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Recommended Citation

Kramnick, Rebecca K. (1992) "RU 486 and the Politics of Drug Regulation in the United States and France," *Cornell International Law Journal*: Vol. 25: Iss. 3, Article 10.

Available at: <http://scholarship.law.cornell.edu/cilj/vol25/iss3/10>

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RU 486 and the Politics of Drug Regulation in the United States and France

One of the most significant medical innovations of recent decades,¹ RU 486, or Mifepristone as the drug is officially known, is a hormonal compound that prevents the implantation of the embryo in the early stages of pregnancy and thus induces abortion.² Medical experts have found the drug to be a highly safe and effective method of terminating an early pregnancy.³ While primarily used for abortion, RU 486 also shows promise in the treatment of certain cancers and other serious diseases.⁴ The French inventor of the drug, Etienne Emile Baulieu,

1. See generally *Editorial Note, THE BIRTH CONTROL TRUST, THE ABORTION PILL: WIDENING THE CHOICE FOR WOMEN* (1989) (proceedings of a conference held on October 26, 1989, at the Royal College of Obstetricians and Gynaecologists, London) [hereinafter *WIDENING THE CHOICE*]. Organizers of the conference deemed RU 486 a "major medical breakthrough." *Id.* at 6. According to Malcolm Macnaughton of the University of Glasgow, a conference participant, "the development of [RU 486] is an advance in reproductive medicine of the same magnitude as the development of the hormonal contraceptive pill." *Id.* at 5. David Grimes, a leading U.S. researcher on RU 486, has called it "the most exciting new drug we've had on the scene in a quarter of a century. . . ." *Early Nonsurgical Abortion Option if U.S. Approves RU 486*, *OB. GYN. NEWS*, Dec. 15, 1989, at 1. See also Thomas Maggio, *Politics in the Drug-Development Process: The Case of Mifepristone*, 46 *AM. J. HOSP. PHARM.* 133 (1989); Joseph Palca, *The Pill of Choice?*, *SCIENCE*, Sept. 22, 1989, at 1319. For medical literature on RU 486 as an abortifacient (an abortion-inducing agent), see *infra* note 21 and accompanying text. For medical literature on other significant medical uses of RU 486, see *infra* note 4 and accompanying text.

2. See *infra* notes 15-17 and accompanying text.

3. See *infra* note 21 and accompanying text.

4. This Note focuses on the use of RU 486 as an abortifacient. RU 486 has, however, also been tested successfully for a number of other significant medical uses. The drug has been tested for its potential to block hormones that cause breast cancer tumors to grow. A French research group found that RU 486 halted cancer growth to a limited extent in 12 of 22 breast cancer patients. *RU 486: The Import Ban and Its Effect on Medical Research: Hearing before the Subcomm. on Regulation, Business Opportunities, and Energy of the House Comm. on Small Business*, 101st Cong., 2d Sess. 61, 74 (1990) [hereinafter *Hearing*] (statement of Kathryn Horowitz). The drug may have wider applicability in the fight against other cancers, such as those of the kidney and bowels. Sam Yen of the University of California at San Diego has reported that experimental RU 486 use by 12 women resulted in greater than 50 percent reductions in fibroid tumors of the uterus. Laurie Garrett, *From Birth, Pill Was Controversial*, *NEWSDAY*, Dec. 4, 1991, at 22. It may also effectively treat viral infections, including, possibly, Acquired Immune Deficiency Syndrome (AIDS). See William Regelson et al., *Beyond 'Abortion': RU-486 and the Needs of the Crisis Constituency*, 264 *J. AM. MED. ASS'N* 1026-27 (1990). A National Institutes of Health study found the drug effective as a

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received the distinguished Lasker Award for his discovery.⁵ Advocates for abortion rights have hailed the drug as providing an important non-surgical option for women facing unwanted pregnancies.⁶

In France, where the drug has been available since 1988, RU 486 is now used in approximately one-third of legal abortions.⁷ Britain's Health Ministry recently approved the drug for use there.⁸ The drug is also available in China, and may soon be available in the Netherlands and in three Scandinavian countries.⁹ The World Health Organization is considering possible introduction of the drug into developing countries, where widespread unsafe surgical abortion practices are estimated to kill approximately 200,000 women each year.¹⁰

At the same time, the drug is not legally available in the United States,¹¹ where it is widely condemned by opponents of legal abortion.

treatment for Cushing's Syndrome—a serious and sometimes fatal condition caused by an excess of glucocorticoids. See *Hearing, supra*, at 83. (statement of George P. Chrousos, Senior Investigator and Section Chief, National Institute of Child Health and Human Development, National Institutes of Health). Swedish scientists at the Karolinska Institute are researching possible use of RU 486 as a once-a-month contraceptive pill. *New Tests Set for 'Abortion Pill'*, MONTREAL GAZETTE, Aug. 13, 1990, at B1.

5. Baulieu received the Albert Lasker Medical Research Award on September 27, 1989. The award is considered to be one of America's most prestigious medical awards, often a "prelude" to the Nobel Prize. LAWRENCE LADER, *RU 486; THE PILL THAT COULD END THE ABORTION WARS AND WHY AMERICAN WOMEN DON'T HAVE IT* 42 (1991).

6. See ETIENNE-EMILE BAULIEU, *THE 'ABORTION PILL'* (1991); Rebecca J. Cook, *Antiprogestin Drugs: Medical and Legal Issues*, 21 *FAM. PLAN. PERSP.* 267 (1989); MICHAEL KLITSCH, ALAN GUTTMACHER INST., *RU-486: THE SCIENCE AND THE POLITICS* (1989) [hereinafter ALAN GUTTMACHER INST. 1989]; LADER, *supra* note 5; Mindy J. Lees, Note, *I Want a New Drug: RU-486 and the Right to Choose*, 63 *S. CAL. L. REV.* 1113 (1990); Sarah Ricks, Note, *The New French Abortion Pill: The Moral Property of Women*, 1 *YALE J.L. & FEMINISM* 76 (1988).

7. Gina Kolata, *After Large Study of Abortion Pill, French Maker Considers Wider Sale*, *N.Y. TIMES*, Mar. 8, 1990, at B10.

8. LADER, *supra* note 5, at 17.

9. *Id.* Efforts to introduce RU 486 in Italy have run into resistance, particularly from The Vatican, despite the advocacy of an Undersecretary of Health, Elena Marinucci. BAULIEU, *supra* note 6, at 117. In 1990 Baulieu received the first "Minerva Prize" ever awarded to a foreigner from the Italian women's organization, Club delle Donne. *Id.* Opinion has been divided on the introduction of the drug in Germany, where there has been resistance to its introduction, but where a ranking federal health official praised RU 486 as a necessary alternative to surgical abortion. *Id.* at 119. Health officials in the former USSR expressed interest in bringing the drug to that country, *id.*, as have officials in Spain, *id.* at 116, Hungary, *id.* at 121, Austria, *id.* at 119, India, *id.* at 122, and Japan, *id.* at 123.

10. BAULIEU, *supra* note 6, at 15. For every woman who dies, an estimated 20 to 30 suffer infections, uterine perforations, and injuries leading to sterility. *Id.* The drug was hailed as an "essential therapeutic advance" with great potential for use in developing countries by Dr. Joseph Spiedel, the president of the Population Crisis Committee, an organization that researches international population issues. Edward Cody, *French Delay Marketing of Abortion Pill*, *WASH. POST*, Oct. 27, 1988, at 1.

11. On July 1, 1992, a pregnant American woman, Leona Benteen, attempted to import RU 486 from Britain for use in the United States under a law allowing for importation for personal use of some drugs approved in other countries, but not the United States. The drug was confiscated upon Benteen's arrival to the United States.

Its critics label RU 486 a "death pill"¹² and have threatened to boycott pharmaceutical companies that market the drug.¹³ The drug's French manufacturer, Roussel-Uclaff, has stated that it has no current plans to apply to the United States Food and Drug Administration (FDA) for a license to market the drug in the United States.¹⁴ The reasons for the French company's refusal to market the drug in the United States, however, extend beyond the threat of boycotts.

This Note will focus on the political, legal, and regulatory dynamics underlying the contrasting stories of the availability of RU 486 in France and its non-availability in the United States. This Note suggests that the crucial difference in the two pictures is that the French government through active governmental intervention in the pharmaceutical market has insulated the issue of drug availability and public health from political and religious views on abortion, whereas the U.S. government has not. A central reason Roussel-Uclaf remains reluctant to apply for a U.S. license to market RU 486 is concern over the neutrality of the federal drug regulatory system given early indications of the agency's negative view on the drug, the agency's great discretionary authority, and, perhaps most importantly, the anti-abortion stance of the Bush Administration.

This Note argues that the U.S. government should take notice of the French government's effort to ensure that scientific and public health concerns are not dominated by the political and moral controversy surrounding abortion. While underlying political and economic differences render the specific market interventionist approach of the French government inappropriate in the United States, the French government's goal of promoting scientific neutrality can and should be incorporated into U.S. drug regulatory policy. While abortion is a divisive political issue in the United States, the contentious moral debate should not impact the health of the women and men who could be benefited by RU 486.

Part I of this Note focuses on the use, safety and desirability of the drug, primarily from a medical perspective, but also from the perspective of its critics. Part II addresses the French approval of RU 486 and steps taken by the French government to promote the availability of the drug in the interest of women's health. In addition, Part II examines

Philip J. Hilts, *Abortion Pills Are Confiscated by U.S. Agency*, N.Y. TIMES, July 2, 1992, at A12.

Benten challenged the confiscation of the drug in federal court. *Benten v. Kessler*, 1992 WL 166263 (E.D.N.Y. 1992). See *infra* Section III B.4 for further discussion of the *Benten* case.

12. 134 CONG. REC. E 1972 (daily ed. June 14, 1988) (statement of Rep. Dornan). Representative Robert K. Dornan is a leading congressional opponent of the drug.

13. Felicity Barringer, *They Keep the Abortion Protest Alive*, N.Y. TIMES, Jan. 23, 1991, at A16. See *infra* notes 47-53 and accompanying text.

14. LADER, *supra* note 5, at 132-33. The company has stated that RU 486 will not be introduced in the United States unless the U.S. government requests an application from the company. *Id.* at 132.

how the French government was able to separate public health concerns from official state abortion policy as well as from religious and other public sentiment on the abortion issue. Part III focuses on the contrasting situation in the United States, where the FDA presents significant obstacles to the drug's introduction. The agency's broad discretion over new drug decisions and apparent susceptibility to political pressure from anti-abortion lobbying have played significant roles in Roussel-Uclaf's decision not to seek U.S. licensing of RU 486. Part III then argues that the FDA's preliminary appraisal of the drug, which banned personal importation, should be interpreted as arbitrary and capricious by a reviewing court.

Part IV of this Note suggests that the United States adapt the French government's concerns about scientific neutrality and public health to the U.S. context by changing its drug regulatory policy. The RU 486 case illustrates that current FDA policy inadequately ensures that the agency will carry out its mandate to protect the public health. The suggested changes would clarify the agency's role in drug approval and eliminate some of the broad areas of agency discretion that are so susceptible to political abuse. This Note suggests that further statutory and regulatory guidelines as well as new agency powers are needed to assure the neutrality of these procedures and to ensure that U.S. consumers are not denied access to an important drug due to the political biases of a federal agency. While these proposals would help ensure fair agency consideration for RU 486, an impartial FDA would have a wider public health impact through improving consumer access to other important, but politically controversial, treatments.

I. RU 486: The Drug and the Debate

A. Medical Background on RU 486

The name "RU 486" derives from the name of the French company marketing the drug, Roussel-Uclaf. The drug, a steroid hormone similar in structure to the natural hormone progesterone,¹⁵ interferes with a woman's body's natural production of progesterone, which is essential for the maintenance of pregnancy.¹⁶ By blocking formation of progesterone, RU 486 prevents implantation of the fertilized egg into the uterine wall in the first weeks of pregnancy and leads to a series of physiological changes whereby the uterus expels its contents.¹⁷

Clinical trials of RU 486 established that it most effectively ensures complete expulsion of the contents of the uterus when used in conjunc-

15. David T. Baird, *What It Is, How It Works and Its Development*, in *WIDENING THE CHOICE*, *supra* note 1, at 12.

16. *Id.*

17. See ALAN GUTTMACHER INST. 1989, *supra* note 6, at 3.

It is believed that by halting progesterone's normal activities, RU 486 has two important direct effects: first, it induces menstrual bleeding and the sloughing off of the uterine lining, a key element to its success as an abortifacient; in addition, the drug is thought to reverse progesterone's calming influence on

tion with a second drug, a prostaglandin compound, which causes the uterus to contract.¹⁸ Approval of RU 486 by the French Ministry of Health provided that the drug only be available in conjunction with a prostaglandin.¹⁹ Approval of the drug also provided that the drug be administered by doctors in clinics or hospitals and required two follow-up visits by the patient, the first for the administration of the prostaglandin and the second to confirm that the abortion was completed.²⁰

RU 486 combined with a prostaglandin provides a safe and effective method of terminating pregnancies of eight or fewer weeks gestational length.²¹ The most comprehensive study of the combination of the drugs (the Silvestre study), conducted with 2,115 French women, concluded that it is as safe and effective as surgical abortion—the most common method of abortion.²² The study found that in ninety-six percent of the cases, the drug successfully induced abortion with no serious side effects.²³ After taking the two drugs, women experienced the equivalent of a heavy menstrual period, lasting an average of about nine days.²⁴ Minimal side effects included “transient abdominal pain” caused by the

the muscular uterine walls and make the uterus more excitable, leading to contractions that help to dislodge the embryo. (footnote omitted).

However, scientists have yet to identify conclusively the exact chain of events that causes RU 486 to induce abortion. *Id.*

18. Peter Coles, *French Government Approves Abortion Pill for Commercial Use*, NATURE, Oct. 6, 1988, at 486.

19. *Id.*

20. *Id.*

21. See Lars Birgeron & Viveca Odland, *Early Pregnancy Termination with Antiprogestins: A Comparative Clinical Study of RU 486 Given in Two Dose Regimens and Epostane*, 48 FERTILITY & STERILITY 565 (1987); M. Bygdeman & M. L. Swahn, *Progesterone Receptor Blockage: Effect on Uterine Contractility and Early Pregnancy*, 32 CONTRACEPTION 45 (1985); L. T. Cameron & D. T. Baird, *Early Pregnancy Termination: A Comparison between Vacuum Aspiration and Medical Abortion Using Prostaglandin or the Antiprogestogen RU 486*, 95 BRIT. J. OBSTETRICS & GYNAECOLOGY 271 (1988); Beatrice Couzinet et al., *Termination of Early Pregnancy by the Progesterone Antagonist RU 486 (Mifepristone)*, 315 NEW ENG. J. MED. 1565 (1986); Mary W. Rodger & David T. Baird, *Induction of Therapeutic Abortion in Early Pregnancy with Mifepristone in Combination with Prostaglandin Pessary*, THE LANCET, Dec. 19, 1987, at 1418; André Ulmann, *Uses of RU 486 for Contraception: An Update*, 36 CONTRACEPTION 27 (1989); Harry A. M. Vervest & Mary A. Haspels, *Preliminary Results with the Antiprogestational Compound RU-486 (Mifepristone) for Interruption of Early Pregnancy*, 44 FERTILITY & STERILITY 627 (1985).

22. Louise Silvestre et al., *Voluntary Interruption of Pregnancy with Mifepristone (RU 486) and a Prostaglandin Analogue*, 332 NEW ENG. J. MED. 645, 648 (1990).

23. *Id.* at 646. Roussel-Uclaf has made an unofficial report of its findings of a 98.5% effectiveness rate of the drug used in 38,000 cases. Kolata, *supra* note 7, at B10.

The French procedure for clinical use of RU 486 has made provision for the event of the drug's failure. Before taking RU 486, French women sign an “informed consent document,” which explains the potential for failure of the drug. The Informed Consent Document Used in France for RU 486, *reprinted in* ALAN GUTTMACHER INST. 1989, *supra* note 6, at 8. The document states that in the event of a failure, “at [the woman's] request and under effective medical supervision” a surgical abortion will be performed. *Id.* The document also requires the woman to agree that if during the course of the RU 486 procedure she wishes to discontinue the treatment and carry the pregnancy to term, she has been “clearly warned that [she and her child] may be susceptible to risks, notably malformation of the fetus or the child.” *Id.*

24. Silvestre, *supra* note 22, at 646.

prostaglandin.²⁵ Only one woman in the study experienced side effects requiring significant medical treatment.²⁶

In April 1991, the French government announced the first death associated with the use of RU 486. A 31-year old woman, with a history of heavy smoking, died of a heart attack after receiving Nalador, a type of ingestible prostaglandin.²⁷ The woman had eleven children and was in her thirteenth pregnancy. Following this announcement, the French government banned the use of RU 486 in women who are over thirty-five or who are "regular smokers," which the government defines as women who have smoked more than ten cigarettes a day for more than two years.²⁸ In response, officials of Roussel-Uclaf announced that RU 486 would be administered with Gemeproste, a synthetic prostaglandin considered to be safer than Nalador.²⁹

Studies confirm that RU 486 is effective only through about the eighth week of pregnancy. The Silvestre study was limited to women who were within forty-nine days of their last menstrual period.³⁰ Studies also have found that the drug is less effective in terminating pregnancies past the seventh or eighth week of gestation since after this time period implantation of the embryo has already been aided by the natural production of progesterone.³¹ Nevertheless, scientific research continues to explore the potential usefulness of the drug in aborting pregnancies beyond the eighth week.³²

Since its legalization in France in late 1988, RU 486 has become increasingly popular and has been used by about 80,000 women.³³ Scientific analyses of the drug project no long-term effects on fertility or any other long-term negative health effects.³⁴ Some scientific uncertainty remains at this stage, however, given the relatively recent introduction of the drug in France.

B. RU 486 Compared to Surgical Abortion Methods

The preferred surgical method for carrying out first trimester abortions in France, in the U.S. and in other countries, is vacuum aspiration of the uterus (also known as suction curettage). With approximately 1.6 million abortions performed annually by this method, it is one of the most common surgical procedures in the U.S.³⁵ Vacuum aspiration is also

25. *Id.* at 646-47.

26. *Id.* at 646.

27. Joyce Price, *Death Hurts Abortion Pill's Chances*, WASH. TIMES, Apr. 19, 1991, at A5.

28. Robin Herman, *French Ban Use of RU 486 By Smokers, Women over 35*, WASH. POST, Apr. 30, 1991, at 25.

29. Price, *supra* note 27, at A5.

30. Silvestre, *supra* note 22, at 645.

31. Couzin et al., *supra* note 21, at 1567.

32. *Id.*

33. BAULIEU, *supra* note 6, at 18.

34. *See supra* note 21.

35. ALAN GUTTMACHER INST. 1989, *supra* note 6, at 11.

considered among the safest surgical procedures, with relatively low risk of side effects or complications.³⁶ When side effects occur, they include hemorrhaging, accidental perforation or laceration of the cervix, as well as a higher risk of reproductive tract infection. These complications often can be treated, but may, in the rare case, lead to sterility.³⁷

RU 486 eliminates these risks of invasive surgery as well as the significant discomfort often associated with the dilation of the cervix that is required for surgical abortion. While surgical abortions generally require a local anaesthesia, RU 486 does not and thus avoids the health risks associated with anaesthesia.³⁸

Another advantage to the use of RU 486 is its usefulness in the very early stages of pregnancy, before a surgical abortion may be medically advisable.³⁹ In addition, the RU 486 method is less expensive than its surgical counterpart. While the average cost of a surgical abortion in the U.S. is \$213,⁴⁰ the RU 486 procedure in France costs the patient the equivalent of \$80.⁴¹

While generally considered as safe as surgical abortion, RU 486's greatest advantage may be more psychological than medical. According to David Grimes of the University of Southern California, a leading U.S. researcher, patients who have had prior surgical abortions say that their experience with RU 486 was less traumatic than with the surgical abortion.⁴² Experts suggest that the relative privacy of the process, in which

36. *Id.*

37. *Id.*

38. *Id.*

39. *See id.* at 13.

40. ALAN GUTTMACHER INST., *Facts in Brief: Abortion in the United States 2* (1990) [hereinafter ALAN GUTTMACHER INST., *Facts in Brief*]. This figure represents the average amount paid in 1986. Costs are slightly higher today. *Id.*

41. Steven Greenhouse, *Fears Confine Abortion Pill to France*, N.Y. TIMES, Mar. 26, 1989, at 18. RU 486's low cost may increase options for poor women, who since Congress' passage of the Hyde Amendment in 1977, have not received Medicaid funding for abortions unless their lives are in danger. In 1987, 12% of abortions performed in the United States were paid for with state funds. ALAN GUTTMACHER INST., *Facts in Brief*, *supra* note 40, at 2. As of August 1990, 13 states used their own funds to pay for abortions. *Id.* When public funds are unavailable for abortion, 20% of Medicaid-eligible women who want to have an abortion carry their pregnancies to term. *Id.*

42. *Abortion Pill Less Traumatic Than Surgery, Study Suggests*, Gannett News Service, Sept. 30, 1990, available in LEXIS, Nexis Library, GNS File. As part of a larger study, Grimes studied the emotional responses of 16 recipients of RU 486. Grimes administered the drug to all 16 women, half of whom were past due for periods but not pregnant, allowing him to test the effects of the drug on women who do not know they are pregnant. *Id.* All of the women in the study had similar cramping, bleeding and other side effects whether pregnant or not. *Id.* Grimes reports that the results "were much comparable to a heavy menstrual period" and said that all of the women in the study "said they would choose the drug again if needed." *Id.*

In an interview, Elizabeth Aubeny, director of a French abortion clinic, stated that, "From a psychological point of view, women seem very happy with the method. They take the pill themselves, they have hospital supervision, but they're not subject to physical manipulation at the hands of strangers." Alan Riding, *Abortion Politics Are Said to Hinder Use of French Pill*, N.Y. TIMES, July 29, 1990, at 1. Aubeny has reported

a woman takes the drug in a clinical setting but experiences the drug's effects in private, contribute to the comparative lack of trauma of the experience.⁴³

Family planning experts maintain that RU 486 potentially may provide even greater privacy advantages to women. While surgical abortions are performed only in specialized clinics or hospitals, RU 486, theoretically, can be administered in any family planning clinic or doctor's office. At a time when picketing outside abortion facilities is commonplace in some communities, the relative anonymity and privacy afforded by the RU 486 method is considered a significant advantage over the surgical method.⁴⁴

The relative privacy offered by RU 486 should not be overstated, however. A scenario whereby women have access to the drug outside a supervised clinical setting may pose severe health and safety consequences. If the drug falls into the hands of a woman who is in a late stage of pregnancy, or if the drug is not used in conjunction with prostaglandin, RU 486 could cause great harm and would, at a minimum, be ineffective. Medical reports uniformly agree that RU 486 should be used only under the careful supervision of a physician.⁴⁵

C. Opposition to RU 486

The aspects of RU 486 that potentially make it a more desirable alternative to a surgical abortion have sparked opposition from groups opposed to any form of legal abortion. Opponents of the drug fear that reducing the physical, psychological and fiscal costs of abortion will increase the likelihood that women will seek the procedure.⁴⁶ Anti-abortion groups have actively opposed the drug in France and Great Britain.⁴⁷ Since availability of the drug was first announced in France, U.S. opponents of abortion have perhaps been most vocal in their oppo-

that 80% of women who tried both methods prefer RU 486. BAULIEU, *supra* note 6, at 94.

43. ALAN GUTTMACHER INST. 1989, *supra* note 6, at 11. The drawn-out length of the RU 486 procedure may be a psychological disadvantage for some women. Terry Gilbert, *Pill Induces Abortion Hangover*, CALGARY HERALD, Oct. 14, 1990, at F1. In an interview, French Family Planning Association officer Marie-France Coulet said that the length of the RU 486 process has proven to be a drawback for some women in France, particularly when they were trying to hide the pregnancy from family members. The majority of the women surveyed by Coulet's organization, however, were satisfied with the procedure. *Id.*

44. LADER, *supra* note 5, at 20-21.

45. BAULIEU, *supra* note 6, at 91-92.

46. 134 CONG. REC. E 1972 (daily ed. June 14, 1988) (statement of Rep. Dornan). Dornan stated: "The proponents of abortion want to replace the guilt suffered by women who undergo abortion with the moral uncertainty of self-deception. Imagine, with the death pill, the taking of a preborn life will be as easy and as trivial as taking aspirin." *Id.*

47. Opponents of the drug have held rallies outside the headquarters of Roussel-Uclaf in Paris. Steven Greenhouse, *A New Pill, A Fierce Battle*, N.Y. TIMES, Feb. 12, 1989, § 6 (Magazine), at 23. See also BAULIEU, *supra* note 6, at 38-39, 113.

sition to the drug.⁴⁸ The president of the National Right to Life Committee, John C. Willke, leads the U.S. movement against the drug, which he has described as a "human pesticide," and has stated that his organization would lead a boycott of Hoechts, Roussel-Uclaf's German parent company if the drug is introduced in the United States.⁴⁹ Willke compares the drug to thalidomide, a sedative widely prescribed in the early 1960s to pregnant women, which led to serious birth defects.⁵⁰ Right to life groups also draw attention to the fact that Hoechts produced poisonous gas for use in German concentration camps during World War II.⁵¹ Willke states that in marketing RU 486, the company now engages in "chemical warfare on the unborn."⁵² When the American Medical Association passed a resolution supporting U.S. testing of the drug, Willke claimed that the physicians involved were supporting the "killing of their little patients."⁵³

II. RU 486 in France

A. Comparison of French and American Drug Regulatory Systems

The French and American drug regulatory systems operate under the same basic premise: a federal agency approves the marketing of new drugs after examining clinical data submitted by the applicant pharmaceutical company.⁵⁴ In the United States, the Food and Drug Administration, a division of the Department of Health and Human Services, approves individual companies' licensing applications. The agency responsible for review of drug registration applications in France is the Direction de la Pharmacie et du Medicament (DPHM) of the Ministry of Health, operating under the statutory mandate of the Public Health Code.⁵⁵ Both agencies employ the conventional four-phased drug clinical experimentation model,⁵⁶ under which the agencies conduct limited monitoring of the applicant's data at the early phases of clinical research and make final licensing decisions at the end of phase III.

48. See Elaine Bingham, *The Curse of RU 486: The Death Pill*, 6 LOMA LINDA U. CENTER FOR CHRISTIAN BIOETHICS UPDATE 4 (May 1990).

49. BAULIEU, *supra* note 6, at 126.

50. Tala Skari, *The Abortion Pill*, LIFE, July 1990, at 72.

51. Bingham, *supra* note 48, at 4.

52. BAULIEU, *supra* note 6, at 35-36.

53. *AMA Endorses Controversial Abortion Pill*, AP, June 28, 1990, available in LEXIS, Nexis Library, AP File [hereinafter *AMA Endorsement*].

54. The pharmaceutical companies in both countries are thus primarily responsible for conducting the clinical trials and assembling data. The French government does play a minor role, however, in the data assembly process. In France, pharmaceutical law provides for an "expert" in the assembling of the data—a scientist hired to conduct the clinical trials and assess the results. The Ministry of Health provides pharmaceutical companies with a list of government-approved experts from which companies may choose based on the type of drug and the qualifications of the various experts. See LEIGH HANCHER, *REGULATING FOR COMPETITION: GOVERNMENT, LAW AND THE PHARMACEUTICAL INDUSTRY IN THE UNITED KINGDOM AND FRANCE* (1990).

55. CODE DE LA SANTÉ PUBLIQUE, art. L. 601, R. 5114-5117 (Fr.).

56. See *infra* notes 132-138 and accompanying text.

One distinction between the two systems is the significant role that an outside advisory committee plays in French drug regulatory decisions. While the Minister of Health retains ultimate authority in licensing decisions, it places great emphasis upon the advisory recommendations of the twenty-eight-member Commission D'Authorisation de Mise sur le Marche des Medicaments (Commission on Marketing Authorizations), which has a statutory role in the consideration of all licensing applications.⁵⁷ The membership of the Commission is drawn largely from the medical profession, but also includes industry and consumer representatives. This advisory committee plays a larger role in approving new drugs than does its U.S. counterpart because, while the FDA has discretion to rely on the recommendations of outside advisory committees, these committees have no statutory role in the drug approval process.⁵⁸

B. French Approval of RU 486

The French Ministry of Health approved RU 486 on September 23, 1988, after Roussel-Uclaf conducted six years of clinical study of the drug. The Ministry also approved strict protective conditions for distribution of RU 486 in regulations subsequently enacted into law.⁵⁹ Each package of the drug receives a specific number to track its distribution and use.⁶⁰ Distribution is limited solely to the public and private hospitals and clinics authorized to perform abortions.⁶¹ Ministry of Health regulations also require that the name of the physician or other official in charge of the authorized medical facility be recorded in an official registry.⁶²

Regulations governing the distribution of RU 486 also require that the drug be taken in conjunction with a prostaglandin, which is administered two days after the initial dose of three 200 mg tablets of RU 486.⁶³ The regulations further mandate that the drug only be given during the first forty-nine days of pregnancy, which is defined as fifty days since the last menstrual period or twenty-one days since the missed period for women with twenty-eight-day cycles.⁶⁴ French abortion law currently requires a seven-day waiting period after a woman's initial visit to a doctor to request an abortion.⁶⁵ Thus, counting this initial visit, the two visits required for the administration of the drug and the prostaglandin,

57. CODE DE LA SANTÉ PUBLIQUE, art. R. 5140-5141 (Fr.).

58. Section IV.C.3.b. of this Note discusses the role of outside advisory committees in the United States. See *infra* note 243 and accompanying text.

59. BAULIEU, *supra* note 6, at 92.

60. Cook, *supra* note 6, at 268.

61. *Id.*

62. *Id.*

63. ALAN GUTTMACHER INST. 1989, *supra* note 6, at 9.

64. AMA Endorsement, *supra* note 53.

65. Law No. 75-17 of 17 January 1975 concerning the voluntary termination of pregnancy (Fr.), art. L. 162-5, (J.O., 18 January 1975, No. 15, at 739-41), translated in 26 INT'L DIG. HEALTH LEGIS. 351, 353 (1975) [hereinafter French Abortion Law].

and the follow-up visit, the entire RU 486 abortion procedure requires four visits to the doctor's office.

In practice, French hospitals and clinics take great protective measures to ensure that the drug does not become available on the black market. Physicians are particularly concerned that women might unknowingly take the drug during later stages of pregnancy when it would be neither safe nor effective, or take it without the necessary follow-up prostaglandin. The drug is "kept under lock and key" in clinics to ensure that it is not taken out of the clinic and transferred to other hands.⁶⁶

C. Government Orders Production of Drug

On October 25, 1988, Roussel-Uclaf announced it would suspend distribution of RU 486 in France.⁶⁷ As its reason, the company's press release cited "French and foreign public opinion and the controversy raised by the possibility of using the antihormone Mifepristone (RU 486) to voluntarily interrupt pregnancy."⁶⁸ Press reports state that company executives and their families received threats after the drug was approved for the French market.⁶⁹ Other reports state that the major reason for the company's action was a threat by the U.S. Right to Life Committee, a leading anti-abortion group, to lead an international boycott of products manufactured by Hoechts.⁷⁰

The company's decision was criticized two days later by a group of over 1,000 doctors attending the World Conference of Gynecology and Obstetrics in Rio de Janeiro. The physicians signed a petition criticizing "the decision of Roussel-UCLAF to suspend the distribution of RU 486 (Mifepristone) in view of the recent approval of RU 486 as safe and effective by the drug regulatory authorities of the governments of China and France."⁷¹ The petition also urged the French government "to ensure that women have access to the benefits of scientific progress."⁷²

On October 28, 1988, Claude Evin, the Minister of Health, met with officials of Roussel-Uclaf and threatened to invoke a French patent law allowing the Ministry to transfer a drug patent to another holder if the original holder does not market the drug.⁷³ In addition, the French government may have used some of its ownership rights in the company

66. Gilbert, *supra* note 43.

67. Cook, *supra* note 6, at 268. The company halted distribution by formally withdrawing its application for a license for the drug. BAULIEU, *supra* note 6, at 40.

68. Roussel-Uclaf press release, Oct. 25, 1988, *quoted in* Cook, *supra* note 6, at 268 (footnote omitted).

69. Peter Coles, *Volte Face on Controversial French Abortion Pill*, NATURE, Nov. 3, 1988, at 4.

70. LADER, *supra* note 5, at 49.

71. Petition from the XIIth Congress of Gynecology and Obstetrics, Rio de Janeiro, Oct. 27, 1988, *quoted in* Cook, *supra* note 6, at 268.

72. *Id.* (footnote omitted).

73. ALAN GUTTMACHER INST. 1989, *supra* note 6, at 1 (footnote omitted).

to exert pressure on it to resume marketing of the drug.⁷⁴ Premier Michel Rocard allegedly approved of the Minister of Health's actions during this period.⁷⁵

Shortly after the government's action, Roussel-Uclaf resumed marketing the drug.⁷⁶ At the time of the government's action, market analysts speculated that the company had sought the government's "order" to manufacture the drug so that it would not appear responsible for marketing the drug.⁷⁷ Roussel-Uclaf denied such allegations.⁷⁸

The Minister of Health's stated goal in pressuring Roussel-Uclaf to continue marketing the drug was that RU 486 was critical to the public health of women.⁷⁹ He also said, in a comment often cited by supporters of the drug, that RU 486 had become the "moral property of women."⁸⁰ The Minister's comments and his government's advocacy for RU 486 are somewhat surprising given the restrictive nature of French abortion law. The following section of this Note will focus on the restrictions on abortion in France against which the Minister's actions appear incongruous.

D. French Abortion Law

France legalized abortion by statute in 1975.⁸¹ Since the nineteenth century, French law had criminalized abortion, implicitly reflecting the societal notion that a woman owed a childbearing duty to her husband, her family, and the state.⁸² The Catholic Church historically buttressed the pro-family policy in France.⁸³ The policy received additional support after World War I from those who feared depopulation.⁸⁴ In 1920, a statute even banned any public discussion or writing about abortion or contraception.⁸⁵ In 1923, the law imposed a penalty of up to five years imprisonment on those who performed abortions and up to two years for women who had abortions.⁸⁶ In 1939, a law entitled "The Decree Law relative to the family and French natality" incorporated the laws of 1920 and 1923.⁸⁷ Later amendments allowed for an abortion if it were

74. The French government owns a minority 36% stock in the company. LADER, *supra* note 5, at 51-52.

75. Rone Tempest, *France Orders Company to Distribute Abortion Pill*, L.A. TIMES, Oct. 29, 1988, at 1.

76. Susan Sachs, *Behind the Abortion Pill Turnaround*, NEWSDAY, Oct. 31, 1988, at 13.

77. *Id.*

78. *Id.*

79. Abigail Trafford, *Medical Moralism*, WASH. POST, Nov. 1, 1988, at Z24.

80. Edward Cody, *France Orders Sale of New Pill*, WASH. POST, Oct. 28, 1988, at A1. The French Minister of Health, Claude Evin, stated, "I consider that if this progress existed, it had become the moral property of women, and that it was therefore my responsibility to say so to Roussel-Uclaf." *Id.*

81. French Abortion Law, *supra* note 65.

82. See DOROTHY M. STETSON, *WOMEN'S RIGHTS IN FRANCE* 53 (1987).

83. *Id.* at 53.

84. *Id.* at 55.

85. *Id.* at 56.

86. *Id.*

87. *Id.*

required to save a mother's life, but still required doctors "to report all diagnoses of pregnancy to the government."⁸⁸

The French government vigorously pursued this pro-family policy until the late 1960s and early 1970s when the abortion reform movement gained momentum.⁸⁹ The 1975 law legalizing abortion in France represents an important historical shift, but still limits women's access to abortion in several significant ways and is considered to be more restrictive than abortion laws in other European countries and the United States.⁹⁰ The law's preamble expressly retains the pro-family policy of the past. The first section of the law explicitly "guarantees the respect of every human being from the commencement of life."⁹¹ It goes on to state that "[t]here shall be no derogation from this principle except in cases of necessity and under the conditions laid down by this Law."⁹² A 1979 amendment stated that "[i]t shall be a national duty to teach this principle [respect for human life] and to provide education concerning responsibility, the acceptance of the child into society and family policy."⁹³

The pro-family tenor of the preamble finds expression in the individual provisions of the act. The 1975 law legalized abortions up to the tenth week of pregnancy for any woman "whose condition places her in a situation of distress."⁹⁴ While the statute designates the woman seeking the abortion to be the judge of whether her distress sufficiently merits abortion,⁹⁵ the law also requires mandatory counseling of the woman seeking the abortion by the clinic or hospital.⁹⁶ A 1979 amendment added that counseling "shall consist of a private interview during which the woman shall be provided with assistance and advice appropriate to her situation, as well as the necessary means to resolve the social problems posed, particularly in order to enable her to keep her child."⁹⁷

88. *Id.* at 56-57.

89. *Id.* at 59.

90. See MARY ANN GLENDON, *ABORTION AND DIVORCE IN WESTERN LAW* (1989). Glendon offers the view that French abortion law is more restrictive than the law in other European countries and in the United States. *But see* Jane M. Cohen, *Comparison Shopping in the Marketplace of Rights*, 98 *YALE L.J.* 1235 (1989) (book review). Cohen criticizes the Glendon thesis, suggesting that French abortion law is less restrictive than that of the United States to the extent that abortions in France are generally publicly-funded, while those in the United States are not. See *supra* note 41 and accompanying text. A 1982 amendment to French abortion law included abortion on the list of medical acts reimbursible by the system of free state medical insurance. Under the system, 70% of the cost of abortions are paid for by the state, with the state paying for 100% of the cost of medically necessary abortions. See GLENDON, *supra*, at 17.

91. French Abortion Law, *supra* note 65, Title I, § 1.

92. *Id.*

93. Law No. 79-1204 of 31 December 1979 on the voluntary termination of pregnancy (J.O., Edition des Lois et Décrets, 1 Jan. 1980, No. 1, at 3-4), translated in 31 *INT'L DIG. HEALTH LEGIS.* 505 (1980).

94. French Abortion Law, *supra* note 65, at Art. L. 162-1.

95. *Id.* at Art. L. 162-4.

96. *Id.*

97. Law No. 79-1204, *supra* note 93, at Art. 162-4.

The law also mandates that the woman be provided with "names and addresses of persons who, either individually or on behalf of an institution . . . are able to provide women and couples facing the problems associated with acceptance of the child with moral or financial assistance."⁹⁸

In a fairly significant restriction of women's access to abortion, the law also requires a week long waiting period between the time a woman requests an abortion and the time she receives one.⁹⁹ This "thinking period" embodies a legislative unease with abortion that is also manifested by the law's requirement that abortions only be performed in officially approved hospitals and clinics and that the number of abortions performed in these establishments "not be greater than one-quarter of all surgical and obstetrical operations performed."¹⁰⁰ A first violation of this provision leads to closure of the establishment for a year; a second violation leads to permanent closure.¹⁰¹ French law also restricts access to abortion for unmarried minors by requiring that one parent consent to a minor's abortion.¹⁰²

The 1975 law also significantly restricts access to abortion after ten weeks of pregnancy. After the tenth week of pregnancy, "therapeutic" abortions only are allowed if two physicians certify that continuation of the pregnancy is "seriously endangering the woman's health or that there is a strong possibility that the unborn child is suffering from a particularly serious disease or condition considered as incurable at the time of the diagnoses."¹⁰³

98. *Id.*

99. French Abortion Law, *supra* note 65, at Art. L. 162-5. In the U.S. case, *City of Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416 (1983), the Supreme Court invalidated a city ordinance containing, among other restrictions on abortion, a mandatory 24-hour waiting period between the time a woman signed a consent form and the time she could receive an abortion. The waiting period provision of *Akron* was overruled, however, by the Supreme Court in a 1992 case, which upheld a Pennsylvania law containing a mandatory 24-hour waiting period between provision of information for informed consent and performance of an abortion. *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 112 S. Ct. 2791 (1992).

100. French Abortion Law, *supra* note 65, at Art. L. 178-1.

101. *Id.*

102. *Id.* at Art. L. 162-7.

103. *Id.* at Art. L. 162-12. In the United States, constitutional law prevents states from placing any restrictions on a woman's access to abortion during the first trimester. U.S. law, however, does permit states to regulate abortion during the second trimester, but "only to the extent that the regulation reasonably relates to the preservation and protection of maternal health." *Roe v. Wade*, 410 U.S. 113, 163 (1973). The constitutionality of restrictions on abortion in the United States is currently in a state of flux, however, after the Court's 1989 decision in *Webster v. Reproductive Health Services*, 492 U.S. 490 (1989), which found that a state may be able to impose restrictions on a woman's access to abortion during the first trimester. *Casey*, decided in the 1992 term, upheld, in addition to the 24-hour waiting period, an "informed consent" provision of the Pennsylvania law requiring that a woman seeking an abortion be provided with information regarding the nature of the procedure, the health risks of abortion and of childbirth, and the probable gestational age of the fetus. The Court did not uphold the provision of the law requiring a married woman to obtain the consent of her husband before obtaining an abortion. *Casey*, 112 S. Ct. 2791

E. Public Health and the Introduction of RU 486 in France

Against the backdrop of French abortion law, the French government's advocacy for RU 486 appears incongruous. While French abortion policy tends to discourage abortion as an option for women facing unwanted pregnancies, the government's support of RU 486 may make abortion a more viable option for many French women. In its action, the Ministry of Health was able to separate public health from politics. The Health Minister supported RU 486 as an important public health advance, putting aside the pro-family implications of French abortion law as well as the historical and present day controversy surrounding abortion in French society.

The government's action appears less incongruous when viewed in light of other recent, controversial, examples of public health activism by the French government. Foremost recently is the government's significant role in promoting the use of contraceptives. Shortly after Prime Minister Francois Mitterand's government came to power in 1981, the Council of Ministers adopted a wide-scale campaign to encourage contraceptive use.¹⁰⁴ Since 1974, contraceptives have been distributed free at government-supported family planning clinics, with costs reimbursed by the national health system.¹⁰⁵ Nevertheless, organizers of the 1981 campaign believed that a general societal ignorance about contraception contributed to high abortion rates.¹⁰⁶ A 1977 study estimated that only thirty-two percent of French women used a modern contraceptive method.¹⁰⁷ In the first year of the campaign, the government opened 1,000 centers for contraceptive information.¹⁰⁸ In addition, the successful campaign included extensive television advertising aimed at encouraging public discussion and providing information on the availability of contraceptives.¹⁰⁹

The French government's activism on behalf of RU 486 may also be understood as part of a recent effort by the Ministry of Health to encourage the early availability in France of important new pharmaceuti-

(1992). Future cases, now pending in lower courts, are expected to test further state law restrictions on abortion.

104. STETSON, *supra* note 82, at 68.

105. *Id.* at 60.

106. *Id.* at 68. A 1977 study indicated that the government was providing insufficient services in the area of family planning. 377 contraceptive information centers provided information to 13 million women of child bearing age. *Id.* at 67.

107. *Id.* at 68. "The incidence of use was much lower among the young farmwomen, workers, and immigrants." *Id.*

108. *Id.*

109. *Id.* The campaign was successful in a number of ways. Physicians responded to the campaign's efforts to facilitate the use of contraceptives. "Whereas in 1965, only four percent of doctors had helped . . . by the mid 1980s, only five percent of French physicians refused to prescribe modern contraceptive methods to patients." *Id.* at 69. The campaign had an effect on the public. In July 1982, a poll revealed that 75% of women and 79% of men approved of the government's policy on contraceptives. *Id.* In January 1984, support had increased to over 80% among both men and women. *Id.*

cal. A 1981 law created a national drug development committee to bring government officials and officials of pharmaceutical companies together to share information about new drugs that might have important public health effects.¹¹⁰ Through the Committee, the government can better monitor the research of drug companies and encourage the marketing of certain drugs that might provide public health advantages. While the availability of RU 486 does not stem from the action of the drug development committee, both the committee's and the Minister of Health's actions in supporting RU 486 exemplify a similar linking of pharmaceutical policy and public health concerns.

III. Obstacles to the Introduction of RU 486 in the United States

Roussel-Uclaf has stated on a number of occasions that it has no plans to apply to the FDA for a license to market RU 486 in the United States.¹¹¹ The company's reason for not applying for a U.S. license appears largely based on economic concerns, such as the threat of boycotts by anti-abortion groups and liability. Nevertheless, it is obvious that any economic loss that Roussel-Uclaf would incur by marketing the drug would be offset to some extent by income from the large potential market for RU 486 in the United States, both as an abortifacient, and for other medical purposes. Consequently, another more significant reason may lie behind the company's refusal to market the drug in the United States—the politics of U.S. drug regulation. This section of the Note argues that both the structure of decision-making at the FDA and the anti-abortion politics of the Bush Administration present significant obstacles to the drug's approval in this country. The possibility that FDA decisions are dominated by political rather than health concerns has, in fact, already been demonstrated in the agency's initial appraisal of the drug, which this section argues should be viewed as an arbitrary and capricious exercise of agency power.

A. Economics of Roussel-Uclaf's Decision

1. Threat of Product Boycott

Roussel-Uclaf's decision not to seek an FDA license for RU 486 has been significantly influenced by the threat of an international boycott of the products of its parent company, Hoechst. Anti-abortion groups have repeatedly stated that they will implement a boycott if Roussel-Uclaf applies for FDA approval.¹¹²

There is good reason to believe that these groups will continue to oppose the introduction of RU 486 in the United States because the

110. Order of 7 April 1981 establishing the Committee on New Drug Development (J.O., Edition des Lois et Décrets, 20 May 1981, Supp. Issue No. 118, at 4870), translated in 32 INT'L DIG. HEALTH LEGIS. 794 (1981).

111. *RU 486 Falling Victim to Presidential Politics*, ABORTION REPORT, Feb. 24, 1992, available in LEXIS, Nexis Library, ABTRPT File.

112. See *supra* note 13 and accompanying text.

drug could have dramatic effects on the efforts of the U.S. anti-abortion movement. The groups believe RU 486 could potentially make abortions easier for women to obtain.¹¹³ In addition, the potential for the administration of RU 486 in any doctor's office would reduce the groups' ability to focus their anti-abortion efforts on abortion clinics. Political commentators have also speculated that RU 486 could affect anti-abortion groups' public support because the drug enables women to abort pregnancies earlier than surgical abortions, and public opinion favors earlier rather than later abortions.¹¹⁴ For example, some abortion opponents have generated public support with pictures of fetuses in late stages of development. When RU 486 is administered, however, the fetus is estimated to be less than 3/4 of an inch long.¹¹⁵

In the past, U.S. anti-abortion groups have used boycotts with some degree of success. In the mid 1980s, the National Right to Life Committee staged a boycott of Upjohn products as a result of Upjohn's marketing of FDA-approved prostaglandins, used to induce late abortions in hospitals.¹¹⁶ Although Upjohn did not withdraw the products from the market as a result of the boycott, in 1985 it stopped further research on abortion-inducing drugs. Upjohn did not blame its decision on anti-abortion lobbying, but rather on the "litigious climate" and the "adverse regulatory climate in the United States."¹¹⁷ These reasons, as they relate to Roussel-Uclaf's decision to market RU 486, will be discussed in the two subsequent sections of this Note.

2. *Liability Concerns*

Upjohn's reference to the "litigious climate" as a component of its decision not to further research abortion drugs is often cited as a reason for the dramatic drop in research into new contraceptive methods in this country.¹¹⁸ Commentators have cited liability concerns as a reason for Roussel-Uclaf's reluctance to attempt to market RU 486 in the United States.¹¹⁹

In the early 1970s, thirteen companies worldwide, eight of them American, were active in researching contraceptive methods.¹²⁰ Today, only one American pharmaceutical company (Ortho) and two outside

113. See *supra* note 46 and accompanying text.

114. See Dorothy Wickendon, *Drug of Choice*, NEW REPUBLIC, Nov. 26, 1990, at 26.

115. *Id.*

116. Gina Kolata, *Boycott Threat Blocking Sale of Abortion-Inducing Drug*, N.Y. TIMES, Feb. 22, 1988, at A1.

117. *Id.*

118. See DEVELOPING NEW CONTRACEPTIVES: OBSTACLES AND OPPORTUNITIES (L. Mastroianni, Jr. et al. eds., 1990); Lisa Kaeser, *Contraceptive Development: Why the Snail's Pace?*, 22 FAM. PLAN. PERSPS. 131, 133 (May/June 1990); Richard Lincoln & Lisa Kaeser, *Whatever Happened to the Contraceptive Revolution?*, 20 FAM. PLAN. PERSPS. 20, 22 (Jan./Feb. 1988).

119. See ALAN GUTTMACHER INST. 1989, *supra* note 6, at 13; Cook, *supra* note 6, at 270.

120. Lincoln & Kaeser, *supra* note 118, at 20.

the United States remain active in the area.¹²¹ A well-publicized large jury award against Ortho for a faulty spermicide may have contributed to this decline in research in the contraceptive area.¹²² In addition, pharmaceutical companies have had difficulty obtaining insurance policies to cover marketed contraceptives in the wake of lawsuits that stemmed from the marketing of the Dalkon shield, an intrauterine device that increased the risk of pelvic infection.¹²³

The role that liability concerns have played in Roussel-Uclaf's decision not to seek FDA approval of RU 486 must, however, also be considered in light of the safety record of RU 486. The drug has been proven highly safe in international clinical trials and in use in France,¹²⁴ and there is evidence that the drug may have advantages over surgical abortions.¹²⁵ While long-term consequences of the use of RU 486 have yet to be identified due to its relatively recent introduction in France and other countries, current medical opinion does not foresee any long-term effect on fertility or other problems resulting from use of the drug as a temporary progesterone blocker.¹²⁶

3. Potential Market for RU 486

The attractiveness of the potential market for RU 486 in the United States should somewhat offset Roussel-Uclaf's concern about the threat of economic boycott and potential liability. The United States has one of the highest abortion rates in the developed world: approximately 1.6 million abortions were performed in the United States in 1988.¹²⁷ RU 486 is most effective in approximately the first seven to eight weeks of pregnancy and is currently used in one-third of the 250,000 abortions that occur each year in France.¹²⁸ In the United States, a similar or larger number of women might be eligible for RU 486-induced abortions, given that fifteen percent of abortions in this country currently take place at eight weeks or less.¹²⁹ This number does not represent the cap on potential usage, however. Pregnant women might seek medical attention sooner than they currently do, if RU 486 succeeded in reducing the fears often associated with a surgical abortion. Consequently, more women might be eligible to use RU 486, thereby increasing the

121. *Id.*

122. The award was made in the case of *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir. 1986).

123. *Lincoln & Kaeser*, *supra* note 118, at 22.

124. *See supra* notes 21-26 and accompanying text.

125. *See supra* notes 42-43 and accompanying text.

126. *See supra* note 21.

127. ALAN GUTTMACHER INST., *Facts in Brief*, *supra* note 40, at 1. The abortion rate in the United States is 28 per 1000 women aged 15-44. The equivalent numbers for other countries are: Canada: 10.2; Great Britain: 14.2; Denmark: 18.3; and Sweden: 19.8. Stanley K. Henshaw, *Induced Abortion: A World Review 1990*, 22 *FAM. PLAN. PERSPS.* 76, 78 (Mar./Apr. 1990).

128. Kolata, *supra* note 7.

129. ALAN GUTTMACHER INST., *Facts in Brief*, *supra* note 40, at 2. It is difficult to estimate, however, how many of these women would choose the RU 486 method.

market for the drug. Consideration of the potential market for RU 486 must also include the strong possibility that the drug will have other medical uses.¹³⁰

B. Politics Behind the Company's Decision

While economic considerations militate both for and against Roussel-Uclaf's seeking to market RU 486 in the United States, political considerations work against such a decision. Roussel-Uclaf officials indicate that President Bush's public stance against abortion and the anti-abortion legislation enacted during the Reagan and Bush administrations have influenced the company's decision not to market the drug in the United States.¹³¹ This section will argue that the company is justified in fearing the role that politics could play in the FDA's handling of an RU 486 application.

The long, complicated drug approval policy provides the FDA with significant discretion over new drug applications. This discretion may easily be invoked against a drug application for non-scientific reasons. In fact, the agency has already used its discretion to ban personal importation of RU 486 apparently in response to political and moral rather than scientific objection to the drug. This section will analyze the FDA's discretion in new drug applications and the influence on the agency by anti-abortion sentiment within the Bush administration. Finally, this section will consider how the FDA responded to political pressure in its preliminary appraisal of RU 486.

1. Discretion and the FDA New Drug Approval Process

The degree of discretion the FDA has over the lengthy new drug procedure and the breadth of its statutory mandate permit politics to play a role in an FDA decision to approve a new drug application. The length and complexity of the process alone gives the agency significant discretion to slow or halt a drug's movement through the system.

The first step of the process requires the drug's sponsor, usually a pharmaceutical company, to file an investigational new drug application (IND) with the agency.¹³² The sponsor must include information indicating that the drug is reasonably safe for clinical testing in humans.¹³³ The award of an IND license exempts the drug from the prohibition on movement of unapproved drugs through interstate commerce.¹³⁴

If the IND license is granted, the sponsor begins clinical testing of the drug in four phases. Phase I of the process involves limited clinical

130. See *supra* note 4 and accompanying text.

131. See *infra* notes 150-56 and 193-94 and accompanying text.

132. 21 C.F.R. § 312.40(a)(1) (1991). See also *Hearing, supra* note 4, at 153-54 (statement of Ronald Chesemore, FDA Associate Commissioner for Regulatory Affairs).

133. See *Hearing, supra* note 4, at 154 (statement of Ronald Chesemore).

134. The FDA has 30 days to decide whether to grant or reject the IND license. 21 C.F.R. § 312.402(b)(1) (1991).

testing of the drug on small groups of individuals ranging from twenty to eighty patients and primarily focuses on safety of the drug for human use.¹³⁵ During Phase II of the process, in larger clinical trials of several hundred patients, researchers collect evidence of efficacy and additional safety data.¹³⁶ Phase III studies focus on the effect of the drug in large controlled and uncontrolled trials ranging from several hundred to thousands of patients.¹³⁷ During this phase, which can range from three to five years, researchers must collect evidence of safety and efficacy to support market approval. Following Phase III testing, a sponsor must file with the FDA a new drug application (NDA) showing the results and analyses of the clinical data.¹³⁸

The locus of the agency's power and discretion lies in its broad standard for the approval of new drugs. Under the Food Drug and Cosmetic Act, the statutory standard is "substantial evidence" of the drug's safety and efficacy.¹³⁹ This standard is vague and gives the agency broad authority over new drug decisions and thus over public health. The Act's definition of "substantial evidence" does not lend any greater clarity to the standard, calling only for:

evidence consisting of adequate and well-controlled investigations, . . . by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use, prescribed, recommended, or suggested in the labeling or proposed labeling thereof.¹⁴⁰

Given the number of potential risks inherent in any drug intended for human consumption, the FDA's great veto power over any new drug under its broad "safe and effective" standard is immediately apparent. According to one critic of the FDA's standard for new drug approval:

a statutory change that can be read as being essentially absolute poses profound difficulties when applied to biological and medical judgments which are rarely absolute. In assessing any new drug or in any proposed course of clinical experimentation, it is almost always possible to raise just one more bona fide scientific objection relevant to safety, which finite experimentation has failed to fully satisfy.¹⁴¹

135. *Id.* § 312.21(a).

136. *Id.* § 312.21(b).

137. *Id.* § 312.21(c).

138. The agency has six months under the regulations to respond to the application, but this is often extended by agreement between the sponsor and the agency. 21 C.F.R. § 314.100 (1991).

139. New drugs must meet this standard of safety and efficacy to be approved for marketing under 21 U.S.C. § 355(d). This standard was added to the Act through an amendment in 1962. The significance of the 1962 amendments to the Act will be discussed in Section IV of this Note. See *infra* notes 202-06.

140. 21 U.S.C. § 355(d) (1988).

141. Gerald D. Laubach, *Federal Regulation and Pharmaceutical Innovation, in REGULATING HEALTH CARE: THE STRUGGLE FOR CONTROL* 60, 66 (Arthur Levin ed., 1980).

Considerable critical commentary has focused on the breadth of the agency's standard and the high degree of discretion it gives the agency over drug regulatory decisions. Much of the commentary argues that FDA discretion, the uncertainty that pharmaceutical companies have about the standard, and the length of the U.S. drug regulatory process have led to a significant drop in U.S. pharmaceutical innovation. Critics argue that these factors have led to a "drug lag," whereby the United States trails foreign countries in the development of pharmaceuticals.¹⁴²

One leading critic of the "drug lag" argues that FDA policy has caused the United States to fall behind Britain and Germany in the introduction of new drugs. According to this commentator, "the lag with Europe is not confined to drugs with little or modest medical gain but also includes drugs the FDA itself ranks as significant therapeutic advances . . . [and] there is evidence . . . that regulation has been a major factor contributing to this lag."¹⁴³

The loosely defined statutory standard for FDA acceptance of clinical studies give the agency enormous power. The statutory test requires that studies be "adequate and well controlled."¹⁴⁴ Under this standard, the agency presumably could reject almost any given scientific study.

The agency also exerts great control over the use of foreign clinical test data to support new drug applications. FDA regulations allow for foreign test data to be submitted in support of NDAs.¹⁴⁵ But the standard by which the FDA accepts or rejects foreign test data is vague, in keeping with its other NDA standards, and allows the agency almost complete discretion. According to the regulations, "[i]n general, FDA accepts such studies provided they are well designed, well conducted, performed by qualified investigators, and conducted in accordance with ethical principles acceptable to the world community."¹⁴⁶ While the agency has explicit requirements for ethical conduct of trials, its regulations do not elaborate on the scientific or clinical requirements for "well designed, well conducted trials."¹⁴⁷

The lengthy FDA drug approval process operates under vague Congressional mandates and regulations that do not significantly clarify the agency's role in the process. This lack of clarity lends itself to abuse of

142. See HENRY B. GRABOWSKI, *DRUG REGULATION AND INNOVATION* (1976); *THE INTERNATIONAL SUPPLY OF MEDICINES: IMPLICATIONS OF U.S. REGULATORY REFORM* (Robert B. Helms ed., 1980); Lewis A. Scheindlin, Note, *New Drug Approval: Lannett, the Drug Lag, and the NDA System*, 11 *RUT.-CAM. L.J.* 231 (1980).

143. Henry B. Grabowski, *Regulation and the International Diffusion of Pharmaceuticals*, in *THE INTERNATIONAL SUPPLY OF MEDICINES*, *supra* note 142, at 36.

144. 21 U.S.C. § 355(d) (1988).

145. 21 C.F.R. § 312.120(a) (1991).

146. *Id.*

147. The regulation requires that the foreign country adhere to the ethical requirements of the "Declaration of Helsinki" or their own ethical standards. It also states that "if the foreign country's standards were used, the sponsor shall explain in detail how those standards differ from the 'Declaration of Helsinki' and how they offer greater protection." 21 C.F.R. § 312.120(c) (1991).

power by agency scientists and officials. In fact, potential for abuse was noted by an official agency review panel.¹⁴⁸ As a result, the agency has developed detailed conflict of interest rules and rules about contact between scientists and pharmaceutical companies, aimed primarily at concerns that companies will exert influence over the approval process.¹⁴⁹

2. Politics and the Agency

The role of political pressure in FDA decisions, whether from Congress, the public, or the Executive Branch, which oversees the agency, has not been the subject of much critical attention. Nevertheless, the same vague mandates and high level of discretion afforded to expert "scientific" decisions by the agency would seem to make the agency susceptible to political pressure. In the case of RU 486, pressure is likely to be exerted on the agency due to the strong anti-abortion stance of the Bush Administration.

The Administration in general and President Bush in particular have actively supported the effort to overturn the U.S. Supreme Court decision legalizing abortion, *Roe v. Wade*.¹⁵⁰ The Administration has also supported a law enacted during the Reagan years that cut off funds to international family planning organizations that support abortion.¹⁵¹ In addition, the Bush administration has backed the provisions of the Public Health Service Act that prohibit federally-funded family planning groups from performing abortions or providing information on abortion to pregnant women.¹⁵² During its most recent term, Congress passed legislation overruling this so-called "gag rule" but was unable to win the votes necessary to override President Bush's veto.¹⁵³

There have been signs that the Bush Administration is particularly concerned that RU 486 may be introduced in the United States. During

148. U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, REVIEW PANEL ON NEW DRUG REGULATION 39 (1977).

149. See, e.g., 21 C.F.R. §§ 19-19.55.

150. 410 U.S. 113 (1973). In the cases of *Webster v. Reproductive Health Services* and *Planned Parenthood of Southeastern PA v. Robert P. Casey*, the Justice Department filed Amicus Briefs on behalf of Petitioners urging the Court to overturn *Roe v. Wade*. Bush has stated that he is opposed to abortion "except when the life of the mother is threatened or when there is rape or incest." Robert Pear, *GOP Faces Fight on Abortion Issue*, N.Y. TIMES, May 26, 1992, at A15. All Republican party platforms since 1980 have called for a Constitutional amendment to protect "unborn children" and urged the appointment of anti-abortion judges. *Id.*

151. 22 U.S.C. § 216b(f)(1)-(2) (1982).

152. 42 U.S.C. § 300 et seq. (1992).

153. Philip J. Hilts, *Easing of Abortion Curb Is Disputed*, N.Y. TIMES, Mar. 31, 1992, at A18. The Administration announced in March 1992 that its rule forbidding abortion counselling in 4000 government-funded family planning clinics did not apply to doctors, but only to counselors and nurses. *Id.* Legal experts and medical organizations have challenged this interpretation, arguing that the rule makes no distinction between doctors and other professionals and that the Administration's interpretation carries no legal weight. Anti-abortion groups are expected to challenge an effort to exempt doctors from the rules. *Id.*

the fall 1990 Congressional session, President Bush threatened to veto a bill reauthorizing the Public Health Service Act for reasons including concerns that federal research funds would be used to investigate RU 486.¹⁵⁴ Ultimately, concerns over whether the bill would permit funding of abortion-related scientific research prevented the bill from making it off the Senate floor.¹⁵⁵

Thus, there is strong evidence that RU 486 will face political opposition from the Bush Administration and its supporters in Congress when and if the FDA reviews an application for the drug.¹⁵⁶ The FDA's broad statutory mandate and the absence of significant review gives the agency tremendous discretion over new drug licenses—discretion that could easily mask decisions based on political pressure. Not surprisingly, these factors have played a significant role in Roussel-Uclaf's decision not to apply to the FDA for a new drug license. Moreover, the company's fear of political influence upon the FDA have already proven accurate by the FDA's initial appraisal of RU 486.

3. *FDA Import Ban*

It is unclear how the FDA would respond to a new drug application for the marketing of RU 486. The agency already has shown itself to be susceptible to political pressure on the issue of RU 486. In its preliminary appraisal of RU 486, the agency banned personal importation of

154. CONG. Q., Sept. 29, 1990, at 3124. At issue was the Senate version of the Public Health Service reauthorization bill, S. 110, § 6(B)(3)(b) *cited in* 136 CONG. REC. S13,675 (daily ed. Sept. 25, 1990), which allocated grants to "public and private entities" to "promote the development, evaluation, and bringing to the marketplace of new and improved contraceptive devices, drugs, and methods." Debate on the Senate floor included concerns that the provision could effectively lift the ban on federal funding for research on abortifacients. Senator Coats argued that research on RU 486 might be funded under the proposed provision, despite the fact that "RU 486 is not simply a contraceptive, and research into its modes of operation is not simply the promotion of conception. . . . It can and does induce abortion." 136 CONG. REC. S13,943 (daily ed. Sept. 26, 1990) (statement of Sen. Coats).

155. 136 Cong. Rec. S13,943 (daily ed. Sept. 26, 1990) (statement of Sen. Coats). There was also significant opposition from abortion opponents to the "Chafee amendment" to the Act, which would have allowed federally-funded family planning groups to engage in "non-directive" abortion counseling. *See* 136 CONG. REC. S13,940 (daily ed. Sept. 26, 1990).

156. Federal agencies are generally susceptible to political influence from the Executive Department through Presidential appointment and Executive oversight of administrative rulemaking. *See* Harold H. Bruff, *Presidential Power and Administrative Rulemaking*, 88 YALE L.J. 451, 461-75 (1979); Lloyd N. Cutler & David R. Johnson, *Regulation and the Political Process*, 84 YALE L.J. 1395, 1410 (1975).

In recent years, the White House Office of Management and Budget (OMB) has taken on an increasingly significant role in the oversight of agency rulemaking. In 1987, the OMB was a chief architect of new FDA rules amending the drug approval provisions of the FACA. *See* Kathleen M. O'Connor, Note, *OMB Involvement in FDA Drug Regulations: Regulating the Regulators*, 38 CATH. U. L. REV. 175, 186 (1988). OMB involvement in FDA regulations has focused primarily on furthering the Reagan/Bush Administration's goal of deregulation. The OMB's access to the FDA raises the potential of the OMB influencing the FDA to further the Administration's policies on abortion.

the drug.¹⁵⁷

Since July 1988, the FDA has allowed individuals to import unapproved foreign drugs into the United States in limited quantities. This "personal importation" policy, which has never been the subject of formal regulation,¹⁵⁸ was unveiled at an AIDS conference and is widely viewed as an attempt by the agency to diffuse controversy surrounding its reportedly slow approval of new AIDS drugs.¹⁵⁹ The policy has since enabled people with AIDS to obtain some non-FDA-approved drugs from abroad.¹⁶⁰

The personal importation policy has been most heavily utilized by persons with life-threatening diseases and diseases for which no effective treatment currently exists. However, the FDA importation policy is not limited to those purposes. The policy, set out in the FDA's Regulatory Procedures Manual, allows the FDA to decide on a case-by-case basis whether a given drug may be imported under the policy.¹⁶¹ According to the manual, "FDA personnel may use their discretion to examine the background, risk, and purpose of the products before making a final decision."¹⁶² The manual also provides that:

in deciding whether to exercise discretion to allow personal shipments of drug (sic) or devices, FDA personnel should consider a more permissive policy in the following situations: when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a serious 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

157. U.S. FOOD & DRUG ADMIN., IMPORT BULLETIN #66-B13 "RU 486" (1988) [hereinafter IMPORT BULLETIN]; U.S. FOOD & DRUG ADMIN., IMPORT ALERT #66-47 AUTOMATIC DETENTION OF ABORTIFACIENT DRUGS (1989) [hereinafter IMPORT ALERT].

158. U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, CH. 9-71, COVERAGE ON PERSONAL IMPORTATIONS (1989) [hereinafter MANUAL].

159. *What's News—FDA Now Formally Allows Personal-Use Drug Imports*, WALL ST. J., July 25, 1988, at A1.

160. A non-profit organization, People with AIDS Health Group, runs an import service under the aegis of the personal importation policy for people with AIDS, and imports promising drugs that are unavailable in the United States from England and Germany. Gina Kolata, *Company Devised AIDS Drug Test Partly as Sales Tool*, N.Y. TIMES, Jan. 10, 1991, at B9. In addition to people with AIDS, individuals with Alzheimer's Disease have made use of the importation policy to obtain access to experimental Alzheimers drugs available in Canada and Mexico, but not the United States. *Punishing Alzheimers Patients*, WALL ST. J., Feb. 14, 1989, at 14 (Editorial).

161. MANUAL, *supra* note 158, at RPM 9-71-20. Importations are policed by customs officials who report questionable foreign pharmaceutical products imported in personal baggage or more often in mailed packages, to district FDA offices. See *Hearing*, *supra* note 4, at 151 (statement of Ronald Chesemore).

162. MANUAL, *supra* note 158, at RPM 9-71-30.

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 begun in a foreign country.¹⁶³

In September 1988, three days after RU 486 was approved by the French government for use in French abortion clinics, the drug was specifically excluded from the personal importation policy by an FDA bulletin.¹⁶⁴ On June 6, 1989, the FDA issued a formal "import alert" in which it clarified its position on importation of RU 486, stating that "the intended use of such drugs could pose a risk to the safety of the user."¹⁶⁵ At a Congressional hearing held on the subject of the RU 486 import ban in November 1990, an FDA official explained why the FDA had placed the ban on the drug. Ronald Chesemore, FDA Associate Commissioner of Regulatory Affairs, testified that the agency took the action "because as an abortifacient, RU 486 is not proposed for treatment of a serious condition for which no alternative treatment exists."¹⁶⁶ In addition, Chesemore testified, "[n]or could the Agency conclude that RU 486 and the prostaglandins, as they might be used, posed no significant health risks."¹⁶⁷

The Congressional hearing uncovered evidence that the FDA's action was not based on health and safety concerns but was a highly political response to active lobbying by anti-abortion members of Congress in the weeks preceding the imposition of the ban. According to the testimony of the Committee chairman, the FDA file upon which the import ban was based contains "no records of injuries due to the drug, . . . no records of a black market, foreign or domestic, . . . and no record that there has been any attempt to import the drug into the United States."¹⁶⁸ In addition, the ban was imposed despite the stringent controls placed on the drug's availability in France, which make taking the drug outside supervised clinical settings illegal, and make it virtually impossible for anyone to smuggle the drug out of the country.¹⁶⁹

163. *Id.*

164. IMPORT BULLETIN, *supra* note 157.

165. IMPORT ALERT, *supra* note 157.

166. *See Hearing, supra* note 4, at 159 (statement of Ronald Chesemore).

167. *Id.*

168. *Id.* at 2 (statement of Rep. Ron Wyden). The following interchange took place at the hearing on RU 486 between Committee Chairman Wyden and FDA Commissioner Chesemore:

Wyden: At the time of the issuance of the import alert, did the FDA have any evidence that a black market was developing on RU 486 in the United States?

Chesemore: I do not believe we had any concrete evidence. We were concerned that the possibility could exist.

Wyden: At the time of the import alert, did the FDA have any evidence of surreptitious entry of RU 486 in the United States?

Chesemore: We did not.

169. The following interchange took place at the hearing when Rep. Wyden questioned FDA Commissioner Chesemore on the subject of the restrictions placed on RU 486's availability in France:

Wyden: But how were people going to get it except under these tightly controlled circumstances that Roussel-Uclaf has established? The most charita-

While FDA files on the import ban do not contain scientific evidence that may have prompted the agency to clarify its position on RU 486 in June 1989, they do reveal evidence of political lobbying by opponents of abortion. The evidence includes an inquiry about the agency's policy on the drug in April 1989 by Senator Jesse Helms, a chief Congressional opponent of abortion, and a letter addressing the subject of an import ban by eleven anti-abortion House members.¹⁷⁰ Also in the file was a letter dated June 9 from the then FDA Commissioner Frank Young, who publicly opposed abortion.¹⁷¹ This letter responded to one Congressman with a statement of the FDA's policy on the drug.¹⁷²

At the Congressional hearing critics accused the FDA of placing politics above public health considerations. As one medical witness testified: "There was an obvious political decision and not a scientific one, and it puts in question the rationality of the FDA's review."¹⁷³ The next section of this Note will examine the rationality of the FDA's ban on personal importation of RU 486 from a legal perspective.

4. *Ban as Arbitrary and Capricious*

The legality of the import ban on RU 486 has recently been tested. On July 1, 1992, a pregnant American woman, Leona Benten, attempted to import the drug into the United States from Britain under the FDA personal use exception. She alerted customs authorities of her intent, and was met at John F. Kennedy International Airport in New York by representatives of the FDA and customs officers who seized the drug from her. Benten later said that she had attempted the importation in order

ble thing I can say about your policy is it is overkill because nobody is going to be able to do this anyway. The company tightly restricts it. You gathered no evidence that would suggest that the company or individuals were not complying with it.

Chesmore: Because the product was unapproved in this country, we had no evidence of what might happen in this company, Mr. Chairman. We certainly were aware of the tight controls that were in existence in France.

Wyden: If you had looked, you would have found that the only way you can get it is under tightly controlled circumstances. This great fear that you had couldn't materialize because the drug couldn't get out that way.

170. *Hearing, supra* note 4, at 43. Chairman Wyden's testimony also included the following:

Let us turn to what is in the FDA file. For the most part, it is filled with letters and correspondence from anti-abortion activists and their allies in Congress. These communications are remarkable both for their character and their timing. It would seem when certain folks pressed FDA's button, the FDA was only happy to respond quickly. For example, only 19 days elapsed between one particular high-level congressional demand on FDA to stop personal importation of the drug and the RU-486 import ban. This certainly has to be a new land-speed record for an agency response to congressional inquiries.

Hearing, supra note 4, at 2 (statement of Rep. Wyden).

171. SEATTLE POST-INTELLIGENCER, Nov. 20, 1990, at A3.

172. *Hearing, supra* note 4, at 63 (Memorandum prepared by Small Business Subcommittee staff).

173. *Hearing, supra* note 4, at 66 (statement of William Regelson, Professor of Medicine, Medical College of Virginia).

to test the validity of the import ban in court.¹⁷⁴

Benten challenged the seizure of the drug in federal court, alleging that the ban on personal importation was illegally promulgated by the FDA. The U.S. District Court for the Eastern District of New York entered a preliminary injunction in Benten's favor, ordering the return of the drug to her.¹⁷⁵ The District Court held that the import ban was an "arbitrary and capricious" exercise of FDA power, in violation of the Administrative Procedures Act (APA), and was not based on valid factual evidence.¹⁷⁶ The U.S. Court of Appeals for the Second Circuit stayed the injunction pending appeal and Benten filed an application with the U.S. Supreme Court to vacate the stay.¹⁷⁷ The Supreme Court denied the application, holding that Benten had failed to demonstrate likelihood of success on the merits of her claim for return of the drug.¹⁷⁸

Even if the Supreme Court had found that the ban was illegally promulgated, such a ruling would likely have little practical effect on American women's access to RU 486, however, as the FDA would likely then reissue the ban legally, with a relevant scientific basis, such as fears that personal importation would lead to uncontrolled personal use of the drug.¹⁷⁹ In addition, the agency might find that RU 486 can not be legally exported from France under French law.¹⁸⁰ Although the FDA could thus rewrite its import ban so that it would withstand judicial scrutiny, challenges to the current ban like that brought by Benten are still regarded as useful by advocates of RU 486 because they bring attention to the FDA's record on the drug and the Agency's general susceptibility to political pressure with regard to the abortion issue.

This Note supports the position adopted by the Eastern District, rather than that of the Supreme Court, in light of the political maneuvering and absence of scientific inquiry surrounding the adoption of the import ban by the FDA. The Eastern District, in its decision to grant Benten a preliminary injunction, did not, unfortunately, provide sufficient analysis of the ban to support its finding that the FDA acted illegally. This discussion is intended to fill some of the gaps in the District Court's opinion, and aid future challengers of the ban.

174. Philip J. Hilts, *Abortion Pills Are Confiscated by U.S. Agents*, N.Y. TIMES, July 2, 1992, at A12.

175. *Benten v. Kessler*, 1992 WL 166263 (E.D.N.Y. 1992).

176. *Id.* at 7-8.

177. *Benten v. Kessler*, 112 S. Ct. 2929 (1992) (syllabus).

178. *Id.* at 2930.

179. This is a valid concern given the potential dangers of self-administration without prostaglandin. See *supra* note 21 and accompanying text. This Note does not advocate uncontrolled personal importation of RU 486 into the United States. Importation of the drug in such a manner could have a disastrous impact on the health of women. This analysis does, however, support lifting of the import ban with restrictions. Under such a scenario, a woman could be allowed to import RU 486 and prostaglandin, for use under close medical supervision. This will be further discussed in Section IV of this Note.

180. See Coles, *supra* note 18.

The Eastern District Court held that the import ban was arbitrary and capricious agency action, but did not elaborate on this finding. The court did, however, identify the correct standard of review, as the appropriate standard of review for informal agency action under the APA is the arbitrary and capricious standard.¹⁸¹ Under this standard, as defined by the Supreme Court in *Citizens to Preserve Overton Park v. Volp*, a reviewing court must engage in a two-part inquiry.¹⁸² It must first determine whether the decision-maker acted within the scope of his or her statutory authority as prescribed by the governing statute. Then the court must determine whether the actual choice made was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."¹⁸³ Under the latter test, a court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment."¹⁸⁴

Under the first part of the two-step *Overton Park* inquiry, it is likely that a court would find that the FDA acted within the scope of its statutory authority in issuing the import ban. The Food Drug and Cosmetic Act gives the FDA the authority to regulate the importation of drugs that are not approved for use in the United States.¹⁸⁵

It is the second part of the *Overton Park* test that the RU 486 import ban fails. In reviewing FDA regulations in *Almay, Inc. v. Califano*,¹⁸⁶ the U.S. Court of Appeals for the D.C. Circuit, described the second part of the *Overton Park* standard as requiring "an inquiry into the facts and a determination of whether [the] decision was (1) based on 'a consideration of the relevant factors' and (2) free of such error as would deprive it of a rational basis."¹⁸⁷ In *Almay*, the court held that FDA regulations governing hypoallergenic cosmetics were arbitrary and capricious under the *Overton Park* standard because the agency's findings were based solely on a dictionary definition, a report from the American Medical Association, and unreliable survey data.¹⁸⁸

Given the FDA's apparent lack of health and safety data on RU 486, a reviewing court following the *Almay* reasoning should find that the import ban was not based on a consideration of the relevant scientific

181. 5 U.S.C. § 706(2)(a) (1988).

182. 401 U.S. 402 (1971). In *Overton Park*, the Supreme Court reviewed a decision by the Secretary of the Department of Transportation to route a highway through a public park. Courts often apply the arbitrary and capricious standard of review enunciated in the case to informal notice and comment rulemaking. However, courts also apply the standard to other types of informal agency actions, such as the Secretary of Transportation's park placement decision in *Overton Park*. STEPHEN BREYER & RICHARD STEWART, ADMINISTRATIVE LAW AND REGULATORY POLICY 619 (1985).

183. *Overton Park*, 401 U.S. at 414.

184. *Id.* at 416.

185. 21 U.S.C. 381(a) (1988).

186. 569 F.2d 674 (D.C. Cir. 1977).

187. *Id.* at 681.

188. *Id.* at 682.

factors.¹⁸⁹ Additionally, the FDA did not appear to consider its own guidelines on the appropriateness of import bans. According to the guidelines, FDA personnel are to “recommend . . . the issuance of an import alert if they encounter: personal importation of products that represent either a direct or an indirect risk; the promotion of unapproved foreign products for mail-order shipment; or repeated importation of products that represent a health fraud.”¹⁹⁰ The FDA’s action against RU 486, made without evidence of personal importation or threat of importation, seems to contravene the agency’s own guidelines for the appropriateness of import bans. The ban was apparently issued purely for a symbolic purpose. A reviewing court would consider whether the FDA’s apparent failure to follow its own guidelines constituted a failure to consider a “relevant factor” under *Overton Park*. In addition, a reviewing court would likely find that the agency’s apparent heavy reliance on political considerations was not a “relevant factor.”

In reviewing the ban, a court would, however, have to be mindful of the great degree of discretion the Supreme Court has traditionally granted the FDA in making decisions about drug availability. As the Court stated in a case in which it upheld an FDA determination of a new drug application, “[e]valuation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background.”¹⁹¹

Assuming that a court held the FDA’s action to be arbitrary and capricious as applied to a particular complainant, the FDA would most likely issue a second import ban based on more “relevant factors” such as documentary evidence regarding dangers of uncontrolled personal use of the drug. The agency could also construe or revise its guidelines to give it greater discretion in preventing importation of the drug, arguing that RU 486—as an abortifacient—is not intended for treatment of a “serious condition.” As the policy is currently drafted, it is so discretionary that it provides almost no constraints on the FDA’s ability to stop the importation of a particular drug.

While overturning the import ban would likely lead to the FDA’s reissuing the ban on a different basis, continued challenges to the current ban are useful for a number of reasons. Challenges such as the one brought by Leona Benten bring public attention to the agency’s susceptibility to political influence on the abortion issue. Perhaps the attention will make the agency wary of succumbing to such bias in the future, both out of fear of judicial review and of loss of public confidence. Challenges to the ban also send the message to drug companies that the FDA’s decision-making process is not going unchecked and that politics does not have a rightful place in U.S. drug regulation. As the next sec-

189. It is possible that the FDA has already recreated its RU 486 file to reflect concerns expressed during the hearing about the lack of scientific basis for the import ban.

190. MANUAL, *supra* note 158, at 9-71-40.

191. *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653-54 (1973).

tion of this Note will discuss, the import ban has sent the opposite signal to Roussel-Uclaf and other drug companies that might want to license RU 486 or other controversial products.

5. *The Company's Reaction to the Politics of the FDA*

While Roussel-Uclaf has not publicly stated it as such, the import ban is widely said to have confirmed the company's fears that U.S. regulators have taken a negative view of RU 486 and are highly susceptible to lobbying from abortion opponents.¹⁹² The politics of the FDA, in combination with the Bush Administration's anti-abortion stance, is a top concern of the company as it contemplates future marketing of its product.¹⁹³ While the company has begun plans to market the drug in Britain, Scandinavia, and the Netherlands, the head of international marketing at Roussel-Uclaf has stated that "selling in the United States is out of the question at the moment."¹⁹⁴

The drug's inventor told a U.S. audience in February 1992 that Roussel-Uclaf would "delay a decision to seek approval for the drug pending the outcome of the U.S. presidential election."¹⁹⁵ Baulieu stated that RU 486 is being held "hostage" to American politics, and added, "I sincerely hope that after the election—if a Democrat or George Bush is elected—he will follow the rule that if there is a good drug, one should let doctors and patients have it."¹⁹⁶

There have been other consequences of the import ban. According to the Congressional hearing on RU 486, since the imposition of the import ban, Roussel-Uclaf has in many cases stopped supplying RU 486 to U.S. researchers who are investigating other uses of the drug.¹⁹⁷ The decline in the supply of the drug in the United States has been interpreted as a business decision by the company to use its drug supply only in countries where approval of the drug is imminent.¹⁹⁸ As a member of

192. *Hearing, supra* note 4, (statement of Rep. Wyden).

193. *Id.*

194. Alan Riding, *Abortion Politics Are Said to Hinder Use of French Pill*, N.Y. TIMES, July 29, 1990, at A1.

195. ABORTION REPORT, *supra* note 111.

196. *Id.*

197. Scientists conducting studies on other uses of RU 486 testified at the congressional hearing that the import ban had negatively affected their access to the drug. Kathryn Horowitz, a University of Colorado breast cancer specialist, testified that she was told by the FDA that she could no longer receive the drug in the mail from the manufacturer, nor could she travel to France and import the drug back into the United States. *House Subcommittee Hearing on RU 486*, ABORTION REPORT, Nov. 20, 1990, available in LEXIS, Nexis Library, ABRPT File. George Chrousos, a National Institute of Health researcher, testified that the atmosphere surrounding the import ban led to Roussel-Uclaf's reluctance to supply the drug for government-sanctioned study under an officially filed investigational new drug applications. Maura Reynolds, *U.S. Ban on Abortion Pill Said to Hurt Research on Cancer, Other Dread Diseases*, L.A. TIMES, Nov. 20, 1990, at A23. An FDA official testified that the import ban did not extend to samples for testing under an approved application, and that the FDA was mistaken when it informed researchers otherwise. *Id.*

198. *See Hearing, supra* note 4, at 3 (statement of Rep. Wyden).

Congress testified at the oversight hearing: “[t]he drug’s manufacturer has made a business decision only to use its supplies in countries where government regulators will give them a fair shake.”¹⁹⁹

The next section addresses what is perhaps the most troubling aspect of the FDA’s handling of RU 486, the agency’s abdication of its statutory public health role. By allowing political considerations to dominate drug decision-making, the agency is ignoring its dual public health role of keeping ineffective and dangerous drugs off the market while promoting the availability of safe and effective new medicines.

IV. FDA Decisionmaking and Public Health

Prior sections of this Note have described the effect of FDA discretion and abortion politics on the availability of RU 486 in the United States. This section will turn to what is perhaps the heart of the issue—how the FDA’s past and probable future bias against RU 486 rejects the agency’s statutory role as protector of public health. By allowing politics to dominate health considerations in its appraisal of a drug’s safety and efficacy, the FDA has abdicated its dual public health role—to screen out dangerous drugs from the U.S. market and to ensure that safe and useful drugs reach the American public.

This section will first consider the FDA’s role as protector of the public health and then address the public health advantages of RU 486. The section will then propose changes in FDA policy that would ensure agency adherence to its statutory public health role and prevent political influence in the review of controversial products like RU 486. These suggested changes in FDA policy focus primarily on limiting agency discretion, which allows political pressure to infiltrate the personal importation policy and in the new drug approval process in general.

In considering the need for change in this area, policy makers would be best served by considering the French government’s action on behalf of RU 486. The French government’s specific market-interventionist technique does not provide a helpful lesson for the FDA, which has neither patent law rights or ownership to use as leverage over Roussel-Uclaf.²⁰⁰ Two aspects of the French government’s action, however, are useful in the U.S. context. The first is the French Health Minister’s stated goal to promote public health and eliminate ideological impediments to public health progress. The second is the French government’s ability to separate French abortion law, which places significant restrictions on legal abortion, from public health concerns regarding the availability of a safe and effective abortion method. These two aspects of the French model can and should be integrated into U.S. drug policy. If the suggested changes are effective, they will help eliminate arbitrary

199. *Id.*

200. *See supra* notes 73-74 and accompanying text. United States patent law rights do not depend on whether the patent owner exercises those rights. *See* Patent Act, 35 U.S.C. § 27(d)(4) (1988).

government decision-making in drug application decisions and remove the extra-market impediments that now block U.S. consumer access to innovative pharmaceuticals like RU 486.

A. The FDA's Role in Promoting Public Health

The Supreme Court has held that the Food Drug and Cosmetic Act's "overriding purpose [is] to protect the public health."²⁰¹ Consequently, a primary function of the FDA is to protect the public from access to dangerous drugs. While the Act does not explicitly define the agency's public health role, the legislative history of the Act reveals a clear Congressional intent to protect the public from dangerous drugs. Initial passage of the Act in 1938 and its subsequent amendment in 1962 were prompted by highly-publicized scares over the availability of dangerous drugs. Public furor over deaths caused by Elixir Sulfanilamide led to the passage of the original Act in 1938, which introduced the requirement that a manufacturer prove the safety of a drug before marketing.²⁰² The 1962 amendments to the Act, requiring a manufacturer to prove drug efficacy as well as safety, derived momentum from the thalidomide tragedy in Europe.²⁰³ The drafters of the 1962 amendments sought to avoid similar situations in the United States. According to one backer of the 1962 amendments:

Our duty, as I conceive it, is to make assurance doubly sure that we here in the United States may never be the victims of a tragedy of the magnitude of the one associated with the use of thalidomide in Germany and Great Britain. Whatever inadequacies now exist in legislation covering this vital field must most certainly be taken care of promptly, so that we may rest secure that the very medicines which hold out such bright promise of our ultimate freedom from disease do not themselves become a cause of fear.²⁰⁴

Nevertheless, the FDA's restrictive role of keeping unsafe drugs out of the market is only half of its public health responsibility. Equally important is the FDA's responsibility to provide the public with access to important new drugs. This theme was continually stressed in the floor debate on the 1962 amendments. According to one of the supporters of the 1962 amendments to the Act:

[W]hile we are charged with the responsibility of providing the Food and Drug Administration with the tools necessary to protect the public and prevent abuses and misuse of drugs in this country, we must also be fully aware of the public welfare to the extent also that we do not act to retard the development of drugs that are life prolonging or lifesaving. Thus public welfare becomes a two way street; one which provides protection from abuses on the one hand and the other which provides the continued

201. *United States v. An Article of Drug*, 394 U.S. 784, 798 (1969).

202. Dixie Farley, *How FDA Approves New Drugs*, FDA CONSUMER, Dec. 1987-Jan. 1988, at 10.

203. *Id.*

204. 108 CONG. REC. 21068 (1962) (statement of Rep. Fogarty).

advantages to which the public is entitled through the research and development of new and effective drugs.²⁰⁵

Or, as another backer of the amendments stated: "Safety is, of course, only one of our responsibilities in health matters . . . as important as providing all possible assurances of safety, is our obligation to maintain a legislative framework in which the benefits of new drug discoveries can be brought rapidly to those who need them."²⁰⁶

This affirmative role to promote public health is revealed in the FDA's system for review of new drug applications. The FDA prioritizes review of drug applications for products with the greatest "treatment potential," which the agency defines as drugs that "may effectively treat or diagnose a disease not adequately treated or diagnosed by any marketed drug."²⁰⁷ Drugs that offer only a "modest gain" or "little or no gain" are assigned lower priority in the FDA's review procedure.²⁰⁸

B. RU 486 and Public Health

RU 486 is undoubtedly a strong candidate for FDA approval. While the agency requires elaborate clinical data,²⁰⁹ the drug has been the subject of extensive international scientific scrutiny and has been generally found "safe and effective"—the agency's standard for the awarding of new drug applications.²¹⁰ Experts have found the drug to be as safe as surgical abortion and to have advantages over that method.²¹¹ Thus, RU 486 would not appear to pose any significant problems to the FDA acting in its restrictive role of policing dangerous drugs.

FDA approval of RU 486 would facilitate introduction into the United States of a drug with important public health advantages. The FDA would thus be faithfully executing its role as promoter of important new medicines. The health advantages of RU 486 as an abortifacient²¹² are significant because it provides a non-surgical alternative to what is one of the most common surgical procedures performed in the United States.²¹³ There is evidence that RU 486 provides significant psychological advantages over surgical abortion and is less expensive.²¹⁴ Medical experts have described the drug as the most significant innovation in reproductive medicine since the invention of the contraceptive pill.²¹⁵

Nevertheless, agency discretion and political influence render the approval process problematic.²¹⁶ The FDA's broad discretion over the

205. 108 CONG. REC. 21057 (1962) (statement of Rep. Collier).

206. 108 CONG. REC. 21068 (1962) (statement of Rep. Fogarty).

207. Farley, *supra* note 202, at 12.

208. *Id.*

209. *See supra* notes 132-40 and accompanying text.

210. *See* 21 U.S.C. § 355(d) (1988).

211. *See supra* notes 21-26 and accompanying text.

212. For other potential uses of RU 486, see *supra* note 4 and accompanying text.

213. *See supra* notes 35-43 and accompanying text.

214. *See supra* notes 40-43 and accompanying text.

215. *See supra* note 1 and accompanying text.

216. *See supra* Part III of this Note, notes 150-56 and accompanying text.

approval of new drugs allows politics to dominate scientific and health considerations in the agency decision-making process. The import ban on RU 486 reveals how abortion politics can influence the agency acting within an area of its discretion.²¹⁷ To ensure that politics does not bar the availability of RU 486 or any other product with public health benefits, FDA policy must be changed to curtail some of the agency's easily abused discretion.

C. Changes to FDA Policy

1. Clarifying FDA Personal Importation Policy

One area of FDA policy that should be amended to safeguard public health interests is the FDA personal importation policy, which now enable U.S. citizens to obtain some foreign drugs that remain domestically unapproved.²¹⁸ The current policy is poorly designed and invites arbitrary decisions.²¹⁹ In the case of RU 486, the policy may have unjustifiably deprived Americans of an important medical innovation. Moreover, it has certainly given the impression to drug companies and consumers that the FDA is highly susceptible to political pressure on the issue of drug availability. This section suggests changes to the current personal importation policy that could reduce the likelihood of arbitrary agency decisions and, consequently, reduce the harmful effects of drug availability decisions. In addition, the changes should generally benefit public health by facilitating consumer access to important foreign medical treatments.

a. Medical Conditions for Which Personal Importation is Allowed

The FDA's personal importation policy must be clarified to prevent seemingly political decisions like the RU 486 import ban. As it stands, the policy, which is broad and highly discretionary,²²⁰ lacks clear guidelines and greatly increases the possibility of arbitrary decision-making on the part of the agency. One section of the guidelines, for example, refers to a "permissive policy" for drugs for treatment of a "serious con-

217. See *supra* Section III.B.3 of this Note, notes 164-73 and accompanying text.

218. See *supra* notes 158-63 and accompanying text.

219. Other FDA import ban decisions have been criticized. One example is the agency's ban on the importation of THA, a drug used to treat Alzheimer's disease, which is manufactured by Pharmoscience, Inc., a Canadian company. A small number of U.S. Alzheimer's patients had used the personal importation policy to obtain supplies of the drug from Canada in the summer and fall of 1988. In December 1988, the FDA placed an import ban on THA, stating that the drug was potentially dangerous to the human liver. Up until the time that importation of the drug was banned, families of patients reported that the drug was highly effective, and had considerably improved the quality of life for family members with the disease. Critics of the FDA's decision have since uncovered evidence that the agency may have not been responding to safety concerns, but rather had been concerned that if the drug was widely available in this country through personal importation, introduction of the drug in this country would be slowed because fewer patients would agree to submit to the clinical trials required for new drug approval. WALL ST. J., *supra* note 160.

220. See *supra* Section III.B.3 of this Note.

dition.”²²¹ At the Congressional hearing on the RU 486 import ban, an FDA official testified that the agency can apply these guidelines on a “case by case basis” and that “discretion has also been used to allow importation of unapproved drugs where the intended use of the drug is appropriately identified, the use is not for treatment of a serious condition, and the drug is not known to represent a significant health risk.”²²² The FDA has wide discretion in that it may rely on a serious condition requirement for denying personal importation, but may also waive the requirement.

If the serious condition requirement is to be a major factor in FDA decisions to allow personal importation of drugs, the agency should make this clear in its guidelines. In doing so, the agency should define “serious condition”²²³ and clarify the requirement that no “effective treatment” be commercially available in this country.²²⁴ In defining this latter standard, the agency should specify how it would approach a condition for which other treatments are commercially available, but are more burdensome for the patient.²²⁵

In making its import ban decisions, the FDA should rely on the advice of an expert panel to a greater extent than it does currently.²²⁶ This would both provide an outside check on political bias and guarantee input from medical practitioners most familiar with patient needs.

b. Import Ban

The FDA must also clarify the standard by which a drug is placed under the “import ban” status. Currently the agency need not meet proof standards for health or safety concerns before implementing an import ban. Rather, the agency relies on its discretionary, informal guidelines which, as in the case of RU 486, are highly susceptible to abuse.²²⁷ A new policy should include a standard of proof such as the “safe and effective” standard for personal use of the new drug approval process.²²⁸ In addition, the new guidelines could require the agency to make public the studies and other data that it uses to make its import

221. *MANUAL*, *supra* note 158, at 9-71-30(c).

222. *Hearing*, *supra* note 4, at 156 (statement of FDA Associate Commissioner Chesemore).

223. Under a reasonable interpretation of the current guidelines, an unwanted pregnancy may be a “serious condition.” This would be particularly so if pregnancy posed a significant health risk to the mother.

224. *MANUAL*, *supra* note 158, at 9-71-30(c).

225. Such a provision would clarify the Agency’s position on drugs like RU 486, for which there are commercially available alternatives to the drug (i.e., surgical abortion), but which offer advantages over the commercially available option (in the case of RU 486—decreased health risks, fewer side effects and increased patient privacy. *See supra* Part I.B of this Note.)

226. *See infra* notes 243-48 and accompanying text. For a discussion of the role of French advisory groups, *see supra* Part II.A of this Note.

227. *See supra* Part III of this Note.

228. A higher standard might even be appropriate given the dangers associated with personal importation.

ban decisions, as it does currently in the area of new drug approval decisions.²²⁹

The agency should take further measures to ensure that a ban on personal importation does not hinder research on use of an unapproved drug. The policy could protect individual researchers from a personal importation ban by ensuring a continued supply of the drug. This could be done by exempting research-related importation from the ban. The difficulties that researchers have had obtaining RU 486 since the import ban might have been prevented by the FDA's clarification of its policy with regard to the use of unapproved drugs for experimental purposes.²³⁰

Because the current import ban process is conducted entirely within the agency, it provides certain parties, like Congressional insiders, great access to the decision-makers, while the public, whose health motivates the policy, is largely excluded from the decision-making process. This inequity could be addressed by a statutory requirement that import ban decisions be made only after the public has had an opportunity to be heard, a requirement that could be implemented in either of two ways. The first would mandate that import bans be promulgated under the notice and comment rulemaking procedure; the bans would be implemented only after the public, including the medical community, had an opportunity to submit comments.²³¹ A second statutory scenario, offering a greater degree of public participation, would require the FDA to undertake formal rulemaking and hold public hearings on its import ban decisions.²³² Public hearings would provide the agency with testimony from various interested parties. Where appropriate, the statute could enable the FDA to implement a temporary import ban under a designated standard of proof. Such a ban would prevent potentially dangerous importation during the decision-making process.

229. If, as may have been the case in the THA ban, the agency denies importation when it may interfere with the new drug approval process in the United States, this factor should be clearly delineated in the guidelines. The agency should also be required to prove sufficient grounds for this kind of concern.

230. See *supra* note 197 and accompanying text.

231. See Administrative Procedure Act (APA), 5 U.S.C. § 553 (1988). Notice and comment rulemaking requires an agency to

(1) publish a general notice of proposed rulemaking in the Federal Register specifying the time and place of the rulemaking proceedings, the legal authority relied upon for their issuance, and the content or subject matter of the rules; (2) provide opportunity for 'interested persons' to comment on the proposed rules by written submission and, at the option of the agency, opportunity for oral argument'; (3) issuance, when rules are finally promulgated, of a 'concise general statement of their basis and purpose'; (4) provision, in the case of substantive rules, that they shall not be effective in less than 30 days after promulgation.

BREYER & STEWART, *supra* note 182, at 562.

232. An amendment to FACA could require the FDA to review import bans under the formal rulemaking provision of the APA, 5 U.S.C. § 556 (1988). Congress might very well find this public hearing requirement to be unduly burdensome, however.

While stricter guidelines for the implementation of import bans and a public hearing process would not eliminate behind-the-scenes lobbying by insiders in Congress or the Administration, it could reduce the potential for abuse under the existing vague and highly discretionary policy. Clear standards for personal importation would give reviewing courts greater ability to police agency decisions in this area. This is of particular importance, for courts are often unwilling to interfere in decisions resulting from broad agency discretion.²³³ In addition, the publicity accompanying a public hearing could encourage accountability of agency decision-makers. Clarifying and rewriting the current personal importation guidelines will narrow the agency discretion that led to the questionable RU 486 decision and thus prevent similarly arbitrary drug availability decisions. Several factors, however, would render the adoption of notice and comment rulemaking preferable to internal policy guideline changes. Chief among them would be the opportunity for public input. A public comment session would provide consumers, medical experts, and others an opportunity to participate in the formulation of the policy and would ensure that the agency consider a range of perspectives before reaching a decision. A court might be more willing to review action taken under a notice and comment rule than under discretionary internal policy guidelines.²³⁴ Heightened review would limit the effect of political bias on agency decision making.

2. *Extending the Benefits of the Personal Importation Policy*

In the interest of public health, the FDA should change its personal importation policy to allow the importation of drugs such as RU 486, which are only appropriately administered under highly controlled circumstances. Current guidelines require that the recipient of an imported drug specify the physician under whose care they are receiving the medication.²³⁵ New guidelines could require that "imported" drugs travel directly to a patient's personal physician and be administered in accordance with specified agency procedures. This would expand the options available to an individual seeking to import a foreign drug that might require administration under clinical supervision.²³⁶ Regulations of this sort would significantly increase public health benefits by allowing patient access to drugs like RU 486, for which the safety concerns are a function of the administration of the drug rather than the drug's effectiveness.²³⁷

233. See *supra* note 191 and accompanying text.

234. See *supra* note 176 and accompanying text.

235. MANUAL, *supra* note 158, at 9-71-30(c).

236. Some cancer therapies require administration to a patient by a physician under carefully controlled circumstances. Liability concerns might, however, result in the refusal of many physicians to administer RU 486 before it is approved by the FDA.

237. See *supra* note 21 and accompanying text.

3. Safeguarding the New Drug Approval Process

The FDA's new drug approval process should be changed to ensure that public health concerns, and not political issues, dominate the agency's new drug decisions. These changes would not only facilitate approval of RU 486 by the agency, but would be significant to the success of other drugs as well.²³⁸ This section focuses first on general regulations that might serve to depoliticize the new drug approval process. The section then turns to the agency's discretion over the acceptability of foreign test data and the safeguarding of this area from political abuse.

a. Congressional Clarification of New Drug Approval Standard

The FDA's statutory mandate under the new drug approval section of the Food and Cosmetic Act (FACA) is broad and affords great discretion to the agency.²³⁹ The problem with the current standard is not that it specifically allows for political influence, but that the breadth of the "safe and effective" standard lets the agency mask political decisions behind "scientific" decisions. In the case of RU 486, despite the wealth of medical evidence supporting the drug,²⁴⁰ the agency has great discretion to pronounce it "unsafe" or "ineffective."

No statutory or regulatory change will eliminate political influence from FDA decision-making. Nevertheless, a Congressional clarification of the new drug approval standard might send a message to agency officials. By excluding political and non-scientific influences from FDA decision-making, Congress would make clear its intention to limit agency discretion. While the current standard introduced by the 1962 amendments to FACA gives the agency broad discretion to police new drugs for health and safety problems, Congress now faces a FDA that may be willing to subordinate public health to political concerns. Congress could address this unanticipated development by passing legislation that would explicitly forbid the FDA from allowing politics to enter its decision-making.

Clarification of the new drug approval standard might also serve the important purpose of facilitating judicial review of agency decisions. Courts have traditionally been highly deferential to FDA new drug decisions.²⁴¹ A standard that explicitly precluded political considerations would provide a foundation for a finding of arbitrary and capricious action under the deferential *Overton Park* standard of review.²⁴² The

238. The Federal government in 1988 banned federal financing of research on uses of fetal tissue. This does not bode well for the success of drug research that might require the use of such technology. The use of fetal tissue is critical to current research of Parkinson's disease. Similarly, drugs in the area of fertility control and new reproductive technology could be affected by FDA bias. See Philip J. Hilts, *Groups Set Up Panel on Use of Fetal Tissue*, N.Y. TIMES, Jan. 8, 1991, at C3.

239. See *supra* notes 139-41 and accompanying text.

240. See *supra* notes 21-26 and accompanying text.

241. See *supra* note 191.

242. See *supra* notes 182-84 and accompanying text.

standard might also provide an additional incentive for agency decision-makers to adhere to scientific considerations in new drug decisions.

b. Increased Role for Advisory Committees

While clarification of the new drug approval standard might facilitate heightened judicial review of agency decisions, greater use by the FDA of advisory committees might also provide an important internal check on agency decision-making. An amendment to FACA providing for an increased role of outside advisory committees would serve the same goal as clarifying the standard for new drug approval; it would ensure that scientific rather than political considerations dominate agency decision-making.

In particular, FACA should be amended to require the FDA to consult outside advisory committees earlier in the new drug approval process. The FDA has in place a system of external advisory committees, which, at the agency's discretion, review products at the new drug approval stage.²⁴³ A drug like RU 486, however, because of its controversial nature, is likely to be referred to one of the FDA standing advisory committees upon application.²⁴⁴ But just as politics has affected consideration of the drug at the personal importation stage, it might affect appraisal of the drug before the new drug approval stage—at the IND stage or at the approval stage of the Phase I or Phase II clinical testing procedures.²⁴⁵ New regulations could establish a mechanism whereby potentially controversial drugs would be referred to an advisory committee at an early stage of the new drug approval process. The regulations would also require the relevant advisory committee to review the agency's preliminary decisions for scientific bases and monitor the drug's path through the agency to prevent political delay or sabotage.

The FACA should also be amended to require agency consideration of the advisory committee's findings. A greater role for outside advisory committees in FDA decision-making would bring the U.S. system closer to the French model where the Commission of Marketing Authorizations plays an important role in new drug decisions. Like the French Commission, FDA standing advisory committees for new drug approval are comprised primarily of members of the medical community, including practicing physicians who can provide the FDA with important infor-

243. 21 C.F.R. §§ 14.1(a)(1), 14.1(b)(2) (1991). Some drugs statutorily require approval by an outside advisory committee. An example in such a category are drugs that affect the health of pregnant women or that may have fertility effects. RU 486 does not fit in this category of drugs as it has been traditionally understood. It is not a drug that, as an unintended side effect, affects the health of pregnant women, neither is it a drug that affects fertility.

244. Either the standing advisory committee on fertility and maternal drugs or the advisory committee on obstetrics and gynecology would appear to be appropriate. See 21 C.F.R. § 14.10 (1991). For a list of all the FDA's standing advisory committees, see 21 C.F.R. § 14.10 (1991).

245. See *supra* notes 132-36 and accompanying text.

mation on the public health application of a new product.²⁴⁶ Unlike their French counterpart,²⁴⁷ FDA advisory committees do not have a clear statutory role in the decision-making process; the agency is not required to consider the standing committee's views in its final decision on the licensing of a new drug.²⁴⁸ An amendment that required agency consideration of advisory committee recommendations would provide for meaningful input from the medical community and would presumably ground FDA decisions in scientific findings. A statutory requirement that the FDA consider its advisory committee's conclusions on any given drug would also facilitate judicial review of the reasonableness of an agency determination.

D. Acceptability of Foreign Test Data

As a result of funding and other constraints there is little ongoing research into new reproductive technologies in the United States, including new forms of birth control.²⁴⁹ Thus, it is increasingly likely that controversial medical innovations, like RU 486, will be developed and marketed abroad. Consequently, the FDA's provisions on the acceptability of foreign test data for new drug applications will become increasingly important. As previously discussed, the FDA's standard for acceptability of foreign test data is extremely vague.²⁵⁰

The FDA should amend its standards for the acceptance of foreign clinical data to explicitly preclude political considerations; as this Note has suggested, the new drug approval standard should be amended for the same purpose. In addition, regulatory guidelines detailing acceptability of foreign studies would provide greater assurance to foreign pharmaceutical companies that applications based on foreign studies will be treated fairly, and the agency will not employ broad discretion to mask political decisions regarding foreign products.

E. Promoting the Availability of Important Foreign Drugs

Preceding sections of this Note have suggested ways in which the FDA personal importation policy and the new drug approval process can be safeguarded from political abuse to ensure the greatest consumer access to medical innovations. Suggested changes to the new drug approval policy would obviously affect the availability of domestic drugs (drugs invented and tested by U.S. pharmaceutical companies) and foreign

246. FDA technical advisory committees, which include the standing committees that review the NDA's for various products, may include consumers or industry members, but only the technical members can vote. Joseph L. Lakshmann, *Nontechnical Representation on the FDA's Advisory Committees: Can There Be More?*, 44 *FOOD DRUG COSM. L.J.* 181, 185 (1988). Some critics of the system have suggested that the FDA include more non-technical advisers on its panels. *See id.* at 186-89.

247. *See supra* note 57.

248. 21 C.F.R. § 14.5 (1991).

249. *See supra* notes 118-23 and accompanying text. *See also* note 154 and accompanying text.

250. *See supra* note 145-47 and accompanying text.

drugs (those invented and tested outside the United States). This section focuses specifically on how the FDA can more aggressively encourage the introduction of successful foreign drugs into the U.S. market. The section suggests that the United States adapt the French drug development scheme discussed earlier in this Note,²⁵¹ and implement a similar system for (1) identifying successful foreign treatments and (2) encouraging the marketing of such treatments in the United States.

Through either statutory amendment to the FACA or rulemaking pursuant to the agency's authority to regulate new drugs, the agency should create a drug-development body required to monitor foreign medical developments for potentially important and beneficial innovations. The body could consist of medical practitioners and scientists, familiar with patient needs and current drug availability, who would be able to identify foreign products that would provide treatments currently unavailable in the United States. The body's actions should be carefully monitored to ensure that it consider "potentially useful" drugs under a standard employing health and scientific factors and excluding political considerations. Regulations could require that the outside advisory group system be used to monitor the workings of the internal drug development body and check for political abuse.

In addition, the drug development body could work to encourage pharmaceutical companies or other sponsors of promising treatments to seek FDA approval of their drugs. Consumer reliance on the personal importation policy is a sign of the agency's failure to encourage the marketing of promising treatments in the United States. Under a new program to encourage drug development, U.S. consumers could rely on the established channel for new medical innovations—the new drug approval process—rather than turning to less reliable alternatives such as the personal importation policy. Members of the new drug development body could meet periodically with pharmaceutical companies and assist in the development of test protocols and provide other assistance to facilitate FDA approval of important innovations. This new relationship between the agency and the companies would also have to be carefully monitored to prevent abuse and compromise of FDA standards on behalf of a particular product.

Conclusion

The history of RU 486 in the United States reveals inadequacies in the current drug approval system. These failings have damaging consequences for public health. By allowing political bias to surround its decision-making, the FDA has abdicated its statutory responsibility and betrayed U.S. consumers. This Note has suggested that FDA policy should be amended to safeguard the drug-approval process from political bias at its various stages. Following the French example, the U.S. government should act to further scientific progress, and protect inno-

251. See *supra* note 57 and accompanying text.

vative and useful products from ideological forces. While the availability of abortion is an issue on which not all can agree, public health should not be held hostage to this moral debate. The FDA is obligated to assist women facing unwanted pregnancies, cancer patients, and others for whom RU 486 and other new drugs hold out hope; the agency is required to help provide the best medical care that science makes available.

The most effective way for the United States to ensure that its citizens are not denied important medical advances is for U.S. government leaders to adopt a public position of neutrality in public health policy, as did their French counterparts. U.S. health officials through their words and U.S. health policy through its actions need to affirm that scientific progress is the “moral property” of all.

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