I. INTRODUCTION

THE NEW DRUG called RU 486 has sparked a considerable amount of controversy. On one side are the doctors and patients who see the drug as a major medical breakthrough. They see RU 486 as a relatively safe, effective and private method for termination of a pregnancy. On the other side of the controversy are those who see RU 486 as a “death pill,” as an easy way to terminate even more unborn lives than occur at present. This paper presents that controversy. Part I discusses the science of the RU 486. Part II presents in detail the social controversy surrounding RU 486. Part III then discusses how the FDA approval process works and how it might be applied to RU 486. Next, Part IV shows how politics can present a major obstacle to RU 486’s introduction and discusses whether these obstacles are constitutionally proscribed. Finally, Part V considers whether it is wise to allow politics to dictate the introduction of a beneficial technology.

In the final analysis, even though there are many permissible ways in which politics may present barriers to RU 486 as another vehicle for reproductive choice, it would be better to have the FDA approve the drug. FDA approval will result in the regulation of RU 486—in the name of safety and choice.

II. THE SCIENCE OF RU 486

Mifepristone, commonly known as RU 486, is a progesterone antagonist. The hormone progesterone performs a central role in the menstrual cycle. It causes the lining of the uterus to prepare for the implantation of a fertilized egg and when no egg implants, the progesterone level decreases and the lining is expelled.¹ RU 486 prevents the body from receiving progesterone. The progesterone is still produced by the body, but the body does not “read” the proges-

¹ This paper was written under the supervision of Rebecca Dresser, Professor of Law at Case Western Reserve University School of Law. Direction was also provided by Professor Jonathan Entin.

terone levels and functions as if it were not present. Depending on when the progesterone antagonist, RU 486, is introduced into the body, the effects on the reproductive cycle will vary.

For example, progesterone seems to be essential for ovulation to occur. Thus, if RU 486 blocks the reception of progesterone, ovulation will not occur. For women whose bodies cannot tolerate the overload of estrogen found in the “pill,” RU 486 presents a valuable alternative. The drawback of this use is that in order to maintain suppression of ovulation, RU 486 must be taken constantly. Also because the long term effects of RU 486 are unknown, RU 486 taken as an ovulation suppressor does not appear to be an acceptable alternative to “the pill”. RU 486 may also be used as an “implantation inhibitor” similar to the IUD. RU 486 taken during the last 10-12 days of the cycle in small amounts may suppress progesterone enough to make the uterine lining uninhabitable and thus prevent implantation. However, the natural variation of the menstrual cycle presents a problem for this type of use because it is difficult to determine when to start taking the drug.

The most commonly thought of use for RU 486 is as a “morning after” pill. This is a misconception. The drug is actually taken at the end of the cycle, before the expected menstrual period, rather than the “morning after” unprotected sexual intercourse. RU 486 inhibits the physical action of progesterone, causing the lining of the uterus to be expelled. As a result, RU 486 could be used in this manner as a “menstrual regulator.” While this use of RU 486 has advantages over currently used steroid preparations for providing postcoital contraception, RU 486 taken alone is only 80% effective. Given a 20% chance of pregnancy after unprotected sex, RU 486 as a menstrual regulator has an overall failure rate of 4%. Because of this failure rate, Dr. Baulieu, RU 486’s primary re-

5. Baulieu, supra note 4.
6. Id.
7. (20% chance of failure x 20% chance of pregnancy). Baulieu states that the 4% failure rate is “too high for the monthly use of RU 486 as a menses inducer.” Baulieu, supra note 4, at 1355. This may seem odd because the RU 486 as an abortion technique has a 4% failure rate as well. Baulieu seems to mean by this comment that women cannot and should not depend on the RU 486 every month, but rather should use it only occasionally when necessary, that is when the threat of pregnancy is great.
searcher, suggests that RU 486 should be reserved only for occasional postcoital contraception after unprotected sex and should not be relied upon for "menstrual regulation."  

Finally, we come to the use of RU 486 which has stirred so much controversy — interruption of pregnancy. RU 486 has been shown to be an effective method for the termination of pregnancy in the first 7-8 weeks of pregnancy. Again, RU 486 blocks reception of progesterone, thus causing the lining of the uterus to break down and then to be naturally expelled in much the same way a menstrual cycle occurs.

In France, over 2,115 women at 450 centers have used the RU 486 procedure with a success rate of 96%. The procedure used in France consists of a single dose of RU 486 taken orally, followed about 3 days later by a small dose of synthetic prostaglandin. Prostaglandins help induce the womb to contract and expel its contents. Alone, prostaglandins have been used to interrupt early pregnancy but this use is considered unacceptable due to undesirable side effects. However, these unacceptable side effects are significantly lessened when prostaglandins are taken in small doses, and when taken in conjunction with RU 486 the result is an increased success rate in the interruption of pregnancy.

After the prostaglandin is taken, the woman will experience bleeding and expulsion in about 24 hours. The bleeding continues for about 10 days which is only slightly longer than after abortion.

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8. Id.
10. The time in which RU 486 can be used effectively has varied. The latest study done on the effectiveness of RU 486 in France states that RU 486 was administered in cases of pregnancy of less than 49 days or 7 weeks. The study defined "duration of pregnancy" as "duration of amenorrhea [absence of bleeding] calculated from the first day of the last menstrual period." Silvestre, Voluntary Interruption of Pregnancy with Mifepristone (RU 486) and a Prostaglandin Analogue, 322 NEW ENG. J. MED. 645 (1990). Fertilization is assumed to occur 14 days after the start of the last menses and thus the women to whom RU 486 was administered were actually not more than 5 weeks pregnant. (14 days [days which she was most likely not pregnant] - 49 days = 35 or 5 weeks). All durations in this paper will refer not to the actual duration of the pregnancy, but rather in terms of number of weeks since the last menses.
14. Baulieu, supra note 4, at 1354. These side effects include intense nausea, vomiting and cramps.
15. Id.
16. Id.
by vacuum aspiration. The bleeding with the RU 486 is typical of a heavy menstruation period. RU 486 is then metabolized by the body and the ovulatory cycle is restored.

Some commentators, as well as the drugs opponents, have expressed a fear over the effects of RU 486 on a continued pregnancy as a result of an unsuccessful RU 486 procedure. Abortion opponents cite studies in rabbits that showed a malformed skull as a result of an unsuccessful termination. This effect, however, has little relevance for humans. The malformed skull in the rabbit occurs as a result of the contraction of the uterus caused by the prostaglandin. However, the size of the rabbit's uterus in relation to the fetus bears little relationship to the human uterus in relation to the fetus at 7 weeks. Thus, this malformity appears to be unique to the animal and presents little danger to a human fetus. Further, although RU 486 does cross the placenta to the fetus, there is no evidence of a teratogenic or fetotoxic effect.

There is also concern for the fertility of women after repeated RU 486 procedures. But, since the drug functions by depriving the system of a vital element rather than overloading it with one, as in the case of administration of high doses of estrogen currently used in rape, it is anticipated to be relatively free of long term consequences. Further, the high rate of metabolism of RU 486 in the body decreases the likelihood of long-term effects. Further, there is an anecdotal report by Dr. Baulieu that there have been at least three women who have successfully brought pregnancies to term with no adverse side effects.

III. THE CONTROVERSY: POLITICS AND CHOICE

A. The Effect of RU 486 on Social Practices

The RU 486 procedure has sparked a significant amount of con-

17. Id.
18. Id.
19. An important feature of the RU 486 is its metabolism in the body. RU 486 metabolizes from the body in about 12 - 24 hours. Baulieu, supra note 4, at 1353.
20. Id.
21. Cahill, supra note 9, at 6.
22. Dowie, supra note 2, at 85.
24. Dowie, supra note 2, at 85.
25. Baulieu, supra note 4, at 1355.
26. Cahill, supra note 9, at 5.
27. Baulieu, supra note 4, at 1356.
28. Id. at 1355.
troversy. This controversy revolves around the changes that may occur in the practice of abortion and the consequential impact that those changed social practices may have on the abortion debate.

The RU 486 procedure, as discussed above, amounts to the taking of a few pills within the first 7-8 weeks of pregnancy and then a shot or suppository a few days later. The pills can be obtained by any physician willing to prescribe them which eliminates the need to travel to an abortion clinic. Finally, the abortion occurs in the privacy of the woman's home in the form of what has been characterized as a "heavy menstrual period."

This procedure has the potential to have notable consequences on reproductive practices in the United States. There are approximately 3 million unplanned pregnancies in the U.S. each year of which about half are aborted. Of those pregnancies aborted, only half are performed in the first eight weeks of pregnancy. In France, one out of four pregnancies are terminated using the RU 486 procedure. If the statistics hold true, this would amount to approximately 400,000 pregnancies terminated in the U.S. by the RU 486 procedure.

The fact that RU 486 can only be used in the first 8 weeks of pregnancy may lead to more pregnancies terminated prior to eight weeks. Typical surgical abortions performed before eight weeks have a greater chance of failure than abortions performed later because the fetus is so small before eight weeks that it is easily missed during the procedure. Thus, women may be dissuaded from earlier abortions for fear of failure of the procedure. How-

ever, the RU 486 procedure works best in the early weeks of preg-
nancy, and therefore, those women who must wait or risk failure, may be able to have earlier abortions.

The RU 486 may also change the practice of "waiting and putting off" confirmation of pregnancy fears. Women often put off con-

31. Id.
32. Id.
33. Id. at 13.
34. Even though the RU 486 procedure has a 4% failure rate which is comparable to the failure rate of early surgical abortion, the effectiveness of surgical abortions depends to a certain extent on the skills of the provider and therefore in actuality the effectiveness rate of the early surgical abortion may vary from provider to provider. While the RU 486 effectiveness rate has no relation to the skill of the provider, and therefore remains constant, the effect of this is that the provider may dissuade a woman from an abortion which he feels is too early because he is not confident of his skill to perform the earlier abortion. See Klitsch, supra note 30, at 12.
firming pregnancy fears in hopes that they are not pregnant. By the
time the pregnancy is confirmed and the abortion decision made,
the pregnancy has progressed to or beyond eight weeks.\textsuperscript{35} Depending on the acceptance of the RU 486 procedure,\textsuperscript{36} with the knowledge that RU 486 could only be used prior to eight weeks, women may be more willing to seek early confirmation of pregnancy fears in order to take advantage of the procedure. Thus RU 486 may make an earlier abortion a more desirable alternative to the stress of worrying about a potential pregnancy.

B. The Ethical Controversy

It is the possibility that earlier abortion may become less pain-
ful, less humiliating, and perhaps more frequent, that has sparked
the ethical and political debate. The primary concern of the oppo-
nents of RU 486 is that easy access to early abortion will be a disin-
centive to contraception and will discourage self-critical abortion
decisions.\textsuperscript{37} Opponents of RU 486 fear that the abortion decision will be trivialized by a small pill taken at home.\textsuperscript{38} They feel that women will not undertake a discriminating decision to abort; that they will enter into the abortion without fully contemplating the implications of their decision to abort.\textsuperscript{39}

These fears may have some merit but they significantly devalue
the fact that abortion is a traumatic decision at any point during
pregnancy.\textsuperscript{40} The fact that abortion will be less public and less hu-
miliating, as women will no longer be forced to cross picket lines
and engage in violence in order to obtain the abortion, does not
lessen the fact that she has chosen to abort her pregnancy. Most
women will still prefer to avoid the decision, regardless of the ease
of the procedure. Thus, the fear that contraceptives will be forgone
in the face of the RU 486 is unwarranted.

\textsuperscript{35} Micheal Klitsch, of the Allan Guttmacher Foundation, states that on the average five weeks pass before a woman will suspect that she is pregnant and another 3 weeks pass before she is willing to confirm her pregnancy. \textit{Id.}

\textsuperscript{36} Few studies have been conducted on this subject, but because of the increased pri-

vacy (i.e. the woman would not have to go to the abortion clinic and be subjected to picket
lines) associated with the procedure and the non-invasiveness of the procedure, it appears
that at least some women would opt for the RU 486 procedure. At least one small study done
in England stated that 10 out of the 13 participants preferred the RU 486 to the surgical
method. Urquhart & Templeton, \textit{Acceptability of Medical Pregnancy Termination}, 1988 LAN-
CET 106.

\textsuperscript{37} Cahill, \textit{supra} note 9, at 5.

\textsuperscript{38} Kolata, \textit{supra} note 11.

\textsuperscript{39} Id.

\textsuperscript{40} 134 Cong. Rec. E 1328 (May 2, 1988).
Further, the argument that women will prefer RU 486 to contraception assumes that the RU 486 procedure is easier than avoiding the abortion decision and that the RU 486 procedure is less traumatic than current abortion procedures. Although women may prefer RU 486 because of its noninvasive nature and increased privacy as opposed to surgical abortion, the procedure may not be considered as "easy" as surgical abortion.

First, the length of the RU 486 procedure cuts against the argument that it is easier than surgical abortion. With RU 486 a woman will have to make at least 3 trips to her practitioner to complete the procedure. Further, the abortion with RU 486 is not complete for at least 24 hours. In a surgical abortion the procedure is performed and the abortion complete when the woman leaves the abortion clinic. Thus, the RU 486 places the burden of the abortion on the woman who can only be blatantly aware of the consequences of her choice.

Further, the argument that RU 486 will trivialize the abortion decision carries even less weight. With RU 486 there is the distinct possibility that the woman will be able to see the fetus that she aborts as the fetus may be expelled during the bleeding. This leads to the conclusion that women who abort using this procedure may be likely to experience more psychological distress and may be more aware of the consequences of their decision than with surgical abortion. Consequently, women will become even more conscious of their decision and perhaps even more likely to avoid abortions in the future.

The ethical arguments that the RU 486 procedure will frustrate contraceptive use and trivialize the abortion decision is certainly groundless. In fact, women may find that with RU 486 the abortion decision takes on greater significance because they are no longer passive witnesses to the procedure, rather they are the actor and they cannot deny responsibility for their choice.

C. The Effect of RU 486 on the Abortion Debate

Some commentators have expressed the opinion that RU 486

41. Silvestre, supra note 10, at 646.
43. Janet Callu, Associate Director of the Atlanta Feminist Women's Health Center said of the French women who have participated in the clinical trials that "[t]hey feel in control, conscious that they are doing this to themselves, not just as a patient." Lake, The New French Pill, 117 McCall's 62 (1990).
could have the effect of total diffusion of the abortion debate. Leonard Cole of Rutgers University suggests that, on a personal level regardless of legalities, the RU 486 may simply make abortion “a matter of fact” and thus, a “nonissue.” He cites the contraceptive debate of the mid-sixties for the proposition that technological advances aid in taking the issue from the public forum. Granted, the Supreme Court’s verdict in *Griswold v. Connecticut* helped clear up the contraceptive debate, but Professor Cole correctly states that “[n]o court edict, however, could suddenly uproot an individual’s moral rationale for opposing birth control.” He further asserts that the widespread use of “the pill” diffused the issue of “whether or not it should be used,” and focused the issue on whether or not a woman wanted to use the drug.

Likewise, RU 486 may make abortion simply a matter of fact rather than a matter of public debate. The abortion debate has *Roe v. Wade* to give it legal sanction in the same way *Griswold* gave legal sanction to contraceptive use. But, as Professor Cole points out, the contraceptive debate had a drug which took the debate from the public forum. And now the abortion debate possesses a drug which may be exactly what is needed to subside the public debate. Unfortunately, the abortion debate has a fetus where the contraceptive debate had only prevention of conception. This may be enough, even with *Roe* and RU 486, to keep abortion from becoming ‘a matter of fact’.

On a more concrete level, RU 486 may have the effect of taking some of the abortion opponents’ political tools out of their arsenal and, at least, reduce the furor of the debate. For example, even though RU 486 should be taken under medical supervision, that supervision can be obtained from any doctor not necessarily from an abortion clinic. Thus, the Right to Life activists may find themselves without a place to picket and protest. On that same line, because the fetus is aborted at a very early stage, the abortion opponents may lose one of their most effective weapons — gory pictures of aborted fetuses. Finally, public concern over abortion appears to be linked to the gestational age of the fetus, thus, the early abor-

45. 381 U.S. 479 (1965).
47. *Id.* (emphasis added).
50. *Id.*
tion performed with RU 486 may reduce public concern over abortion. This lessening of the public outcry coupled with the loss of certain visible political tools may just “rescue the nation from a political nightmare” as Cole predicts.\textsuperscript{52}

At the legal level, RU 486 may strengthen the woman’s privacy interest and therefore help to diffuse the abortion debate within the courts. The woman’s privacy interest is strengthened because RU 486 can be taken at home. The Court in \textit{Griswold} placed great emphasis on the ability of the state to police the use of contraceptives and the inherent notion that the decision to use contraceptives fell within the “privacies of life.”\textsuperscript{53} The Court further stated that it would be repulsive to our sense of liberty to allow the police to enter a bedroom to look for “telltale” signs of contraceptive use.\textsuperscript{54} As in \textit{Griswold}, the fact that the act is done in the privacy of the home as opposed to the medical setting may bring the privacy interest further within the realm of \textit{Griswold} and “the privacies of life.”\textsuperscript{55}

However, this does not appear to be a realistic distinction. Even though the majority in \textit{Griswold} noted that the privacy of the marital bedroom and marriage in general were of foremost concern,\textsuperscript{56} cases such as \textit{Eisenstadt v. Barid}\textsuperscript{57} and \textit{Carey v. Population Services International}\textsuperscript{58} further clarified and limited the holding in \textit{Griswold}. The Supreme Court stated in \textit{Eisenstadt} that “it is the right of the individual to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.”\textsuperscript{59} Hence, the focus is not on the physical place where the act takes place which grants it protection; it is the privacy interest in making the decision which grants it constitutional approval. The privacy interest in the abortion debate is simply whether a woman has the right to choose to terminate a pregnancy.

However, even though RU 486 may not strengthen the woman’s privacy interest, it may weaken the states’ ability to intrude upon this private decision making. Because RU 486 is used so early in

\begin{thebibliography}{9}
\bibitem{52} Cole, \textit{supra} note 44, at 223.
\bibitem{53} 381 U.S. 479, 483 (1965).
\bibitem{54} \textit{Id.}
\bibitem{55} \textit{Id.}
\bibitem{56} \textit{Id.}
\bibitem{57} 405 U.S. 438 (1972) (right to privacy extends to unmarried persons’ access to contraception).
\bibitem{58} 431 U.S. 678 (1977) (state may not require only licensed pharmacists to distribute contraception).
\bibitem{59} 405 U.S. at 488.
\end{thebibliography}
the pregnancy, the states' interest may not be strong enough to trump a woman's fundamental right to make personal decisions regarding childbirth. Even though *Webster v. Reproductive Health Services* significantly narrowed the holding in *Roe v. Wade* it did not overrule *Roe*'s main holding — that a woman has a fundamental right to decide whether to bear a child. In *Webster*, the Court decided that the trimester framework of *Roe* had lost its usefulness due to the advances of medical science. The simple holding of the Court was that the state had a compelling interest in protection of potential life at viability and therefore could require testing to determine viability. This holding in no way changes the fact that a woman still has a fundamental right to privacy, including the right to abort her pregnancy. The only thing that has changed is the nature of the state's interest at different points in the pregnancy. RU 486 is used early in the pregnancy, and therefore, it is doubtful that the state could advance a compelling enough interest in potential life prior to eight weeks which would override the woman's right to privacy. Thus, so long as a woman still has a right to an abortion, the use of the RU 486 procedure may help to protect and reinforce that right.

All of the above comments are, of course, speculative but regardless of the specific effects that RU 486 may have on the practice of abortion and the abortion debate, the fact remains that this potent drug will have some sort of impact. The opponents of RU 486 fear this impact and appear willing to use everything within their power to prevent the use of RU 486 in the United States. The remainder of this paper will focus on what forces could withhold RU 486 from U.S. women and how politics plays a role in that withholding.

61. 401 U.S. 113 (1973).
62. 109 S.Ct. at 3058 ("This case therefore affords us no occasion to revisit the holding of *Roe*, which was that the Texas statute unconstitutionally infringes on the right to an abortion derived from the Due Process Clause, and we leave it undisturbed"(citations omitted)).
63. *Id.* at 3056.
64. *Id.* at 3056-57.
65. The rest of the paper assumes that a corporation, either Rousell or an American corporation, will choose to market RU 486 in this country. This is, of course, a huge leap of faith because a corporation will need to decide first whether there is a market large enough for the drug; whether the venture would be profitable. Corporations do not "champion" causes unless those causes will be profitable. Second, the corporation will need to deal with the inhospitable legal climate in the U.S concerning products liabilities. One of the major reasons cited for the lack of reproductive technologies entering the market is the huge cost of defending, not to mention losing, products liabilities law suits. And lastly, the corporation will need to be able to survive the abortion politics in the U.S.. There is always the potential
IV. GOVERNMENTAL OBSTACLES

A. FDA Approval Process

What impact RU 486 will have on abortion practices and whether, in fact, it will diffuse the abortion debate is really a moot point at present. Until RU 486 is made available in the United States we will not know the answers to those questions. RU 486 has numerous obstacles to overcome before it will be available in the U.S., and one of the most significant appears to be approval by the federal Food and Drug Administration (FDA).

Generally, before any drug intended for human use can be shipped in interstate commerce, it must be approved as "safe and effective" by the FDA.66 This "safe and effective" standard is met by a showing of "substantial evidence" in support of the safety and effectiveness of the drug.67 In order to meet this requirement, a manufacturer must first conduct tests on animals, and then include these results in its application for an Investigational New Drug exemption (IND).68 The IND allows the manufacturer to ship the drug in interstate commerce for further testing on humans.69 The results of these clinical studies on humans, which take two to ten years to obtain, become the basis for a New Drug Application (NDA) which permits the drug to be marketed. The FDA then reviews the application to determine 1) if the drug is safe and effective, 2) whether it can be manufactured consistently, and 3) whether the benefits of the drug outweigh the risks.70 This is an extraordinarily burdensome and expensive procedure71 but is typically the only procedure for boycott from the anti-abortionists. Also, the company must take into consideration the instability of the right to abortion. But see supra notes 44-64 and accompanying text.

66. Federal law states that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) . . . of this section is effective with respect to such drug." 21 U.S.C. § 355(a) (1984).

67. 21 U.S.C. § 335(d) (1984). The burden of showing that there is substantial evidence is on the manufacturer of the drug. This burden is met by "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug. . . [and to] conclude[] . . . that the drug will have the effect it purports or is represented to have . . . ." 21 U.S.C. § 335(d).

68. Issacs & Holt, Drug Regulation, Product Liability and the Contraceptive Crunch: Choices are Dwindling, 8 J. LEGAL MED. 533, 534 (1987).

69. 21 C.F.R § 335(i) (Supp. VI 1986) (exemption of "drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs" from the requirements of § 335(a)-(h)).

70. Issacs, supra note 68, at 536. The FDA's review primarily consists of a review of the evidence presented by the manufacturer.

71. The estimated cost to a manufacturer of introducing a single new contraceptive is 50
way to introduce a drug into interstate commerce.

An alternative to this process may be available for RU 486. In the past, the FDA required at least some of the data presented for the basis of approval to be from studies done in the United States.\textsuperscript{72} In 1985, however, the FDA promulgated new regulations for the NDA which allow approval of a new drug solely on the basis of foreign data. This regulation states:

(b) As sole basis for marketing approval. An application based solely on foreign clinical data meeting U.S. criteria may be approved if: (1) The foreign data are applicable to the U.S. population and U.S. medical practice; (2) the studies have been performed by clinical investigators of recognized competence; and (3) the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means.\textsuperscript{73}

This regulation recognizes that the FDA's foremost consideration must be the quality of the data submitted, not the country of origin.\textsuperscript{74} Although there is concern over certain problems with foreign data, the FDA believes that the regulation addresses these concerns.\textsuperscript{75}

Most of the numerous studies conducted on RU 486 have been done in foreign countries,\textsuperscript{76} thus it would seem that the most expedient way to bring RU 486 to the United States market is to seek FDA approval based solely on foreign data. The problem with this approach is that the FDA has considerable leeway in deciding whether it will actually approve the drug solely on foreign data.

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\textsuperscript{73} 21 C.F.R. § 314.106(b) (1985).
\textsuperscript{74} 50 Fed. Reg. at 7483.
\textsuperscript{75} Id. at 7484. Of foremost concern is that the data presented is from "adequate and well-controlled investigations."
\textsuperscript{76} All of the studies conducted on RU 486 are far too numerous to mention. A selected few include: Couzinnet, Le Strat, Ulmann, Baulieu, Schaison, \textit{Termination of Early Pregnancy by the Progesterone Antagonist RU 486 (mifepristone)}. 315 New Eng. J. Med. 1565 (1986) (French study); Cameron & Baird, \textit{Early Pregnancy Termination: a Comparison Between Vacuum Aspiration and Medical Abortion with Prostaglandin or the Antiprogestogen RU 486}, 95 Br. J. Obst. Gyn. 271 (1988) (British study); Silvestre, Dubois, Renault, Rezvani, Baulieu, & Ulmann, \textit{Voluntary Interruption of Pregnancy with Mifepristone (Ru 486) and a Prostaglandin Analogue}, 322 New Eng. J. Med. 645 (1990) (French study). All of these studies have confirmed that RU 486 is safe and effective.

\textsuperscript{76} Galen, \textit{Birth Control Options Limited by Litigation}, Nat'l L. J., Oct. 20, 1986, at 28. See also Rutherford v. American Medical Association, 379 F.2d 641, 643 (7th Cir. 1967) ("The fact that compliance might be expensive and burdensome is not unfairness in the procedure, but a consequence of a reasonable Congressional scheme for the introduction of new drugs").

First, the foreign data may be attacked on the grounds of the competency of the investigators. However, based on the international reputation of the researchers at Rousell, this attack may be fruitless. Further, the data may be attacked on the grounds of its validity or the impossibility of an on-site inspection by the FDA inspectors. Disputes on the validity of the experiments seem unlikely because the results of the studies submitted by Rousell have already been duplicated. Lastly, the investigations themselves can be attacked on the requirement that they be “adequate and well-controlled studies.”

However, should the FDA decide not to allow foreign data to be used, RU 486 could still proceed through the normal FDA approval process. There have already been clinical trials of RU 486 as an abortifacient in the United States. In 1986, the University of Southern California tested the drug on approximately 400 women at a variety of doses in different stages of pregnancy. Further research is still being conducted at USC. Doctor Misell, director of the research, described his work as “general research” which constituted second-stage FDA trials in order to determine the correct dosage at the various stages of pregnancy. Based on the extensive use of the RU 486 in France and the research done at USC, there appears to be enough existing data for submission and approval by the FDA.

The question remains, however, whether the FDA will actually approve RU 486. The FDA is charged with the responsibility of determining whether a drug is “safe and effective.” This means that the FDA will investigate whether the drug does what the manufacturer says that it does (effectiveness) and whether the benefits of using the drug outweigh the risks of using the drug (safety). Applying this standard to RU 486, the FDA would be hardpressed not to approve the drug. The most recent report on RU 486 shows that it has an effectiveness rate of 96% and more importantly that it

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78. Id.
79. 21 U.S.C. § 335(d).
80. Palea, supra note 13, at 1321.
82. Id.
83. Kolata, supra note 11.
84. 21 C.F.R. § 355(d).
lacked "any major health risks or side effects." 86 Another study shows that the RU 486 procedure is as effective as vacuum aspiration and that it "offers an effective alternative to surgery for early abortion." 87

Opponents of the drug cannot dispute that the drug is effective as a means of abortion. What is disputed is whether the drug meets the standards of safety. Opponents of the drug argue that taking the drug may be "risky". They point to the possibility of hemorrhaging and the possibility of incomplete abortions leading to infections which might impair future fertility and conclude that these risks are too great. 88

On their own these concerns might be valid; but when viewed in relation to other means of abortion these concerns lose their validity. The RU 486 procedure does fail in about 4% of the cases, but this is comparable to the failure rate of vacuum aspiration. 89 Further, the incidence of hemorrhaging which indicates transfusion, appears to be no more frequent than in vacuum aspiration. 90 Finally, even the possibility of ectopic pregnancies which would not be aborted by RU 486 and the possibility of failure are not sufficient reasons for the FDA to withhold approval. Rather, these possibilities argue strongly for the medical supervision which would be provided as a result of FDA regulation of the drug and the procedure. 91

Certainly, the FDA must take these risks into account in an effort to ensure the "safety and effectiveness" of the drug. The weight assigned to these risks will depend on the various factors that go into the decision making process. One of these factors may unfortunately be the politics of the abortion debate discussed in the next section.

V. POLITICAL BARRIERS

RU 486 seeks to enter the United States at a time when the

86. Silvestre, supra note 10.
88. Kolata, supra note 11.
89. A British comparison of vacuum aspiration and RU 486 shows that the failure rate of 4% with vacuum aspiration and 5% with the RU 486 procedure. Silvestre, supra note 10. Vacuum aspiration is the most commonly used technique for early abortions. Cameron & Baird, supra note 87.
90. Id.
91. Silvestre, supra note 10, at 648.
abortion debate has created an inhospitable political climate. For example, the Bush Administration has supported restrictions on RU 486 presented by conservative legislators. Further, it is currently illegal for the National Institutes of Health to support any research on any abortifacient such as RU 486. And finally, the FDA has already placed restrictions on RU 486. In June of 1989, the Commissioner of the FDA, Frank Young, wrote to Representative Robert K. Dornan of California, with a guarantee that the FDA would not permit the RU 486 to be imported for personal use, something that the FDA has allowed for other drugs. Therefore, it is quite possible that regardless of the medical progress that RU 486 represents, and regardless of the fact that the drug may be wholly “safe and effective,” abortion politics may present a major barrier to the introduction of RU 486 to the U.S. market.

A. Congressional Politics

The abortion debate has long been an element of the congressional agenda and has strong supporters on both sides. Consequently, it is possible that Congress may use its political power to prohibit the introduction of RU 486 into the U.S. market. Such congressional action has, in fact, been attempted. In 1986, Representative Robert Dornan of California presented a limitations rider to the Department of Health and Human Services appropriations bill which attempted to limit the jurisdiction of the FDA concerning the approval of RU 486. The amendment stated:

"No funds under this Act may be used by the Secretary of Health and Human Services - (1) to continue an exemption under Section 505(i) of the FDCA for the drug RU 486 when used as a drug to cause an abortion or as an abortifacient; or (2) to consider any application under section 505 of such Act of the approval of a new drug application for such drug used for such purpose."

The use of limitation riders has been consistently criticized. As a means to establish public policy, the appropriations process is incomplete and the implementation of limitation riders is plagued by practical problems. But, Congress often resorts to limitation riders when faced with an emotional issue which needs, in Congress'
eyes, immediate attention such as in response to pending or recent agency action or to large scale public protest of court rulings. Obviously, Representative Dornan saw that RU 486 needed the immediate attention of Congress. The rest of his colleagues did not and the amendment was dropped.

The constitutionality of the limitation rider is not disputed, but it is not without limits. First, an appropriations rider cannot impose additional duties on an agency or require judgments and determinations not otherwise required by law. This simply means that Congress can not “legislate” in the appropriation riders; they can only “appropriate.” Furthermore, the action taken by the appropriations rider cannot be in violation of the Constitution. Thus, if a “Dornan” type amendment was in fact passed prohibiting approval of RU 486, two issues would be raised: first, whether the amendment imposed additional duties on the agency and second, whether the amendment directs the agency to act in violation of the Constitution.

Assuming that Congress passed the Dornan Amendment, this amendment might be challenged because it imposes additional duties on the FDA. This type of challenge defeated some of the early Hyde Amendments which prohibited the use of Medicaid funds for abortion. The first Hyde Amendment prohibited the use of federal funds except where the life of the mother was in danger. The House Chair found that the amendment could not stand because the administrative agency would have to determine whether the mother’s health was, in fact, in danger. This would impose additional duties upon the agency.

In the case of the Dornan Amendment, it is possible that the FDA would need to determine if the drug was to be used “to cause an abortion or as an abortifacent.” However, this seems tenuous because in order for a manufacturer to get an investigational new drug exemption under section 505(i) of the FDCA, the manufac-

97. *Id.* at 462.
98. Unfortunately, the final disposition of the amendment is unclear. There is no record of the rejection of the amendment, there is only the final bill which does not include the Dornan amendment. See H.R. 4783.
100. H.R. 21, cl.2, § 843 (reprinted in H.R. Doc. No. 403, 95th Cong., 2d Sess. 534 (1979)).
101. See Devins, *supra* note 96, at 474. The basic idea is that Congress cannot do anything that is in violation of principles embodied in the Constitution.
103. *Id.*
turer has the burden of proving that the drug is safe for its intended use and would be required to state its use as an abortifacient.\textsuperscript{104} Thus, the amendment would not place any "additional duties not required by law"\textsuperscript{105} upon the FDA.

The only other way that the Dornan amendment could be invalidated is by constitutional challenge. One might argue that the prohibition of the FDA’s approval of RU 486 is unconstitutional as a denial of due process of law, in violation of the fifth amendment of the Constitution.\textsuperscript{106} The Supreme Court in \textit{Roe v. Wade},\textsuperscript{107} held that the right to privacy implicit in our concept of ordered liberty, encompasses a woman's decision whether or not to terminate her pregnancy.\textsuperscript{108} That fundamental right has not been withdrawn. Even though the Supreme Court in \textit{Webster v. Reproductive Health Services}\textsuperscript{109} narrowed the holding in \textit{Roe},\textsuperscript{110} the fundamental right to an abortion has remained strong.\textsuperscript{111}

However, even though women have the right to seek an abortion, it is settled law that the government is not under a positive obligation to aid in the exercise of that fundamental right.\textsuperscript{112} Constitutional rights are typically conceptualized as simply immunities from active governmental abridgment.\textsuperscript{113} This principle was used in \textit{Harris v. McRae}\textsuperscript{114} to allow the "Hyde Amendment" to withstand constitutional scrutiny. The Hyde Amendment, in the form of a limitations rider, denied federal funding under Medicaid for any abortion.\textsuperscript{115} The appellant argued that by not funding abortion the United States government denied indigent women the right to an abortion.

The Supreme Court found that the Hyde Amendment left "indigent women with at least the same range of choice in deciding

\textsuperscript{104} 21 U.S.C. § 335(d).
\textsuperscript{105} House Rules, \textit{supra} note 100.
\textsuperscript{106} U.S. CONST. amend. V (No person shall be... deprived of life, liberty, or property, without due process of the law...).
\textsuperscript{107} 410 U.S. 113 (1972).
\textsuperscript{108} \textit{Id.} at 153.
\textsuperscript{109} 109 S.Ct. 3040 (1989).
\textsuperscript{110} \textit{Id.} at 3058 ("To the extent indicated in our opinion, we would modify and narrow Roe... ").
\textsuperscript{111} The Court in \textit{Webster} simply enlarged the time at which the state’s interest becomes compelling, which would in effect narrow the scope of the abortion right. But it did not change the fact that the right to privacy still encompasses the right to seek an abortion.
\textsuperscript{113} \textit{Harris v. McRae}, 448 U.S. 297, 315-17 (1980).
\textsuperscript{114} \textit{Id.}
\textsuperscript{115} 123 Cong. Rec. 19,700 (1977).
whether to obtain a medically necessary abortion as she would have had if Congress had chosen to subsidize no health care costs at all."\textsuperscript{116} Even though it found that the government did not have to remove obstacles to choice, the Court affirmed the fact that "the government may not place obstacles in the path of a woman's exercise of her freedom of choice."\textsuperscript{117}

Thus, realizing the fact that Roe still stands, that women have the right to seek an abortion, and that although the government does not have an obligation to fund abortion, the government may not place obstacles in the way of the exercise of freedom of choice, the Dornan Amendment appears unconstitutional as an obstacle to a woman's right to an abortion. By denying the FDA jurisdiction over RU 486, the United States government would have removed that option from the realm of choice. This would not have been a matter of removing obstacles to choice, as in Harris. Rather, the denial of approval would have been an affirmative obstacle in the way of a woman's choice in violation of the fifth amendment's due process clause.

Of course, there is the argument that through the Dornan Amendment the government would not have infringed upon a woman's right to choose. As in Harris, the choice to terminate a pregnancy is still present but simply limited to those procedures currently available. Also, by approving RU 486 the government would be using federal funds to fund abortion which Harris and Maher make clear it is not obligated to do. However, even though the government is not obligated to fund abortion, it is obligated to refrain from creating obstacles to that choice. Because RU 486 cannot become a legal choice without governmental approval, denial of that approval based solely on the politics of abortion would be an obstacle to choice which the government cannot create.

Thus, it appears that Congress could not constitutionally prohibit the approval of RU 486 by the FDA. Of course, any decision on the constitutionality of Congress' action is made by the Supreme Court and because there are arguments on both sides, the decision remains unresolved.

B. The FDA and Politics

Presently, without any outright political move by Congress, the only governmental obstruction to the introduction of RU 486

\textsuperscript{116} 448 U.S. at 317.
\textsuperscript{117} Id.
would be a refusal by the FDA to approve the drug. All the medical data seem to indicate that the drug is "safe and effective." But that decision rests with the FDA. What factors the FDA uses to refuse approval for the drug may cause some concern. Can and should abortion politics be one of these factors? The question then becomes — if the FDA does not approve the drug, on what grounds could a non-approval decision be challenged?

Within certain limits, patients have a constitutional right to choose among various treatments for their conditions. For example, in *Andrews v. Ballard* 118 and *Rogers v. State Board of Medical Examiners*, 119 the courts held that the constitutional right of privacy encompassed the patients access to a particular form of treatment. In neither case, however, did the patients seek access to an unapproved treatment. 120 Further, the Tenth Circuit in *Rutherford v. United States*, 121 held that although cancer patients had a constitutional right to decide whether or not to seek treatment, the ability to receive a particular treatment or at least a medication was within the legitimate area of governmental interest in protecting health. 122 Thus, it appears that if the FDA did not approve RU 486, a woman could not claim an invasion of a constitutional right to choose the RU 486.

There may, however, be an argument that in disapproving RU 486 the FDA acted arbitrarily and irrationally in violation of its statutory mandate. 123 In resolving the safety and effectiveness issue, the FDA will weigh the drug's potential benefits against the risks entailed in using the drug. 124 The approval of an NDA by the FDA must rest on substantial evidence and further the FDA must refuse approval of an NDA if there is "a lack of substantial evidence that

119. 371 So. 2d 1037 (Fla. Dist. Ct. App. 1979), aff'd on other grounds, 387 So. 2d 937 (Fla. 1980).
120. In *Andrews*, the plaintiffs sought access to acupuncture which the state sought to regulate out of existence. The District Court found that the statute was unconstitutional because the state had no compelling state interest. 498 F. Supp. at 1041.
121. 616 F.2d 455 (10th Cir.), cert. denied, 449 U.S. 937 (1980).
123. § 706(2)(A) of the Administrative Procedure Act states that a reviewing court "shall... (2) hold unlawful and set aside agency action, findings and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A) (1986). Further, the FDA's statutory mandate directs the FDA to decide approval issues based on a substantial evidence standard. 21 U.S.C. § 355(d)(5) (the Secretary may refuse approval if "there is a lack of substantial evidence" in support of the safety and effectiveness of the drug (emphasis added)).
the drug is effective. Substantial evidence is defined by statute as evidence consisting of adequate and well-controlled investigation, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports to have...

This substantial evidence standard appears rather objective, but it is possible that the FDA could manipulate the standard and find that 1) the studies were not adequate and well-controlled or 2) that the experts who did the studies were not of sufficient competency to evaluate the drug. Thus, the question on judicial review would be whether the FDA's refusal was justified based on the lack of substantial evidence presented by the manufacturer. As was discussed above, there appears to be enough evidence to substantiate the claim that RU 486 is safe and effective. Thus, the FDA would need to be certain that it was not the abortion politics which caused the denial of approval for RU 486.

Another possible argument which may lead to some recourse for the manufacturer of RU 486 if the FDA were to refuse approval is the rule of law that "an administrative hearing of such importance and vast potential consequences must be attended, not only with every element of fairness but with the very appearance of complete fairness." This means that the persons who make the determination of approval or disapproval must not have shown any tendency that they "pre-judged" the application before hearing all the evidence. The implications of this pre-judgment rule for RU 486 is that any person within the FDA who sits in judgment of RU 486 must not have stated views that he or she would not approve the drug. If they do so, they must be disqualified. Frank Young, Commissioner of the FDA, informed Representative Dornan that the FDA would not allow RU 486 to be brought into the country for personal use. This may lead to his disqualification from the hearing board of RU 486's application because it could be argued that he has already pre-judged the drug and thus would deny the manufacturer due process as a result. It could be argued, however, that the decision to allow importation for personal use is based on other factors,

unlike those used to approve the drug for marketing and thus have no bearing on his views on the safety and effectiveness of the drug.

All of this discussion, of course, assumes that politics may infiltrate the FDA's decision making process and that as a result the FDA would not approve the drug. This may not be true however. In prior years the FDA has received requests not to approve a drug simply based on abortion politics. When Searle sought approval of a drug used to treat ulcers, the FDA was inundated with requests by abortion opponents not to approve the drug because one of the side effects of the drug was the causing of abortion.129 Abortion opponents feared that the drug would be used primarily for abortion.130 The FDA approved it nonetheless.131 Thus, it appears that the FDA may not be susceptible to influence by politics and would base its approval or refusal simply on the objective criteria set forth by statute.

VI. NEED FOR GOVERNMENTAL REGULATION OF RU 486

Although it appears that there may be ways to ensure that the politics of abortion do not infiltrate the approval process of RU 486, it is possible that it may. It is also possible that Congress may find some constitutional way to ensure refusal of RU 486, but that refusal to approve may not be a wise thing to do. Many commentators have suggested that without governmental regulation an illegal black market would make the drug available.132 A black market might be supplied by doctors receiving the drug from Roussell or wholesalers. There is also the possibility of any chemist synthesizing the drug.133 Thus, it is quite possible that if the United States government does not regulate the RU 486 there will be a black market and the dangers of misuse associated with a black market.

The potential for misuse of a black market for RU 486 poses a great threat to the safety of women in the U.S. The drug, without a doctor's supervision, may be used later in a pregnancy which could lead to hemorrhaging without termination of the pregnancy. There is also the possibility of an incomplete expulsion which could result in infection.134 Further, there would probably be no follow up medi-

130. Id.
131. Id.
132. Id. at 17.
133. Id.
cal supervision to alert the woman to the need for medical attention until it was too late.\textsuperscript{135} Lastly, those who would be likely to obtain the drug on the black market would be those to whom the government should give the most protection — teenagers, the uneducated, and the poor.

The fact of the matter is that RU 486 will get to the market because of its potential in other areas of medicine. It is this fact which speaks strongly for its approval and regulation by the FDA. "Once a drug is approved by the FDA for one use, there is no federal law prohibiting a doctor from prescribing it for other reasons."\textsuperscript{136} Thus, there would be an even greater supply for the black market, and the drug would be used for abortion whether the government likes it or not.

\textbf{VII. CONCLUSION}

RU 486 presents an interesting case study in medicine and politics. Many think that politics should not play any role in medical decisions at all. In 1986, after Roussell announced its decision to withdraw RU 486 from the market, the French government threatened Roussell with a transfer of its patent. The Minister of Health, Claude Evin, stated that he could not permit the abortion debate to deprive women of a product that represents medical progress. From the moment governmental approval was granted, RU 486 became the moral property of women, not just the property of the drug company.\textsuperscript{137} The key in this statement is that the RU 486 represents medical progress. In line with this comment, George Annas, professor of health law at Boston University, put the debate in solid terms. He asks: "What if there was an effective pain-killer developed in another country but a group thought it was better to suffer than introduce it into the U.S. market. I feel that, just as it should be a personal choice whether suffering is redemptive or a bad thing, it should be a personal choice what procedure a person uses to accomplish a [permissible] goal."\textsuperscript{138}

The fact remains that abortion is not only a permissible medical decision but a constitutional right. Doctors are angered by what they see as infringement of politics on what they regard as sound

\textsuperscript{135} Id.


\textsuperscript{138} Boston Globe, Oct 2, 1988, at 3 col. 1.
and necessary medical practice. Likewise, women are angered by what they see as the minority dictating to them what risks they must subject themselves to in order to exercise their Constitutional right to an abortion. RU 486 would allow many women to avoid surgical abortion with the concurrent risks of infection, cervical injury, and uterine perforation. Further, RU 486 would grant the abortion decision the privacy that it deserves. We, as a society, must offer people the best that science can provide so that there may be more flexibility and personal initiative in the control of familial and social problems. RU 486 would provide that flexibility and personal initiative.

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140. Baulieu, *supra* note 4, at 1355.
141. *Id.*