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Implications of FDA Approval of RU-486: Regulating Mifepristone Within the Bounds of the Constitution

BY BRADLEY E. CUNNINGHAM*

INTRODUCTION

On September 28, 2000, the United States Food and Drug Administration ("FDA") approved mifepristone (commonly known as RU-486) for sale in the United States.1 Mifepristone, dubbed by some as the "abortion pill,"2 was developed in 1982 by French researcher Dr. Etienne-Emile Baulieu3 and approved in France in September 1988.4 Soon thereafter, other European nations, including Great Britain and Sweden, followed suit in approving the drug.5 The controversy surrounding abortion in the United States, however, delayed approval of mifepristone on this side of the Atlantic.6 In fact, in 1989 the Bush administration implemented a ban on the importation of mifepristone.7 In the wake of FDA approval, the question now facing legislatures, and eventually the courts, is how to regulate mifepristone within the bounds of the Constitution.8

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5 See Muhl, supra note 3, at 322.
6 See Richards, supra note 4, at 126.
The purpose of this Note is to explore the different options now available to legislatures, both at the state and federal levels, seeking to regulate the use of mifepristone and the chances for such measures to survive judicial scrutiny. Regulating this drug is especially difficult because mifepristone blurs the traditional line between abortion and contraception.9 Part I of the Note generally explains how mifepristone works, including a discussion of its various uses and possible adverse affects.10 Part II sets forth a summary of the current constitutional standards that govern abortion, including an examination of how other commentators have proposed that such standards might apply to mifepristone.11 Part III examines the options available to Congress and state legislatures in regulating mifepristone and the inherent difficulties that such regulations must address.12 This section examines the tightrope that state legislatures must walk in order to enact meaningful legislation that will survive judicial scrutiny. Finally, Part IV concludes with a discussion of the broad social implications that the debate over mifepristone will certainly bring to the forefront of the United States’ domestic social agenda during the (second) Bush administration and beyond.13

9 Id. at 732. The distinction between contraception and abortion is blurred because mifepristone can be effective “before fertilization, in the ‘grey’ period between fertilization and implantation, and after implantation.” Id. The “grey” period has been largely ignored because, before the introduction of mifepristone, all methods of preventing pregnancy fell neatly under the categories of either contraception or abortion. See id.

10 See infra Part I. In order to understand all of the complexities inherent in the regulation of mifepristone, one must fully appreciate how the drug operates. Without a baseline understanding of the underlying science, a thorough legal analysis is all but impossible.

11 See infra Part II. Since the drug only recently achieved FDA approval, there is no case law directly addressing the recent legislation targeted at mifepristone. Therefore, any discussion of paradigms for regulation must begin with an examination of the seminal Supreme Court cases dealing with abortion and contraception. Equally important in this respect is an overview of how other commentators have addressed the problem of applying those existing judicial standards to a completely new technology.

12 See infra Part III. At the federal level, the focus of this Note is on the proposed “RU-486 Patient Health and Safety Act.” S. 251/H.R. 482, 107th Cong. (2001). At the state level, the focus is on proposed legislation in Kentucky. See infra notes 141-48 and accompanying text.

13 See infra Part IV. George W. Bush’s victory in the 2000 presidential election has predictably changed the political landscape as it relates to abortion, contraception, and mifepristone.
Mifepristone was originally developed in 1982 by French researcher Dr. Etienne-Emile Baulieu. The French government approved mifepristone in September 1988, and the drug was first marketed by the French pharmaceutical company Roussel-Uclaf. On October 26, 1988, Roussel-Uclaf suspended distribution of the drug due to a threatened boycott by Roman Catholic groups and threats from militant pro-life organizations in the United States. Four days later, however, the French Minister of Health intervened, ordering the company to resume distribution or have its patent revoked. The drug has since been approved for use in Great Britain and Sweden.

Approval in Great Britain and Sweden, however, was no guarantee that approval in the United States would logically follow. Fears of the hostile social and political environment surrounding abortion in the United States have always made Roussel-Uclaf reluctant to pursue marketing the drug in this country. In 1989, the first Bush administration banned mifepristone from import into the United States by individuals. Abortion is a dominant political issue, and the pro-life Bush administration was determined to keep the drug out of this country.

The inherent administrative hostility towards abortion, however, eased with the election of President Clinton. In early 1993, that administration...
made lifting the import ban on RU-486 a top priority and ordered a reexamination of the existing FDA policy. This constituted an important shift in policy and paved the road for ultimate FDA approval.

One of the major obstacles in bringing mifepristone to the United States was finding a distributor willing to market it in a country where hostility towards abortion runs high. In April 1993, Roussel-Uclaf announced that it had given the Population Council, a New York-based nonprofit research institution, the U.S. rights to mifepristone. The Population Council subsequently conducted clinical trials involving over 2000 women in the United States which proved that mifepristone is safe and effective for early abortion. The results of those tests, which ran from September 1994 to September 1995, were published in the New England Journal of Medicine in 1998. After the clinical trials, the FDA conditionally approved mifepristone in September 1996. Although the FDA concluded that the drug was safe and effective, it noted that there were some additional issues that needed to be addressed by the Population Council before final approval could be obtained. Such issues included providing additional manufacturing, labeling, and other information. Finally, on September 28, 2000, the FDA approved mifepristone for sale in the United States.

B. How Mifepristone Works and Its Relevant Safety Issues

Although the end result is essentially the same, mifepristone gives women a viable alternative to aspiration abortion. Mifepristone is a drug

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24 This is not to say, however, that there is not some anti-abortion sentiment in Europe as well. At a meeting of the Roussel-Uclaf stockholders in 1988, protesters outside equated mifepristone to the gas chambers of Nazi Germany, shouting, “You are turning the uterus into a crematory oven!” Brooks, supra note 15, at 268.
28 See Kim Painter, RU-486 May Be Available in U.S. Next Year, USA TODAY, Sept. 19, 1996, at 1A.
29 Id.
30 Id.
31 Kaufman, supra note 1, at A1.
32 Aspiration abortion is commonly referred to as “suction abortion” or “vacuum aspiration.” This procedure involves “insertion of a vacuum tube (cannula) into the uterus to evacuate the contents. Such an abortion is typically performed on an
that blocks receptors of progesterone, a key hormone in the establishment and maintenance of human pregnancy.\textsuperscript{33} Mifepristone induces abortion when administered in early pregnancy and when followed by a dose of synthetic prostaglandin, a drug that causes uterine contractions and that makes mifepristone more effective.\textsuperscript{34}

Medical abortions using mifepristone have become fairly common in Europe, where approximately 500,000 women have used the drug.\textsuperscript{35} The clinical trials sponsored by the Population Council showed mifepristone to be effective in terminating ninety-two percent of pregnancies up to forty-nine days in duration.\textsuperscript{36} In addition, ninety-six percent of women in the same clinical trial indicated that they would recommend the drug to others as an alternative to aspiration abortion.\textsuperscript{37} The studies indicate that mifepristone is a safe alternative to aspiration abortion for women seeking abortion of pregnancy of forty-nine days or less.\textsuperscript{38} Furthermore, it is an entirely noninvasive procedure and does not involve the risks associated with anesthesia.\textsuperscript{39}

Mifepristone, like most other drugs, presents the possibility of adverse side effects.\textsuperscript{40} Although many of the side effects are relatively harmless, there is a potential for serious side effects in some women.\textsuperscript{41} Possible unwelcome side effects include bleeding, nausea, fatigue, and hemorrhaging.\textsuperscript{42} In a typical case, bleeding and spotting will last between eight to ten days.\textsuperscript{43} In about one of one hundred women, though, bleeding can be so heavy that a surgical procedure will be required to stop it.\textsuperscript{44}

Besides terminating pregnancy, many other possible uses for mifepristone have been identified by researchers.\textsuperscript{45} These other beneficial uses
include the treatment of breast cancer, non-malignant brain tumors, Cushing’s syndrome, AIDS, diabetes, depression, and obesity. Additionally, in small doses mifepristone can be used to prevent pregnancy in much the same manner as the “morning-after pill,” a method of emergency contraception that is effective within five days of unprotected intercourse.

II. THE APPLICABLE CONSTITUTIONAL STANDARDS

The U.S. Supreme Court first addressed abortion in the landmark case of Roe v. Wade. In what has become one of the most hotly-debated Supreme Court decisions ever, the Court held that women have a constitutionally protected right to obtain an abortion and that such a right is fundamental. The Court’s recognition of abortion as a fundamental right was significant. A right that is deemed fundamental can only be limited by state regulation if such regulation is justified by a “compelling state interest.” The Court held further that the implied right of privacy embodied in the Fourteenth Amendment and other amendments limiting state power against the individual were sufficiently implicated by a woman’s decision to maintain or terminate a pregnancy. The Court adopted a framework for state regulation that was based on dividing the term of pregnancy into trimesters. In the first trimester, states could not prevent a woman from obtaining an abortion, and doctors had sole discretion to decide whether or not they wanted to perform the procedure.

46 Id.
47 See Anna Glasier et al., Mifepristone (RU 486) Compared with High-Dose Estrogen and Progestogen for Emergency Postcoital Contraception, 327 NEW ENG. J. MED. 1041 (1992). It is a common misconception that mifepristone and the “morning-after pill” are one and the same. This is not the case. Whereas the “morning-after pill” is only effective soon after fertilization, mifepristone can be used as an abortifacient up to approximately seven weeks following fertilization. See Westside Pregnancy Resource Center, Emergency Contraception or Abortion?: About Abortion Pills, at http://www.w-cpc.org/sexuality/ecp.html (last modified Dec. 28, 2001).
49 Id. at 154.
50 Id. at 155.
51 Id. at 153 (“This right of privacy, whether it be founded in the Fourteenth Amendment’s concept of personal liberty and restrictions upon state action . . . or . . . in the Ninth Amendment’s reservation of rights to the people, is broad enough to encompass a woman’s decision whether or not to terminate her pregnancy.”).
52 See id. at 162-66.
53 See id. at 164.
In the second trimester, states could enact regulations for the purpose of promoting their interest in the health of the mother, provided that such regulations were reasonably related to maternal health. Finally, in the third trimester, states were given greater latitude to protect their interest in potential human life. Much of this distinction was based on the fact that sometime during the third trimester the fetus becomes viable. The Court, however, did not declare at exactly what point viability occurs. Thus, in the third trimester, states were free to regulate or even proscribe abortion, except in cases where, according to appropriate medical judgment, abortion was necessary to protect the life or health of the mother.

Since the Supreme Court decided *Roe*, the Court's ideology has shifted toward conservatism. With the election of George W. Bush in 2000, it appears likely that this trend will continue for several years to come. Thus, although the essential holding from *Roe* is still intact, this ideological shift has resulted in several decisions that have served to weaken that holding and allow for greater state regulation of abortions.

In *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the Supreme Court upheld *Roe* but rejected its trimester framework. The opinions in *Casey* are illustrative of how the ideology of the Court has splintered regarding its prior decision in *Roe*. The judgment of the Court was announced by Justices O'Connor, Souter, and Kennedy, who argued that *Roe* should be upheld but suggested that the trimester framework was not necessary to its central holding. They concluded that the trimester framework was too inflexible in its prohibition of all state regulations aimed at the protection of fetal life before viability. Chief Justice

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54 See id.
55 See id. at 164-65.
56 "Viability" is loosely defined as the point at which a fetus is capable of surviving independently outside of the womb. See *Colautti v. Franklin*, 439 U.S. 379, 388-89 (1979).
57 *Roe*, 410 U.S. at 164-65.
58 Twelve consecutive years of Republican administration from 1980-1992 had a substantial impact on the ideology of the Court, as liberal justices Blackmun and Marshall were replaced by the more conservative Thomas and Scalia.
60 Id. at 869.
61 See id. at 844-61. The Court noted that "[w]henever it may occur, the attainment of viability may continue to serve as the critical fact, just as it has done since *Roe* was decided; which is to say that no change in *Roe*’s factual underpinning has left its central holding obsolete, and none supports an argument for overruling it." Id. at 860 (emphasis added).
62 See id.
Rehnquist, with whom Justices White, Scalia, and Thomas joined, argued that *Roe* was erroneously decided and should be overruled. Justices Blackmun and Stevens, on the other hand, argued in separate opinions that the Court should reaffirm the central holding from *Roe* in its entirety.

The most important aspect of the Court's plurality holding in *Casey* was that it set forth a new standard to replace the trimester framework from *Roe*. The "undue burden" standard adopted by the Court provided that any state regulation with the purpose and "effect of placing a substantial obstacle in the path of a woman’s choice" to have an abortion prior to viability would be unconstitutional. This new standard, rather than relying on a distinction between trimesters, instead focuses on pre-viability versus post-viability to determine when the state’s interest in potential life becomes compelling. The Court in *Casey* defined "undue burden" as follows:

A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus. A statute with this purpose is invalid because the means chosen by the State to further the interest in potential life must be calculated to inform the woman’s free choice, not hinder it. And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman’s choice cannot be considered a permissible means of serving its legitimate ends.

This is a much more forgiving definition than that articulated in *Roe* in terms of allowing for state regulation of abortions. The Court concluded that states must be given more leeway to regulate pre-viability abortions and that *Roe*'s trimester framework did not allow enough flexibility in that regard. With the new "undue burden" test, the right of a woman to choose

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63 See id. at 944 (Rehnquist, C.J., concurring in the judgment in part and dissenting in part).
64 See id. at 912 (Stevens, J., concurring in part and dissenting in part); id. at 923 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part).
65 Id. at 877.
66 Id.
67 Id.
68 See Silverberg, supra note 18, at 1606.
69 See *Casey*, 505 U.S. at 872.
to terminate her pregnancy remains protected, but the Court achieved some level of compromise by giving more deference to the states' interest in protecting the unborn.\textsuperscript{70}

The Pennsylvania statute at issue in \textit{Casey} required women seeking an abortion to receive information about the risks of abortion and viable alternatives\textsuperscript{71} and also required minors to obtain parental consent or to go through a judicial bypass procedure for special cases.\textsuperscript{72} The statute also required spousal notification\textsuperscript{73} and a twenty-four hour waiting period between the initial medical consultation and the abortion procedure.\textsuperscript{74} Using the "undue burden" test, the Court held that all of these measures were permissible under the Constitution, with the exception of the spousal notification requirement, which it held violated the "undue burden" standard.\textsuperscript{75}

Of course, one of the most difficult constitutional issues presented by mifepristone is that it can act as either a contraceptive or an abortifacient.\textsuperscript{76} This distinction causes the debate over mifepristone essentially to splinter into two different lines of constitutional analysis. On one hand, since mifepristone acts as an abortifacient, the standards set forth in \textit{Roe} and \textit{Casey} are applicable. On the other hand, since mifepristone can also be used as a contraceptive, the analysis is complicated as a similar, yet distinct, line of cases can be brought into the fold. In terms of individual rights, historically there has been little or no distinction made between preventing a pregnancy and terminating one.

The Supreme Court addressed the issue of contraception in its landmark decision of \textit{Griswold v. Connecticut}.\textsuperscript{77} That case was the first to relate the right to use contraception to the right to privacy embodied in the "penumbras" of the First, Third, Fourth, Fifth, and Ninth Amendments.\textsuperscript{78} At issue in \textit{Griswold} was a Connecticut statute that made it a crime to use "any drug, medicinal article or instrument for the purpose of preventing conception."\textsuperscript{79} The Court held that the relationship of marriage was within

\textsuperscript{70} \textit{See id.}

\textsuperscript{71} Pennsylvania Abortion Control Act, 18 PA. CONS. STAT. ANN. § 3205(a) (West 2000).

\textsuperscript{72} \textit{See id.} § 3206(a), (c).

\textsuperscript{73} \textit{Id.} § 3209.

\textsuperscript{74} \textit{See id.} § 3205.

\textsuperscript{75} \textit{Casey}, 505 U.S. at 879.

\textsuperscript{76} \textit{See Prothro, supra} note 8, at 725-30.

\textsuperscript{77} \textit{Griswold v. Connecticut}, 381 U.S. 479 (1965).

\textsuperscript{78} \textit{See id.} at 484.

\textsuperscript{79} \textit{Id.} at 480.
the "zone of privacy" protected by the Constitution and that the Connecticut statute banning the use of contraceptives unduly infringed upon that zone.\textsuperscript{80} The Court recognized the right of a married couple to use contraception as fundamental and, therefore, states could not deprive citizens of that right absent a compelling interest.\textsuperscript{81} Although the Court upheld the right of married persons to use contraceptives in \textit{Griswold}, this would not be the last time the Court would consider the issue of contraception.

Several years after \textit{Griswold}, a similar, yet distinct, issue regarding contraception came before the Court in \textit{Eisenstadt v. Baird}.\textsuperscript{82} Whereas \textit{Griswold} had recognized a constitutionally protected right for married persons to use contraceptives, \textit{Eisenstadt} explored the nature of that right as it related to unmarried persons. At issue was a Massachusetts statute that made it illegal to distribute contraceptives to unmarried persons but allowed such distributions to married persons with a prescription.\textsuperscript{83} The Court held that this law violated the Equal Protection Clause of the Fourteenth Amendment because the distinction between married and unmarried persons is not sufficient to justify a legal distinction allowing one group to obtain contraceptives while denying such access to the other.\textsuperscript{84} As the Court stated, "If the right to privacy means anything, it is the right of the individual, married or single, to be free from unwanted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."\textsuperscript{85}

In light of the decision that an individual now has a fundamental right of access to contraceptives, any law banning mifepristone from being distributed as a contraceptive would appear to be squarely at odds with the Court's holding in \textit{Eisenstadt}. Furthermore, several years later in \textit{Carey v. Population Services International},\textsuperscript{86} the Court effectively solidified the right to contraception as fundamental under the Constitution, holding that an abridgment of an individual's ability to obtain contraceptives must satisfy the rigors of strict scrutiny.\textsuperscript{87}

As at least one commentator has pointed out, the distinction between contraception and abortion took on special significance in the Court's

\textsuperscript{80} See id. at 485-86.
\textsuperscript{81} See id. at 485.
\textsuperscript{83} See id. at 440-41.
\textsuperscript{84} See id. at 454-55.
\textsuperscript{85} Id. at 453.
\textsuperscript{87} See id. at 687-89.
opinion in *Casey.* Although there had previously been two distinct lines of cases regarding contraception and abortion, the *Casey* opinion effectively merged the two concepts, but at the same time it produced inherent inconsistencies. The Court reinforced the fundamental right to contraception to the point of virtual certainty, thereby making it all but impossible for any later decision to rebuke it. Stare decisis demands as much. On the other hand, a woman's right to obtain an abortion was seriously eroded, further complicating matters in the debate over mifepristone. Thus, under *Casey,* regulations of abortion only need to satisfy the relatively lenient "undue burden" standard, while similar regulations pertaining to birth control must be backed by a compelling state interest and must be able to withstand strict judicial scrutiny. Hence, if mifepristone becomes available in its dual capacity of contraceptive and abortifacient, regulations pertaining to the drug will be subject to two competing levels of scrutiny even though only one substance is sought to be regulated. Dealing with this inherent duality will be among the most difficult challenges facing legislatures and courts after mifepristone becomes widely distributed in the United States.

### III. Paradigms for Regulation of RU-486

Regulation of mifepristone at both the state and federal level will require a new statutory context that addresses the inevitable gray areas that the drug is sure to inhabit. The most pressing legal problem surrounding abortion is perhaps not a legal problem at all but, rather, one of differing philosophies. To address the issues presented by mifepristone, lawmaking bodies will be forced to synthesize and rethink the current paradigms of regulation pertaining to abortion, contraception, and other new advances in medicine.

In order to accomplish this, regulation must occur on a series of distinct levels. On the first level is the more specific legislation which deals with mifepristone in each of its capacities. In essence, there will need to exist one set of regulations for mifepristone as an abortifacient and another set for mifepristone as a contraceptive. On the second level, however, there

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88 See Silverberg, *supra* note 18, at 1607.
89 *Id.* at 1606.
90 See *id.*
91 *Id.* at 1607.
must exist a more generalized method of regulation that encompasses the
drug as a singular substance capable of being used in a variety of contexts.
In formulating such legislation, particular care must be taken in walking the
constitutional tightrope that exists on the line between abortion and
contraception. In this respect, certain inherent difficulties will surely arise.

A. The Federal Context

On February 6, 2001, Senator Tim Hutchinson (R-Ark.) and Representa-
tive David Vitter (R-La.) co-sponsored legislation designed to restrict the
distribution of mifepristone. The bill, officially referred to as the “RU-486
Patient Health and Safety Protection Act,” states in pertinent part that:

[T]he drug 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 less, determined on the basis of
starting at the principal medical office of the physician and traveling
to the hospital, using the transportation means normally used by the
physician to travel to the hospital, and under the average conditions
of travel for the physician.

Obviously, the first question that must be addressed with any such
legislation, consistent with Planned Parenthood of Southeastern Pennsyl-
vania v. Casey, is to what extent the measure places an “undue burden” on
a woman’s ability to obtain an abortion. Examining the first two subparts
of the Act, it is clear that the only doctors who would be allowed to

93 RU-486 Patient Health and Safety Protection Act, S. 251/H.R. 482, 107th
Cong. (2001); see also Kaufman, supra note 2, at A4 (discussing a virtually
identical bill introduced by Representative Tom Coburn (R-Okla.)).
94 S. 251/H.R. 482, § 2.
distribute mifepristone would be those who are already capable of performing traditional abortions.\textsuperscript{96} This, of course, places a rather severe limitation on the availability of mifepristone, as the number of doctors qualified to perform abortions is quite small when compared with the total number of doctors generally.\textsuperscript{97} It is debatable, however, whether or not such a provision places an "undue burden" on a woman's ability to procure an abortion.

On one hand, the state certainly has a compelling interest in the health of its citizens, and in an emergency situation the doctor prescribing mifepristone may have no choice but to perform a traditional abortion.\textsuperscript{98} Therefore, one can certainly argue that there is a compelling interest in only allowing doctors so qualified to administer the drug. Furthermore, the law seems narrowly tailored to accomplish the state's legitimate purpose without being overbroad.

On the other hand, allowing the FDA to determine which physicians are sufficiently "qualified" would, to a certain extent, displace the current state laws governing doctors and pharmacists.\textsuperscript{99} Additionally, some doctors fear the possible secondary effects that may result from direct marketing of the drug to physicians or facilities, rather than to pharmacies.\textsuperscript{100} For instance, unless information concerning those who receive the drug is kept strictly confidential, doctors fear that certain pro-life groups might use such information to plot attacks against particular physicians or facilities.\textsuperscript{101}

The first two subparts of the Act deal directly with the level of skill and expertise possessed by the prescribing physician.\textsuperscript{102} Supporters of the Act might argue that this requirement is essential for the safety of women and

\textsuperscript{96} See S. 251/H.R. 482, § 2(1)-(2).

\textsuperscript{97} This is particularly a problem in rural areas, where doctors willing to perform an abortion might be nonexistent. As it stands now, women in such areas wanting to obtain an abortion must often travel hundreds of miles to larger cities in order to receive them. See American Civil Liberties Union Freedom Network, April 9, 2001: Memorandum on Mifepristone Restrictions, at http://www.aclu.org/congress/l040901a.html (Apr. 9, 2001).

\textsuperscript{98} See Hanson, supra note 92, at 169 (stating that four percent of RU-486 abortions require surgical intervention).


\textsuperscript{100} See id.

\textsuperscript{101} Id.

\textsuperscript{102} See RU-486 Patient Health and Safety Protection Act, S. 251/H.R. 482, 107th Cong. § 2(1)-(2) (2001).
does not pose a difficult constitutional issue. Opponents, however, point out that the type of certification mandated by the Act is not necessary for the safe distribution of mifepristone and does not comport with current medical practice. For example, according to the American College of Obstetricians and Gynecologists ("ACOG"), there are currently no standards or methods for certifying a doctor as a surgical abortion provider.

The Act's third requirement, that the administering physician must be "certified for ultrasound dating of pregnancy and detecting ectopic pregnancy," is designed to ensure that women requesting mifepristone are within the five-to-eight week time frame in which mifepristone is effective. According to the ACOG, ultrasound dating is not necessary for accurately determining the age of the fetus or for determining whether or not there is an ectopic pregnancy. Also, as is the case with several of the Act's requirements, new standards for certification would have to be established, as there are no current methods of certification that comport with the language set forth in the Act.

The last requirement of the Act is that the dispensing physician be located near a hospital. It could be argued that this provision is justified on safety grounds because any unexpected emergency resulting from use of mifepristone or from the pregnancy generally would almost certainly require hospital facilities. Opponents, however, note that the number of women who require hospitalization as a result of complications from mifeprisone is quite small and does not justify such a stringent measure. Furthermore, they argue that the dispensing physician does not have to be the same physician who is in the emergency room if complications do arise and also that many drugs with much higher rates of complications have no similar requirement. The ACOG believes that this requirement discriminates against women and physicians in rural areas.

103 ACOG, supra note 99.
104 Id.
105 S. 251/H.R. 482, § 2(3).
106 Muhl, supra note 3, at 329.
107 ACOG, supra note 99.
108 See id.
109 S. 251/H.R. 482, § 2(5).
110 ACOG, supra note 99.
111 Id.
112 Id.
Obviously, there are valid arguments both for and against each of the requirements set forth in the proposed Act. Supporters of the Act see each requirement as essential to the safe and responsible distribution of mifepristone. Those who oppose the Act view it as a politically motivated attempt to excessively regulate a safe and effective drug. The ultimate question for the courts, however, will be whether or not the provisions of the Act, or of any similar legislation, constitute an "undue burden" in violation of Casey.

As stated earlier, the Court in Casey upheld a statute which required women seeking an abortion to receive pertinent information about abortion and viable alternatives. The Court also approved a parental consent requirement for minors and a twenty-four hour waiting period between consultation and surgery. The spousal notification requirement, however, was held to be an "undue burden." Thus, in evaluating the constitutionality of the provisions set forth in the Act, or in any subsequent legislation relating to mifepristone, one must necessarily utilize the conclusions set forth in Casey as a guideline. Are the provisions of the Act as burdensome on a woman’s right to choose as the spousal notification requirement that was struck down in Casey? Those in favor of the Act will, of course, point out the government's legitimate interest in protecting the health and safety of women seeking abortions via mifepristone. Conversely, those in opposition to this and other similar legislation will note that such extensive regulation of a drug that has been proven safe and effective is unwarranted and clearly a political attempt to further a pro-life agenda. The ultimate answer, of course, likely will be dictated more by political ideology than by objective constitutional analysis. The "undue burden" standard is extremely amorphous and allows a great deal of "wiggle room" for any court which might address the issue. The more complicated task facing any such court, of course, will be to address the dual nature of mifepristone as both a contraceptive and an abortifacient.

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114 Id. at 885-87.
115 Id. at 899-901.
116 Id. at 887-98.
117 States are generally given a great deal of leeway to enact health and safety legislation. See 37712, Inc. v. Ohio Dep’t of Liquor Control, 113 F.3d 614, 622 (6th Cir. 1997).
118 ACOG, supra note 99.
119 See Casey, 505 U.S. at 833.
B. The State Context

In addition to federal regulation, state legislatures are also proposing legislation to deal with mifepristone. A growing number of states plan to apply parental notification laws to mifepristone before it is given to women under eighteen wanting to end pregnancies. Currently, thirty-two states require at least one parent to be notified before a minor can have an abortion. Although a determination of when life begins is central to deciding whether a substance should be classified as an abortifacient or a contraceptive, the courts have routinely dodged such a large philosophical question. State legislatures, on the other hand, have not been quite so timid.

In *Webster v. Reproductive Health Services,* for example, the Court upheld the preamble to a Missouri statute which stated that "[t]he life of each human being begins at conception." The statute was upheld because the Court viewed it as merely stating a value judgment and as having no significant effect on the right of a woman to obtain an abortion. The plaintiffs in that case argued that such a definition of when life begins could prevent health care providers from prescribing or dispensing certain birth control methods that acted after fertilization. The Court, however, refused to consider that particular issue, instead focusing exclusively on abortion. Thus, it is presumably an open question as to whether or not liability for prescribing post-fertilization forms of birth control, such as the IUD (intrauterine device), might lead to criminal liability for health care providers in states with statutory language similar to that upheld in *Webster.* Interestingly, although a literal reading of the language in the Missouri statute would seem to suggest that use of the IUD or morning-after pill would constitute abortion, no court, in Missouri or elsewhere, has ever held this to be the case.

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124 See *Webster,* 492 U.S. at 506.
125 Id. at 505-06.
126 Id. at 507.
This seemingly inconsistent legislative stance towards abortion and contraception, while not squarely addressed by the Supreme Court, has been encountered by various lower courts. In *Margaret S. v. Edwards*, for example, the Louisiana abortion statute defined abortion as "the deliberate termination of a human pregnancy after fertilization..." The concern of the plaintiff health care providers was that such a definition would be construed to apply to post-fertilization contraceptives such as the "morning-after pill" and the IUD. On this point, the Court ignored the literal meaning of the statute's text and explicitly held that such post-fertilization forms of contraception, along with everyday birth control pills, should not be construed as falling under any definition of abortion.

While the court in *Margaret S.* upheld the language of the Louisiana statute at issue and expressed the view that it simply did not apply to any form of contraception, the Seventh Circuit Court of Appeals used a different approach in confronting a similar statute in Illinois. In *Charles v. Carey*, the statute at issue defined "abortifacient" as "any instrument, medicine, drug, or any other substance or device which is known to cause fetal death... whether or not the fetus is known to exist when such substance or device is employed." Furthermore, the statute defined a fetus as "a human being from fertilization until birth." The court held that the language of the statute was overbroad because it might be applied to post-fertilization forms of contraception.

In light of these and other decisions dealing with legislative attempts to define when life begins, it becomes obvious that when lawmaking bodies succumb to political pressures to legally define life as beginning at conception, such actions have the potential of actually causing a result that is squarely opposite from what was intended. Within the context of regulating mifepristone, a legislative statement that life begins at conception is far too simplistic to deal with the reality of the problems that must be addressed. As the above cases indicate, the courts have been unwilling, for the most part, to allow postcoital contraception to fall within the laws governing abortion. Therefore, any realistic paradigm for the regulation of

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131 *Margaret S.*, 488 F. Supp. at 190-91.
132 *Id.* at 191.
133 *Charles v. Carey*, 627 F.2d 772 (7th Cir. 1980).
134 *Id.* at 789.
135 *Id.*
136 See *id.*
mifepristone must acknowledge this judicial tendency and remain flexible enough to allow for the drug's dual nature. To do otherwise would be to produce legislation that is contradictory, inconsistent, and without principle.137

Essentially, from a legal standpoint, the problem becomes one of trying to decide how many proverbial angels can dance on the head of a pin. Attempting to determine at what point life begins, and therefore, what legal standards to apply to mifepristone or other postcoital contraceptives, is an exercise in futility. Even the Court in Roe v. Wade recognized as much when it stated:

We need not resolve the difficult question of when life begins. When those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus, the judiciary, at this point in the development of man's knowledge, is not in a position to speculate as to the answer.138

It is apparent that when state legislatures attempt to do what the Supreme Court advises cannot effectively be done, legal dilemmas are sure to arise. For instance, depending on exactly when a woman takes mifepristone, she might feasibly be subject to the distinct legal standards of Griswold v. Connecticut and Planned Parenthood of Southeastern Pennsylvania v. Casey simultaneously.139 At what point does one standard cease to exist and the other begin? As one commentator points out, the timeline could be anywhere from two to thirty days after unprotected intercourse.140 From the standpoint of the legislature, it is like trying to determine at what point a mass of individual grains of sand becomes a beach or how many hairs one must lose to be considered "bald." The point, of course, is that the Court in Roe was wise to avoid the issue of when life begins, and state legislatures would benefit from following suit, rather than yielding to political pressure from the right. Even for those legislators who support a pro-life agenda, it is clear that an attempt to define that which defies definition will only hamper their cause in the long run.

In what appears to be a knee-jerk reaction to FDA approval, some state legislators immediately introduced seemingly oversimplistic legislation. This seems to be the case in Kentucky, for example, where a bill request for

137 See Hanson, supra note 92, at 186.
139 See Protho, supra note 8, at 733.
140 Id.
the 2002 regular session was submitted that would have extended the
definition of abortion to include mifepristone. The bill request has since
been withdrawn. The bill proposed to amend Kentucky Revised Statute
(“K.R.S.”) § 311.720 to include the use of mifepristone in the definition of
“abortion”; amend K.R.S. § 311.732 to prohibit prescribing mifepristone
for minors under the age of sixteen (16); and amend K.R.S. § 311.990 to
establish the penalty for violations. As it stands now, the definition of
abortion in Kentucky, as stated by K.R.S. § 311.720 is “the use of any
means whatsoever to terminate the pregnancy of a woman known to be
pregnant with intent to cause fetal death.” Under K.R.S. § 311.732,
however, a somewhat less expansive definition of abortion includes

the use of any instrument, medicine, drug or any other substance or device
with intent to terminate the pregnancy of a woman known to be pregnant
with intent other than to increase the probability of a live birth, to preserve
the life or health of the child after live birth, or to remove a dead fetus.

The word “fetus” is defined as “a human being from fertilization until
birth.”

The problem encountered by the proposed Kentucky law, as will surely
be the problem faced by countless other state legislatures, is that mifepris-
stone does not fit neatly within the established abortion framework. It will
certainly take more to effectively regulate mifepristone than simply adding
it to the statutory definition of abortion. It is not realistic to attempt to apply
the same regulation to a drug as one would to a procedure. Regulating the
prescription of mifepristone presents a whole host of challenges for
legislatures and agencies that are not covered by the regulations pertaining
to abortion. To begin with, a drug, unlike a procedure, can be trafficked on
a black market. This problem alone requires an independent framework
through which the problem of illegal distribution can be effectively
controlled. Another problem, discussed earlier, is the dual capacity of
mifepristone as both an abortifacient and a contraceptive. Finally, the

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141 Bill Request 103 was submitted by Representative J.C. “Bo” Ausmus, III,
on September 29, 2000. It was withdrawn on November 15, 2000. H.R. 103, 2002
142 Id.
144 Id. § 311.732(1)(c).
145 Id. § 311.720(5).
146 See Silverberg, supra note 18, at 1592.
147 See supra Part II.
The drug presents unique problems in terms of women potentially sharing prescriptions.\textsuperscript{148} At whatever point the drug becomes a viable contraception alternative, the line drawing will become subjective at best.

C. The French Model as a Guideline

It has been argued that the most effective paradigm for both state and federal regulation is one based on the French model.\textsuperscript{149} Indeed, it seems that the United States would be wise to look to the regulatory framework of a country that has now had some experience with mifepristone. In France, as is the case in many European countries, abortion is not the hot button issue that it is on this side of the Atlantic. Thus, the laws governing the distribution of mifepristone in those countries are less about ideology and more about safe and effective regulation.

In France, in order to obtain mifepristone, health centers must be authorized to do so by the government and must comply with strictly enforced regulations.\textsuperscript{150} The number of pills distributed to each pharmacy is closely monitored so that every pill is thoroughly accounted for, and patients receiving mifepristone are required to sign a consent form.\textsuperscript{151}

In addition to the regulation of health care centers distributing mifepristone, the French system takes further precautions on the patient level. Women seeking to obtain mifepristone must make a total of four visits to a health care facility.\textsuperscript{152} On the initial visit, the woman has a general consultation with her doctor, including a discussion of various available options, at which time she is tested to confirm that the beginning of her last menstrual period was no longer than forty-two days prior to the date of the consultation.\textsuperscript{153} On the second visit, which by law must be at least one week after the first if the woman is less than seven weeks pregnant, the woman ingests three tablets of mifepristone under the direct supervision of her physician.\textsuperscript{154} On the third visit, two days later, the patient receives another drug, prostaglandin, which causes the mifepristone pills to be more effective.\textsuperscript{155} On the fourth and final visit, the woman returns so that the physician can confirm that the abortion was successful.\textsuperscript{156}

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\textsuperscript{148} See Brooks, \textit{supra} note 15, at 274-75.  \\
\textsuperscript{149} \textit{Id.} at 274.  \\
\textsuperscript{150} \textit{Id.}  \\
\textsuperscript{151} See \textit{id.}.  \\
\textsuperscript{152} Richards, \textit{supra} note 4, at 119.  \\
\textsuperscript{153} \textit{Id.}  \\
\textsuperscript{154} \textit{Id.}  \\
\textsuperscript{155} \textit{Id.}  \\
\textsuperscript{156} \textit{Id.}
While the goal of state regulation should be to facilitate the safe administration of mifepristone, the politics of the issue cannot be denied.\textsuperscript{157} It is likely that many states will promote legislation of mifepristone that, while claiming to be safety measures, are actually more akin to political attempts to make the drug difficult to obtain. This is a problem not as widely addressed under the French model, since the abortion debate in Europe is not as intense as the debate that takes place here in America.\textsuperscript{158}

The French model provides a workable guideline for federal and state legislatures to follow in their own efforts to regulate mifepristone in the United States. Furthermore, regulations following the French model would not be inconsistent with legislation such as the proposed federal Act discussed earlier.\textsuperscript{159} Legislation such as the proposed federal Act might accomplish the objective of providing an all-encompassing set of regulations for mifepristone. Whether or not such legislation will adequately address the multi-dimensional aspects of mifepristone is a question that remains to be answered. Furthermore, when other uses for mifepristone do become more prominent, the Supreme Court will need to reexamine some of its fundamental positions on contraception and abortion so as not to create a constitutional paradox.

IV. CONCLUSION

In the wake of FDA approval of mifepristone, state and federal lawmakers must now formulate an effective paradigm for the safe and efficient regulation of the drug in a way that complies with existing constitutional standards. Inherent difficulties arise, however, in that mifepristone does not fit neatly within the frameworks of either abortion or contraception which, in the United States, are governed by distinct legal principles.

The best way to regulate mifepristone is not to simply include it within the definition of existing abortion laws, but rather, to formulate a distinct set of statutes and regulations narrowly tailored to deal with the unique problems that the drug presents. As has been suggested by others who have considered the issue, one approach to the regulation of mifepristone is to look to other countries that have already dealt with the issue.\textsuperscript{160} Since the debate over abortion is less heated overseas, a regulatory framework based

\textsuperscript{157} See Muhl, supra note 3, at 337.
\textsuperscript{158} Id.
\textsuperscript{159} See supra Part III.A.
\textsuperscript{160} See supra Part III.C.
on that which exists in France and other European countries may be the most objective way to approach regulation in the United States. The regulatory framework in France, for example, entails strict monitoring of distribution and use while balancing pro-life concepts such as waiting periods with the pro-choice advantage of a safe alternative to aspiration abortion.\textsuperscript{161}

Although the legislation introduced thus far in Congress would likely survive judicial scrutiny, it acts only as an extension of existing abortion law and does not reflect the fundamental change in approach that mifepristone's uniqueness requires. Rather than a well-thought-out and well-researched paradigm, conservative members of Congress, within weeks of mifepristone's FDA approval, proposed knee-jerk legislation in response, no doubt, to overwhelming political pressure to take immediate action.\textsuperscript{162} In such a case, no matter what ideology or beliefs concerning abortion one harbors, quality of legislation should not suffer for the sake of speed.

In years to come, it is unlikely that the controversy surrounding mifepristone, at least so far as its abortion capability is concerned, will simply fade away. Abortion is a timeless issue that has yet to be resolved by human conscience and understanding. New technologies will serve only to change the form, not the substance, of the debate. After mifepristone, other drugs and technologies are sure to follow, but the question of when life begins may be one that remains permanently unresolved.

\textsuperscript{161} See \textit{supra} Part III.C.
\textsuperscript{162} See \textit{supra} Part III.A.