the court held that where the FDA sought to reclassify medical devices relying on "voluminous materials" and "hundreds of studies" and created a detailed administrative record, the FDA's action could not be characterized as arbitrary and capricious.¹⁶⁶ The *Ethicon* court reasoned that the central issue to be determined is whether there was a record to support the agency's classification decision. It would not extend the scope of judicial review to assess the validity of the conclusion itself. In its view, even if a plaintiff argues that the FDA's conclusion itself is wrong based on the substance of the record, the court may not review the FDA's decision.¹⁶⁷ The *Ethicon* court's view of its limited role assures that administrative agencies will have wide discretion. Notwithstanding *Ethicon's* rationale, a necessary part of a court's assessment of whether an agency decision is arbitrary or capricious depends on evaluating whether a decision

utory authority have the force and effect of law . . . an agency is bound by its own formal, published regulations that protect the important rights of the public."), *cert. denied*, 464 U.S. 1046 (1984), *rehearing denied*, 465 U.S. 1055 (1985).

¹⁶³ *Upjohn Mfg. Co. v. Schweiker*, 681 F.2d 480 (6th Cir. 1982) (finding that FDA undertook fact finding procedures and created a detailed record and, thus, did not act arbitrarily).

¹⁶⁴ *Shapiro & Glicksman*, *supra* note 60, at 867-68.

¹⁶⁵ "Administrative record" in this context refers to a body of evidence containing internal documents such as correspondence, memoranda or reports and external documents including scientific studies and manufacturer's information which provides the basis for FDA decisions. This material may or may not be published or available to the public.

¹⁶⁶ 762 F. Supp. 382, 387-89 (D.D.C. 1991). "It is clear that this record, replete with substantial, valid scientific evidence, more than adequately supports the agency's determination that there exists sufficient information to characterize and understand the generic class . . . and to establish the safety and effectiveness or these devices." *Id.* at 389.

¹⁶⁷ *Id.* at 387.

reasonably follows from the administrative record.¹⁶⁸ Similarly, in *National Association of Pharmaceutical Manufacturers v. Department of Health and Human Services*, a suit involving the FDA's proposed regulations for the manufacture of drugs, the court defined an adequate administrative record as one that offers a "thorough and comprehensible statement of the reasons for [the FDA's] decision."¹⁶⁹ The *National Association* court explicitly required the FDA to demonstrate a reasoned basis for its decision to take regulatory action stating, "[T]he agency must explain the basis for its actions."¹⁷⁰ The court held that the administrative record explaining the proposed regulations, containing summaries of the FDA's enforcement and inspection reports, and including 2000 pages of public comments and a 306 page FDA response to these comments was satisfactory. The record also included documents reflecting the FDA's meetings with industry and educational groups.¹⁷¹ These cases suggest that when the FDA articulates reasonable reasons for its decisions and documents its reasoning, courts should defer to its judgment. In the absence of an administrative record, however, courts are not so indulgent of an agency's discretion.

2. Insufficient Evidence to Support the Import Ban

The *Benten* court pointedly asserted that no administrative record was put before the court and that it was "unlikely that any such record exists."¹⁷² Thus, the FDA acted improperly by issuing an import ban prior to assembling an administrative file upon which to base an enforcement decision. The absence

¹⁶⁸ See *supra* note 158.

¹⁶⁹ *National Ass'n of Pharmaceutical Mfrs. v. Department of Health and Human Servs.*, 586 F. Supp. 740, 756 (S.D.N.Y. 1984) (quoting *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 701 (2d Cir. 1975), *cert. denied*, 423 U.S. 827 (1975)).

¹⁷⁰ *Id.* at 755.

¹⁷¹ *Id.*; see also *Synthetic Organic Chem. Mfrs. Ass'n v. Secretary, Dep't of Health and Human Services*, 720 F. Supp. 1244, 1257 (W.D. La. 1989) (finding that agency's classification and subsequent publication of certain carcinogens was based on extensive laboratory studies by agency scientists and was not arbitrary or capricious); *Upjohn Mfg. Co. v. Schweiker*, 681 F.2d 480, 483 (6th Cir. 1982) (FDA's factfinding procedures concerning safety and efficacy of newly approved drug were "stated in detail. . . . Nothing more [was] required.").

¹⁷² *Benten v. Kessler*, 799 F. Supp. 281, 290 (E.D.N.Y. 1992).

of any administrative record creates a presumption that the action taken is arbitrary and capricious. To defeat Ms. Benton's claim that the import ban was arbitrary and capricious, the FDA had to support its rationale with a record. Yet the government was unable to produce an administrative file on RU 486.¹⁷³ According to the FDA's response to a comprehensive Freedom of Information Act ("FOIA") request dated February 1991, the FDA had not investigated whether the drug posed a safety risk, had not identified any ongoing studies that made such an assertion and was not aware of any injuries that had resulted from the drug's use in this country.¹⁷⁴

Since the broadly worded FOIA request covered any relevant documents in FDA's possession, whether the documents were generated by the Agency, by a member of the Bush administration or other persons, any safety concerns the FDA

¹⁷³ When considering the administrative record, the "focal point for judicial review should be the administrative record already in existence." *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (arbitrary and capricious test applied to Comptroller of Currency's denial of National Bank Charter). The court must compare the record and the reasons the agency offered. *Benton*, 799 F. Supp. at 290.

¹⁷⁴ Letter from Julie Mertus, Attorney, American Civil Liberties Union Reproductive Freedom Project, to Freedom of Information Staff, FDA (Feb. 6, 1991) (attached to Order to Show Cause with Temporary Restraining Order, *Benton* (No. CV-92-3161)). Despite a letter with over sixteen specific inquiries probing the contents of such an administrative record, the response letter from FDA's Center for Drug Evaluation and Research stated that "[w]e have searched our files in the Center for Drug Evaluation and Research and cannot locate any document which would be responsive to your request with regards to your items 1, 2, 3, 4, 5, 6, 8, 10, 11, 12, 13, 14, 15, 16, and 17." Letter from Eulah M. Jones, Lead FOI Technician, Center for Drug Evaluation and Research, FDA to Julie Mertus, Attorney, American Civil Liberties Union Reproductive Freedom Project (Mar. 12, 1991) (on file with the *Brooklyn Law Review*). The Center for Drug Evaluation and Research is the unit of the FDA responsible for providing scientific and other documentation to FDA officials to assist administrative decisionmaking. Telephone Interview with Fredda Shere-Valenti, Division of Import Operations and Policy, FDA (Oct. 6, 1992). If this division of the FDA possessed no relevant documents concerning RU 486, it is difficult to imagine who in the agency had such information.

The Center for Drug Evaluation and Research's response left only requests Nos. 7 and 9 to the Import Operations Branch, the enforcement branch of the FDA. The Import Operations Branch then replied, providing the letters written by Senators encouraging a ban on RU 486 importation in response to request No. 9 and indicating that "According to our Import Operations Branch, FDA does not have any information concerning item No. 7 of your request." Letter from Terry L. Roseby, Consumer Safety Officer, Office of Enforcement, FDA to Julie Mertus, Attorney, American Civil Liberties Union Reproductive Freedom Project (Mar. 7, 1991); see *supra* notes 11-46 and accompanying text.

might have had involving RU 486 would have been supported by documents. As the *Benten* court noted, "The FDA is required by its own regulations to preserve complete files of the bases of 'every significant FDA decision on any matter under the laws administered by the Commissioner, whether it is raised formally, for example, by a petition, or informally, for example, by correspondence.'"¹⁷⁵ The absence of any relevant documents in FDA files relating to deliberations about safety, possible importations or examples of RU 486's use in this country implies a single undisputed conclusion: the FDA did not issue the automatic detention order for RU 486 based on any substantive research or independent investigations.¹⁷⁶

Even if some of these documents, such as internal memoranda, may have been unavailable through a FOIA request because the FDA could invoke agency privilege, the language of the request was sufficiently broad to require, at the very least, that the agency identify such documents and state that it was withholding them.¹⁷⁷ Yet the response letters from the

¹⁷⁵ *Benten*, 799 F. Supp. at 290 (citing 21 C.F.R. § 10.70 (1993)).

¹⁷⁶ Several commentators have affirmed this conclusion. One family planning expert has asserted that "Federal officials have . . . stated that . . . the alert was . . . imposed for political reasons only. . . ." Klitsch, *supra* note 1, at 280. This conclusion is echoed by Counsel to the Subcommittee on Regulation, Business Opportunities, and Energy of the House of Representatives' Committee on Small Business, Graydon Forrer. Telephone Interview with Graydon Forrer, *supra* note 12. Mr. Forrer characterized the import ban as motivated by "purely political" concerns. *Id.* The Subcommittee's Chairman, Representative Ron Wyden, has held hearings on FDA's decision to impose the import ban on RU 486. *See supra* note 4. When the Subcommittee attempted to subpoena documents reflecting the FDA's decisionmaking on RU 486, the FDA was cooperative but did not supply any documents that reflected a scientific basis or other apolitical reason to exclude imports of RU 486. *Id.* Moreover, no other evidence has surfaced to suggest that the agency was motivated by concerns for the health and safety of the public when it imposed the import ban. In the absence of an administrative record, it is unclear what specific events prompted the first FDA action taken by the Director of Field Operations in September 1988, imposing the ban on RU 486. *See supra* note 110. If viewed in context with the letters from conservative members of Congress, however, the second agency action against the drug, in June 1989 seems to be in response to such criticism. *See supra* note 111. Indeed, such letters may have been highly persuasive to political appointees in the FDA responsible for setting RU 486 policy. The imposition of a revised, more specific import alert was consistent with the Bush Administration's stance on abortion.

¹⁷⁷ Administrative agencies have a well-recognized privilege with respect to internal documents regarding administrative decisionmaking. The policy behind this privilege is the agency's interest in its ability to make both routine and controversial decisions free of undue or inhibiting public scrutiny. This privilege, how-

FDA's Center for Drug Evaluation and Research and the Office of Enforcement suggest that no internal documents concerning the safety, risks or importation of RU 486 existed. Without an administrative record to support its imposition of the import ban on RU 486, the FDA's action was, as a matter of law, arbitrary and capricious.¹⁷⁸

Since the FDA did not provide the court with an administrative record that could illuminate the agency's consideration of the risks associated with RU 486 and the reasons that led them to ban all unapproved abortifacients, it is difficult for critics to assess the FDA's rationale and characterize it as reasoned. One could look to the agency's own regulations to evaluate the import ban according to the FDA's articulated standard. An agency is "bound to follow procedures required by its own regulations."¹⁷⁹ In considering whether an import ban should have been imposed, the FDA was obligated to follow its own "Policy Guidance for Personal Importation of Unapproved Drugs" and to assess the risk of permitting importation.¹⁸⁰ Under this standard, the FDA evaluates four factors to determine if the importation of an unapproved drug should be permitted for personal use. These factors include: whether the banned drug poses a substantial health risk, whether a commercial black market exists for the drug, whether other persons have attempted to import the drug and whether the drug would be used with physician supervision.

Upon considering each of these factors, the FDA's safety rationale for imposing an import ban on RU 486 still appears arbitrary, capricious and wholly insupportable. Large-scale clinical studies on the safety and efficacy of the drug contradict the FDA's conclusion that the importation of RU 486 would result in a substantial health risk to the public.¹⁸¹ In fact, during oral argument on the preliminary injunction in *Benten v. Kessler*, counsel for the FDA and the Customs Service seemed to have few reservations about the safety of the

ever, does not relieve an agency of its legal obligation to indicate to the requester that it is withholding documents on that basis.

¹⁷⁸ *Benten*, 799 F. Supp. at 288.

¹⁷⁹ *Id.* at 290.

¹⁸⁰ See *supra* notes 97-106 and accompanying text.

¹⁸¹ See *supra* notes 11-31 and accompanying text.

drug.¹⁸² Indeed, counsel even suggested that Leona Benten leave the country to take the medication on an airplane much as one might take aspirin or other over-the-counter medication.¹⁸³

While the medical benefits and safety of RU 486 are not disputed by scientific studies, the first factor the FDA should consider, there remains a question of whether a black market currently exists for the drug—the second factor evaluated by the FDA. Indeed, the FDA's concern about unsupervised use, while legitimate, is not sufficiently persuasive to warrant the imposition of the ban, since the FDA and Customs agents under the personal use exception evaluate each application. Case-by-case determinations provided for by the personal use regulation would serve to protect the health of importers. Customs agents and FDA personnel could require proof that the importer will use the drug while under the care of a physician and will not resell the drug. Also there is no existing evidence suggesting that the personal importation of RU 486 will spur the growth of a black market. Since there is no underground traffic in RU 486 currently, and since no one had ever attempted to import the drug prior to July 1992, RU 486 would have met the second and third criteria for personal importation set forth by the FDA's "Policy Guidance."

To the extent that the health risk might be greater if RU 486 was obtained on a black market and taken without a doctor's supervision, the fourth factor, this danger exists with other drugs that the FDA has permitted to be imported for personal use. For example, the FDA has permitted HIV-positive patients to import at least two unapproved drugs of questionable merit. The agency allowed the unapproved drug Compound Q to be imported for personal use, sold on the black market and tacitly approved large-scale human trials.¹⁸⁴ Although this drug was linked to a number of deaths and its users experience severe symptoms ranging from partial paralysis to temporary blindness, the FDA waited more than a year to issue an import alert.¹⁸⁵ Similarly, the anti-viral drug, dex-

¹⁸² *Benten*, 799 F. Supp. at 281.

¹⁸³ *Id.*

¹⁸⁴ *Myers*, *supra* note 100, at 330.

¹⁸⁵ *Id.* at 310.

tran sulfate, was popular with AIDS patients, who had imported it for their personal use.¹⁸⁶ The FDA issued an automatic detention order for dextran sulfate only when studies demonstrated that it was ineffective. The ease with which AIDS patients were able to import Compound Q and dextran sulfate is in stark contrast to the FDA's quick action to impose the import ban on RU 486, a much safer and more effective drug than either of these examples. This contrast suggests that FDA decisions regarding importation are not based primarily on health and safety concerns and that drugs that may induce abortions will be subject to disparate treatment. Nor can these examples be distinguished from RU 486 by arguing that terminally ill patients should have greater access to unapproved drugs. There is no requirement in the personal use exception that requires one to have a serious illness to import unapproved drugs for one's personal use.

At least one commentator has addressed the FDA's concerns about persons who would use an unapproved drug without a doctor's supervision.¹⁸⁷ Since "prohibition of a product . . . must be a last resort for the state as it constitutes a complete abrogation of choice," the FDA must rely on the existing system of limited access to potent drugs through the use of prescriptions and licensed pharmacies to protect the safety of the public.¹⁸⁸ It is not enough that the potential for misuse by the public exists; rather, the question is whether a distribution system is in place to safeguard against such misuse. Other *approved* drugs pose substantially greater health risks to the public than certain unapproved drugs, and by restricting their availability to "prescription-only," the FDA's interest in public health and safety is met.¹⁸⁹

In summary, the conclusion that the FDA acted in an arbitrary and capricious manner appears indisputable. Not only did the FDA evaluate the drug without assembling an administrative record of any kind, it immediately imposed an absolute ban on a safe and effective chemical alternative to

¹⁸⁶ *Id.*; see also Wendy K. Mariner, *Equitable Access to Biomedical Advances: Getting Beyond the Rights Impasse*, 21 CONN. L. REV. 571, 574-75 (1989).

¹⁸⁷ Elizabeth G. Patterson, *Health Care Choice and the Constitution: Reconciling Privacy and Public Health*, 42 RUTGERS L. REV. 1, 2 (1989).

¹⁸⁸ *Id.* at 82.

¹⁸⁹ *Id.* at 45.

surgical abortion, while permitting other, more dangerous drugs to be imported. In addition, the FDA's regulatory response to RU 486 seems particularly untenable when the FDA excludes the drug if it will be used to terminate a pregnancy but permits the drug to be imported for personal use as an anti-cancer agent.

III. SOCIAL AND LEGAL DEVELOPMENTS INVOLVING RU 486: IDEAS TO CONSIDER

Much of this Note has been devoted to exploring the potential medical uses of RU 486, explaining the role of the FDA as a regulatory body, exploring why the FDA imposed the ban on imports of RU 486 and evaluating whether the district court correctly decided that the agency wrongly denied Ms. Benten access to RU 486.¹⁹⁰ What may be lost in the retelling of Ms. Benten's story, however, are the broader implications for our system of participatory government that these events suggest.

RU 486 and the *Benton* case provide an opportunity to critique existing law and judicial decisions, and to consider and challenge the level of institutional attention to and financial support for research on women's health care needs and delivery of services by governmental agencies, government-sponsored research programs and the medical establishment.¹⁹¹ Perhaps Ms. Benton's attempt to obtain RU 486 would have been aided had FDA regulations provided different avenues for asserting her interest in the drug to substantiate her claim. Procedural regulations that permit for notice and comment periods are closely circumscribed vehicles for gathering information. It is not clear that even existing notice and comment

¹⁹⁰ See also Csilla Muhl, *RU-486: Legal and Policy Issues Confronting the Food and Drug Administration*, 14 J. LEGAL MED. 319 (1993) (survey of debate concerning the FDA's import ban on RU 486).

¹⁹¹ Legal scholarship in recent years has turned to examining "outsider" narratives to explore the role of law and to examine judicial decisions. Critical legal scholars argue that storytelling in legal journals provides a means to communicate with lawmakers and adjudicators in a professional voice through an accessible medium. Then, the act of presenting alternative, non-hegemonic narratives becomes a means to effect law reform. For a discussion of the importance of storytelling, see Richard Delgado, *Storytelling for Oppositionists and Others: A Plea for Narrative*, 87 MICH. L. REV. 2411 (1987).

procedures ensure that interested persons have an opportunity to influence the development of FDA policy in a meaningful way. Therefore, one must ask, how can the FDA and, ultimately, Congress ensure that there is a meaningful notice and comment process as it currently exists?

One answer is to have Congress write enabling legislation to encourage greater judicial review of agency action as a final safeguard for the public interest. But that may not be realistic. Perhaps, then, the judiciary must stake out a greater role in curbing the discretion of administrative agencies if Congress is unable or unwilling to do so. The *Benten* case suggests that currently the judicial system, with the exception of the District Court for the Eastern District of New York, is willing to sanction broadly sweeping discretionary powers for an agency even on highly controversial questions. Ms. Benten's predicament dramatized how difficult it may be in the future both to encourage an agency to hear a politically sensitive point of view and to confront agency actions in court, even when a legal challenge reflects the interests of a less politically powerful group.

A. *Silence and Participation—Women's Health Care*

Both judicial review and a determination that a period of notice and comment pursuant to the APA was required were essential in this case in order to ensure that there was an opportunity for women seeking to import RU 486 to communicate with the FDA. After the *Benten* decision, however, in the absence of a formal communication mechanism other than the formal notice and comment procedure, the FDA was free to ignore the loud clambering of the public outside of agency walls.¹⁹² Permitting an agency to avoid responding to public

¹⁹² One commentator suggests that one way to ensure that the public has an opportunity to comment on FDA policies that impact their lives would be to supplement existing APA rules governing procedures the FDA must follow when issuing regulations. *Debora C. Fliegelman, Comment, The FDA and RU 486: Are Politics Compatible with the FDA's Mandate of Protecting Public Health and Safety?*, 66 TEMP. L. REV. 143, 144 (1993) (the imposition of the ban on RU 486 was a political action). By requiring the FDA to file an impact statement similar to the environmental impact statement required of developers, the public would be able to assess the scientific basis for specific rulings. Presumably, these procedures could require the FDA to articulate what impact its decisions would have on dif-

comment in this way is both shortsighted and frighteningly undemocratic.¹⁹³

For many, the outcome of this case was particularly frustrating precisely because issues of women's health historically have been largely ignored by the Department of Health and Human Services. Within the Department, both the National Institutes of Health ("NIH") and the FDA have particular influence on American lives whether through identifying research priorities or regulating one-fourth of all consumer products sold in the United States.¹⁹⁴ Women's health advocates have struggled for two decades to encourage government officials and researchers to include women in research and drug protocols in order to assess how diseases manifest themselves

ferent populations affected by the regulation. Such a procedural requirement would provide greater notice to interested persons while assisting the public's ability to understand a regulation by encouraging the FDA to disclose its view of the scope of a regulation's impact.

As proposed, this additional procedural safeguard will not sufficiently constrain the FDA from arbitrary decisionmaking. First, if the proposed regulations are submitted to representatives in the medical community, the narrowness of the consulted group becomes an issue. Surely, gathering the comments of a medical body should not substitute for an open process where any potentially affected person could comment. Women should be able to speak directly to the agency through oral or written submissions. The importance of an open process with women speaking their own truths is particularly important precisely because of the history of the agency's inattention to women's health concerns.

Second, even if the FDA does spell out more carefully the evidentiary basis of a decision and its vision of how a regulation may impact a particular group's health, nothing in this proposal suggests that the FDA must draw unbiased conclusions after a thorough evaluation of a regulation's impact. The process as envisioned is more rigorous and time-consuming but still leaves the FDA subject to political influence. The FDA's impact statement could easily reflect political bias and, thus, would be little more than a standard policy paper.

Since women's perspectives on RU 486 and other health issues particular to women have been generally absent from debates about health care, and if additional procedural requirements would not ensure that the FDA acts free from undue political pressure, then the importance of judicial review becomes even clearer.

¹⁹³ See Crittenden, *supra* note 80; McGarity, *supra* note 84.

¹⁹⁴ Orrin G. Hatch, *The Future Direction of the Food and Drug Administration*, 48 FOOD DRUG COSM. L.J. (15) (1991):

Today, the FDA covers a greater portion of our lives than ever envisioned by writers of the Federal Food, Drug, and Cosmetic Act. The FDA is responsible for regulating more than \$700 billion worth of goods sold annually to Americans; that constitutes about twenty-five percent of the total expenditures for personal consumption in the United States each year.

in women and to determine how women respond to treatment. Until 1990, NIH grantees routinely excluded women from studies.¹⁹⁵ Although the leading causes of death for women are heart disease, cancer and strokes, the prototypical study population has been overwhelmingly male, with study results applied to women.¹⁹⁶ The medical establishment has been widely criticized in recent years for its willingness to diagnose and treat women based on research studies involving men only. For example, a landmark study used 20,000 male subjects to determine if the use of aspirin decreased the likelihood of heart attacks. Although almost one-half of all heart attack victims are female, no women were included in a study, the results of which will continue to guide treatment of women.¹⁹⁷

Other examples of gender bias influencing research priorities and project design have been documented. For instance, researchers interested in women's health issues had difficulty securing funding; in 1990, a five-year, comprehensive \$50-million breast-cancer study was tabled for budgetary reasons, although a fifteen-year \$142-million study involving lowering cholesterol in men had recently concluded.¹⁹⁸ Critics have also noted that bias infects studies when researchers conceptualize women's health care research only as "reproductive" and "all other."¹⁹⁹ From this evidence of gender bias in medical research, health care professionals have concluded that women's health needs must be addressed through further research into

¹⁹⁵ For a comprehensive statement of NIH's planned response to gender disparities in research and treatment, see Bernadine Healy, *Women's Health, Public Welfare*, 266 JAMA 566 (1991) (Ms. Healy was the first female director of the NIH). See also Bernadine Healy, *Women's Health is Our Modern-Day Suffrage Movement*, 110 LADIES HOME J. 138 (1993) (interview with Dr. Healy, given after she left the NIH post, providing opportunity for her to reflect on her contributions as director).

¹⁹⁶ See Vivian W. Pinn, *Women's Health Research: Prescribing Change and Addressing the Issues*, 268 JAMA 1921 (1992) (editorial commenting on need for greater attention on women's health issues).

¹⁹⁷ See Joanne Silberner, *Health: Another Gender Gap: A Crackdown on Research Bias Against Women Should Produce Change*, U.S. NEWS & WORLD REP., Sept. 24, 1990, at 54.

¹⁹⁸ *Id.*

¹⁹⁹ See Carolyn M. Clancy & Charlea T. Massion, *American Women's Health Care: A Patchwork Quilt with Gaps*, 268 JAMA 1918 (1992) (description of impediments to health care for women).

women's health issues. Without a scientific base of knowledge based on research on women, current therapies may be ineffective or even harmful.

In addition to affecting medical research projects, gender bias has negative effects on the testing for, and diagnosis and treatment of, disease in women. Studies demonstrate that there are disparities in women's access to diagnostic procedures and that therapeutic intervention is more available to men than to women.²⁰⁰ For instance, women are less likely to receive transplants, kidney dialysis and coronary bypass surgery than men.²⁰¹ Equally troubling is evidence suggesting gender bias in clinical decisionmaking. Doctors are more likely to attribute women's health complaints to psychological causes than physical ailments.²⁰² The growing presence of female doctors may help diminish some gender discrimination in the clinical setting. At least one study suggests that female physicians spend more time with female patients and encourage patient participation.²⁰³ Although female professionals groomed by the medical establishment may bring gender bias to their practices, if women are encouraged to participate more actively in discussions of their health care needs, presumably more of their needs will be met.

In response to evidence of systemic gender bias in the medical system, a number of reform proposals—institutional, legislative, and research plans—have been initiated by different entities. Among the agencies, the NIH, in 1990, created an "Office of Research on Women's Health" to "address inequities in women's health research."²⁰⁴ Also, members of Congress, particularly female legislators, have sponsored legislation designed to attack the problem of inadequate resources and to draw to attention to women's health issues.²⁰⁵ Women's advo-

²⁰⁰ For an excellent editorial describing gender bias in diagnoses and treatment, see *Gender Disparities in Clinical Decision Making*, 266 JAMA 559 (1991). To consider the question of gender discrimination in the mental health context, see D'Vera Cohn, UPI, *The Psychological Gender Gap: Women's Health Needs are Often Ignored, Experts Say*, WASH. POST, Jan. 16, 1985, at Z19.

²⁰¹ *Gender disparities*, *supra* note 200, at 559.

²⁰² *Id.*

²⁰³ See generally Clancy & Massion, *supra* note 199.

²⁰⁴ Pinn, *supra* note 196, at 1921.

²⁰⁵ See *Omnibus Women's Health Legislation Package*, THE GRAY SHEET, Sept. 20, 1993, at 24-25 (FDC Reports); THE BLUE SHEET, Sept. 15, 1993, at 14-16 (FDC

cacy on behalf of women's health seems to have had some effect: there is a push among researchers to remedy the existing lack of scientific knowledge of women's health issues. In 1993, the NIH awarded the first research contract to launch a \$625 million, fifteen-year comprehensive study of women's health issues.²⁰⁶ Research alone, however, will be not alleviate gender bias in the health care system. Even as researchers begin to consider women's health issues, many health care professionals argue that a more systemic approach is necessary to eliminate gender discrimination. They advocate greater emphasis on women's health in medical training—now limited to obstetrics and gynecology—and seek ways to encourage more women to become faculty members and researchers.²⁰⁷

Thus, part of the story of RU 486 is that the FDA's disparate treatment of the drug marks another chapter in the troubling history of women's health policy at the national level. In light of this history, women's interest and participation in policymaking about women's health issues should be encouraged. Yet by imposing the alert and characterizing it as internal policy rather than a substantive rule, the FDA avoided involving women in a crucial decisionmaking process. Therefore, at a time when the health care establishment agrees that it wants to encourage greater discussion on women's health issues, the FDA simply refused to engage in dialogue with women concerning RU 486, effectively silencing women's voices. The courts should have ensured that women's participation and comments concerning RU 486 were at least solicited before upholding the FDA's discretion to ban its import for personal use.

Reports).

²⁰⁶ See U.S. Dept of Health and Human Services, *NIH Launches Largest Study of Women's Health*, 108 PUBLIC HEALTH REP. 258 (1993); see also Paul Cotton, *Women's Health Initiative Leads Way as Research Begins to Fill Gender Gaps*, 267 JAMA 469 (1992); Ruth Kirschstein, *Largest US Clinical Trial Ever Gets Under Way*, 270 JAMA 1521 (1993).

²⁰⁷ For summary of proposed medical school curriculum changes and conference proceedings regarding the creation of a women's health specialty, see Andrew A. Skolnick, *Women's Health Specialty, Other Issues on Agenda of "Reframing" Conference*, 268 JAMA 1813 (1992).

B. Looming Constitutional Questions

It is particularly ironic that the FDA would seek to limit debate concerning a class of drugs, the antiprogestins, that will raise unique constitutional questions. In a democratic society, citizens should expect that when scientific developments promise to have important legal, political and social implications, procedural safeguards that ensure an inclusive process and communication would be enforced rather than dismissed as unimportant.

The simultaneous development of RU 486 as both a birth control method and an abortifacient presents a factual circumstance that challenges existing constitutional jurisprudence on rights of access to birth control and abortion services. Presumably some states will seek to limit access to the drug. States could try to regulate the drug as either a birth control method or an abortifacient, since it is likely that the drug eventually will be available for both uses.²⁰⁸

In response to these efforts, women who want to use the drug for either purpose will have at least three legal arguments to assert. First, since the FDA will have approved the drug for use as an abortifacient and, probably, limited access through a by-prescription-only requirement, women may argue that the federal regulatory scheme, as administered by the FDA, has preempted further state action restricting distribution of the drug.²⁰⁹ Second, women may assert that restric-

²⁰⁸ See Part I.A., *supra*.

²⁰⁹ The Supreme Court set forth three means by which federal legislation preempts state law on the same subject in *Pacific Gas and Elec. v. State Energy Resources Conservation Comm'n*, 461 U.S. 190, 203-204 (1973) (when a state, asserting economic motives, sought to impose a moratorium on building new nuclear plants until a permanent disposal system for nuclear waste could be developed, preemption doctrine did not apply; federal law only occupied the field of nuclear safety regulation). Additional state regulations are impermissible: (1) if Congress has expressly preempted further state action; (2) if the stated federal interest—such as uniformity of laws—is sufficiently dominant that Congress' "intent to supersede state law . . . may be found" from a pervasive regulatory scheme; or (3) if state law conflicts with federal law. *Id.*

In the case of RU 486, the safety and efficacy of the drug will be evaluated by the FDA before it is available for distribution in this country. Although the Food, Drug and Cosmetic Act does not explicitly preempt state regulation of drug distribution, there is a strong federal interest in establishing national uniform standards concerning consumers' access to drugs. The FDA uses the drug approval process, labelling requirements and by-prescription-only status to limit consumers'

tions on access to RU 486 would violate their privacy interests and fundamental right to birth control and, in the case of women seeking to take RU 486 three or four weeks after conception, such restrictions would violate women's right to choose abortion. Third, women would argue that restrictions that limit the use of RU 486 within two weeks of fertilization violate the Equal Protection Clause of the Fourteenth Amendment. The following exploration focuses on the last two of these arguments, emphasizes the development of privacy rights and suggests that the Court—if it seeks to uphold states' attempts to regulate RU 486's distribution—will find itself constrained by its privacy rights decisions. Indeed, the emergence of RU 486 as a reproductive technology may result in a future Supreme Court decision reestablishing a woman's fundamental constitutional right to choose abortion without state-imposed restriction in the first few weeks after fertilization and implantation.

As a result of thirty years of court decisions involving privacy rights, few state restrictions on the use of contraceptives are constitutionally permitted, but the right to abortion may be regulated rather freely as long as regulations do not overburden the exercise of that right. The Court's most recent decision on abortion regulations firmly reiterates and, at least rhetorically, further enhances the constitutionally privileged

purchases of potentially harmful medicines. This regulatory scheme is detailed and rigorous. As such, the federal regulation of drugs by the FDA represents a comprehensive process ensuring drugs' safety and efficacy. The national regulatory scheme also provides pharmaceutical companies with a national market free of piece-meal, specialized state regulations which would inhibit interstate commerce.

Since the FDA's complex scheme serves two substantial federal interests, namely guaranteeing that only safe and effective drugs will be sold to American consumers and establishing a national marketplace for pharmaceuticals, Congressional intent to preempt further regulation reasonably may be inferred. States seeking to limit distribution of RU 486 would have to rest their authority to do so on some equally substantial state interest, and any regulatory proposal could not directly conflict with existing federal law. States probably would assert interests in maternal health, the safety of the drug and fetal life. Since Congress explicitly charged the FDA with regulating drugs' efficacy and safety, the federal scheme should effectuate the first two asserted state interests. As for the state interest in fetal life, states would have to demonstrate that their interest in fetal life beginning at the moment of conception, standing alone, is so significant that the preemption doctrine should not apply to state regulation of RU 486. Even under *Casey*, it is unlikely that the Court would characterize a state interest in a fertilized egg at the moment of conception as substantial.

status of the right to contraceptives.²¹⁰ Since RU 486 has a dual nature as both a contraceptive and an abortifacient, attempts by states to regulate the drug will be complicated by the Court's relatively recent emphasis of the distinction between contraception and abortion, and its reliance on that distinction to legitimize greater state regulation and restriction of abortion. Presumably, if the right to contraception—as distinguished from the right to abortion—had not been emphasized as a result of the change in the abortion right's constitutional status, the right to contraception would be less entrenched in the Court's privacy jurisprudence. Furthermore, if the Court had not distinguished the right to contraception, state regulation of RU 486 perhaps would be easier to justify constitutionally. But particularly after *Casey*, the Court would have a difficult time upholding distribution restrictions on RU 486 without providing a sharply different interpretation of privacy rights. Ultimately, RU 486 may prove to be a scientific development that forces the court to directly confront whether a woman has a fundamental constitutional right, as she did under *Roe v. Wade*, to choose abortion in the first few of pregnancy—a choice that is possible using RU 486 but not the surgical abortion technique—rather than merely a right that cannot be unduly burdened.

The distinction between contraception and abortion is a relatively recent one in constitutional jurisprudence. In the late 1960s and 1970s, the Court did not differentiate the constitutional rights at issue; rather, the Court recognized that the right to privacy translated into a fundamental right to use birth control and to have an abortion.

1. Birth Control Cases

The landmark opinion in *Griswold v. Connecticut* was the first to recognize that the constitutional right to privacy, originating in the First, Third, Fourth, Fifth, Ninth and Fourteenth Amendments, included a derivative right to use contraceptives.²¹¹ The *Griswold* Court considered whether the executive director and the medical director of a health clinic could be

²¹⁰ *Planned Parenthood v. Casey*, 112 S. Ct. 2791, 2807 (1992).

²¹¹ 381 U.S. 479, 485-86 (1965).

prosecuted under a criminal state statute for giving "information, instruction, and medical advice to married persons" regarding contraceptives and for prescribing contraceptive devices.²¹² The Court's conclusion that the statute was unconstitutional set the stage for the next constitutional challenge to state limits on access to birth control.

Although *Griswold* involved the rights of married persons, seven years later the Supreme Court extended constitutional protection to single persons seeking access to contraceptives. The Court's decision in *Eisenstadt v. Baird* concluded that a state statute criminalizing the distribution of contraceptives to unmarried persons, but permitting distribution to married persons, violated the Equal Protection Clause of the Fourteenth Amendment.²¹³ Unequivocally stating that no meaningful distinction could be drawn between the privacy interests of individuals in marital relationships and single individuals, the Court stated that both groups must have equal access to contraceptives. In one of the most quoted sentences in subsequent privacy jurisprudence, the Court articulated its rationale: "If the right to 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."²¹⁴ Thus, after *Eisenstadt*, an individual's right of access to contraceptives was constitutionally guaranteed. Therefore, an outright ban on a particular contraceptive technology, such as RU 486, would appear to be constitutionally invalid under *Eisenstadt*.²¹⁵

²¹² *Id.* at 480.

²¹³ 405 U.S. 438, 443 (1972) (lecturer on contraception gave contraceptive foam to an unmarried female student in violation of a state law prohibiting contraceptive distribution to unmarried persons for contraceptive purposes).

²¹⁴ *Id.* at 453.

²¹⁵ Both *Griswold* and *Eisenstadt*, as well as other privacy cases such as *Roe v. Wade*, were cited with approval in *Planned Parenthood v. Casey*. See *infra* notes 219-23 and accompanying text.

In addition to recognizing a constitutional right of access to contraceptives for unmarried persons, *Eisenstadt* presents a model for evaluating the constitutional status of restrictions on access to contraceptives. Since some states will seek to regulate the distribution of RU 486 as a birth control method, Justice White's concurrence, joined by Justice Blackmun, indicates that a state would have to demonstrate a compelling state interest for the Court to affirm the constitutional validity of such restrictions. *Id.* at 463-64. And this strict scrutiny standard re-

A number of years following *Eisenstadt*, the Court again considered the right of access to birth control in *Carey v. Population Services International*, concluding that the right to birth control is fundamental, and that any state regulation involving contraceptives must be based on a compelling state interest

mains the appropriate standard of review for regulations of contraceptives even after *Casey*. Justice White argued that if a state asserts a public health interest in regulating a contraceptive that may pose a health risk, "we may not accept on faith the State's classification of a particular contraceptive as dangerous to health. Due regard for protecting constitutional rights requires that the record contain evidence that a restriction on distribution of vaginal foam [and other contraceptives] is essential to achieve the statutory purpose." *Id.* at 464. Thus, a state statute criminalizing the distribution of contraceptives that are to be sold only pursuant to a prescription would presumably be constitutional under *Eisenstadt*. Since the FDA restricts access to other chemical contraceptives, such as the birth control pill, Depo-Privera and Norplant, to sale by prescription only, it is likely that RU 486 would be regulated similarly. Then states could constitutionally prohibit over-the-counter sales of RU 486 by arguing the states' interests in public health.

More constitutionally suspect than statutes restricting RU 486 to sale-by-prescription-only status would be any additional state regulations peculiar to the distribution of RU 486 and not other chemical contraceptives. Since the *Eisenstadt* Court characterized a prescription requirement for access to a birth control method as "a substantial burden" to place on the exercise of a constitutional right, any additional restrictions would augment the substantial burden felt by a woman seeking to use a chemical contraceptive like RU 486. Even if the prescription requirement is justified by a strong state interest in public health, under *Eisenstadt* a state would have to make a strong evidentiary showing that further procedural restrictions—beyond the prescription requirement—would be warranted by a state interest in health. And the nature of these state-imposed restrictions also would be at issue: it appears unlikely that the Court would even entertain a state's assertion of an interest not related to the health of the contraceptive user. For example, in *Eisenstadt*, the Court dismissed Massachusetts' asserted interest in deterring premarital sexual intercourse, ridiculing it as "prescrib[ing] pregnancy as punishment for fornication." *Id.* at 448.

Although the *Eisenstadt* Court glossed over the question of whether a state could restrict access to contraceptives to further some other state interest, resting its decision on the disparate treatment of married and single persons, in the case of RU 486 the state's interest in health would be protected by the sale-by-prescription-only requirement. *Id.* at 453. Any health risks that a woman would encounter by using RU 486 would be managed through the medical protocol prescribed by the dispenser of the drug. Other proposed state regulations that states might want to adopt modeled after restrictions on access to abortion, such as waiting periods, state-mandated counseling to encourage a woman to carry a pregnancy to term and parental consent provisions, would have to be justified by a state's interest not in the woman's health, but rather in a *potential* pregnancy that *might* occur if a woman did not use the drug as a contraceptive. After *Eisenstadt*, it seems unlikely that a state could show a sufficiently compelling reason to justify additional restrictions on access to RU 486 as a contraceptive. The Court probably would invalidate this type of regulation as interfering with the exercise of the fundamental constitutional right to contraceptives.

and must be narrowly tailored to meet the asserted interest.²¹⁶ The *Carey* opinion demonstrates how the Court at that time connected the right to birth control and the right to abortion: "[r]estrictions on the distribution of contraceptives clearly burden the freedom to make such decisions," and limiting their distribution through licensed pharmacists "clearly imposes a significant burden on the right of the individuals to use contraceptives." The Court thus drew an analogy to access to abortion; restrictions on access to contraceptives and abortion services must survive strict scrutiny, and the state must be able to demonstrate a compelling interest to justify any regulation.²¹⁷

Although subsequent cases have lessened the stringency of the standard of review of restrictions concerning abortion, *Carey* reflects the development of privacy jurisprudence and the theoretical interconnectedness of the constitutional right to contraceptives and abortion services. At the philosophical center of each major decision in birth control cases is the notion of independent individual judgment and private decisionmaking. During this period before the Court began to uphold state restrictions on abortion services, the Court conceived of the privacy right as applying to both decisions about conception and abortion. *Carey* expresses this underlying principle by noting that the right to contraceptives should be seen not as constitutionally distinct but as part of the "constitutionally protected right of decision in matters of childbearing that is the underlying foundation of the holdings in *Griswold*, *Eisenstadt v. Baird* and *Roe v. Wade*."²¹⁸

2. Birth Control Versus Abortion

The conceptual synthesis that marked the Court's decisions regarding the right to birth control and the right to abortion ended definitively in 1992 with the Court's opinion in

²¹⁶ 431 U.S. 678 (1977) (states may not ban mail-order company from distributing contraceptives, must demonstrate a compelling state interest when seeking to regulate distribution of contraceptives and may not constitutionally proscribe advertising of contraceptives).

²¹⁷ *Id.* at 687-89.

²¹⁸ *Id.* at 688-89.

Planned Parenthood v. Casey.²¹⁹ This case is notable both for the philosophical shift it embodies and for what clues it holds regarding future privacy jurisprudential development and what, if any, future constitutional protection will be accorded to RU 486.

In *Casey*, the Court declared the right to contraceptives as even more explicitly sacrosanct than in prior opinions, while fundamentally undercutting the right to abortion. The opinion supports, at length and with eloquence, the existence of a fundamental right to birth control, notes that precedent connects the premises behind the birth control right to the constitutional underpinnings of the abortion right and, then, in a theoretical shift from the earlier birth control cases, explains that the constitution simply does not protect the act of abortion in the same way that it does birth control.

The *Casey* decision substantially eases the standard for review of statutory restrictions on abortion, holding that only those restrictions that imposed an "undue burden" on the exercise of the abortion right would be unconstitutional.²²⁰ As the *Casey* Court changed the standard of review for statutory restrictions on the right to abortion, radically increasing the number of restrictions that are constitutionally permissible, the Court distinguished the right to abortion from the right to contraceptives.²²¹ Nevertheless, in the case of the right to birth control, the Court adhered to the premises underlying constitutional protection of this right, reiterating again the guarantee of *Griswold*, *Eisenstadt* and *Carey*:

there is a realm of personal liberty which the government may not enter. . . . It is settled now, as it was when the Court heard arguments in *Roe v. Wade*, that the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood.²²²

The Court even went so far as to state frankly that "[i]n some critical respects the abortion decision is of the same character as the decision to use contraception to which [*Griswold*, *Eisenstadt* and *Carey*] afford constitutional protection. We have

²¹⁹ 112 S. Ct. 2791 (1992).

²²⁰ *Id.* at 2821.

²²¹ "Abortion is a unique act." *Id.* at 2807.

²²² *Id.* at 2805 (citing *Carey*, *Eisenstadt* and *Griswold* among others).

no doubt as to the correctness of those decisions."²²³ Thus, *Casey* sets forth two profoundly different levels of constitutional protection accorded to two related activities—choosing a contraceptive and choosing an abortion which are closely connected in their aim—the avoidance of pregnancy and childbirth, but not traditionally in time.

Hence, as a result of *Casey*, the Court has two distinct standards: the Court will strictly scrutinize state restrictions on contraceptives but will uphold regulations on abortions as long as they are rationally related to a state interest and do not impose a substantial burden on the right to choose. After *Casey*, stare decisis would make it difficult to revisit the constitutionality of statutory restrictions on contraception. Yet some states will undoubtedly seek to impose such restrictions when RU 486 becomes available as a contraceptive. At that time, if the Court attempts to reason that state regulation of RU 486 either as a contraceptive or early-stage abortifacient is constitutional, it will find itself confronted by its lyrical pronouncements about the special constitutional protection afforded birth control use.

3. Constitutional Regulation of RU 486?

The Court's analytical distinction between contraception and abortion, which provides a constitutional basis for state restrictions on abortion, cannot survive the development of RU 486 as the following set of related hypotheticals will demonstrate. In fact, the Court's discussion of this distinction in *Casey* may make constitutionally valid statutory regulation of RU 486²²⁴ more unlikely unless the Court is willing to nar-

²²³ *Id.* at 2807.

²²⁴ The hypotheticals assume that any state regulation is more detailed and burdensome than a prescription requirement. Under *Eisenstadt*, see *supra* note 215, requiring a prescription to obtain potentially dangerous contraceptive material may place a substantial burden upon the right recognized in *Griswold*, but that burden is justified by a strong state interest and does not, as did the statute at issue in *Griswold*, sweep unnecessarily broadly or seek 'to achieve its goals by means having a maximum destructive impact upon' a protected relationship. *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965). Federal determination of which drugs will be placed on the by-prescription-only schedule is less troubling because the federal interests in safety and efficacy are indisputable. Additional distribution requirements to be imposed on drugs by states, however, do raise the question of what

row sharply its interpretation of *Casey* and characterize the right to birth control as less than fundamental.

Consider the following hypothetical:

Woman A seeks to use RU 486 as a birth control method at a fairly low daily dosage. She is not pregnant. Her state of residence passes a statute sharply restricting access to the drug, arguing that although it may be used as a birth control pill, RU 486 may also be used as an abortifacient. The state asserts, therefore, that the statute is constitutional. The woman brings a suit arguing that her constitutional right to choose a birth control method is violated by the restrictive statute and that she has chosen to use RU 486 for health reasons because it is safer than standard birth control pills and IUDs.

Since RU 486 is the only drug that appears to function as both a method of birth control and an abortifacient after implantation,²²⁵ it is unclear how the Court would interpret state statutes that might seek to limit access to the drug once it was approved for use. Nevertheless, because the drug would function like birth control pills and IUDs, preventing implantation of a fertilized egg in the wall of the uterus, a woman presumably could assert successfully her fundamental constitutional right to choose a form of birth control. She would argue that the state can not demonstrate a sufficiently compelling state interest that trumps her privacy interest. This is especially true if RU 486 presents a lesser health risk than other non-barrier birth control methods. Woman A could cite *Casey* and *Griswold*'s progeny in support of her position, characteriz-

state interest is being promoted.

²²⁵ The morning after pill, a form of birth control pill, only works up to 72 hours after fertilization; the IUD will only impede implantation and will not typically cause a fetus to be expelled. See also Martha A. Field, *Killing "The Handicapped"—Before and After Birth*, 16 HARV. WOMEN'S L.J. 79 (1993). She describes implantation:

The embryo up to this point is sometimes described as a "pre-embryo," more similar to organs or tissue than to anything that is alive. The pre-embryo has much less chance for survival than an implanted embryo. Before implantation, the fertilized ovum has a few undifferentiated cells but no organ structure and no spinal column. . . . Twinning also can take place prior to implantation but not after. If state legislatures were given a free hand to cut back on abortion a state might try to use this time as the cut-off for abortion. The embryo would be considered life but the pre-embryo would not be.

Id. at nn.214-16 and accompanying text. Implantation is complete fourteen days after fertilization.

ing as fundamental her right of access to RU 486 as a contraceptive. Moreover, under these cases, a state would have to show a compelling state interest in a potentially fertilized egg before a statute restricting a woman's use of RU 486 could be upheld. But under the strict scrutiny standard, it is unlikely that a state could successfully make this showing.

In addition to her privacy rights argument, Woman A would also assert that state restrictions violate her right to equal protection under the Fourteenth Amendment. As the Supreme Court stated in *San Antonio v. Rodriguez*, where the exercise of a fundamental right is at issue, a state must treat similarly situated persons equally.²²⁶ A state may not interfere with the exercise of the right without demonstrating a compelling interest for doing so.²²⁷ Under *Rodriguez*, a court would apply strict scrutiny when evaluating a state's regulation of RU 486.²²⁸ Woman A would claim that her fundamental right is abridged by the state's regulation and that the state has not asserted a compelling interest to support the state statute. She would note that she is identically situated to a woman using an IUD or birth control pills. A court probably would be persuaded by this argument and invalidate the regulation on equal protection grounds as well.

Contrast the following hypothetical to the one above.

Woman B, who does not use RU 486 as a birth control method, visits her doctor believing that an egg was fertilized. Because she is within fourteen days of fertilization, however, implantation has not taken place. She asks her physician for a prescription for a higher single dose of RU 486 and for a prostaglandin. Her state has enacted a statute which permits wide access to the lower dosage of RU 486 associated with its use as a birth control method, but which imposes restrictions on access to the higher single dosage of RU 486. The state characterizes RU 486 as an abortifacient and imposes restrictions that are similar to restrictions on abortion services. The restrictions include parental consent for minors, a procedure whereby a woman must receive specific counseling by a doctor emphasizing the value of childbirth and risks associated with abortion and a 24-

²²⁶ 411 U.S. 1 (1973) (since education is not a fundamental right and wealth is not a suspect classification, state education financing scheme that relies on local districts to supplement state aid with local property taxes does not violate the equal protection rights of school children from poorer school districts).

²²⁷ *Id.* at 17.

²²⁸ *Id.* at 28.

hour waiting period before receiving the drug.²²⁹ The state would argue that, under these circumstances, the woman must demonstrate that these restrictions are constitutionally invalid for they do not impose an undue burden on Woman *B*'s ability to obtain an abortion.

Since RU 486 functions medically like the birth control pill or IUD, Woman *B* is similarly situated to Woman *A* and would assert similar privacy and equal protection arguments.²³⁰ Even if the state were to regulate access to RU 486 based on Woman *B*'s intent or the dosage of RU 486 she seeks, those regulations similarly would fail.

Should the state be able to restrict Woman *B*'s access to RU 486 if it knows that the drug is being sought deliberately to avoid implantation and pregnancy, even though the drug functions in the same way for Woman *A*? What state interest is at stake and how should that interest be compared with Woman *B*'s privacy interest? The state could not reasonably assert a compelling interest in a fertilized egg, even under *Casey*. The only interest the state could assert would be grounded in its expectation that, if left alone, the fertilized egg would implant.²³¹ Since under these circumstances the drug functions like other contraceptives, the question of Woman *B*'s intent presumably would not control which standard of review would apply.²³²

One indicia of intent would be RU 486 dosage level. Since the state could not adequately demonstrate a compelling interest in a fertilized egg, regulations based on dosage, therefore,

²²⁹ *Planned Parenthood v. Casey*, 112 S. Ct. 2791, 2822-33 (1992).

²³⁰ She carries a fertilized egg but implantation has not taken place. The dose of RU 486, acting like the pill or an IUD, will cause her to expel the egg.

²³¹ But that has never been sufficient to allow the state's interest to trump the woman's privacy interest. Indeed, under *Casey*, not only does a woman have a constitutional right to avoid implantation through the use of contraceptives, but she also has a right to abort an *implanted fetus* up until the point of viability. Thus, by logic, the state could not have a greater right in a fertilized, but not-yet-implanted, egg.

²³² Clearly since it is difficult for a woman to know precisely when she ovulates and even more difficult to approximate the time fertilization or implantation occurs, any attempt by a state to regulate the administration of RU 486 immediately after fertilization seems impractical at best. If a state wanted to regulate access to RU 486 when a woman's use of the drug could be characterized as causing an abortion, the question becomes how to make this determination. Is it at three weeks post-fertilization? At four weeks?

also would be constitutionally invalid. Even though states might characterize RU 486 as an abortifacient, *Casey*-like restrictions imposed on Woman A's use of RU 486 as a birth control method or on Woman B's use of RU 486 to avoid implantation would not survive the Court's scrutiny under either a privacy or equal protection rights rationale.

Finally, consider a third hypothetical.

Woman C has been using a barrier contraceptive method, misses her period and suspects she is pregnant. She believes she is three weeks pregnant and if she cannot gain access to RU 486, she will have to wait an additional three weeks for a surgical abortion. Even though her state of residence wants to restrict sharply access to abortifacient drugs, it has been frustrated by the Court's decisions in hypotheticals one and two. The state argues that this is a case where there is no ambiguity concerning the use of RU 486 as a birth control method. Woman C suspects that implantation has occurred and she is certain that she wants to terminate the pregnancy. She would argue that at this stage in pregnancy, her interest in her right to choose abortion trumps any state interest in fetal life.

Woman C's argument presents a novel question for the Court's consideration.

In light of these hypotheticals—and to answer the constitutional question posed by Woman C's dilemma—one must consider how the approval of RU 486 will influence the development of constitutional jurisprudence concerning birth control and abortion. The development of RU 486 may require the Court to hold once again, as it had in *Roe v. Wade*, that women have a fundamental constitutional right to choose abortion in the first six weeks after fertilization. The Court has never tried to balance individual liberty and privacy interests against state interests in the first six weeks of pregnancy. Since surgical abortions generally are performed *after* six weeks of pregnancy, modern courts never have been faced with this dilemma.²³³ Nor have the courts tried to regulate a drug that

²³³ Surgical aspiration abortions generally are performed once a pelvic exam confirms pregnancy, five or six weeks after fertilization. If a surgical abortion is performed prior to six weeks, there is a possibility that the abortion will not be successful. See THE BOSTON WOMEN'S HEALTH COLLECTIVE, *THE NEW OUR BODIES OURSELVES* 294-96 (1984).

Note that at common law, abortion was permissible until the time of "quickening," when a woman would feel fetal movements in her uterus. *Casey*, 112 S. Ct. at 2859 (Rehnquist, C.J., dissenting in part and concurring in part).

confounds easy categorization as a birth control method or an abortifacient. Therefore, most of the constitutional debate about abortion has focused on questions of viability and a trimester framework, based on three-month intervals, to evaluate and determine the rights of the woman vis-à-vis the state.²³⁴ What the Supreme Court has not considered is the vagueness—historically, philosophically, physically and morally—of the first days, first weeks and first month during which an egg is fertilized and implanted. And yet the development of RU 486 and Woman C's arguments challenge the Court to shift radically its focus to this ambiguous time in pregnancy.

The hypotheticals above, especially Woman C's unique situation, suggest that because the Court has drawn a strict line between birth control and abortions and, correspondingly, has characterized a woman's constitutional privacy interests in contraception and abortion very differently, the Court is at a jurisprudential crossroads. The Supreme Court will have to consider whether its separate analysis and differentiation of the constitutional rights associated with birth control and abortion remain meaningful if the applicable constitutional standard depends not on viability but on fertilization, implantation and the fourteen days thereafter.²³⁵ Since RU 486 may

²³⁴ *Casey* rejects the trimester framework articulated by *Roe* in favor of drawing a line at viability, at which point states may limit a woman's ability to choose abortion significantly. *Id.* at 2821. Other restrictions such as mandated counseling sessions, counseling waiting periods and parental consent requirements are permissible even before viability. *Id.* at 2822-33.

²³⁵ RU 486 provides an opportunity to reconstruct the constitutional debate itself and locate a woman's abortion decision at a time when the fetus is irrefutably dependant on the woman's life. At three weeks after fertilization, for example, viability is not in question and even birth is less of a certainty. Pro-life advocates could not suggest that the fetus could live outside of the woman, even with technological assistance. Thus, with the development of RU 486, pro-choice advocates could challenge the Court's historical focus on viability as misplaced.

The Court has traditionally considered the state interest in a fetus primarily by identifying when the fetus could live outside the woman. As scientific technology has improved, the point of viability has moved closer to conception. The court has emphasized that *Roe v. Wade's* trimester structure was flawed precisely for this reason. Therefore, the significance of the state interest has been conceptualized and evaluated by focusing on viability.

Proponents of women's right to choose abortion would argue that, by focusing on viability, the Court has emphasized the likelihood that the fetus will be born, thus maximizing the state interest. Pro-choice advocates could respond that viability, as an analytical framework for understanding women's constitutional interests, inappropriately minimizes these interests and could use RU 486 to refocus

be used as a birth control method, any restrictions on its use must be tested against a woman's fundamental right to use birth control, particularly because it is intellectually disingenuous to distinguish between the use of RU 486 as a birth control method or "abortifacient" prohibiting implantation.²³⁶ And as the hypotheticals demonstrated, it would be extremely difficult to restrict the use of RU 486 as an abortifacient a few weeks after implantation without engaging in the relatively inaccurate and difficult job of trying to categorize users of the drug based on their menstrual cycles to determine which group would be subject to further regulation. Therefore, state statutes imposing *Casey*-like restrictions on RU 486 either as a contraceptive or abortifacient would be unconstitutional.

In summary, RU 486 may provide the Court with a means to unify its constitutional privacy jurisprudence by presenting a factual circumstance that confounds the Court's theoretical distinction between birth control and abortion rights. With the development of RU 486, the Court may conclude that *Casey*'s undue burden standard is an inappropriate test for balancing a woman's constitutional privacy interest against a state's interest in a fetus just a few weeks after fertilization. Instead, the Court may eventually hold that women have a fundamental

the abortion debate.

²³⁶ A constitutional problem also arises in the context of drafting a statute restricting access to the drug. How can the statute be worded to impose restrictions on women like Woman C in the early weeks after implantation but leave Woman B's access unrestricted in light of her "fundamental constitutional right" to birth control? Would this law then require Woman B—whose fertilized egg has not implanted—to prove when her last period occurred in order to show that she "stands in the shoes" of Woman A, who uses RU 486 as a birth control method, so that Woman B can obtain RU 486 without restrictions? This kind of requirement is unworkable. Women's menstrual cycles vary; even a woman who is accustomed to an average cycle of twenty-eight days may ovulate late one month. That woman erroneously would think that she was like Woman C when, in actuality, she would be like Woman B. And many women do not have cycles that are predictable enough to be able to tell definitively when they had ovulated, when the egg would have been fertilized and when the egg would have been implanted. The practical problems of enforcing such a rule seem too great. Then could the statute impose restrictions on access to certain dosages? Such a statute would fail also because of the problems articulated in hypothetical two. Thus, the third hypothetical suggests that the state would have a very difficult time writing a constitutionally valid statute restricting women's access to RU 486. This would be true even though Woman C is more like the contemporary woman seeking a surgical abortion, where the Court has recognized the state's interest in imposing certain restrictions even during the first trimester. *Casey*, 112 S. Ct. at 2822-33.

right to RU 486 as an abortifacient.

This exploration of what the development of RU 486 means for the future of constitutional privacy doctrine demonstrates that the public has a clear stake in the governmental regulation of RU 486. The uniqueness of the drug's properties has encouraged people to speak out about the drug and suggests that creating an opportunity for public comment about the drug's availability in the United States would have served the public interest. Since RU 486 has promise as a new form of birth control and abortion, the legal significance of the drug's character is of particular interest to women as a class.

CONCLUSION

Benten v. Kessler offered the Supreme Court an opportunity to comment on three substantive issues, namely, whether the import ban was a legislative rule under the APA, whether judicial review of the FDA's import ban was appropriate and whether the agency's action was arbitrary and capricious. The Supreme Court's virtual silence in response suggests that, particularly on controversial topics, the High Court prefers to allow an agency great latitude in its enforcement decisions, even when an agency appears to have acted improperly.

Yet the Supreme Court's reticence to review the FDA's decision to guarantee sufficient public involvement in agency rulemaking is troubling. The FDA's actions with regard to RU 486 were hasty and violated both the agency's internal regulations and the requirements of the APA. The import ban effectively shut down a channel for public debate about the drug by eliminating an opportunity for the public—and, particularly, women—to make their views known through the APA's notice and comment procedure. Furthermore, the FDA's actions were not founded on a thoughtful examination of the relevant health and safety data on RU 486. Even so, only the district court in *Benten* considered whether judicial review was appropriate and whether the ban should be voided as arbitrary and capricious.

The importance of participatory administrative rulemaking cannot be overstated in light of the broad discretion exercised by administrative agencies. In the interest of ensuring that the public may "weigh in" on issues it believes are important, courts should require that agencies scrupulously follow the

APA rulemaking model. This is especially true where, as Part III of this Note has demonstrated, highly charged issues of abortion and birth control restrictions may affect the substantive privacy rights of all American women.

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