Politics and Pills:
The Challenges the FDA Faced in Bringing Abortion-Inducing Pills to the US Market

As Meika Loe writes in the introduction of her book *The Rise of Viagra: How the Little Blue Pill Changed Sex in America*, the launch of Viagra into the US pharmaceutical market met with much fanfare. By 1998, the year that the drug was introduced, America was transitioning into a new era of sexuality, and sex was becoming less of a cultural taboo (Loe, 2004: 13). Very quickly, Viagra turned into its own phenomenon, being featured in television shows and movies, as well as being advocated by famous figures (Loe, 2004: 18). But when the FDA approved mifepristone and misoprostol, more commonly known as RU 486, in September, 2000, there were no celebrities endorsing it. There were no television shows about the girl next door going to the doctor the day the pregnancy test turned out positive. Eight years after its introduction, junk E-mails pour into people’s inboxes trying to sell cheap Viagra. In the past five years, one would be hard-pressed to find an electronic advertisement for readily available mifepristone or misoprostol. Both Viagra and the abortifacient pills help to turn sexual intercourse from a means of reproduction into a regular practice for those not wanting children. Yet when the target of a drug is to negate the consequences of sex rather than increase the number of people who can have it, a stigma that still exists in American society is touched upon. Although the FDA had substantial evidence on the safety and efficacy of the pills to quickly approve them, it delayed their sanction mainly because of pressure put on the agency by antiabortion advocates. Furthermore, when the FDA finally did approve the drugs, it received backlash for how stringent it made the restrictions on the drugs’ dosage. The FDA thus received outside pressure at every
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step in its approval of mifepristone and misoprostol, from its initial consideration of the drugs to after it had sanctioned the drugs.

Despite the fact that RU 486 is infamous as an abortion-inducing pill in the US, its origins have nothing to do with reproduction. According to Judson Gooding and Roger Williams in their article “RU 486: the Fuss, the Facts, and the Fears,” researchers at the Paris-based pharmaceutical company Rousel Uclaf were not interested in a developing an abortifacient when they synthesized RU 486 in 1980 (Gooding and William, 1991: 65). Rather, the scientists were looking for a drug that would “block the action of certain hormones” like cortisol, which is produced in the adrenal gland. They found that their new drug also blocked the action of progesterone, which is necessary to maintain pregnancy as it enables the embryo to stay attached to the uterine wall. When they administered RU 486 to pregnant women, researchers found RU 486 to be 80% successful as an abortifacient. Researchers also found that when another drug, prostaglandin, was taken two days after RU 486, the rate of successful termination of pregnancy increased to 96%. Consequently, prostaglandin, which causes uterine contractions, was added to the regimen (Gooding and William, 1991: 66). Once RU 486 had been tested on 2,000 women, the French minister of health approved the drug as a means to end pregnancies less than seven weeks along. When the Catholic Church and other morally concerned French groups protested the drug, Roussel Uclaf promptly took the drug off the market only to have the minister of health restore it two days later.

Given the backlash that RU 486 received in its own country of origin, it is not surprising that the drug caused controversy in the US, as well. In the February 4, 1997 edition of The Washington Post, Caryle Murphy reflected on the controversy that RU 486 had been causing as a drug that had not yet attained FDA approval. By the time the drug had hit the American scene, it
had assumed the name mifepristone (as RU 486 was Roussel Uclaf’s name for the drug), and prostaglandin had assumed the name misoprostol. Murphy laments that the strongest argument from the antiabortion groups who were against the abortifacient’s approval was that the safety of the drugs had not yet been well established (Murphy, 1997). As it is the FDA’s job to ensure the safety of the drugs it approves, a lack of understanding of the dangers of a drug would be a sound reason to stall its introduction to the market. By the time of Murphy’s article, however, more than 200,000 women in China and Europe had taken the drug combination, and research from other countries on the drugs abounded with findings that they were safe. In the article “Early abortion induction by a combination of mifepristone and oral misoprostol…” by Hazem El-Refaey and Allan Templeton in the *British Journal of Obstetrics and Gynaecology*, the safety of mifepristone and misoprostol is unquestionable. El-Refaey and Templeton report that several studies before their 1994 inquiry had already established the “safety and efficacy of medical termination of early pregnancy” by the combination of the pills (El-Refaey and Templeton, 1994: 792). The researchers cite patient compliance as the greatest pitfall of the strict regimen, not its side effects. In another study headed by El-Refaey, misoprostol was administered to women shortly after giving birth as a means to cut down on post-partum hemorrhaging, which causes 17% to 40% of maternal deaths in some parts of the world (El-Refaey et al., 1997: 336, 339). Administration of the drug during labor was found, in fact, to reduce hemorrhaging from an 18% to a 5% incidence rate in laboring women (El-Refaey et al., 1997: 338). The drugs were even considered safe when not used for their common abortifacient purpose.

If international studies on the pills were not enough to deflate American antiabortion proponents’ arguments that the pills were “unsafe,” more than 2,100 women in the United States had participated in trials of the pills by the time Murphy had written his article in *The
Of these 2,100 women who had tried the regimen, only 26 required hospitalization for complications associated with the drugs. The drugs had been shown to be safe as an abortifacient in the US and abroad, and misoprostol’s safety was further proven when used in laboring women. Safety was not the issue holding back mifepristone and misoprostol from entering the US market, as antiabortion advocates wanted to believe, so the FDA must have had other reasons to not approve the drugs quickly.

Of course, just because a drug is deemed safe does not mean it is without side effects and risk. Along with Murphy’s article in *The Washington Post*, Gina Kolata writes in the July 20, 1996 edition of *The New York Times* about the concerns that were still in the air about the side effects of the new medicinal option for abortion. The Population Council, a “nonprofit family-planning research organization” was charged with heading the American studies on the abortion pills (Kolata, 1996). Dr. C. Wayne Bardin of the Population Council reported to an FDA committee in a July 19, 1996 meeting that the “most common adverse side effect” of the medicinal abortion was pain. The most serious side effect of severe bleeding occurred in only 1.4% of the women they studied. In fact, as reported by David Baird in *The British Journal of Obstetrics and Gynaecology*, the side effects of the drug-induced abortion are completely comparable to those associated with spontaneous abortions, which occur in 15% of all pregnancies (Baird, 1994: 367). Not only are the serious side effects of medical abortions rare, but they are as great a health risk as abortions that are natural.

Another factor in assessing the side effects of the mifepristone/misoprostol abortion option is to compare the medical abortion side effects and risks to those of surgical abortions. If the pills offered an alternative to surgical abortions, the alternative should be of comparable or lesser risk than the original option if it is to not raise any flags. Studies such as one in Scotland
conducted by F. L. Howie et al. had already compared the consequences on women of having a surgical, aspiration abortion as opposed to having a drug-induced abortion. The results of the study as also reported in *The British Journal of Obstetrics and Gynaecology* show that the long-term physical and psychological effects of a surgical (i.e., vacuum aspiration) abortion and of a medical abortion were comparable (Howie et al., 1997: 829). Furthermore, in an article in by Daniel Haney in The Associated Press, Dr. Beatrice Couzinet of a French team investigating the pill reasons that a medical abortion is less risky than a surgical abortion because a surgical abortion “carries risk of anesthesia, surgical complications, [and] infertility” (Haney, 1986).

Thus researchers and doctors agreed that medical abortions promised to harm a woman no more than a surgical abortion. For a woman who responds adversely to anesthesia, a medical abortion would be a less risky procedure for her than a surgical abortion. Since surgical abortions were already being performed in the United States, it would seem reasonable for the FDA to approve this new method for abortion as a comparably safe alternative. Finally, an online brochure entitled “FDA: The Nation’s Premier Consumer Protection and Health Agency,” the FDA reports that its goal in drug regulation is to ensure that drugs “for humans are safe and effective,” as was clearly shown for the mifepristone/misoprostol studies (FDA, 2002: www.fda.gov). In this same brochure, the FDA prides itself in approving drugs “as fast as, or faster than, anywhere else in the world.” Clearly the FDA does not want to delay a drug’s approval needlessly if it supposes that one of its positive attributes is sanctioning drugs quickly. Furthermore, it had plenty of evidence that the pro-life argument that the drugs were unsafe was unfounded. Yet the FDA still dragged its feet in approving the mifepristone/misoprostol combination while countries in Europe already had.
According to Gina Kolata’s article, the Population Council had requested approval of mifepristone and misoprostol in March of 1996 (Kolata, 1996). By July of that same year, an FDA advisory committee recommended the drug for approval, a sensical decision given all the evidence that the drug was safe and effective. So while the medical evidence pointed to the approval of mifepristone and misoprostol as the logical choice for the FDA, there must have been some other motivating factor for it to delay its sanction. As a government agency, the FDA is not immune to politics, and pills that induce abortion would surely not escape a political uproar. Since abortion has been a point of contention in American politics in the late twentieth century, it would stand to reason that pills that allow a woman sidestep a surgical abortion would meet with backlash from antiabortion groups. In his article “Methotrexate and Misoprostol to Terminate Early Pregnancy” in the August 1995 *New England Journal of Medicine*, a study in which Richard Hausknecht uses abortion-inducing drugs to treat women with the dangerous condition of an ectopic pregnancy, Hausknecht laments the politics of such drugs. Despite studying abortifacients for the legitimate treatment of a serious condition, Hausknecht understands that unless the political situation surrounding abortive pills changes “it will be some time before mifepristone becomes clinically available in the United States” (Hausknecht, 1995: 537). According to an article by Marc Kaufman in the September 29, 2000 edition of *The Washington Post*, antiabortion advocates were fearful that the approval of the pills would cause an increase in abortions. While an increase in the abortion rate due to the availability of medical abortions would seem like a legitimate concern, the evidence did not support such fears. Kaufman reports that the introduction of medical abortions into Israel, Europe, and China did not cause a rise in their abortion rates (Kaufman, 2000). Furthermore, the abortion rate in the United States had been “dropping significantly for the past decade,” which seems to indicate that the
abortion rate would not suddenly sky-rocket with mifepristone and misoprostol’s introduction into the market.

Whether or not abortion opponents’ arguments that medical abortions would cause an increase in the abortion rate in the US were valid, their concerns about the consequences of the FDA approving mifepristone and misoprostol caused a political stir that slowed the drugs’ approval. Marc Kaufman cites “abortion politics, including boycott threats against potential drugmakers” as a major contributing factor to the delay of the drugs’ approval after they were deemed safe and effective in the 1996 committee meeting previously discussed (Kaufman, 2000). Political opposition getting in the way of the drugs’ approval is also seen in how Republican Representative Tom Coburn of Oklahoma was able to lead the House to deny the FDA funding to test mifepristone and misoprostol twice. Although the Senate was able to block the House’s attempt to deny the FDA funding, the House’s actions show how the FDA could not escape the political stir its approval of the abortion drugs was causing (Kaufman, 2000). The threat of having its funds taken away was not the only pressure being put on the FDA as it moved toward approval of mifepristone and misoprostol. In the midst of its investigation into the abortion drugs, the FDA found itself without a chief. When President Clinton nominated Dr. Jane Henney for the position, her approval by the Senate was slowed when Republican Senator Michael Enzi became concerned with Dr. Henney’s position on the abortion drugs. As reported by Samuel Goldreich in the September 3, 1998 edition of The Washington Times, the senator threatened to block Dr. Henney’s approval unless she answered questions about whether the FDA would consider the pill’s effect on the fetus rather than just the mother (Goldreich, 1998). The abortion debate so closely followed the FDA’s decision about the pills that antiabortion advocates were willing to drag the dispute into the decision to approve the new FDA chief.
Senator Enzi’s political maneuver made little sense given that surgical abortions were already legal, but his actions demonstrate the pressure the FDA was facing as it was trying to evaluate the abortion drugs solely on the basis of their safety and efficacy. The FDA may have been able to disprove abortion foes’ arguments about the pills being unsafe, but it could hardly stop politicians’ maneuvers.

Despite being under a political magnifying glass as it considered the approval of mifepristone and misoprostol as abortifacients, the FDA finally approved the drugs in late September of 2000. Of course, the controversy over the drugs did not end with their sanction. In the article “Vaginal Misoprostol Administered 1, 2, or 3 Days After Mifepristone for Early Medical Abortion” by Eric Schaff et al. published in *The Journal of the American Medical Association* right after mifepristone and misoprostol were FDA-approved, the authors criticize the restrictive dosage timing the FDA required for doctors to administer the drugs. When the FDA approved the drug combination as abortifacients, it mandated that misoprostol be administered exactly two days after mifepristone, which would require a woman to go back to her doctor two days after receiving the mifepristone dose to take her misoprostol dose (Schaff et al., 2000: 1948-9). Since the 48-hour dosing was the regimen being used in the countries which had approved these abortive drugs previous to the United State’s approval, all the research that these other countries had done to show the drugs’ efficacy relied on this specific dose indication. Schaff et al. believed that requiring women to follow the 48-hour regimen put an unnecessary burden on them. The timing disallowed women to start the drug combination on a Thursday or Friday since the clinic from which she got her pills would most likely be closed over the weekend.
Eric Schaff et al. argued that the FDA should have investigated the efficacy of 24 and 72-hour regimens before restricting dosage to a 48-hour time period. To test these different time periods of dosage, Schaff et al. administered misoprostol vaginally rather than orally, since misoprostol is more effective when given vaginally. While their tests showed that the vaginal delivery of misoprostol was equally effective when given at 24, 48, or 72 hours after mifepristone, the FDA had only approved the use of oral misoprostol. By not looking into alternative methods for taking misoprostol, Schaff et al. argued that the FDA was putting undue burden on women seeking medical abortions. Yet the FDA had already been slowed by the heat it took for investigating the drugs as a new abortion option. Further testing of mifepristone and misoprostol outside of their proven safe and effective dosing would have prolonged the approval process even more.

Simply put, the FDA was in a no-win situation. The FDA had delayed its approval of mifepristone and misoprostol in large part due to political pressure, but once it had finally sanctioned the drugs, it received further backlash from those who supported the drugs through their research on its safety and effectiveness. Questions over the FDA’s approval of the drugs did not end with criticism over the restrictive dosing time. The deaths of eight women worldwide were linked to the drugs in the five years following the FDA’s approval of the drugs as reported by Salynn Boyles on December 30, 2005 at FoxNews.com (Boyles, 2005: www.foxnews.com). According to Boyles, the deaths caused a stir from antiabortion advocates for the FDA to revoke their approval of the drugs. A closer look into the deaths, however, shows that had the patients’ doctors strictly followed the FDA’s guidelines, their deaths may not have occurred. In an article written by Andrew Bridges for the April 10, 2006 edition of The Associated Press, the American deaths are all linked to an infection similar to that caused by
incorrect tampon use. According to Bridges, the FDA had advised doctors to watch out for such infections it knew were liable to occur in taking the drugs (Bridges, 2006). Given that the infection is treatable with antibiotics, the FDA acted appropriately in not banning the drugs despite the insistence by antiabortion advocates that it should. The FDA had set the guideline for doctors to watch patients for infections after taking the abortive drugs, and it should not ban the drugs for causing the deaths of patients whose doctors did not follow that guideline.

Furthermore, in an article by Jonathan Rockoff in the March 18, 2006 edition of *The Baltimore Sun*, all the American deaths associated with the pill occurred after women had taken misoprostol vaginally (Rockoff, 2006). While the risk of death due to taking misoprostol vaginally has not been investigated by the FDA, since it only looked at the oral administration of the drug, it had only approved the drug in its oral form. Despite the fact that the deaths associated with the drugs occurred after they were improperly administered, the FDA received political pressure even after it had approved the drugs to reverse its decision.

The FDA faced much political pressure and criticism as it evaluated and subsequently approved mifepristone and misoprostol as abortion-inducing drugs. Although it had enough evidence in 1996 for a committee to recommend the drugs’ approval, political pressure encouraged the FDA to wait until 2000 to approve them. Even after the FDA had sanctioned the drugs, criticism still surrounded its decision and there was further pressure to ban the drugs. While controversy was sure to follow drugs that induce abortions, that controversy should be strictly the politicians’ problem. It may be an effective political maneuver to filibuster a nomination for the FDA chief, but to jerk around the nation’s agency for deciding drugs’ safety and efficacy with purely political motives hardly seems right. The FDA should be allowed to operate insulated from political opinion. Senators and Representatives have no place in judging
the fitness of a drug for the US market, and as such they should leave this decision to the agency meant for that very purpose. It is unfortunate that the FDA’s actions in approving the abortion pills could not escape political limelight. While French, British, and Chinese women were benefiting from the additional option of abortion via pills, women in the US had to wait for the FDA to overcome bullying from conservative congressmen and other antiabortion proponents before it approved the pills for the American market. While the FDA continues to receive criticism from congressmen and abortion researchers alike, for the sake of the many women who find themselves in need of an abortion, the FDA should continue to stand its ground in allowing women to have safe, effective medical abortions.
REFERENCES


