

RU-486: A DRAMATIC NEW CHOICE OR FORUM FOR CONTINUED ABORTION CONTROVERSY?

MANDEE SILVERMAN*

INTRODUCTION

The legal right to choose to have an abortion in America has always been a kind of mirage. . . .

The right to choose became the right to convince a judge that you should have an abortion because you couldn't dare tell your parents. It became the right to walk through keening demonstrators, strangers begging you not to kill your baby. It became the right to be treated by a doctor who the next day could end up dead, murdered because of his work.¹

Given the present-day realities regarding the availability of abortion, women have the right to terminate their pregnancy but lack the access. According to a 1988 survey, 83% of counties in the United States have no abortion provider, and some states have only one doctor willing to perform abortions.² For example, women in certain areas of Michigan have to travel eleven hours to the nearest abortion provider, only to wait twenty-four hours before undergoing the procedure; in many rural areas of Texas, the closest provider is often 300 miles away.³

This Note explores the extent to which the approval of mifepristone (formerly known as RU-486) may increase the availability of abortion to women seeking to terminate their pregnancies. Mifepristone and medical abortion have the potential to “chang[e] abortion from a stigmatized procedure to a routine part of medical

* J.D. candidate, New York University School of Law, 2002; B.S., with Distinction, University of Virginia, 1999. I would like to thank Professor Sylvia Law of NYU for her guidance and patience throughout the development of this Note. Thank you also to the board and staff of *Annual Survey*, especially Sandra Park, for their editorial assistance. Finally, I am grateful to my parents for their love and support.

1. Anna Quindlen, *RU-486 and the Right to Choose*, NEWSWEEK, Oct. 9, 2000, at 86.

2. Sandra G. Boodman, *Should Non-Physicians Perform Abortions? Shortage of Trained Providers of the Procedure Leads to a Controversial Proposal*, WASH. POST, Feb. 15, 1994, Health, at 7 (discussing a survey done by the Alan Guttmacher Institute).

3. Rachel Zimmerman, *Wrangling over Abortion Intensifies as RU-486 Pill Nears Market*, WALL ST. J., Nov. 14, 2000, at B1 [hereinafter Zimmerman, *Wrangling over Abortion*].

care carried out by a doctor a woman knows and trusts,” and to make abortions available beyond clinics and in the privacy of physicians’ offices.⁴ According to the American College of Obstetricians and Gynecologists, “[The approval of mifepristone] is a relief for women and their physicians. It should increase the number of physicians offering abortion and enhance the privacy of the abortion decision. Both factors should help reduce the level of violence against physicians and their patients.”⁵ Yet, despite the hope that mifepristone will meet the compelling need for increased access to abortion, its approval will likely be no more than an empty promise; the drug’s potential will be circumscribed by the same attitudes, opponents, and legislation that inhibit access to surgical abortion.

Part I briefly reviews the obstacles women historically have faced in obtaining abortions, including a lack of providers and funding, harassment and violence, and restrictive legislation. Part II provides a detailed background of mifepristone, describing its arduous approval process and comparing the regimen to other methods of abortion. It highlights the advantages of mifepristone as an alternative to surgical abortion, but concludes that the drug’s potential to make abortion more accessible will be highly dependent upon physicians’ willingness to prescribe it. Finally, it considers mifepristone’s effect on the overall abortion rate and examines the current Bush Administration’s anti-abortion stance. Part III outlines the Food and Drug Administration’s stringent restrictions on distribution of mifepristone and posits that the so-called “fast-track” process under which the drug was approved may make it easier for the current Bush Administration to remove it. It then analyzes “RU-486 Patient Health and Safety Act of 2001,” a bill currently pending in Congress that would impose even further restrictions on the distribution of mifepristone and has the potential to eliminate the availability of the drug altogether. Finally, Part IV examines how mifepristone will be treated under current Supreme Court jurisprudence and state statutes restricting abortion through outright bans, so-called “TRAP” (Targeted Regulation of Abortion Providers) measures, physician-only laws, mandatory delay and informed consent regulations, and parental involvement require-

4. Hanna Rosin, *Pain, Penance and RU-486: Pill Isn’t Likely to Change the Difficult Emotional Calculus of Abortion*, WASH. POST, Oct. 14, 2000, at A4.

5. Press Release, W. Benson Harer, Jr., president, American College of Obstetricians and Gynecologists, Statement of the American College of Obstetricians and Gynecologists on the FDA Approval of Mifepristone for Use with Misoprostol in Early Abortion (Sept. 28, 2000), http://www.acog.org/from_home/publications/press_releases/nr09-28-00.htm.

ments. It concludes that mifepristone and medical abortion must be characterized separately from surgical abortion in order for the drug to increase effectively the ability of women to choose to terminate their pregnancies.

I OBSTACLES TO OBTAINING ABORTIONS

In the United States, approximately one in four pregnancies are terminated by abortion.⁶ Although the abortion rate among American women is high by the standards of developed countries,⁷ rates are declining and have reached their lowest point in twenty years.⁸ More than one-half of abortions occur within the first eight weeks of gestation, three-quarters within twelve weeks, and almost 99% within twenty weeks.⁹

The decline in abortion rate, without a concurrent drop in pregnancy rates, may be more indicative of the difficulties women face in obtaining an abortion than a decreased wish or need to terminate a pregnancy. The accessibility of abortion is limited by a lack of providers, harassment and violence, imposed regulation, prohibitive cost, and other barriers.

As of October 2000, there were an estimated 2000 abortion providers in the United States to perform nearly 1.5 million abortions annually. According to the president of the American Academy of Family Physicians, while physicians do not have a “‘statutory, constitutional or ethical’ duty to perform a procedure they are not comfortable with, the profession does have ‘an obligation, if a service is legal and needed, to help the patient access it.’”¹⁰ However, “[a]bortion has been marginalized within mainstream medicine.”¹¹

6. See ALAN GUTTMACHER INST., *SHARING RESPONSIBILITY: WOMEN, SOCIETY AND ABORTION WORLDWIDE* 54 app. tbl. 4 (1999).

7. As of 1996, the abortion rate for women of reproductive age was 23 per 1000 in the United States, 14 per 1000 in the United Kingdom, 12 per 1000 in France, and 19 per 1000 in Sweden. See *id.* at 54 app. tbl. 4.

8. In 1975, there were 22 abortions per 1000 women; in 1980, over 29 abortions per 1000 women; in 1984, over 28 abortions per 1000 women; and in 1990 over 27 per 1000 women. See *id.* at 55 app. tbl. 5.

9. HENRY J. KAISER FAMILY FOUND., PUB. NO. 3129, *ABORTION IN THE U.S.*, <http://www.kff.org/content/2001/3170/AbortionintheUS.pdf> (2001).

10. Vida Foubister, *RU-486 Approval Redraws Abortion Practice*, AM. MED. NEWS (Oct. 23/30, 2000), at 2 (quoting Richard Roberts, M.D.), available at http://www.ama-assn.org/sci-pubs/amnews/pick_00/pr121023.htm.

11. *Id.* at 2 (quoting Wendy Chavkin, M.D., M.P.H., professor of public health and obstetrics-gynecology at Columbia University).

An overwhelming majority, 91%,¹² of abortions in the United States currently take place in clinics, as private physicians and hospitals decline to provide the service.¹³

Contributing to the shortage of abortion providers, few new physicians are motivated or trained to perform abortions. Programs created to train physicians to perform abortions began to be abandoned in the 1980s.¹⁴ While a 1978 study showed that 26% of programs required residents to perform first trimester abortions as part of their training, by 1995 only 12% of programs provided routine abortion training.¹⁵

In recognition of the potential public health problem posed by lack of abortion training, the Accreditation Council for Graduate Medical Education ("ACGME") sets forth explicit requirements for the inclusion of abortion training as a standard part of obstetrics and gynecology residency education.¹⁶ A "cautiously optimistic"¹⁷ 1998 study revealed that 46% of programs report that they routinely offer first trimester abortion training and 44% routinely offer second trimester training.¹⁸ However, this abortion training is considered optional, and residents who object to the procedure are excused from participation.¹⁹ The low number of abortions that take place in hospitals, 7%, may also adversely affect the adequacy of the training.²⁰ If new physicians lack adequate training in abortion care, they will be "unable to provide a procedure that an estimated 43% of U.S. women will undergo by forty-five years of age; moreover, they [will not be] well prepared to offer women accurate medical information on all of their pregnancy options."²¹

12. Rene Almeling et al., *Abortion Training in U.S. Obstetrics and Gynecology Residency Programs*, 1998, 32 FAM. PLAN. PERSP. 268, 268 (2000).

13. *See id.* at 268–71, 320.

14. Sylvia A. Law, *Silent No More: Physicians' Legal and Ethical Obligations to Patients Seeking Abortions*, 21 N.Y.U. REV. L. & SOC. CHANGE 279, 283, 299 (1994–95).

15. Almeling, *supra* note 12, at 268.

R

16. AM. MED. ASS'N, GRADUATE MEDICAL EDUCATION DIRECTORY 2001–2002, at 171. However, the ACGME requirement is limited by the exception that "[n]o program or residency with a religious or moral objection shall be required to provide training in or to perform induced abortions." *Id.*

17. Almeling, *supra* note 12, at 320.

R

18. *Id.* at 271. The authors of the study explicitly noted the low response rate (69%) as possibly indicating a response bias. Or, even in the absence of such a bias, discrepancies may exist between respondents' and residents' perceptions of what is "routine" training. *See id.*

19. *See id.* at 270.

20. *See id.* at 268.

21. *Id.* at 320.

Well-publicized and prevalent instances of harassment and violence have scared off providers and women seeking to end their pregnancies. Twenty percent of abortion clinics experienced “severe” anti-abortion violence, and approximately 41% faced “moderate” levels of violence in 1999.²² While this is a significant decline from the 52% of clinics reporting severe violence in 1994,²³ it still means that roughly one-half of women seeking an abortion will have to endure some form of threat to their physical or emotional well-being. Additionally, although there has been a decreasing trend in abortion violence, the percentage of clinics reporting staff resignations as a result of anti-abortion violence has increased, thus further reducing the number of providers.²⁴

State laws enacted by anti-abortion legislators have also restricted access to abortion. For instance, the Supreme Court has upheld a state’s right to impose informed consent requirements designed to discourage abortion.²⁵ However, it has been argued that “[t]hese laws do not promote informed choice, but rather conscript physicians as messengers of the state’s anti-abortion stance.”²⁶ Moreover, even

[i]f the physician says nothing about abortion, silence carries the implicit message that abortion is unavailable, immoral, dangerous, unfeasible, or irrelevant to the patient’s situation. . . . The scarcity of quality abortion services in many parts of the country underscores the need for physician guidance to help the patient find the medical services that she wants and needs.²⁷

Finally, the cost of abortion services may pose an insurmountable obstacle. Beginning in 1977, the Hyde Amendment put severe restrictions on federal Medicaid funding of abortions for indigent

22. TRACY SEFL ET AL., FEMINIST MAJORITY FOUND., 1999 NATIONAL CLINIC VIOLENCE SURVEY REPORT 2, 5 (2000), *available at* <http://www.feminist.org/research/cvsurveys/1999/1999ClinicSurvey.htm>. “Severe” anti-abortion violence includes death threats, stalking, bombings, arson, blockades, chemical attacks, bomb threats and arson threats. *See id.* at 2. While clinics across the nation were plagued, the violence was concentrated in Alabama, Arizona, California, Florida, Michigan, New York, North Carolina, Pennsylvania, Texas, and Virginia. *See id.* at 4.

23. *Id.* at 5 chart 1.

24. *See id.* at 11. Of the clinics reporting resignations, 32% lost a physician, 23% lost a counselor, and 20% lost a nurse. *Id.*

25. *See* Planned Parenthood v. Casey, 505 U.S. 833, 881–85 (1992) (plurality opinion).

26. Law, *supra* note 14, at 302.

27. *Id.* at 302–03 (footnote omitted).

women.²⁸ Following an amendment in 1993, funds can be used only to preserve the woman's life or in situations of rape or incest.²⁹ Additionally, states have the option to use their own funds to pay for abortions, and a number of states have been ordered to pay by their state courts.³⁰ "Currently, 19 states pay the cost of most or all abortions for Medicaid clients, and 29 states pay according to the current federal standard"³¹ Even for those women who have health insurance through their employment, many of those policies do not cover abortion.³² In the absence of financial assistance, women incur severe hardships in obtaining abortion, and many of these women face health risks by delaying their abortions until they can raise the necessary funds.³³

II

THE LONG ROAD TO APPROVAL OF RU-486

After years of scientific review and politicized battle, on September 28, 2000, the Food and Drug Administration ("FDA") approved mifepristone, or Mifeprex (previously known as RU-486), for the termination of early pregnancy, defined as forty-nine days or less, counting from the beginning of the last menstrual period.³⁴ According to former Commissioner of Food and Drugs, Jane E. Henney, M.D., "The approval of mifepristone is the result of the FDA's careful evaluation of the scientific evidence related to the safe and effective use of the drug."³⁵ The FDA has imposed various regulations upon the distribution of the drug, while disregarding many other harsh restrictions proposed by anti-abortion proponents. The approval has been lauded as "one of the most significant advances in women's reproductive health since development of the birth control pill, making what's legally permissible actually

28. Elizabeth Nash, *Public Funding of Abortion for Poor Women: Where Things Stand*, 4 GUTTMACHER REP. ON PUB. POL'Y 13 (2001), available at <http://www.agi-usa.org/pubs/journals/gr040113.pdf>.

29. *See id.*

30. *Id.*

31. *Id.*

32. Jennifer Templeton Schirmer, Note, *Physician Assistant as Abortion Provider: Lessons from Vermont, New York, and Montana*, 49 HASTINGS L.J. 253, 275 (1997).

33. *Id.*

34. *FDA Approves Mifepristone for Termination of Early Pregnancy*, FDA CONSUMER, Nov.-Dec. 2000, http://www.fda.gov/fdac/features/2000/600_ru486.html.

35. U.S. Dep't of Health & Human Servs., *FDA Approves Mifepristone for the Termination of Early Pregnancy*, HHS NEWS, at <http://www.fda.gov/bbs/topics/news/NEW00737.html> (Sept. 28, 2000).

available.”³⁶ Danco Laboratories, the drug’s domestic distributor, estimates that by 2004 it will be used for 29% of all abortions in the United States.³⁷

A. Background

Mifepristone, first developed in 1980, is used in conjunction with misoprostol³⁸ to terminate pregnancy by effectively causing a miscarriage. Mifepristone acts to block progesterone, a hormone needed to maintain pregnancy; without progesterone, the uterus lining cannot prepare for a fertilized egg.³⁹ Misoprostol, officially approved by the FDA for the treatment of ulcers, also causes the uterine muscles to contract to expel the fetal tissue, in a so-called “off-label” use of the drug.⁴⁰ Because doctors can legally prescribe any approved drug for any purpose, separate approval of misoprostol was not required by the FDA for use in abortions.

Mifepristone was approved in France in 1988 as an early abortion method, and in the early 1990s, the United Kingdom and Sweden followed suit.⁴¹ Since that time, the drug has been approved in eighteen countries, and more than 500,000 women have used it in Europe alone.⁴² Although the prior Bush administration banned its importation for “personal use” in 1989, President Clinton acted swiftly in 1993 to lift the ban.⁴³

The drug’s long-awaited approval was based on data from clinical trials in both France and the United States. Clinical trials

36. Editorial, *New Option for Women*, L.A. TIMES, Sept. 29, 2000, at B8.

37. David Whitman & Stacey Schultz, *A Little Pill but a Big Dispute: Approval of the Abortion Drug Changes the Medicine and Politics of the Issue*, U.S. NEWS & WORLD REP., Oct. 9, 2000, at 18, 19.

38. Misoprostol is sold under the name Cytotec and is distributed by Searle, a division of the Pharmacia Corporation.

39. *FDA Approves Mifepristone for Termination of Early Pregnancy*, *supra* note 34.

40. See Rachel Zimmerman, *Clash Between Pharmacia and FDA May Hinder the Use of RU-486*, WALL ST. J., Oct. 18, 2000, at B1. Potential difficulties loom with regard to the need for misoprostol to complete termination of the pregnancy. On August 23, 2000, Searle issued a letter to health-care providers, warning that Cytotec should not be given to pregnant women because it can cause miscarriages and referring to the adverse side effects when the drug is used off-label to induce labor. At the same time, the pharmaceutical company revised the label for Cytotec stating that the drug should not be used for abortions. It is possible that this will put providers at risk of liability if they choose to administer the two-drug regimen to induce miscarriage. See *id.*

41. Foubister, *supra* note 10, at 1.

42. See Aaron Zitner, *FDA Approves Use of Abortion Pill*, L.A. TIMES, Sept. 29, 2000, at A1 [hereinafter Zitner, *FDA Approves Use of Abortion Pill*].

43. Foubister, *supra* note 10, at 1-2.

R

R

R

conducted in France involved approximately 1700 women.⁴⁴ Over 95% of these women had a complete medical abortion.⁴⁵ The remaining women received surgical intervention “for excessive bleeding, incomplete abortions, or ongoing pregnancies at the end of the protocol.”⁴⁶

Population Council, the drug’s domestic sponsor responsible for pre-marketing studies and post-marketing surveillance, conducted numerous clinical trials in the United States. One such study, conducted from September 1994 to September 1995, sought to evaluate the acceptability of the mifepristone-misoprostol combination to women and providers.⁴⁷ The drug combination was administered to over 2000 pregnant women.⁴⁸ The study defined failure as the need for surgical intervention to complete the termination.⁴⁹ The report noted that such failures were influenced by patients’ attitudes, expectations, and tolerance of side effects and by providers’ understanding and aptitude for using the method.⁵⁰ Success rates varied by duration of pregnancy: 92.1% among women with pregnancies of forty-nine days or less, 83% for pregnancies of fifty to fifty-six days, and 77.5% for pregnancies of fifty-seven to sixty-three days.⁵¹

Going beyond clinical success rates, the trial also examined the reasons medical abortion was chosen. The most frequently cited reason (37.4%) was the avoidance of surgery and the noninvasive nature of the therapy.⁵² Other reasons included: similarity to a natural miscarriage (19.4%); safety and reduced side effects (12.0%);

44. FOOD & DRUG ADMIN., MIFEPREX (MIFEPRISTONE) TABLETS LABEL, at <http://www.fda.gov/cder/foi/label/2000/20687lbl.htm> (last visited October 1, 2001) [hereinafter FDA, MIFEPREX].

45. *Id.* The success rate in France was approximately 3% higher than in the United States. *Id.* This difference is likely related to the lack of clinician experience in the United States as compared to the decade of experience in France. See Irving M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 NEW ENG. J. MED. 1241, 1241–42 (1998).

46. See FDA, MIFEPREX, *supra* note 44.

47. Beverly Winikoff et al., *Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol: Results of a Large Multicenter Trial in the United States*, 7 ARCHIVES FAM. MED. 360, 360–61 (1998).

48. *Id.* at 360. The drugs were administered in the same manner as the FDA approved treatment regimen. See *infra* Part III for discussion of the FDA regimen.

49. *Id.* at 361.

50. *Id.* For instance, women less committed to completing the regimen would be more likely to request surgical intervention than to wait while the therapy takes its course.

51. *Id.* at 361–62.

52. *Id.* at 362. Abortion using mifepristone is free from the risk of uterine perforation and complications caused by anesthesia, usually associated with surgi-

57/2000

REPRODUCTIVE RIGHTS

255

“political commitment to abortion rights” and choice for women (10.7%); and previous experiences with surgical abortion (10.2%).⁵³

All participants received counseling at the first visit and an overwhelming majority (95.6%) felt such counseling was adequate.⁵⁴ Among the women who found the counseling to be inadequate, 36% felt that the severity and duration of side effects should have been better explained.⁵⁵ As with any drug, mifepristone may cause side effects, including, most significantly, cramping and vaginal bleeding.⁵⁶ Although it is normal to experience some bleeding and spotting up to sixteen days after treatment, about 1% of women will need surgery to stop heavy bleeding.⁵⁷ Other common side effects include nausea, vomiting, headache, and diarrhea.⁵⁸ Less frequent are reports of pelvic pain, fainting, and dizziness.⁵⁹

A vast majority of the women in the study (87.6%) ranked their overall experience as very or moderately satisfactory.⁶⁰ Approximately half of the women had previously had a surgical abortion, and three-quarters of those women rated the medical abortion as more satisfactory than the surgical abortion.⁶¹ Nearly all women would recommend it to others (95.7%) or would choose the regimen again (91.8%).⁶² The features of the regimen that caused the most dissatisfaction related to feared or actual pain and cramping (22.5%); waiting, uncertainty, and fear of the unknown (13.9%); and feared or actual nausea, vomiting, and diarrhea (10.8%).⁶³

cal abortion. See Claude J. Aguiillaume & Louise B. Tyrer, *Current Status and Future Projections on the Use of RU-486*, CONTEMP. OB/GYN, June 1995, at 23, 34.

53. Winikoff, *supra* note 47, at 362.

R

54. *Id.*

55. *Id.*

56. U.S. Dep’t of Health & Human Servs., *supra* note 35. These side effects are similar to those of a spontaneous miscarriage. PLANNED PARENTHOOD, MIFEPRISTONE: EXPANDING WOMEN’S OPTIONS FOR EARLY ABORTION, at http://www.plannedparenthood.org/library/abortion/mif_fact.html (current as of Oct. 2001) [hereinafter PLANNED PARENTHOOD, MIFEPRISTONE].

R

57. U.S. Dep’t of Health & Human Servs., *supra* note 35.

R

58. FDA, MIFEPREX, *supra* note 44.

R

59. *Id.*

60. Winikoff, *supra* note 47, at 363.

R

61. *Id.*

62. *Id.*

63. *Id.* at 364.

*B. Comparison of Medical Abortion to Other Methods of Abortion Used During the First Trimester*⁶⁴

Currently, the most common first trimester method of abortion is suction curettage or vacuum aspiration.⁶⁵ This procedure can be performed in a clinic or private doctor's office up to thirteen weeks into the pregnancy.⁶⁶ Using local anesthesia, the cervix is stretched open slightly and fetal material is removed with suction in a single procedure that lasts about five to ten minutes.⁶⁷ Similar to medical abortion, common side effects include severe cramping and some bleeding.⁶⁸ Complications from this method are extremely rare, but include infection, excessive bleeding, uterine perforation, incomplete abortion, and continuing pregnancy.⁶⁹ A study conducted from January 1993 to December 1995 showed that the procedure was 99.5% effective in terminating pregnancy through twelve weeks of gestation.⁷⁰

Still, health care professionals have been providing medical abortions for years, through a combination of the drugs methotrexate and misoprostol to terminate a pregnancy within the first fifty-

64. It should be noted that medical abortion is not the same as emergency contraceptive treatment (i.e., the so-called "morning-after pill"). The morning-after pill, essentially a high-dose birth control pill, can prevent fertilization of the egg or prevent the fertilized egg from attaching to the uterus when taken within seventy-two hours of unprotected sex. NAT'L ABORTION RIGHTS ACTION LEAGUE, MIFEPRISTONE, METHOTREXATE AND EMERGENCY CONTRACEPTION, <http://www.naral.org/mediaresources/fact/mifepristone.html> (Jan. 4, 2001). Since pregnancy is defined as the implantation of the fertilized egg in the uterus, the woman who successfully takes the morning after pill never becomes pregnant. Medical abortion, on the other hand, terminates a pregnancy by inducing a miscarriage.

65. Karen E. Walther, Comment, *Partial Birth Abortion: Should Moral Judgment Prevail over Medical Judgment?*, 31 LOY. U. CHI. L.J. 693, 697 (2000).

66. *Id.* Thus, vacuum aspiration is available to women seeking to terminate their pregnancies for an additional six weeks over the "window" of availability for medical abortion.

67. NAT'L ABORTION FED'N, MAKING YOUR CHOICE: A WOMAN'S GUIDE TO MEDICAL ABORTION (2001), available at http://www.earlyoptions.org/patient_brochure.html (last visited Feb. 19, 2001).

68. *Id.*

69. *Id.* See also *Stenberg v. Carhart*, 530 U.S. 914, 923 (2000) (plurality opinion) ("Vacuum aspiration is considered particularly safe. The procedure's mortality rates for first trimester abortions are, for example, 5 to 10 times lower than those associated with carrying the fetus to term.").

70. John M. Westfall et al., *Manual Vacuum Aspiration for First-Trimester Abortion*, 7 ARCHIVES FAM. MED. 559, 560 (1998). While no blood transfusions, hospitalizations or deaths were reported, there was one case of uterine perforation. *Id.*

six days.⁷¹ Methotrexate, on the market for more than forty years, has long been used to treat tubal pregnancies and certain gynecologic cancers.⁷² Thus, as with misoprostol, its use in medical abortions is “off-label.” The methotrexate-misoprostol combination takes longer than the mifepristone-misoprostol regimen: women take a dose of methotrexate and three to seven days later insert a dose of misoprostol vaginally.⁷³ While many times the abortion will occur within twenty-four hours of the second dose, there have been cases in which it took four to five weeks for complete termination.⁷⁴

C. *Advantages of Mifepristone-Misoprostol Induced Abortion*

The American College of Obstetricians and Gynecologists (“ACOG”) supports the use of mifepristone in combination with misoprostol for induction of labor and medical abortion as providing an “effective and safe alternative to surgical abortion.”⁷⁵ “American women . . . have a new option for abortion very early in pregnancy, when it is safest. They finally have access to a drug that has been used safely for many years by other women throughout the world. No longer are American women limited to surgical abortions.”⁷⁶ Medical abortion avoids the invasive nature of surgery and the inherent risks of anesthesia. Additionally, as compared to surgical abortion, the drug regimen increases control, particularly if the woman is allowed to take the pill in her own home. According to one woman who underwent the regimen, “I felt like I was carrying it out myself. It probably was more uncomfortable [than a surgical abortion] but then someone else is doing that to me, and I didn’t want that.”⁷⁷

Mifepristone has “great promise” to provide increased privacy for this very intimate treatment.⁷⁸ “Most significantly, [the drug

71. Susan Okie, *RU-486 Joining Methotrexate in Reshaping Abortion*, WASH. POST, Oct. 13, 2000, at A3.

72. *Id.*

73. *Id.*

74. *Id.*

75. Press Release, American College of Obstetricians and Gynecologists, ACOG Supports Use of Misoprostol for Medical Abortion and Labor Induction (quoting AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, MIFEPRISTONE FOR MEDICAL PREGNANCY TERMINATION (2001)) (Nov. 30, 2000), http://www.acog.org/from_home/publications/press_releases/nr11-30-00-3.htm.

76. Harer, *supra* note 5.

77. Marc Kaufman, *For One Woman, Drug was the Right Choice: Sense of Control, Not Having to Wait Cited as Benefits*, WASH. POST, Sept. 29, 2000, at A18.

78. See Press Release, American Civil Liberties Union, *ACLU Hails FDA Approval of Safe, Early-Option Abortion Pill* (Sept. 28, 2000) (quoting Catherine Weiss,

combination] should give women who live far from an abortion provider better access to a safe, private, and early option for ending unwanted pregnancies.”⁷⁹ One of the promised benefits of the drug is that it can be administered in the privacy of a private physician’s office. If that goal is realized,⁸⁰ women will be able to obtain an abortion without crossing picket lines at abortion clinics; physicians will be able to prescribe it shielded from threats and the violence that has claimed lives. According to the chair of the American Academy of Family Physicians:

The biggest barrier [to performing abortions] is no one wants to be known as an abortionist and actually nobody wants to go around advertising that they had an abortion. So if you can do something that’s really private, between the physician and the patient, that’s a big win for patients who need this service.⁸¹

D. Accessibility

Ultimately, mifepristone’s potential to make abortion more accessible to women looking to end an early pregnancy is highly dependent upon whether physicians will be willing to prescribe it. A survey conducted from January 2000 to April 2000 of over 750 women’s health care providers yielded optimistic results of views, experiences, and expectations with regard to medical abortion.⁸² Two in five gynecologists interviewed said they were “very” or “somewhat” likely to prescribe mifepristone upon FDA approval.⁸³ As could be expected, those most willing to administer the drug are those gynecologists (26% of those interviewed) who report having routinely or occasionally performed elective abortions in the last five years.⁸⁴ Among family practitioners, only 9% stated they were “very” likely to prescribe the drug upon approval, and 22% stated

director of the American Civil Liberties Union’s Reproductive Freedom Project), <http://www.aclu.org/news/2000/n092800.html>.

79. *Id.*

80. See *infra* Part III.D for discussion of accessibility in doctor’s offices.

81. Foubister, *supra* note 10, at 2 (quoting Bruce Bagley, M.D.). However, some women may prefer the anonymity of a clinic and may not want their personal physician to know that they had an abortion. See Gina Kolata, *Wary Doctors Spurn New Abortion Pill*, N.Y. TIMES, Nov. 14, 2000, at F1 [hereinafter Kolata, *Wary Doctors*].

82. VIEWS OF WOMEN’S HEALTH CARE PROVIDERS ON ABORTION: AN UPDATE ON MIFEPRISTONE, AND WHAT HAPPENS AFTER FDA APPROVAL, A NATIONAL SURVEY (The Henry J. Kaiser Family Found., Menlo Park, Cal.), June 2000 [hereinafter KAISER FAMILY SURVEY].

83. *Id.* at 2.

84. *Id.*

they were “somewhat” likely.⁸⁵ However, in the early months of the drug’s availability, private physicians tended to avoid it. According to a Danco spokesperson, the majority of the early orders for the drug came from Planned Parenthood and independent abortion clinics.⁸⁶

Aware that many doctors are conflicted about providing the pill, in November 2000, anti-abortion activists mailed every private physician in the United States a pamphlet vividly describing its possible side effects.⁸⁷ Only time will tell whether physicians who are uncomfortable performing a surgical abortion as a threshold issue will be comfortable prescribing a pill that may force them to perform the same procedure in case of failure.⁸⁸ But, the pill may allow medical professionals who stopped performing surgical abortions because of fears of threats and violence to again provide the service to their patients.⁸⁹

Still, a provider’s decision to administer the mifepristone-misoprostol regimen might be influenced by a number of different procedural and administrative aspects of the treatment. An exploratory study conducted in fall 1996 by Carole Joffe, a sociology professor at the University of California at Davis (the “Joffe exploratory study”), revealed that experienced providers of surgical abortion (twenty of twenty-five surveyed), while motivated to provide medical abortion by a “principled commitment to make all possible options available to their patients,” found the regimen to be “cumbersome and challenging.”⁹⁰

85. *Id.*

86. Kolata, *Wary Doctors*, *supra* note 81, at F1. Danco Laboratories began shipping Mifeprex to medical providers in late November 2000, at a price of \$270 for the drug. Zimmerman, *Wrangling Over Abortion*, *supra* note 3, at B1. That cost excludes the price of misoprostol, the doctor’s charge, counseling, and other fees.

87. Raja Mishra, *Doctors Avoiding RU-486*, BOSTON GLOBE, Dec. 5, 2000, at A1.

88. The majority of those providers involved in the Kaiser Family Survey who stated they were unlikely to prescribe the drug were those who personally oppose performing any kind of elective medical abortion. Many fewer providers stated that their lack of willingness to prescribe the drug was due to safety or efficacy concerns or fear of violence. KAISER FAMILY SURVEY, *supra* note 82, at 4; *see generally* Kolata, *supra* note 81, at F1.

89. However, physicians may have difficulty maintaining anonymity based on state laws and efforts of anti-abortion activists. As of November 2000, anti-abortion activists had set up an Internet site entitled “RU-486 Registry” to list doctors who prescribe mifepristone. Zimmerman, *Wrangling Over Abortion*, *supra* note 3, at B1. To deal with potential threats, some physicians have set up systems to screen patients before setting up appointments to administer the drug. Kolata, *Wary Doctors*, *supra* note 81, at F1.

90. Carole Joffe, *Reactions to Medical Abortion Among Providers of Surgical Abortion: An Early Snapshot*, 31 FAM. PLAN. PERSP. 35, 35-36 (1999).

R

R

R

R

R

R

One such obstacle to administering the drug regimen in private doctors' offices is the time it takes to counsel the patient and administer the drug.⁹¹ Several doctors noted that "the quality and quantity of counseling" for medical abortion is different from, and possibly greater than that for surgical abortion, particularly because many patients are misinformed about the procedure.⁹² This is particularly burdensome in the states that require that the physician counsel the patient personally.⁹³

The need for an ultrasound to "adequately size the very early pregnancies involved and to ascertain that the abortion has been completed" may also significantly impact who provides medical abortions.⁹⁴ Very few family practitioners own an ultrasound machine.⁹⁵ Additionally, physicians in rural areas most in need of abortion options are less likely to have ultrasound equipment or the expertise to use it.⁹⁶ Thus, a requirement for ultrasonography may effectively limit accessibility to urban or suburban gynecologists and clinics.

However, medical abortion is arguably more amenable to family practice than to the surgical model (i.e., "managing a case" as opposed to "completing a procedure").⁹⁷ A family practitioner who has been a longtime surgical abortion provider observed that medical abortion "feels more natural for a family doctor, giving medication and helping somebody through the side effects."⁹⁸ Regardless of his or her specialty, whether a provider will feel comfortable requesting backup surgical services from a colleague, asking that colleague to do ultrasounds, or sending a patient to the local hospital in an emergency situation "will depend heavily on the individual's sense of the larger climate surrounding abortion in that particular community."⁹⁹

Despite the lack of availability in doctors' offices, medical abortion is broadly obtainable at clinics. Soon after the FDA's approval, Planned Parenthood began offering American women the early

91. *Id.* at 36. "The cardinal rule of abortion counseling is that a woman should not get an abortion unless it is her freely made and informed choice." *Id.*

92. *Id.*

93. *See infra* Part IV.B.

94. Joffe, *supra* note 90, at 37. Most participants in the Joffe exploratory study "emphatically felt it unthinkable to do medical abortions without ultrasound." *Id.*

95. *See id.*

96. Kolata, *Wary Doctors*, *supra* note 81, at F1.

97. Joffe, *supra* note 90, at 37.

98. *Id.*

99. *Id.* at 38.

R

R

R

medical abortion option.¹⁰⁰ Planned Parenthood offers the option nationally, including at its New York City clinics (since December 4, 2000),¹⁰¹ its Massachusetts clinics (since January 2001), its Denver clinics (since March 2001),¹⁰² and its Metropolitan Washington clinics (despite a congressional prohibition on paying for abortions with public funds).¹⁰³ Other clinics where the drug is available include Women's Health Specialists and the Pregnancy Consultation Center sites in northern California.¹⁰⁴

For many women, regardless of whether the medical abortion is provided by a private physician or in a clinic, the cost may present an insurmountable barrier in the absence of financial assistance. The complete medical abortion, including sonograms, counseling, the two drugs and backup surgery if necessary, can cost up to \$450 in a clinic and \$700 in a private doctor's office, making the regimen no cheaper and possibly more expensive than surgical abortion.¹⁰⁵

Fortunately, while no state requires health insurers and HMOs to cover surgical abortions, most major health insurers have indicated that they will cover medical abortions. Aetna Inc. and Cigna Corporation cover the drug as a standard benefit, but, as with surgi-

100. Press Release, Planned Parenthood, Planned Parenthood Health Centers to Begin Offering Early Medical Abortion Using Mifepristone (RU-486) (Nov. 16, 2000), *available at* <http://www.plannedparenthood.org/about/pressreleases/111600mife.html>. Planned Parenthood accounts for 20% of abortions nationally. Denise Gellene, *RU-486 Abortion Pill Hasn't Caught on in U.S.*, L.A. TIMES, May 31, 2001, at A1.

101. Press Release, Planned Parenthood, Planned Parenthood of NYC Health Centers Begin Offering New Early Option Abortion Pill (Dec. 4, 2000), *available at* <http://www.ppnyc.org/new/releases/earlyoptionoffer.html>. From December 2000 to May 2001, Planned Parenthood of New York City completed over 650 abortions with Mifeprex. Rachel Zimmerman, *Ads for Controversial Abortion Pill Set to Appear in National Magazines*, WALL ST. J., May 23, 2001, at B1. From January through April of 2001, about 12% of abortions at Planned Parenthood of New York City used mifepristone. By contrast, at Planned Parenthood of Los Angeles, the percentage of women choosing Mifepristone was under 1%. Gellene, *supra* note 100, at A18. This difference may be attributable to the "highly visible advertising campaign" for the drug in New York City as opposed to the absence of promotion elsewhere in the United States. *Id.*

102. Allison Sherry, *Clinic Prescribing Abortion Pill: Controversial RU-486 Available Locally*, DENVER POST, Mar. 15, 2001, at B01, *available at* 2001 WL 6746578.

103. Avram Goldstein, *D.C. Health Programs Won't Offer RU-486: Congressional Ban on Public Funding of Abortions Restricts Services, Officials Say*, WASH. POST, Dec. 16, 2000, at B3.

104. Kevin Fagan, *Abortion Pill Available in North State: Four Clinics First to Tell Their Policy to the Public*, S.F. CHRON., Dec. 14, 2000, at A25.

105. Rachel Zimmerman, *Insurers Are Likely to Cover Abortion Pill – Obstacles Such as Training and Laws Mean Impact Won't Be Immediate*, WALL ST. J., Oct. 2, 2000, at A2.

cal abortion, Aetna will allow employers to choose to exclude it from coverage.¹⁰⁶ Kaiser Permanente of California and Empire Blue Cross & Blue Shield of New York cover mifepristone as they do any FDA-approved drug.¹⁰⁷ United Health Group of Minneapolis has indicated that it will cover mifepristone as an office procedure and not a pharmacy matter, and, like Aetna, will allow employers to exclude its coverage.¹⁰⁸ However, the intricacies of insurance practices may serve as an obstacle to accessibility, particularly given the cost of the procedure.¹⁰⁹ Importantly, access will likely be unavailable to poor patients covered by Medicaid, as under current federal law use of federal funds to pay for abortions, except in the case of rape or incest, is prohibited.¹¹⁰

E. Predicted Effect on Abortion Rate

It is hoped that the drug regimen will serve as an incentive for women who are choosing to terminate a pregnancy to do so at an earlier stage, when there are considerably fewer risks and complications.¹¹¹ Opinion polls consistently show that Americans find abortions performed in the first few weeks of pregnancy less troubling than those performed in the second and third trimesters.¹¹² Unlike later-term abortions, medical abortions are similar to the natural, spontaneous abortions that often occur in early pregnancy.

In France, the drug accounts for 70% of early-term abortions.¹¹³ While more women in France are having earlier abortions since the approval of the drug more than ten years ago, it has not

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

110. Nash, *supra* note 28. In March 2001, the Department of Health and Human Services notified state directors of Medicaid that the government will apply the same restrictions that have been imposed on federal coverage of surgical abortions following the passage of the Hyde Amendment in 1976. See Amy Goldstein, *Medicaid Coverage of RU-486 Limited: Restrictions Affect Low-Income Women*, WASH. POST, Mar. 31, 2001, at A9.

111. Prior to the approval of mifepristone, 88% of abortions took place within the first trimester. Since one-half of those take place during weeks eight through twelve, the drug has the potential to shift abortion even earlier. David J. Garrow, *Now, Another Pill Promises a Revolution*, N.Y. TIMES, Oct. 1, 2000, § 4 (Week in Review), at 3. A woman's risk of dying from abortion-related complications (0.4 deaths per 100,000 procedures performed before eight weeks gestation) is significantly lower than her risk of dying from pregnancy or childbirth (seven deaths per 100,000 live births). ALAN GUTTMACHER INST., *supra* note 6, at 33.

112. Whitman & Schultz, *supra* note 37, at 22.

113. Zitner, *FDA Approves Use of Abortion Pill*, *supra* note 42, at A1.

R

R

R

R

increased the total number of abortions.¹¹⁴ The same is true in the United Kingdom and Sweden.¹¹⁵ However, some experts predict that there may be a modest increase in the overall abortion rate in the United States.¹¹⁶ This is not surprising given the difficulties in gaining access to surgical abortion in this country and the differences in the perception of abortion here as compared to in Europe. For instance, the absence of threats and picketers so prevalent in this country allows European women easier access to clinics to obtain abortions.¹¹⁷ But here, medical abortion has the potential of changing the landscape: altering perceptions about abortion, increasing the number of providers, and allowing women to avoid clinics. The factors cumulatively may impact the abortion rate in the United States as the drug offers women who would otherwise not have had access to a provider the opportunity to have an abortion.¹¹⁸

This hypothesis assumes that those ardent, vocal and sometimes violent opponents of surgical abortion will not be every bit as ardent, vocal and violent in their crusade to stop women from having a medical abortion. A number of abortion opponents, however, have already spoken out against the approval of mifepristone. For example, Representative J.C. Watts Jr., chairman of the House Republican Conference, stated, “Do-it-yourself abortion has no place in a civilized society.”¹¹⁹ Interviews show that the American public may agree, with some declaring: “[n]o person or group who claims to care about women would subject women to [mifepristone], a drug that has only one purpose—to kill an unborn child;”¹²⁰ “[t]aking a pill seems too easy, as if getting an abortion is no different than treating a headache;”¹²¹ and “[i]f you’re going to make it so that people can make a snap decision, then . . . a lot of women

114. *Id.*

115. Aaron Zitner, *Abortion Pill's Effect in U.S. Hard to Predict*, L.A. TIMES, Sept. 30, 2000, at A1.

116. *Id.*

117. *Id.*

118. *Id.*

119. Robin Toner, *Joy and Outrage: Ruling Raises Stakes in Election and Points Up Partisan Divide*, N.Y. TIMES, Sept. 29, 2000, at A1.

120. Rachel Zimmerman & Sarah Lueck, *FDA Approves the RU-486 Abortion Pill: Decision Puts Few Curbs upon Access, Expected to Begin Within Month*, WALL ST. J., Sept. 29, 2000, at A3.

121. Dirk Johnson, *Pill Seen as Offering Privacy to Women*, N.Y. TIMES, Sept. 30, 2000, at A10.

are going to make choices that they're going to regret for the rest of their lives."¹²²

Even more influential in determining the impact of the mifepristone-misoprostol regimen is the current Administration, which has been described as "deeply, and cleverly, hostile to abortion."¹²³ At the October 3, 2000 presidential debate, George W. Bush said, "I was disappointed in the [approval of Mifeprex] because I think abortions ought to be more rare in America. And I'm worried that that pill . . . will cause more people to have abortions."¹²⁴ One of his first acts upon taking office was to ban the use of U.S. funds to aid international family planning clinics that provide abortion services.¹²⁵ High-ranking members of the current Bush Administration are also very outspoken against abortion. While serving as governor of Missouri, Attorney General John Ashcroft championed legislation "mandating that life begins at conception, and eliminating abortion services at public hospitals."¹²⁶ Also labeled "one of the most fanatically antiabortion senators in history," Ashcroft will play a key role in judicial appointments and, concomitantly, may have enormous impact on abortion provision.¹²⁷ Secretary of Health and Human Services Tommy Thompson has said that he will conduct a new review of the safety of mifepristone, although he has not yet done so.¹²⁸

This political climate has set the stage for the "Unborn Victims of Violence Act," passed by the House of Representatives in April 2001 and currently pending in the Senate, which would make it a separate federal crime to injure or kill the fetus of a pregnant woman.¹²⁹ Although South Carolina Representative Lindsay O. Gra-

122. *Id.*

123. Carole Joffe, *Bush's Antichoice Assault*, THE NATION, May 28, 2001, at 5.

124. Robert Pear, *Thompson Says He Will Order a New Review of Abortion Drug*, N.Y. TIMES, Jan. 20, 2001, at A17.

125. *Bush Fires Quickly on Abortion*, L.A. TIMES, Jan. 23, 2001, at B8.

126. Press Release, Janet Benshoof, Center for Reproductive Law and Policy, Ashcroft's Passion, (Jan. 19, 2001), at http://www.crlp.org/pr_01_0119ash.html.

127. Joffe, *supra* note 123, at 5. Although he repeatedly asserted at his confirmation hearings that he accepts *Roe v. Wade* as "settled law," it is unlikely Ashcroft will actively combat anti-abortion terrorism as his predecessor Janet Reno did. *Id.*

128. Pear, *supra* note 124, at A17. According to Thompson, "I do not intend to roll back anything unless it is proven to be unsafe." *Id.* Yet, as governor of Wisconsin, Thompson signed and "actively championed" the state's "partial-birth abortion" ban, which was the "harshest in the nation, imposing a possible penalty of life imprisonment against doctors deemed to violate its prohibitions." Press Release, Ctr. for Reprod. Law and Policy, Tommy Thompson Cannot be Trusted with Women's Health, at http://crlp.org/pr_01_0119thom.html (Jan. 19, 2001).

129. Unborn Victims of Violence Act of 2001, H.R. 503, 107th Cong. (2001).

R

R

ham, the bill's sponsor, asserts that it is aimed at fetal protection, the pro-choice community views it as a first step to secure "personhood" status for the fetus, regardless of stage of development.¹³⁰ By providing the fetus with the same legal protections as the woman, the bill renders it impossible for a woman to obtain an abortion without violating the fetus's rights.

III REGULATION

As approved by the FDA for medical termination of intrauterine pregnancy up to forty-nine days from the woman's last menstrual period,¹³¹ the mifepristone-misoprostol treatment regimen involves at least two visits to a doctor's office, clinic or hospital.¹³² Recognizing the need to make women fully aware of the consequences of taking the drug, the FDA requires that during the first visit, the woman receive counseling and a Medication Guide that clearly explains how to take the drug, who should avoid taking it, and what side effects can occur.¹³³ The woman then takes 600 milligrams of mifepristone orally in the doctor's office or clinic.¹³⁴ Two days later she goes back and, if she is still pregnant, ingests 400 micrograms of misoprostol.¹³⁵ The woman returns approximately fourteen days after first taking the mifepristone to determine whether the pregnancy has been terminated.¹³⁶ In the rare instances in which the pregnancy is not terminated,¹³⁷ surgical abortion may be necessary.¹³⁸

130. Juliet Eilperin, *House GOP Pushes New Abortion Limits*, WASH. POST, Mar. 16, 2001, at A1 (quoting New York Representative Jerrold Nadler's argument that "[t]he real purpose is to establish a doctrine, contrary to the Supreme Court decision in *Roe v. Wade*, that the fetus is a separate person This is driven by the politics of abortion rather than the substantive effort to fight violence against women.").

131. In the United Kingdom and Sweden, the regimen is used for medical abortion up to sixty-three days from the first day of the last menstrual period. Planned Parenthood, *Mifepristone*, *supra* note 56.

132. U.S. Dep't of Health & Human Servs., *supra* note 35.

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.*

137. See *supra* Part III.A for discussion of failure rates.

138. See *supra* Part III.A for discussion of need for surgical abortion.

A. FDA Regulation

The FDA has broad authority to require restrictions on distribution to ensure safe and effective use of drugs. Such restrictions are very rare as the FDA generally approves or rejects medical products and does not regulate how physicians use them.¹³⁹ In this case, the agency approved mifepristone under a set of rules that are used for licensing so-called “fast-track” drugs under the FDA Modernization Act of 1997 (“Modernization Act”).¹⁴⁰ Fast-track programs are designed to aid the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that promise significant treatment advances.¹⁴¹ A condition is serious when it is “associated with morbidity that has a substantial impact on day-to-day functioning.”¹⁴² The FDA has determined that the termination of an unwanted pregnancy is a serious condition within the scope of this subsection.¹⁴³

Under the Modernization Act, the FDA may designate a drug for fast-track review only if the drug demonstrates the potential to address unmet medical needs. Where there are existing therapies for the condition, it is sufficient to show that the drug improves

139. Diana Zuckerman, *What the FDA Should Learn from the RU-486 Marathon*, WASH. POST, Oct. 22, 2000, at B2.

140. 21 U.S.C. § 356 (West 1999).

141. U.S. DEP’T OF HEALTH & HUMAN SERV. ET AL., GUIDANCE FOR INDUSTRY: FAST TRACK DRUG DEVELOPMENT PROGRAMS—DESIGNATION, DEVELOPMENT, AND APPLICATION REVIEW 1 (1998), available at <http://www.fda.gov/cder/guidance/index.htm> [hereinafter GUIDANCE FOR INDUSTRY]. Historically, the FDA has limited accelerated approval to drugs for AIDS, mycobacterial infections, and cystic fibrosis treatments. Vivian I. Orlando, Note, *The FDA’s Accelerated Approval Process: Does the Pharmaceutical Industry Have Adequate Incentives for Self-Regulation?* 25 AM. J.L. & MED. 543, 555 (1999).

142. GUIDANCE FOR INDUSTRY, *supra* note 141, at 4.

143. Memorandum from the Center for Drug Evaluation and Research, to NDA 20-678 MIFEPREX (mifepristone) Population Council 6 (Sept. 28, 2000) (on file with the New York University Annual Survey of American Law) [hereinafter CDER Memo]. The FDA offered little explanation for its classification of pregnancy as a “serious condition.” While the agency may have been considering the relatively high mortality rates of carrying the fetus to term as compared to aborting in the first trimester, see *Stenberg v. Carhart*, 530 U.S. 914, 923 (2000) (plurality opinion); ALAN GUTTMACHER INST., *supra* note 6, it appears possible that the classification was motivated more by political reasons than health concerns. As discussed *infra*, fast-track status allows the Department of Health and Human Services to remove the drug from the market quickly. 21 U.S.C. § 356(b)(3) (West 2000). However, a spokesperson for the FDA said the agency used the fast-track protocol “in order to have more ‘control over how [mifepristone] is prescribed,’ not to make recall easier.” FDA: RU-486, Blood Filtering, Claritin, Tobacco, AM. HEALTH LINE, Jan. 29, 2001, available at LEXIS, Med. and Health Care Materials Library.

R

R

efficacy, has fewer side effects, treats previously untreated aspects of the condition, or provides a more convenient method of treatment.¹⁴⁴ With regards to mifepristone, the FDA has stated that the avoidance of invasive surgery is a “meaningful therapeutic benefit” of medical abortion over existing abortion procedures.¹⁴⁵

Given the presence of a “serious condition” and “meaningful therapeutic benefit,” mifepristone was approved under the accelerated process, which provides the FDA with significant control over the distribution of the drug:

If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:

Distribution restricted to certain facilities or physicians with special training or experience; or

Distribution conditioned on the performance of specified medical procedures.

The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.¹⁴⁶

Pursuant to its authority under 21 C.F.R. § 314.520, the FDA has required that the drug be given only to physicians who can accurately determine the gestation age of the fetus and who can detect an ectopic pregnancy.¹⁴⁷ This limits the number of physicians who can administer the drug to those who are very familiar with managing early pregnancies. Additionally, the drug is not available in pharmacies and is not legally available over the Internet.¹⁴⁸ Recognizing the potential and very serious threat of incomplete abortion or severe bleeding, the FDA requires the physicians who

144. GUIDANCE FOR INDUSTRY, *supra* note 141, at 6–7.

145. CDER Memo, *supra* note 143, at 6.

146. 21 C.F.R. § 314.520 (2001).

147. *FDA Approves Mifepristone for Termination of Early Pregnancy*, *supra* note 34. The drug’s labeling warns that it should not be used for women with confirmed or suspected ectopic (i.e., tubal) pregnancies among other conditions, including chronic failure of the adrenal glands, current long-term therapy with certain steroids, or bleeding disorders. *Id.*

148. CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., MIFEPRISTONE QUESTIONS AND ANSWERS, at <http://www.fda.gov/cder/drug/infopage/mifepristone/mifepristone-qa.htm> (Sept. 28, 2000) [hereinafter CDER, MIFEPRISTONE Q&A]. The drug will be supplied only to licensed physicians who sign and return a Prescriber’s Agreement to Danco Laboratories, the drug’s distributor. Moreover, distribution will be subject to specific requirements imposed by Danco, including procedures for storage, dosage tracking, and damaged product returns. FDA, MIFEPREX, *supra* note 44.

R

R

R

R

prescribe the drug to be able to perform surgery.¹⁴⁹ Alternatively, and particularly important in the case of a family practitioner administering the drug, they must have made plans in advance to provide this care through others.¹⁵⁰

The FDA only requires that administration be “under the supervision of a qualified physician.”¹⁵¹ Although the approval letter seems to indicate that the physician must fully explain the procedure to the patient, according to the Center for Drug Evaluation and Research, states may allow a supervised health care provider, such as a certified nurse practitioner or a nurse midwife, to dispense the drug.¹⁵²

Additionally, the FDA has required that the physician notify Population Council, the sponsor of the drug responsible for postmarketing studies, of any failure to terminate the pregnancy at the conclusion of the treatment procedure and of any hospitalization, transfusion, or other serious events.¹⁵³ Also, the physician must record the Mifeprex package serial number in each patient’s record.¹⁵⁴

Beyond these restrictions, the FDA has broad authority to suspend approval of the drug. Because fast-track drugs are allowed on the market after supposedly less testing than other medications, these rules also give the FDA authority promptly to remove a drug from the market if problems arise.¹⁵⁵ Under the Modernization

149. *FDA Approves Mifepristone for Termination of Early Pregnancy*, *supra* note 34.

150. *Id.* Note that there is no requirement that the physician have admitting privileges in a hospital.

151. FDA, MIFEPREX, *supra* note 44.

152. CDER, MIFEPRISTONE Q&A, *supra* note 148. Note also that while state law may set restrictions on minors obtaining surgical or medical abortions, the FDA itself has not set any such age restrictions. *Id.*

153. Letter from the Ctr. For Drug Evaluation & Research, Food & Drug Admin., to Sandra P. Arnold, Population Council (Sept. 28, 2000) (announcing approval of Mifeprex drug), at <http://www.fda.gov/cder/foi/applletter/2000/20687appltr.htm> (last visited Oct. 1, 2001).

154. *Id.*

155. Susan Okie, *Pulling Abortion Pill Would Not be Difficult; FDA Rules on ‘Fast-Track’ Drugs Could Allow Bush Administration Quick Removal*, WASH. POST, Jan. 28, 2001, at A5. As a recent example, the FDA removed the adult-diabetes drug Rezulin on March 21, 2000, based on pre-marketing clinical data and postmarketing safety data, which indicated that “patients have safer alternatives” and that continued use of Rezulin “poses an unacceptable safety risk to patients.” *After Rezulin*, DIABETES FORECAST (Am. Diabetes Assoc., Alexandria, Va.), May 2000, at 20, at <http://www.diabetes.org/main/community/forecast/page20.jsp> (last visited Oct. 7, 2001). However, while Rezulin was approved under fast-track protocol in March 1997, the FDA did not act “promptly” in withdrawing the drug from the market. In fact, the drug was linked to eighty-nine confirmed reports of liver failure, in-

R

R

R

Act, the Secretary of Health and Human Services may withdraw approval of a fast-track product using “expedited procedures” if:

- (A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;
- (B) a post-approval study of the fast track product fails to verify clinical benefit of the product;
- (C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or
- (D) the sponsor disseminates false or misleading promotional materials with respect to the product.¹⁵⁶

Under general rules for withdrawal of approval, if the Secretary finds that there is “an imminent hazard to the public health,” he may suspend the approval of the application with respect to any drug, subject to an expedited hearing.¹⁵⁷

Thus, the fast-track process could make it easier for the current Bush Administration to remove the drug. A new FDA commissioner could reinterpret the existing data to find that the pill is unsafe or ineffective. The drug could also be pulled from the market if the restrictions on distribution are not followed. Although presumably the new administration cannot suspend approval “simply because of [its] antipathy toward abortion,” Secretary of Health and Human Services Tommy Thompson could declare the drug an “imminent health hazard” since it ends the life of an unborn child.¹⁵⁸ While such action would remove the drug from the market immedi-

cluding sixty-one deaths, and was pulled off the market in Britain in late 1997. *See id.* The Rezulin experience underscores the need to conduct strict post-market surveillance to ensure that a speedily approved drug is as safe and effective as promised. *FDA Drug Monitoring Falls Short*, L.A. TIMES, Mar. 23, 2000, at B8.

156. 21 U.S.C. § 356(b)(3) (West 2000).

157. 21 U.S.C. § 355(e) (West 2000). “The *imminent hazard* may be declared at any point in the chain of events which may ultimately result in harm to public health. The occurrence of the final anticipated injury is not essential to establish that an *imminent hazard* of such occurrence exists.” 21 C.F.R. § 2.5(a) (2001). In reviewing the Secretary’s decision to suspend approval, a court is limited to a determination of whether that decision was “arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law.” *Forsham v. Califano*, 442 F. Supp. 203 (D.D.C. 1977). The *Forsham* court, the first to confront the Secretary’s power under 21 U.S.C. § 355(e), recognized the broad authority of the Secretary to suspend so long as he articulates a “rational connection between the facts submitted to him and the choice he made” to do so. *Id.* at 206.

158. Sarah Lueck, *Abortion Foes Face Tough Battle Against RU-486 Drug*, WALL ST. J., Feb. 12, 2001, at A28. According to an official at the Department of Health and Human Services, a drug can be removed from the market only if it is ineffective or unsafe. *Id.* The long-standing availability of data does not preclude a finding of an imminent hazard. *Forsham*, 442 F. Supp. at 209.

ately, such a use of secretarial power has only been used once before.¹⁵⁹

B. Proposed Bill

Immediately upon approval, anti-abortion activists and members of Congress sought to limit the drug's distribution and use. On October 6, 2000, now-retired Representative Tom Coburn of Oklahoma and Senator Tim Hutchinson of Arkansas introduced legislation in Congress to reduce the availability of Mifeprex, by limiting distribution to physicians who currently perform abortions, are credentialed to perform ultrasound procedures, and have completed a government approved training program. According to Representative Coburn, "[t]he freedom of doctors to weigh the risks and benefits and then to act in the best interest of their patients is not at all affected by [the proposed] legislation"¹⁶⁰

Although the bill failed to gain broad support and was initially abandoned in late 2000, its introduction was significant. In light of its strict review, FDA approval "ha[d] never before been questioned in such a manner."¹⁶¹ Of the nearly 600 drugs approved since 1995, Congress did not impose additional distribution requirements on any drug, "let alone one proven as safe and effective as mifepristone."¹⁶²

In a more favorable political climate marked by an anti-abortion administration, Senator Tim Hutchinson and Representative David Vitter (R-LA) reintroduced the "RU-486 Patient Health & Safety Act" on February 6, 2001. The Act seeks, again, to impose restrictions on the distribution of the drug, most of which were considered and rejected by the FDA in its approval of mifepristone in September 2000. The bill would require the Secretary of the Health and Human Services to modify the conditions of the approval of mifepristone such that the drug

159. Leuck, *supra* note 158. In 1977 under 21 U.S.C. § 355(e), the Secretary of Health and Human Services removed the adult-diabetes drug phenformin hydrochloride from the market, upon discovering that it had caused hundreds of deaths. *Forsham*, 442 F. Supp. at 203.

160. Letter from Tom A. Coburn, M.D., to the American College of Obstetricians and Gynecologists (Oct. 16, 2000) (on file with the New York University Annual Survey of American Law), available at <http://www.fda.gov/ohrms/dockets/00/Nov00/111500/cdp0001.pdf> [hereinafter Coburn Response Letter].

161. Alicia Wallace, *FDA Approval of Mifepristone Immediately Targeted*, NAT'L NOW TIMES, Winter 2001 available at http://63.111.42.146/nnt/nnt_article.asp?id=9123&y=2001&v=7&q=Winter&n=1 (last visited Jan. 28, 2001).

162. *Id.*

may not be prescribed by any person other than a licensed physician who meets the following requirements:

- (1) The physician is qualified to handle complications resulting from an incomplete abortion or ectopic pregnancy.
- (2) The physician has been trained to perform surgical abortions and has met all applicable legal requirements to perform such abortions.
- (3) The physician is certified for ultrasound dating of pregnancy and detecting ectopic pregnancy.
- (4) The physician has completed a program regarding the prescribing of such drug that uses a curriculum approved by the Secretary.
- (5) The physician has admitting privileges at a hospital to which the physician can travel in one hour or less¹⁶³

The requirement that providers be able to perform surgical abortions is driven by the need to perform a dilation and curettage or other form of vacuum aspiration in the unlikely event of incomplete abortion.¹⁶⁴ While most gynecologists are skilled at performing these procedures, and frequently perform dilation and curettage procedures for a variety of conditions not dealing with abortion, ACOG opposed a similar restriction when it was proposed in fall 2000 in the Coburn-Hutchinson bill. The organization's opposition is based on the idea that requiring abortion training "is not necessary to administer mifepristone correctly and safely," that certification of abortion training "does not reflect current medical practice," and that "there is no method to certify physicians as surgical abortion providers or for any other type of surgery."¹⁶⁵ Moreover, according to Kate Michelman, president of the National Abortion Rights Action League, "[r]equiring the prescribing doctor to be trained in surgical abortions . . . would mean the drug would be widely available only at abortion clinics, which have been targeted by protesters in the past, instead of in the privacy of a woman's doctor's office."¹⁶⁶

163. S. 251, 107th Cong. (2001), H.R. 482, 107th Cong. (2001).

164. See Coburn Response Letter, *supra* note 160.

165. Press Release, American College of Obstetricians and Gynecologists, Analysis of the Possible FDA Mifepristone Restrictions (Jul. 27, 2000), at http://www.acog.org/from_home/publications/press_releases/nr10-12-00.htm [hereinafter ACOG, Analysis of Restrictions].

166. Bill Walsh, *Abortion Drug May Get New Rules: Bill Requires More Training for Doctors*, TIMES-PICAYUNE (New Orleans), Feb. 7, 2001, at A9.

The requirement that the provider be trained in ultrasonography is in recognition of the “critical[ly] important[ce]” of the diagnosis of ectopic pregnancy and determination of gestation age to the safety of the patient.¹⁶⁷ In explaining the same requirement in his proposed bill, Coburn stated that it guards against the possibility that “the patient errs by two weeks in recalling the date of her last period, or dismisses the pain that might suggest an ectopic pregnancy.”¹⁶⁸ Again, ACOG opposed the same restriction when it was proposed last fall on the grounds that it is not necessary to administer the drug safely and correctly: “Physicians and patients can quite accurately date a woman’s pregnancy.”¹⁶⁹ Additionally, as of October 2000, the American Institute of Ultrasound in Medicine and the American College of Radiology, the only certifying bodies for ultrasound in the United States, did not certify physicians to provide specific ultrasound procedures.¹⁷⁰ Moreover, such a requirement will make medical abortion more costly than surgical abortion and will limit its providers to only those who have the expensive equipment.¹⁷¹

Although the training requirement may be justified as “a perfectly reasonable precaution to protect patients” in the “use of a potentially risky new drug,”¹⁷² such an imposition has been opposed on several grounds. ACOG denied the need for such a requirement based on “unequivocal” evidence from clinical trials demonstrating the drug’s safety and efficacy and stated its position that “the FDA is not an educational institution and has no mechanism in place to develop medical curricula.”¹⁷³ Moreover, such a requirement would make nearly half of the gynecologists who were likely to offer the drug less likely to prescribe it.¹⁷⁴

Finally, the requirement that the provider have admitting privileges was prompted by a view that the FDA standard merely requiring that the provider have arranged for back-up emergency care facilitates “irresponsibility” and acts to “dump[]” “women who suffer complications . . . on the emergency care system.”¹⁷⁵ ACOG

167. Coburn Response Letter, *supra* note 160.

168. *Id.*

169. ACOG, Analysis of Restrictions, *supra* note 165 (citing Charlotte Ellertson et al., *Accuracy of Assessment of Pregnancy Duration by Women Seeking Early Abortions*, THE LANCET LTD., Mar. 11, 2000, at 877).

170. ACOG, Analysis of Restrictions, *supra* note 165.

171. Joffe, *supra* note 90; *see also* discussion *supra* Part III.D.

172. Coburn Response Letter, *supra* note 160.

173. ACOG, Analysis of Restrictions, *supra* note 165.

174. KAISER FAMILY SURVEY, *supra* note 82, at 5.

175. Coburn Response Letter, *supra* note 160.

R

R

R

R

R

R

R

R

opposed the same restriction, citing a *New England Journal of Medicine* article which stated that only 2% of women who used the drug regimen required hospitalization, underwent surgical intervention, or received intravenous fluid.¹⁷⁶ ACOG also argued that women who miscarry or have spontaneous abortions frequently require the same services and care as those women undergoing medical abortion, and that this care is appropriately provided at their physicians' offices.¹⁷⁷ Finally, ACOG stressed the impact such restriction would have on access: "The FDA has imposed no similar requirements on drugs that are far more likely to cause complications requiring emergency care. This requirement discriminates against physicians in rural areas, and creates a significant barrier to access for women in these areas."¹⁷⁸

At a press conference in early 2001, Vitter said, "Last fall, the Clinton-Gore FDA caved into political pressure from the abortion lobby and hurriedly approved the abortion drug without crucial health protections for those who use it. Our legislation corrects that mistake."¹⁷⁹ Vitter and Hutchinson said their bill provides "common sense patient protections" for women opting to use mifepristone to end a pregnancy. Hutchinson said, "I have no doubt that if women were asked whether their doctor should be required to be able to read an ultrasound, handle complications and get them admitted to the hospital in case of an emergency, they would not hesitate to demand those levels of competence."¹⁸⁰

While the current bill shows more promise of being passed than its predecessor, it is not without its ardent opponents. Representative Nita Lowey, a member of the Congressional Pro-Choice Caucus, said: "If President Bush signs a bill with these restrictions you may as well pull the drug from the market."¹⁸¹ Kate Michelman, president of the National Abortion Rights Action League, called the bill "an unprecedented political intrusion" into

176. ACOG, Analysis of Restrictions, *supra* note 165 (citing I.M. Spitz, et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 NEW ENG. J. MED. 1241, 1241 (1998)).

R

177. ACOG, Analysis of Restrictions, *supra* note 165.

R

178. *Id.*

179. *RU-486 Bill Reintroduced*, ACOG LEGISLATIVE NEWS (Feb. 9, 2001), available at http://www.acog.org/from_home/departments/dept_notice.cfm?recno=26&bulletin=1435.

180. The Associated Press, *Proposal Surfaces to Restrict Abortion Pill: 2 Republicans Want More Qualifications for Prescribing Doctors*, ST. LOUIS POST-DISPATCH, Feb. 7, 2001, at A4.

181. *RU-486 Bill Reintroduced*, *supra* note 179.

R

the FDA's drug approval process.¹⁸² Gloria Feldt, president of Planned Parenthood Federation of America, spoke out against the proposed legislation: "The reproductive rights and health of American women are being threatened by a handful of legislators who want their personal ideology to replace the judgment of doctors and scientists. . . . Today, they are seeking to restrict access to mifepristone. Tomorrow, it will be all forms of abortion."¹⁸³

IV LEGAL BARRIERS TO ACCESSIBILITY

Mifepristone's potential to broaden accessibility to early term abortions is very much subject to anti-abortion legislators' ability to enact laws restricting its use. Unfortunately, current Supreme Court jurisprudence indicates that states will be able to erect significant hurdles, so long as they are not "substantial obstacles," in the path of the woman seeking to terminate her pregnancy.

A. *Abortion Rights and Casey*

In its landmark decision *Roe v. Wade*, the Supreme Court held that a women's right to privacy under the Due Process Clause of the Fourteenth Amendment applied to her decision about whether to have an abortion.¹⁸⁴ Prior to viability, "the attending physician, in consultation with his patient, is free to determine, without regulation by the State, that, in his medical judgment, the patient's pregnancy should be terminated."¹⁸⁵ However, the personal privacy right to abortion is "not unqualified," but rather "must be considered against important state interests in regulation."¹⁸⁶ Specifically, under *Roe*, protection of fetal life is a "compelling state interest" after viability, so long as the law allowed abortions necessary to protect the life or the health of the woman.¹⁸⁷ Thus, the Court left

182. Walsh, *supra* note 166.

183. Press Release, Gloria Feldt, Planned Parenthood, *Planned Parenthood Opposes Hutchinson-Vitter Legislation Restricting Access to Early Abortion Pill* (Feb. 6, 2001), available at <http://www.plannedparenthood.org/about/pressreleases/020601hutch.html>.

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

185. *Id.* at 163.

186. *Id.* at 154.

187. *Id.* The Court held that while sufficient state interest was not present throughout the entire pregnancy, those interests became more compelling "as the woman approached term." *Id.* at 162-63. The rationale behind this idea was that the mortality rate for full-term pregnancies is higher than for abortions during the first trimester. *See id.* at 163.

open the possibility that states could restrict women's access to abortion.¹⁸⁸

In 1992, the Supreme Court reaffirmed what it considered to be the "essential holding" in *Roe*, ruling that women have a right to terminate their pregnancies before viability and to obtain abortions past that point if necessary to preserve their lives or health.¹⁸⁹ Additionally, the *Casey* Court held that states have legitimate interests in regulating abortion throughout the entire pregnancy to protect both maternal health and fetal life.¹⁹⁰

While reaffirming a woman's right to terminate her pregnancy before viability,¹⁹¹ the Court weakened the "compelling state interest" requirement of *Roe*, ruling that states may enact laws that promote their compelling interest in the potential life, even pre-viability, so long as the laws do not unduly burden the woman:¹⁹²

The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it. Only where state regulation imposes an undue burden on a woman's ability to make this decision does the power of the State reach into the heart of the liberty, protected by the Due Process Clause. . . . An undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place a substantial obstacle in

188. See generally Jean Reith Schroedel et al., *Women's Rights and Fetal Personhood in Criminal Law*, 7 DUKE J. GENDER L. & POL'Y 89 (2000).

189. *Planned Parenthood v. Casey*, 505 U.S. 833, 845–46 (1992). "The woman's right to terminate her pregnancy before viability is the most central principle of *Roe v. Wade*. It is a rule of law and a component of liberty we cannot renounce." *Id.* at 871.

190. *Id.* at 846. In his dissent, Justice Blackmun noted, "when the State restricts a woman's right to terminate her pregnancy, it deprives a woman of the right to make her own decision about reproduction and family planning—critical life choices that this Court has deemed central to the right to privacy." *Id.* at 927 (Blackmun, J., dissenting). Blackmun further stated, "[a] state's restrictions on a woman's right to terminate her pregnancy also implicate constitutional guarantees of gender equality. State restrictions on abortion compel women to continue pregnancies they otherwise might terminate." *Id.* at 928 (Blackmun, J., dissenting).

191. *Id.* at 871.

192. *Id.* at 874–76. On remand, the Third Circuit recognized that the Supreme Court set a "new standard for facial challenges to pre-viability abortion laws" by requiring only that "a plaintiff show an abortion regulation would be an undue burden 'in a large fraction of the cases.'" *Planned Parenthood v. Casey*, 14 F.3d 848, 863 n.21 (3d Cir. 1994) (citing *Casey*, 505 U.S. at 895).

the path of a woman seeking an abortion before the fetus attains viability.¹⁹³

The statute at issue was the Pennsylvania Abortion Control Act of 1982, as amended in 1988 and 1989.¹⁹⁴ The Act required that the woman give her informed consent prior to the abortion procedure, that she be provided with certain information at least twenty-four hours before the procedure, that a minor obtain the informed consent of at least one parent (with judicial bypass), that a married woman show that she has notified her husband (with certain exceptions), and that facilities providing abortion services comply with reporting requirements.¹⁹⁵

The informed consent requirement was not considered a substantial obstacle to obtaining an abortion, based in part on the finding that the statute “does not prevent the physician from exercising his or her medical judgment.”¹⁹⁶ “[T]he right protected by *Roe* is a right to decide to terminate a pregnancy free of undue interference by the State. Because the informed consent requirement facilitates the wise exercise of that right, it cannot be classified as an interference with the right *Roe* protects.”¹⁹⁷ Finding that the “24-hour delay does not create any appreciable health risk,”¹⁹⁸ and that the increased costs of travel and increased exposure to “the harassment and hostility of antiabortion protestors demonstrating outside a

193. *Casey*, 505 U.S. at 874–78. Justice Stevens defined undue burden slightly differently: “A burden may be ‘undue’ either because the burden is too severe or because it lacks a rational justification.” *Id.* at 920 (Stevens, J., dissenting). Justice Scalia scathingly criticized the undue burden standard as “doubtful in application as it is unprincipled in origin,” *id.* at 985 (Scalia, J., dissenting), “hopelessly unworkable in practice,” *id.* at 986, and “ultimately standardless.” *Id.* at 987. In *Stenberg v. Carhart*, Scalia continued his critique of the standard, stating that the undue burden analysis requires “a conclusion that can not be demonstrated true or false by factual inquiry or legal reasoning. It is a value judgment” 530 U.S. 914, 954 (2000) (Scalia, J., dissenting).

194. 18 PA. CONS. STAT. ANN. §§ 3201–3220 (West 1990).

195. See *Casey*, 505 U.S. at 844.

196. *Id.* at 881–85.

197. *Id.* at 887. However, according to Justice Stevens, “the information requirements . . . do not serve a useful purpose and thus constitute an unnecessary—and therefore undue—burden on the woman’s constitutional liberty to decide to terminate her pregnancy.” *Id.* at 922 (Stevens, J., dissenting). Additionally, Justice Blackmun was “unconvinced that there is a vital state need for insisting that the information be provided by a physician rather than a counselor.” *Id.* at 935 (Blackmun, J., dissenting).

198. *Id.* at 885 (plurality opinion).

clinic”¹⁹⁹ do not impose an undue burden, the waiting period was not considered a substantial obstacle to obtaining an abortion.²⁰⁰

The spousal notification requirement, “likely to prevent a significant number of women from obtaining an abortion,”²⁰¹ was found to impose a substantial obstacle and was thus struck down.²⁰² However, the parental consent requirement, previously held to be permissible, was upheld.²⁰³ Record-keeping and reporting requirements, previously held to be “reasonably directed to the preservation of maternal health,”²⁰⁴ were not considered to be substantial obstacles and were upheld as well.²⁰⁵ *Casey*’s weakening of *Roe* and its introduction of the “undue burden” threshold leave the door open for states’ regulation and restriction of medical abortion.

B. Current State Laws’ Applicability to Medical Abortion

Although it would be difficult for the states to ban the use of the drug outright, many states have sought to restrict its availability through increased regulation. According to one pro-choice advocate, “[d]espite mifepristone’s great potential to improve medical services for women, anti-abortion state legislatures have already erected a labyrinth of laws restricting all abortion.”²⁰⁶ In 1999 alone,

199. *Id.* at 886.

200. *Id.* at 885–87. Again, Justice Stevens disagreed, finding “no evidence that such a delay serves a useful and legitimate purpose” and concluding that the twenty-four hour delay is an undue burden. *Id.* at 921 (Stevens, J., dissenting).

201. *Id.* at 893 (plurality opinion).

202. *Id.* at 894 (finding that the “proper focus of constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant”).

203. *Id.* at 899.

204. *Id.* at 900 (citing *Planned Parenthood v. Danforth*, 428 U.S. 52, 80 (1976)).

205. *Id.* at 900–01. However, Justice Blackmun points out that the district court found that “many physicians, particularly those who have previously discontinued performing abortions because of harassment, would refuse to refer patients to abortion clinics if their names were to appear on these reports,” and as such the requirement would present a substantial obstacle. *Id.* at 939 (Blackmun, J., dissenting).

206. Gina Kolata, *Ready in 4 Weeks: Woman Will Be Able to End Early Pregnancy in Her Own Home*, N.Y. TIMES, Sept. 29, 2000, at A1 (quoting Janet Benshoof, president of the Center for Reproductive Law and Policy) [hereinafter Kolata, *Ready in 4 Weeks*]. Ms. Benshoof also noted, “[Gynecologists and family practitioners] have no idea that [medical abortion] is a dungeon of criminal law. . . . Once you do an abortion, the laws may apply even if it’s just giving women a pill.” Trisha Flynn, *RU-486 Could Prompt a Medical McCarthyism*, DENVER POST, Oct. 8, 2000, at K2, available at 2000 WL 25830388.

439 bills were introduced in state legislatures to restrict abortions.²⁰⁷

1. Outright Bans

To date, there have been no instances of a state successfully overruling an FDA decision approving a drug.²⁰⁸ Although such an action could possibly constitute impermissible state preemption of federal authority,²⁰⁹ state laws have been proposed that would effectively ban the use of mifepristone. On February 5, 2001, for example, state Representatives Bill Graves and Kevin Calvey of Oklahoma each introduced bills that would make it unlawful for “any person to prescribe, dispense, distribute, or otherwise make available mifepristone (RU-486)” in the state.²¹⁰

Some proposed legislation is less explicit, but would have the effect of an outright ban. Although subsequently blocked by court action brought by the Center for Reproductive Law and Policy (“CRLP”),²¹¹ a Michigan law signed by Governor John Engler in December 2000 would have prohibited physicians from terminating pregnancy through the use of medical abortion.²¹² The law sought to amend a pre-existing delay and counseling mandate, to prohibit state-issued literature from describing any procedure that uses medication that has not been expressly approved by the FDA for use in performing an abortion, and to make it illegal to perform any procedure not discussed in the literature.²¹³ Although mifepristone has been approved by the FDA for the express purpose of terminating pregnancy, it must be used in combination with misoprostol. Because the latter drug is only expressly approved for use in ulcer treatment, its “off-label” use in abortion would have been prohibited by the Michigan law.

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

208. *Id.*

209. *Id.*

210. H.B. 1038, 48th Leg., 1st Sess. (Okla. 2001); H.B. 1809, 48th Leg., 1st Sess. (Okla. 2001).

211. See Press Release, Center for Reproductive Law and Policy, Michigan Reverses Ban on RU-486 (Apr. 11, 2001), at http://www.crlp.org/pr01_0411MIban.html [hereinafter CRLP, Michigan Reverses Ban].

212. See Press Release, Center for Reproductive Law and Policy, CRLP Files First Lawsuit in the Nation Against Ban on RU-486 Abortions (Feb. 12, 2001), at http://www.crlp.org/pr_01_0212mimife.html [hereinafter CRLP, CRLP Files First Lawsuit].

213. *Id.*

CRLP filed suit in February 2001 in federal court, seeking an injunction to block the law.²¹⁴ CRLP argued that the law “creates an undue burden on a woman’s fundamental right to terminate a pregnancy.”²¹⁵ On April 11, 2001, CPLR reached a settlement with the state of Michigan to eliminate the requirement that all abortion literature be state-produced, to acknowledge that misoprostol has been approved by the FDA for use with mifepristone, and to provide for an emergency exception to the twenty-four hour waiting period.²¹⁶

Even with the apparent success of the settlement, the law may force abortion providers to abandon the use of the methotrexate-misoprostol combination, since methotrexate was approved by the FDA only for cancer treatment. Additionally, the law continues to threaten surgical practices as well, because the drug digoxin, used to soften fetal tissue for surgical abortion, was approved by the FDA only for treating cardiovascular disease.²¹⁷ Moreover, the law itself signaled a willingness on the part of legislatures to use creative (or “back door”) means to block abortion procedures.

An outright ban on mifepristone, whether it be express or implicit, has the potential to create an “undue burden” on women seeking abortion by forcing them to choose an alternative procedure that may be riskier, delay having the abortion, or forego the abortion altogether.²¹⁸ Ultimately, the choice to have an abortion is the woman’s to make, in consultation with her health care provider²¹⁹ and the selection of abortion method is very much a part of that choice.²²⁰ After all, “a woman choosing abortion must be entitled in every instance to the technique that she and her physician think is optimal for the preservation of her health interests, reading ‘health’ broadly to include her psychological and emotional well-being, as well as her physical condition.”²²¹ For instance, the non-invasive option of medical abortion permits both the woman with severe allergies to anesthesia and the woman with acute phobias of surgery to terminate their pregnancies.

214. CRLP, CRLP Files First Lawsuit, *supra* note 212.

215. Stephanie Simon, *Abortion Rights Group Challenges Mich. Health Law*, L.A. TIMES, Feb. 27, 2001, at A12.

216. CRLP, Michigan Reverses Ban, *supra* note 211.

217. Simon, *supra* note 215, at A12.

218. See generally Walther, *supra* note 65.

219. *Roe v. Wade*, 410 U.S. 113, 163 (1973).

220. Walther, *supra* note 65, at 728.

221. Ann MacLean Massie, *So-Called “Partial-Birth Abortion” Bans: Bad Medicine? Maybe. Bad Law? Definitely!*, 59 U. PITT. L. REV. 301, 365 (1998).

R

R

R

R

R

2. TRAP Laws

Several states limit women's reproductive choices by enacting laws known as TRAP measures (Targeted Regulation of Abortion Providers).²²² These laws, which act as an additional layer of governmental intrusion and oversight, have been characterized as a "much more subtle discrimination against abortion but as significant as any anti-abortion tactic."²²³ TRAP measures restrict the medical practices or facilities of abortion providers by imposing regulations that are "different and more stringent than regulations applied to comparable medical practices."²²⁴ For instance, certain regulations require state inspection of patient records or mandate unique structural and administrative specifications where abortions are performed, such as air flow and door width.²²⁵ Other states require that fetal remains be examined by a doctor.²²⁶

TRAP schemes, enforceable in sixteen states,²²⁷ have the effect of deterring physicians from providing abortion services "by subjecting them to criminal and civil penalties, exposing them to harassment, and intruding significantly into their practice of medicine, resulting in reduced access for women to abortion services."²²⁸ The issue raised is whether those regulations apply only to clinics offering surgical abortions. If they are extended to medical abortions, any family practitioner who prescribes the mifepristone-misoprostol combination will need to comply or face penalties. This would hamper the ability to move abortions from the picket lines and vio-

222. CTR. FOR REPROD. LAW & POLICY, *Targeted Regulation of Abortion Providers (TRAP): Avoiding the Trap*, CRLP PUBLICATIONS (Ctr. for Reprod. Law & Policy, New York, N.Y.), Feb. 2001, available at http://www.crlp.org/pub_fac_trap.html (Feb. 2001) [hereinafter CRLP, *Avoiding the Trap*].

223. Anne Gearan, *High Court Allows State's Restrictions for Abortion Clinics*, VIRGINIAN-PILOT, Feb. 27, 2001, at A6.

224. CRLP, *Avoiding the Trap*, *supra* note 222. Such restrictions are "medically pointless and treat early-term abortions differently from other similarly low-risk medical procedures." Gearan, *supra* note 223, at A6.

225. Zitner, *FDA Approves Use of Abortion Pill*, *supra* note 42, at A1.

226. For instance, North Dakota law requires medical certification before final disposition of a fetus. N.D. CENT. CODE § 23-02.1-20 (1991 & Supp. 1999). Some abortion opponents have argued that states that require examination of fetal tissue could interpret the laws strictly to force women to collect the products of a drug-induced miscarriage and take them to their doctor's offices, and that such a requirement could deter use of the drug. Claiborne, *supra* note 207, at A1.

227. These states include Alabama, Arkansas, Connecticut, Florida, Kentucky, Michigan, Mississippi, Missouri, Nebraska, North Carolina, Pennsylvania, Rhode Island, Tennessee, and Wisconsin. The measures in Arizona and Texas are currently being challenged in court. CRLP, *Avoiding the Trap*, *supra* note 222.

228. *Id.*

R

R

R

R

R

lence surrounding abortion clinics to the privacy of the doctor's office.

TRAP schemes restricting pre-viability abortions may become even more prevalent following the Supreme Court's recent refusal to hear the challenge to South Carolina's Regulation 61-12, a series of regulations on abortion clinics that were substantially revised in 1996.²²⁹ Regulation 61-12 applies to any "facility in which any second trimester or five or more first trimester abortions are performed in a month," and would apply equally to doctors performing surgical and medical abortions.²³⁰ Additionally, the regulations provide for periodic inspections, require that every abortion be performed by a physician who is licensed by the state, and mandate testing for sexually transmitted diseases.²³¹

The Regulation was first challenged in 1996 and was originally blocked by a district court in 1999.²³² The district court concluded that the Regulation "serve[d] no legitimate state interest" and operated as an undue burden on a woman's right to seek an abortion, resulting from "increased costs, delays in the ability to obtain abortions, decreased availability of abortion clinics, increased distances to travel to clinics, unlimited inspections of clinics, and compromises to patient confidentiality."²³³

The Fourth Circuit reversed, upholding the constitutionality of Regulation 61-12 on the grounds that:

(1) the Regulation serves a valid state interest and is little more than a codification of national medical- and abortion-association recommendations designed to ensure the health and appropriate care of women seeking abortions; (2) the Regulation does not 'strike at the abortion right itself' (3) the increased costs of abortions caused by implementation of the Regulation . . . are . . . modest and have not been shown to burden the ability of a woman to make the decision to have an abortion; and (4) abortion clinics may rationally be regulated as a class while other clinics or medical practices are not.²³⁴

Following the Supreme Court's denial of certiorari, lawyers for four doctors who perform most of the first trimester abortions in South Carolina sought a preliminary injunction to prevent the reg-

229. *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000), *cert. denied*, 121 S. Ct. 1188 (2001).

230. 61 S.C. CODE ANN. REGS. 12 § 101(B) (Supp. 2000).

231. 61 S.C. CODE ANN. REGS. 12 (Supp. 2000).

232. *Greenville Women's Clinic*, 222 F.3d at 162.

233. *Id.* at 163.

234. *Id.* at 159 (citation omitted).

ulations from taking effect, and on March 1, 2001, a district court granted the injunction.²³⁵ According to Bonnie Scott Jones, staff attorney with CPLR, “If the attorney general . . . had his way, these regulations would be used to temporarily ban all abortions in South Carolina. . . . [His] eagerness to begin enforcing the regulations when no physician can possibly comply demonstrates that his goal is not advancing women’s health and safety, but advancing his political agenda against abortion.”²³⁶ The preliminary injunction gives providers 120 days to comply with the regulations.²³⁷ The outcome of the challenge to South Carolina’s Regulation 61-12 suggests that TRAP schemes may limit the availability of medical abortions as well.

3. Physician Only Laws

More than forty states and the District of Columbia have “physician only” laws, which prohibit non-physicians from performing abortions.²³⁸ Many of these laws originally were passed in order to protect women from the horrifying complications that resulted from abortions performed by untrained, “back-alley” practitioners, a prevalent problem prior to 1973 and the “legalization” of abortion.²³⁹ *Roe v. Wade* expressly upheld the constitutionality of such laws, concluding that “the State may define the term ‘physician’ . . . to mean only a physician currently licensed by the State, and may proscribe any abortion by a person who is not a physician as so defined.”²⁴⁰

Three years later, the Supreme Court reaffirmed that holding in *Connecticut v. Menillo*.²⁴¹ In *Menillo*, the Court held that Connecticut’s criminal abortion statute, which prohibited an attempted abortion by “any person,” could continue to be enforced against

235. Press Release, Center for Reproductive Law and Policy, Federal Court Blocks Enforcement of Anti-Abortion Regulations (Mar. 1, 2001), at http://www.crlp.org/pr_01_0301scregistro.html.

236. *Id.*

237. *Id.*

238. Roslyn Y. Bazzelle, Comment, *Mazurek v. Armstrong: Should States be Allowed to Restrict the Performance of Abortions to Licensed Physicians Only?*, 24 T. MARSHALL L. REV. 149, 177 (1998).

239. *Id.*

240. 410 U.S. 113, 165 (1973).

241. 423 U.S. 9, 10–11 (1975) (explaining that the criminal statutes against abortion were only unconstitutional as applied to physician-induced abortions, not abortions induced by non-physicians).

non-physicians, and further stated that the abortion right did not encompass abortions performed by non-physicians.²⁴²

The insufficiency of the State's interest in maternal health is predicated upon the first trimester abortion's being as safe for the woman as natural childbirth at term, and that predicate holds true only if the abortion is performed by medically competent personnel under conditions ensuring maximum safety for the woman.²⁴³

More recently, the Court was confronted with a challenge to the constitutionality of a Montana statute prohibiting physician assistants from performing abortions.²⁴⁴ Physicians and physician assistants brought action, claiming, among other things, that the "physicians only" provision imposed a substantial obstacle in the path of women seeking a pre-viability abortion in violation of *Casey*.²⁴⁵ In upholding the statute, the Supreme Court referred to the notion in *Casey* that "[o]ur cases reflect the fact that the Constitution gives the States broad latitude to decide that particular functions may be performed only by physicians, *even if an objective assessment might suggest that those same tasks could be performed by others.*"²⁴⁶ Prior to the Court's ruling, "the number of licensed medical practitioners willing to perform abortions dropped from twenty in 1982 to twelve in 1996, primarily due to increasing harassment against providers."²⁴⁷ Following the ruling, and as a result of Montana's legislation, that number has decreased to eleven for the entire state.²⁴⁸

An abortion, especially in the first trimester, is a relatively simple and safe procedure, and regulations such as the ones in *Roe*, *Menillo* and *Mazurek* that restrict competent medical personnel "do not appreciably advance the state's interest in maternal health."²⁴⁹ Midlevel clinicians (i.e., physician assistants, nurse practitioners, and certified midwives) routinely perform procedures that are as

242. *Id.* at 11.

243. *Id.*

244. *Mazurek v. Armstrong*, 520 U.S. 968 (1997).

245. *Armstrong v. Mazurek*, 906 F. Supp. 561, 564 (D. Mont. 1995), *vacated by* 94 F.3d 566 (9th Cir. 1996).

246. *Mazurek*, 520 U.S. at 973 (emphasis added) (quoting *Planned Parenthood v. Casey*, 505 U.S. 833, 885 (1992)).

247. See Schirmer, *supra* note 32, at 264 (citing Brief for Plaintiffs-Appellants at 4, *Armstrong v. Mazurek*, 94 F.3d 566 (1996)).

248. The statute only affected one physician assistant. *Mazurek*, 520 U.S. at 973.

249. Bazzelle, *supra* note 238, at 167.

medically complex as first trimester abortions.²⁵⁰ At some clinics, “physician assistants and nurse practitioners provide the majority, if not all, of the clinics’ obstetric and gynecological care, except for abortions.”²⁵¹ For example, physician assistants perform endometrial biopsies (requiring the administration of local anesthesia), IUD and Norplant insertions and removals (requiring dilation of the cervix), pelvic exams, and testing and treatment for sexually transmitted diseases and prenatal care.²⁵² The need for physician backup in the case of complications is not unique to abortion and could arise in connection with any of these procedures. Moreover, physician assistants have safely performed abortions in Vermont and New York (and, prior to *Mazurek*, Montana),²⁵³ and a 1986 study of 2,500 procedures found no significant difference in complication rate between abortions performed by physicians and those done by physician assistants.²⁵⁴

“Physicians only” requirements pose a threat to women seeking to terminate their pregnancies in at least two ways. First, they limit the number of providers in an already shrinking pool. It is axiomatic that “the fewer abortion providers there are, the less accessible abortion becomes, rendering the ‘right’ to an abortion little more than a hollow promise.”²⁵⁵ Secondly, the laws inhibit women’s ability to seek help from arguably more accessible and less expensive providers.²⁵⁶ This is especially true in states that require that a physician perform counseling as well.

If states extend their “physician only” laws to the administration of mifepristone, they will unnecessarily restrict the availability of medical abortion. Due to constraints on physicians’ time, it is unreasonable to prohibit women from receiving counseling from midlevel clinicians. It is imperative that women understand the

250. Sylvia A. Law, *Rethinking Sex and the Constitution*, 132 U. PA. L. REV. 955, 1020 n.233 (1984).

251. Schirmer, *supra* note 32, at 254.

252. *Id.* at 268.

253. Donna Lieberman and Anita Lalwani, *Physician-Only and Physician Assistant Statutes: A Case of Perceived but Unfounded Conflict*, 49 J. AM. MED. WOMEN’S ASS’N 146, 146–48 (1994). Physician assistants have been performing abortions in Vermont and Montana, and approximately one-quarter of New York physicians assistants have performed first-trimester abortions. See Schirmer, *supra* note 32, at 269.

254. Boodman, *supra* note 2, at 7.

255. Bazzelle, *supra* note 238, at 174.

256. Schirmer, *supra* note 32, at 254. In his dissent in *Casey*, Justice Blackmun noted district court findings that requiring a physician, rather than an assistant, to give the patient the requisite informed consent materials increased the cost of abortion, making it even more financially burdensome for poor women. *Planned Parenthood v. Casey*, 505 U.S. 833, 935 (1992) (Blackmun, J., dissenting).

R

R

R

R

R

ramifications of the procedure, and due to prevalent misconceptions, counseling may take longer. Moreover, physician assistants and certified nurse practitioners are permitted to prescribe drugs under the supervision of licensed physicians and, in many cases, do prescribe drugs with more serious and frequent complications than mifepristone. Finally, midlevel clinicians are fully capable of performing a first trimester surgical abortion if the two-drug regimen fails, and have already formed relationships with physicians and emergency rooms for backup in the case of complications.

4. Mandatory Delay and Informed Consent

Other state regulations impose restrictions directly on the woman seeking the abortion. Currently, seventeen states enforce burdensome laws requiring that a woman delay her choice a certain number of hours or days after receiving state-mandated literature.²⁵⁷ Critics of such legislation assert that it causes women to incur greater health risks associated with aborting later in the pregnancy.²⁵⁸ Additionally, it disproportionately affects poorer women and those that live farther away from a provider by forcing them to incur the costs of additional trips.²⁵⁹ Although the medical risks associated with abortion procedures are minimal, they rise “geometrically from the first trimester to the second.”²⁶⁰ The timing of the abortion is crucial to certain kinds of procedures, particularly the mifepristone-misoprostol regimen.

A study conducted from August 1989 to July 1995 tested the effect of mandatory delay and counseling laws in Mississippi on the timing of abortion.²⁶¹ Similar to most state-directed counseling laws, Mississippi’s law requires that the physician inform the woman

257. *Mandatory Delays and Biased Information Requirements*, CRLP PUBLICATIONS (Ctr. for Reprod. Law & Policy, New York, N.Y.) Feb. 2001, available at http://www.crlp.org/pub_fac_manddelay1.html. South Carolina requires a one-hour delay; Indiana requires an eighteen hour delay; Idaho, Kansas, Kentucky, Michigan, Nebraska, North Dakota, Ohio, Pennsylvania, South Dakota, and Virginia all require a twenty-four hour delay; Arkansas requires a twenty-four hour delay, state-directed counseling, and the option to view the state-prepared materials; Louisiana, Mississippi, Utah and Wisconsin not only require a twenty-four hour delay, but also require that the woman receive the information in person from a health care provider, thus requiring two trips to the provider, rather than permitting the dissemination of information over the phone or through the mail. *Id.*

258. Ted Joyce & Robert Kaestner, *The Impact of Mississippi’s Mandatory Delay Law on the Timing of Abortion*, 32 FAM. PLAN. PERSP. 4, 4 (2000).

259. *Id.* Added expenses include the costs of travel, childcare, and lost work time.

260. *Id.* at 12.

261. *Id.* at 4.

of the probable gestational age of the fetus, the risks associated with induced abortion, and the availability of financial assistance if she carries the fetus to term.²⁶² The woman must also be informed of the availability of state-prepared material that describes her “un-born child” and a list of agencies that provide alternatives to abortion.²⁶³

Mississippi’s law has been interpreted to require that the information be conveyed in person, requiring two separate visits to the provider in the case of surgical abortion (and three in the case of medical abortion involving mifepristone).²⁶⁴ The study concluded that the law had a “substantial and statistically significant effect on the timing of abortion.”²⁶⁵ Although there was a decline in the overall abortion rate, after the mandatory delay and counseling law was enacted in 1992 there was a marked shift from early procedures towards abortions late in the first trimester and second trimester.²⁶⁶ The overall effect of the law was to delay an abortion about four days for women whose closest provider was in-state; timing was relatively unaffected for women whose closest provider was in one of the border states that did not have a similar law.²⁶⁷

While a portion of the increased delay observed in Mississippi may represent greater deliberation over the decision to terminate the pregnancy, the fact that so many women left the state for their abortion once the law took effect suggests that many found the two-visit requirement to be “too costly or perhaps considered the information provided to be unnecessary.”²⁶⁸

Generalizing outside of their state, the authors of the Mississippi study predict that a mandatory delay and counseling law would have little effect on the timing of abortions in small eastern states like Massachusetts, Rhode Island, and Connecticut, where women can easily cross state lines to obtain an abortion.²⁶⁹ Two-visit requirements in larger western states, where it is more difficult to travel out-of-state, would have a more significant impact on the timing of abortion.²⁷⁰

262. *Id.* at 5.

263. *Id.*

264. *Id.*

265. *Id.* at 12.

266. *Id.* at 7–8.

267. *See id.*

268. *Id.* at 12.

269. *Id.*

270. *Id.*

The Mississippi study provides important insight on the effect such mandatory delay and counseling laws would have on women seeking a mifepristone-misoprostol induced abortion. A four-day delay may seem minor, but each day is significant when dealing with a short, seven-week window of opportunity. Mandatory delay laws would undoubtedly reduce the availability of medical abortion, if not eliminate the option altogether.

Regardless of the problems with mandatory delays, there is a definite need for counseling in connection with the administration of the mifepristone-misoprostol regimen. The need for informed consent is broadly recognized in all areas of health care; the health care provider must *objectively* communicate the information reasonable patients would need in order to make informed decisions about their medical care.²⁷¹ Too often, however, the states force providers to be the messengers of anti-abortion propaganda. Such provision of biased information was sanctioned by the Supreme Court in *Casey*:

Even in the earliest stages of pregnancy, the State may enact rules and regulations designed to encourage [the woman] to know that there are philosophic and social arguments of great weight that can be brought to bear in favor of continuing the pregnancy to full term and that there are procedures and institutions to allow adoption of unwanted children as well as a certain degree of state assistance if the mother chooses to raise the child herself.²⁷²

Information of this sort assumes that the woman has not already carefully considered the consequences of her decision to terminate her pregnancy. Regardless of the means of termination, “a woman’s decision to terminate her pregnancy is nothing less than a matter of conscience.”²⁷³

Instead, what the woman needs is objective counseling about what to expect with the procedure. This is crucial in the case of the mifepristone-misoprostol regimen. A woman must be made aware of the potential side effects and possible need for surgical intervention. She must understand that the miscarriage may occur at any time after the ingestion of the drugs—at home, en route to the doctor’s office, in the doctor’s office—and that she may be alone when that happens. Because it is so hard to predict the timing of

271. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972) (requiring that physicians communicate the information reasonable patients would want to know to make informed decisions about their medical care).

272. *Planned Parenthood v. Casey*, 505 U.S. 833, 872 (1992).

273. *Id.* at 916 (Stevens, J., dissenting).

the miscarriage, the availability of a twenty-four hour telephone support line may be beneficial.²⁷⁴ It is true, “[w]hat is at stake is the woman’s right to make the ultimate decision. . . .”²⁷⁵ It is equally true that her health care provider must supply her with the *objective* information needed to make that decision, free from biased literature that inhibits her ability to make her own choice.

5. Parental Involvement

Historically, states have generally preserved the right of parents to make health care decisions on their children’s behalf, on the theory that young people are unable to make fully informed decisions on their own.²⁷⁶ Over the past thirty years, however, the tide has shifted, and minors’ authority over their health care decisions has been expanded, in part due to recognition that many minors will not seek needed services if forced to tell their parents.²⁷⁷ Still, while many states authorize minors to consent to contraceptive services, testing and treatment for HIV and other sexually transmitted diseases, prenatal care and delivery services, treatment for alcohol and drug abuse, and outpatient mental care, many of these same states “restore” parental rights in the abortion arena.²⁷⁸ Only Connecticut, Maine and the District of Columbia have laws that affirm a minor’s independent choice to have an abortion.²⁷⁹ Forty-three states have laws requiring a minor woman to obtain the consent of or notify at least one parent or guardian prior to an abortion, although such measures are enforced in only thirty-three states.²⁸⁰

274. Winikoff, *supra* note 47, at 365.

275. *Casey*, 505 U.S. at 877.

276. Heather Boonstra & Elizabeth Nash, *Minors and the Right to Consent to Health Care*, THE GUTTMACHER REPORT ON PUBLIC POLICY, Aug. 2000, reprinted in *Minors and the Right to Consent to Health Care*, ISSUES IN BRIEF (Alan Guttmacher Inst., New York, N.Y.) available at http://www.agi-usa.org/pubs/ib_minors_00.html (last visited Oct. 1, 2001).

277. *Id.*

278. *Id.*

279. *Id.*

280. *Restrictions on Young Women’s Access to Abortion Services*, CRLP PUBLICATIONS (Ctr. for Reprod. Law & Policy, New York, N.Y.), July 2001, available at http://www.crlp.org/pub_fac_restrictions.html. Parental consent is enforced in Alabama, Idaho, Indiana, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, Missouri, North Dakota, Oklahoma, Pennsylvania, Rhode Island, Tennessee, and Wyoming. In Maine, North Carolina, South Carolina, and Wisconsin, the measure provides for alternatives to parental consent, such as permitting the minor to obtain the consent of one parent or sibling, providing a doctor-authorized waiver, or requiring specialized counseling. Parental notification measures are enforced in Arkansas, Georgia, Kansas, Minnesota, Nebraska, South Dakota, Texas and Virginia. In Delaware, Iowa, Maryland, Ohio, and West Virginia the measures provide

However, most states explicitly permit that same pregnant minor to place her child up for adoption without parental involvement.²⁸¹ Of the states that require parental notification before minors can obtain an abortion, Arkansas, Georgia, Idaho, Nebraska, Rhode Island, South Carolina, Tennessee, Texas and Virginia have indicated that their notification laws apply to medical abortion as well.²⁸²

Three reasons were recognized by the Supreme Court in *Belotti v. Baird* as justifying parental involvement in the decision to terminate a pregnancy: “the particular vulnerability of children; their inability to make critical decisions in an informed, mature manner; and the importance of the parental role in child rearing.”²⁸³ Advocates of mandatory parental involvement argue that abortion should be treated differently from other reproductive health services because the decision to terminate a pregnancy “is less a medical choice than a major life decision.”²⁸⁴ Whether or not that is true, it is necessary for the state to take reasonable measures to ensure that the pregnant minor is making an informed decision. Sometimes, that will involve parental involvement. But the scope of the debate does not change whether the termination of an unplanned pregnancy is accomplished through surgery or a pill.²⁸⁵

for alternatives similar to those previously listed. Utah’s parental notification measure contains no judicial bypass procedure. The constitutionality of the Idaho, Alaska, and Arizona statutes requiring parental consent and the Colorado and Florida statutes requiring parental notification are currently being challenged.

281. Boonstra & Nash, *supra* note 276.

282. Jeffrey Collins, *RU-486 Needs OK from Parent: Many States Agree Pill is Under Same Rules as Surgical Abortions*, DETROIT NEWS, Oct. 11, 2000, at 8A. It is interesting to note that in comparison to Virginia, the District of Columbia has no parental consent law, and Maryland’s law grants physicians broad discretion to decide whether consent is necessary. Jennifer Lenhart, *Va. Curbs RU-486 Use by Minors: Law Appears Strictest in Area on Abortion Pill*, WASH. POST, Oct. 10, 2000, at B1.

283. 443 U.S. 622, 634 (1979).

284. *Id.* at 640–41. Of course, the decision to continue a pregnancy is also a “major life decision.”

285. In a case still pending, Florida’s intermediate state court of appeal unanimously found the state’s law requiring parental notification for minors obtaining abortions to be constitutionally valid. *State v. N. Fla. Women’s Health & Counseling Servs., Inc.*, 2001 Fla. App. LEXIS 1217, at *2 (Dist. Ct. App. Feb. 9, 2001). The court found a compelling state interest in facilitating the ability of parents and guardians to provide appropriate medical care for minors. *Id.* at *18. However, the court expressly noted that it did not consider whether the statute can be constitutionally applied to medical abortion procedures. *Id.* at *23 n.3 (“The evidence presented below was limited to the risks associated with surgical abortions as practiced at the time of the hearing and did not address the risks associated with RU-486. . . . It is not clear on this record when, if ever, RU-486 can be safely administered to minors, or when, if ever, it will be administered to minors in Florida.”).

CONCLUSION

Mifepristone's great potential for increasing the availability of abortion to women seeking to terminate early pregnancies is threatened by a "labyrinth of laws restricting all abortion."²⁸⁶ In order to make the accessibility of medical abortion a reality it will be necessary to prevent state legislators from enacting laws that effectively act as outright bans, restrict the medical practices or facilities of abortion providers, limit distribution to licensed physicians, or mandate that a woman delay her choice. At the same time, to protect the physical and emotional well-being of the woman, it is necessary that the states continue to require informed consent and mandatory counseling, so long as the counseling is objective. Only then will mifepristone be able to fulfill its promise of providing a safe, effective, and private alternative to surgical abortion.

286. Kolata, *Ready in 4 Weeks*, *supra* note 204, at A1.