Approval of RU-486 as a Postcoital Contraceptive

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"Many people ignore the fact that the incidence of abortion reflects the state of contraception."1

"The real problem with emergency postcoital contraception is not its failure rate or its side effects but the fact that so few women and adolescents who have had unprotected intercourse actually use it."2

I. INTRODUCTION

Each year in the United States, 3.5 million women unintentionally become pregnant.3 Moreover, approximately 1.5 million abortions are performed annually,4 making the United States’ abortion rate one of the highest among Western countries.5 Meanwhile, the number of women and children living below the poverty level continues to increase.6 These facts indicate that women urgently need additional methods of fertility control. For many women who unintentionally become pregnant, the consequences are not disastrous. For these women, the decision whether to have an abortion, give the child up for adoption, or keep the child may be clear and have no long-term

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4. Djerassi, supra note 1, at 356.
5. Stanley K. Henshaw, Induced Abortion: A World Review, 1990, 22 FAM. PLAN. PERSP. 76, 78 (1990). According to statistics compiled by Henshaw, among countries with complete statistics, only Japan, South Korea, Singapore, China, the Soviet Union, Turkey, Hungary, Czechoslovakia, Bulgaria, Yugoslavia, and Cuba have abortion rates higher than that of the United States. Id.
6. U.S. BUREAU OF THE CENSUS, STATISTICAL ABSTRACT OF THE UNITED STATES: 1992 458 (1992). According to the Census Bureau statistics, in 1979 there were 13.5 million families headed by a female householder living below the poverty level. Id. In 1990, the number had risen to 17.2 million. Id.
adverse effects. However, many women face an agonizing dilemma when none of these three options appears viable.

Postcoital contraceptives, which act after fertilization but before a fertilized egg implants in the womb,\textsuperscript{7} offer women greater control over their own fertility. For example, many unintended pregnancies result from contraceptive failure, such as a condom breaking.\textsuperscript{8} In these cases, a woman may realize she is at risk of becoming pregnant and use a postcoital contraceptive to prevent an unwanted pregnancy. One such contraceptive, popularly known as the "morning-after pill" because it must be administered within seventy-two hours of unprotected intercourse, has been available for some time but has not been widely used.\textsuperscript{9}

A significant development in postcoital contraception occurred in 1992 when scientists reported in The New England Journal of Medicine that RU-486, the so-called "abortion pill," was highly effective as a postcoital contraceptive.\textsuperscript{10} RU-486, a synthetic drug most widely used as an abortifacient,\textsuperscript{11} was developed in France more than a decade ago.\textsuperscript{12} Because the drug is highly effective in terminating early pregnancies,\textsuperscript{13} it has been extremely controversial in this country.\textsuperscript{14} The heated political debate over abortion, strident opposition from right-to-life groups, and the antiabortion stance of the Reagan and Bush administrations\textsuperscript{15} have prevented RU-486 from being submitted to the United States Food and Drug Administration (FDA) for

\begin{itemize}
\item \textsuperscript{7} Postcoital Contraception—An Appraisal, 1976 Population Rep. 141.
\item \textsuperscript{8} Trussell et al., supra note 3, at 269.
\item \textsuperscript{9} See infra notes 105–120 and accompanying text. Unprotected intercourse refers to sexual intercourse during which no contraceptive methods are used, putting the woman at risk of becoming pregnant.
\item \textsuperscript{10} See Glasier et al., supra note 2, at 1041.
\item \textsuperscript{11} "Abortifacient" is defined as "[a]n agent that produces abortion." Stedman's Medical Dictionary 3 (25th ed. 1990). "Abortion" is defined as "[g]iving birth to an embryo or fetus prior to the stage of viability at about 20 weeks of gestation." Id.
\item \textsuperscript{12} Etienne-Emile Baulieu & Mort Rosenblum, The "Abortion Pill" 16-17 (1991) [hereinafter The Abortion Pill]. The drug takes its name from the French company that developed it, Roussel-Uclaf. The original number of the molecular compound is RU 38468; mifepristone is the generic name. Etienne-Emile Baulieu, RU-486 as an Antiprogesterone Steroid; From Receptor to Contraception and Beyond, 262 JAMA 1808, 1810 (1989) [hereinafter Contraception].
\item \textsuperscript{14} Id. at 12.
\item \textsuperscript{15} Joseph Palca, The Pill of Choice?, 245 Science 1319, 1321 (1989); see also infra notes 33–34 and accompanying text.
\end{itemize}
approval. However, new abortion policies instituted by the Clinton administration appear to be paving the way for submission and ultimate approval of the drug. This Comment argues that if RU-486 were approved as a postcoital contraceptive rather than as an abortifacient, the drug would be of greater overall benefit to women seeking to control their fertility.

FDA approval of RU-486 as a postcoital contraceptive would be of greater overall benefit to women than approval of the drug as an abortifacient in a number of ways. First, women would have a broader range of birth control options. Dr. Etienne-Emile Baulieu, the developer of RU-486, has pointed out that women may need several different forms of birth control during their fertile lives, because factors relevant to contraception, including changes in age and in the status of their personal lives, vary over a woman's lifetime. Under certain circumstances, a woman may find invaluable a method of birth control that allows decision making to occur after intercourse.

The second major benefit to women of FDA approval of RU-486 as a postcoital contraceptive is that fewer women will require abortions or even face the decision whether to abort. Abortion may raise significant medical and moral issues that are implicated only slightly, if at all, by methods of fertility control that act before a pregnancy has been established. In the United States, the vast majority of abortions are performed legally during the first trimester, and no significant complications result. However, abortions performed illegally or in the later stages of pregnancy may be associated with serious health risks and even death. In addition, many women would not

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18. Contraception, supra note 12, at 1808.
20. Induced Termination, supra note 19, at 3235. The National Abortion Federation in Washington, D.C. estimates that in 1990 there was one complication per 1,000 abortions. Id.
21. Id. at 3238. Between 1972 and 1974, the number of deaths per 100,000 illegal abortions was approximately eight times greater than for legal abortions. W. Cates, Jr.
choose abortion under any circumstances because they regard it as taking life. Even among women who believe that abortion must remain legal and available, support for abortion may decrease as pregnancy advances and the fetus begins to look more and more like a person. Reducing the occurrence of unwanted pregnancies will therefore free women from facing what for many is an anguishing moral and ethical dilemma.

Although the need for abortion is unlikely to be completely eradicated, there is little doubt that wider availability and use of postcoital contraceptive methods could help to reduce significantly the number of abortions performed each year in the United States. A 1989 survey of two hundred Planned Parenthood patients who had abortions showed that thirty percent had realized right away that they might be pregnant and would have preferred the morning-after pill to an abortion if they had been aware of the treatment. In the Netherlands, where postcoital contraceptives have been available for years, the treatment is cited as the leading reason for an abortion rate one fifth of that of the United States.

In addition to benefitting women, FDA approval of RU-486 as a postcoital contraceptive will also benefit the drug's manufacturers and marketers. Such a strategy will allow both the drug's French manufacturer, Roussel-Uclaf, and companies in the United States to avoid much of the abortion controversy that has surrounded RU-486. Many people who are vehemently opposed to abortion will continue to oppose RU-486 as a postcoital contraceptive, both because of its potential use in terminating established pregnancies and because of a belief that even an unimplanted fertilized egg deserves the same protection as a fetus or a person. However, fewer people oppose birth control than oppose abortion, and the legal right to privacy in choosing to use birth control has been firmly established in this country since the Supreme Court's decision in Griswold v. Connecticut. In upholding this right, courts have not distinguished between birth control methods that act before or after

23. Id.
25. 381 U.S. 479 (1965).
fertilization. Thus, those involved in manufacturing, distributing, and marketing RU-486 should focus on its use as a birth control method and work to educate the public about this new use of the drug. This strategy will reduce vulnerability to boycotts or other politically motivated obstacles that could impair wide distribution of a much-needed new drug. With this fear assuaged, manufacturers and marketers will be in a position to maximize profits from licensing the drug in the United States.

Finally, the medical community will benefit if RU-486 is approved as a postcoital contraceptive. Doctors will have another option available to offer women seeking to control their fertility. Moreover, doctors who oppose abortion would probably be more comfortable prescribing RU-486 as a postcoital contraceptive because the medical profession generally views pregnancy as beginning with successful implantation, not with fertilization. Reducing the need for abortion will allow medical resources to be directed toward other pressing health problems, such as AIDS and other sexually transmitted diseases. Furthermore, minimizing the abortion controversy at the regulatory level will mean that the drug is available to doctors sooner than it otherwise would be. Because a drug approved by the FDA for one use may be prescribed for other uses, doctors will gain access to RU-486 for testing in a wide range of applications including, and in addition to, fertility control.

To support the argument that RU-486 should be approved as a postcoital contraceptive, Part II of this Comment examines the background and development of the drug, the controversy it has engendered, and the drug's recently discovered contraceptive potential. Part III provides a short look at the process by which the FDA approves new drugs and discusses how RU-486 would likely progress through this process. Part IV begins by examining the current postcoital contraceptive regimen, the morning-after pill, and discusses the obstacles associated with the use and the availability of this method. Part IV then discusses the legal, medical, and policy reasons for approving RU-486 as a postcoital contraceptive.

26. See infra notes 178-195 and accompanying text.
27. See infra notes 128-133 and accompanying text.
28. See infra notes 95-100 and accompanying text.
II. RU-486: "THE MORAL PROPERTY OF WOMEN"

A. Background

RU-486 was approved for use by the French government in 1988.\(^\text{29}\) Although the drug has now been used by more than 100,000 French women,\(^\text{30}\) its introduction was not without considerable controversy. Almost immediately after the drug was licensed, Roussel-Uclaf withdrew it in the face of threatened boycotts and opposition from the Catholic church.\(^\text{31}\) However, the French government intervened two days later, stating that governmental approval had made RU-486 "the moral property of women" and that if Roussel-Uclaf did not market the drug, the rights would be given to another company.\(^\text{32}\)

In the United States, introduction of RU-486 was blocked in large part by the Bush administration.\(^\text{33}\) However, the Clinton administration promptly set about dismantling the anti-abortion policies of the previous two administrations.\(^\text{34}\) Furthermore, the medical profession and the public have indicated for some time that the drug would be well received. For example, in June 1990, the American Medical Association adopted a resolution supporting the drug's clinical application in abortion.\(^\text{35}\) Similarly, in February 1991, the American Association for the Advancement of Science went on record favoring broad medical availability of RU-486.\(^\text{36}\) In addition, fifty-nine percent of those responding to a recent Harris poll favored making the drug available, and thirty-seven percent said they would be willing to try it.\(^\text{37}\) The following section describes how the drug works and its current use and effectiveness.

\(^{29}\) The Abortion Pill, supra note 12, at 41.


\(^{31}\) The Abortion Pill, supra note 12, at 43-44.

\(^{32}\) Id. at 49.


\(^{34}\) For example, the Clinton administration lifted restrictions on abortion counselling at federally funded clinics and on fetal tissue research. President Clinton also instituted a review of the ban on importing RU-486. Clinton Signs Memoranda on Abortion, Fetal Tissue, REUTERS, Jan. 22, 1993, available in LEXIS, Nexis Library, Reuters File [hereinafter Clinton Signs Memoranda]; Roussel-Uclaf Waits for Word from U.S., REUTERS, Jan. 25, 1993, available in LEXIS, Nexis Library, Reuters File.

\(^{35}\) Regelson, supra note 16, at 335.

\(^{36}\) Id.

\(^{37}\) Virginia Kallianes, Bitter Pill for Abortion Foes, NEWSDAY, July 21, 1989, (Viewpoints Section), at 78.
B. Current Use as an Abortifacient

RU-486 works by binding to progesterone receptors in the uterus, thus inhibiting the activity of progesterone, a hormone essential to maintain pregnancy.\(^{38}\) Progesterone prepares the uterus for implantation of the fertilized egg. After implantation, progesterone sustains the embryo until the placenta has formed.\(^{39}\) Without progesterone, the uterine lining breaks down and the uterus secretes prostaglandins, which produce muscle contractions that expel the fertilized egg or fetus.\(^{40}\) To induce abortion during the early weeks of pregnancy,\(^{41}\) a single 600 mg dose of the drug is given orally.\(^{42}\) Researchers found that administering a synthetic prostaglandin, which causes uterine contractions, increased the effectiveness of RU-486.\(^{43}\) According to Roussel-Uclaf, the drug is eighty-five percent effective when taken alone.\(^{44}\) In combination with a prostaglandin, however, RU-486 is successful in causing abortion in ninety-six percent of cases.\(^{45}\)

Its success rate is impressive, but RU-486 is not without side effects. It may cause nausea, cramping, and bleeding.\(^{46}\) In addition, about four percent of abortions are incomplete and require surgical intervention.\(^{47}\) Some concern about the drug’s effects on children born as a result of an unsuccessful abortion has been expressed,\(^{48}\) but studies on monkeys have suggested there is no risk to the fetus if pregnancy continues.\(^{49}\) Studies report that women who had successful abortions using RU-486 have returned to normal ovulatory cycles.\(^{50}\) In addition, several women who later became pregnant and chose to continue their pregnancies gave birth to normal children.\(^{51}\)

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39. Id.
40. Herman & Chapman, supra note 13, at 12.
41. RU-486 is effective as an abortifacient only up to the seventh week of pregnancy. See id. at 13.
42. See Contragestion, supra note 12, at 1812.
43. Herman & Chapman, supra note 13, at 13.
44. Id.
45. Id.
46. Id. at 13.
47. Id. at 12.
48. Id.
49. Contragestion, supra note 12, at 1812.
50. Id.
51. Id.
In addition to its use as an abortifacient, RU-486 has been demonstrated to be useful in treating various illnesses and disorders.\textsuperscript{52} Furthermore, the drug has potential uses as a regular contraceptive\textsuperscript{53} and a means to induce labor or to expel fetuses that have died in utero during the later stages of pregnancy.\textsuperscript{54} However, in the words of Dr. Baulieu, "RU-486's great promise is in preventing pregnancy in the first place."\textsuperscript{55} The next section further explores that potential.

C. Preventing Pregnancy with RU-486

In October 1992, The New England Journal of Medicine published the results of a study in which women who had had unprotected intercourse were given either a 600 mg dose of RU-486 or the morning-after pill estrogen and progestogen regimen.\textsuperscript{56} No statistically significant difference in the failure rates was seen.\textsuperscript{57}

The difference in side effects was significant, however. More than one third of those receiving RU-486 had no symptoms, compared to only thirteen percent of those who received the estrogen and progestogen regime.\textsuperscript{58} Furthermore, the incidence of nausea, vomiting, headache, and breast tenderness among those in the RU-486 group was substantially lower.\textsuperscript{59} These results are strengthened by another study involving a randomized trial of three emergency birth control treatments:

\textsuperscript{52} See Regelson, supra note 16, at 331.
\textsuperscript{53} Joannie Schrof, Reproduction Showdown, U.S. News & World Rep., Mar. 22, 1993, at 32, 34. Dr. Baulieu suggests that the most feasible way to use RU-486 as a regular contraceptive would be to take a low dose of the drug throughout the month. Id. Such a method would closely resemble the current birth control pill regimen, but without the steady stream of hormones and their side effects. European studies have also indicated that RU-486 may be effective as a once-a-month pill, taken shortly after ovulation or shortly before a woman expects her menstrual period. Id. The advantages of this use are that the monthly intake of medication is reduced, it is more convenient than other contraceptives, and it is more flexible because if a woman is not sexually active in a given month, she does not need to take the drug. The disadvantage of this method is that because menstrual cycles are irregular, the timing of the dose would be difficult to pinpoint. Id.
\textsuperscript{54} Herman & Chapman, supra note 13.
\textsuperscript{55} The Abortion Pill, supra note 12, at 174.
\textsuperscript{56} Glasier et al., supra note 2, at 1041-42.
\textsuperscript{57} Id. at 1042. Of 402 women treated with RU-486, none became pregnant; there were four pregnancies among 398 women treated with the standard regimen. Id.
\textsuperscript{58} Id. at 1043.
\textsuperscript{59} Id. In particular, 17\% of women in the standard regimen group reported severe nausea on the day of treatment compared to only 2\% of women who received RU-486. Id.
the standard estrogen and progestogen morning-after pill, another birth control pill called danocrine, and RU-486. Women who received RU-486 and danocrine experienced much less nausea and vomiting, and none of the women who took RU-486 became pregnant.

According to the New England Journal study, the only apparent disadvantage of RU-486 is that more women who received the drug experienced a delay in the onset of their next menstrual period. This delay may add to a woman's anxiety. However, the likelihood of late menses can be predicted based on where the woman was in her cycle at the time of treatment. In addition, extremely sensitive home pregnancy tests are now available and can be used to reassure women that they are not pregnant.

The results of this study indicate that RU-486 should be approved by the FDA as a postcoital contraceptive. In an editorial accompanying the New England Journal study, leading medical and legal researchers argued that by depriving women who need emergency contraception of this drug, the Bush administration was perpetrating a "national disgrace." The authors of the editorial noted that objections to FDA approval of RU-486 as an abortifacient "do not relate to pursuing approval for its use as a postcoital contraceptive agent." Part III of this Comment addresses the process by which new drugs obtain regulatory approval and looks at how RU-486 would likely progress through this process.

III. RU-486 AND THE FDA

A. The FDA Approval Process

The Federal Food, Drug, and Cosmetic Act of 1938 required only that drugs introduced into interstate commerce be safe. The 1962 amendments to the Act added the require-
ment that a drug must also be effective. The Act states that new drugs may not be introduced into interstate commerce unless approved by the FDA, and it sets forth the requirements for a sponsor seeking approval of a new drug.

The first step of this process is for a drug's sponsor to submit an Investigational New Drug application (IND), which contains the results of animal studies on the drug's pharmacological and toxicological effects. Next, if the FDA approves the IND application, human testing is carried out in three phases. Phase one studies are conducted on patients or healthy volunteers and are designed to determine how the drug affects humans, what its side effects are, and how effective it appears to be. In phase two, controlled clinical studies are conducted to evaluate the drug's effectiveness in patients with the disease or condition for which the drug is indicated. Phase three involves expanded controlled and uncontrolled studies that are intended to gather more information about safety and effectiveness, which is needed to evaluate the benefits and risks of the drug. All the information gathered from these clinical trials is then submitted to the FDA in the sponsor's New Drug Application (NDA), which forms the basis for the FDA's scrutiny of the drug. In addition to the clinical test results, the NDA must include information about the drug's composition, toxicology, behavior in the body, manufacturing, processing, and packaging. The sponsor must also specify the conditions the drug is being promoted to treat.

Under the Act, the FDA has 180 days from the date an NDA is filed to approve or to reject the application. In prac-

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71. Id. § 355(b).
73. Id. § 312.23(a)(5)(ii).
74. Id. § 312.21(a)-(c).
75. Id. § 312.21(a).
76. Id. § 312.21(b).
77. Id. § 312.21(c).
78. Id. § 314.50.
79. Id. § 314.50(d)(i)-(vi) (listing and describing the specific FDA requirements). See generally Dixie Farley, How FDA Approves New Drugs, 21 FDA CONSUMER 7, 9 (1987).
81. Id. § 314.100(a).
tice, however, extensions are the rule. The average approval time for a new drug is two years. The FDA may contact the sponsor or investigators at any time during its review to discuss problems with the data. Moreover, the agency requires the sponsor to report promptly and to investigate any serious and unexpected "adverse drug experience."

At the FDA, INDs and NDAs are classified to determine review priority on the basis of the drug's chemical type and potential benefit. Drugs featuring an active ingredient never before marketed in this country and representing an important therapeutic gain are given the highest priority review. Because of its new molecular structure and potential for widespread use, RU-486 would likely receive high review priority.

B. RU-486: Outlook and Strategies for FDA Approval

In December 1992, the FDA indicated that European clinical trials of RU-486 may be sufficient for the agency to conduct its review process. A 1985 revision of NDA regulations allows approval on the basis of foreign studies alone. Thus, the company ultimately selected to market the drug could complete safety trials and submit an NDA before the end of 1993. The time required for agency review would be shortened to between four and six months. However, this expedited process is based on the assumption that approval will be sought for RU-486 as an abortifacient. Clinical studies of the drug as a postcoital contraceptive are much fewer in number, and it is not clear whether the studies would be sufficient to satisfy the FDA's requirements. However, even if more clinical trials were required, it is unlikely that this additional time will signif-

82. Farley, supra note 79, at 9.
83. 21 C.F.R. § 314.102 (1993); Farley, supra note 79, at 11.
84. 21 C.F.R. § 314.80(c)(i) (1993).
85. Farley, supra note 79, at 12.
86. Id. AIDS drugs are an exception to this ranking system; they are given review priority above all other drugs. Id.
88. Farley, supra note 79, at 10.
89. Schrof, supra note 53, at 32.
90. Id.
91. See id.
92. There are numerous clinical studies of RU-486 in early pregnancy. See THE ABORTION PILL, supra note 12, at 208-11; Contragestion, supra note 12. In contrast, the Author is aware of only two clinical studies of RU-486 as a postcoital contraceptive. See Glasier et al., supra note 2; Webb et al., supra note 60.
icantly delay entry of RU-486 into the American market. The delay would be offset by time saved in resolving the political controversy surrounding the characterization of RU-486 as an abortifacient.

The FDA approves about seventy-five percent of all NDAs submitted. Approval of an NDA opens the door for the sponsor to market a drug as soon as its production and distribution systems are in place. Once a drug has been approved for a specific medical use, a doctor may prescribe it for any purpose, whether approved for that purpose or not. A 1975 case, F.T.C. v. Simeon Management Corp., established that the FDA does not have jurisdiction to regulate the administration of a drug by a doctor. A doctor prescribing drugs for nonapproved uses is a common medical practice. However, a drug company cannot promote, advertise, or label a drug for non-approved purposes. Although there is little incentive for a manufacturer to seek approval for a new use, drugs are often readily available for nonapproved uses.

At least one commentator believes that RU-486 can meet the FDA's efficacy and safety standards for use as an abortifacient. Alternatively, the drug's sponsor could seek FDA approval for a use unrelated to fertility control, thus enabling doctors to prescribe the drug for use both as an abortifacient and a contraceptive. However, this strategy would not solve many of the problems posed by the current lack of a widely available postcoital contraceptive. Because extensive clinical trials would be required, a greater delay would occur before the drug became available for any use. In addition, fears about incurring liability would make doctors reluctant to prescribe RU-486 for fertility-related uses if the drug were

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94. Id.
97. Id. at 706.
98. Kapp, supra note 95, at 20.
100. Kapp, supra note 95, at 21.
103. See infra notes 141-157 and accompanying text.
approved only for a completely different use.\textsuperscript{104} And, as Part IV explains, RU-486 would likely remain unavailable as a postcoital contraceptive at federally funded clinics.

With this background in mind, Part IV makes the argument that RU-486 should be submitted and approved as a postcoital contraceptive. To illustrate the need for a new drug for this use, Part IV begins by examining the current emergency contraceptive regimen, the morning-after pill.

IV. \textbf{Why Seek Approval of RU-486 as a Postcoital Contraceptive?}

A. \textit{Problems with Current Availability and Use of Postcoital Contraceptives: The Morning-After Pill}

1. Existing Postcoital Contraceptives

Although emergency contraception has been used for at least two thousand years, it was not until the 1960s that practical methods evolved.\textsuperscript{106} In 1973, diethylstilbestrol (DES), a synthetic estrogen, became the only postcoital contraceptive ever to be given FDA approval.\textsuperscript{106} Despite questions about its safety and efficacy, DES is still approved for use as an emergency contraceptive for rape victims.\textsuperscript{107}

Today, the most widely used postcoital contraceptive regimen consists of a concentrated dose of Ovral, a combined estrogen and progestogen birth control pill.\textsuperscript{108} Four tablets are prescribed, with two taken immediately and two more taken

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\item \refnumber{104} Cotler, supra note 102, at 135.
\item \refnumber{105} Grimes & Cook, supra note 33, at 1088.
\item \refnumber{106} Hoffman, supra note 22, at 30. Between 1947 and 1971, DES was prescribed to pregnant women to prevent spontaneous abortion (expulsion of the fetus during the first 12 weeks of gestation) and miscarriage (fetal expulsion between the 12th and 28th weeks of gestation). Corey Scott Cramin, Note, \textit{Emotional Distress Damages for Cancerphobia: A Case for the DES Daughter}, 14 Pac. L.J. 1214, 1218 (1983). In 1971, several studies were published linking the use of DES by pregnant women to vaginal cancer in their daughters. Id. The FDA then suspended the use of DES by pregnant women. The FDA now requires a warning label stating that use of the drug by pregnant women increases the risk of vaginal abnormalities in their offspring. Id. at 1219.
\item \refnumber{107} Cotler, supra note 102, at 126. For a discussion of the medical studies of DES and the case law arising from its use by pregnant women, see generally Naomi Sehiner, Comment, \textit{DES and a Proposed Theory of Enterprise Liability}, 46 Fordham L. Review 963 (1978).
\item \refnumber{108} Arieiff, supra note 24. Ovral, the most extensively used birth control pill in the world today, is approved by the FDA for use as a regular oral contraceptive. Id. When used in this way, one tablet is taken each day for three weeks, and menstruation occurs during the fourth week.
\end{itemize}
twelve hours later. The pills must be taken within seventy-two hours of unprotected intercourse. A concentrated dose of birth control pills taken after unprotected intercourse prevents pregnancy by temporarily disrupting a woman's hormonal patterns. By altering the release of hormones from the ovaries, the hormones in the pills disturb the development of the uterine lining and disrupt the transport of a fertilized ovum through the fallopian tubes. Thus, depending on how soon after unprotected intercourse a woman takes the morning-after pill, the treatment either prevents fertilization of the egg or stops the fertilized egg from implanting.

Although studies have found that Ovral used in this way is ninety-eight percent effective in preventing pregnancy, other studies have challenged the efficacy of this regimen. Many studies base their success rates on the total number of women included in the study rather than the number of women potentially pregnant, leading to charges that the failure rate of postcoital contraception is grossly underestimated. In response to this criticism, further studies maintain that emergency contraceptive regimen can be expected to reduce the expected number of pregnancies by seventy-five percent.

Ovral is not the only postcoital contraceptive currently in use. Recently, a second hormonal regimen consisting of 600 mg of danocrine has been employed. However, the results on the efficacy of this method have been mixed, with some studies reporting failure rates as high as ten percent. In addition, postcoital insertion of an IUD is extremely effective in preventing pregnancy, but this method is invasive, associated with side

109. Id.
110. Id.
111. Trussell et al., supra note 3, at 269.
112. Hoffman, supra note 22, at 12.
116. Id. The likelihood that a woman who has had unprotected intercourse is at risk of pregnancy varies substantially depending on when in her menstrual cycle the intercourse occurred. For example, a woman's chance of becoming pregnant on her most fertile day is only about 25%. Hoffman, supra note 22, at 13.
117. Trussell et al., supra note 3, at 269.
118. Id.
119. Id.; see also Glasier et al., supra note 2, at 1041.
effects, and can be used only by women who have had at least one child.\textsuperscript{120}

2. "Contraception" Versus "Contragestion"

Because postcoital contraception acts after fertilization, Dr. Baulieu, the developer of RU-486, has suggested the term "contragestion" to distinguish these methods from contraception, which for most people is synonymous with preventing fertilization.\textsuperscript{121} One important difference between the two "contragestives" discussed here is that RU-486 may be used as either a regular monthly contraceptive or as emergency birth control. The morning-after pill is used strictly as an emergency treatment.\textsuperscript{122} To understand the status of, and obstacles to, the use of the morning-after pill, this Comment explores some considerations that apply to both emergency or regular use of a contragestive.

In 1989, a prominent contraception researcher ranked a once-a-month menstruation-inducing pill second on a priority list of new contraceptive methods.\textsuperscript{123} The researcher, Dr. Carl Djerassi, stated that such a menses inducer could become the single most effective method for reducing the forty million to fifty million abortions performed annually in the world.\textsuperscript{124} For a variety of reasons, however, contraceptive research in this country has come to a virtual standstill.\textsuperscript{125} Of the nine major pharmaceutical companies conducting research and development in contraception in 1970, only one was still involved in that field in 1987.\textsuperscript{126} Today, the United States government

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\item Glasier et al., supra note 2, at 1041; Grimes & Cook, supra note 33, at 1088.
\item Contraception, supra note 12, at 1813. Dr. Baulieu explains that "contraception" is a contraction of "contra-conception." Similarly, the word he has coined, "contragestion," is a contraction of "contra-gestation." Id.
\item Arief, supra note 24; see also infra note 206 and accompanying text.
\item Djerassi, supra note 1, at 358-59. First on Dr. Djerassi's list of new contraceptive methods was a new spermicide with antiviral properties. Id. at 358.
\item Id. at 359.
\item Dr. Djerassi attributes the halt of contraceptive research and development to three causes: (1) reduced funding; (2) the Reagan administration's policy of preventing government agencies from supporting contraception research; and (3) the fact that developing countries have focused their efforts to control population growth on issues such as education and optimum use of existing birth control methods, rather than the search for new contraceptive methods. Id. at 358. Dr. Djerassi also points out that infertility, rather than contraception, is currently the more popular area of human reproductive biology for scientists to explore. Id.
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\end{footnotesize}
spends less on contraceptive research in a year than the Defense Department spends on defense in fifteen minutes.127

One of the obstacles to the development of contragestives lies in the tension between medical and moral definitions of pregnancy. The medical profession views pregnancy as beginning when implantation is complete.128 Implantation is a process that takes about a week and does not begin until five to six days after fertilization.129 Thus, fertilization is not the "unique determining event in the conception of a new human being." Dr. Baulieu, for example, views the generation of human life as a continuous process.131 The view of fertilization as a process rather than an event is particularly compelling because a large number of fertilized eggs fail to implant, and many embryos are spontaneously aborted before they have developed into a fetus.132 In fact, between twenty-two percent and thirty-one percent of conceptions end in spontaneous abortion before or after implantation.133

On the other hand, the moral viewpoint asks not only when a pregnancy has been established, but also the more difficult question of when a new life can be said to exist. Basically, there are three positions: (1) Life begins at conception.134 (2) Life begins sometime during pregnancy.135 (3) Life does not begin

127. Cotler, supra note 102, at 131 (citing NEWSDAY, Jan. 12, 1979, at 77).
128. See Grimes & Cook, supra note 33, at 1089. The definition of pregnancy as beginning with completed implantation has been adopted by the American College of Obstetricians and Gynecologists. Cook, supra note 38, at 267.
129. Grimes & Cook, supra note 33, at 1089.
130. Id.
131. Contragestion, supra note 12, at 1813.
132. Cook, supra note 38, at 267.
133. Allen Wilcox et al., Incidence of Early Loss of Pregnancy, 319 NEW ENG. J. MED. 189, 192-93 (1988). Dr. Wilcox reported that 22% of all early established pregnancies detected by the presence of a hormone did not survive to the stage of being recognized by a conventional pregnancy test. Combining these early losses with losses that occurred later among recognized pregnancies resulted in an overall loss rate of 31%. Id.
134. Don Colburn, A Morning-After Pill; New Study Says RU-486 Works Better Than Current Methods, WASH. POST, Oct. 13, 1992, (Health section), at 7. Many antiabortion groups such as Right to Life take the view that life begins with conception. Richard Glasow, education director of the National Right to Life Committee, has stated, "The union of the sperm and the ovum is the beginning of human life." Id. This view is also reflected in the language of some state abortion statutes. See infra notes 175-186 and accompanying text.
135. See Grimes & Cook, supra note 33, at 1089. The view that life begins when implantation is complete is widely held by the medical and scientific communities. Id. Courts have also taken the view that life begins during pregnancy, without specifying an exact point. See infra part IV.B.
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until birth.\textsuperscript{136} Antiabortion groups, which generally follow the first view, have opposed research and design of postcoital contraceptives because these methods act to prevent implantation of a fertilized ovum.\textsuperscript{137} As Dr. Albert Yuzpe, the developer of the most widely used morning-after pill regimen, has stated, "A contraceptive method that exerts its effects after fertilization has occurred is for some unacceptable."\textsuperscript{138}

The fact that Ovral is widely available as a regular birth control pill has somewhat diffused opposition. Antiabortion groups have acknowledged that Ovral's availability as a regular birth control pill makes preventing the pill's use as a postcoital contraceptive virtually impossible.\textsuperscript{139} Thus, if a new drug, such as RU-486, were approved and marketed specifically as a postcoital contraceptive, it would be considerably more vulnerable to such opposition because it acts after fertilization. However, the education director of National Right to Life has predicted that if the proponents of RU-486 successfully identify the drug with contraception rather than solely with abortion, opposition from the right-to-life movement could be seen as reactionary.\textsuperscript{140}

3. Obstacles to the Use of Current Postcoital Contraceptive Methods

FDA approval of RU-486 as a postcoital contraceptive would remove many existing obstacles to the use of a postcoital contraceptive. The biggest problem with the current postcoital contraceptive regimen is the lack of knowledge about the treatment. A recent \textit{New York Times Magazine} article called the morning-after pill "the best-kept contraceptive secret in America."\textsuperscript{141} Although it is widely prescribed on college campuses, the morning-after pill is still largely unknown to teenagers and women in their thirties and forties.\textsuperscript{142} Many gynecologists do not even know about the regimen, although it

\begin{itemize}
  \item \textsuperscript{136} David Brushwood, \textit{Must a Catholic Hospital Inform a Rape Victim of the Availability of the "Morning-After Pill"?}, 47 AM. J. HOSP. PHARMACY 395, 396 (1990).
  \item \textsuperscript{137} Cotler, supra note 102, at 131.
  \item \textsuperscript{138} Arieff, supra note 24.
  \item \textsuperscript{139} Id.
  \item \textsuperscript{140} Sarah Ricks, \textit{The New French Abortion Pill: The Moral Property of Women}, 1 YALE J.L. & FEMINISM 75, 93 n.90 (1989).
  \item \textsuperscript{141} Hoffman, supra note 22, at 12.
  \item \textsuperscript{142} Id.
\end{itemize}
has been the standard of care for rape victims in hospital emergency rooms for at least a decade.\footnote{143} Several factors account for the relative obscurity and inaccessibility of postcoital contraception. First, many health care practitioners are reluctant to prescribe the morning-after pill because they fear that the high dose of hormones could have adverse health effects.\footnote{144} While the treatment is generally considered safe, some practitioners take the view that the risk of pregnancy from one act of unprotected intercourse is not significant enough to disrupt a woman's hormones.\footnote{145} Moreover, the side effects of the treatment can be severe. More than one half of the women who take the morning-after pill experience nausea, headaches, and breast tenderness. About one fifth suffer from vomiting as well.\footnote{146}

Second, the manufacturers of birth control pills have not applied for FDA approval to market their products as emergency contraceptives, and it is unlikely they will do so.\footnote{147} The disincentive is largely financial. The approval process is likely to take an average of five years and cost tens of millions of dollars.\footnote{148} Because postcoital contraception involves a one-time use of only four to eight pills, it is far less lucrative than regular oral contraceptives, which a woman takes daily for three out of every four weeks.\footnote{149} In addition, federal regulations have been widely interpreted as requiring contraceptive drugs and devices provided by federally financed family planning clinics\footnote{150} to be approved by the FDA for the use prescribed.\footnote{151} Thus, the

\footnotesize
\footnote{143} Id. at 14-15. 
\footnote{144} Trussell et al., supra note 3, at 270. 
\footnote{145} Hoffman, supra note 22, at 30. 
\footnote{146} Glasier et al., supra note 2, at 1043. 
\footnote{147} Hoffman, supra note 22, at 30. 
\footnote{148} Id. 
\footnote{149} Id. 
\footnote{150} Title X provides federal grants for family planning services. 42 U.S.C. § 300(a) (1988). 
\footnote{151} W. Archer, Office of Population Affairs, Dept of Health and Human Servs., Prohibition on the Use of Depo-Provera in Title X Family Planning Projects, Program Instruction Series OPA-91-1 (May 10, 1991). A 1991 memorandum from the Deputy Assistant Secretary for Population Affairs to regional health administrators stated, "It is longstanding policy of the Office of Population Affairs that contraceptive drugs and devices provided, either directly or through referral, by Title X supported family planning projects must have been approved for contraceptive purposes by the Food and Drug Administration." Id. The regulations state that "[e]ach project supported under this part must: (1) Provide a broad range of acceptable and effective medically approved family planning methods. . . and services." 42 C.F.R. § 59.5(a)(1) (1992) (emphasis added).}
morning-after pill is unavailable at clinics that receive federal funding under Title X.\textsuperscript{152} This means that millions of low-income women and teenagers are denied access to this method of postcoital contraception.\textsuperscript{153}

Third, the fear of incurring liability may deter doctors from prescribing emergency contraceptives, even though a drug approved by the FDA for one use may legally be prescribed for non-approved uses.\textsuperscript{154} Damage awards in birth defect cases are among the highest in medical malpractice lawsuits.\textsuperscript{155} Damages have been awarded even where a product was employed for its FDA-approved use and where no link had been established between the product and birth defects.\textsuperscript{156} For example, in 1986, a court awarded $4.7 million to a woman who claimed that her child’s birth defects were caused by the spermicide Ortho-Gynol.\textsuperscript{157}

For these reasons, the morning-after pill is inadequate to meet women’s needs for postcoital contraception. If approved as a postcoital contraceptive, RU-486 would help significantly in meeting this need, thereby reducing the need for abortion. With the need for such a new drug established, Section B discusses how this new contragestive would fit into the existing legal framework governing birth control and abortion.

\textbf{B. Griswold, Casey, and the Right to Privacy: Where Does RU-486 Fit In?}

RU-486 as a postcoital contraceptive is conceptually similar to two currently used methods of birth control, the morning-after pill and the IUD, because both of these may act after fertilization.\textsuperscript{158} Although the IUD and RU-486 differ in their chemical and mechanical effects, they are substantially similar from a legal standpoint because both interfere with the nurturing uterine environment so that pregnancy does not continue.\textsuperscript{159} It is important to note that the morning-after pill and the IUD are not generally considered abortifacients. Although

\begin{itemize}
  \item \textsuperscript{152} Hoffman, \textit{supra} note 22, at 14.
  \item \textsuperscript{153} \textit{Id.}
  \item \textsuperscript{154} Trussel et al., \textit{supra} note 3, at 270; see \textit{supra} notes 95-100 and accompanying text.
  \item \textsuperscript{155} Hoffman, \textit{supra} note 22, at 30.
  \item \textsuperscript{156} \textit{Id.}
  \item \textsuperscript{157} Wells \textit{v.} Ortho Pharmaceutical Corp., 788 F.2d 741, 747 (11th Cir.), cert. denied, 479 U.S. 950 (1986).
  \item \textsuperscript{158} See \textit{supra} notes 108-120 and accompanying text.
  \item \textsuperscript{159} Ricks, \textit{supra} note 140, at 80.
\end{itemize}
many antiabortionists oppose any method that may act after fertilization, their opposition has not coalesced as a drive to ban either the IUD or the morning-after pill.160

This conceptual similarity suggests that RU-486 should be treated the same as the IUD and the morning-after pill for legal and regulatory purposes if RU-486 is submitted only for postcoital contraceptive use. Whether the drug is considered a contraceptive or an abortifacient is important because of the differences between the legal treatment of the right to contraception and the right to abortion. The constitutional right not to procreate by choosing to use contraception was established in Griswold v. Connecticut161 and further strengthened by Eisenstadt v. Baird162 and Carey v. Population Services International.163 Grounded in privacy, this fundamental right not to procreate remains relatively uncontroversial and unchallenged. On the other hand, the right to choose abortion has become increasingly controversial in the twenty years since the Supreme Court held in Roe v. Wade164 that a constitutionally protected right to abortion exists, at least until the point of fetal viability.165

Recent abortion cases have underscored that Roe's foundation is shaky. For example, in Webster v. Reproductive Health Services,166 the Court upheld a Missouri statute limiting delivery of abortion services in the third trimester.167 Similarly, in the most recent case, Planned Parenthood of Southeastern Pennsylvania v. Casey,168 the Court narrowly upheld a woman's basic right to seek abortion, but clarified the Webster Court's holding that a state may regulate that choice even in the early stages of pregnancy.169 Under Casey, a state statute regulating abortion may be constitutional so long as it does not impose an undue burden on a woman's right to choose abortion.170 Challenges aimed at clarifying what constitutes an undue burden are sure to follow. However, because Casey did not overturn

160. Cook, supra note 38, at 270.
161. 381 U.S. 479 (1965).
162. 405 U.S. 438 (1972).
165. Id. at 164-65.
167. Id. at 519-20.
169. Id. at 2818.
170. Id. at 2820.
Roe, it now appears likely that some level of constitutional protection for the right to choose abortion will remain.

Because RU-486 is effective as an abortifacient only during the very early stages of pregnancy, its use as an abortifacient would probably be safe from governmental interference even under the narrowing of Roe that has occurred with Webster and Casey. One commentator has suggested that even if RU-486 was approved as a monthly contraceptive, its use would likely be governed by federal abortion law rather than by contraceptive law because of the drug's potential to be used intentionally as an abortifacient.\(^{171}\) However, the same commentator recognized a slight possibility that the drug would be placed under regulations on contraception.\(^{172}\) Thus, if RU-486's proponents focus solely on the drug's use as a postcoital contraceptive, the result may be to put RU-486 firmly in the area of private contraceptive decision making that has enjoyed undiminished protection under Griswold and its progeny.

From the standpoint of increasing women's birth control options, the consequences of the FDA approving RU-486 as a contraceptive would be dramatic.\(^{173}\) Federal regulation of contraceptives is limited to their initial entry into the market and to the requirement that some forms be prescribed by a doctor.\(^{174}\) Thus, approval of RU-486 as a postcoital contraceptive is the best means of ensuring that the drug will remain available to women for contraceptive use, even if future court decisions further restrict the right to abortion.

With the regulatory framework of abortion somewhat clarified, the most pressing legal problem surrounding abortion is also a philosophical one. In state legislatures and the courts, the narrow view that life begins at fertilization appears to be on a collision course with itself because courts since Roe have refused to address the question of when life begins. For example, the preamble to the Missouri statute upheld in Webster states that "[t]he life of each human being begins at conception."\(^{175}\) However, the Court did not consider whether this language would render the statute unconstitutional as infringing on the right to birth control. Instead, the Court upheld the preamble on the grounds that it merely stated a value judgment

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171. Ricks, supra note 140, at 82.
172. Id. at 76.
173. Id. at 81.
174. Id.
and did not regulate abortion. The Webster Court rejected the plaintiffs' claims that the preamble's definition of life could prevent doctors from prescribing birth control methods that act after fertilization, such as the IUD.

Indeed, despite legislative determinations such as Missouri's, which are completely inconsistent with medical definitions of when life begins, no court has ever held that the morning-after pill or the IUD is abortion, even though that conclusion would appear to be logically dictated by such statutory language. In at least two cases, lower federal courts have confirmed the view that birth control methods that act after fertilization are not abortion. In Margaret S. v. Edwin Edwards, Louisiana's abortion statute was challenged as being impermissibly vague because it defines abortion as "the deliberate termination of human pregnancy after fertilization..." The plaintiffs, which included a number of health clinics and doctors, charged that, under this definition, birth control methods such as the IUD or the morning-after pill would be outlawed as abortifacients. The court held that the definition was no more vague than that in most abortion statutes and stated that "[a]bortion, as it is commonly understood, does not include the IUD, the 'morning-after' pill, or for example, birth control pills." Thus, the statute was upheld because the court essentially disregarded its literal meaning.

However, another court struck down similar provisions contained in an Illinois abortion law. In Charles v. Carey, plaintiffs claimed that the statute's definition of "abortifacient" was overbroad and impermissibly infringed on the right to birth control. The statute 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." The

177. Id. at 505-06.
182. Id.
183. 627 F.2d 772 (7th Cir. 1980).
184. Id. at 789.
185. Id. (quoting S.B. 47, the Illinois Abortion Law of 1975, § 2(10) (current version at ILL. REV. STAT. ch. 720, paras. 515 (1992))).
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court held that the statute, which defined fetus as "a human being from fertilization until birth," was overbroad because it would include the IUD.\textsuperscript{186}

A recent California case provides further support for the legal proposition that contraception that acts after fertilization is not abortion. In \textit{Brownfield v. Daniel Freeman Marina Hospital},\textsuperscript{187} the plaintiff was taken to the defendant's emergency room after being raped.\textsuperscript{188} Her mother asked for information about the morning-after pill, but the Catholic hospital refused to provide the information.\textsuperscript{189} California's abortion law states that religious institutions may not be held liable for failure to permit or perform an abortion.\textsuperscript{190} The plaintiff, who did not become pregnant despite not receiving the treatment, sought a declaration that the hospital's failure to provide information about the morning-after pill constituted failure to provide optimal emergency treatment for rape victims.\textsuperscript{191} She also sought an injunction requiring the hospital to provide the morning-after pill or to stop treating rape victims and instead transport them to another emergency room.\textsuperscript{192}

The court held that California's abortion law exempting religious institutions from participating in abortions did not shield the hospital from liability for refusing to provide information about the morning-after pill.\textsuperscript{193} The court agreed with the plaintiff that postcoital contraception is not abortion, relying in part on \textit{Margaret S.}\textsuperscript{194} The court thus held that a rape victim may have a cause of action when she can allege that (1) a skilled practitioner would have provided her with information about, and access to, postcoital contraception; (2) she would have elected such treatment if offered; and (3) she was damaged by the hospital's failure to provide access to the treatment.\textsuperscript{195}

From a jurisprudential standpoint, postcoital contraception is generally regarded as squarely within laws governing contra-

\textsuperscript{186} \textit{Charles}, 627 F.2d at 789.
\textsuperscript{187} 256 Cal. Rptr. 240 (Ct. App. 1989).
\textsuperscript{188} \textit{Id.} at 242.
\textsuperscript{189} \textit{Id.}
\textsuperscript{190} \textit{CAL. HEALTH & SAFETY CODE} § 25955(c) (West 1984).
\textsuperscript{191} \textit{Brownfield}, 256 Cal. Rptr. at 242.
\textsuperscript{192} \textit{Id.} at 242.
\textsuperscript{193} \textit{Id.} at 245.
\textsuperscript{194} \textit{Id.}
\textsuperscript{195} \textit{Id.} In this case, the court affirmed the trial court's dismissal because the plaintiff had not alleged facts demonstrating that her injury required equitable relief. \textit{Id.} at 245.
ception, rather than those governing abortion. RU-486, if approved as a postcoital contraceptive, should not be treated differently. Because the drug's effect is similar to two fertility control methods that the courts have repeatedly held do not constitute abortion, treating RU-486 differently would produce inconsistent, unprincipled law.

In addition to these legal arguments, Section C argues that there are compelling medical reasons to approve RU-486 as a contraceptive.

C. Medical Advantages of RU-486 as a Postcoital Contraceptive

From a medical standpoint, RU-486 has important advantages over currently used emergency contraceptives. As the studies comparing RU-486 with the standard estrogen and progestogen morning-after regimen have demonstrated, RU-486 not only produces far fewer side effects, but it may also be more effective. Because it does not involve a large, concentrated dose of hormones, those health care practitioners who fear the possible health effects of the current postcoital contraceptive regimen may be more comfortable prescribing RU-486. Another advantage is that, unlike the current morning-after pill, RU-486 does not require immediate medical intervention following unprotected intercourse. Instead, it may be taken at any time before a woman expects her menstrual period, or even in early pregnancy. If RU-486 were to be developed as a once-a-month pill for regular contraceptive use, it would offer women the additional advantage of taking only twelve pills per year, rather than over 250.

An even more urgent medical reason to approve RU-486 as a postcoital contraceptive is that this strategy would most quickly make the drug available to a broad medical constituency that stands to benefit from it. Among the more pressing health problems that RU-486 shows promise in helping to alleviate are breast cancer and AIDS. However, development of these uses of the drug has been obstructed by the abortion debate. The longer the drug is embroiled in a controversy at

196. See Glasier et al., supra note 2, at 1044; Trussell et al., supra note 3, at 273.
197. THE ABORTION PILL, supra note 12, at 18.
198. Djerassi, supra note 1, at 359.
200. Id. at 332.
the regulatory level because of its use in early abortions, the longer it will be unavailable to researchers to aid in the treatment of these and other diseases and disorders. As noted above, however, FDA approval of RU-486 for a use altogether unrelated to fertility control would fail to maximize the drug's most important benefit: giving women more control over their own fertility.

That need for control implicates policy arguments in favor of approving RU-486 as a postcoital contraceptive. Section D explores the policy aspects of approving RU-486 as a postcoital contraceptive.

D. Policy Considerations: Preventing Abortion

One of the most important policy reasons to approve RU-486 as a postcoital contraceptive is its potential in reducing the demand for therapeutic abortion. The recent New England Journal of Medicine study comparing RU-486 to the morning-after pill concluded that the demand for abortion would be reduced if family planning services that included RU-486 as a postcoital contraceptive were widely available.201 Estimates are that postcoital contraception could be used by about three-quarters of those women whose unintended pregnancies result from either the failure of a birth control method or from the failure to use a method properly or consistently.202 Family planning specialists have stated that if postcoital contraception were widely available, the number of unintended pregnancies could be reduced by at least 1.7 million, thereby reducing the number of induced abortions by approximately 800,000 per year.203

However, wide availability of RU-486 as a postcoital contraceptive would pose some problems not encountered with the current morning-after pill. Because the current postcoital contraceptive regimen is likely to be physically unpleasant, women are unlikely to rely heavily on its use as a substitute for regular birth control.204 Removing this unpleasantness could result in increased reliance on contraception after the fact, possibly distracting women from the importance of using barrier methods.

201. Glasier et al., supra note 2, at 1044.
202. Trussell et al., supra note 3, at 269.
203. Id. at 270.
204. Hoffman, supra note 22, at 15.
not only to prevent pregnancy, but to protect themselves from AIDS and other sexually transmitted diseases.\textsuperscript{205}

On the other hand, broad availability of postcoital contraceptives can serve as a bridge. Following a woman's initial visit to a doctor or clinic for emergency contraception, she can then be counseled about and encouraged to use regular birth control. Furthermore, health care practitioners will be able to shift a large proportion of their energy and resources from providing abortions to focusing on other health care services, such as the prevention and the treatment of AIDS and other sexually transmitted diseases. The fact that some people may be unable or unwilling to plan ahead for birth control is not a reason to withhold or restrict use of emergency contraception. In the words of Dr. Louise Tyrer, a vice president of Planned Parenthood, "The medical profession does not encourage people to use the postcoital method except in an emergency and certainly not on a regular basis, but it's better than getting pregnant and having an abortion."\textsuperscript{206}

FDA approval of RU-486 as a postcoital contraceptive would further aid in the goal of reducing abortions by making an emergency contraceptive available to millions of women who rely on federally-funded clinics for their health care. Such clinics are now precluded from offering the morning-after pill because birth control pills are not FDA approved for that use.\textsuperscript{207} As a matter of policy, health care that includes complete contraceptive services should be available to all women, not just those who can afford to see a private physician. In addition, giving low-income women increased control over their fertility is critically important. Ensuring that families are planned with only the number of children that parents can emotionally and financially care for is an important step in breaking the cycle of poverty that affects millions of women and children in this country.

V. CONCLUSION

Focusing on the use of RU-486 as a postcoital contraceptive will avoid much controversy and best serve the needs of women and the goals of society. The drug is an important means of fertility control that has been demonstrated to be safe and effective, and it should be made available now. The need for addi-

\textsuperscript{205} Id.
\textsuperscript{206} Arieff, supra note 24.
\textsuperscript{207} See supra notes 150-153 and accompanying text.
tional methods of fertility control is highlighted by predictions that the world population will increase by at least one billion people every twenty years during the coming century.\textsuperscript{208} Dr. Baulieu has pointed out that increasing population remains a pressing problem, despite the recent worldwide trend toward a slowing of the increase.\textsuperscript{209}

The best way to slow population growth is to reduce the number of unintended pregnancies by giving women the best available means to control their fertility. Wider availability of postcoital contraceptives has the proven potential to reduce sharply the incidence of unintended pregnancies and abortions. President Clinton has stated, "Our vision should be of an America where abortion is safe and legal, but rare."\textsuperscript{210} RU-486, used as a postcoital contraceptive, can best help achieve that vision.

\footnotesize
\begin{itemize}
  \item 208. Contragestion, supra note 12, at 1808.
  \item 209. Id.
  \item 210. Clinton Signs Memoranda, supra note 34.
\end{itemize}