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GRISWOLD, THE FDA, AND THE STATE LEGISLATOR: THE REGULATION OF MIFEPREX

Mifeprex is the brand name for mifepristone, also known as RU-486, or the French abortion pill.¹ On September 28, 2000, the Food and Drug Administration (“FDA”) approved the use of Mifeprex for “the medical termination of intrauterine pregnancy through 49 days’ pregnancy.”² “Mifeprex is the first [FDA] approved early option pill providing women with a safe and effective non-surgical option for ending early pregnancy.”³

This Note will first present background information on Mifeprex, including how the drug works as an abortifacient, possible side effects of the drug, other uses of the drug, and a brief history of the drug’s FDA approval and arrival into the US market. This Note will then provide a brief summary of the current legal standards under which abortion law and regulation is evaluated. Finally, this Note will address several questions brought about by the approval of Mifeprex. First, how will this drug, with its unique ability to act as both a contraceptive and abortifacient, affect the current abortion debate? Second, how will current state legislation on surgical abortion cover Mifeprex medical abortion? Third, how will Mifeprex’s status as a drug affect possible state legislation, especially in relation to distribution and availability? And finally, how will the inherent differences between surgical abortion and the non-invasive⁴ Mifeprex procedure effect challenges to old abortion laws? This Note will conclude that Mifeprex is certainly a horse of a different color that will have a profound effect on the abortion debate. The legislation regarding this drug will be varied. Regulation will range from state laws specifically addressing non-surgical abortions to federal laws regarding only the administration of Mifeprex.

1. The name RU-486 comes from the original French manufacturer Roussel-Uclaf’s 36,486 product. André Ulmann et al., *RU 486*, 262 SCI. AM. 42 (1990).

2. FDA Approval Letter, *MIFEPREX (Mifepristone) Tablets*, available at <http://www.fda.gov/eder/foi/appltr/2000/20687appltr.htm> (last visited Mar. 1, 2002).

3. *Mifeprex: Frequently Asked User Questions*, available at <http://earlyoptionpill.com> (last visited Mar. 1, 2002).

4. *See id.*

BACKGROUND

The Drug – How it Works

Mifeprex blocks progesterone, a hormone that prepares the lining of the uterus for the implantation of a fertilized egg.⁵ Once the drug blocks progesterone, “the uterine lining softens, breaks down and bleeding begins.”⁶ The lining also begins to secrete prostaglandin, which causes the uterus to contract and expel the egg.⁷

In order to induce the equivalent of a miscarriage, a patient must ingest six hundred milligrams of Mifeprex in the first of three doctor’s visits.⁸ Two days later, the patient will take four hundred micrograms of a second drug, misoprostol.⁹ Misoprostol, a drug previously approved by the FDA for the prevention of ulcers,¹⁰ is a prostaglandin used to supplement the prostaglandin naturally produced by the uterine lining.¹¹ This second drug helps complete the expulsion process.¹² Finally, the patient visits a third time approximately twelve days following the second visit to ascertain that the pregnancy has been successfully terminated.¹³

Side Effects and Administrator Requirements

Mifeprex does have possible side effects, which are thoroughly detailed on the FDA-approved labeling.¹⁴ Women who have confirmed or suspected tubal pregnancies, intrauterine devices (IUDs) in place, adrenal gland failure, current long-term corticosteroid therapy, allergies to the medication, or bleeding disorders should not use Mifeprex.¹⁵ Additionally, potential candidates are warned that in one out of every one hundred women

5. *Id.*

6. *Id.*

7. Robin Herman, *The Politics of the Abortion Pill*, WASH. POST, Oct. 3, 1989, at Health 12; Ulmann et al., *supra* note 1, at 42.

8. FDA News Release (Sept. 28, 2000), available at <http://www.fda.gov/bbs/topics/NEWS/NEW00737.html> (last visited Mar. 1, 2002).

9. *Id.*

10. *Id.*

11. See *Mifeprex: Frequently Asked User Questions*, *supra* note 3.

12. *Id.*

13. *Id.*

14. FDA New Release, *supra* note 8; *Mifeprex: Frequently Asked User Questions*, *supra* note 3.

15. FDA Approves Mifepristone for the Termination of Early Pregnancy, WASH. POST, Sept. 28, 2000, available at <http://www.washingtonpost.com/> (last visited Nov. 15, 2000).

“bleeding can be so heavy that it requires a surgical procedure (curettage) to stop it.”¹⁶

Due primarily to these risks, the FDA and federal law require that physicians who administer the drug have the ability to assess the duration of pregnancy accurately, diagnose ectopic pregnancies, and “provide surgical intervention in cases of incomplete abortions or severe bleeding, or have made plans to provide such care through other[s].”¹⁷ Each patient must be provided with a patient agreement and medical guide,¹⁸ and the administering physician must give her the opportunity to read the materials and ask questions.¹⁹ The doctor must obtain a signed patient agreement from each patient receiving Mifeprex.²⁰

Quick Comparison with Surgical Abortions

The FDA has approved Mifepristone for “the termination of early pregnancy, defined as 49 days or less, counting from the beginning of the last menstrual period.”²¹ The combination of Mifepristone and misoprostol is ninety-six percent effective in terminating pregnancies, as opposed to the ninety-seven percent effectiveness of surgical abortions.²² Risks associated with surgical abortions vary greatly from the possible risks described above.²³ Risks typically associated with surgical abortions such as injuries to the cervix or uterus, infections, and complications from anesthesia are avoided through the use of Mifepristone.²⁴

The costs of the two procedures are expected to be very similar due to the number of times women who choose the Mifepristone option are required to visit their doctor under the FDA approval.²⁵ Additionally, the use of Mifepristone is more time-consuming; the

16. Center for Drug Evaluation and Research, *Mifepristone Medication Guide*, available at <http://www.fda.gov/cder/drug/infopage/mifepristone/medguide.htm> (last visited Aug. 8, 2002).

17. FDA Approval Letter, *supra* note 2.

18. *Mifepristone Medication Guide*, *supra* note 16.

19. *Id.*

20. *Id.*

21. FDA News Release, *supra* note 8.

22. See Ulmann et al., *supra* note 1, at 47. Because the pill's efficiency begins to drop after forty-nine days, the FDA has approved it for use only within this period and has required that doctors who prescribe the pill have experience in dating a pregnancy. *Feds Approve RU-486*, Sept. 29, 2000, available at <http://usnews.about.com/newsissues/usnews/library/weekly/aa092800a.htm> (last visited Nov. 15, 2000).

23. Leonard A. Cole, *The End of the Abortion Debate*, U. PA. L. REV. 217, 217 (1989).

24. *Id.*

25. *Id.*

procedure occurs over days rather than hours, and requires more recuperation time.²⁶

*Alternative Uses for Mifepristone (That Blur the Line)*²⁷

Mifepristone also has the potential for working as an effective postcoital contraceptive.²⁸ When the drug is taken prior to the implantation of a fertilized egg, as what has typically become known as a "morning after pill"²⁹ studies have shown that it is more effective than alternatives (approved for use in the United States) which use high doses of estrogen and progesterone to induce shedding of the uterine lining and prevent implantation.³⁰ Benefits to women who use Mifepristone in this way also include a one dose administration as opposed to several doses required by other "morning after pills."³¹ Additionally, side effects associated with hormone based alternatives, such as nausea and vomiting, are not as frequent or intense in women who took Mifepristone.³²

Although complete studies have not been performed, Mifepristone has also been shown to work as an alternative to daily birth control pills.³³ Benefits to such use might include fewer side

26. *Id.*

27. Introduced in this section are uses for Mifepristone that tend to blur the difference between contraception and abortion. Because the drug can potentially be used along a continuum, to prevent fertilization, to prevent implantation, and to cause a fertilized egg's expulsion from the lining after implantation, it questions the lines between these uses and the current legal standards employed to protect rights. See *infra* notes 62-79 and accompanying text. Additionally, current FDA regulation regarding "off-label use" of prescription drugs may allow doctors to prescribe Mifeprex for these other uses without express approval by the FDA. See *infra* notes 112-20 and accompanying text.

28. Not included in this discussion are several uses for the drug that do not have reproductive control applications. It is interesting to note, however, that Mifepristone can be used to induce labor and lactation, treat tumors such as breast cancer and meningioma, and some studies have show that it may prove a viable treatment for skin wounds and Cushing's Syndrome. See Etienne-Emile Baulieu, *Contraception and Other Clinical Applications of RU-486, an Antiprogestosterone at the Receptor*, 245 SCIENCE 1351, 1355-56 (1989) (discussing uses of RU-486 in treating cancer); Ulmann et al., *supra* note 1, at 48 (stating that RU-486 triggers lactation in monkeys); Jeremy Cherfas & Joseph Palca, *Hormone Antagonist with Broad Potential*, 245 SCIENCE 1322 (1989) (discussing research on non-abortifacient applications of RU-486).

29. Anna Glasier et al., *Mifepristone (RU 486) Compared with High-Dose Estrogen and Progesterone for Emergency Postcoital Contraception*, 327 NEW ENG. J. MED. 1041, 1041-44 (1992) (discussing how RU-486 prevents implantation of a fertilized egg).

30. *Id.*

31. *Id.*

32. *Id.* at 1042-43.

33. Cherfas & Palca, *supra* note 28, at 1322 (discussing the use of RU-486 as an alternative to hormone using birth control pills).

effects than hormone alternatives, fewer pills to remember,³⁴ and an alternative for women who cannot take estrogen or progestogen and therefore cannot tolerate birth control pills currently on the market.³⁵

The History of the Drug in the United States

A brief overview of the history of the development of Mifepristone, and of the difficulties faced by those interested in the drug's availability in the United States, offers foreshadowing of some of the possible legislation that might be enacted to curtail its availability and use. Mifepristone has been available in markets outside of the United States since the 1980s.³⁶ The drug was first synthesized by Dr. Etienn-Emile Baulieu, a French scientist, in 1980.³⁷ A few years later, Baulieu and his colleagues combined the drug with a dose of prostaglandin to increase uterine contractions and promote the expulsion of the fertilized egg.³⁸ France began trials in 1982 and RU-486 became available in October of 1988 "after the French Minister of Health declares RU486 'the moral property of women' and orders Roussel Uclaf to return RU486 to the market following the company's decision to withdraw the drug in the wake of anti-abortion pressure."³⁹ China began trials in 1983, the United Kingdom in 1991, and Sweden in 1992.⁴⁰ By 1999, Mifepristone had been approved in Switzerland, Austria, Belgium, Denmark, Spain, Finland, Greece, Germany, Israel, the Netherlands, Sweden, and the United Kingdom.⁴¹

34. Mifepristone would only be taken for three days each cycle rather than every day. *Id.* at 1332.

35. David P. Hamilton, *RU 486: More than an Abortion Pill*, *TECH. REV.*, May-June 1990, at 18.

36. See Claude J. Aguilhaume & Louise B. Tyrer, *Current Status and Future Projections on Use of RU-486*, *CONTEMP. OB/GYN*, June 1995, at 23, 24.

37. Ulmann et al., *supra* note 1, at 44.

38. *Id.*

39. *The Fight to Make Mifepristone Ru-486 Available to U.S. Women: A Chronology in Brief*, available at <http://www.feminist.org/gateway/ru486two.html> (1996) (last visited Mar. 1, 2002) (providing a timeline of events on the way to Mifeprex approval) [hereinafter *Chronology*].

40. Mifepristone: A Brief History, available at <http://www.plannedparenthood.org/library/ABORTION/Mifepristone.html> (last visited Mar. 1, 2002).

41. Sharon Lerner, *After 10 Long Years, American Women May Finally Get the Abortion Pill — With Restrictions that Could Obliterate All it Has to Offer. RU Pissed Off Yet?*, available at www.villagevoice.com/issues/0035/lerner.php (Aug. 30 — Sept. 5, 2000) (last visited Mar. 1, 2002).

Clinical trials of RU-486 actually began in the United States in 1983 at the University of Southern California.⁴² Faced with a possible backlash from American anti-abortion activists, however, the original developer of the drug, Roussel Uclaf's parent company Hoechst AG stated that it did not intend to "market or distribute RU486 outside of France."⁴³ Additionally, the drug was put on an import alert, banning importation of the drug for personal use.⁴⁴

Finally, in May of 1994, Roussel Uclaf assigned its U.S. patent rights for RU 486 to the Population Council, a not-for-profit group, that began clinical trials involving American women.⁴⁵ Work towards approval of the drug continued to encounter difficulties.⁴⁶ Pressure from anti-abortion activists continued to build, and in 1997, the Hungarian company that had originally agreed to manufacture the drug for U.S. markets backed out.⁴⁷ Subsequently, it was decided that Danco Laboratories would be formed for the purposes of marketing and distributing the drug and that actual manufacturers of the drugs would be kept secret.⁴⁸

Mifepristone was finally approved by the FDA on September 28, 2000.⁴⁹

CURRENT LEGAL STANDARDS

Background

"It is settled now ... that the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood."⁵⁰

The Supreme Court began its recognition of reproductive rights in 1965.⁵¹ In *Griswold v. Connecticut*, the Court first recognized a

42. *Chronology*, *supra* note 39.

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. Lerner, *supra* note 41.

48. *Id.*

49. *Id.* It is interesting to note that Mifeprex was approved under a section of FDA regulatory statute that is usually reserved for the approval of lifesaving drugs. A true "fast track" section, it is usually reserved for drugs that are going to be used to treat severely life-threatening illnesses. Questions, therefore, arise as to whether the approval of the drug can therefore be challenged or if it must be approved under a more appropriate section, and if it required reapproval, would the drug receive it under the new administration.

50. *Planned Parenthood v. Casey*, 505 U.S. 833, 849 (1992).

51. *Griswold v. Connecticut*, 381 U.S. 479, 479 (1965).

constitutional right to use contraceptives.⁵² In *Griswold*, the Court struck down a Connecticut statute prohibiting the use of "any drug, medicinal article or instrument for the purpose of preventing conception."⁵³ The Court recognized that, implicit in the Constitution are values whose "existence is necessary in making the express guarantees fully meaningful."⁵⁴ The Court found privacy to be one such value.⁵⁵ The Court then found that the marriage relationship was fit within a "zone of privacy,"⁵⁶ and any law that violated this right and sought "to achieve its goals by means having maximum destructive impact upon" a protected relationship must be unconstitutional.⁵⁷

In 1972, this right of privacy was extended to unmarried people in *Eisenstadt v. Bairde*.⁵⁸ In that case the Court relied upon the Equal Protection Clause of the Fourteenth Amendment when it held a Massachusetts statute unconstitutional.⁵⁹ The statute banned the distribution of contraceptives to unmarried people, but allowed married couples to obtain them through distribution by prescription.⁶⁰ The Court stated, "If the right to privacy means anything, it is the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."⁶¹

Finally, in *Carey v. Population Services*,⁶² the Court held that a state's regulation of contraception will be scrutinized under a strict scrutiny test and that any regulation "may be justified only by a 'compelling state interest' ... and ... must be narrowly drawn to express only the legitimate state interests at stake."⁶³ Thus, *Carey* created a fundamental right to use contraception that remains today.⁶⁴

52. *Id.* (holding that married persons have a right to marital privacy, including a right to use contraception).

53. *Id.* at 480.

54. *Id.* at 483.

55. *Id.* at 485.

56. *Id.* at 485.

57. *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965).

58. 405 U.S. 438 (1972).

59. *Id.* at 443.

60. *Id.*

61. *Id.* at 453.

62. 431 U.S. 678 (1977).

63. *Id.* at 688 (quoting *Roe v. Wade*, 410 U.S. 113, 155 (1973)).

64. *Id.*

Abortion Law

This initial recognition of a right of privacy involving reproduction and conception eventually led to a natural expansion of the doctrine to cover a woman's right to an abortion.⁶⁵ Under current legal standards, a woman has a constitutional right to have an abortion, a right that was first recognized in *Roe v. Wade*.⁶⁶ In 1992, the Court modified its holding in *Roe*,⁶⁷ but maintained steady in its finding of a woman's constitutional right to abortion.⁶⁸

In its 1992 decision, the Court likened a woman's right to an abortion to the right to contraceptives, but also spent a great deal of time distinguishing the two rights.⁶⁹ "It should be recognized, moreover, that in some critical respects the abortion decision is of the same character as the decision to use contraception, to which *Griswold v. Connecticut*, *Eisenstadt v. Baird*, and *Carey v. Population Services International* afford constitutional protection."⁷⁰

The Court, however, distinguished abortion from contraception stating that abortion is a unique right.⁷¹ It recognized that the state has a stronger interest in regulation of abortion than it does regarding issues of contraception.⁷²

In *Casey*, the Court abandoned the trimester test developed in *Roe*,⁷³ where the state had a varied interest in the regulation of abortion depending on the length of the pregnancy, and the first trimester of pregnancy was left beyond the control of any state interference whatsoever.⁷⁴ Instead, the Court developed a standard in *Casey* that looked to the viability of the fetus to determine the validity of state interest and the amount of state intrusion into a woman's liberty right that would be allowed.⁷⁵ Under this

65. *Roe v. Wade*, 410 U.S. 113 (1973).

66. *Id.*

67. It is interesting to note that under the Court's decision in *Roe*, the use of RU-486 could not be regulated as a procedure because the FDA has only approved it for use within the first forty-nine days or less, counting from the beginning of the last menstrual period. Under the *Roe* trimester test, where government regulation on abortion was not allowed so long as the abortion procedure took place within the first trimester, the RU-486 abortion could not be regulated. As discussed in the third section of this Note, however, regulation of the drug is a possibility even under the *Roe* trimester test. See *infra* notes 82-94 and accompanying text.

68. *Planned Parenthood v. Casey*, 505 U.S. 833, 833-34 (1992).

69. *Id.* at 849-53.

70. *Id.* at 852.

71. *Id.*

72. *Id.*

73. *Roe v. Wade*, 410 U.S. 113, 113 (1973).

74. *Id.* at 114.

75. *Casey*, 505 U.S. at 879.

standard post-viability abortions can be prohibited except "where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."⁷⁶

On the other hand, pre-viability abortions may not be prohibited outright.⁷⁷ Regulation of such abortions is allowed provided that such regulation is rationally related to the state's interests,⁷⁸ and not unduly burdensome on a woman's ability to obtain an abortion.⁷⁹ A regulation related to a state's interest is not unconstitutional if it simply has "the incidental effect of making it more difficult or more expensive to procure an abortion."⁸⁰ If a woman does not abort before viability, it is assumed that she "has consented to the State's intervention on behalf of the developing child."⁸¹

THE DRUG AND THE LAW

According to the National Abortion and Reproductive Rights Action League (NARAL), in 2000 439 bills aimed at restricting a woman's access to abortion were introduced in state legislatures.⁸² Of these 439 bills, seventy were passed in thirty-four states.⁸³ As evidenced by the pressure exerted by anti-abortion advocates in preventing the introduction of RU-486 into the United States' market, there will be legislative action to restrict access to the now-approved drug.⁸⁴

Current Statutes – Do They Cover Medical Abortion?

"Having failed to prevent the federal government from approving the abortion pill RU-486, anti-abortion advocates

76. *Id.* (quoting *Roe*, 410 U.S. at 164-65).

77. *Id.* at 878-79.

78. Generally, these interests include the protection of the health of the mother or an interest in the potential life of the fetus. *Id.*

79. *Id.* at 877-89 (stating that a state regulation is overly burdensome if it "has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus"). *Id.* at 877.

80. *Id.* at 874. Parental notification periods that contained judicial bypass clauses, waiting periods, and state encouragement to choose childbirth were all held by the Court to fulfill the necessary requirements as both rationally related to a state's interest and not unduly burdensome. *Id.* at 879-87.

81. *Id.* at 870.

82. William Claiborne, *Abortion Foes Want States to Curb RU-486*, WASH. POST, Oct. 5, 2000, at A1.

83. *Id.*

84. See *supra* notes 36-49 and accompanying text.

nationwide are now mobilizing to restrict its use through new state laws."⁸⁵ Anti-abortion activists have already indicated "they will seek to have bills introduced or existing abortion control laws amended to at least restrict distribution of the drug or impede women's access to it."⁸⁶

In some cases, existing abortion laws already cover the possibility of drug-induced termination of pregnancies. For instance, Arizona's Criminal Code §13-3604 defines the solicitation of abortion as the solicitation "from any person a medicine, drug or substance whatever,... an operation,... with the intent thereby to procure a miscarriage."⁸⁷ Delaware has another drug-inclusive statute, "'Abortion' means an act committed upon or with respect to a female, whether by another person or by the female herself, whether directly upon her body or by the administering, taking or prescription of drugs or in any other manner, with intent to cause a miscarriage of such female."⁸⁸

In other states, the language in existing statutes is so broad it might cover medical abortions without the addition of language, including specific mention of drugs. Arkansas Code § 5-61-101 states that "[i]t shall be unlawful for any person to induce another person to have an abortion or to willingly terminate the pregnancy of a woman known to be pregnant with the intent of causing fetal death unless such person shall be licensed to practice medicine in the State of Arkansas."⁸⁹

Problems arise with the possibility that laws meant to cover surgical abortions are strictly interpreted to also cover medial abortions.⁹⁰ Those staunchly opposed to the drug have suggested using statutes in some states that require a physician or pathologist to examine fetal tissue after an abortion.⁹¹ These opponents hope to dissuade women from using the drug by requiring them to collect all products of their medical "drug-induced miscarriages" and take them to their doctor for examination.⁹² Such requirements would

85. Claiborne, *supra* note 82.

86. *Id.*

87. ARIZ. REV. STAT. ANN. § 13-3604 (West 1999).

88. DEL. CODE ANN. tit. 11, § 651 (1999). Other states that have similar laws that use specific language to include drug-induced terminations include (non-exhaustive list): Alabama, Georgia, Illinois, New Mexico, North Carolina, Tennessee and the District of Columbia. ALA. CODE § 13A-13-7 (2000); GA. CODE ANN. § 16-12-140 (2000); 720 ILL. COMP. STAT. 510/2 (West 2000); N.M. STAT. ANN. §30-5-3 (Michie 1978); N.C. GEN. STAT. § 14-44 (2000); TENN. CODE ANN. § 39-15-201 (2000); D.C. CODE ANN. § 22-201 (1981).

89. ARK. CODE ANN. § 5-61-101 (Michie 1987).

90. Claiborne, *supra* note 82.

91. *Id.*

92. *Id.*

likely render the drug virtually useless, or at a minimum severely curtail its use.

Some of the other proposed statutes do not act to curtail the drug's use by such drastic means, but instead propose restrictions on its availability.⁹³ These proposed statutes would demand that physicians who prescribe the drug to meet certain standards and requirements.⁹⁴

Federal Proposal – The Coburn-Hutchinson Bill

On October 4, 2000, a week after the FDA gave its final approval for the use of Mifepristone in medical abortions, Representative Tom Coburn (R – Oklahoma) and Senator Tim Hutchinson (R – Arkansas) introduced legislation in Congress.⁹⁵ This legislation would require that doctors who prescribed and administered Mifeprex be able to perform surgical abortions, thus limiting the use of the drug to abortion clinics and thereby defeating the pro-choice lobby's goal of expanding abortion access beyond the clinical setting.⁹⁶

Drug Regulation – The States and the FDA

State restrictions on access to Mifepristone will be limited to restrictions on possible providers and other access related issues.⁹⁷ In addition to the prohibition of an outright ban on abortion resulting from the Supreme Court's ruling in *Casey*,⁹⁸ states lack the authority to override federal FDA administrative rulings.⁹⁹ An outright prohibition on sale of the drug would constitute a preemption of federal authority that has never been upheld in the food and drug arena.¹⁰⁰ When questioned, FDA officials stated that they knew of no instances in which states have successfully overruled an agency decision approving or disapproving a drug.¹⁰¹

93. *Id.*

94. *Id.*

95. David E. Rovella, *Abortion Pill Fight Shifts to the Hill*, NAT'L REV. L.J., Oct. 16, 2000, at A4.

96. *Id.*

97. *Id.*

98. 505 U.S. at 852.

99. Rovella, *supra* note 95.

100. *Id.*

101. Claiborne, *supra* note 82.

Experts have suggested, however, that there may be a way around the FDA approval.¹⁰² The FDA approved the use of Mifepristone; the follow up drug, Misoprostol, was previously approved by the FDA, but for the purpose of preventing ulcers.¹⁰³

Under current law, doctors can prescribe drugs for uses other than those listed on the labels, in other words, for uses other than those for which the drug has been specifically approved.¹⁰⁴ Because the FDA has not actually approved a drug for an "off-label" use, however, states can impose strict limitations on a drug's off-label use.¹⁰⁵ For instance, many states had an outright ban on the sale of fen-phen.¹⁰⁶ This was allowed because the combination of the therapy's components, fenfluramine and pnenolamine, was not specifically approved by the FDA.¹⁰⁷ Some argue that this sets precedent for a ban on the Mifepristone and Misoprostol combination of drugs.¹⁰⁸ The argument is shaky, however, because all of the pre-approval testing of Mifeprex was performed in conjunction with Misoprostol.¹⁰⁹ Therefore, it can be said that the approval of Mifepristone for the specific use in medical abortions implicitly implies approval of Misoprostol for use with it.¹¹⁰ Ultimately, it seems that states can do little to create an outright ban the sale of Mifeprex.¹¹¹

102. Charles Ornstein, *Abortion Foes Shift Focus to States to Limit Pill*, ARIZ. REPUBLIC, Oct. 8, 2000, at J1.

103. See Letter from Searle to Healthcare Provider (Aug. 23, 2000), available at <http://www.fda.gov> (last visited Nov. 1, 2000).

104. Off-label use is described as the prescription of a drug for a use, or in a manner not authorized by the FDA, basically, when the actual use varies from that described on the FDA approved package insert. Off-label use applies to non-FDA approved use, dose variation, and use on a population, such as children, for which the drug has not been approved. See generally Veronica Henry, *Off-Label Prescribing: Legal Implications*, 20 J. LEG. MED. 365 (1999) (discussion off-label drug use and legal implications); Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181 (1999) (describing off-label use and policy).

105. *Id.*

106. *Id.* Fen-phen was eventually taken off the market in 1997 at the FDA's urging after it was linked to heart-valve damaging users of the combination drug.

107. See Ornstein, *supra* note 102.

108. See *id.*

109. Karen Lee, *Sensitive Benefit Issues Attend RU-486 Approval*, EMPLOYEE BENEFIT NEWS, Dec. 1, 2000. Searle is a division of drug conglomerate Pharmacia Corporation that manufactures Misoprestol. The company did not initially approve of the drug's use in terminating pregnancies and has gone so far as to advise doctors not to use the drug for medical abortions. *Id.* Recently, however, Searle has retracted this warning. *Id.*

110. *Id.*

111. See Ornstein, *supra* note 102.

Contraceptive or Abortifacient – A Special Problem

In her piece, *RU 486 Examined: Impact of a New Technology on an Old Controversy*,¹¹² Gwendolyn Prothro examined the unique aspects of RU-486's available uses as a contraceptive, a "morning after pill", and an abortifacient.¹¹³

Physiologically, the RU 486 technology "blurs the distinction between contraception and abortion" because it operates before fertilization, in the "grey" period between fertilization and implantation, and after implantation. RU 486's range of effectiveness suggests that there is not a bright-line distinction between preventing pregnancy and terminating it in its early stages.¹¹⁴

Her argument is that because RU-486 cannot be classified as only a contraceptive or abortifacient, it blurs the semi-bright line drawn by the Supreme Court and stated clearly in *Casey*.¹¹⁵ This argument, that RU 486 changes the dynamic between contraception and abortion by making them "points on a continuum" is well framed by her question, "is the use of RU 486 one day after intercourse so clearly different from its use three, five, or ten days later?"¹¹⁶

Under the current legal framework, a woman who takes RU-486 as a contraceptive is covered by *Griswold*¹¹⁷ and its progeny, and is free to act without state interference.¹¹⁸ A woman who takes RU-486 in her eighth week of pregnancy will probably be subject to *Casey*,¹¹⁹ and will have to comply with any state regulations limiting her actions.¹²⁰

Because of these unique, flexible qualities, the courts will have to face certain questions that have fallen by the wayside and draw certain lines that they have avoided in the past. Courts will have to determine the standard to be applied to the post-fertilization and

112. Gwendolyn Prothro, *RU 486 Examined: Impact of a New Technology on an Old Controversy*, 30 U. MICH. J. L. REF. 715 (1997).

113. *Id.*

114. *Id.* at 732 (quoting David Savage & Karen Tumulty, *Behind the Scenes Battle Rages over "Abortion Pill,"* L.A. TIMES, May 14, 1989, at 1).

115. *Id.* at 733.

116. *Id.* (quoting Brief of Amici Curiae 274 Organizations in Support of *Roe v. Wade* on Behalf of Appellees, at 8 n.12).

117. *Griswold v. Connecticut*, 381 U.S. 479 (1965).

118. *Id.* at 485; see also *supra* notes 64-81 and accompanying text.

119. 505 U.S. 833 (1992).

120. Prothro, *supra* note 112, at 733; see also *Casey*, 505 U.S. at 849-53.

pre-implantation time periods, the current "grey" period that has, up to now, been left without specific guidelines.¹²¹ This erosion of the bright line between contraception and abortion will inevitably broaden and deepen the abortion debate. Although RU-486 certainly strengthens the argument that a unified continuum approach should be taken to abortion control, where the courts will fall on this issue is yet to be seen.¹²²

CONCLUSION

"What's significant about RU-486 is that it doesn't change the legal dynamic.... It changes the real world dynamic...."¹²³ Whether this is true remains to be seen.

With the approval of Mifeprex by the FDA, women in the U.S. gained access to a relatively safe and effective (the two very things required for FDA approval) alternative to the invasive procedure of a surgical abortion. Questions remain, however. It is possible that this drug will never live up to its potential. Will states be able to effectively render the pill useless, legislating away many of its benefits, including increased privacy and accessibility for women seeking abortions? Certainly this is a possibility; however, it does seem unlikely that states would be able completely to prevent access to the drug by banning the drug completely.

Although the states cannot effectively overrule FDA approval, they may be able to legislate distribution requirements. (Will the FDA be able to fight off attacks on its approval through "supremacy" arguments?) Legislation on a local level resembling the Coburn-Hutchinson bill could take from the drug one of its main assets: the accessibility factor. If the drug is only being distributed where surgical abortions are being performed, the increased privacy and accessibility are taken away.

Existing statutory language in many states already cover the use of drugs to induce pregnancy termination. Will other states follow? Certainly states are moving very quickly to legislate access to this drug, and there are major political forces pulling in both

121. Prothro, *supra* note 112, at 735. This could very well be problematic, as the time of implantation varies, sometimes by days, and cannot be predicted with exact precision. Additionally, in order to determine whether implantation has occurred, extremely private information would need to be ascertained.

122. *Id.* at 740.

123. Rovella, *supra* note 95 (quoting Professor Jonathan Entin, Case Western Reserve University School of Law).

directions. Although states will legislate, it remains to be seen how they will legislate and how this legislation will be received.

Any new legislation will likely lead to litigation. The mutability of RU-486 in its use across the "privacy" spectrum will bring up issues that will require the courts to revisit the lines that have been drawn and, if nothing else, define the "grey area" that currently exists between contraception and abortion.

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