Approval of the “abortion pill”, RU-486, in the United States occurred twelve years after France's Ministry of Health approved the pill for medical abortions. For over a decade, a combination of conservative presidents and the mobilization of pro-life groups kept the pill off the market. These interest groups framed the debate surrounding the pill in the abortion arena, effectively hinging its approval on morals rather than the drug’s safety and efficacy. Anti-abortion groups wielded a variety of tactics to delay the drug's approval including lobbying U.S. Congressmen, threatening a boycott of Hoescht products, publicly decrying the drug based on moral grounds and, in an interesting twist, framing the issue under women's rights. RU-486 was eventually approved for use in the United States, demonstrating that interest groups’ influence is not omnipotent and political currents can often override vocal minorities. However, the case study of RU-486 provides substantial evidence that when safe scientific advances clash against powerful interest groups, these groups can significantly hinder the process of approval.

Introduction

The arrival and legalization of RU-486 or the “abortion pill” in the United States was a long and arduous process during which mobilized many interest groups. The debate continued from the time of the drug’s introduction in France in 1988, until the Food and Drug Administration’s approval of RU-486 on September 28, 2000. The drug was strongly contested by anti-abortion groups who actively rallied to try to prevent its availability in the United States. Opponents of RU-486 employed multiple tactics and framed the issue in various arenas, ranging from abortion to women’s rights. Pro-life interest groups significantly influenced Roussel Uclaf, RU-486’s manufacturer, to prevent the drug from arriving in the United States, and at one point forced RU-486 off the French market. The primary focus of this paper is assessing the influence that pro-life interest groups in the United States had on the international distribution of RU-486 and their attempts to delay RU-486 from coming to market in the United States. This paper argues that despite the positive scientific results of the RU-486 clinical trials, the significant period of time between the approval of the drug in France and in the United States demonstrated that the antiabortionists’ outcry over the nature of RU-486 constituted a more significant political challenge in the United States than the actual safety of the drug itself.

Medical Usage of RU-486

RU-486 is an abortofacient that was created as an alternative to surgical abortion to terminate unwanted or dangerous pregnancies. Almost twelve years after RU-486 was made available to French women, American women gained access to the drug. On September 28, 2000, the FDA approved RU-486 (generic name mifepristone) for terminating intrauterine pregnancies through the forty-ninth day of pregnancy.1 The drug is distributed by Danco Laboratories, a single product company created for the sole purpose of distributing RU-486 (Mifeprex in the United States).2

RU-486 is a synthetic steroid, an antiprogesterone that interferes with a woman’s pregnancy. The drug causes the endometrial lining of the pregnant woman’s uterus to soften and break down.3 Alone, RU-486 is only 64-85% percent effective in aborting the fetus and expelling it from the uterus3, and is clinically ineffective. To increase the effectiveness of the drug (defined by the FDA as “the complete expulsion of products of conception without the need for surgical intervention”4) the woman must also take misoprostol, a prostaglandin analogue, two days after ingesting RU-486.4 The prostaglandin causes myometrial contractions and, according to clinical trials conducted in the United States and France, results in complete medical abortion at least 92% of the time.5,6

In a memo to the Population Council, the group that owns the U.S. rights to RU-4867, the FDA stipulated the following qualifications for any physician who could provide mifepristone:

- Ability to assess the duration of pregnancy accurately
- Ability to diagnose ectopic pregnancies

• Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
• Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, given her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well
• Must report any hospitalization, transfusion or other serious events to the sponsor or its designate.

Because of the possible side effects of mifepristone and misoprostol, including excessive bleeding (sometimes to the point of requiring blood transfusion or surgery), the FDA imposed the above requirements to ensure the safety of patients taking RU-486 and misoprostol. To guarantee that a woman is fully informed about the abortion process via RU-486, the physician is required to counsel her regarding the procedure and guarantee that she has access to any medical services (such as surgery) that could possibly be necessary.

Although medical abortions are less invasive than surgical abortions, they actually require more medical visits than the latter technique. Unlike surgical abortions that require only one visit to physician or clinic, RU-486 abortions require three visits to a physician. On the first visit, the physician counsels the patient about RU-486 and if the patient decides to continue with the abortion, three tablets (200mg each) of mifepristone are then administered to be taken orally. The second visit occurs two days later and the physician checks to see if the pregnancy has been terminated. If not, the patient must take two misoprostol tablets (a total of 40μg) and stay under physician observation for four hours. The patient then returns approximately two weeks after the initial visit to ensure that the pregnancy has been effectively terminated. If the pregnancy is not terminated, the physician must discuss and present alternative options.

Interest Group Politics and Framing
Abortion is legal in the United States and has been since the Roe v. Wade decision by the Supreme Court in 1973. Abortion’s legal status, however, has done nothing to quell the debate that surrounds it. The company Roussel Uclaf, owned by the German corporation Hoescht, developed RU-486 in France and the World Health Organization (WHO) announced the success of its clinical trials in 1988. Roussel Uclaf reported that clinical trials in Great Britain, China, France, and Sweden demonstrated that a combination of RU-486 and prostaglandin therapy resulted in abortion 95% of the time, without many serious complications. Immediately, following the results of the studies anti-abortion activists in the United States prepared to combat the growing popularity of the drug.

The opponents of RU-486 employed many political tactics to block the approval of RU-486. They framed the issue in the abortion arena, attracting pro-life groups to their cause; the women’s rights arena, utilizing rhetoric of the women’s rights movement by arguing that the drug could harm women in addition to their unborn fetuses; and threatened to boycott the drug’s manufacturer (Roussel Uclaf) and its parent company’s (Hoescht) products.

Framing
One of the major tactics of antiabortionist groups was to frame RU-486 in the abortion arena. Richard Glasgow, the education director for the National Right to Life Committee (NRLC), a prominent pro-life interest group in the United States, voiced the fear of many pro-life groups. He worried that RU-486 would trivialize abortion by “bolster[ing] the comparison between taking the drug and swallowing an aspirin.” The pro-life groups frequently employed rhetoric emphasizing that RU-486 would further devalue human life due to the decreased intensity of the medical abortion.

Medical abortions using RU-486 take place within a doctor’s private office, as opposed to an abortion clinic. This posed a threat to pro-life groups because many of their protests occurred outside abortion clinics and they worried that RU-486 would signal an end to the effectiveness of using these locales to garner media attention. In 1982, over 75% of abortions in the U.S. occurred in abortion clinics, providing pro-life activists with easily accessible protest sites that generated media coverage – sites they did not want to lose. The pro-life interest groups’ fears were not, however, grounded in fact. RU-486 is only effective until the 49th day of pregnancy, and any abortion after this period would have to be performed surgically.

In an ironic twist, pro-life groups decided to adopt rhetoric from the women’s rights movement, a movement that had argued for contraception and the legalization of
abortion. The issue was framed in terms of concern for the safety of women through a number of tactics. In 1988, the National Right to Life Committee together with women’s groups and consumer advocates opposed particular provisions in a U.S. bill that decreased the liability of manufacturers who produced defective products. (22) NRLC opposed the bill specifically because it would decrease the liability of any drug manufacturer that produced RU-486 in the United States if women encountered problems during the abortion. (23) Women’s groups, although they too believed that this bill would diminish protection of women who had been hurt by contraceptive use, did not want to align themselves with the NRLC, and framed their opposition under the auspices of consumers’ rights. 23

In an attempt to ensure that RU-486 would be excluded from the new liability laws if the bill were to pass, “NRLC supported an amendment, sponsored by Congressman Gerry Sikorsky (D-Minn.), that would have removed all drugs or medical devices used as contraceptives or to facilitate abortions from the broad protections of the bill.” 23 If passed, this amendment would have presented a significant obstacle for any pharmaceutical company willing to manufacture RU-486. As RU-486 was only 95% effective when used in conjunction with misoprostol during clinical trials, a 5% possibility existed that the fetus would not be aborted. If any of these children were born with birth defects or problems, unrestricted liability for the company meant that women could sue if the birth defect was linked to RU-486. 24 In part because of the large mobilization of interest groups against the bill, it was defeated in Congress and drug companies (among other industries) remained liable for defective products. 25 This was a large blow to the prospects of RU-486 production in the United States, as any company that produced it would remain in danger of severe lawsuits.

**Boycotts**

The most effective threat that interest groups wielded over Roussel Uclaf and Hoescht was the threat of an economic boycott of both companies’ products. 26 The night before Roussel Uclaf’s annual meeting in June 1988, NRLC’s executive director, David O’Steen publicized a letter the group had written to the French ambassador.

“...We are especially incensed that the abortion pill’s proponents have announced that they intend to make women of Third World countries a special target for the death drug’s use... If Roussel Uclaf or any other pharmaceutical company attempts to manufacture or market RU-486, [the] National Right to Life Committee would seriously consider joining with other pro-life groups around the world to initiate a boycott of the products of Roussel Uclaf and firms affiliated with it through the parent company Hoescht. 27

The French government was a minority shareholder in Roussel Uclaf 28, and NRLC seized on this to associate them with the company’s perceived immorality. They hoped that the publicized threat of a boycott would place pressure on both Roussel Uclaf and Hoescht to cease their development of RU-486. By citing the safety of women in developing countries, NRLC again borrowed framed the issue in the context of the women’s rights movement. 28

The major benefit of RU-486 is its oral administration, which eliminates the need for an invasive surgical procedure. This was touted as a significant advance for the safety of pregnant women in third world countries where sterile surgical environments are rare. 29 NRLC, however, turned the issue on its head. In addition to claiming that the distributors would market the drug to uninformed women in developing countries, they also cited safety concern for women taking the drug. 30 Yet, even as the group advocated this version of women’s rights, women’s rights groups themselves actually supported RU-486. 31

The threat of a boycott demonstrated the effect of a vocal minority in the United States on an internationally based company. Although the French Minister of Health, Claude Évin, approved the drug for marketing in September of 1988, Hoescht pressured Roussel Uclaf to stop marketing the pill. 32 “Hoescht... feared that the boycott threats by the American anti-abortion movement could cripple [its] $6-billion-a-year American subsidiary.” 33 Despite the fact that 59% of Americans favored introducing RU-486 to the U.S. (according to an October 1988 poll), the vocal anti-abortionist minority’s threat of a boycott caused Hoescht to lean on Edouard Sakiz, the chairman of Roussel Uclaf, to halt the drug’s production. 35

Eventually Sakiz succumbed to corporate pressure. He had assumed that the political outcry from pro-life interest groups would drop after the government approved RU-486 for marketing, but protests and threats from NRLC and other pro-life interest groups (mainly based in the United States, but some in France) escalated after the approval. 36 On October 21, less than one month after the drug’s approval, Sakiz and the Roussel Uclaf board voted to take it off the market. 36 Pierre de Rible, Roussel’s deputy financial leader assessed the influence of American pro-life groups. “The pressure groups from the United States are very powerful, maybe even more so than in France.” 37 The U.S. groups framing and threats significantly influenced
Roussel Uclaf’s decision, despite the fact that the drug was legalized only for French and not U.S. use.

The Counter-Protest: the influence of proponents of RU-486

Interest group politics are not a one-way street. Both opponents and proponents of RU-486 were capable of influencing the international distribution of the abortion pill. Roussel Uclaf’s announcement regarding the withdrawal of RU-486 was well timed to illicit an outcry from supporters of RU-486. The decision was announced during the meeting of the World Congress of Gynecology and Obstetrics, where physicians, professors, and other pro-choice groups immediately mobilized to protest the company’s decision. They compiled a list of Roussel Uclaf’s other products, and physicians stated that they would boycott them to show that, according to one professor, “Medical groups and family planning clinics… have a voice, not only right-to-life groups.” Other groups such as the National Abortion Rights Action League (NARAL), Planned Parenthood, and even the French Minister of Women’s Rights, Michèle Andrè, all denounced the decision and framed their dissent in the same general context: Roussel Uclaf was conceding to a small minority and consequently ignoring the potential benefits to many women worldwide. The protest of these pro-choice groups did not go unheard, but once again, the distributors of RU-486 made their decision based on economics. The French government accepted the legality of abortion and did not want to rekindle the debate, and decided to use its power as a minority shareholder of Roussel Uclaf to bring RU-486 back to market by threatening to give the patent rights of the drug to a company willing to market it. Evin, the French Minister of Health, “feared that if the antiabortion movement was triumphant in its crusade against Roussel, it would begin fighting for a repeal of the 1975 French law legalizing abortion.” Roussel Uclaf did not want to lose its patent rights for a likely profitable drug (even in the currently hostile political environment), and put RU-486 back on the market on October 28, 1988, only one week after it had been withdrawn.

The Delayed Arrival in the United States: the influence of interest groups

Although RU-486 was distributed throughout France, dealing a blow to the antiabortionist groups, the debate over the drug did not subside. In February 1989, Congressman Robert Dornan (R-CA), sponsored H.R. 619, a bill that specifically banned funding for RU-486 in the United States. A federal ban on funds for abortion research was already in effect, but because RU-486 also had other potential clinical uses, such as treating Cushing’s disease, breast cancer and endometriosis, the bill never came to a vote. The government, however, was in the midst of a series of pro-life administrations, and during the Reagan and Bush administrations, RU-486 was classified as “a banned drug,” and no research was undertaken with Federal funding. Furthermore, U.S. interest groups gained a major victory in their attempt to delay the arrival of RU-486 to the U.S. when Hoescht decided not to distribute RU-486 outside of France. Although the company claimed that it was a company policy not to market abortofacients, “in the case of RU-486, it [was] the commercial and public relations consequences of the antiabortion groups’ moral outrage that seem[ed] to underlie the decision of so many pharmaceutical companies to avoid the drug and of Roussel to limit its distribution and licensing.” Roussel Uclaf explicitly stated that if they were to market RU-486 outside of the country, they would only do so if a foreign government demanded it. Due to the conservative political environment in the United States in the late 1980s and early 90s, this effectively ensured that the product would not come to the United States.

When Bill Clinton was elected in 1992, the pro-choice interest groups’ finally gained a chance to be heard. The Clinton Administration pressured Roussel-Uclaf to donate the U.S. rights of RU-486 to the Population Council, a nonprofit organization for advancing reproductive health, and finally in 1994, the administration succeeded. The Population Council applied for approval of RU-486 from the FDA in 1996, and the FDA deemed mifepristone “approvable” according to clinical trial data from France, but noted that the Council needed to find a manufacturer in the United States willing to produce the drug, properly label of the drug, and deal with other concerns.

Despite this triumph for pro-choice advocates, antiabortionist interest groups still attempted to prevent the appearance of the drug on the market. Pharmaceutical companies were wary of entering the political fray, and pro-life interest groups focused their efforts on keeping RU-486 from being manufactured. As a result, Teva, Merck, Abbot Laboratories, Johnson & Johnson and Pharmacia & Upjohn all refused to manufacture the drug. Finally, Danco Laboratories proved to be the answer for allowing the production of RU-486 in the United States. Danco was created specifically to market RU-486, leaving it immune to threats of a boycott because there were simply no other

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products to boycott. The Population Council subsequently reapplied for approval of RU-486 in both 1999 and 2000 and the FDA deemed the drug clinically effective and ready for market on September 28, 2000. The FDA prohibited RU-486 distribution by pharmacists, instead giving the sole privilege to certified physicians.

Conclusion

Scientific work is supposed to be factual and unbiased. But, what happens though when a scientific advance clashes with moral values? The case of RU-486 demonstrated the power of American antiabortionist interest groups in dictating the fate of the controversial drug’s legalization in the United States. Despite the positive results of the RU-486 clinical trials, antiabortionist groups framed the issue in the abortion arena, derailing the debate from centering on the safety of the drug. Their most powerful tool, however, in the fight against RU-486 was the threat of a boycott against Roussel Uclaf and its parent company, Hoechst’s products. Because of Hoechst’s significant business in the United States, the company decided that protecting its international image was a higher priority than allowing the distribution of the revolutionary drug.

Women in the United States, however, now have access to RU-486. Despite the twelve-year lapse between the initial distribution of medical abortions in France and the United States, the legalization of RU-486 showed that interest groups are not invincible. Although they can wield significant power and make credible threats, other forces are also at work in the political arena. The French Minister of Health’s request for Roussel Uclaf to put RU-486 back on the market in 1988 and Clinton’s request for Hoechst to allow the Population Council to obtain the rights to the drug if they refused to market it in the United States, were followed by compliance of the companies.

During the first eighteen months mifepristone was available in the United States, over 18,000 medical abortions were performed. However, it has not revolutionarily changed the abortion landscape as pro-life activists feared. The debate surrounding abortion is far from over, as South Dakota proved when it banned abortions in 2006. RU-486 has not ended the abortion wars nor eliminated the need for abortion clinics. The approval process, however, gave pro-life and pro-choice activists a forum to renew the debate over the morality of abortion, and demonstrated the wide-reaching influence of U.S. pro-life interest groups.

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