

RU-486: A PRESCRIPTION FOR CONTROVERSY

Margaret Gregory

Writer's comment: Initially, I was at a loss for a research topic in English 101 (Advanced Composition). But the idea of writing about the controversial drug, RU-486, came to me one night while watching the news. The story I saw discussed distribution of RU-486 to high schools in France and juxtaposed France's more liberal stance toward the drug with its illegal status in the U.S. I had my topic, and many questions. Was RU-486 used as an emergency contraceptive? What were its physiological effects within the body? After a little research into what I discovered was often called "the abortion pill," my investigation became more personal; if I was faced with the decision to have an abortion, would I want the option of RU-486.

— *Margaret Gregory*

Instructor's comment: For my English 101: Advanced Composition courses, I assign a research paper (developed by my colleague Jared Haynes) that asks students to analyze various points of view on a controversial issue without taking a stand. This requirement to suspend opinion, to analyze *all* sides of an issue instead of just the one agreed with, is difficult but also rewarding, modeling the "real-life" work one must do in the face of complicated political and personal issues. Margaret's paper provides an excellent model. She wisely sidesteps the emotional "Abortion: Pro or Con?" element, focusing narrowly on RU-486, the so-called abortion pill. She draws our attention primarily to scientific and medical controversy, with forays into history, politics, and economics, drawing attention to facts instead of emotional or personal appeals. Her research and careful approach challenge the assumption that pro-choice must favor legalization and antiabortion must oppose it. She helps us to see RU-486 as a separate issue with specific benefits and drawbacks, making her own nicely balanced contribution to the controversy.

— *Pamela Demory, English Department*

Picture yourself as a sixteen-year-old girl. Your friends and family used to describe you as happy, vivacious, and carefree. But as you have been awaiting your period, now two weeks overdue, you have become sullen and agitated with worry. Two more weeks go by and you buy a home pregnancy test. You perform the test only to find out what you already know. It doesn't really matter how you got pregnant—the condom tore, your boyfriend lied about pulling out, you forgot to take your birth control pills—it just matters that you are and you don't want to be. To complicate matters, let's say that you are from a strict Catholic family with very devout parents, and you cannot possibly bring yourself to talk to them about it. After a few weeks of seemingly endless painful deliberation that you thought you would never have to endure, you have your best friend take you to an abortion clinic. Picketers block the front door to the clinic carrying signs that read “Abortion = Murder.” Before you can even begin to process the words on the signs, your best friend grabs you by the arm and pulls you past the crowd and into the small lobby of the clinic. Expecting an ordinary doctor's office waiting room, you are unsettled by the unfamiliarity of the stark décor. The lobby is nothing but an entryway with a front desk encapsulated by bulletproof glass. While checking in you speak to the receptionist through a hole in the glass, as though you are paying for gasoline at a station after midnight. Now more than ever you feel scared and alone.

Since the legalization of surgical abortions in 1973, this has become a common scenario for women seeking to terminate a pregnancy. Of course, some go through the process with fewer obstacles and complications than others. However, as the issue of abortion in the United States has become one of the most volatile and violent debates of the past thirty years, experts in the field have been searching for a way to make abortion a less traumatic and less complicated experience for women. Scientists were successful in the early eighties with the discovery of the drug RU-486. According to Aaron Zitner of *The Boston Globe Magazine*, many pro-life organizations call the drug “the human pesticide” and the Pope has been quoted as calling RU-486 the “pill of Cain” (5). Commonly known as “the French abortion pill,” the drug induces a spontaneous abortion of the fetus without the need for surgery. Rather than taking the time to visit a clinic, receive a general anesthetic, undergo the surgery, and recover, now a woman can take some “pills and water,” expel the fetus and get back to her ordinary life (2). The drug is legal in parts of Europe and China but has been thrown into legal limbo in the United States ever since Clinton took office in 1993. Although pro-choice and reproductive health organizations argue that the drug is a safe and effective alternative to surgical abortion, the strong antiabortion movement in the U.S. not only regards the drug as an instrument of murder, it questions RU-486's safety and fears that the legalization of the drug may prompt more women to seek abortions. The practical matter of demand for the drug is also an issue: are enough women even interested in using RU-486 to make its manufacture profitable?

History

RU-486 was essentially stumbled upon. In the early eighties, scientists with the French pharmaceutical company, Groupe Roussel Uclaf, were investigating cancer fighting drugs. Amid their research of certain compounds' effects on the endocrine system, Roussel scientists were “drawn to one with unusual characteristics, which carried the lab identification tag, RU-486” (4). It was soon discovered that the drug deprived the uterus of the hormone progesterone and essentially caused a miscarriage (4). RU-486, named after its French manufacturer, was given the generic scientific name mifepristone and excited French scientists began to test the drug at some length (4).

Five years later, in 1987, RU-486 had been put through a series of European trials and was found to be a phenomenally effective and safe new way of ending a pregnancy (4). Mifepristone taken alone had extremely unpredictable failure rates (Cabezas 142); however, when taken with another drug, usually a

prostaglandin (Cabezas 142), the failure rate was as low as 5% (Zitner 4). That meant that RU-486 had a success rate of 95%. The drug was discovered to have the side effects commonly associated with a miscarriage, such as nausea, cramps, and bleeding (7), but there was believed to be no risk of infection such as sometimes accompanies surgical abortions. Roussel Uclaf deemed RU-486 safe, successful, and suitable for the public by 1988.

Despite the support for RU-486, in the face of formidable opposition and threats of boycotting from antiabortion groups all over the world, but most notably in the United States, Roussel and the French government balked at bringing the drug to market (4-5). But heavy pressure from feminists and reproductive health specialists convinced the French government to legalize mifepristone, and two days after Roussel had said it would discontinue the manufacture of the drug, the government ordered the company to manufacture and distribute RU-486 to France (6).

RU-486 was legalized in France in 1988. That same year the Chinese began to manufacture and distribute their own “unlicensed” version of mifepristone in China (Derman and Peralta 8). By 1992, medical abortions had become a reality in Great Britain and Sweden (Zitner 9). In the U.S., President Clinton’s administration began to change the conservative attitudes that had revolved around abortion during President Bush’s administration. Clinton’s Democratic administration lobbied intensely with Roussel’s German parent company, Hoechst, to get RU-486 into the United States (Zitner 9). Hoechst agreed to initiate the process. But afraid of American pro-life “protests and boycott threats,” the company simply donated the U.S. rights to the drug to a nonprofit research agency, the Population Council (9). Since that time, the path to legalizing mifepristone in the U.S. has been mired by faulty leadership, required secrecy, and countless liability lawsuits. According to Zitner, RU-486 has become “like a storm locked in a closet” - it has “been pushed into a kind of limbo”(3).

What is RU-486?

RU-486, or mifepristone, is “a synthetic hormone that is used as a first trimester abortifacient” (Derman and Peralta 6). In order for a woman’s uterus to sustain an implanted zygote, or fertilized egg, into a growing fetus, her body must begin to produce increased amounts of the hormone progesterone (Zitner 40). Progesterone prepares the uterine lining for successful implantation and aids in the development of the placenta which facilitates nourishment and protects the fetus to term (4). RU-486’s main function is that of a “progesterone antagonist” (Derman and Peralta 8). According to Cabezas, RU-486 “blocks the receptors where progesterone attaches to the cells, thus leading them to be unresponsive to progesterone” (142). Derman and Peralta relate the subsequent physiological effects: “As the early pregnancy loses its support [because of RU-486’s block on progesterone receptors], hCG levels fall, and thus support for the corpus luteum [a progesterone-secreting structure] wanes. Prior to seven weeks gestation, an ongoing pregnancy requires corpus luteum support. Thus, when the corpus luteum degenerates early, the pregnancy is inevitably lost” (8).

Although the drug causes a release of prostaglandin (an unsaturated fatty acid involved in the contraction of a smooth muscle such as the uterus) from the implantation site, it is most often the case that RU-486 is not effective in expelling the fetus (8). Prostaglandin, in the form of oral medication or a vaginal suppository, must be taken in conjunction with RU-486 in order to complete the abortion (8). It is the addition of the prostaglandin that brings the success rate up to 95% (8).

Surgical vs. Medical Abortions

Abortion is by no means a twentieth-century discovery. Documentation of abortion has been discovered in ancient Egypt, China, and Rome (Cabezas 141). As of the writing of this paper, surgical abortions done within the first trimester of pregnancy are the only legal means of obtaining an abortion in

the U.S. According to Cabezas, “For many years the methods [of abortion] have been based on mechanical dilation of the cervix and removal of uterine contents” (142). One of the earliest methods used was dilation and curettage, commonly known as D&C, in which the cervix is dilated and the uterine contents are scraped out (142). The invention of the vacuum aspiration machine brought about a safer method of abortion, known as an MVA (manual vacuum aspiration) abortion, that proved to be less painful and caused 50% fewer complications in patients (142). These two methods of surgical abortion are practiced in the U.S. today, MVA abortions being the most utilized method (Zitner 7). These can be performed up to twenty weeks gestation (Cabezas 142), easily surpassing the twelve-week maximum allowance imposed by the law on first trimester abortions. The complications associated with surgical abortions include excessive bleeding, pelvic infection, cervical injury, and uterine perforation (142).

Compared to surgical abortions, a medical abortion may be easier for some women, but RU-486 is not so simple as taking “pills and water,” and it is only effective if taken within the first seven weeks of gestation (Virgo et al. 143). According to Virgo et al., in order to obtain RU-486 in England and France (and theoretically in the U.S.), the patient must make three visits to her doctor. On the first day, the patient receives RU-486 and the pregnancy is aborted. On the third day, the patient receives the drug containing prostaglandin which induces uterine contractions to expel the aborted fetus (146). A follow-up visit is required fifteen days later to ensure that “the miscarriage has taken place and that no complications have resulted”(146). If it is determined that the miscarriage failed, then a doctor immediately performs a surgical abortion (146).

Although RU-486 is considered a safe method of medical abortion, it is not without side effects. As with many drugs, side effects range from mild to acute and depend on an individual’s specific bodily reaction. The side effects “are primarily related to the added prostaglandin rather than to RU-486” (Derman and Peralta 8), and may include heavy bleeding, cramping, diarrhea, nausea, vomiting, fever, and passage of tissue (Cabezas 143; Virgo et al. 146). A survey of women who had medical abortions using RU-486 through the South Avenue’s OB-GYN Group in Rochester, New York, shows the variance in side effects. One patient wrote that it was “painless” with “no emotional trauma.” However, another wrote: “Scared - woke up in a pool of blood” (Zitner 9).

Benefits

Supporters of the legalization of RU-486 suggest there are a number of reasons why medical abortions may be preferable to surgical abortions. The potential for privacy is one of the most significant reasons (Cabezas 145). A medical abortion would require more trips to the doctor’s office, but because the drug could be prescribed by a woman’s gynecologist, she would never have to enter an abortion clinic and would safely avoid any possible acts of violence and any antiabortion protesters (Zitner 2). RU-486 may also make abortion less traumatic for adolescents. Because it is a “less frightening option,” young women may be persuaded to go through with abortions earlier and thus more safely (Cabezas 145). As medical abortions cause less infectious complications, Cabezas argues that they could be used in developing countries and other places where it is “unsafe and inadequate” to administer surgical abortions (145) and thus potentially save the lives of the nearly 70,000 women who are killed every year as a result of unsafe abortions (141). Women may also favor RU-486 for its less invasive quality (Evenson 4). Finally, although there are more physical side effects associated with RU-486, the psychological and emotional effects on women who choose RU-486 seem to be less disturbing. As one patient relates, “I threw up constantly. It gives me nausea thinking about it. But every time I see an abortion protest on TV, or imagine those people waving those horrible fetus pictures in my face, I think, ‘this was a better way’”(Evenson 4).

Drawbacks

Many professionals in the field remain unconvinced that RU-486 is a safe product that has been thoroughly tested. Once the Population Council obtained the patent to RU-486, they intended to do research and trials, as well as to find investors and a manufacturer, in secret to avoid the threat of antiabortion protesting and violence (Zitner 10). Because all testing so far has been done in secret, results have not been easily accessible; any dangerous effects of the drug that were recorded in individual case records were not disclosed. Complications could have arisen that were not included in a study's final report, and so a potential patient may not be able to make an informed decision about RU-486 for lack of complete information (Zitner 17; Marshner 2).

As antiabortion groups have tried to compile evidence against RU-486, many have discovered cases in which RU-486 has put patients' lives in grave danger. Many antiabortionists who study and write about RU-486 retain a very biased stance against the drug and it can be difficult for a layperson to determine whether their scientific findings would be validated by an authoritative body such as the American Medical Association or the Food and Drug Administration. However, their results do remind us that using RU-486 does entail risks. For example, pro-life Catholic scientist, Lawrence Roberge, calls attention to the drug's half-life, "a pharmaceutical term to describe the time period by which one half of the active drug is broken down by the body and/or removed from the body"(2). RU-486 has a half-life of 25.5 to 47.8 hours, depending on the dosage (2). Drugs also have a metabolite which is the "by-product" of the drug after it is metabolized in the liver (2). According to Roberge, the half-life plus the metabolite mean that RU-486 may linger in the bloodstream, acting like a weaker version of itself, up to fifteen days after the abortion (2). Connie Marshner, a writer for a pro-life magazine, identifies the most pressing medical concern to be the lack of knowledge of the drug's long-term effects in that "there are no long-term studies of the effect of RU-486 on animals, much less humans" (7).

Both advocates and critics of RU-486 do call attention to the seriousness of certain side effects, most notably the severe hemorrhaging sometimes caused by the drug. The death of a French woman in 1991 and the reoccurrences of women needing blood transfusions as a result of taking RU-486 have complicated the drug's perceived safety (Evenson 4). Advocates of the drug emphasize the importance of the follow-up visit and the patient's careful monitoring of her body (Evenson 4; Cabezas 145). Critics emphasize that RU-486 also has the potential to kill mothers and should therefore be called a "poison" (Marshner 7).

The Market

Despite the drawbacks of RU-486, some studies have shown a high level of interest in mifepristone as an alternative to surgical abortions. In a study done by E. Cabezas, 500 Cuban women seeking abortions were evaluated. Half underwent surgical abortions, while the other half received RU-486. Between the two, the group treated with the medical method suffered significantly more from side effects, most notably nausea, vomiting, cramping, and bleeding, while the surgical group only had a higher incidence of fever (144). Yet when the women's satisfaction with their abortion method was also analyzed, researchers found that those who underwent the medical abortion gave significantly higher satisfaction ratings despite the higher incidence of side effects (145). Another study done by Virgo et al. showed similar results. Women seeking abortions at an Illinois abortion clinic were asked to complete a survey on a voluntary basis regarding RU-486. Although only 30.9% reported that they would try RU-486 if faced with a future abortion (151), 76% of the women who completed the survey "expressed interest in learning about [RU-486]" (148). Further, the authors of the study were surprised to find that 40.5% of respondents "reported they would use birth control more often if RU-486 were available" (149). While these results are inconclusive, as the women were only basing the claim on theoretical and *not actual* experience with RU-486 (and the authors of the study indicate that their questions may have been misunderstood by some of the

respondents), such findings could be seen as potential benefits of RU-486 legalization.

Opponents of RU-486 are quick to point out that it is not a miracle drug and that it does not necessarily make abortion easier. Marshner calls RU-486 “a long, drawn-out procedure”(5) which may turn off many women who just want to get the procedure completed in one timely visit and who may then opt for the surgical method. The numerous medical precautions also suggest the drug is not for everyone. The patient is advised to be a non-smoker, under thirty-five (Evenson 4), and it is imperative that she return for her follow up visit: “The follow-up is so important because [RU-486] is not 100% effective. If it’s not effective, you could damage the fetus” (4). In Virgo et al.’s study only 51.4% of respondents displayed a willingness to return for the follow-up visit (150-1). If only half of the women return for a follow-up, many would put themselves in potentially dangerous situations. Because RU-486 is not 100% effective, a small percentage of women would have to undergo a surgical abortion anyway. If people then deem RU-486 to be a defective product, or hold the drug accountable for extended pain and suffering, and even death, the drug manufacturer’s liability lawsuits could be astronomical (Zitner 14-15).

Conclusion

The debate over RU-486 reflects the debate over abortion in general - it remains unresolved. Most proponents of abortion are in favor of RU-486. At this point it carries great potential to be a safe alternative to surgical abortions. Women can undergo an abortion without the world watching and for some people that makes the experience more tolerable. For other women, the side effects and potential hazards of RU-486 may be too risky or painful to endure. Antiabortionists are naturally opposed to RU-486 because it causes abortion, but their critique of the drug’s safety forces us to look at such potential dangers with a critical eye. Our country’s ambivalent stance on abortion may never allow RU-486 to be legalized here, but that will probably not keep people from the pursuit of a less traumatic, more compassionate alternative to our current methods of abortion.

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