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The Life of the Abortion Pill in the United States

Julie A. Hogan

Eleven years after mifepristone¹, the drug that chemically induces abortion and hence coined the abortion pill, was approved for use in France, American women still do not have access to the drug, although women in at least ten other nations do.² In 1988, Americans thought the *Abortion Pill [was] on the Horizon*.³ In 1993, almost five years later, American women still did not have access to the drug, although many women's hopes were raised by newspaper headlines claiming that the *Door May Be Open for [the] Abortion Pill to Be Sold in [the] U.S.*⁴ and newspaper accounts predicting that mifepristone would be available in the United States in 1996.⁵ In 1996, the headlines reported that the *Approval of [the] Abortion Pill by the FDA [was] Likely Soon*.⁶ Yet, mifepristone was still not available in 1999, and newspaper headlines were less optimistic about pre-

¹Mifepristone is the generic name for RU-486, the designation given the drug by its French maker, Roussel-Uclaf.

²Mifepristone has been available in Great Britain since 1991, China and Sweden since 1992, and Austria, Belgium, Denmark, Finland, Germany, Greece, the Netherlands, and Spain since 1999. See *Reproductive Health Product Development/Medical Abortion Frequently Asked Questions* (last modified Dec. 22, 1999) <<http://www.popcouncil.org/faqs/abortion.html>>.

³Lloyd Shearer, *Abortion Pill on the Horizon*, THE RECORD (Northern New Jersey), Mar. 20, 1988, at 14.

⁴*E.g.*, Philip J. Hilts, *Door May Be Open for Abortion Pill to Be Sold in U.S.*, N.Y. TIMES, Feb. 25, 1993, at A1 [hereinafter Hilts, *Door May Be Open*].

⁵See Katherine Q. Seelye, *Accord Opens Way for Abortion Pill in U.S. in 2 Years*, N.Y. TIMES, May 17, 1994, at A1 [hereinafter Seelye, *Accord Opens Way*]; Adam Pertman, *Arrival of RU-486 Could Intensify Abortion Debate*, BOSTON GLOBE, May 22, 1994, at 1.

⁶Shankar Vedantam, *Approval of Abortion Pill by the FDA Is Likely Soon*, SAN DIEGO UNION-TRIB., July 20, 1996, at A1. See also Julia Duin, *Abortion 'Pill' Gets Panel OK Final Approval by FDA Seen Near*, WASH. TIMES, July 20, 1996, at A1.

dictions of its availability. For example, a headline in *The Washington Post* on March 23, 1999 read *Abortion Pill Inches Closer to Production; American Marketer Hopeful that Drug Will Be Available by Year End.*⁷ As of March 2000, one year later, the United States Food and Drug Administration, the FDA, has still not approved mifepristone. The question is why not.

During the last eleven years, the efforts of those fighting to make mifepristone available in the United States have been thwarted by those fighting just as valiantly to keep it out. The struggle between the two groups is evident in every decision made, be it by the patent owner, the manufacturer, the FDA, or the President, regarding the drug's future and approval in the United States. This paper will examine the ideology behind the struggle of these two groups and its effect on the life of the abortion pill, mifepristone, in the United States. Part I will describe how mifepristone works to chemically induce an abortion, review the safety and effectiveness of the drug, and discuss other medical uses of the drug. Part II will identify the key players in the struggle to bring mifepristone to the United States and discuss the motivations and ideologies behind each groups' efforts. Part III will review the history of mifepristone in France, from its invention to its approval. Part IV will discuss the history of mifepristone in the United States and examine the impact of the political struggle regarding the drug on mifepristone's availability (or lack thereof) in the United States.

Part I

⁷Marc Kaufman, *Abortion Pill Inches Closer to Production; American Marketer Hopeful that Drug Will Be Available by the End of the Year*, WASH. POST, Mar. 23, 1999, at Z7.

A. How Mifepristone Works

Mifepristone is an antihormone and more specifically, a progesterone antagonist. Essentially, mifepristone interrupts hormonal messages by interfering with the hormones function in the body.⁸ Hormones must bind with corresponding receptors in order to function and emit the correct message.⁹ Progesterone is a hormone essential to the maintenance of pregnancy. Before implantation, progesterone thickens the uterine lining, making it hospitable; after implantation, more progesterone is secreted, which sends a message to the brain to suppress the next ovulation; and as the embryo develops into a fetus, the placenta secretes progesterone, which calms the uterine contractions, protecting the embryo from being dislodged.¹⁰ Mifepristone is able to terminate pregnancy by binding to progesterone receptors and blocking the work of the hormone.¹¹ The man credited with the invention of mifepristone, Dr. Etienne-Emile Baulieu, analogizes the mifepristone to a false key; the mifepristone is able to enter the uniquely fashioned key hole, the receptor, instead of the progesterone.¹² The progesterone, which is secreted, circulates, but it has no effect.¹³ Deprived of the essential progesterone action, the gestation process cannot continue.¹⁴ The mifepristone will break down the embryo's bond to the uterine wall. Contractions will begin, since the progesterone did not work to calm the uterine muscles,

⁸*See, e.g.*, ETIENNE-EMILE BAULIEU with MORT ROSENBLUM, *THE ABORTION PILL* 16-17 (1991).

⁹*See, e.g., id.*

¹⁰*See, e.g., id.* at 13.

¹¹*See, e.g., id.* at 16-17.

¹²*See id.* at 17.

¹³*See id.*

¹⁴*See id.*

and the cervix will soften and widen.¹⁵ A menstrual like blood flow will ensue and the embryo will be washed from the body.¹⁶

B. Safety and Effectiveness

The first clinical trial was conducted in 1982 by Dr. Walter Herrmann in Geneva; 9 out of 11 women, administered mifepristone in a dose of 200 milligrams a day for four days, successfully terminated their pregnancy.¹⁷ During this study, Herrmann noted that the rate of prostaglandin in the blood went up during the termination of the pregnancy.¹⁸ Dr. Baulieu and his colleagues immediately combined the administration of mifepristone with a dose of prostaglandin. Prostaglandin increases the uterine contractions, enhancing the effectiveness of the mifepristone.¹⁹ In the late eighties and early nineties in France, mifepristone was administered in combination with sulprostone or gemeprost.²⁰ The use of sulprostone was discontinued after one death from heart failure after administration of mifepristone and sulprostone.²¹ Dr. Baulieu and his colleagues then began testing mifepristone with misoprostol, an orally adminis-

¹⁵ See *id.*

¹⁶ See *id.*

¹⁷ See *id.* at 85. Also see Beatrice Couzinet et al., *Termination of Early Pregnancy by the Progesterone Antagonist RU486 (Mifepristone) (Original Article)*, 315 NEW ENG. J. MED. 1565 (1986) for results of study on 100 women administered mifepristone alone; mifepristone failed to cause an abortion in 15 of the 100 women.

¹⁸ See BAULIEU, *supra* note 8, at 85.

¹⁹ See *id.* at 210-211.

²⁰ See, e.g., Louise Silvestre et al., *Voluntary Interruption of Pregnancy with Mifepristone (RU 486) and a Prostaglandin Analogue: A Large-Scale French Experience (Original Article)*, 322 NEW ENG. J. MED. 645 (1990) (discussing results of study, with overall efficacy rate of 96%, on women administered mifepristone in combination with sulprostone or gemeprost).

²¹ See Reproductive Health Advisory Committee, *New Drug Application for the Use of Mifepristone for Interruption of Early Pregnancy* 40 (July 19, 1996) (testimony of Irving M. Spitz, M.D.) (on file with author and available from Center for Drug Evaluation and Research [hereinafter Advisory Committee]). In March of 1991, a 31 year old woman in Northern France died of heart failure after an injection of sulprostone following mifepristone administration. The prostaglandin, sulprostone, affects all smooth muscles in the body, including those of the circulatory system. See BAULIEU, *supra* note 8, at 100.

tered prostaglandin rather than the intramuscular or intravaginal prostaglandins administered previously.²² Misoprostol is available in 45 countries and is relatively inexpensive.²³ In addition, it is believed to be safer with regards to cardiovascular complications and more convenient to store and administer.²⁴ Mifepristone will be used in combination with misoprostol, if and when it becomes available in the United States, according to the new drug application, the NDA, submitted to the FDA for drug approval.²⁵ The NDA focuses on three clinical studies, two conducted in France and one in the United States.²⁶ The first French study, study 1, enrolled 1,286 women with a duration of gestation of 49 days or less; the second, study 2, enrolled 2,480 women, 492 with a duration of gestation of 49 days or less, the remainder with duration of gestation of 50 to 69 days.²⁷ Each study consisted of three visits. In the first visit, the women were given 600 milligrams of mifepristone.²⁸ On the second visit, which was approximately 48 hours after the first visit, the women were given 400 milligrams of misoprostol and asked to remain in the clinic for four hours.²⁹ In study 2, if a woman had not had a medical termination within 3 hours, she was given an extra dose of 200 milligrams of misoprostol.³⁰ In both studies, the women were to return two weeks later for a third visit to determine the results

²² See Advisory Committee, *supra* note 21, at 24 (testimony of Irving M. Spitz, M.D.).

²³ See *id.*

²⁴ See, e.g., Allan Rosenfield, *Mifepristone (RU 486) In the United States - - What Does the Future Hold?*, 328 *NEW ENG. J. MED.* 1560, 1560 (1993).

²⁵ See Advisory Committee, *supra* note 21, at 25 (testimony of Irving M. Spitz, M.D.).

²⁶ See *id.*

²⁷ See *id.* at 25-27.

²⁸ See *id.* at 25-26.

²⁹ See *id.*

³⁰ See *id.* at 26.

of the pregnancy termination.³¹ Analysis of the data indicated that the results were identical whether the women had a single dose of misoprostol or an extra dose.³² Combining the studies, there was a complete medical termination of pregnancy within 95.5% of the women with duration of gestation of 49 days or less.³³ Of the 4.5% who did not have a complete medical termination, 1.3% had a continuing pregnancy that was subsequently terminated by dilation and curettage or vacuum aspiration, 2.9% had an incomplete abortion, and 0.3% required dilation and curettage or vacuum aspiration for bleeding.³⁴ In over 75% of the women, the medical termination was complete within 24 hours of misoprostol administration.³⁵

The Population Council, a research institution dedicated to improving women's reproductive health, conducted the clinical trial in the United States from the fall of 1994 to the fall of 1995.³⁶ 2,121 women with a duration of gestation less than 63 days participated in the study at 17 centers throughout the United States.³⁷ The study followed the same protocol, or regimen, as that in the first French study. Women were given 600 milligrams of mifepristone on their first visit; two days later, women returned and were administered 400 milligrams of misoprostol.³⁸ Women then made a third appointment to return 15 days

³¹ See *id.* at 25-26.

³² See *id.* at 28. Researchers do not recommend the second dose of misoprostol because it increases cramping and bleeding but does not increase efficacy. See *id.* at 47 (testimony of C. Wayne Bardin, M.D.).

³³ See *id.* at 28 (testimony of Irving M. Spitz, M.D.).

³⁴ See *id.*

³⁵ See *id.* at 28-29.

³⁶ See Irving M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States (Original Article)*, 338 NEW ENG. J. MED. 1241, 1241 (1998) [hereinafter Spitz, *Early Pregnancy Termination*].

³⁷ See *id.*

³⁸ See *id.*

later for a final assessment.³⁹ The results of this United States clinical trial confirmed those of the French studies. Pregnancy was terminated in 92% of the women with a duration of gestation less than 49 days. As in the French study, a steady decline in the frequency of termination of pregnancy was noted with the increasing duration of gestation (i.e. pregnancy was terminated in only 83% of the women with duration of gestation for 50 to 56 days).⁴⁰ In addition, within 24 hours of the administration of the misoprostol, 75% of the women had expelled the embryo and the medical termination was complete.⁴¹

These clinical studies indicate that mifepristone, administered in combination with misoprostol, is highly effective in terminating pregnancy.⁴² Such clinical trials must also prove the administration of such combination is safe.⁴³ Animal studies, conducted prior to the above clinical studies, show no toxic effects in animals that would be reflected in women.⁴⁴ In the three studies discussed above, there were no deaths or serious cardiovascular outcomes.⁴⁵ All of the

³⁹ See *id.*

⁴⁰ See *id.* at 1242; Advisory Committee, *supra* note 21, at 30 (testimony of Irving M. Spitz, M.D.).

⁴¹ See Spitz, *Early Pregnancy Termination*, *supra* note 36, at 1243.

⁴² The Reproductive Health Advisory Committee voted 6-2 that the French studies indicate that mifepristone is effective for use as an abortifacient. See Advisory Committee, *supra* note 21, at 277-278. See also discussion *infra* Part IV.G.

⁴³ The Reproductive Health Advisory Committee voted 7-0, with one abstention, that the French studies indicate that mifepristone is safe for use as an abortifacient. See *id.* at 284-286. See also discussion *infra* Part IV.G.

⁴⁴ See *id.* at 46 (testimony of C. Wayne Bardin, M.D.). The FDA approved misoprostol, hence deeming it safe for use, in December of 1989. See Food and Drug Administration, *Misoprostol Approval* (visited Mar. 27, 2000) <<http://www.fda.gov/bbs/topics/NEWS/NEW00142.html>>.

⁴⁵ An Iowa doctor highly publicized one particular incident in which he reported one of his patients lost more than half her blood, came close to death, and needed surgery two weeks after taking mifepristone. Tom Carney, 'Abortion Pill' Test Goes Awry for One Patient, DES MOINES REG., Sept. 21, 1995, Metro, at 1. The doctor, Dr. Mark Louviere, believed reports that claimed no complications occurred in the Iowa clinical testing were misleading. See *id.* A spokeswoman for the Population Council insisted that there were no serious complications and that such an incident was within the context of what happened before. *Id.* Planned Parenthood, the testing site at which the patient was administered the mifepristone, reported that the patient was unable to return for her third visit. See Advisory Committee, *supra*

adverse events⁴⁶ related to the pharmacological action of the regimen, most of which were essential for efficacy.⁴⁷

Adverse events, according to a discussion of the results, included painful uterine contractions, nausea, vomiting, diarrhea, headaches, fainting, dizziness, fever, back pain, fatigue and bleeding.⁴⁸ In the French studies, 82% of the women reported painful uterine contractions, 32% of the 82% said such contractions were severe, and 20% of the 82% needed treatment.⁴⁹ In the French studies, only 1 to 2% recorded bleeding as a severe adverse event, although 96.6% of the women bled and according to reports, the bleeding was heavier than the woman's heaviest menstrual period 80% of the time.⁵⁰ The women bled for an average (mean) of 9.1 days.⁵¹ Despite the reporting of such adverse events, 80% of the women required no pain medication at all to use this regimen.⁵²

In contrast, in the United States clinical trial, 68% of the women received at least one medication, usually acetaminophen, for abdominal pain.⁵³ The median duration of bleeding was 13 days in women with duration of gestation of 49 days or less.⁵⁴ Excessive bleeding necessitated blood transfusions in four

note 21, at 234 (testimony of Gloria Feldt, president of Planned Parenthood Federation of America). Dr. Louviere concedes that if the patient had been able to return for her third visit, she probably would have been managed appropriately. *See id.* at 235 (testimony of Mark Louviere, M.D.).

⁴⁶Dr. Bardin referred to the side effects of the regimen as adverse events in his discussion of the safety of the regimen. *See* Advisory Committee, *supra* note 21, at 46-56 (testimony of C. Wayne Bardin, M.D.).

⁴⁷*See id.* at 46-47.

⁴⁸*See id.* at 46-56; Spitz, *Early Pregnancy Termination*, *supra* note 36, at 1244.

⁴⁹*See* Advisory Committee, *supra* note 21, at 49-52 (testimony of C. Wayne Bardin, M.D.). Such treatment included antispasmodics, narcotics, or non-narcotics. *See id.*

⁵⁰*See id.* at 53-54.

⁵¹*See id.* at 53.

⁵²*See id.* at 56.

⁵³*See* Spitz, *Early Pregnancy Termination*, *supra* note 36, at 1244.

⁵⁴*See id.* at 1243.

women and accounted for many of the hospitalizations, surgical interventions, and administration of intravenous fluids, although only 2% of such incidents were reported for women with duration of gestation of 49 days or less.⁵⁵

Apart from the women, there is a concern about the risk to the fetus of administration of mifepristone, in combination with misoprostol. In the studies discussed above, the women participating agreed to terminate their pregnancies surgically if medical termination was not successful.⁵⁶ However, not all women returned for their second and third visit⁵⁷ and outside a controlled study such behavior is likely to escalate. If a woman does not return, there is a risk she may carry her pregnancy to term. In this event, is the fetus safe? Animal toxicology on both mifepristone and misoprostol show teratologic effects in animals, and usually such teratologic effects in animals will translate or have a high possibility of translating to teratologic effects in humans.⁵⁸ Dr. Bardin, an endocrinologist and independent consultant for the Population Council, reported at a 1996 FDA Advisory Committee meeting, that 21 children have been born to women who changed their minds, after mifepristone-misoprostol administration, and three of these children have had congenital anomalies.⁵⁹

C. Other Medical Uses

In addition to its use as an abortifacient, researchers have explored several

⁵⁵ See *id.*

⁵⁶ See *id.* at 1246; Advisory Committee, *supra* note 21, at 32 (testimony of Irving M. Spitz, M.D.).

⁵⁷ See Beverly Winikoff, MD et al., *Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol*, 7 ARCHIVES FAM. MED. 360, 364 (1998) (reporting 5% of women participating in study did not return for third visit)

⁵⁸ See Advisory Committee, *supra* note 21, at 34 (testimony of C. Wayne Bardin, M.D.).

⁵⁹ See *id.* The congenital anomalies were club foot, abnormal fingernails, and an immune disease that led to death. See *id.* at 35.

other potential clinical applications of mifepristone.

Initially, researchers believed mifepristone might have potential as a contraceptive agent or as a post-coital contraceptive after unprotected intercourse.⁶⁰ Many hoped that mifepristone could be used as a once a month contraception. Early studies indicated that the administration of mifepristone during the early luteal phase prevents pregnancy.⁶¹ However, such a use is impractical, for there is no simple method of detecting the proper time for administration.⁶² Although researchers believed that mifepristone could be administered in the late luteal phase to prevent pregnancy, the failure rate of studies, administering mifepristone at such time, ranged from 17 to 19 percent.⁶³ Such a failure rate is unacceptably high. Early studies also indicated that a single dose of mifepristone administered within 72 hours of unprotected sex prevented pregnancy in a high percentage of women.⁶⁴ Such results brought high hopes that mifepristone could be used as a post-coital contraceptive, as well as a once a month contraceptive. However, as research continued, this method was proven to be impractical as a contraceptive, for monthly administration of mifepristone alters the timing of the subsequent month's cycle.⁶⁵ An alteration of one's cycle will also inhibit the effectiveness of mifepristone and may be a safety issue for

⁶⁰ See, e.g., Anna Glasier et al., *Mifepristone (RU 486) Compared with High-Dose Estrogen and Progestogen for Emergency Postcoital Contraception*, 327 NEW ENG. J. MED. 1041 (1992); Lynnete K. Nieman, *The Progesterone Antagonist RU 486: A Potential New Contraceptive Agent (Original Article)*, 316 NEW ENG. J. MED. 187 (1987).

⁶¹ See Irving M. Spitz, *Drug Therapy: Mifepristone (RU 486) - A Modulator of Progestin and Glucocorticoid Action (Review Article)*, 329 NEW ENG. J. MED. 404 (1993) [hereinafter Spitz, *Drug Therapy*].

⁶² See, e.g., *id.*

⁶³ See, e.g., *id.*

⁶⁴ See, e.g., Glasier, *supra* note 60, at 1041-1044; Marcus G. Plescia, M.D., MPH et al., *Mifepristone (RU 486): Current Knowledge and Future Prospects*, 7 ARCHIVES FAM. MED. 219, 221(1998).

⁶⁵ See, e.g., Plescia, *supra* note 64, at 221.

the woman.⁶⁶ These same issues must be addressed before mifepristone can be administered as an occasional post-coital contraceptive. It is believed that these negative side effects may be avoided by decreasing the dose of mifepristone administered, yet researchers have yet to determine an optimal dose.⁶⁷ Studies to date have not found an effective, safe, and practical use of mifepristone as a contraceptive or post-coital contraceptive.⁶⁸

Besides the termination and prevention of pregnancy, researchers have found that mifepristone has other clinical applications within the field of gynecology and obstetrics. Mifepristone is useful for the preoperative preparation of women for surgical abortion late in the first trimester.⁶⁹ Pretreatment with mifepristone softens the cervix and reduces the interval between the administration of prostaglandin and the expulsion of the uterine contents.⁷⁰ Mifepristone has also been proposed to induce labor after intrauterine fetal death and at the end of the third trimester.⁷¹ Researchers have also studied the effects of mifepristone administration in women with endometriosis.⁷² Although no change was observed in the extent of the disease, women reported that administration of

⁶⁶ See, e.g., BAULIEU, *supra* note 8, at 26-27.

⁶⁷ See, e.g., Oskari Heikinheimo, M.D. and David F. Archer, M.D., *Mifepristone: A Potential Contraceptive*, CLINICAL OBSTETRICS & GYNECOLOGY, June 1996, 461, 466.

⁶⁸ See, e.g., E.E. Baulieu, *RU 486 (Mifepristone)*, ANNALS N.Y. ACAD. SCI., Sept. 26, 1997, at 47, 53-56 (discussing studies conducted by the end of 1996 regarding use of mifepristone as contraception).

⁶⁹ See Spitz, *Drug Therapy*, *supra* note 61; Andre Ulmann et al., *Clinical Uses of Mifepristone (MFP)*, ANNALS N.Y. ACAD. SCI., June 12, 1995, at 248, 254 (1995).

⁷⁰ See, e.g., Ulmann, *supra* note 69, at 254.

⁷¹ See, e.g., Ulmann, *supra* note 69, at 252, 256-257; Michael S. Edwards, M.D., *Mifepristone: Cervical Ripening and Induction of Labor*, CLINICAL OBSTETRICS & GYNECOLOGY, June 1996, at 469.

⁷² See, e.g., Arlene J. Morales, M.D. et al., *Mifepristone: Clinical Application in General Gynecology*, CLINICAL OBSTETRICS & GYNECOLOGY, June 1996, at 451, 453-455; L. Michael Kettel, M.D. et al., *Preliminary Report on the Treatment of Endometriosis with Low-dose Mifepristone (RU 486)*, 178 AM. J. OBSTETRICS & GYNECOLOGY 1151 (1998).

mifepristone relieved their pelvic pain.⁷³

Outside the field of gynecology and obstetrics, researchers are hopeful that the progesterone antagonist feature of mifepristone will prove beneficial in treating tumors with progesterone receptors. More specifically, researchers have proposed the use of mifepristone in the treatment of women with certain types of breast cancer, consisting of malignant tumors with progesterone receptors.⁷⁴ Limited preliminary studies indicate that some women with breast cancer may respond to mifepristone treatment.⁷⁵ The National Cancer Institute of Canada is conducting the first large-scale controlled trial of mifepristone in patients with breast cancer.⁷⁶ Researchers have also proposed using mifepristone for the treatment of inoperable meningiomas, benign tumors of the membranes that surround the brain, due to the abundance of progesterone receptors found in such tumors.⁷⁷ Results of preliminary trials indicate that administration of mifepristone may prompt tumor regression.⁷⁸

Finally, in addition to being a progesterone antagonist, mifepristone is a glucocorticoid antagonist. Mifepristone binds to cortisol receptors and blocks the effect of excess cortisol in the circulation.⁷⁹ Therefore, researchers have proposed the use of mifepristone in treatment of Cushing's Syndrome, a condition

⁷³See, e.g., Morales, *supra* note 72, at 455.

⁷⁴See, e.g., Andre Ulmann et al., *RU 486*, SCIENTIFIC AMERICAN, June 1990, at 42, 48; Kathryn B. Horwitz, *The Molecular Biology of RU 486. Is There a Role for Antiprogestins in the Treatment of Breast Cancer?*, 13 ENDOCRINE REV. 146 (1992).

⁷⁵See, e.g., Spitz, *Drug Therapy*, *supra* note 61.

⁷⁶See, e.g., Oliver Sartor, M.D. and William D. Figg, PharmD, *Mifepristone: Antineoplastic Studies*, CLINICAL OBSTETRICS & GYNECOLOGY, June 1996, at 498, 502.

⁷⁷See, e.g., Jeremy Cherfas and Joseph Palca, *Hormone Antagonist with Broad Potential*, SCI., Sept. 22, 1998, at 1322.

⁷⁸See, e.g., Lou Finter, *French Abortion Drug RU 486: U.S. Research Battle Heats Up*, J. NAT'L CANCER INST., Mar. 6, 1991, at 316; Sartor and Figg, *supra* note 76, at 502-503.

⁷⁹See, e.g., Plescia, *supra* note 64, at 222.

that results from chronic exposure to excessive glucocorticoids.⁸⁰ Preliminary studies suggest that treatment with mifepristone will ameliorate the condition of patients with certain types of Cushing's Syndrome.⁸¹ Other applications for the antiglucocorticoid effects of mifepristone include the application of eye drops containing mifepristone to lower eyeball pressure in patients with glaucoma and the use of mifepristone to treat burns and abrasions by accelerating the healing process.⁸²

Most of the large-scale clinical trials to date have focused on mifepristone's application as an abortifacient. However, it is clear that mifepristone has potential beyond its use in terminating pregnancy. Despite researchers' optimism regarding mifepristone's other uses, American researchers have found it difficult to conduct clinical studies within the past decade. The reasons for this difficulty will be explored in Part IV of this paper.

Part II

Since the introduction of mifepristone in France, Americans have been choosing sides and drawing battle lines. On one side stands those opposed to the availability of mifepristone in the United States, on the other those who wish to hasten the availability of mifepristone in the United States. Both, motivated

⁸⁰See, e.g., Oliver Sartor, M.D. and Gordon B. Cutler, Jr., M.D., *Mifepristone: Treatment of Cushing's Syndrome*, CLINICAL OBSTETRICS & GYNECOLOGY, June 1996, at 506.

⁸¹See, e.g., *id.* (discussing prior clinical studies regarding the treatment of Cushing's Syndrome with mifepristone)

⁸²See Cherfas and Palca, *supra* note 77.

by deep ideological beliefs, have been relentless in their fight to win the battle.

A. Anti-abortionists

Anti-abortionists comprise the vast majority of those opposed to the availability of mifepristone in the United States. Their campaign has been spearheaded by the National Right to Life Committee or the NRLC, the Nation's largest pro-life organization, and its fearless leaders, Dr. John Willke, former president, and Dr. Richard Glasow, director of education. Other pro-life organizations, such as the Life Issues Institute, the Family Research Council, and the American Life League, have joined the NRLC to speak out against the approval of mifepristone in the United States.⁸³ The Catholic Church has also voiced its disapproval of the use of mifepristone as an abortifacient, due to the Catholic Church's stance against abortion.⁸⁴

Anti-abortionists fear that the introduction of mifepristone in the United States may undermine their entire campaign against abortion. The NRLC often relies on intimidation to convince women to carry their babies to term by showing women pictures of the fetus during pregnancy. Anti-abortionists fear that this tactic will no longer be useful if mifepristone can be used to terminate pregnancy at an early stage. Dr. John Willke of the NRLC voiced his concern saying, And if what [we] destroy in there doesn't look human, then it will make our job

⁸³See Advisory Committee, *supra* note 21, at 156, 186, 194 (testimony of American Life League, Family Research Council, and Life Issues Institute).

⁸⁴See, e.g., Aaron Zitner, *What Ever Happened to the Saga of RU-486?*, BOSTON GLOBE, Nov. 23, 1997, (Magazine), at 18. An editorial in the Vatican newspaper, believed to represent the views of Pope John Paul II, attacked mifepristone as the pill of Cain: the monster that cynically kills its brothers. *Id.*

more difficult.⁸⁵ Anti-abortionists use these same pictures of fetuses to picket abortion clinics and stage turbulent demonstrations. Such tactics will become less effective, if the use of mifepristone diminishes the number of abortion clinics due to the administration of the drug in doctors' offices.⁸⁶ Those opposed to abortion are also concerned that the simple taking of a pill, mifepristone, is too easy and the moral significance of abortion will diminish; according to Congressman Robert K. Dornan (R-Cal), with the 'death pill', the taking of a pre-born life will be as easy and as trivial as taking aspirin.⁸⁷ Abortion opponents have characterized mifepristone as ushering in an era of guilt-free, responsibility-free, carefree living.⁸⁸

Although all of the anti-abortionists fears may not be accurate according to the facts as is discussed later in Section C, abortion opponents may be accurate in their assessment that they will lose support. Polls show that Americans oppose later abortion at a much greater rate than early abortion.⁸⁹ Mifepristone, in combination with misoprostol, must be used within the first seven weeks of pregnancy in order to effectively terminate pregnancy. Therefore, fewer Americans may be opposed to mifepristone as a form of pregnancy termination compared

⁸⁵Megan Rosenfeld, *Conception and Controversy: The French Doctor and his Pill to Prevent Pregnancy*, WASH. POST, Dec. 18, 1986, at C1.

⁸⁶See Mindy J. Lees, *I Want a New Drug: RU-486 and the Right to Choose*, 63 S. CAL. L. REV. 1113, 1125 (1990).

⁸⁷Csilla Muhl, *RU-486: Legal and Policy Issues Confronting the Food and Drug Administration*, 14 J. LEGAL MED. 319, 339 (1993).

⁸⁸R. Alta Charo, *A Political History of RU-486*, in *BIO-MEDICAL POLITICS* 43, 48 (Kathi E. Hanna ed., 1991) (quoting D. Andrusko, *The Distortion Factor*, THE NATIONAL RIGHT TO LIFE NEWS, January 8, 1991, at 4.)

⁸⁹See EVERETT CARLL LADD and KARLYN H. BOWMAN, *PUBLIC OPINION ABOUT ABORTION* 10, 34 (2d ed. 1999). In a survey by the Gallup Organization for CNN/USA Today in August of 1996, 64% said that abortion should be generally legal in the first three months of pregnancy, while 65% said it should be generally illegal in the second three months of pregnancy. See *id.* at 34.

to surgical abortion.

B. Women's Movement

Those in favor of a woman's right to choose comprise a vast majority of those fighting to hasten the approval of mifepristone in the United States. The woman's movement is spearheaded by the Feminist Majority Foundation, the FMF, and the Abortion Rights Mobilization, ARM, and their fearless leaders, Eleanor Smeal and Lawrence Lader, respectively. The FMF is an organization dedicated to achieving political, economic, and social equality for women.⁹⁰ Lawrence Lader, a 1941 Harvard graduate and former magazine journalist, has fought for the women's right to choose since the early 1960's.⁹¹ He formed the National Abortion Rights Action League, a premier pro-choice organization, and has gone on to crusade for the introduction of mifepristone in the United States; he formed the Abortion Rights Mobilization to do just that.⁹²

Pro-choice advocates support the introduction of mifepristone in the United States, because it will provide women with an additional option which advocates believe has many advantages over that of surgical abortion. First, medical abortion does not involve the risk of surgery, such as injuries to the cervix or uterus, infections, or complications from anesthesia.⁹³ Also, it can be used in the earliest weeks following fertilization; many doctors will not perform a surgical abortion until the seventh week of pregnancy, because the failure rate after

⁹⁰ See Feminist Majority Foundation and Feminist Majority Chronologies (visited Mar. 27, 2000) <<http://www.feminist.org/welcome/index.html>>.

⁹¹ See Zitner, *supra* note 84.

⁹² See *id.*

⁹³ See, e.g., Gwendolyn Prothro, *RU 486 Examined: Impact of a New Technology on an Old Controversy*, 30 U. MICH. J.L. REF. 715, 726 (1997).

such time is almost zero.⁹⁴ Those who support mifepristone believe that the ability to end a pregnancy immediately may lessen the emotional trauma for the woman.⁹⁵ In addition, medical abortion gives more control to the patient.⁹⁶ When you give a woman three tablets of RU 486, she's standing up, she is in her clothes, and she can talk. [With surgical abortion], she is on her back, [and] she has got her feet in stirrups.⁹⁷ Pro-choice advocates also believe women will view medical abortion as a more natural process, more like an induced miscarriage than an abortion.⁹⁸

Finally, medical abortion supporters are hopeful that mifepristone will move abortions out of the clinics and into doctors' offices and eventually private bedrooms. This is important to pro-choice advocates for three reasons. First, as of 1997, surgical abortion was provided in only 16% of U.S. counties.⁹⁹ It is hoped that the use of medical abortion will make abortion more widely available to women. A 1995 survey by the Henry J. Kaiser Family Foundation suggests this may be true; the results revealed that more doctors will be willing to offer mifepristone than to perform traditional surgical abortions.¹⁰⁰ Second, women's access to clinics that provide abortion is often impeded. Abortion clinics have

⁹⁴ See, e.g., Marge Berer, *Inducing a Miscarriage: Women-Centered Perspectives on RU 486/Prostaglandin as an Early Abortion Method*, LAW, MEDICINE, & HEALTH CARE, Fall 1992, at 199, 200.

⁹⁵ See, e.g., *id.*; Zitner, *supra* note 84.

⁹⁶ See, e.g., Berer, *supra* note 94, at 201-202; Sarah Glazer, *Controversy Persists on French Abortion Pill; Efforts to Study the Drug for Other Uses Are Stymied in the U.S.*, WASH. POST, Dec. 10, 1991, at Z7.

⁹⁷ *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, and Energy of the H.R. Comm. on Small Bus.*, 102d Cong. 11 (1991) (statement of Dilys Cossey, chairwoman, British Family Planning Association).

⁹⁸ See, e.g., Berer, *supra* note 94, at 200.

⁹⁹ See, e.g., Gayle Kirshenbaum, *The Stealth Operation to Market RU-486*, GEORGE MAGAZINE, April 1997, at 112, 112.

¹⁰⁰ See *id.*

become the target of protests and violence.¹⁰¹ If the violence has not already prevented the clinic from providing abortion, violence may prevent women from visiting the clinics. In addition, fear of blockades and violence may prevent doctors from advertising their services, leaving women to rely on mere word of mouth.¹⁰² Third, medical abortion in a doctor's office or in one's home would afford women more privacy.¹⁰³ Women would be able to make a choice without the fear of abortion clinic protesters. Such an unimpeded choice has the potential to reduce the stigma of abortion for women.

A study of the acceptability and feasibility of early pregnancy termination by mifepristone, in combination with misoprostol, confirms that many American women would prefer medical abortion to surgical abortion. On the third visit of the United States clinical trial discussed in Part I.B, the participants were questioned about their abortion experience. The results, published in the April 1998 *Archives of Family Medicine*, indicate that 95.7% would recommend this medical abortion to others and 91.2% would choose it again.¹⁰⁴ Even among women for whom the method failed, 69.6% stated they would try it again.¹⁰⁵ The women listed the following as the most positive attributes: no surgery or injections, noninvasive (45.1%), natural, feminine like menses or miscarriage

¹⁰¹ See generally Eric Schaff, M.D., *Redefining Violence Against Women: The Campaign of Violence and the Delay of RU486*, 8 Temp. Pol. & Civ. Rts. L. Rev. 311 (discussing the violence aimed at abortion clinics and their providers).

¹⁰² See Gina Kolata, *Abortion Pill Reaches New U.S. Juncture*, N.Y. TIMES, July 19, 1996, at A10.

¹⁰³ See, e.g., Michelle Lynn Lakomy, *A Meaningful Choice: Two FDA Approved Drugs Are Combined to Perform Medical Abortions*, 18 WOMEN'S RTS. L. REP. 49, 52 (1996) (discussing the privacy advantages of medical abortion).

¹⁰⁴ See Winikoff, *supra* note 57, at 360. See also page 363, which states that 91.8% would choose it again.

¹⁰⁵ See *id.*

(23.6%), less pain than surgical abortion (19.8%), easier emotionally and less frightening (16.9%), and easier, simpler or faster (9.7%).¹⁰⁶ This study confirmed that pro-choice advocates were correct in assuming women would view medical abortion as an option with potential advantages compared to surgical abortion.

Unlike anti-abortionists, those in favor of a women's right to choose have found support from other groups. Institutions dedicated to issues of reproductive health, such as the Alan Guttmacher Institute, and population control, such as the Population Council, have supported and advocated for the approval of mifepristone in the United States. Members of the medical community have also voiced their support for the introduction of mifepristone.¹⁰⁷ The most influential, the American Medical Association, voted to support the legal availability of mifepristone for appropriate research and indicated clinical practices.¹⁰⁸ Medical researchers have begun a campaign of their own for the availability of mifepristone in the United States for additional research on other clinical applications of mifepristone.

C. The Truth behind the Debate

In theory, each side may appear to have drawn their battle lines rationally.

However, the reality of the abortion pill suggests that it may not revolutionize

¹⁰⁶See *id.* at 363-364.

¹⁰⁷See, e.g., Steve L. Heilig, *RU 486: What Physicians Know, Think, and (Might) Do – A Survey of California Obstetrician/Gynecologists*, LAW, MEDICINE, & HEALTH CARE, Fall 1992, at 184 (indicating that majority of obstetricians/gynecologists in California believe mifepristone should be made available for both clinical practice and additional research).

¹⁰⁸See *RU 486: The Import Ban and its Effect on Medical Research: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, and Energy of the H.R. Comm. on Small Bus.*, 101st Cong. 31 (1990) (testimony of P. John Seward M.D., member, board of trustees, American Medical Association).

the abortion debate. The administration of mifepristone, in combination with misoprostol, for termination of pregnancy requires three office visits. This type of medical abortion is not performed in the privacy of one's own home and is not likely to be performed there for some time, due to distribution restrictions.¹⁰⁹ Moreover, the treatment may not become available in doctors' offices for quite some time. Experts believe that clinics that already provide abortions are likely to remain the major providers, until others gain confidence in the method and feel that they will not be harassed by anti-abortionists, which may be quite some time.¹¹⁰ Therefore, medical abortion may not be as widely available as advocates hope.

In addition, it isn't as simple and easy as opponents feared. First, in France, the number of abortions has not increased due to the use of mifepristone, suggesting that it may not trivialize the abortion decision.¹¹¹ Second, as well as requiring three office visits, the method is a gradual process, which can last for several days; during this time, uterine pain and bleeding is common.¹¹² According to the President of the original company holding the patent on mifepristone, [i]t's an appalling psychological ordeal.¹¹³ Some suggest that the gradual process may be a good thing, for it creates an opportunity to dwell on the implications of the pregnancy and abortion and to cope with the conflicting feelings which surface.¹¹⁴ Others fear that women will view the gradual process, including

¹⁰⁹ See discussion *infra* Part IV.G.

¹¹⁰ See Pertman, *supra* note 5; *Main Question about Abortion Pill: Which Doctors Will Prescribe It?*, ST. LOUIS POST-DISPATCH, Sept. 20, 1996, at 1A.

¹¹¹ See Pertman, *supra* note 5.

¹¹² See Spitz, *supra* note 36, at 1243-1244.

¹¹³ RENATE KLIEN ET AL., RU 486 MISCONCEPTIONS, MYTHS AND MORALS 51 (1991).

¹¹⁴ See Berer, *supra* note 94, at 203.

physical pain, as punishment.¹¹⁵ Either way, the method is not as simple as popping a pill, physically or emotionally.

Advocates have also praised medical abortion for it allows a women to terminate pregnancy early, but others are concerned that women may have a higher regret rate due to the need for an early decision.¹¹⁶ Medical abortion is also not a low cost alternative, as some hoped; it is likely to cost the same amount as a surgical abortion.¹¹⁷ Finally, if abortion, both surgical and medical, remains in the clinics, protests and violent demonstrations are likely to continue if not worsen. Michael Policar, the national medical director of Planned Parenthood, said, I don't think anyone should be saying RU-486 [mifepristone] is a panacea because, if anything, things may become more polarized and there could be more violence.¹¹⁸ The introduction of mifepristone may change the political landscape, but probably only over time. Some think its greatest contribution will be paving the way for additional research and forms of medical abortion.¹¹⁹ And at the least, pro-choice advocates would argue, it is another option for women.

Part III

¹¹⁵ See *id.* at 203; Glazer, *supra* note 96.

¹¹⁶ See Glazer, *supra* note 96.

¹¹⁷ See Kirschenbaum, *supra* note 99, at 112 (estimating cost of medical abortion to be about \$300); *Mifepristone Ancillary Costs Are Being Covered by Seattle Area-Insurers*, THE PINK SHEET, Oct. 11, 1999 (stating cost of therapy with mifepristone likely to be equivalent to the cost of surgical abortion).

¹¹⁸ See Pertman, *supra* note 5.

¹¹⁹ See *Main Question About Abortion Pill: Which Doctors Will Prescribe It?*, *supra* note 110.

Mifepristone was first synthesized in 1980 by Georges Teutsch, a chemist for the French pharmaceutical company, Roussel-Uclaf.¹²⁰ Roussel-Uclaf named the drug RU-486. Although not originally synthesized for use in termination of pregnancy, Dr. Etienne-Emile Baulieu, a part time consultant to Roussel-Uclaf, knew it had potential to interrupt pregnancy when he learned of its antiprogesterone properties.¹²¹ Dr. Baulieu had his friend, Dr. Walter Herrmann, administer mifepristone to eleven women.¹²² After successful termination in 9 out of 11 women, Dr. Baulieu was encouraged and clinical studies began on a larger scale.¹²³ In the fall of 1987, Laboratories Roussel, a division of Roussel-Uclaf, applied for a license to market mifepristone alone.¹²⁴ In January of 1988, the Ministry of Health demanded more information on the use of a prostaglandin.¹²⁵ In March of 1988, Laboratories Roussel provided a new application and in September of 1988, the Ministry of Health officially approved RU-486, or mifepristone, for distribution in France.¹²⁶

By the time of Laboratories Roussel's first application for approval, controversy over the drug had already begun. Dr. John Willke, then president of the NRLC, had formed an international federation with headquarters in France and Italy and written letters in July and December of 1987 to the French government describing the alleged dangers of mifepristone and declaring it chemical warfare on

¹²⁰ See BAULIEU, *supra* note 8, at 83.

¹²¹ See *id.* at 83-84.

¹²² See *id.* at 85.

¹²³ See *id.* at 85-86.

¹²⁴ See *id.* at 36.

¹²⁵ See *id.* at 38.

¹²⁶ See *id.* at 38-41.

the unborn.¹²⁷ In June of 1987, anti-abortionists held a three-day conference in New Orleans where they strategized on how to resist RU-486.¹²⁸ Dr. Edouard Sazik, president of Roussel-Uclaf, began receiving as many as 25 threatening letters a day stating such accusations as You kill babies and you will suffer the consequences or Assassins, stop your work of death.¹²⁹ Such letters even threatened the families of Roussel-Uclaf's executives.¹³⁰ On June 22, 1988, the eve of Roussel-Uclaf's annual meeting, the NRLC released a letter it sent to the French government protesting its involvement, through ownership of 40% of the stock of Roussel-Uclaf, with RU-486.¹³¹ The next day, hundreds of abortion opponents protested in front of Roussel-Uclaf's headquarters during the company meeting.¹³²

Roussel-Uclaf and Dr. Sazik, himself, felt the pressure. Company directors contemplated withdrawing the application, before approval, but decided against such a move.¹³³ Instead, the company planned to demur for commercial reasons when it was time to market the drug.¹³⁴ In addition to anti-abortionists, Dr. Sazik was feeling pressure from within the company.

Hoechst A.G., a leading German pharmaceutical firm, owned 54% of Roussel-Uclaf stock at this time.¹³⁵ Hoechst traces its corporate history to I.G. Far-

¹²⁷ *Id.* at 35.

¹²⁸ See Charo, *supra* note 88, at 54.

¹²⁹ Steven Greenhouse, *A New Pill, A Fierce Battle*, N.Y. TIMES, Feb. 12, 1989, §6 (Magazine), at 23.

¹³⁰ See Charo, *supra* note 88, at 46.

¹³¹ See *National Right to Life Urges French Government*, PR Newswire, June 22, 1988. See also BAULIEU, *supra* note 8, at 50 (indicating French government owns a third of Roussel-Uclaf); Alan Riding, *Abortion Politics Are Said to Hinder Use of French Pill*, N.Y. TIMES, July 29, 1990, §1, at 1 (indicating French government owns 36% of Roussel-Uclaf).

¹³² See *Greenhouse*, *supra* note 129.

¹³³ See BAULIEU, *supra* note 8, at 40.

¹³⁴ See *id.*

¹³⁵ See Riding, *supra* note 131; *The Safety and Effectiveness of the Abortifacient RU 486*

ben, the manufacturer of Zyklon-B, which was used in the gas chambers of Auschwitz.¹³⁶ Zyklon-B has been called the human pesticide, and anti-abortionists have used the same name for mifepristone.¹³⁷ During the company's annual meeting on June 23, 1988, protesters dressed as World War II deportees and shouted, You are turning the uterus into a crematory oven.¹³⁸ Hoechst feared such taunts; they did not want to be credited with doing to fetuses what the Nazis had done to the Jews.¹³⁹ Hoechst, also, feared boycotts. The NRLC had already stated its intent to boycott any pharmaceutical company that attempted to manufacture or market mifepristone in the United States.¹⁴⁰ Finally, Wolfgang Higler, the company's chief executive officer, is a devout Roman Catholic; he stated that an abortion pill violates the company's credo to support life.¹⁴¹ Turmoil could also be felt within Roussel-Uclaf. Roussel-Uclaf is a family founded French company, where many employees still see themselves as part of a family.¹⁴² According to Dr. Baulieu in such an atmosphere certain things are simply not done; Fears of a boycott are one thing. Worse are fears of a stain on the family name.¹⁴³ Roussel-Uclaf had proven itself susceptible to public opinion before. In the 1960's, Roussel-Uclaf had decided not to pursue production of the contraceptive pill, because it feared a public and religious

in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization, supra note 97, at 18 (testimony of Dr. Etienne-Emile Baulieu). As of 1997, Hoechst A.G. owned all of Roussel-Uclaf stock. See Zitner, supra note 84.

¹³⁶ See, e.g., Zitner, *supra* note 84.

¹³⁷ *Id.*

¹³⁸ BAULIEU, *supra* note 8, at 38-39.

¹³⁹ Greenhouse, *supra* note 129.

¹⁴⁰ See Richard D. Glasow (editorial), *Doubts Remain on Abortion Pill's Safety*, N.Y. TIMES, Apr. 23, 1988, §1, at 30.

¹⁴¹ Greenhouse, *supra* note 129.

¹⁴² See BAULIEU, *supra* note 8, at 107.

¹⁴³ *Id.* at 108.

backlash.¹⁴⁴

Despite Dr. Sazik's unwillingness to repeat the company's mistake and his own inner struggle between the advancement of science and protecting a company, Dr. Sazik voted to withdraw RU-486 from the French market on October 21, 1988.¹⁴⁵ An inter-office memorandum cited public emotion and the polemic incited by the possibility of using the drug for abortion as reasons for suspending the distribution of the drug.¹⁴⁶ On October 26, 1988, Roussel-Uclaf informed the press that it was pulling RU-486 off the market.¹⁴⁷ On the same day, 10,000 researchers and physicians were gathered in Rio de Janeiro for the World Congress of Gynecology and Obstetrics; Roussel-Uclaf's announcement turned the meeting into a strategy session on how to rescue the drug.¹⁴⁸

Roussel-Uclaf's suspension did not last long. Roussel-Uclaf issued a statement on October 28, 1988 agreeing to put the drug back on the market.¹⁴⁹ Such an announcement was made only after Health Minister Claude Evin told Roussel-Uclaf that the government would use its status as partial owner of Roussel-Uclaf and some special provisions of French law to transfer the patent to another company in order to serve the public good.¹⁵⁰ The Health Minister is said to have been motivated by a fear that the anti-abortion movement, after their triumph in keeping RU-486 off the market, would begin fighting for a repeal of the 1975

¹⁴⁴ See Charo, *supra* note 88, at 58.

¹⁴⁵ See Greenhouse, *supra* note 129.

¹⁴⁶ See BAULIEU, *supra* note 8, at 43.

¹⁴⁷ See Charo, *supra* note 88, at 61.

¹⁴⁸ See *id.* at 63.

¹⁴⁹ See Charo, *supra* note 88, at 65-66.

¹⁵⁰ See *id.* 1968 law holds that if a company refuses to make a drug available, the health minister can withdraw the license and award it to another company. See BAULIEU, *supra* note 8, at 50.

French law legalizing abortion,¹⁵¹ In explaining his decision to the public, he said, I could not permit the abortion debate to deprive women of a product that represents medical progress. From the moment, Government approval for the drug was granted, RU-486 became the moral property of women, not just the property of the drug company.¹⁵² Roussel-Uclaf was, undoubtedly, pleased by the government order, for it relieved the company of the moral burden and shifted responsibility to the government. However, many opponents believe that the move was orchestrated by Dr. Sazik and the Health Minister to shift the blame.¹⁵³ Specifically, anti-abortion groups believed it was a charade and vowed to hold both Roussel-Uclaf and Hoechst responsible.¹⁵⁴

RU-486, or mifepristone, was now available in France, but availability of the drug, in the near future, did not look hopeful for markets abroad. Hoechst instructed Roussel-Uclaf that RU-486 was going nowhere beyond the French borders until it proved itself at home.¹⁵⁵ Roussel-Uclaf decided to keep RU-486 in France. However, in the event that RU-486 would be exported for use as an abortifacient, the company developed a set of conditions that the importing country would have to satisfy. First, abortion must be legal in the country.¹⁵⁶

Two, abortion must be accepted widely by public opinion.¹⁵⁷ Third, a suitable

¹⁵¹See Charo, *supra* note 88, at 65.

¹⁵²Greenhouse, *supra* note 129.

¹⁵³See Charo, *supra* note 88, at 66-67.

¹⁵⁴See *id.* at 67.

¹⁵⁵See BAULIEU, *supra* note 8, at 105.

¹⁵⁶See *id.* at 109; *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, and Energy of the H.R. Comm. on Small Bus.*, 102d Cong. 76 (1992) (letter from Dr. Sazik, President of Roussel-Uclaf to Doctor E.H. Drew of the Hoechst Celanese Corporation).

¹⁵⁷See BAULIEU, *supra* note 8, at 109; *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 76 (letter from Dr. Sazik, President of Roussel-Uclaf to Doctor E.H. Drew of the Hoechst

prostaglandin must be available in the country.¹⁵⁸ Fourth, distribution of the drug must be under tight official control, as with narcotics.¹⁵⁹ Fifth, patients must sign a letter agreeing to a surgical abortion if the pill failed.¹⁶⁰ Dr. Baulieu insists that there was a sixth condition; the company would not sanction exports unless ranking government officials in the country urged them to do it.¹⁶¹ Roussel-Uclaf, in a letter submitted at a 1992 congressional hearing, confirmed Dr. Baulieu's suspicion concerning Roussel-Uclaf's position regarding the export of mifepristone to other countries. Roussel-Uclaf indicated there must be an actual wish for the licensing of mifepristone in a particular country.¹⁶² The letter indicated such a wish could come in the form of a written request from a representative, competent body such as the government or health authorities.¹⁶³

Part IV

A. FDA Approval Process

Celanese Corporation).

¹⁵⁸See BAULIEU, *supra* note 8, at 109; *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 76 (letter from Dr. Sazik, President of Roussel-Uclaf to Doctor E.H. Drew of the Hoechst Celanese Corporation).

¹⁵⁹See BAULIEU, *supra* note 8, at 109; *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 76 (letter from Dr. Sazik, President of Roussel-Uclaf to Doctor E.H. Drew of the Hoechst Celanese Corporation).

¹⁶⁰See BAULIEU, *supra* note 8, at 109; *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 76 (letter from Dr. Sazik, President of Roussel-Uclaf to Doctor E.H. Drew of the Hoechst Celanese Corporation).

¹⁶¹See BAULIEU, *supra* note 8, at 109.

¹⁶²*The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 76 (letter from Dr. Sazik, President of Roussel-Uclaf to Doctor E.H. Drew of the Hoechst Celanese Corporation).

¹⁶³See *id.*

Regardless of Roussel-Uclaf's exporting policy, according to the Federal Food, Drug, and Cosmetic Act, mifepristone cannot be imported into the United States and introduced into interstate commerce until the drug is approved by the FDA.¹⁶⁴ Before the FDA will approve a new drug, a sponsor must apply for approval by submitting a new drug application, an NDA.¹⁶⁵ The NDA must provide sufficient information, for the FDA to determine whether the drug is safe and effective for its proposed use(s) and whether the benefits of the drug outweigh its risks.¹⁶⁶ In addition, the FDA will evaluate the proposed labeling and manufacturing of the drug to determine whether the drug's proposed labeling is appropriate, and, if not, what the drug's labeling should contain and whether the methods used in manufacturing the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.¹⁶⁷

The FDA will review the NDA within 180 days and send the sponsor an approval letter, an approvable letter, or a not approvable letter.¹⁶⁸ The FDA and sponsor may mutually agree to extend the review period, and they often do.¹⁶⁹ The average approval time for a new drug is approximately two years, although drugs that feature an active ingredient not yet marketed in the United States and that represent an important therapeutic gain are given first priority in evaluation and approval.¹⁷⁰ The FDA will send the sponsor an approvable

¹⁶⁴ See 21 U.S.C.A. § 355(a) (West Supp. 1999); 21 U.S.C.A. § 381 (West Supp. 1999).

¹⁶⁵ See 21 U.S.C.A. § 355(b) (West Supp. 1999).

¹⁶⁶ Center for Drug Evaluation and Research, *CDER Handbook* (last modified Mar. 16, 1998) <<http://fda.gov/cder/handbook/index.htm>> [hereinafter *CDER Handbook*]. See 21 U.S.C.A. § 355(d) (West Supp. 1999); 21 C.F.R. § 314.50 (1999) (specifying the information which must be included in an NDA).

¹⁶⁷ *CDER Handbook*, *supra* note 166; 21 U.S.C.A. § 355 (b).

¹⁶⁸ See 21 U.S.C.A. § 355(c) (West Supp. 1999); 21 C.F.R. § 314.100 (West Supp. 1999).

¹⁶⁹ See 21 C.F.R. § 314.100.

¹⁷⁰ See Karen F. Richards, *RU 486: A Promising Birth Control Device Entangled in the*

letter if the agency believes that the NDA substantially meets the necessary requirements and that it can approve the application if specific additional information is submitted or specific conditions are agreed to by the applicant.¹⁷¹ As a practical matter, an approvable letter serves as a mechanism for resolving outstanding issues on drugs that are about to be approved and marketed.¹⁷² An approvable letter often requires changes in the labeling and may request a commitment to do post-approval studies.¹⁷³

Prior to submission of an NDA, the sponsor must conduct clinical trials to evaluate the safety and effectiveness of the new drug for its intended purpose. The FDA may approve the introduction of a drug into interstate commerce solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of a new drug.¹⁷⁴ In order to receive approval to conduct a clinical investigation of a new drug, a sponsor must submit an investigational new drug application, an IND, to the FDA.¹⁷⁵ The IND must include pharmacology and toxicology information regarding the drug, from which the FDA can conclude that the drug is reasonably safe to conduct the proposed clinical investigation.¹⁷⁶ Such information is gathered through in vitro and in vivo laboratory animal testing.¹⁷⁷ An IND is usually submitted for three phases of testing on a new drug. Phase I, the initial introduction of the new drug into humans, is designed to determine the metabolism and pharmacological

Abortion Debate, 6 J. PHARMACY & L. 117, 122.

¹⁷¹ See 21 C.F.R. § 314.110 (West Supp. 1999).

¹⁷² 21 C.F.R. § 314.110.

¹⁷³ See *CDER Handbook*, *supra* note 166.

¹⁷⁴ 21 U.S.C.A. § 355(i) (West Supp. 1999).

¹⁷⁵ See 21 C.F.R. § 312.20 (1999).

¹⁷⁶ See 21 C.F.R. § 312.23(a) (1999).

¹⁷⁷ See *CDER Handbook*, *supra* note 166.

action of the drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence of effectiveness.¹⁷⁸ Phase 2 is conducted to evaluate the effectiveness of the drug for a particular use or treatment and to determine the common short term side effects and risks associated with the drug.¹⁷⁹ Phase 3 is intended to gather additional information about effectiveness and safety that is needed to evaluate the over-all benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.¹⁸⁰

B. Early Clinical Investigations in the United States

Although mifepristone has not received FDA approval for marketing and distribution as a new drug, the FDA has approved clinical testing of the drug in the United States under IND permits. In 1982, Roussel-Uclaf entered an agreement with the Population Council in the United States.¹⁸¹ The Population Council is a non-profit research institution dedicated to exploring the causes and consequences of population growth and to improving women's and men's reproductive health.¹⁸² The Population Council, having developed new forms of contraception such as several types of IUDs, has been a major player in the field of reproductive health for over 45 years.¹⁸³ The agreement gave the Council rights to import mifepristone into the United States for large-scale testing.¹⁸⁴ In 1983, the Population Council obtained an IND to investigate the

¹⁷⁸21 C.F.R. § 312.21(a)(1) (1999).

¹⁷⁹See 21 C.F.R. § 312.21(b) (1999).

¹⁸⁰21 C.F.R. § 312.21(c) (1999).

¹⁸¹See *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 85 (staff memorandum); BAULIEU, *supra* note 8, at 30.

¹⁸²See Advisory Committee, *supra* note 21, at 10 (testimony of Sandra P. Arnold).

¹⁸³See Zitner, *supra* note 84.

¹⁸⁴See *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Oppor-*

use of mifepristone as an abortifacient.¹⁸⁵ The Population Council imported the drug under the agreement it had signed with Roussel-Uclaf and testing began at the University of Southern California School of Medicine in 1984.¹⁸⁶ Dr. David Grimes, a professor of obstetrics and gynecology at the school, conducted studies from 1984 to 1990 to determine the safety and efficacy of mifepristone for early abortion; in one study, Dr. Grimes reported a 90% success rate after administration of 600 milligrams of mifepristone alone.¹⁸⁷

The FDA has issued IND permits to investigate other clinical applications of mifepristone, as well. Beginning in 1983, Dr. George P. Chrousos performed research at the National Institute of Health on the therapeutic use of mifepristone in a subgroup of patients with Cushing's Syndrome.¹⁸⁸ Dr. Stephen Grunberg at the University of Southern California Medical Center has performed trials for treatment of meningioma with mifepristone.¹⁸⁹ Beginning in 1983, the NIH and the Population Council have conducted research regarding the use of mifepristone as a contraceptive agent.¹⁹⁰ Other medical researchers have conducted

tunities and Obstacles to U.S. Commercialization, supra note 97, at 85 (staff memorandum); BAULIEU, supra note 8, at 30.

¹⁸⁵ See *The Safety and Effectiveness of the Abortifacient RU 486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, supra note 97, at 85 (staff memorandum).

¹⁸⁶ See *id.* at 25 (testimony of David Grimes, professor of obstetrics and gynecology and preventive medicine, University of Southern California School of Medicine).

¹⁸⁷ See *id.*

¹⁸⁸ See *RU 486: The Import Ban and Its Effect on Medical Research: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, and Energy of the H.R. Comm. on Small Bus.*, supra note 108 (testimony of George P. Chrousos M.D., senior investigator and section chief, Pediatric Endocrinology, National Institute of Child Health and Human Development, National Institutes of Health).

¹⁸⁹ See *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, supra note 156, at 125 (FDA listing of active investigational new drug projects and level of activity within each of 13 multipatient trials).

¹⁹⁰ See *id.*; *RU 486: The Import Ban and Its Effect on Medical Research*, supra note 108, at 11 (testimony of Lynnette K. Nieman, M.D., National Institute of Child Health and Human Development, National Institute of Health). Under federal law, the NIH cannot conduct research regarding the use of mifepristone as an abortifacient. See RAYMOND TATALOVICH, *THE POLITICS OF ABORTION IN THE UNITED STATES AND CANADA* 97 (1997).

investigations regarding the use of mifepristone to treat such diseases as breast cancer and endometriosis.¹⁹¹

In the late eighties, the FDA issued special permission to ten research groups to use the drug in clinical investigations, yet most of these projects have been discontinued.¹⁹² The Population Council stopped supporting the clinical trials of mifepristone as an abortifacient at the University of South Carolina in 1987.¹⁹³ Although research did continue, the study was abruptly stopped in February of 1990.¹⁹⁴ The supply of mifepristone had run out and Roussel-Uclaf refused to provide more.¹⁹⁵ Dr. Chrousos testified at a November 19, 1990 congressional hearing, regarding the importation of mifepristone, that his supply of the drug had been depleted and that Roussel-Uclaf refused to make any commitment to supply additional quantities.¹⁹⁶ Dr. William Regelson, a professor of medicine at the Medical College of Virginia, testified at the same hearing that after an initial meeting, Roussel-Uclaf refused to meet to discuss supplying the drug for clinical studies regarding Cushing's Syndrome.¹⁹⁷ Dr. Andre Ulmann, medical

¹⁹¹ See *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 125 (FDA listing of active investigational new drug projects and level of activity within each of 13 multipatient trials).

¹⁹² See *id.*; *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 56 (subcommittee staff memorandum).

¹⁹³ The Population Council paid for only three years of the study. See BAULIEU, *supra* note 8, at 140; Gina Kolata, *Boycott Threat Blocking Sale of Abortion-Inducing Drug*, N.Y. TIMES, Feb. 22, 1988, at A1 [hereinafter Kolata, *Boycott Threat*].

¹⁹⁴ See *The Safety and Effectiveness of the Abortifacient RU 486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 85 (staff memorandum); BAULIEU, *supra* note 8, at 140.

¹⁹⁵ See, e.g., *The Safety and Effectiveness of the Abortifacient RU 486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 85 (staff memorandum).

¹⁹⁶ See *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 18 (testimony of George P. Chrousos M.D., senior investigator and section chief, Pediatric Endocrinology, National Institute of Child Health and Human Development, National Institutes of Health).

¹⁹⁷ See *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 4-6 (testimony of William Regelson, M.D., professor of medicine, Medical College of Virginia).

director for Roussel-Uclaf, said only that the company did not give them the drug because our policy is undefined.¹⁹⁸

The question is why, after initial agreement in the early eighties to supply the drug to the United States for testing, Roussel-Uclaf adamantly refused in the late eighties to further supply the drug to United States medical researchers, let alone sponsor the drug for approval as an abortifacient.

C. The Import Alert

The Food, Drug, and Cosmetic Act prohibits the importation of drugs not approved for use in this country.¹⁹⁹ However, the FDA Regulatory Procedures Manual has stated, since 1977, that the FDA will not detain unapproved new drugs imported for personal use.²⁰⁰ In July of 1988, the FDA issued further guidance regarding its mail importation policy, entitled Pilot Guidance for Release of Mail Importations, which outlined the circumstances under which individuals could import unapproved drugs for personal use.²⁰¹ Such guidance was meant to address the predicament of cancer and AIDS patients who, in growing number, sought to import unapproved drugs by mail.²⁰² Forty drugs were initially excluded from the exception, but mifepristone was not.²⁰³ On Septem-

¹⁹⁸Philip J. Hiltz, *F.D.A. Says It Allows Study of Abortion Drug*, N.Y. TIMES, Nov. 20, 1990, at C9.

¹⁹⁹See 21 U.S.C.A. § 381 (West Supp. 1999); *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 48 (Sandra Barnes, Office of General Counsel of FDA).

²⁰⁰See PETER BARTON HUTT AND RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 561 (2nd ed. 1996).

²⁰¹See *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 162-164 (Pilot Guidance for Release of Mail Importations).

²⁰²See Michael J. Brooks, *RU-486: Politics of Abortion and Science*, 2 J. PHARMACY & L. 261, 277 (1994); *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 48 (testimony of Sandra Barnes, Office of General Counsel of FDA) (stating In certain situations, in very limited situations, FDA will occasionally allow in a drug for certain serious and life-threatening conditions where an alternative does not exist.).

²⁰³See Debora C. Fliegelman, *The FDA and RU 486: Are Politics Compatible with the*

ber 26, 1988, the FDA issued an Import Bulletin excluding mifepristone from the Pilot Guidance.²⁰⁴ On February 1, 1989, a formal revision of the FDA's Regulatory Procedures Manual occurred; under the new revision known as the personal use exception, importation for personal use of any drug not listed in an import alert was subject to a case-by-case discretionary decision by the FDA.²⁰⁵ The Regulatory Procedures Manual instructed that the following criteria were to be evaluated to determine whether the FDA should allow importation of the unapproved drug:

1. The drug must be for an individual patient.
2. There must be a small quantity of the drug, a 3 month supply or less.
3. The drug must be intended to treat a condition of serious nature.
4. No other treatment must be commercially available in this country.
5. There must be no known promotion or commercialization of the product.
6. The product must not pose an unreasonable safety risk to the patient.
7. The patient must confirm that the product is for his or her personal use and provide the name and address of a practicing physician who will be responsible for his or her treatment.²⁰⁶

At the time of the revision, mifepristone was not the subject of an import alert, only an import bulletin. Therefore, theoretically, the drug could be imported under the personal use exception, if the drug met the above criteria. On May 5, 1989, eleven members of Congress sent a letter to then FDA Commissioner

FDA's Mandate of Protecting Public Health and Safety?, 66 TEMP. L. REV. 143, 149 (1993).

²⁰⁴ See *id.*

²⁰⁵ See Brooks, *supra* note 202, at 278.

²⁰⁶ See *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 171-172 (Regulatory Procedures Manual).

Frank Young requesting a clarification of the FDA's policy regarding the importation of mifepristone and strongly encouraging a ban of the drug.²⁰⁷ On May 23, 1989, the agency's Import Operations Branch issued a recommendation that mifepristone was not intended to qualify for the personal use exception.²⁰⁸ On June 6, 1989, the FDA issued Import Alert 66-47, concluding that mifepristone is not appropriate for release under the personal importation policy because the intended use of such [a] drug[s] could pose a risk to the safety of the user.²⁰⁹ In a letter to Senator Jesse Helms, dated June 9, 1989, FDA Commissioner Young stated that mifepristone is not appropriate for personal importation because the intended use of this drug makes it likely it would be used without benefit of supervision of a physician and indiscriminate or unsupervised use could be hazardous to the patient's health.²¹⁰

On November 19, 1990, a hearing before the Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business examined the import ban of mifepristone and its effect on medical research.

Congressman Ron Wyden (D-Ore.), chairman of the subcommittee, accused the FDA of arbitrary, political, and unscientific RU 486 policies.²¹¹ He questioned the FDA's issuance of an import alert with no evidence of an active black mar-

²⁰⁷ See *id.* at 183 (letter to Dr. Frank Young from eleven members of congress).

²⁰⁸ See Fliegelman, *supra* note 203, at 149.

²⁰⁹ *Import Alert IA6647* (visited Jan 18, 1999) <http://www/fda.gov/ora/flars/ora_import_ia6647.html>; *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 165-166. Under the Import Alert, if the drug is observed coming into this country either in the mail or on someone's person, it is subject to detention by officials of the FDA and the U.S. Customs Service. See *RU 486: The Import Ban and Its Effect on Medical Research*, at 35 (testimony of Ronald Chesemore, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration).

²¹⁰ *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 181 (letter from Dr. Frank Young to Senator Helms).

²¹¹ *Id.* at 2 (testimony of Chairman Ron Wyden).

ket in the drug, no record of any attempts to import the drug into the United States, and no record of any injuries due to the drug.²¹² Mr. Wyden also remarked on the mere 19 days that elapsed between the congressional demand on the FDA to review the importation policy of mifepristone and the FDA's issuance of Import Alert 66-47.²¹³ He called it a new land speed record for an agency response to congressional inquiries.²¹⁴ Ronald Chesemore, Associate Commissioner of Regulatory Affairs at the FDA, conceded that the FDA had no concrete evidence of a black market and no evidence of surreptitious entry of mifepristone into the United States.²¹⁵ Mr. Chesemore indicated that the FDA was concerned that the publicity of the drug may create a demand for the drug leading to unsupervised distribution.²¹⁶ However, Mr. Chesemore and Dr. Solomon Sobel, director of the FDA's Division of Metabolism and Endocrine Disorders, agreed that there was no evidence to doubt Roussel-Uclaf's strict control of the drug in France.²¹⁷ Mr. Chesemore summed up the agency's position with his statement We certainly just felt like the personal importation of this drug was serious.²¹⁸ The FDA representatives fell back on the fact

²¹² See *id.* at 2,37-44 (testimony of Chairman Ron Wyden).

²¹³ See *id.* at 2, 44-46 (testimony of Chairman Ron Wyden).

²¹⁴ *Id.* at 2 (testimony of Chairman Ron Wyden).

²¹⁵ See *id.* at 37 (testimony of Ronald Chesemore, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration).

²¹⁶ See *id.* at 40-41 (testimony of Ronald Chesemore, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration).

²¹⁷ See *id.* at 37, 46-47 (testimony of Ronald Chesemore, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration and Solomon Sobel, M.D., Director, Division of Metabolism and Endocrine Drug Products) Mifepristone is under the same strict controls in France as surgical abortion. Only authorized centers are allowed to purchase mifepristone; pharmacies must account for every box and supply doctors only the exact amount needed. See BAULIEU, *supra* note 8, at 85.

²¹⁸ *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 43 (testimony of Ronald Chesemore, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration)

that mifepristone does not fit within the personal use exception itself, since it does not treat a life-threatening condition and there is an alternative treatment available.²¹⁹ Mr. Wyden was not satisfied with this response; he wanted to know why mifepristone was singled out, for the FDA does not usually ban a drug merely because it is unapproved, but allows the personal use exception to dictate.²²⁰ In Mr. Wyden's estimation, the FDA should not have made this pro-active move; the import alert was a non-issue.²²¹ Mr. Wyden contended that the FDA's decision was politically motivated, as evidenced by the timing and character of the correspondence between FDA officials and anti-abortion activists.²²²

More importantly, Congressman Wyden was concerned about the consequences of the FDA's action. Mr. Wyden contended that the import alert influenced Roussel-Uclaf's decision regarding seeking approval of mifepristone in the United States and providing sufficient quantities for research purposes.²²³ As discussed in Part IV.B, researchers at the hearing testified regarding Roussel-Uclaf's reluctance to supply the drug for research purposes. Dr. Regelson testified that Roussel-Uclaf may be using the import alert to mobilize people who want the drug; he insisted by withholding the drug from medical researchers and people who need the drug, Roussel-Uclaf may have been attempting to force such individuals to create political pressure to balance the threat of boycotts by anti-

²¹⁹ See *id.* at 42 (testimony of Sandra Barnes, Office of General Counsel of FDA).

²²⁰ See *id.* at 50 (testimony of Chairman Ron Wyden); Fliegelman, *supra* note 203, at 158.

²²¹ *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 50 (testimony of Chairman Ron Wyden).

²²² See *id.* at 2 (testimony of Chairman Ron Wyden). See also, *Benten v. Kessler*, 799 F.Supp. 281, 286 (E.D.N.Y. 1992), in which Judge Sifton accuses the FDA of basing its decision on political considerations.

²²³ See *id.* at 2-3 (testimony of Chairman Ron Wyden)

abortionists.²²⁴

Congressman Wyden chaired yet another congressional hearing, on July 28, 1992, focusing on the impact of the import alert of mifepristone on medical research and new drug development. Almost two years later little had changed. Mr. Wyden was disappointed, if not angry, to report that Roussel-Uclaf decided to go forward with important new breast cancer trials in Canada, although many United States institutions wished to conduct the studies.²²⁵ The committee heard testimony from David Grow, a man with recurrent meningioma, in which he recounted his difficulties in obtaining mifepristone from Roussel-Uclaf to treat his condition. Roussel-Uclaf told him that he could arrange a compassionate use exemption from the import alert through the FDA; the FDA told him he could not receive a compassionate use exemption without a written guarantee of supply from the company, which Roussel-Uclaf would not provide without an IND.²²⁶ Congressman Wyden insisted that Roussel-Uclaf was being sent a clear message: Don't try applying for a general drug approval for RU 486 in this count[sic]; you won't get a fair shake.²²⁷ Dr. Marjorie Braude, from the American Medical Women's Association, testified that during discussions with the Roussel-Uclaf research staff, the staff indicated that the import alert was one of the factors which led to their determination that the United States

²²⁴ See *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 4-6 (testimony of William Regelson, M.D., professor of medicine, Medical College of Virginia). See also discussion *infra* Part IV.D regarding boycott threats.

²²⁵ See *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 2 (testimony of Chairman Ron Wyden).

²²⁶ See *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 12-15 (testimony of David J. Grow).

²²⁷ *Id.* at 2 (testimony of Chairman Ron Wyden).

does not fulfill the necessary criteria for exportation of the drug.²²⁸ In fact, Dr. Braude stated that one of the Roussel-Uclaf representatives said that the import alert has a chilling effect because this drug is differently singled out.²²⁹ The FDA may have been genuinely concerned about safety. As discussed previously, mifepristone is not safe for unsupervised use. Moreover, American physicians have not received the necessary training to supervise administration of mifepristone for medical abortion.²³⁰ Even Dr. Baulieu, who believes that the entry of mifepristone into the United States depends entirely on the abortion issue, said at a 1991 congressional hearing that the FDA behaved very rightly.²³¹ At that time, he believed that the individual use of mifepristone to interrupt pregnancy was not reasonable and could be medically dangerous.²³² In addition, Import Alert 66-47 remains in effect today. The FDA did not change its position, even after President Clinton ordered the Department of Health and Human Services and the FDA to review the import alert of mifepristone.²³³

Regardless, the evidence suggests that the import alert influenced Roussel-Uclaf's decision not to supply mifepristone to American researchers and women. Roussel-Uclaf believed the FDA to be singling out mifepristone, and it perceived such action to signify the power of the political climate in the United States regarding abortion.²³⁴

D. Boycott Threats and Economic Concerns

²²⁸ See *id.* at 17-19 (testimony of Marjorie Braude, M.D., chairperson, Governmental Affairs Committee, American Medical Women's Association).

²²⁹ *Id.* at 25 (testimony of Marjorie Braude, M.D., chairperson, Governmental Affairs Committee, American Medical Women's Association).

²³⁰ See *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 7 (testimony of Dr. Etienne-Emile Baulieu).

²³¹ *Id.* at 6.

²³² See *id.* at 6-7.

²³³ See discussion *infra* Part IV.F.

²³⁴ In fact, the FDA did single out mifepristone, although it may have been forced to take such action by inquiries from both congress members and Customs. See *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 42-43 (testimony of Ronald Chesemore, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration).

Roussel-Uclaf and its majority shareholder feared such power, especially when exerted in the form of threatened boycotts. Since 1988 the NRLC and other anti-abortion groups, including pro-life hospitals, have threatened to boycott any company that attempts to manufacture or market the abortion pill in the United States.²³⁵ Dr. Glasow of the NRLC has also said that the NRLC will organize a boycott, despite the primary use of the drug, unless the drug is the only one available to treat a life-threatening condition.²³⁶ In late 1988, the RCR Alliance registered with Congress as lobbyists and then sent the Hoechst chairman an outline of its three pronged strategy, including a boycott of any United States financial firm that was holding Hoechst stock in its international funds.²³⁷ In mid-March of 1989, the International Right to Life Federation urged consumers to boycott Roussel-Uclaf and Hoechst and said it may extend the boycott to other French products, if France did not stop its chemical warfare against unborn children.²³⁸

The NRLC has used boycotts as a tactic before. In 1983, the NRLC boycotted all Upjohn products.²³⁹ The group sent members wallet-sized cards listing alternatives to drugs that Upjohn made.²⁴⁰ In 1985, Upjohn stopped all

²³⁵ See Kolata, *Boycott Threat*, *supra* note 193; Glasow, *supra* note 140; Seelye, *Accord Opens Way*, *supra* note 5; Joseph Schuman, *Fearing U.S. Boycotts, Hoechst Gives Away World Rights to Abortion Pill*, Associated Press, Apr. 8, 1997.

²³⁶ See Kolata, *Boycott Threat*, *supra* note 193.

²³⁷ See Charo, *supra* note 88, at 69.

²³⁸ *Id.* at 70 (quoting *Anti-abortion Movement Calls for Boycott of French Pill*, Reuters Library Report, Mar. 15, 1989).

²³⁹ See Kolata, *Boycott Threat*, *supra* note 193.

²⁴⁰ See Gina Kolata, *Any Sale in U.S. of Abortion Pill Still Years Away*, N.Y. TIMES, Oct. 30, 1988, §1, at 1 [hereinafter Kolata, *Any Sale*].

research on drugs to induce abortion or prevent pregnancy.²⁴¹ Upjohn representatives said that such research was stopped because of the adverse regulatory climate in the United States and because of the litigious climate.²⁴² Jessly Bradford, a spokeswoman for Upjohn, said that the boycott had no discernible effect; she claimed that Upjohn was never able to detect any impact on sales of stocks.²⁴³ In 1993, Upjohn continued to sell two drugs that induced abortion despite NRLC's boycott.²⁴⁴ However, Dr. Glasow, as well as a representative of the Population Council, argued that the boycott was the principal reason for the halt on research.²⁴⁵ At the least, one can be sure that Dr. Glasow felt victory, as he reported, in 1988, that Upjohn discontinued an earlier second-trimester abortion drug, declined to develop a similar Japanese drug, and closed its research facilities for developing new drugs for contraception and abortion.²⁴⁶

Hoechst is a big business. In the early 1990's, Hoechst's earnings approached 30 billion dollars, over 6 billion of which were in North America and mainly in the United States.²⁴⁷ A highly organized boycott by Catholic hospitals, which control approximately 1/3 of all hospital beds in the United States, could severely reduce the company's sales; some say such a boycott was Hoechst's greatest fear.²⁴⁸ Dr. Andre Ulmann, head of endocrinology in the research, development, and marketing department of Roussel-Uclaf, said the decision was

²⁴¹ See Kolata, *Boycott Threat*, *supra* note 193.

²⁴² *Id.*

²⁴³ Kolata, *Any Sale*, *supra* note 240.

²⁴⁴ See Calvin Sims, *The Politics of Dealing with the Threat of Boycott*, N.Y. TIMES, Mar. 14, 1993, §4, at 2.

²⁴⁵ See Kolata, *Boycott Threat*, *supra* note 193.

²⁴⁶ See Kolata, *Any Sale*, *supra* note 240.

²⁴⁷ See, e.g., Riding, *supra* note 131.

²⁴⁸ See LAWRENCE LADER, A PRIVATE MATTER 125 (1995); Zitner, *supra* note 84.

a simple one; he said, We [Roussel-Uclaf] were not going to put our \$600 million in revenues from other products at risk.²⁴⁹ Dr. Baulieu confirmed that Roussel-Uclaf's reluctance to market the pill in the United States was due to a fear of a backlash in the United States against its majority shareholder, Hoechst.²⁵⁰ In 1990, Arielle Mouttet, the head of international marketing at Roussel-Uclaf, said that selling in the United States [was] out of the question for the moment.²⁵¹ She said, Hoechst has interests in the U.S. and cannot do any old thing. It can't close its eyes to this reality.²⁵²

One may ask why the minority of Americans with moral opposition has such power.²⁵³ First, Roussel-Uclaf and Hoechst, as shown already in their original withdrawal of mifepristone from the French market, were and are sensitive to public opinion. Second, Roussel-Uclaf and Hoechst had to consider other economic factors in making their decision whether to market or supply mifepristone in the United States. The threat of a boycott, in combination with these two factors, may have made the introduction of mifepristone into the United States a risk not worth taking.

Roussel-Uclaf had to determine whether marketing the drug would be profitable. Pharmaceutical companies examine profitability of a new drug from four standpoints.

First, a company must assess the size of the market and the likely price of

²⁴⁹Sims, *supra* note 244.

²⁵⁰See Riding, *supra* note 131.

²⁵¹*Id.*

²⁵²*Id.*

²⁵³See *Pills and Parallels*, BOSTON GLOBE, Oct. 6, 1988, at 20 (quoting Dr. Irving Spitz of the Population Council saying The presumed power of antiabortion groups is upsetting.... It should be challenged.)

the product.²⁵⁴ Originally, experts estimated that the market for mifepristone would be large. However, these estimates incorrectly assumed that mifepristone could be used as a contraceptive and compete in the \$697 million oral contraceptive market.²⁵⁵ A more realistic estimate for United States sales of mifepristone is \$100 million.²⁵⁶ This is small compared to sales of other drugs; United States consumers spent \$11 billion on drugs to treat high blood pressure in 1996 and more than \$1.4 billion on antihistamines.²⁵⁷

Second, a company must assess the difficulty and expense of obtaining FDA approval.²⁵⁸ According to Dr. Baulieu, in order to meet FDA requirements, Roussel-Uclaf would have to spend at least \$70 million.²⁵⁹ As discussed in Part IV.C, Roussel-Uclaf believed that politics would be involved in the regulatory process. Moreover, the Upjohn Company's failure to receive approval for Depo-Provera, an injectable contraceptive, after a long and expensive effort, already gave the United States regulatory system a reputation for being a hostile environment for contraception research and development.²⁶⁰ Although the FDA may have had valid non-political reasons for its decisions, manufacturers per-

²⁵⁴ See Charo, *supra* note 88, at 81; *U.S. Pharmaceutical Research and Development, and Its Impact on Women's Health: the Technology Deficit in Contraception, Cancer, and Reproductive Disease and Conditions, Hearing Before the Subcomm. on Regulation, Bus. Opportunities, and Energy of the H.R. Comm. on Small Bus.*, 102d Cong. 18-22 (1992) (testimony of Joseph J. Spiedel, M.D., associate professor of clinical medicine, and head, Division of Nephrology, Robert Wood Johnson Medical School at Camden).

²⁵⁵ See Charo, *supra* note 88, at 52, 81.

²⁵⁶ See Zitner, *supra* note 84.

²⁵⁷ See *id.*

²⁵⁸ See Charo, *supra* note 88, at 81; *U.S. Pharmaceutical Research and Development, and Its Impact on Women's Health: the Technology Deficit in Contraception, Cancer, and Reproductive Disease and Conditions*, *supra* note 254, at 18-22 (1992) (testimony of Joseph J. Spiedel, M.D., associate professor of clinical medicine, and head, Division of Nephrology, Robert Wood Johnson Medical School at Camden).

²⁵⁹ See BAULIEU, *supra* note 8, at 140.

²⁶⁰ See Charo, *supra* note 88, at 83.

ceive the process to be influenced by abortion politics. The Upjohn company, although it has tested mifepristone in its laboratories, has no interest in pursuing manufacture of it.²⁶¹ A company representative said, FDA standards are so high, and the chances of getting something approved so low, it just isn't worth it.²⁶² Also, the time necessary to obtain FDA approval shortens the period of market exclusivity reducing profits.²⁶³

Third, a company must factor in costs associated with product liability claims.²⁶⁴ Since the product liability litigation regarding the Dalkon Shield IUD, pharmaceutical companies have been sensitive to the risk of litigation with reproductive products.²⁶⁵ Liability costs are a particular problem with reproductive products, because they treat people who are healthy at the beginning.²⁶⁶ Therefore, there is a high burden of proof for the safety of the product.²⁶⁷ Product liability can be high even for a safe product.²⁶⁸ G.D. Searle pulled its IUD from the market although it was never found to be defective, after the IUD drew more than 2000 lawsuits.²⁶⁹ The cost of litigation, itself, could bankrupt a company, even if the company is blameless. Moreover, liability insurance is difficult to get

²⁶¹ See *id.* at 82.

²⁶² Rosenfeld, *supra* note 85.

²⁶³ See Muhl, *supra* note 87, at 340.

²⁶⁴ See Charo, *supra* note 88, at 81; *U.S. Pharmaceutical Research and Development, and Its Impact on Women's Health: the Technology Deficit in Contraception, Cancer, and Reproductive Disease and Conditions*, *supra* note 254, at 18-22 (1992) (testimony of Joseph J. Spiedel, M.D., associate professor of clinical medicine, and head, Division of Nephrology, Robert Wood Johnson Medical School at Camden).

²⁶⁵ See *U.S. Pharmaceutical Research and Development, and Its Impact on Women's Health: the Technology Deficit in Contraception, Cancer, and Reproductive Disease and Conditions*, *supra* note 254, at 20 (1992) (testimony of Joseph J. Spiedel, M.D., associate professor of clinical medicine, and head, Division of Nephrology, Robert Wood Johnson Medical School at Camden).

²⁶⁶ See Zitner, *supra* note 84.

²⁶⁷ See *id.*

²⁶⁸ See *id.*

²⁶⁹ See *id.*

and very expensive.²⁷⁰ Litigation also harms the company's reputation.²⁷¹

Roussel-Uclaf and Hoechst had specific reason to worry. In addition to threats of boycotts, Hoechst had been threatened with the fear of litigation. The RCR Alliance threatened to tie Hoechst up in litigation by finding plaintiffs in developing countries where the drug might be distributed.²⁷² Also, mifepristone, administered in combination with misoprostol, to terminate pregnancy has an almost 5% rate of failure.²⁷³ The company's biggest worry may have been the fact that mifepristone and misoprostol have been shown to have teratologic effects. If a woman is administered both mifepristone and misoprostol and carries her pregnancy to term, her fetus is at risk. A child with birth defects is one of the most sympathetic plaintiffs.

According to Dr. Baulieu, liability profoundly worried Hoechst.²⁷⁴ However, according to Eleanor Smeal, of the FMF, based on her interviews with scientists, manufacturers, and pharmaceutical leaders, the introduction of mifepristone is not a product liability issue.²⁷⁵ Ms. Mouttett, head of international marketing at Roussel-Uclaf, told the staff of the Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business that Roussel-

²⁷⁰ See *U.S. Pharmaceutical Research and Development, and Its Impact on Women's Health: the Technology Deficit in Contraception, Cancer, and Reproductive Disease and Conditions*, supra note 254, at 20 (1992) (testimony of Joseph J. Spiedel, M.D., associate professor of clinical medicine, and head, Division of Nephrology, Robert Wood Johnson Medical School at Camden).

²⁷¹ See BAULIEU, supra note 8, at 138-139.

²⁷² See Charo, supra note 88, at 70.

²⁷³ See Spitz, *Early Pregnancy Termination*, supra note 36, at 1241. See also Gary M. Samuelson, *DES, RU-486, and Deja Vu*, 2 J. PHARMACY & L. 56 (discussing possible exposure of companies that manufacture RU 486 and comparing such liability to that of DES liability).

²⁷⁴ See BAULIEU, supra note 8, at 138.

²⁷⁵ See *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, supra note 97, at 46 (testimony of Eleanor Smeal, president, the Feminist Majority Foundation).

Uclaf does not think a lot about United States' product liability laws that make new drugs risky ventures because of potential adverse effects. Even so, product liability must have been at least a factor in Roussel-Uclaf and Hoechst's decisions regarding the marketing and distribution of mifepristone. As Dr. John Spiedel, of the Population Crisis Committee, testified at a congressional hearing regarding development of reproductive products, If you knew that there was a community of lawyers out there just waiting for a problem so they could sue you, you might think twice before bringing a drug to the U.S.²⁷⁶

Finally, a company must factor in costs associated with loss of public good will.²⁷⁷ Such an assessment includes losses from a potential boycott. In addition to a boycott, Hoechst feared the risk of being accused of mass murder and drawing attention to its relation to the manufacturer of cyanide gas used at concentration camps during the holocaust.²⁷⁸ The RCR Alliance threatened to focus public attention on Hoechst's predecessor, I.G. Farben, as well as Hoechst's South African Assets.²⁷⁹ Hoechst, led by a Roman Catholic President, also feared offending the Roman Catholic community and the Vatican.²⁸⁰ In short, mifepristone meant trouble and disorder, and according to Dr. Baulieu,

²⁷⁶ *U.S. Pharmaceutical Research and Development, and Its Impact on Women's Health: the Technology Deficit in Contraception, Cancer, and Reproductive Disease and Conditions*, supra note 254, at 20 (1992) (testimony of Joseph J. Spiedel, M.D., associate professor of clinical medicine, and head, Division of Nephrology, Robert Wood Johnson Medical School at Camden).

²⁷⁷ See Charo, supra note 88, at 81; *U.S. Pharmaceutical Research and Development, and Its Impact on Women's Health: the Technology Deficit in Contraception, Cancer, and Reproductive Disease and Conditions*, supra note 254, at 18-22 (1992) (testimony of Joseph J. Spiedel, M.D., associate professor of clinical medicine, and head, Division of Nephrology, Robert Wood Johnson Medical School at Camden).

²⁷⁸ See BAULIEU, supra note 8, at 108.

²⁷⁹ See Charo, supra note 88, at 69.

²⁸⁰ See BAULIEU, supra note 8, at 43.

neither was welcome in Hoechst's boardroom.²⁸¹

This last factor appears to have been the most influential in Roussel-Uclaf's decisions. The staff of the Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business conducted interviews with United States manufacturers and concluded that the charged political environment, more than concerns about manufacturer liability or other problems, [was] the primary roadblock to domestic abortifacient and contraceptive research.²⁸² Ms. Mouttet, the company's marketing director, told the subcommittee staff that the company's marketing strategy is more affected by real or perceived political issues than questions of sales and profit margins.²⁸³ She said that anti-abortion politics and the threat of a United States' boycott are something we [Roussel-Uclaf] take very seriously.²⁸⁴

After an assessment of these four factors, it is likely that Roussel-Uclaf did not estimate the profitability of mifepristone in the United States to be high. The potential market, as compared to other drugs, was small, in the early nineties. Roussel-Uclaf would need to invest a substantial amount of time and money to obtain FDA approval. The chance of product liability litigation was high due to the rate of failure as well as the risk to the fetus. Lastly, the threat of boycotts, as well as other smear campaigns stimulated by the political controversy over abortion in the United States, frightened the companies. As Dr. Baulieu said,

²⁸¹ See *id.* at 109.

²⁸² *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 67 (staff memorandum).

²⁸³ See *id.* at 71.

²⁸⁴ *Id.*

With such a risk and no glory, what was the motivation?²⁸⁵

E. Pressuring Roussel-Uclaf

Advocates of the abortion pill decided they needed to provide the motivation. As discussed before, *infra* Part IV.A, the FDA will not approve a drug for marketing and distribution in the United States unless a sponsor applies for approval. Pro-choice advocates and medical researchers decided to create political pressure to balance the anti-abortionists' threats so that Roussel-Uclaf would take the necessary steps to bring mifepristone to the United States. Jennifer Jackman of the FMF said, Roussel-Uclaf is not convinced that there is public support for RU 486 in the United States. The sense we got from them is that the more public support we could demonstrate, the more willing Roussel-Uclaf would be to make it available in the United States.²⁸⁶ As was said at a 1991 Congressional hearing, some kind of activity must... come that would show this company that it is in their interests to act in what it seems the majority indicate are the interests of the... country.²⁸⁷

The FMF set out to garner support for mifepristone and make Roussel-Uclaf aware of such support. In June of 1989, after traveling to France to assess the potential of mifepristone, the FMF launched the nation's largest public education drive on mifepristone. Eleanor Smeal, president of the FMF, said We intend to visit the pharmaceutical leaders, the medical health leaders to urge

²⁸⁵BAULIEU, *supra* note 8, at 140.

²⁸⁶Finter, *supra* note 78.

²⁸⁷*The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 49 (testimony of R.L. MacKenzie, chairman and CEO, Gynopharma, Inc.).

them to rise up against this... know-nothing movement that is denying the best of medical research and the best that modern medicine can provide for the modern woman.²⁸⁸ After the July 1989 decision of the Supreme Court in *Webster v. Reproductive Services*, where the Court expanded state powers to restrict abortion services, even those privately funded, in state facilities, the FMF renewed its support for mifepristone, asserting the greater need for office-based abortion in the wake of *Webster* and its potential impact on abortion clinics.²⁸⁹

The FMF was able to garner support. In July of 1990, a ten member delegation, including Eleanor Smeal, other feminist leaders, and prominent scientists, flew to Paris to meet with Roussel-Uclaf and Hoechst officials to urge the introduction of mifepristone into the United States.²⁹⁰ During discussions with Dr. Sazik, president of Roussel-Uclaf, the delegation presented over 115,000 petitions from American citizens in support of RU-486.²⁹¹ According to Dr. Baulieu, Dr. Sazik told the delegation that he was already persuaded and that its target was Hoechst.²⁹² The delegation also met with Hoechst officials, but, according to Baulieu, it did not change anyone's mind there.²⁹³ In February of 1992, yet another FMF delegation met with officials from Hoechst, deliver-

²⁸⁸ See Charo, *supra* note 88, at 72 (quoting *Abortion Pill to Be Tested as Contraceptive*, CHICAGO TRIB., Oct. 3, 1989, News, at 5.

²⁸⁹ See Charo, *supra* note 88, at 72. See also *Webster v. Reprod. Health Serv.*, 492 U.S. 490 (1989).

²⁹⁰ See *FMF - The Fight to Make RU486 Legal* (visited Jan. 18, 1999) <<http://www.feminist.org/gateway/ru486two.html>>; Glazer, *supra* note 96. See also *RU 486; The Import Ban and Its Effect on Medical Research*, *supra* note 108, at 187-259 (Feminist Majority Foundation, Scientists, Health Care Professionals, and Academicians for RU 486, petition signatories).

²⁹¹ See *FMF - The Fight to Make RU486 Legal* (visited Jan. 18, 1999) <<http://www.feminist.org/gateway/ru486two.html>>.

²⁹² See BAULIEU, *supra* note 8, at 137.

²⁹³ *Id.*

ing an additional 110,000 petitions.²⁹⁴ In April of 1992, after receiving a \$10 million gift²⁹⁵, the FMF announced its Web of Influence Campaign; the goal of the Web of Influence Campaign was to educate the public on United States' companies that do business with Hoechst and Roussel-Uclaf and to encourage those companies to ask that mifepristone be distributed in the United States.²⁹⁶ Meanwhile, other feminist leaders were at work. Faye Wattleton, President of the Planned Parenthood Federation of America, made three trips to Paris to plead with Roussel-Uclaf.²⁹⁷ Molly Yard, the former President of the National Organization for Women and Dr. Allen Rosenfield, the former chairman of the Planned Parenthood Federation, lobbied Roussel-Uclaf on behalf of their delegations.²⁹⁸ At the National Women's marches in Washington D.C., leaders spoke about the importance of mifepristone.²⁹⁹ Feminists also picketed outside plants of a Hoechst subsidiary in New Jersey.³⁰⁰

Others attempted to use their political clout to influence Roussel-Uclaf. Representative Barbara Boxer (D-CA) stimulated seventy of her colleagues in Congress to request that Roussel-Uclaf make the drug available.³⁰¹ In a letter to Dr. Sazik, the congress men and women assured Roussel-Uclaf that they were willing to remove, through legislation, policy or regulatory obstacles to medical progress

²⁹⁴ See *FMF - The Fight to Make RU486 Legal* (visited Jan. 18, 1999) <<http://www.feminist.org/gateway/ru486two.html>>.

²⁹⁵ See Susan Jenks, *Feminist Group Plans Economic Pressure Campaign for Access to RU 486*, J. NAT'L CANCER INST., April 1992, at 562-563.

²⁹⁶ See *FMF - The Fight to Make RU486 Legal* (visited Jan. 18, 1999) <<http://www.feminist.org/gateway/ru486two.html>>.

²⁹⁷ See BAULIEU, *supra* note 8, at 144-145.

²⁹⁸ See LADER, *supra* note 248, at 126.

²⁹⁹ See *id.*

³⁰⁰ See *id.*

³⁰¹ See William Regelson, *RU 486: How Abortion Politics Have Impacted on a Potentially Useful Drug of Broad Medical Application*, PERSPECTIVES IN BIOLOGY AND MEDICINE, Spring 1992, at 330, 334.

that are motivated by political rather than scientific concerns.³⁰² Former New York City Mayor David Dinkins wrote to President Bush, Roussel-Uclaf officials, and the mayors of 33 major cities urging them to formally encourage Roussel-Uclaf to begin exporting mifepristone into the country.³⁰³ The citizens of New Hampshire passed a resolution encouraging the introduction of mifepristone into the United States for use as a method of early pregnancy termination as well as for research on breast and other cancers³⁰⁴; the state of California followed, passing a similar resolution.³⁰⁵

Congressman Ron Wyden chaired three congressional hearings discussing both the obstacles to commercialization of mifepristone in the United States and the effect of the import alert on medical research regarding mifepristone.³⁰⁶ Medical researchers participated in the hearings testifying about their medical research with mifepristone and their difficulties obtaining the drug from Roussel-Uclaf.³⁰⁷ During these hearings, Mr. Wyden and the medical researchers attempted to mobilize the medical community and assert pressure on Roussel-Uclaf. Clinicians in California formed a group, Physicians for RU 486 to protest continuing research restrictions.³⁰⁸ In addition, on February 6, 1991, Mr. Wyden introduced a bill to make Import Alert 66-47 ineffective and to prevent the issuance

³⁰²BAULIEU, *supra* note 8, at 152.

³⁰³See Finter, *supra* note 78.

³⁰⁴See *id.*

³⁰⁵See Jenks, *supra* note 295.

³⁰⁶See *RU 486: The Import Ban and Its Effect on Medical Research*, *supra* note 108; *The Safety and Effectiveness of the Abortifacient RU 486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97; *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156.

³⁰⁷See discussion *infra* Part IV.C.

³⁰⁸See Jenks, *supra* note 295.

of another import alert unless the FDA found that such drug was being imported for illegal use.³⁰⁹ 68 other congress men and women co-sponsored the bill, slightly more than half the names needed to force it out of committee or at least get another hearing on mifepristone.³¹⁰ The bill was never passed.

Despite all of these efforts, Roussel-Uclaf showed no signs that it planned to introduce the drug into the United States in the near future. In 1990, Ms. Mouttet, head of international marketing at Roussel-Uclaf, said that selling in the United States [was] out of the question at the moment.³¹¹ In December of 1991, Ms. Mouttet said that the company would not provide the drug for research on its abortion properties in the United States because it had no plans to market the drug here in the near future.³¹² She said, We consider abortion a very controversial issue in the United States. We don't want to be involved in this debate. So there is no reason to set up a trial for RU 486.³¹³

Hoechst-Roussel Pharmaceuticals Inc. of Somerville, New Jersey, owned by both Hoechst and Roussel-Uclaf³¹⁴, held the option rights to apply for government approval to market mifepristone in the United States.³¹⁵ In 1985,

Hoechst-Roussel Pharmaceuticals gave up its rights to test and market mifepri-

³⁰⁹See H.R. 875, 102d Cong. (1991). Senator Cranston introduced the same bill in 1992. See S. 2268, 102d Cong. (1992).

³¹⁰See H.R. 875; Jenks, *supra* note 295.

³¹¹Riding, *supra* note 131.

³¹²See Glazer, *supra* note 96.

³¹³*Id.*

³¹⁴In December of 1991, Hoechst AG, or Hoechst, was 100% owner of Hoechst corporation. Hoechst corporation was holding company and owner of 100% of Hoechst Celanese. Hoechst-Roussel Pharmaceuticals Inc. was owned 80% by Hoechst Celanese and 20% by Roussel-Uclaf. See *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 336-337 (letter to Congressman Wyden from Ernest H. Drew, President and CEO of Hoechst Celanese).

³¹⁵See *id.* at 336-338.

stone in the United States.³¹⁶ Hoechst-Roussel Pharmaceuticals said it was not interested in testing and marketing the drug because it did not fit in with the Hoechst-Roussel Pharmaceuticals product line and scientific and product expertise.³¹⁷ Like Roussel-Uclaf, Hoechst-Roussel Pharmaceuticals showed no signs of changing its mind. In March 1990, Edward Norton, a spokesman for Hoechst-Roussel Pharmaceuticals, defined the company's position. He said, We've been petitioned, we've been yelled at, and we've been telephoned by everybody. But our formal position hasn't changed in two years, and I don't expect it to change.³¹⁸

After Hoechst-Roussel Pharmaceutical refused to test and market mifepristone, Roussel-Uclaf was free to license the drug to other companies in the United States. However, in line with its policy of not involving itself within the American abortion debate, Roussel-Uclaf made no efforts to license the drug to another company.

Since the usual methods, such as lobbying and petitioning, did not seem to be having an effect on Roussel-Uclaf's stance, one man, Lawrence Lader, decided to try a more drastic approach. As discussed *infra* Part II.B, Lawrence Lader has fought for the women's right to choose since the early 1960's. Mr. Lader fought long and hard for the legalization of abortion. In 1966, he published a survey of abortion practices. His book is cited eight times in the Supreme

³¹⁶*See id.* at 336-338.

³¹⁷*See id.* Hoechst-Roussel Pharmaceuticals makes chemicals, fibers, plastics, and printing materials as well as a variety of drugs. According to a Standard & Poor's register of corporations in 1988, the company had annual sales of \$1.7 billion. Kolata, *Boycott Threat*, *supra* note 193.

³¹⁸LADER, *supra* note 248, at 126.

Court's *Roe v. Wade* decision.³¹⁹ He has made the introduction of mifepristone into the United States his next battle. He formed the Abortion Rights Mobilization, an organization committed to the introduction of mifepristone in the United States. In the early nineties, Mr. Lader was looking for a way to dramatize the absurdity of their [Roussel-Uclaf, Hoechst, and President Bush] positions and bring the importance of RU 486 to the country and the media in vivid and simple terms.³²⁰

Drawing on a tactic used by his mentor, Margaret Sanger, the birth control pioneer³²¹, Mr. Lader devised a perfect plan. He would have a pregnant American woman go to Britain and secure one dose of mifepristone, which she could carry to New York to be administered by one of ARM's doctors. Such action would directly challenge Import Alert 66-47 and be sure to draw media attention. Putting the plan into action was difficult. Mr. Lader had to find a doctor in Britain willing to supply the drug, an American doctor to administer the pills, and a woman suitable for the task and prepared to handle the consequences. That woman was Leona Benten. Ms. Benten traveled with Mr. Lader to Britain, where they received the supply of mifepristone, 600 milligrams (one dose). On July 1, 1992, Ms. Benten and Mr. Lader returned to the United States, she carrying the mifepristone, he the prostaglandin, and, as they had hoped, they were stopped at Customs.³²² ARM had sent notification of its chal-

³¹⁹ See Zitner, *supra* note 84.

³²⁰ LADER, *supra* note 248, at 129.

³²¹ Margaret Sanger had arranged for a Japanese doctor to mail contraceptives to her medical director in New York, making sure that the government knew of it and the package was seized. See *id.*

³²² See *id.* at 135-136.

lence of the law to both the FDA and U.S. Customs; ARM had also notified the media.³²³ Upon their return, Ms. Benten and Mr. Lader were greeted by a barrage of reporters at the airport. According to Mr. Lader, he, Ms. Benten, and ARM accomplished their mission of focusing national attention on RU 486 and at the same time putting pressure on the government and Hoechst-Roussel to start the long process of bringing the pill to American women.³²⁴

In accordance with Import Alert 66-47, Ms. Benten was not allowed to bring the mifepristone into the United States; Customs seized the pills. The plan was not over yet, however. Ms. Benten, with the help of ARM, challenged the import alert in court. At a hearing, before Federal District Judge Charles P. Sifton, on July 10, 1992, lawyers argued, on behalf of Ms. Benten, that the FDA regulations covered importation of an unapproved drug for personal use, that the ban terming mifepristone dangerous was backed by no scientific evidence, and that the FDA had not asked for public testimony, regarding the regulations, as was required by the administrative law.³²⁵ Mr. Lader felt that they would get a fair chance since Judge Sifton was appointed by President Carter, but he was surprised by the judge's strong support.³²⁶ On July 14, Judge Sifton ruled that the Government had acted illegally when agents of the United States Customs Office and the FDA confiscated the pills and ordered the government to return the pills to Ms. Benten immediately.³²⁷ Judge Sifton reasoned that the regulations which, combined with the import alert, instructed Customs to

³²³ *See id.* at 135.

³²⁴ *Id.* at 136.

³²⁵ *See id.* at 137.

³²⁶ *See id.*

³²⁷ *See* Benten v. Kessler, 799 F.Supp. 281 (E.D.N.Y. 1992).

seize the drug, were promulgated without notice-and comment-procedures, as required by Federal law and therefore, Ms. Benten was entitled to a return of the drugs.³²⁸

The victory for Ms. Benten was short. On the afternoon of July 14, the United States Court of Appeals for the Second Circuit stayed Judge Sifton's order.³²⁹ Her lawyers immediately filed an emergency request with the Supreme Court to uphold Judge Sifton's order and erase the appeals court's stay. The Supreme Court accepted the appeal. However, on July 18, the Supreme Court, by a seven to two vote, refused to order the government to return the pills to Ms. Benten.³³⁰ The Supreme Court held that Ms. Benten failed to demonstrate that there was a substantial likelihood of success on her claim that she was entitled to the return of the pills because the regulations, which Customs officials relied on to seize the pills, were promulgated without notice-and-comment procedures required by Federal law.³³¹ Justice Stevens argued, in dissent, that the Government's holding of the pills would constitute an undue burden upon Ms. Benten's constitutionally protected abortion rights.³³² The Court refused to express a view on the merits of this assertion, concluding that such a claim was not properly before the Court for it was not addressed by the District Court, the Court of Appeals, or Ms. Benten.³³³

The victory was a bit sweeter for Mr. Lader and ARM. Mr. Lader said, The

³²⁸ See *id.*

³²⁹ See Philip J. Hiltz, *Thomas Expedites Suit on Abortion Pill*, N.Y. TIMES, July 16, 1992, at A18.

³³⁰ See *Benten v. Kessler*, 505 U.S. 1084, 1085 (1992).

³³¹ See *id.*

³³² See *id.* at 1085-1086.

³³³ See *id.* at 1085.

case had been a legal gamble from the start, of course, but it had turned out far more successfully than anyone expected. Leona personally had lost, but the movement had made a striking advance in bringing the issue of RU 486 to national attention and shaking up the government's rigidity in the process.³³⁴ The tactic did not, however, encourage Roussel-Uclaf to change its stance regarding the introduction of mifepristone into the United States. Frustrated by Roussel-Uclaf, advocates of mifepristone began to brainstorm and explore other avenues through which introduction of mifepristone into the United States could be achieved. Some suggested approving the drug in the United States for a use, other than as an abortifacient, such as a post-coital contraceptive or a drug to widen the cervix.³³⁵ Once a drug is approved for marketing and distribution in the United States, it can be prescribed by physicians, at their discretion, for any condition.³³⁶ Therefore, once approved, physicians could use the drug to perform a medical abortion. Advocates of this strategy argued that it would accelerate the process because it would avoid the abortion controversy.³³⁷ This strategy was never fully developed or explored, except on a theoretical level. Another possible route toward introduction of mifepristone into the United States was through the individual states. For example, in California, under state law,

³³⁴LADER, *supra* note 248, at 139.

³³⁵*See, e.g.*, Karen F. Richards, *RU 486: A Promising Birth Control Device Entangled in the Abortion Debate*, 6 J. PHARMACY & L. 117 (1997) (suggesting marketing mifepristone as a birth control device to avoid political taint); Kari Hanson, *Approval of RU-486 as a Postcoital Contraceptive*, 17 U. PUGET SOUND L. REV. 163 (1993) (suggesting marketing mifepristone as a postcoital contraceptive rather than as an abortifacient). One problem with such theories is that, as discussed *infra* Part I.C, the safety and effectiveness of mifepristone as a form of contraception has yet to be proven.

³³⁶*See* 37 Fed. Reg. ¶ 16,503 (1972); 52 Fed. Reg. ¶ 8802-8803. *See also* 21 C.F.R. § 312.2(d) (1999).

³³⁷*See, e.g.*, Richards, *supra* note 335; Hanson, *supra* note 335.

the state bureau can approve the sale of drugs not approved by the FDA, provided that they have been tested and are manufactured and distributed solely within California.³³⁸ Lawrence Lader, ARM, and the FMF announced another strategy - the removal of Roussel-Uclaf's patent on mifepristone. ARM had conducted research regarding a little known law authorizing patent removal in certain circumstances.³³⁹ ARM lawyers found that patent removal was rare and most patent removals had occurred during emergency situations in both world wars.³⁴⁰ According to Mr. Lader, lawyers felt that this approach could be kept as a threat to Roussel-Uclaf, although its chances of success were skimpy.³⁴¹ Finally, some suggested starting a company to research, develop, and market the drug in the United States. Eleanor Smeal indicated that the FMF was interested in forming a consortium of small pharmaceutical companies.³⁴² Other family planning and feminist health groups, as well as groups of financiers, expressed an interest as well.³⁴³

Before any of these strategies came to fruition, Roussel-Uclaf showed signs that it may be willing to discuss possible methods of introduction into the United States. What changed Roussel-Uclaf's mind? It was the election of President Clinton.

F. The Role of the President

³³⁸ See Charo, *supra* note 88, at 79.

³³⁹ See LADER, *supra* note 248, at 147; 28 U.S.C.A. § 1498 (West Supp. 1999).

³⁴⁰ See LADER, *supra* note 248, at 147.

³⁴¹ See *id.* at 147. See also Lawrence Lader, *RU-486, Made in America*, N.Y. TIMES, Mar. 17, 1994, at A23 [hereinafter Lader, *RU-486, Made in America*].

³⁴² *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 59 (testimony of Eleanor Smeal, President of the Feminist Majority Foundation); Jenks, *supra* note 295.

³⁴³ See Charo, *supra* note 88, at 45-46.

From 1980 to 1992, the United States was run by Republican leaders, President Reagan and President Bush. Each of whom was a pro-life advocate. Reagan advocated that life begins at conception and asserted that the unborn should be protected by the constitutional guarantees of life, liberty, and the pursuit of happiness.³⁴⁴ Reagan declared January 17, 1988 the National Sanctity of Human Life Day, dedicated to protecting the unborn.³⁴⁵ In 1988, Bush carried the pro-life mantle for his party and throughout his term, sustained the pro-life policies of his predecessor.³⁴⁶ During the Reagan-Bush years, abortion has been said to have colored appointments and policies in ways that hurt women.³⁴⁷ The Reagan-Bush administration instituted and administered two policies, in particular, that were clearly anti-abortion.

At a United Nations population conference in Mexico City, James Buckley, the head of the United States delegation, outlined the Reagan administration's plan to tighten enforcement of a policy barring the use of United States foreign aid to pay for or promote abortions.³⁴⁸ The policy, coined the Mexico City Policy, directed the Agency for International Development, AID, to withhold AID funds from nongovernmental organizations, or NGOs, that engage in a wide range of activities, including providing advice, counseling, or information regarding abortion or lobbying a foreign government to legalize or make abortion available.³⁴⁹ AID suspended contributions to the International Planned Par-

³⁴⁴ See TATALOVICH, *supra* note 190, at 156.

³⁴⁵ See BAULIEU, *supra* note 8, at 134.

³⁴⁶ See TATALOVICH, *supra* note 190, at 157.

³⁴⁷ See Sara Engram, *Clinton Era Means Reproductive Freedom for Women*, TORONTO STAR, Nov. 9, 1992, at D1.

³⁴⁸ See Robert Blair Kaiser, *Population Conference Hears Abortion Warning*, SAN DIEGO UNION-TRIB., Aug. 9, 1984, at A3.

³⁴⁹ See Memorandum, Mexico City Policy, PUB. PAPERS 10 (Jan 22, 1993).

enthod Federation and the United Nations Fund for Population Activities on the grounds that in some cases they finance abortion clinics.³⁵⁰ It has been said that such a policy affected the World Health Organization's, WHO, advocacy of mifepristone out of fear that the United States would retaliate by cutting contributions to its budget.³⁵¹

In February of 1988, Reagan imposed what has come to be known as the gag rule. According to the gag rule, the counseling of women on the option of having an abortion was prohibited in 4,000 family planning clinics that receive Federal financing.³⁵² The Department of Health and Human Services, HHS, attempted to modify the gag rule, at what it argued was President Bush's direction, to allow doctor's to freely communicate and advise their Title X patients regarding abortion.³⁵³ However, in *National Family Planning and Reproductive Health Association, Inc. v. Sullivan*, a Federal Court of Appeals said that the HHS could not make such a modification without adhering to notice-and-comment rulemaking requirements.³⁵⁴

With the election of President Clinton, a pro-choice advocate, United States policy related to abortion began to change. During his 1992 campaign, Clinton promised to select only Supreme Court judges who supported abortion rights.³⁵⁵

³⁵⁰ See Riding, *supra* note 131.

³⁵¹ See *id.* In 1982, WHO signed an agreement with Roussel-Uclaf. Under the agreement, in the event that Roussel-Uclaf decided not develop mifepristone in a WHO member nation who wanted to use it, Roussel-Uclaf would provide the mifepristone directly to WHO or cede rights to another manufacturer. See BAULIEU, *supra* note 8, at 30.

³⁵² See 42 C.F.R. Part 59.8 (a)(1) (1992) (suspended in 1993); 53 Fed. Reg. ¶ 2922 (1988).

³⁵³ See Nat'l Family Planning and Reprod. Health Ass'n, Inc. v. Sullivan, 979 F.2d 227, 230 (D.C. Cir. 1992).

³⁵⁴ See *id.* at 241.

³⁵⁵ See Dan Balz and Edward Walsh, *Clinton 'Close to Decision' on Ticket; Gore Seen as Leading Contender; Kerrey Makes Trip to Arkansas*, WASH. POST, July 8, 1992, at A1.

He also expressed his view that mifepristone should be tested and examined in the United States.³⁵⁶ Soon after his election, Clinton took action supporting this statement. On the twentieth anniversary of *Roe v. Wade*, Clinton signed five abortion-related memorandums.³⁵⁷ Clinton denounced the Mexico City Policy, as not required by law and unwarranted.³⁵⁸ He directed AID to remove the restrictions of the policy on all current AID grants to NGOs and to exclude them from future grants.³⁵⁹ Clinton ordered the Secretary of Health and Human Services to suspend the gag rule pending the promulgation of new regulations in accordance with the notice-and-comment procedures of the Administrative Procedure Act.³⁶⁰ Clinton, also, ordered the Department of Health and Human Services to review the import alert of mifepristone and promptly assess initiatives by which the department could promote the testing, licensing, and manufacturing of mifepristone in the United States.³⁶¹ As Clinton signed the above memoranda, he called for an America where abortion is safe and legal but rare.³⁶²

Immediately after Clinton's memorandum to the Secretary of Health and Hu-

³⁵⁶ See *id.*

³⁵⁷ See 58 Fed. Reg. ¶ 6439 (1993) (directing Department of Defense to permit abortion in military hospitals overseas if women pay for the operation themselves); 58 Fed. Reg. ¶ 7455 (1993) (ordering Secretary of Health and Human Services to suspend the gag rule); 58 Fed. Reg. ¶ 7457 (1993) (directing Secretary of Health and Human Services to lift the moratorium on transplant research using organs from aborted fetuses), 58 Fed. Reg. ¶ 7459 (1993) (directing the Secretary of Health and Human Services to instruct the FDA to review import alert on RU-486), Memorandum, Mexico City Policy, PUB. PAPERS 10 (Jan 22, 1993) (ordering AID to suspend the Mexico City Policy).

³⁵⁸ See Memorandum, Mexico City Policy, PUB. PAPERS 10 (Jan 22, 1993).

³⁵⁹ See *id.*

³⁶⁰ See 58 Fed. Reg. ¶ 7455 (1993). On February 5, 1993, the Secretary of Health and Human Services suspended the gag rule. See 58 Fed. Reg. ¶ 7468 (1993).

³⁶¹ See 58 Fed. Reg. ¶ 7459. It was so ordered on February 5, 1993. See 58 Fed. Reg. ¶ 7468 (1993).

³⁶² Remarks by the President During Signing of Presidential Memoranda, PUB. PAPERS 7-8 (Jan. 22, 1993).

man Services regarding mifepristone, the FDA focused on encouraging and facilitating the submission of an NDA for mifepristone.³⁶³ The then Commissioner of the FDA, Dr. David Kessler, immediately wrote to Dr. Sazik, the President of Roussel-Uclaf, requesting a meeting to discuss the FDA's interest in receiving an NDA and met with Dr. Sazik on February 24, 1993.³⁶⁴ The two met on February 24, 1993 and discussed how the drug could be brought to market in the United States. Roussel-Uclaf emphasized the importance of finding a way to achieve this goal without the involvement of Roussel-Uclaf.³⁶⁵ They agreed on three other groups suitable to bring the drug to market in the United States: a United States pharmaceutical firm, a research center, or a university.³⁶⁶ Dr. Kessler received a strong commitment from Dr. Sazik that he would find a way to bring mifepristone to the United States market.³⁶⁷ On April 20, 1993, Dr. Kessler and Dr. Sazik held another meeting and the FDA announced that Roussel-Uclaf agreed to license the drug and technology to the Population Council.³⁶⁸ According to the FDA, Roussel-Uclaf agreed to provide the FDA with its toxicology and chemistry data on the drug within a few weeks.³⁶⁹

However, a year later, in April of 1994, Roussel-Uclaf and the Population Council had not reached an agreement. According to reports, negotiations were

³⁶³ See *RU-486, Status Report on the U.S. Commercialization Project, Transfer of Anti-Progestin Technology to the United States*, 103d Cong. 6 (1994) (testimony of Hon. David M. Kessler, M.D., Commissioner, FDA).

³⁶⁴ See *id.*; Hiltz, *Door May Be Open*, *supra* note 4.

³⁶⁵ See *Meeting with Roussel-Uclaf on RU-486* (visited Jan. 21, 1999) <<http://www.fda.gov/bbs/topics/Answers/Ans00472.html>>.

³⁶⁶ See *id.*

³⁶⁷ See *RU-486, Status Report on the U.S. Commercialization Project, Transfer of Anti-Progestin Technology to the United States*, *supra* note 363, at 6 (testimony of Hon. David M. Kessler, M.D., Commissioner, FDA).

³⁶⁸ See *id.* at 7; Warren E. Leary, *Maker of Abortion Pill Reaches Licensing Pact with U.S. Group*, N.Y. TIMES, Apr. 21, 1993, at A18.

³⁶⁹ See Leary, *supra* note 368.

on-going through out the year, but no agreement could be reached. Why were negotiations taking so long? Some rumored that Hoechst was trying to stall the negotiations in the hope that Clinton would not be re-elected in 1996 and in that event, that the United States would exert less pressure on the company to bring mifepristone to the United States.³⁷⁰ It was also rumored that Hoechst was under heavy pressure from Pope John Paul II to halt use of the drug. A government aide said that one meeting between Hoechst officials and Clinton administration officials was devoted almost entirely to discussions of the religious pressures being exerted on the company.³⁷¹ Others familiar with the negotiation believed Roussel-Uclaf to be concerned about potential product liability, as well as still concerned about the threat of boycott.³⁷² Sandra Waldman, director of public information at the Population Council, said that Roussel-Uclaf's primary concern was that the drug be controlled and regulated to ensure proper use.³⁷³ A representative of Roussel-Uclaf also indicated that extensive discussions were conducted regarding the prescription and distribution system of the drug in this country in order to protect the health and safety of American women.³⁷⁴

Whatever the reason, advocates of mifepristone became quickly frustrated once again and renewed pressuring Roussel-Uclaf with vigor. The FMF had never

³⁷⁰ See Seelye, *Accord Opens Way*, *supra* note 5.

³⁷¹ See *id.*

³⁷² See Tamar Lewin, *Plans for Abortion Pill Stalled in U.S.*, N.Y. TIMES, Oct. 13, 1993, at A17 [hereinafter Lewin, *Plans for Abortion Pill*]; LADER, *supra* note 248, at 153 (stating that Hoechst asked to be indemnified for any loss of business in the United States).

³⁷³ See Seelye, *Accord Opens Way*, *supra* note 5. See also Lewin, *Plans for Abortion Pill*, *supra* note 372.

³⁷⁴ See RU-486, *Status Report on the U.S. Commercialization Project, Transfer of Anti-Progestin Technology to the United States*, *supra* note 363, at 16 (testimony of Lester Hyman, Swidler & Berlin, representing Roussel Uclaf). In France, there is a large amount of government control of doctors and clinics, especially in this field. According to Roussel-Uclaf, it is easier to assure proper education, delivery, and supervision of the procedure in France than it will be in the United States. See *Id.*

stopped its campaign. In November of 1992, after Clinton's election, the FMF sent letters to Roussel-Uclaf and Hoechst informing them that Clinton's election and the election of more women and pro-choice members of Congress effectively removed the political obstacles to mifepristone in this country.³⁷⁵ Frustrated with negotiations, in January of 1994, the tenth month of such negotiations, the FMF shipped another 50,000 petitions to Hoechst on the 20th anniversary of *Roe v. Wade*.³⁷⁶ In February of 1994, it was announced that British clinics would begin making mifepristone available to American women³⁷⁷; advocates hoped that increased availability of mifepristone would help pressure Roussel-Uclaf to allow it to be sold in the United States.

Once again, Lawrence Lader found it necessary to take more drastic measures to make Roussel-Uclaf stand up and take notice. Mr. Lader, in conjunction with ARM, decided to make and test a version of the pill in the United States to prove to Roussel that we have competitive American scientists and that we refuse to be stalled any longer by Roussel's blockade of American interests.³⁷⁸ The Chinese government had already made a proven copy of the pill.³⁷⁹ ARM ran tests to compare Roussel-Uclaf's pill with the Chinese copy and determined that the active ingredients in both pills were indistinguishable.³⁸⁰ At a press

conference in New York on February 17, 1993, Mr. Lader announced the results

³⁷⁵ *FMF - The Fight to Make RU486 Legal* (visited Jan. 18, 1999) <<http://www.feminist.org/gateway/ru486two.html>>.

³⁷⁶ *See id.*

³⁷⁷ *See* Tamar Lewin, *British Clinic to Offer Abortion Pill to Americans*, L.A. Daily News, Feb. 18, 1994, at N13.

³⁷⁸ LADER, *supra* note 248, at 141-142.

³⁷⁹ *See id.* at 141.

³⁸⁰ *See id.* at 142.

of such testing.³⁸¹ ARM then set out to make its own copy of Roussel-Uclaf's pill. After raising money and finding skilled scientists, both difficult tasks, ARM built its own lab in Westchester, New York and began producing a copy of RU-486.³⁸² In late March of 1993, ARM had produced 50 grams of mifepristone, only enough to perform a medical abortion on about 100 women.³⁸³ ARM could test the pills, without a patent problem, as long as the pills were not sold to the women.³⁸⁴ Mr. Lader said testing of this small a number was simply symbolic, [to] prove to the country that RU 486 could be made here, and [that] a lot more of the drug would be available shortly thereafter.³⁸⁵ In a press conference, on April 1, 1993, Mr. Lader showed the pill to reporters, asserting that ARM's purpose was to pressure Roussel-Uclaf and instigate them into immediate and decisive action.³⁸⁶ ARM also sent a letter to the Population Council offering its full cooperation.³⁸⁷

Meanwhile, ARM had learned from its Washington contacts that the FDA might give serious consideration to approving testing of its mifepristone pill.³⁸⁸ In May of 1993, ARM met with a panel of FDA scientists, whom suggested that ARM cross-reference under the Population Council's existent IND.³⁸⁹ The Population

³⁸¹ See *id.* at 142-143.

³⁸² See *id.* at 143-145. ARM's efforts were further complicated by the fact that it originally planned to test the pill under New York's mini-FDA law, which allowed a new drug to be cleared by state authorities rather than Federal FDA. Under such a law, every ingredient in the pill had to be bought within the boundaries of New York. See *id.*

³⁸³ See *id.*

³⁸⁴ See 35 U.S.C.A. § 271(e)(1) (West Supp. 1999); Under 35 U.S.C. 271 (e)(1), ARM is free to copy the drug for research purposes as long as it does not sell it for profit; such provision also includes the distribution as part of a research trial. See *id.*

³⁸⁵ LADER, *supra* note 248, at 146-147.

³⁸⁶ *Id.* at 149.

³⁸⁷ See *id.*

³⁸⁸ See *id.* at 148.

³⁸⁹ See *id.* at 151; 21 C.F.R. § 312.23(b) (1999) (allowing reference to information submitted previously).

Council said that it had no objections to ARM cross-referencing to its IND, but that Roussel-Uclaf would also have to agree, since the research data for the Population Council's IND came from Roussel-Uclaf.³⁹⁰ ARM decided it would have to do its own testing to obtain an IND. ARM ran toxicology tests on rats and dogs to prove that no ingredient in its pill could be dangerous; it also ran bioequivalency studies on rats and rabbits to show that its pill's actions on reproduction and other functions were equivalent to that of RU-486.³⁹¹ ARM then submitted a protocol for testing to the FDA.³⁹² ARM also had to find a manufacturer to supply the drug for testing of two to three thousand women. The Westchester lab was not capable to supply the necessary quantities. Convinced that manufacturing must take place over seas due to the violence in the United States, ARM found a British plant to manufacture its drug.³⁹³ In March 1994, Mr. Lader announced, in *The New York Times*, ARM's testing plan and its hope that testing would begin at the end of the year.³⁹⁴

While Mr. Lader and ARM were hard at work manufacturing a copy of RU-486, Roussel-Uclaf and the Population Council continued negotiations. Only after then Secretary of Health and Human Services, Dr. Donna Shalala set a May 15 deadline for concluding the negotiations, did the two companies come to an agreement.³⁹⁵ On May 17, 1994, Roussel-Uclaf announced that an agreement

³⁹⁰ See LADER, *supra* note 248, at 152 ; 21 C.F.R. § 312.23(b) (requiring authorization of person who submitted the information previously).

³⁹¹ See Lader, *supra* note 248, at 156.

³⁹² See *id.* at 156.

³⁹³ See *id.* at 155-156.

³⁹⁴ See Lader, *RU-486, Made in America*, *supra* note 341, at A23.

³⁹⁵ See *RU-486, Status Report on the U.S. Commercialization Project, Transfer of Anti-Progestin Technology to the United States*, *supra* note 363, at 6 (testimony of Hon. David M. Kessler, M.D., Commissioner, FDA).

with the Population Council had been reached.³⁹⁶ According to the agreement, Roussel-Uclaf granted all of the pill's patent rights and technology, for use in the United States, to the Population Council without remuneration.³⁹⁷ In return, Roussel-Uclaf rid itself from any liability from product liability claims.³⁹⁸ Most likely, Roussel-Uclaf, also, hoped to distance itself from the controversy regarding the pill in the United States and any potential boycotts. However, it is unlikely that the agreement will serve that purpose. After Roussel-Uclaf's first meeting with the FDA, one anti-abortion group indicated its intention to boycott Roussel-Uclaf and Hoechst if a marketing application was filed in the United States.³⁹⁹

Although it took a long year of negotiations, President Clinton, the Department of Health and Human Services, and the FDA succeeded in their efforts to encourage Roussel-Uclaf to help make medical abortion with mifepristone a reality for American women. A year and a half is actually a relatively small amount of time when considered in light of Roussel-Uclaf's staunch position for the previous five years. Why did Roussel-Uclaf change its tune so quickly? As discussed in Part III *infra*, Roussel-Uclaf had developed a policy for exporting mifepristone; this policy was usually referred to as the five pre-requisites, although Dr. Baulieu indicated and Roussel-Uclaf confirmed in 1992 that there was a sixth pre-requisite. Since France began the use of misoprostol in 1991, the United States has met the five re-requisites. Abortion is legal in the United

³⁹⁶ See Seelye, *Accord Opens Way*, *supra* note 5.

³⁹⁷ See *id.*

³⁹⁸ See *id.*

³⁹⁹ See Hilts, *Door May Be Open*, *supra* note 4.

States and accepted by the majority of society.⁴⁰⁰ Misoprostol has been available in the United States since the beginning of 1989.⁴⁰¹ Tight official control of the drug is possible in the United States. Finally, women can be required to agree to have a surgical abortion if medical abortion fails.

The United States had not fulfilled the sixth pre-requisite, however. As discussed earlier in this section, the Reagan and Bush administration were pro-life and instituted anti-abortion policies. According to a 1993 *New York Times* report, Roussel-Uclaf refused to seek Federal approval for the drug during the Bush administration because of what the company said it felt was an atmosphere hostile to abortion.⁴⁰² At a May 16, 1994 congressional hearing regarding the transfer of mifepristone's patent rights to the Population Council, a representative of Roussel-Uclaf cited the Reagan-Bush administration's views as one of the reasons that mifepristone was not available in the United States as of that date. The representative noted that Bush spoke stridently against any procedure that would result in the early termination of pregnancy.⁴⁰³ Finally, the representative testified that, It was only when President Clinton changed the

⁴⁰⁰According to a 1998 survey by Hart/Teeter Research for NBC News/Wall Street Journal, 60% of Americans believe that the choice on abortion should be left up to the woman and her doctor. See LADD & BOWMAN, *supra* note 89, at 22. However, Roussel-Uclaf could argue that there is too much controversy over abortion, so that this pre-requisite is not actually met. See Riding, *supra* note 131 (quoting Ms. Mouttet of Roussel-Uclaf who said, in reference to the pre-requisites, abortion is not an unchallenged right).

⁴⁰¹The FDA announced approval of misoprostol to prevent stomach ulcers that plague millions of patients taking drugs prescribed for arthritis on December 27, 1988. Misoprostol is marketed by G.D. Searle as Cytotec. See Food and Drug Administration, *Misoprostol Approval* (visited Mar. 27, 1999) <<http://www.fda.gov/bbs/topics/NES/NEW00142.html>>. Before misoprostol was available, neither of the other prostaglandins, sulprostone or gemeprost, were available in the United States.

⁴⁰²See Lewin, *Plans for Abortion Pill*, *supra* note 372.

⁴⁰³See *RU-486, Status Report on the U.S. Commercialization Project, Transfer of Anti-Progestin Technology to the United States*, *supra* note 363, at 16 (testimony of Lester Hyman, Swidler & Berlin, representing Roussel Uclaf).

government policy and specifically asked Roussel to make the procedure available, here, that our client, out of respect for the President of the United States, agreed to make every effort to comply with his request.⁴⁰⁴ It appears the hidden sixth factor may have been the determinant one regarding mifepristone's future in the United States.

G. The Road to Approval

Once Roussel-Uclaf granted the Population Council all United States' patent rights to mifepristone, the Population Council was free to sponsor an NDA for the approval of mifepristone in the United States. The Population Council, immediately, indicated its intention to file an NDA, but said that the NDA would take between nine and sixteen months to prepare.⁴⁰⁵ In May of 1993, the Council had launched a massive effort to plan and prepare for clinical trials, the filing of an NDA for mifepristone, the identification of a manufacturer and distributor, and fund-raising to support the expense.⁴⁰⁶ However, since negotiations with Roussel-Uclaf took so long, the Population Council had to put these efforts on hold in the fall of 1993.⁴⁰⁷ Only as the two companies neared agreement did the Population Council recommence its planning phase.⁴⁰⁸ At the congressional hearing regarding the transfer of mifepristone's patent rights to the Population Council, a representative of the Population Council projected that mifepristone

⁴⁰⁴ *Id.*

⁴⁰⁵ *See id.* at 11 (testimony of Hon. David M. Kessler, M.D., Commissioner, FDA).

⁴⁰⁶ *See id.* at 18 (testimony of James S. Boynton, Christy & Viener, representing the Population Council).

⁴⁰⁷ *See id.*

⁴⁰⁸ *See id.*

would be on the market in the United States sometime in 1996.⁴⁰⁹

According to former FDA Commissioner, Dr. Kessler, before the FDA will approve an application for mifepristone, the Population Council has to perform clinical trials in the United States and have a running manufacturing operation.⁴¹⁰ As discussed infra Part I.B, the Population Council began conducting clinical trials in the fall of 1994 at seventeen sites through out the United States. Finding a manufacturer proved a more difficult task for the Population Council. In the early nineties, only one major American pharmaceutical firm was doing research in female reproduction.⁴¹¹ Controversy regarding female reproduction began with oral contraceptives, continued with IUDs, and is alive today.⁴¹² The manufacture of mifepristone is the epitome of such controversy. Since the introduction of mifepristone in France, anti-abortionists have done their best to stir up such controversy. As soon as the Population Council and Roussel-Uclaf announced their agreement, anti-abortion groups sent a clear message to American manufacturers repeating their threat that they would boycott whatever American company is chosen to make and market the pill.⁴¹³ Businesses avoid such controversy. In addition to loss of public good will, businesses fear internal controversy. Businesses are concerned that involving themselves in controversy will

⁴⁰⁹Mr. Boynton said it would be our hope that it would be possible for the drug to be on the market in the United States sometime in 1996. *Id.* at 18 (testimony of James S. Boynton, Christy & Viener, representing the Population Council).

⁴¹⁰*See id.* at 11 (testimony of Hon. David M. Kessler, M.D., Commissioner, FDA).

⁴¹¹*See The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 36 (testimony of R. L. MacKenzie, chairman and CEO, Gynopharma, Inc.); *The Effect of Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers*, *supra* note 156, at 11 (testimony of Hon. Patricia Schroeder (D-Colo.)).

⁴¹²*See The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 36 (testimony of R. L. MacKenzie, chairman and CEO, Gynopharma, Inc.).

⁴¹³*See Seelye, Accord Opens Way*, *supra* note 5.

divide their staff and make the firm less productive in the long run.⁴¹⁴ Before involving themselves in such controversy, a United States manufacturer would undergo the same profitability analysis, discussed regarding Roussel-Uclaf in Part IV.D. High research costs, relatively low potential profit, and the enormous risk of liability suits, hardly, made the project more attractive.⁴¹⁵ Experts suggested that the project was more suited for a small pharmaceutical company rather than a large one. A smaller company would have relatively smaller risks but greater potential reward than a large company.⁴¹⁶ Smaller companies have limited product lines. Therefore, in the event of a liability suit or a boycott, a small company is not putting a large amount of other product lines at risk.⁴¹⁷ One small manufacturer, even, suggested that a boycott can be helpful to a small company. Unlike a large company, the manufacturer suggested that a boycott will not damage a small company's reputation, but that a small company will thrive on the publicity.⁴¹⁸ Also, estimated profits might be trivial to a large company, compared with its other products, but such profits could be large for a smaller company.⁴¹⁹ Finally, a smaller company may be able to avoid internal controversy, due to the limited number of employees and

⁴¹⁴See Kathleen Day, *Protest Fears Spur Effort to Keep Name of Abortion Pill's Maker Secret*, WASH. POST, Sept. 21, 1996, at D1; See *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 36 (testimony of R. L. MacKenzie, chairman and CEO, Gynopharma, Inc.).

⁴¹⁵See Kolata, *Any Sale*, *supra* note 240. For example, Life Dynamics Inc., a group specializing in finding ways to sue abortion providers for malpractice, sent around a memo asking to be informed of physicians performing chemical abortions and for any information about women who deliver handicapped babies subsequent to a failed chemical abortion. See Kirschenbaum, *supra* note 99, at 124.

⁴¹⁶See Kolata, *Any Sale*, *supra* note 240.

⁴¹⁷See Kolata, *Any Sale*, *supra* note 240; Day, *supra* note 414.

⁴¹⁸See *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 36 (testimony of R. L. MacKenzie, chairman and CEO, Gynopharma, Inc.).

⁴¹⁹See Kolata, *Any Sale*, *supra* note 240.

the company's clear purpose.⁴²⁰

A growing concern for both large and small manufacturers, however, was the increasing violence surrounding abortion. In the early 1980s, Operation Rescue began picketing abortion clinics and providing sidewalk counseling to visitors of such clinics.⁴²¹ However, things quickly changed from peaceful to violent. In 1982, members of a group known as the Army of God kidnapped an Illinois abortion doctor and his wife.⁴²² In 1984, the Army of God sent a threatening letter to Supreme Court Justice Harry Blackmun, author of *Roe v. Wade*, and in 1985, a bullet shattered a window in his home.⁴²³ In 1993, the first abortion provider killing occurred.⁴²⁴ Dr. David Gunn was shot to death in front of the Pensacola, Florida clinic where he performed abortions.⁴²⁵ One anti-abortion leader responded to his death with the following statement: This shooting, while unfortunate, will result in babies['] lives being saved.⁴²⁶

In 1994, the Freedom of Access to Clinic Entrances Act, FACE, was passed. FACE, having outlawed peaceful strategies utilized by Operation Rescue⁴²⁷, grounded such operations to a halt and violence steadily increased. As of

⁴²⁰ See *The Safety and Effectiveness of the Abortifacient RU486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization*, *supra* note 97, at 36 (testimony of R. L. MacKenzie, chairman and CEO, Gynopharma, Inc.).

⁴²¹ See Schaff, *supra* note 101, at 314.

⁴²² See *id.* at 315.

⁴²³ See *id.*

⁴²⁴ See *id.* at 316.

⁴²⁵ See *id.*

⁴²⁶ Seth Faison, *Abortion Doctor Wounded Outside Kansas Clinic*, N.Y. TIMES, Aug. 20, 1993, at A12.

⁴²⁷ FACE prohibits the use of force, threat of force, or physical obstruction to intentionally injure, intimidate, or interfere with any person obtaining or providing reproductive Health Services. See Freedom of Access to Clinic Entrances Act, 18 U.S.C.A. § 248(a)(1) (West Supp. 1999). FACE defines physical obstruction to mean rendering impassable ingress or egress from a facility that provides reproductive health services. See 18 U.S.C.A. § 248(e)(4) (West Supp. 1999).

November 1998, 15 attempted murders had been recorded since 1991.⁴²⁸ A web site called the Nuremberg Files, listing doctors and clinic workers, was created to provide information for those wishing to organize in their community.⁴²⁹ Critics insist that the true intention of the web site is to create a hit list; one doctor's name was crossed off the web site after his murder.⁴³⁰ The pool of people endangered has quickly widened and their zone of safety has decreased.⁴³¹ In 1994, an abortion doctor and his escort were shot to death.⁴³² In December of 1994, John Salvi III went on a shooting spree in two Boston clinics; Salvi killed a receptionist and another clinic worker and injured five other people, including visitors.⁴³³ In 1998, an abortion doctor was killed by a sniper in his own home.⁴³⁴

Some of the violence has been shown to be directly related to the use of mifepristone. The December 1994 shooting by John Salvi occurred at a clinic participating in the Population Council's clinical trials and distributing mifepristone.⁴³⁵ In November of 1994, the clinic had made a public announcement that it would make the drug available.⁴³⁶ On November 12, protesters demonstrated outside the clinic.⁴³⁷ On that fateful day in December, the clinic's receptionist was killed and three others injured.⁴³⁸ In response, the clinic stopped making the

⁴²⁸ See Jennifer Gonnerman, *The Village Voice: The Terrorist Campaign Against Abortion* (visited Feb. 9, 2000) <<http://www.villagevoice.com/features/9845/gonnerman.shtml>>.

⁴²⁹ See Schaff, *supra* note 101, at 316.

⁴³⁰ See Gonnerman, *supra* note 427.

⁴³¹ See *id.*

⁴³² See LADER, *supra* note 248, at 187.

⁴³³ See Zitner, *supra* note 84; LADER, *supra* note 248, at 215.

⁴³⁴ See Gonnerman, *supra* note 428.

⁴³⁵ See Carolyn Ryan, *Clinic Stops Distributing Abortion Pill Brookline Killings Prompt Move*, PATRIOT LEDGER (Quincy, Mass.), Jan. 31, 1995, at 26.

⁴³⁶ See *id.*

⁴³⁷ See *id.*

⁴³⁸ See *id.*

drug available.⁴³⁹

In response to fear of violence, as well as boycott threats, the FDA and the Population Council have made an unprecedented agreement to bring the pill to market with the manufacturer's name remaining secret.⁴⁴⁰ Even with the promise of secrecy, major pharmaceutical firms were not rushing in to do this [manufacture mifepristone], according to Council president, Margaret Catley-Carlson.⁴⁴¹ Perhaps, manufacturers worried that it would be impossible to keep the manufacturer hidden. Anti-abortion groups believe that once mifepristone becomes a drug on the market that the information will reach their groups.⁴⁴² Paul Schenk, a minister who helped organize Operation Rescue, is confident that informants will come forward be it from production, marketing, or the delivery system.⁴⁴³

Since the pharmaceutical firms that the Council approached were not interested, Population Council officials requested proposals. According to President Catley-Carlson, the Council received five proposals.⁴⁴⁴ Amongst those willing to help the Council were Mr. Lader and ARM. Mr. Lader met with President Catley-Carlson on June 24, 1994 and offered the Council use of ARM's British plant.⁴⁴⁵ Mr. Lader assured Ms. Catley-Carlson that the British plant would minimize costs and that it could ensure security, due to the country's intolerance

⁴³⁹ See *id.*

⁴⁴⁰ See Day, *supra* note 414. See generally Schaff, *supra* note 101 (discussing how violence has frightened away potential manufacturers of mifepristone).

⁴⁴¹ Carlyle Murphy and Kathleen Day, *Abortion Pill's U.S. Debut Snagged by Business Dispute; Sponsor Seeks to Oust Associate for not Disclosing Disbarment*, WASH. POST, Jan. 12, 1997, at A1.

⁴⁴² See Kirschenbaum, *supra* note 99, at 124.

⁴⁴³ See *id.*

⁴⁴⁴ See Murphy and Day, *supra* note 441.

⁴⁴⁵ See LADER, *supra* note 248, at 158.

of anti-abortion furor.⁴⁴⁶ According to Mr. Lader, Ms. Catley-Carlson listened politely, but he received the distinct impression that the Council planned to spend a significant amount of time interviewing potential manufacturers and sources of funding.⁴⁴⁷ Mr. Lader did, however, convince the Council to consider ARM's British plant.⁴⁴⁸ In July, ARM and the Population Council signed a mutual secrecy agreement and ARM gave the Council all of its documents and contracts regarding the plant.⁴⁴⁹

Since the Population Council appeared to be moving slow and after the November 1994 election, the majority of congress was pro-life, ARM began to vigorously pursue its plan to test its copy of mifepristone on 2000 to 3000 women.⁴⁵⁰ On March 14, 1996, the *San Francisco Chronicle* announced that ARM had filed a request with the FDA to begin tests of its pill.⁴⁵¹ In addition, the chronicle announced the testing of methotrexate, a drug used to treat cancer patients, as an abortifacient.⁴⁵² Methotrexate has been available in the United States since 1954; therefore, doctors could administer it as an abortifacient at their discretion.⁴⁵³ The disclosure of these two studies was designed to put pressure on the Population Council.⁴⁵⁴

Four days later, on March 18, 1996, the FDA received an NDA from the Pop-

⁴⁴⁶ *See id.*

⁴⁴⁷ *See id.* at 159.

⁴⁴⁸ *See id.*

⁴⁴⁹ *See id.*

⁴⁵⁰ *See id.* at 160.

⁴⁵¹ *See* Sabin Russell, *Abortion-Rights Group Asks to Test RU-486 Copy/UCSF Scientists also Trying Another Version of Pill*, S.F. CHRON., Mar. 14, 1996, at A3.

⁴⁵² *See id.* Methotrexate blocks the use of folic acid, a vitamin needed by the rapidly growing fetal cells, and thus causes fetal death. *See* LADER, *supra* note 248, at 208.

⁴⁵³ *See* Lakomy, *supra* note 103, at 51; 37 Fed. Reg. ¶ 16,503; 52 Fed. Reg. ¶ 8802-8803.

⁴⁵⁴ *See* Russell, *supra* note 451.

ulation Council for the use of mifepristone in combination with misoprostol.⁴⁵⁵ The FDA accepted the application on the basis of foreign clinical data in the form of two large clinical trials conducted in France.⁴⁵⁶ The FDA accepted the application with the understanding that the Population Council would, during the course of the FDA's review of the application, submit data from its United States clinical trial.⁴⁵⁷

On July 19, 1996, the Reproductive Health Drug Advisory Committee of the Center for Drug Evaluation and Research convened to review the data from the clinical trials of mifepristone as an abortifacient and provide a recommendation to the FDA on the safety and effectiveness of the drug for its intended use. The Committee heard from representatives of the Population Council and the FDA regarding the safety and effectiveness of mifepristone and misoprostol for medical abortion and the acceptability of the regimen to women.⁴⁵⁸ After hearing such testimony, the Committee agreed, with a vote of 6 for and 2 abstentions, that taking into consideration the overall evidence for safety and effectiveness of the regimen, that the benefits outweigh the risks for the use of the regimen for medical abortion in the United States.⁴⁵⁹ The committee recommendation

⁴⁵⁵ See Advisory Committee, *supra* note 21, at 4 (testimony of David A. Kessler, M.D.); Food and Drug Administration, *FDA Issued Approvable Letter for Mifepristone*, Sept. 18, 1996 (visited Mar. 27, 2000) <<http://www.fda.gov/bbs/topics/answers/ans00758.html>>.

⁴⁵⁶ See Advisory Committee, *supra* note 21, at 5 (testimony of David A. Kessler, M.D.). The FDA accepts foreign clinical studies not conducted under an IND if the studies are well designed, well conducted, performed by qualified investigators, and conducted in accordance with ethical principles acceptable to the world community. 21 C.F.R. § 312.120(a) (1999). In certain circumstances, the FDA may approve an application based solely on foreign clinical data. See 21 C.F.R. § 314.106(b) (1999).

⁴⁵⁷ See Advisory Committee, *supra* note 21, at 5 (testimony of David A. Kessler, M.D.).

⁴⁵⁸ See *id.* at 21-94,121-44 (testimony of Irving M. Spitz, M.D., C. Wayne Bardin, M.D., Beverly Winikoff, M.D., Ridgley C. Bennett, M.D., and Lisa Rarick, M.D.). Also see discussion *infra* Part I.B and II.B regarding the safety and effectiveness of mifepristone and the acceptability of the regimen to women.

⁴⁵⁹ See Advisory Committee, *supra* note 21, at 298.

was not binding on the FDA, but the FDA is said to consider committee recommendations very carefully.⁴⁶⁰ The committee noted the lack of the final United States clinical data in their review and requested an opportunity to review such data, if it is significantly different than the French data.⁴⁶¹

The committee also commented on the proposed labeling and distribution of the drug. The committee had two concerns regarding the proposed labeling. First, the committee believed that the cautions, conditions, and exclusions, included in the trial protocol, should be included in the labeling and patient information leaflets with a warning that there is no data as to what the effects would be with these associated conditions.⁴⁶² For example, the French clinical trials excluded women who were over 35 and smokers.⁴⁶³ Second, the committee recommended that the information regarding surgical termination, in the event of failure of the medical abortion, should make it clear that, although the risk is unknown, there is a risk to the fetus.⁴⁶⁴ Regarding distribution of the drug, the committee exhibited considerable unease.⁴⁶⁵ According to the NDA, the drug will be provided directly to providers and will not be sold in pharmacies.⁴⁶⁶ It will be provided only to physicians who have training in the dating of pregnancy, the diagnosis of ectopic pregnancy, and how to do a surgical abortion and who have access to facilities for surgical abortion and for emergency treatment of any complications.⁴⁶⁷ Physicians will be required to supervise administration

⁴⁶⁰ See *CDER Handbook*, *supra* note 166.

⁴⁶¹ See Advisory Committee, *supra* note 21, at 282.

⁴⁶² See Advisory Committee, *supra* note 21, at 306.

⁴⁶³ See *id.* at 44 (testimony of Irving M. Spitz, M.D.).

⁴⁶⁴ See *id.* at 306.

⁴⁶⁵ *Id.* at 324.

⁴⁶⁶ See *id.* at 81 (testimony of Beverly Winikoff, M.D.).

⁴⁶⁷ See *id.* at 81, 317.

and records must be kept for each dose used.⁴⁶⁸ These precautions are to be taken in order to make sure that the drug is provided as safely as it has been in clinical trials and other countries, such as Britain and France. The committee agreed with the concept of the proposed distribution, but questioned its feasibility in practice and more specifically how the Population Council and the manufacturer were going to ensure adequate training of providers.⁴⁶⁹

After the advisory committee meeting, FDA Commissioner, Dr. Kessler, indicated that the FDA intended to act on the Population Council's NDA within the six month user fee deadline of September 18, 1996.⁴⁷⁰ Advocates of mifepristone hoped that the FDA would be true to its word due to the upcoming Presidential election; opponents felt that the FDA was rushing a decision in fear that Clinton may not be re-elected. True to its word, on September 18, 1996, the FDA issued an approvable letter for mifepristone in combination with misoprostol for early medical abortion.⁴⁷¹ According to the letter, the agency determined that substantial clinical data demonstrated the safety and efficacy of mifepristone, in combination with misoprostol, when used under medical supervision.⁴⁷² As discussed *infra* Part IV.A, an approvable letter is an action frequently used by

⁴⁶⁸ See *id.* at 81 (testimony of Beverly Winikoff, M.D.).

⁴⁶⁹ See *id.* at 325.

⁴⁷⁰ The Prescription Drug User Fee Act of 1992 says that the FDA should act on priority applications within six months. See *FDA Deadline for Mifepristone Decision is Sept. 18; Efficacy of Mifepristone for Pregnancy Termination Established by Two French Studies Cmte Says*, THE PINK SHEET, July 22, 1996, at 3. This deadline is also in accordance with 21 U.S.C. § 355(n) (1999), which requires the FDA to make a final decision within 90 days of a scientific advisory panel's recommendation.

⁴⁷¹ See Food and Drug Administration, *FDA Issued Approvable Letter for Mifepristone*, *supra* note 455; Population Council, *FDA Issues Approvable Letter for Mifepristone Medical Abortion*, Sept. 18, 1996 (visited Jan. 6, 2000) <<http://www.popcouncil.org/news%5Fviews/approvable.html>>.

⁴⁷² See Food and Drug Administration, *FDA Issued Approvable Letter for Mifepristone*, *supra* note 455; Population Council, *FDA Issues Approvable Letter for Mifepristone Medical Abortion*, *supra* note 471.

the FDA to indicate that safety and efficacy data have passed agency review, but that additional information must be submitted before the FDA can grant final approval for marketing. The FDA indicated that additional information on other issues, including the manufacturing process and labeling, must be submitted before the FDA can make a final decision.⁴⁷³ Most likely, the FDA has similar concerns to those of the advisory committee regarding labeling and distribution. Also, the FDA cannot approve a drug for marketing unless the sponsor has proven that the drug can be appropriately manufactured. As of September 1996, the Population Council said they had found a manufacturer,⁴⁷⁴ but it is likely the manufacturing process itself was not complete and operational. Normally, approvable letters are answered within ten days, and shortly thereafter, an approval letter is issued.⁴⁷⁵ Yet over three years later, an approval letter has still not been issued for mifepristone, in combination with misoprostol, for use as an abortifacient. What happened?

H. Legal Pitfalls

The first sign of trouble was in November of 1996. On November 4, 1996, the Population Council filed suit against Joseph D. Pike.⁴⁷⁶ Mr. Pike was one of the five, whom submitted a proposal to the Population Council for the dis-

⁴⁷³See Food and Drug Administration, *FDA Issued Approvable Letter for Mifepristone*, *supra* note 455; Population Council, *FDA Issues Approvable Letter for Mifepristone Medical Abortion*, *supra* note 471.

⁴⁷⁴See Day, *supra* note 414.

⁴⁷⁵See Tamar Lewin, *Lawsuits' Settlement Brings New Hope for Abortion Pill*, N.Y. TIMES, Nov. 13, 1997, at A14 [hereinafter Lewin, *Lawsuits' Settlement*]; 21 C.F.R. § 314.110 (1999) (requiring response, to approvable letter, by applicant within 10 days).

⁴⁷⁶See Tamar Lewin, *Dispute May Delay Abortion Drug in U.S.*, N.Y. TIMES, Nov. 6, 1996, at A16 [hereinafter Lewin, *Dispute May Delay*]. Advances in Health Technology, AHT, filed suit also. *See id.*

tribution and manufacture of mifepristone. Mr. Pike had a prior relationship with the Council, having worked with it in the effort to bring the copper-T intrauterine, another product shunned by large manufacturers, to the American market.⁴⁷⁷ President Catley-Carlson said that the prior business relationship was a deciding factor in choosing Mr. Pike for the mifepristone project.⁴⁷⁸ President Catley-Carlson also said that the Council was attracted to Mr. Pike's proposal because it suggested setting up a nonprofit group called Advances in Health Technology, AHT.⁴⁷⁹ Under the proposal, AHT would be separate from the Council and handle highly visible educational programs and deal with what President Catley-Carlson called the public defense of mifepristone.⁴⁸⁰

Having accepted Mr. Pike's proposal, the plan was set into action. AHT was created as a separate entity in July of 1995.⁴⁸¹ In December of 1995, AHT was licensed by the Council to market mifepristone.⁴⁸² AHT then immediately sub-licensed the marketing rights to Mr. Pike as previously agreed to by all three parties.⁴⁸³ AHT was publicly identified as the licensee, but Mr. Pike was not.⁴⁸⁴ Under the December 1995 contract, Mr. Pike was to set up a company to receive the raw mifepristone from the manufacturer, which was already chosen by the Council but not identified, and then package and distribute the

⁴⁷⁷ See Tamar Lewin, *Abortion Pill's Legal Woe May Be Nearing an End*, N.Y. TIMES, Jan. 25, 1997, §1, at 5 [hereinafter Lewin, *Abortion Pill's Legal Woe*].

⁴⁷⁸ Murphy and Day, *supra* note 441.

⁴⁷⁹ *See id.*

⁴⁸⁰ *Id.*

⁴⁸¹ See James A. Miller, *Revealing Lawsuits Delay RU-486 Deployment* (visited Jan. 6, 2000) <<http://www.hli.org/publications/hlir/1997/hr029701.html>>.

⁴⁸² See Murphy and Day, *supra* note 441.

⁴⁸³ *See id.*

⁴⁸⁴ *See id.* Mr. Pike was not publicly identified until the lawsuit was filed. *See id.*

pills.⁴⁸⁵ Another company was to test and market the mifepristone for potential uses other than early abortion.⁴⁸⁶ Both companies were to pay royalties and licensing fees to both the Council and AHT and keep the profits.⁴⁸⁷ Mr. Pike set up a network of interlocking companies in California. Danco Laboratories was created to handle the marketing and distribution of mifepristone as an abortifacient.⁴⁸⁸ NeoGen Pharmaceuticals was created to test and market mifepristone for other medical indications.⁴⁸⁹ NeoGen Holdings, another company created by Mr. Pike, ultimately controlled these two entities.⁴⁹⁰ It was Mr. Pike's job to raise money from investors to finance the mifepristone project. Mr. Pike created NeoGen Investors, a California limited partnership.⁴⁹¹ Mr. Pike then set out to raise money by the sale of private placement limited partnership units in NeoGen Investors.⁴⁹²

The Population Council's suit charges Mr. Pike with fraud and seeks to have his interest in the drug transferred to a receiver.⁴⁹³ In 1993, Mr. Pike pleaded guilty to a misdemeanor forgery charge in a 1985 North Carolina real estate deal, where he falsely inflated the cost of a piece of property to two investors.⁴⁹⁴ Mr. Pike was subsequently disbarred.⁴⁹⁵ Mr. Pike's legal problems were first brought to the attention of the Population Council by an investor in the project.⁴⁹⁶ When

⁴⁸⁵ See *id.*

⁴⁸⁶ See *id.*

⁴⁸⁷ See *id.*

⁴⁸⁸ See Miller, *supra* note 481; Lewin, *Dispute May Delay*, *supra* note 476.

⁴⁸⁹ See Miller, *supra* note 481.

⁴⁹⁰ See *id.*

⁴⁹¹ See *id.*

⁴⁹² See *id.*

⁴⁹³ See Lewin, *Dispute May Delay*, *supra* note 481.

⁴⁹⁴ See Murphy and Day, *supra* note 441; Lewin, *Dispute May Delay*, *supra* note 476.

⁴⁹⁵ See Murphy and Day, *supra* note 441; Lewin, *Dispute May Delay*, *supra* note 476.

⁴⁹⁶ See Murphy and Day, *supra* note 441.

questioned, Mr. Pike said it was a different Joseph D. Pike.⁴⁹⁷ Mr. Pike's spokesman said that he called the Council twenty-four hours later to say that he had been disbarred.⁴⁹⁸ President Catley-Carlson said that she did not learn the truth for a few weeks.⁴⁹⁹ Having become aware of Mr. Pike's legal problems, the Council began negotiations to have him withdraw from the venture.⁵⁰⁰ When he refused, the Council filed suit.

The complaint states that Mr. Pike's fraud imperils the mifepristone project.⁵⁰¹ It states that unless Mr. Pike is expeditiously removed, it will be much more difficult, if not impossible, to raise the additional funds that are still needed to fund the project.⁵⁰² The Council also feared that Mr. Pike's legal problems provided another weapon, to ideological opponents, with which to attack the project.⁵⁰³ The complaint also alleges that Mr. Pike has not accounted for all the money invested.⁵⁰⁴ In mid-1996, Mr. Pike represented to the Council that he had raised approximately \$14 million through the sale of limited partnership units.⁵⁰⁵ The Council asserted that as of the end of July 1996, \$1.6 million of the proceeds of such offering were being held by NeoGen Industries, an entity of which the Council had never before heard and whose name had been changed by Mr. Pike four times.⁵⁰⁶ At that time, the Council was unclear what happened

⁴⁹⁷ See *id.*

⁴⁹⁸ See *id.*

⁴⁹⁹ See *id.*

⁵⁰⁰ See David R. Olmos, *Abortion Pill Maker Denies Suit Charges; Litigation: NeoGen of San Diego Says It Didn't Try to Conceal the Criminal Records of Its Chief Partner*, L.A. TIMES, Nov. 6, 1996, at D2.

⁵⁰¹ See Lewin, *Dispute May Delay*, *supra* note 476.

⁵⁰² See *id.*

⁵⁰³ See *id.*

⁵⁰⁴ See *id.*

⁵⁰⁵ See Miller, *supra* note 481.

⁵⁰⁶ See *id.*

to the other \$12.4 million.⁵⁰⁷ The Council sought injunctive relief and did not sue on the contract, which implies that Mr. Pike did not breach the terms of the contract.⁵⁰⁸

Mr. Pike moved to dismiss the Council claims. However, U.S. District Judge Sonia Sotomayer rejected Mr. Pike's motion and set trial for March 31, 1997 on the issue of whether Mr. Pike defrauded the Council by not disclosing his disbarment.⁵⁰⁹ Meanwhile, the mifepristone project was at a standstill, the Population Council having refused to move forward with the project until Mr. Pike sold his holdings.⁵¹⁰ In February of 1997, the Population Council and Mr. Pike reached a settlement and avoided going to trial. Under the settlement, Mr. Pike agreed to sell a substantial portion of the equity in the marketing venture to existing investors. According to the Council, Mr. Pike retains a modest, although passive, equity interest in the project, but has signed documents agreeing not to reinsert himself into the project in any managerial capacity.⁵¹¹ According to a *New York Times* report, Mr. Pike retains a 25% interest.⁵¹²

Also, under the settlement, a new company, Advances for Choice, was created; AHT was folded into Advances for Choice.⁵¹³ The Population Council announced that Advances for Choice would be run by Jack Van Hulst, a phar-

⁵⁰⁷ See *id.*

⁵⁰⁸ See *id.*

⁵⁰⁹ See Murphy and Day, *supra* note 441.

⁵¹⁰ See Lewin, *Lawsuits' Settlement*, *supra* note 475.

⁵¹¹ Population Council, *Mifepristone: Litigation Settled: A New Company Is Formed to Take Control of Project in the U.S.*, Feb. 12, 1997 (visited Jan. 6, 2000) <<http://www.popcouncil.org/news%5Fviews/newcompany.html>>; Caryle Murphy, *Abortion Pill Accord Clears Way for Sales*, WASH. POST, Feb. 13, 1997, at A1.

⁵¹² See Lewin, *Lawsuits' Settlement*, *supra* note 475.

⁵¹³ See Population Council, *Mifepristone: Litigation Settled: A New Company Is Formed to Take Control of Project in the U.S.*, *supra* note 511.

maceutical executive who has experience in turning around manufacturing facilities.⁵¹⁴ Shortly thereafter, Advances for Choice underwent a name change to Advances/Neogen.⁵¹⁵ In June of 1997, Mr. Van Hulst's relationship with Advances/Neogen was unclear; Advances/Neogen said that Mr. Van Hulst's relationship with the company may be changing; the Population Council said that Mr. Van Hulst was now serving as a consultant.⁵¹⁶ In July of 1997, *The New York Times* reported that Mr. Van Hulst was no longer the chief executive and a new leader would be named.⁵¹⁷ Mr. Van Hulst's removal was yet another sign of potential problems.

The Population Council faced other legal trouble in November of 1996. Giant Group, a Los Angeles investment group, signed an agreement with Mr. Pike on July 24, 1996, where Mr. Pike agreed to negotiate exclusively with the Giant Group until September 30, 1996.⁵¹⁸ Giant Group wished to invest \$6 million in return for a 26% share of the mifepristone project.⁵¹⁹ The Giant Group and Mr. Pike never reached an agreement. According to Mr. Pike, Giant never submitted a presentable offer.⁵²⁰ Also, Mr. Pike discovered that Mr. Sugarman, the head of Giant Group, agreed to pay \$619,000 to settle securities charges arising from his takeover of a fast food chain.⁵²¹ In October of 1996, Giant filed

⁵¹⁴ See *Mifepristone (RU-486) Distribution to Be Headed by Former Generic Exec Van Hulst*, THE PINK SHEET, Feb. 17, 1997 at T&G-7.

⁵¹⁵ See James A. Miller, *RU-486 Lawsuits: Chapter Two* (visited Jan. 6, 2000) <<http://www.hli.org/publications/hlir/1997/hr089709.html>>.

⁵¹⁶ See *Richter Exit From RU-486 Bulk Supply Agreement Could Jeopardize Danco Patent Rights*, THE PINK SHEET, June 16, 1997 [hereinafter *Richter Exit*].

⁵¹⁷ See Tamar Lewin, *Group Is Intensifying Its Campaign to Distribute Abortion Pill*, N.Y. TIMES, July 2, 1997, at A21 [hereinafter Lewin, *Group Is Intensifying*].

⁵¹⁸ See Lewin, *Dispute May Delay*, *supra* note 476.

⁵¹⁹ See Lewin, *Lawsuits' Settlement*, *supra* note 475.

⁵²⁰ See Olmos, *supra* note 500.

⁵²¹ See Lewin, *Dispute May Delay*, *supra* note 476.

fraud charges against Mr. Pike and the Population Council, accusing Mr. Pike of concealing his past legal and professional problems.⁵²² In November of 1997, Giant Group settled the suit with the Population Council.⁵²³

Another business dispute plagued the mifepristone project in early 1997. In February, Gedeon Richter, a Hungarian manufacturer, informed the Population Council that it was terminating the manufacturing agreement entered into by the companies in 1995.⁵²⁴ Under the agreement, Gedeon Richter agreed to manufacture all of Danco Laboratories requirements for bulk mifepristone in the United States, for at least five years.⁵²⁵ A separate manufacturer, yet to be named, would put mifepristone into tablet form.⁵²⁶ In addition, Gedeon Richter agreed to create pilot scale batches and to file a drug master file with the FDA.⁵²⁷ Gedeon Richter would replace Roussel-Uclaf as the manufacturer on the Population Council's NDA submission.⁵²⁸ According to the approvable letter, issued on September 18, 1996, the FDA would merely require Gedeon Richter to demonstrate, through submission of its own drug master file, the comparability of its manufacturing processes and the bulk drug substances it produces to those of Roussel-Uclaf.⁵²⁹ On January 18, Gedeon Richter told the Council that its drug master file was ready for submission.⁵³⁰ In mid-February, two days after the Population Council told Gedeon Richter that it would need to

⁵²² See Lewin, *Lawsuits' Settlement*, supra note 475.

⁵²³ See *id.*

⁵²⁴ See *Richter Exit*, supra note 516.

⁵²⁵ See *id.*

⁵²⁶ See *id.*

⁵²⁷ See *id.*

⁵²⁸ See *id.*

⁵²⁹ See *id.*

⁵³⁰ See *id.*

ship material for the trial batch to the FDA within the next few weeks, Gedeon Richter informed the Population Council of its intention to terminate the contract.⁵³¹

After months of negotiating, Danco Laboratories filed suit on May 9 in New York Supreme Court alleging breach of contract by Gedeon Richter.⁵³² The lawsuit states that Danco and the Council are having great difficulty finding another manufacturer and even if they did, that the project is likely to be delayed 3 to 5 years.⁵³³ The suit also states that Gedeon Richter's breach of contract could cause financial losses in excess of \$200 million.⁵³⁴ Sandra Waldman, director of public information at the Population Council, said, what's laid out in the court papers is the worst-case scenario.⁵³⁵ She emphasized that Gedeon Richter, Danco, and the Population Council were continuing to negotiate as of June 1997 and that meanwhile, Danco was actively looking for new manufacturers.⁵³⁶ As of March 2000, Ms. Waldman was unwilling to comment on the status of this litigation.⁵³⁷

The Population Council's legal and business disputes prompted questions regarding its business judgment. There is no question that the Population Council should be criticized for failing to review Mr. Pike's background before licensing him the market rights to mifepristone. Due diligence is a routine step performed

⁵³¹ *See id.*

⁵³² *See* Caryle Murphy, *Abortion Pill's U.S. Sponsor Suing Hungarian Drug Firm*, WASH. POST, June 12, 1997, at A3 [hereinafter Murphy, *Abortion Pill's U.S. Sponsor*]

⁵³³ *See id.*

⁵³⁴ *See id.*

⁵³⁵ *Id.*

⁵³⁶ *See* Caryle Murphy, *Abortion Pill Dispute May Delay Debut; U.S. Sponsor Losing European Supplier*, WASH. POST, June 11, 1997, at A1.

⁵³⁷ Electronic Mail, dated Feb. 24, 2000, from Sandra Waldman, Director, Public Information, Population Council to author, responding to author's questions regarding mifepristone.

before entering business transactions. Their, Mr. Pike's and the Population Council's, business relationship, is no defense for the failure to perform due diligence. Moreover, some also question the choice of Mr. Pike's proposal, arguing that the proposal was too complex and that he is not a professional. As to the former, the Population Council may not have had much choice. According to reports, no major pharmaceutical company was willing to touch the project. Johnson & Johnson, Schering-Plough, Pharmacia & Upjohn, and Pfizer have all indicated that they will not get involved with the project.⁵³⁸ As for the latter, a Council staffer at the time reported that the mifepristone project did attract a fair number of venture capitalists, but that they all seemed sleazy to the Council.⁵³⁹ The staffer said that Mr. Pike, whom the Council had worked with before and was recommended by Forrest Greenslade, a former consultant to the Council, looked pretty good in comparison.⁵⁴⁰

Gloria Feldt, president of the Planned Parenthood Federation of America, believes that the major pharmaceutical companies' unwillingness to be involved with the project, as a result of anti-abortion politics, caused the unusual business arrangement.⁵⁴¹ The Council, agreeing that the arrangement was unusually complex and secretive, also cites abortion politics as the cause.⁵⁴² The Council insists that secrecy was necessary due to the violent nature of politics.⁵⁴³ Nevertheless, the Council should not have allowed the confidentiality surrounding the

⁵³⁸ See, e.g., Laura Fraser, *The Abortion Pill's Grim Progress*, MOTHER JONES, Jan. 1, 1999, at A1.

⁵³⁹ See Kirschenbaum, *supra* note 99, at 115.

⁵⁴⁰ See *id.*

⁵⁴¹ See Lewin, *Abortion Pill's Legal Woe*, *supra* note 477.

⁵⁴² See Murphy and Day, *supra* note 441.

⁵⁴³ See *id.*

project to prevent it from being aware and advised of Mr. Pike's arrangement. The Population Council's failure to continually supervise the project again indicates a lack of business judgment.

As well as affecting business relations, the secrecy surrounding the project and the Population Council's refusal to provide key details regarding the project have also fueled the anti-abortion groups' campaign. Gracie Hsu, a policy analyst with the Family Research Council, argues, Women ought to be aware of who will manufacture the drug, who is behind it, and what the track records of those people are.⁵⁴⁴ The Family Research Council also insists that it is imperative that women be able to hold the company accountable; the Family Research Council fears that such secrecy jeopardizes the safety of women's health.⁵⁴⁵

As of November 1997, a little over a year after the introduction of mifepristone had appeared so imminent, mifepristone was no closer to being introduced in the United States. If anything, the prospects for mifepristone's future in the United States were more dismal. The mifepristone project had spawned at least seven lawsuits.⁵⁴⁶ Danco Laboratories and the Population Council had failed to find a new manufacturer.⁵⁴⁷ The project was often strapped for cash. In addition to the added expenses, investor relations had deteriorated.⁵⁴⁸ Far after

⁵⁴⁴*Id.* See Kirschenbaum, *supra* note 99, at 125.

⁵⁴⁵See Zitner, *supra* note 84; Kirschenbaum, *supra* note 99, at 125. The FDA will require information about the drug be included on the label and women will have standard recourse for liability claims. See Kirschenbaum, at 125.

⁵⁴⁶See Zitner, *supra* note 84. Other lawsuits include the filing of lawsuits by investors and potential investors against Mr. Pike and by an employee for nonpayment of wages. See *id.*

⁵⁴⁷See Lewin, *Lawsuits' Settlement*, *supra* note 475.

⁵⁴⁸When control passed from Mr. Pike to three general partners, others who invested in the deal were promised an option to get their money back, but no rescission offer was made; investors said when they wrote or called the general partners their letters and calls were not returned. See *id.*

the usual response time of ten days, the Council had still failed to submit all the information requested by the FDA in its approvable letter.⁵⁴⁹

I. Recent Developments

After Gedeon Richter's termination of its contract with Danco Laboratories, Danco had to begin the unenviable task of finding a manufacturer once again. The anti-abortionists had not stopped their efforts. Anti-abortionists continued to threaten manufacturers with the fear of a boycott. In April of 1997, the NRLC announced a boycott of Allegra, a Hoechst antihistamine, in response to Roussel-Uclaf and Hoechst's agreement to grant the rights to mifepristone to Dr. Sazik, president of Roussel-Uclaf.⁵⁵⁰ The boycott, announced in full-page advertisements in USA Today and other publications⁵⁵¹, sent a clear message to manufacturers that the 'NRLC means business'. Anti-abortion violence continued. In February of 1998, the Army of God planted a bomb at a women's clinic in Birmingham, Alabama.⁵⁵² The group then sent a letter to Reuters claiming responsibility for the bomb and threatening additional bombings directed at manufacturers and distributors of mifepristone.⁵⁵³ Finally, several mutual funds with anti-abortion agenda have said that they will exclude manufacturers of mifepristone from their portfolios.⁵⁵⁴ Aquinas President, Frank Rauscher, wrote to drug companies whose stock he owned, pointing out the litigation risk

⁵⁴⁹ See Murphy, *Abortion Pill's U.S. Sponsor*, *supra* note 532.

⁵⁵⁰ See Julie Rovner, *US Antiabortionists Boycott Allergy Drug*, THE LANCET, April 12, 1997 at 1079; Joseph Schuman, *Fearing U.S. Boycotts, Hoechst Gives Away World Rights to Abortion Pill*, Associated Press, Apr. 8, 1997.

⁵⁵¹ See Rovner, *supra* note 550.

⁵⁵² See 'Army of God' Claims It Bombed Alabama Clinic, WASH. POST, Feb. 3, 1998, at A5.

⁵⁵³ See *id.*

⁵⁵⁴ See Fraser, *supra* note 538.

to any firm that manufactured or distributed mifepristone and indicated he would drop a company that got involved.⁵⁵⁵ Mr. Rauscher claims that Merck, Johnson & Johnson, Schering-Plough, Pharmacia & Upjohn, and Pfizer have indicated to him that they will not get involved.⁵⁵⁶ Although hiding under the guise of product liability concerns, Mr. Rauscher was primarily motivated by ethical concerns.

Within Congress there has also been efforts to block the introduction of mifepristone into the United States. In both 1998 and 1999, Congressman Tom Coburn (R-Okla.) introduced an amendment to the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act to block approval of the drug by the FDA. The amendment stated that none of the funds appropriated or otherwise made available by this Act may be used by the Food and Drug Administration for the testing, development, or approval (Including approval of production, manufacturing, or distribution) of any drug for the chemical inducement of abortion.⁵⁵⁷ There was much discussion, on the House floor, regarding the consequences of such an amendment. Mr. Coburn argued that the purpose of the amendment is to limit the FDA's ability to approve any drug that has its sole purpose, its listed intended use, to eliminate and terminate an unborn child.⁵⁵⁸ Other congress members asserted that FDA lawyers indicate that the amendment will prevent the FDA from dealing with

⁵⁵⁵See Associated Press, *House Votes to Halt FDA Approval of RU-486 Abortion Opponents Claim Victory Over Pill*, CHICAGO TRIB., June 18, 1998, at 12.

⁵⁵⁶See Fraser, *supra* note 538.

⁵⁵⁷H.R. 1906, 106 Cong. (1999); 145 Cong. Rec. H. 3780 (1999). See also H.R. 4101, 105 Cong. (1998); 144 Cong. Rec. H. 5075. The 1998 amendment is identical to the 1999 amendment quoted above except that the phrase appropriate or otherwise is excluded.

⁵⁵⁸See 145 Cong. Rec. H 3780; 144 Cong. Rec. H. 5075.

any drug that is brought to them for approval that may have the consequence of terminating a pregnancy.⁵⁵⁹ For example, according to the FDA lawyers, the amendment would have prevented the approval of methotrexate, which is used to treat cancer patients but also can be used to terminate pregnancy. After much discussion, the House voted to adopt the amendment in 1998, with a vote of 223-202, and in 1999, with a vote of 217-214.⁵⁶⁰ The Senate never voted on the issue; in both years, the amendment died during conference.⁵⁶¹

As those opposed to abortion fought to keep mifepristone from American women, Mr. Lader and ARM continued in their quest to make medical abortion with mifepristone a reality for American women as soon as possible. In July of 1996, ARM received permission from the FDA to conduct a study of its pill.⁵⁶² The study consisted of testing on 2,000 women in Rochester, New York and clinics in the midwest and the west coast, including Oakland and San Francisco, California.⁵⁶³ In July of 1997, ARM announced that its study would be expanded, due to funding from John Merck, to at least 10,000 women.⁵⁶⁴ In March of 1999, ARM reported that more than 3,000 women had taken mifepristone under the program in the prior 18 months.⁵⁶⁵ ARM has been testing several variations on

⁵⁵⁹ See 145 Cong. Rec. H. 3780.

⁵⁶⁰ See *House Votes to Halt FDA Approval of RU-486, Abortion Opponents Claim Victory Over Pill*, CHICAGO TRIB., June 25, 1998, at 12; 145 Cong. Rec. H. 3780.

⁵⁶¹ See J.M. Lawrence, *RU-486 Delays Enraging Feminists; 'Abortion Pill' Debate Reaching Fever Pitch*, Boston Herald, Apr. 3, 2000, at 23; Annette Fuentes, *A Hard Pill to Swallow: The 10-Year Fight for Mifepristone*, IN THESE TIMES, Mar. 21, 1999, Reproductive Rights and Wrongs, at 10; *FDA Appropriations*, THE PINK SHEET, Oct. 18, 1999.

⁵⁶² See *New Round of Test for Abortion Pill*, CHICAGO TRIB., July 31, 1996, at 6.

⁵⁶³ See Russell, *supra* note 451; Larry D. Hatfield, *Abortion Pill Clone to Make Bay Area Debut French RU-486 Copy Out in S.F., Oakland Next Month*, S.F. EXAMINER, Aug. 20, 1996, at A7.

⁵⁶⁴ See Lewin, *Group is Intensifying*, *supra* note 517.

⁵⁶⁵ See Marc Kaufman, *Abortion Pill Inches Closer to Production; American Marketer Hopeful that Drug Will Be Available by the End of the Year*, WASH. POST, Mar. 23, 1999, at Z7.

the Population Council's regimen. ARM's trials are studying a lower dose, 200 milligrams, of mifepristone.⁵⁶⁶ ARM believes that a lower dose may be equally effective in terminating pregnancy, but have a lower incidence of side effects.⁵⁶⁷ The ARM protocol also calls for only two doctor's visits rather than three; women are allowed to take misoprostol vaginally at home.⁵⁶⁸ Today, ARM testing continues under an IND. ARM has not announced any plans to submit an NDA, but is primarily concerned with providing mifepristone to women, while the Population Council fights for approval.⁵⁶⁹ The FMF web-site lists the 15 clinical sites where ARM's drug is available to women today.⁵⁷⁰

While ARM made medical abortion a real possibility for American women, Danco Laboratories continued to look for a manufacturer. Finally, in June of 1998, Danco announced that it had found a manufacturer willing to make the drug.⁵⁷¹ In March of 1999, a spokeswoman for Danco, indicated that all of FDA's outstanding issues were regarding the manufacturing of mifepristone and that the FDA still had to inspect the new manufacturing plant.⁵⁷² She also expressed Danco's belief that mifepristone would be available by the end

⁵⁶⁶ See *Mifepristone Ancillary Trial Costs Are Being Covered by Seattle Area Insurers*, THE PINK SHEET, Oct. 11, 1999; Kaufman, *supra* note 565.

⁵⁶⁷ See Sara Silver, *Activist Offers Abortion Pill In Clinical Trials*, July 2, 1997, The Record Online <<http://www.bergen.com/abortion/pill.htm>>.

⁵⁶⁸ See *Mifepristone Ancillary Trial Costs Are Being Covered by Seattle Area Insurers*, THE PINK SHEET, Oct. 11, 1999; Kaufman, *supra* note 565; *Mifepristone Research at the University of Rochester* (visited Apr. 10, 2000) <<http://www.urmc.rochester.edu/hh/choices/ourres.html>>.

⁵⁶⁹ ARM also states that the study is being done to help obtain approval and to optimize the labeling of mifepristone. See *Mifepristone Research at the University of Rochester* (visited Apr. 10, 2000) <<http://www.urmc.rochester.edu/hh/choices/ourres.html>>.

⁵⁷⁰ See *Reproductive Rights - Mifepristone Trials* (visited Apr. 10, 2000) <<http://www.feminist.org/rrights/mifetrials.html>>.

⁵⁷¹ See Katherine Q. Seelye, *House Votes to Block F.D.A. on Approval of Abortion Pill*, N.Y. TIMES, June 25, 1998, at A20.

⁵⁷² See Fuentes, *supra* note 561.

of 1999.⁵⁷³ In January of 2000, the drug had still not been approved. However, a Danco spokesman indicated that all required data was submitted to the FDA.⁵⁷⁴ A spokeswoman for the Population Council expressed its hope that the FDA would approve the drug by the end of the first quarter of 2000.⁵⁷⁵ Such hopes were dashed on February 18, 2000, when the FDA issued another approvable letter to the Population Council indicating that remaining questions still need to be resolved before final marketing approval for mifepristone, administered in combination with misoprostol, can be granted.⁵⁷⁶ Immediately after, Danco Laboratories said it was preparing information to satisfy the FDA's request⁵⁷⁷ and that it is confident it can answer the FDA's questions.⁵⁷⁸ Sandra Waldman, a spokeswoman for the Population Council, indicated that all outstanding issues involve the manufacturing and labeling of the drug.⁵⁷⁹ The FDA declined comment, but did indicate that a final decision could come in six months.⁵⁸⁰ Advocates of the pill are outraged at the continued delay and are concerned about the upcoming presidential election.⁵⁸¹ George W. Bush

⁵⁷³ See *id.*

⁵⁷⁴ See Laurel Campbell, *Sides Ready as Abortion Pill Nears Approval by FDA*, Scripps Howard News Service, Jan. 7, 2000.

⁵⁷⁵ See Campbell, *supra* note 574.

⁵⁷⁶ See Food and Drug Administration, *FDA Issues Approvable Letter for Mifepristone*, Feb. 18, 2000 (visited Mar. 27, 2000) <<http://www.fda.gov/bbs/topics/Answers/Ans1005.html>>. This action was in response to the information recently submitted by the Population Council regarding the outstanding issues from the approvable letter issued in September of 1996. See *id.*

⁵⁷⁷ *Mifepristone*, THE PINK SHEET, Feb. 21, 2000.

⁵⁷⁸ Edward R. Silverman and Robert Schwaneberg, *Abortion Pill Gets Conditional Approval from FDA*, KNIGHT-RIDDER TRIB. BUS. NEWS, Feb. 19, 2000.

⁵⁷⁹ See Marc Kaufman, *FDA Again Delays Abortion Pill Approval; Questions on the Manufacturing and Labeling of RU-486 Remain Unresolved*, WASH. POST, Feb. 19, 2000, at A2.

⁵⁸⁰ See Silverman and Schwaneberg, *supra* note 578; Food and Drug Administration, *FDA Issues Approvable Letter for Mifepristone*, *supra* note 576 (indicating that agency has six month goal for acting on information submitted in response to an original action under the Prescription Drug User Fee Act).

⁵⁸¹ See Lawrence, *supra* note 561; Tamar Lewin, *Pending F.D.A. Approval, French Abortion*

has said that if he is elected, he will try to keep mifepristone off the market.⁵⁸² Sandra Waldman says, there's still reason to be optimistic.⁵⁸³ Yet optimism is difficult to muster, after years of hearing hopeful predictions, which have never come to fruition.

As of March 2000, the FDA has still not granted final marketing approval for the use of mifepristone, in combination with misoprostol, for medical abortion.

Part V

For over a decade, anti-abortion groups have worked to keep mifepristone out of the United States while pro-choice groups, as well as medical researchers, have strategized to counteract such pressure. Anti-abortionists have threatened to boycott the product lines of any company involved with the distribution or manufacture of mifepristone, as well as boycott investments in any such company. Less explicitly, anti-abortion groups have instilled a fear of violence in potential manufacturers, since anti-abortion groups have shown time after time that they are not above using violence. On the other side, pro-choice groups have attempted meeting with the patent owner and potential manufacturers to rationally discuss the issues; such groups have also attempted to persuade such companies with petitions by showing them the majority is behind mifepristone.

Pill Is Getting Limited Use Here, N.Y. TIMES, §1, at 22 [hereinafter Lewin, *Pending F.D.A. Approval*].

⁵⁸²See Lewin, *Pending F.D.A. Approval*, *supra* note 581.

⁵⁸³Silverman and Schwaneberg, *supra* note 578.

Medical researchers have participated in congressional hearings to discuss the issues and urge governmental action. Only those who have circumvented traditional FDA approval to provide the drug to women, such as Lawrence Lader, have had any real success. Not surprisingly, so far the anti-abortionists are winning the battle; they have successfully delayed the introduction of mifepristone for over a decade and although its approval now appears imminent, it's still a guess... on when the drug will be available.⁵⁸⁴

From the start, the abortion controversy has tainted the life of the abortion pill in the United States. Anti-abortion members of Congress prompted the FDA to issue an import alert for mifepristone. In turn, Roussel-Uclaf, which was already shown to be sensitive to public opinion, perceived the FDA's singling out of mifepristone as a reflection of the government's disapproval of the drug. The perceived disapproval by the government, coupled with anti-abortion threats, caused Roussel-Uclaf to stop supplying the drug for medical research, let alone consider applying for approval in the United States. Pro-choice groups and medical researchers were unable to persuade Roussel-Uclaf to change its staunch position. Only when President Clinton, responding to his pro-choice electorate, requested that the Department of Health and Human Services review the import alert of mifepristone and promptly assess initiatives by which the department could promote the testing, licensing, and manufacturing of mifepristone in the United States, was Roussel-Uclaf willing to talk. Even with the Chief Officer of the United States behind it, Roussel-Uclaf hesitated. The company still felt the

⁵⁸⁴Campbell, *supra* note 574.

pressure of anti-abortion groups, more specifically the Vatican had begun heavily pressuring Roussel-Uclaf and Hoechst to stop the distribution of mifepristone. Not until a year after negotiations began was an agreement reached between Roussel-Uclaf and the Population Council.

Although it was said that there would be no barriers once Roussel-Uclaf decided to bring mifepristone to the United States, the problems did not stop there. After a successful United States' clinical trial, the FDA issued an approvable letter. Proponents of mifepristone believed approval was imminent. However, the project hit a snag. American manufacturers were not immune to the controversy surrounding the drug. They too feared boycotts and violence. In return for working with the drug, companies wanted confidentiality. The FDA and the Population Council, in an unusual move, agreed to provide the desired secrecy. After major pharmaceutical firms refused to touch the project, the Population Council agreed to an unusual business proposal. The proposal was unique and quite complex, and the need for confidentiality prevented the Population Council from scrutinizing the project and the leader's actions. Moreover, the Council's decisions evidenced a lack of good business judgment. As a consequence, the Council became entrenched in legal and business disputes. The project lost valuable time and money. Having also lost a manufacturer, the Council and its distributor, Danco, had to begin looking anew; anti-abortion threats were still in the air and the recent legal disputes further tainted the project.

After a difficult search, Danco found a new manufacturer, and the Population

Council was finally able to submit a response to the September 1996 approvable letter. However, not all outstanding issues have been adequately addressed, according to the FDA. The FDA issued another approvable letter, on February 18, 2000, indicating there are remaining questions to be resolved. Assuming Danco and the Population Council can file a timely response to such issues, a final decision regarding the drug should be made by the end of 2000. However, a glance at history suggests that this may not be a valid assumption. If history is any indication, there is no telling what could go wrong. But still there is a real possibility that American women will have access to mifepristone in the year 2000.

After a ten year long delay, it is hard to say that pro-choice groups have won the battle. The battle may not even be over. Anti-abortionists will continue to make themselves heard. For example, in response to the FDA's issuance of the second approvable letter, anti-abortion groups repeated their threat to boycott any manufacturer.⁵⁸⁵ Abortion opponents have also indicated that they will picket places where the drug is available.⁵⁸⁶ And the victory may not have the impact many hoped. Mifepristone has been hailed as a drug that will change the abortion landscape, providing greater, as well as safe, access to abortion for women. Such success remains to be seen; FDA approval alone will do little to help women, if the drug is not adequately supplied by manufacturers and provided by doctors. In any event, American women will wait a while longer

⁵⁸⁵ See Silverman and Schwaneberg, *supra* note 578.

⁵⁸⁶ See Stacey Schultz, *Long-awaited Abortion Pill Will Offer More Privacy - but No Less Controversy*, U.S. NEWS & WORLD REP., Feb. 28, 2000, at 79.

for the abortion pill.⁵⁸⁷

⁵⁸⁷*FDA Approval of Sale of Abortion Pill in U.S. to Be Delayed Longer*, WALL STREET J., Feb. 22, 2000, at B39.