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Politicized Science: The Manipulated Approval of RU-486 and Its Dangers to Women's Health



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POLITICIZED SCIENCE: THE MANIPULATED APPROVAL OF RU-486 AND ITS
DANGERS TO WOMEN’S HEALTH

BY CHRISTOPHER M. GACEK

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Politicized Science: The Manipulated Approval of RU-486 and Its Dangers to Women’s Health

BY CHRISTOPHER M. GACEK

I. Introduction

Since the Food and Drug Administration (“FDA”) approved the abortion pill RU-486 on September 28, 2000, an estimated 600,000 American RU-486 abortions have been performed. RU-486’s ability to bring an end to a human life developing in the womb is known to all, but the drug’s considerable harmful effects on women’s health have been minimized or ignored completely. Instead, the major media have been fully engaged in defending RU-486 despite an American track record that includes deaths and over a thousand reports of complications – many of them serious or life-threatening.

Since 2000, several organizations, including the Family Research Council, have unearthed a vast amount of information regarding safety concerns about the drug, as well as evidence documenting the Clinton Administration’s manipulation of the FDA approval process.[†] This pamphlet provides an overview of what we now know about the drug’s approval and the dangers posed by RU-486 to women’s health.

[†] Much of the information used for this report was obtained through Freedom of Information Act requests filed by Concerned Women for America (“CWA”) and Judicial Watch. The author would like to thank the American Association of Pro Life Obstetricians and Gynecologists (“AAPLOG”), CWA, and the Christian Medical and Dental Association for permission to extensively reference their “Citizen Petition” filed with FDA (Aug. 20, 2002) (located at: <http://www.aaplog.org/ru486index.htm>); and the “Response” (Oct. 10, 2003) to the Population Council found on the same webpage.

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II. What is RU-486?

Since ancient times there have been many failed attempts to produce chemicals capable of aborting pregnancies.² Two millennia would pass before modern science could design such a drug.³ That drug was RU-486 or mifepristone (also, Mifeprex[®]). In 1988 France became the first the nation to license RU-486, and efforts were soon under way to bring mifepristone to market in the United States.⁴



RU-486 developer Dr. Etienne-Emile Baulieu holds RU-486 pills on October 31, 1988 in Paris. The FDA announced on September 28, 2000 that the controversial abortion pill had been approved for sale in the U.S.

Progesterone is the most important chemical in human pregnancy.⁵ It prepares the uterus for the implantation of the embryo and plays an essential role in maintaining a pregnancy thereafter. RU-486 acts as a progesterone “antagonist” because it prevents progesterone from binding to its receptors, which are located in critical cells of the uterine lining (*i.e.*, endometrium). Metaphorically, RU-486 is like a “blank” key that fits into a key hole but cannot turn the lock; this useless key (RU-486) prevents a working key (progesterone) from entering the key hole and turning the lock’s mechanism. RU-486’s blockade of progesterone receptors leads to the deterioration of the uterine lining in which the embryo is implanted. As this deterioration worsens, the uterus is no longer able to sustain the pregnancy and the embryo is destroyed.

The FDA-approved regimen calls for 600 mg of RU-486 to be taken within 49 days of the onset of the woman’s last menstrual period (referred to as “days LMP” below). However, RU-486 cannot reliably kill the embryo and cause uterine evacuation of the dead tissue.⁶ Accordingly, misoprostol must be taken one to two days after RU-486 to trigger the uterine contractions needed to expel the remaining “products of conception.” Misoprostol (Cytotec[®]) is a prostaglandin approved by the FDA to prevent ulcers in patients who take non-steroidal anti-inflammatory drugs, but powerful uterine contractions commence after a pregnant woman ingests misoprostol.⁷

Even when taken together, the RU-486/misoprostol regimen frequently fails. The American clinical trials demonstrated that this regimen, which the FDA would later approve, was only “successful” in 92% of pregnancies within 49 days LMP, 83% at 56 days LMP, and 77% at 63 days LMP.⁸ Because of this high failure rate and concomitant need for surgical follow-up, the FDA only approved the mifepristone-misoprostol regimen for use out to

49 days LMP, but this restriction was essentially meaningless given the liberal “off-label” prescribing characteristics of U.S. food and drug law.⁹

III. The Clinton Administration Finds a Worthy Partner

In the late 1980s and 1990s the abortion movement pushed to bring RU-486 to the United States for several reasons. First, it was believed that RU-486 would bring abortion into mainstream medical practice where it could be prescribed widely.¹⁰ Second, the abortion movement faced a steep decline in the number of doctors willing to perform surgical abortions, and RU-486 was intended to be a means whereby general practitioners could perform abortions.¹¹ Third, making it possible for non-surgeons to chemically abort pregnancies would expand the geographical area in which abortions could be performed. Fourth, if abortions were performed in settings other than abortion clinics (*i.e.*, doctor’s offices), groups like Operation Rescue could not interfere with the procedure.¹²

President and Mrs. Clinton needed no encouragement to do the bidding of the abortion movement. Both were, and are, deeply committed proponents of abortion on demand, and the proof of this came quickly. *In his second full day in office*, January 22, 1993, President Clinton directed Department of Health and Human Services (“HHS”) Secretary Donna Shalala to assess initiatives to “promote the testing, licensing, and manufacturing of RU-486 or other antiprogestins in the United States.”¹³ Donna Shalala and the administration’s FDA Commissioner, David Kessler, immediately launched a major effort to find an American RU-486 marketer. The administration was assisted by a major well-funded effort to place external pressure on the drug’s manufacturers, Roussel-Uclaf (“Roussel”) and its parent, Hoechst. Three



Former HHS Secretary Donna Shalala and former U.S. President Bill Clinton

organizations – Feminist Majority Foundation, Reproductive Health Technologies Project, and Abortion Rights Mobilization – focused on this task and other efforts to marshal public support.¹⁴

Kessler and others in the administration pressured Roussel to assign its American RU-486 rights to the Population Council, a New York-based population control group. On May 16, 1994, the Population Council was given the U.S. commercial rights to RU-486.¹⁵ This step would not have been taken without receipt of President Clinton’s letter to Dr. Eduard Sarkiz, Chairman of Roussel’s Supervisory Board, on May 16, 1994, stating that it was “important for the health of women in the United States that they have access to the widest possible range of safe and effective medical treatments.”¹⁶

Clinton administration memos discovered and published by Judicial Watch in 2006 are revealing. For example, on May 11, 1994, HHS Chief of Staff Kevin Thurm wrote a lengthy memo to Carol Rasco, Assistant to the President for Domestic Policy, discussing the steps needed to bring mifepristone to market. Thurm stipulated that if Roussel were to provide “information and transfer its technology to the Population Council,”

an application could be filed at the FDA in six to twelve months.¹⁷ He then added: “Many of the scientific decisions on the proper use and distribution of the drug have already been considered by the FDA, based on information already provided to FDA by Roussel and the Population Council. Roussel would not need to finish its United States clinical trials before filing a marketing application with FDA; such trials could be used to refine the use of the drug at a later time.”

Thurm’s comments are disturbing because they indicate that important decisions about RU-486 had been made long before a company existed that could have submitted the requisite filings on the drug. Additionally, the U.S. data was not available for review, and these determinations were being made in a haphazard fashion far outside the normal channels developed by the FDA for the consideration of drug applications.

Six years were needed to obtain FDA approval, but space does not permit a detailed description of all the missteps that caused the delay.¹⁸ Eventually, Danco Laboratories (“Danco”), a company chartered in the Grand Cayman Islands, was created to market and distribute RU-486 in the United States. Interestingly, the Population Council did not transfer its RU-486 patent rights to Danco. Furthermore, Danco is a “one trick pony.” It makes no other drugs, nor will it develop any. Danco exists only to make and sell RU-486, and its lack of a drug “pipeline” decreases the regulatory leverage the FDA can exert over it.

Finally, nothing says more about Danco’s supposed concern for women’s health than the character of its medical director, Dr. Richard Hausknecht. In 1994, Hausknecht was using methotrexate and misoprostol “off label” in freelance abortion clinical trials. Dr. Mitchell Creinin, a top RU-486 abortion advocate, characterized Hausknecht’s behav-

ior as “downright unethical.”¹⁹ The experiments ended in September 1994 when the FDA ordered Hausknecht to “stop performing the abortions unless he gets the backing of a medical institution and submits his data and procedures to the FDA for review.”²⁰

IV. The FDA Considers and Approves the RU-486 Application (1996-2000)

The Population Council filed its New Drug Application (“NDA”) on March 18, 1996. The FDA’s Reproductive Health Drugs Advisory Committee (“Advisory Committee”) met on July 19, 1996, to consider aspects of the application.²¹ The meeting was noteworthy for several reasons.

First, the Advisory Committee approved of RU-486’s safety and effectiveness based on French data supplied to the applicant by Roussel. Preliminary results of the American trials were available, but the American data was not sufficient for approval. The FDA does not typically approve a drug based primarily on foreign data. Dr. Mary Jo O’Sullivan, a member of the Advisory Committee, asked why the meeting was being held “at this time when the [U.S.] data is not finalized.”²² Not only was the data not finalized, but the Advisory Committee was never reconvened to consider the completed American trial data. The American data presented a lower completed abortion rate than did the French data, and that data should have been presented to the Committee.

Second, in June 1996 the FDA inspected the reports from Roussel underlying the French data and found them to be marked by “carelessness, fraud, evidence tampering, and the systematic under-reporting of serious adverse events.”²³ The under-reporting consisted of accounts of “a patient

bleeding with two subsequent aspirations; convulsions reported as fainting; and expulsion which was actually a surgical evacuation; bleeding, nausea and contractions, or bleeding and pelvic pain.”²⁴ The FDA admonished the French investigator but still accepted the data. Worse yet, the FDA did not tell the members of the Advisory Committee that the quality of the data was suspect and rule violations had been found.



Former FDA Commissioner Dr. David Kessler

Third, FDA Commissioner David Kessler, M.D., chaired the Advisory Committee meeting. Given his aggressive actions to obtain rights to the drug for the Population Council, this should not surprise us. However, later events revealed the extent of Kessler’s pro-abortion partisanship. On January 18, 2005, David Kessler was given a lifetime achievement award by NARAL Pro-Choice America.²⁵ At the award dinner Kessler said, “The threat to a woman’s right to choose concerns me gravely as a citizen and as a physician.”²⁶ Later, as Dean of the School of Medicine of a California university, Kes-

sler addressed NARAL’s Sixth Annual Peninsula Power of Choice Luncheon, a fundraiser held in Palo Alto, California, on October 4, 2006.

Fourth, the Advisory Committee members were marked by conflicts of interest and bias. Eight of the 11 members “were either affiliated with an abortion organization or ha[d] made pro-choice statements in the past.”²⁷ The committee chairman, Ezra Davidson, served on Planned Parenthood’s advisory board in 2002.²⁸ Jane Zones and Deborah Narrigan were members of the Advisory Committee, and both had been board members of the pro-abortion lobbying group, the National Women’s Health Network.²⁹ Finally, the Advisory Committee’s executive secretary was Philip Corfman, M.D., who served as an advisory committee member for the pro-abortion Center for Reproductive Health Research and Policy, and currently sits on the board of directors for the pro-abortion Reproductive Health Technologies, discussed above, where his web bio boasts of his role in the RU-486 approval.³⁰

Fifth, the Population Council established a non-profit organization, American Health Technologies (“AHT”), to market RU-486; Danco was created later. AHT’s president and CEO was Dr. Susan Allen, M.D. Allen was not an obstetrician-gynecologist.³¹ Her testimony before the Advisory Committee alarmed the doctors when she suggested that non-surgeons could be instructed in a couple of days at training seminars to safely perform D&Cs, the surgical procedure that cleans the uterus of its contents.

The Advisory Committee’s Decision

At the public hearing, the Advisory Committee voted 6-2 that efficacy had been established. Two members (Henderson and O’Sullivan) voiced concerns about the data presented. O’Sullivan wanted

to see the American data. An unnamed member thought that worse U.S. data should prompt another meeting to be held. The Committee voted 7-0-1 (1 abstention) in favor of safety and 6-2 that the benefits of the drug exceeded its risks.

The Home Stretch for RU-486 (1999-2000)

By the late 1990s it was clear to the FDA that RU-486/misoprostol abortions would not kill the embryo and evacuate the uterus in a significant percentage of cases.³² Such uterine contents would have to be removed surgically.



There were other serious side effects that had to be monitored as well (*e.g.*, severe hemorrhage and the masking of ectopic pregnancies by the symptoms accompanying a medical abortion). The FDA appears to have concluded in 1999 that additional safety requirements were needed for the drug to be marketed safely. Nevertheless, the Population Council was largely uncooperative.³³ In order to gain greater regulatory leverage over the drug, the FDA appears to have decided to consider RU-486 under the restricted distribution provisions of

its “accelerated approval” regulations—known as “Subpart H.”³⁴

The FDA’s “Accelerated Approval” or Subpart H Regulations

HIV/AIDS prompted the FDA to reconsider its drug approval process in the 1980s-1990s. Critics argued that new drugs could be approved more quickly if they were tested *not* for their effect on hard “endpoints” like morbidity and mortality but on endpoints that could act as their “surrogates.”³⁵ In December 1992 the FDA approved its “Subpart H” regulations to address this problem for “certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses . . .”³⁶ In addition to the “surrogate endpoint” feature just described,³⁷ Subpart H also contained a rule section dealing with the approval of drugs whose distribution was restricted due to hazards presented by the drug. Indeed, RU-486 was approved using this provision.³⁸

Political Pressure Overturns FDA Safety Precautions Proposed in June 2000

Around June 1, 2000, the FDA privately proposed a list of “Qualifications for Physician Recipients.” They were: (1) physicians prescribing RU-486 would have to be licensed to practice medicine; (2) physicians would have to be trained to perform surgical abortions; (3) the physician would have to be trained to evaluate the age of the pregnancy using ultrasound;³⁹ (4) the physician would have to be able to use ultrasound to confirm an intrauterine pregnancy (*i.e.*, not ectopic); (5) the physician would have to have “satisfactorily completed training certified by the distributor in the mifepristone treatment procedure, including mechanism of action, appropriate use, proper administration,

follow-up, efficacy, adverse events, adverse event reporting, complications, and surgical indications”; and (6) the physician must have “continuing access (e.g., admitting privileges) to a medical facility equipped for instrumental pregnancy termination, resuscitation procedures,⁴⁰ and blood transfusion at the facility or [one hour’s] drive from the treatment facility.”⁴¹

Items 1 and 2 attempted to ensure that licensed physicians capable of performing surgery would prescribe RU-486. Item 3 focused on the fact that RU-486’s failure rate increases dramatically after the 49th day of pregnancy LMP; only ultrasound evaluations can accurately indicate whether a pregnancy is beyond Day 49. Item 4 reflected the fact that giving RU-486 to a woman with an ectopic pregnancy is forbidden, and ultrasound is the standard method used to locate a pregnancy. Item 5 reflected the fact that a drug as dangerous as RU-486 should only be given by doctors trained in its use. Finally, Item 6 is most revealing. The FDA determined that it would be dangerous for a woman taking RU-486 not to be in the care of a physician who could quickly admit her into a properly equipped hospital.⁴² This list should make any but the most biased observer realize that RU-486’s use is complicated and fraught with dangers.

The reaction of the Population Council, the abortion industry, and the pro-abortion press came fast and furious. The Population Council and Danco objected strenuously to the proposed restrictions, and leaked stories to the press claiming that the FDA’s proposals “regarding the labeling and distribution of mifepristone would severely limit women’s access to the drug if and when it is approved.”⁴³ The American Medical Association and the American College of Obstetricians and Gynecologists (“ACOG”) aggressively acted to persuade the acting FDA Commissioner, Jane Henney, to reverse the FDA’s proposed restrictions.⁴⁴ Dr. Eric

Schaff, an RU-486 advocate and researcher, told the *New York Times* that such restrictions would kill “the drug if it can’t be used by primary care providers.”⁴⁵ Schaff also pointed out the obvious: “The whole idea of mifepristone was to increase access.”⁴⁶

Pro-abortion politicians soon reared their heads. For example, Senator Barbara Boxer (D-CA) wrote to Dr. Henney on June 9, 2000:

“According to news reports, the FDA is considering placing draconian restrictions on the accessibility of RU-486 as a condition of its approval . . . In 1996, the FDA found RU-486 to be safe and effective. Therefore, it is a mystery to me why the FDA would even consider restricting access to it.”⁴⁷



Barbara Boxer (D-CA)

On June 22, 2000, U.S. Representative Lynn Woolsey (D-CA) wrote to Dr. Henney, stating that she was “deeply concerned about recent press reports about proposed restrictions.”⁴⁸ The Public Advocate for the City of New York, Mark Green, a long-time New York liberal politico, wrote to Dr. Henney on September 22, 2000. Green informed her: “Earlier this week Planned Parenthood of New York City, NARAL-New York, the Access Project and Physicians for Reproductive Health and Choice joined me in convening a public hearing in New York City on pending action by [FDA] on mifepristone . . .” He added that he was “also

concerned about the restrictions on access to RU-486 that FDA is said to be considering.”⁴⁹

The final shoe dropped at the FDA itself. You may recall Susan Allen, described above, with regard to her 1996 testimony at the FDA’s RU-486 hearing. In 1998 Allen was hired to work in the FDA’s Reproductive and Urologic Drug Products Division in the FDA’s Center for Drug Evaluation and Research (“CDER”). This division oversaw processing of the RU-486 application. She was promoted to “team leader” for reproductive drugs in 1999. Allen—who, as noted, was not an obstetrician-gynecologist—became acting director of the Division in January 2000 and permanent director on June 18, 2000.⁵⁰ Even though Allen had to recuse herself from direct involvement in the RU-486 approval, it is hard not to conclude that she was given this position to send a career-defining message to the division staff.

In any event, the FDA quickly abandoned its proposed physician qualifications. The agency even gave ground on issues not even raised by the June 1, 2000 proposal.⁵¹ By mid-July 2000 the FDA was in full retreat, and RU-486 was approved pursuant to its Subpart H regulations on September 28, 2000.

V. The FDA Violates Its Rules in Approving RU-486

The FDA approval of RU-486 was problematic legally in several ways.

First, even though the Food, Drug & Cosmetic Act prohibits approval of a drug application based solely on uncontrolled clinical trials, the FDA did exactly that. The RU-486 trials were uncontrolled because the drug was never compared to a control group of women having surgical abortion. Comparison of the test group with a control group

is needed to eliminate investigator (and agency) bias.

Second, RU-486 did not qualify for Subpart H approval because pregnancy is not a “serious or life-threatening illness.” Additionally, the FDA’s failure to conduct controlled comparisons of RU-486 and surgical abortions was especially egregious



because Subpart H explicitly requires a demonstration of “therapeutic benefit...over existing treatments...”⁵² Subpart H provides these examples of therapeutic benefit: the “ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy.”⁵³ Women who have standard RU-486 abortions must be able to tolerate a D&C because the RU-486/misoprostol abortion regimen has a substantial chance of failure: a surgical procedure is the back-up for RU-486 users. Furthermore, a head-to-head comparison of abortion methods would have shown RU-486 to be demonstrably

less effective and less safe.⁵⁴ In sum, RU-486 does not provide the requisite benefits.

Third, the agency mandated a previously unapproved use for misoprostol. Misoprostol was approved by the FDA to prevent people who take non-steroidal anti-inflammatory drugs (*e.g.*, ibuprofen) from getting ulcers. When given to pregnant women it causes uterine contractions to commence. When it approved the RU-486 regimen, the FDA mandated that a new, unrelated indication for misoprostol be placed on the mifepristone label (*i.e.*, the package insert). Peter Barton Hutt, a former FDA general counsel, observed that the agency's treatment of misoprostol "sets an extra-ordinary precedent" because the FDA [is] "seemingly encouraging a drug's unapproved use."⁵⁵ The FDA has been adamant for years in stopping pharmaceutical companies from promoting a drug for purposes other than those approved by the agency. Thus, every copy of the RU-486 label distributed by Danco, approved by the FDA, promotes a required off-label use of the drug.

VI. RU-486 Endangers the Lives and Health of the Women Who Use It

Six years of RU-486 adverse event reports ("AERs") have produced "real world" data not available before the U.S. approval.⁵⁶ The FDA reporting system for drug complications is voluntary, so there is large-scale underreporting of drug side-effects. The FDA has estimated that it receives reports for only 1-10 percent of drug complications.⁵⁷ In the case of mifepristone, providers agree to report complications to Danco. However, the AERs reveal that a sizable proportion of women with RU-486 complications have to seek medical attention in emergency rooms. ER doctors have no obligation

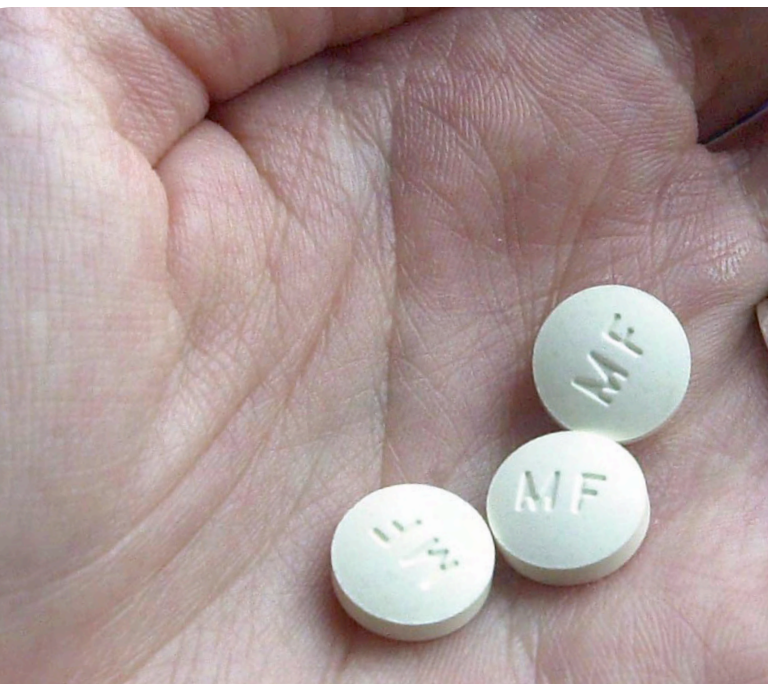
to report RU-486 adverse events. A generous estimate would be that the FDA is receiving reports on only 3-4 percent of RU-486 complications—at most.⁵⁸

Nevertheless, the 1,000+ reports are significant because they confirm that large numbers of mifepristone patients require surgical intervention for infection, hemorrhage, complications from ectopic pregnancy, and incomplete abortions. Such complications could not be a surprise to the FDA, for they were well-known and documented by the early 1990s.⁵⁹ One recent article has been published by two obstetrician-gynecologists, Peggy Gary and Donna Harrison, who analyzed 607 of the American AERs—the total then available.⁶⁰ Since the publication of that article, the FDA has stopped releasing AERs pertaining to RU-486 fatalities that have been requested pursuant to the Freedom of Information Act.

Infection

To date there have been six North American deaths stemming from the use of the RU-486 abortion regimen.⁶¹ Five Americans and one Canadian have died from septic shock stemming from infection by the anaerobic bacteria *Clostridium sordellii*. One of those young women was Holly Patterson, 18, of Livermore, California. Her death became known nationally, and her father, Montgomery Patterson, has been heroic in attempting to compel the FDA to recognize RU-486's safety problems. After notifying the public of the third and fourth septic shock deaths in July 2005, the FDA took the unusual step of releasing an "FDA Public Health Advisory" on July 19, 2005.⁶² On that day the FDA also announced that "the Prescribing Information, Medication Guide, and Patient Agreement for Mifeprex (mifepristone) have been updated to convey information concerning infection with *Clostridium sordellii*."⁶³

In women of childbearing age lethal infections caused by *C. sordellii* were rare in the U.S. prior to RU-486's approval. Aside from blocking progesterone receptors, two scientists have written independently that RU-486 may impair the innate immune system—making possible the sudden onset of septic shock.⁶⁴ In addition to the deaths, Gary and Harrison found 66 infection cases in their review of FDA AERs.⁶⁵ At least 46 were serious or life-threatening—two of these infections occurred in girls age 13-17 years old. Four women who survived life-threatening infections were in septic shock at the time of presentation to the emergency room.⁶⁶ Infection is a serious gynecological problem because women often develop pelvic inflammatory disease (from infection in the uterus, Fallopian tubes, and ovaries). Approximately one in four of these women will eventually be diagnosed with a blockage of the Fallopian tubes that renders them sterile.



On May 11, 2006, the Centers for Disease Control (“CDC”) in Atlanta hosted a conference, “Emerging Clostridial Disease Workshop,” which focused, in part, on the *C.sordellii* deaths.⁶⁷ A future research agenda developed from the conference has yet to be announced. An important aspect of the conference was the revelation that various studies, one involving the use of RU-486 in mice and published in 1992,⁶⁸ have noted that the interruption of the innate immune system can cause highly elevated rates of septic shock in selected lab animals. RU-486's cortisol-blocking properties give the chemical this ability—which some liken to removing the adrenal gland.

Hemorrhage

The FDA informed Chairman Mark Souder that 116 cases of severe bleeding requiring transfusions had been reported to the FDA by March 31, 2006.⁶⁹ Gary and Harrison reported that 237 of their 607 AERs reported hemorrhage and that 42 cases were life-threatening.⁷⁰ All of the patients who experienced “life-threatening” bleeding would have died had they not received timely access to medical and surgical services. One Swedish teenager did bleed to death. In December 2006 the death of a 31 year-old healthy Taiwanese mother of two, who used RU-486 as an abortifacient, was reported.⁷¹

The heavy bleeding produced by mifepristone-prostaglandin abortions was well known in the 1990s.⁷² A British multi-center trial (1990) had five of 579 women receive transfusions and curettage.⁷³ One U.S. study participant wrote in the *Los Angeles Times* in 1990 that she continued to bleed for three months after her abortion.⁷⁴ In the U.S. clinical trial, excessive bleeding necessitated blood transfusions in four women (n=2015) and accounted for 25 of 27 hospitalizations (includ-

ing emergency-room visits).⁷⁵ One participant from Iowa almost bled to death and was saved only by rapid surgical intervention and transfusions.⁷⁶ The FDA's Janet Woodcock nonchalantly told a congressional subcommittee that the agency fully "expected" this pattern of hemorrhage when it approved the drug. In her testimony to Chairman Mark Souder in May 2006, Woodcock seemed to believe that the FDA's mere expectation and apparent prediction of such serious side effects made the agency's judgment immune from criticism.

Ectopic Pregnancies

Two percent of American pregnancies are "ectopic." That is, they develop outside the uterus—usually in the fallopian tubes. When an ectopic pregnancy ruptures, the woman will rapidly bleed to death internally unless she undergoes immediate surgery. The signs and symptoms of ectopic pregnancy (*e.g.*, cramping and bleeding) resemble those experienced by a woman undergoing an RU-486 abortion. An endangered RU-486 patient might delay treatment thinking her symptoms were due to the RU-486 abortion—not an ectopic pregnancy. Gary and Harrison found 17 AERs involving ectopic pregnancies including 11 ruptures and one death.

Surgical Abortions on RU-486

RU-486's track record in the U.S. has come under criticism even from abortionists. E. Hakim-Elahi, M.D., looked at Planned Parenthood's 2003 reported complications and concluded in a letter to *Ob.Gyn News*: "If I were to receive such a report from a surgical abortion clinic, I would recommend to health authorities that the clinic be immediately shut down."⁷⁷ Hakim-Elahi declared flatly, "Medical abortion with the present drug regimen is *unsafe*."⁷⁸

Following the announcement of another RU-486 death in March 2006, a *New York Times* article carried statements from abortionists who expressed doubt about the regimen's safety.⁷⁹

Dr. Warren Hern of Denver, Colorado, asserted that using drugs "[is] a lousy way to perform an abortion."⁸⁰ Additionally, the *Times* interviewed Dr. Damon Stutes of Reno, Nevada who agreed with Hakim-Elahi and Hern: "The complications associated with RU-486 far exceed the complications of surgical abortion."⁸¹ While admitting that he was uncomfortable in agreeing on anything with abortion opponents, he said, "But the truth is the truth."

VII. Conclusion

In retrospect it is clear that those pushing for U.S. approval of RU-486 lived under a set of delusions about the drug's potential political and professional impact. RU-486 has produced none of the effects of normalizing abortion that were predicted for it. RU-486 is not accepted as a compromise politically, and it has not attracted doctors willing to use it. To the contrary, RU-486 has been a public relations disaster for the abortion movement as its manifest dangers have had to be repeatedly explained away.

The Clinton administration twisted pharmaceutical industry arms and broke rules to force RU-486 approval through the FDA. RU-486 and surgical abortions were not compared in trials—as required by scientific standards. Staff concerns about RU-486's safety were crushed politically.

Despite the Clinton administration's Herculean eight-year effort to bring the drug to market, RU-486 was just becoming widely available when George W. Bush assumed the presidency. Consequently, the overwhelming proportion of RU-486's adverse events and 600,000 deaths in the womb

have occurred during President Bush's presidency and his party's control of Congress. Both the GOP president and Congress knew of the approval irregularities and dangers posed by RU-486, yet no serious effort was made to correct the situation. Of all the committees and subcommittees on the Hill, only Representative Mark Souder's held a hearing (on May 17, 2006) to explore mifepristone's safety.

The President needs to remedy the threat to women's health posed by RU-486. Six years of American RU-486 use have made clear that RU-486 doesn't just kill the unborn—it endangers the lives of those who use it. President Bush should do the right thing and reverse this approval based on the abuse of process that gained its approval and the dangerousness that characterizes RU-486. Respect for the law and concern for women's health demand no less.



After the septic shock deaths of several women who received RU-486 from its clinics, Planned Parenthood adopted a new off-label RU-486 regimen on March 17, 2006.

FOOTNOTES

- 1 RU-486 is not a “morning after pill” or an “emergency contraceptive” like Plan B. RU-486 destroys an embryo or fetus already implanted in the uterus.
- 2 Bernard N. Nathanson, “Drugs for the Production of Abortion: A Review,” 25 *Obstetrical and Gynecological Survey* (1970, no. 8): 727-731, 728. For an encyclopedic discussion of the history of abortion techniques, see Joseph W. Dellapenna, *Dispelling the Myths of Abortion History* (Durham, N.C.: Carolina Academic Press, 2006): 29-56.
- 3 Methotrexate, a folic acid antagonist developed for use in chemotherapy, has been used “off label” to produce abortions since the 1970s. An “off-label” use constitutes a lawful but unapproved use. See “Off-label use” at Wikipedia (go to: <http://en.wikipedia.org/wiki/Off-label_use>). On methotrexate’s use as an abortifacient, see Bernard N. Nathanson, M.D., “The Abortion Cocktail,” *First Things* 59 (January 1996): 23-26 (go to: <<http://www.firstthings.com/ftissues/ft9601/articles/nathanson.html>>). See Dellapenna, note 2 above, for a discussion of the toxicity and ineffectiveness of abortifacients prior to the advent of RU-486.
- 4 Lawrence Lader, *A Private Matter: RU 486 and the Abortion Crisis* (Amherst, NY: Prometheus Books, 1995): 115-241.
- 5 If one breaks down “progesterone,” one sees in its roots “pro-” and “-gestation.”
- 6 Irving M. Spitz, M.D., C. Wayne Bardin, M.D., Lauri Benton, M.D., and Ann Robbins, “Early Pregnancy Termination with Mifepristone and Misoprostol in the United States,” *New England Journal of Medicine* 338 (Apr. 30, 1998): 1241-47, 1243 (Table 1). In the U.S. Clinical Trials, *mifepristone alone* produced “successful” abortions in only 40% of pregnancies within 49 days LMP, 12% at 56 days LMP, and 4% at 63 days LMP.
- 7 Misoprostol is now used in standard obstetrical practice to induce labor in women whose pregnancies are at full term.
- 8 Spitz *et al.*, 1242-1243 (incl. Table 1).
- 9 Soon after the FDA approved RU-486, Planned Parent-

- hood, the National Abortion Federation, and ACOG moved to an off-label regimen in which 200 mg. RU-486 would be taken orally with 800 micrograms of misoprostol administered vaginally. Planned Parenthood also administered the RU-486 out to 63 days LMP. However, Planned Parenthood abandoned that regimen on March 17, 2006 and now administers RU-486 only to 56 days LMP with oral misoprostol administration. NAF does not appear to have adopted the new Planned Parenthood protocol. See ACOG Practice Bulletin, No. 67, "Medical Management of Abortion," *Obstetrics & Gynecology* (October 2005); 106: 871-82; see also, National Abortion Federation, "NAF Protocol for Mifepristone/Misoprostol in Early Abortion" (Washington, D.C.: National Abortion Federation, March 2006).
- 10 Margaret Talbot, "The Little White Bombshell," *New York Times Magazine* (July 11, 1999): 39-43 (go to: <<http://www.nytimes.com/library/magazine/home/19990711mag-abortion-pill.html>>). ("One of my real ... hopes for this method,' says Carolyn Westhoff, an OB-GYN at Columbia University medical school who offers medical abortion as part of a clinical trial, 'is that it will help get abortion back into the medical mainstream and out of this ghettoized place it's been in.' And if that is indeed the scenario we're looking at – a scenario in which abortion is folded far more seamlessly into regular medical practice – then it has implications not only for women's experience of abortion but for the politics of abortion as well.")
 - 11 Talbot, "The Little White Bombshell," ("Not only are mifepristone abortions, by nature, more discreet than their surgical equivalents (like vacuum aspiration), but the practitioners who prescribe them will almost certainly constitute a larger and a more varied group than the dwindling corps of OB-GYNs willing to do surgical abortions."); also, David A. Grimes, M.D., "Clinicians Who Provide Abortions: The Thinning Ranks," *Obstetrics and Gynecology* 80 (October 1992): 719-723 ("Access to abortion services in the United States has become increasingly limited because of a decrease in rural hospital providers and a growing shortage of clinicians willing to offer this service. As of 1988, 83% of United States counties had no identified provider.").
 - 12 Lader, *A Private Matter*, 225.
 - 13 "Importation of RU-486," Memorandum for the Secretary of Health and Human Services, *Public Papers of the Presidents: Administration of William J. Clinton, 1993* (Jan. 22, 1993), 11. As will be discussed below, an "antiprogesterone" is a drug that blocks the functioning of progesterone.
 - 14 For a detailed account of the Feminist Majority Foundation's campaign to bring RU-486 to the United States, see Jennifer Jackman, "Anatomy of a Feminist Victory: Winning the Transfer of RU 486 Patent Rights to the United States, 1988-1994," *Women & Politics*, vol. 24 (3): 81-99. Jackman served as Director of Policy and Research for the Feminist Majority Foundation.
 - 15 Judicial Watch, "The Clinton RU-486 Files" (Washington, D.C.: 2006); go to: http://www.judicialwatch.org/printer_5769.shtml.
 - 16 Judicial Watch, "The Clinton RU-486 Files," Tab E.
 - 17 Kevin Thurm, HHS Chief of Staff, Memo to Carol Rasco, Assistant to the President for Domestic Policy (May 11, 1994); see Judicial Watch, "The Clinton RU-486 Files," Tab D.
 - 18 Randy O'Bannon, "Extensive Background Information on RU-486" (Washington, D.C.: National Right to Life, 2001) succinctly describes the complex financial and corporate arrangements made to bring RU-486 to market (go to: <<http://www.nrlc.org/RU486/ru486info.html>>).
 - 19 Carol Jouzaitis, "Doctor's Abortion-Drug Technique Draws Fire," *Chicago Tribune* (Sept. 12, 1994): 1, 14.
 - 20 Ibid.
 - 21 *Hearings on New Drug Application for the Use of Mifepristone for Interruption of Early Pregnancy* (July 19, 1996), FDA Advisory Committee (*FDA Mifepristone Hearings Transcript*). Transcript may be found on the internet at: <<http://www.fda.gov/cder/archives/mifepristone/MIF005201.pdf>>.
 - 22 *FDA Mifepristone Hearings Transcript* at 37.
 - 23 American Association of Pro Life Obstetricians and Gynecologists, Christian Medical and Dental Association, and Concerned Women for America, *Citizen Petition re: Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Days' Gestation*, before the Department of Health and Human Services, Food and Drug

- Administration (August 20, 2002), 40-41 (cited as “Citizen Petition”).
- 24 Citizen Petition, 41.
- 25 David Brody, “RU-486: The Uncontrolled Birth Control Pill,” Christian Broadcasting Network (Feb. 28, 2005) (available at: <<http://www.cbn.com/cbnnews/news/050228a.aspx>>). “NARAL,” which stands for “National Abortion Rights Action League,” was the organization’s previous name. The group was founded in 1969 by Bernard Nathanson, Larry Lader, and Betty Friedan.
- 26 Ibid.
- 27 Ibid.
- 28 Planned Parenthood is the largest abortion provider in the United States.
- 29 Jones participated as consumer representative at the meeting but did not vote on the RU-486 questions; Narigan did vote for approval of the RU-486 NDA.
- 30 Corfman’s biography reads: “Philip Corfman was the first Director of the Center for Population Research at NIH and subsequently held a similar position at the World Health Organization in Geneva. Following this, he held leadership positions for the review of new drugs and devices for reproductive health at the FDA and was a major participant in the FDA’s effort to make emergency hormonal contraceptives and mifepristone available to American women....” This webpage may be found at: <<http://www.rhfp.org/about/board/default.asp>>.
- 31 *FDA Mifepristone Hearings Transcript* at 317. Allen stated during her testimony that she was not an “OBGYN physician.” *Id.* at 321.
- 32 Spitz, *et al.*, 1242-1243 (incl. Table 1).
- 33 Citizen Petition, 49-55.
- 34 The FDA’s Accelerated Approval Regulations are set forth at 21 C.F.R. Part 314, Subpart H (“Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses”) (“Subpart H”). See 21 C.F.R. § 314.500ff. Drugs approved under Subpart H may be found at: <http://www.fda.gov/cder/rdmt/accappr.htm#NDAs> Approved Under Subpart H.
- 35 In the 1992 notice of rulemaking, the FDA described a “surrogate endpoint” as “a laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and that is expected to predict the effect of the therapy.”
- 36 21 C.F.R. § 314.500.
- 37 21 C.F.R. § 314.510 (“Surrogate Endpoints”).
- 38 21 C.F.R. § 314.520(a). The FDA first used the “restricted distribution” provision of its rules in 1998 to approve the dangerous drug, thalidomide, to treat leprosy.
- 39 The only way that a pregnancy’s age can be determined accurately is to date the pregnancy using ultrasound.
- 40 “Resuscitation procedures” implies that the medical facility would have a “crash cart” and personnel trained in ACLS (“Advanced Cardiac Life Support”) and ATLS (“Advanced Trauma Life Support”). The personnel at the medical facility would be trained in rapidly starting an IV, intubation, cardiac defibrillation, and administration of life saving medications. Medical facilities with an Emergency Room routinely have a “crash cart” and personnel trained in working through a “Code Blue.”
- 41 Citizen Petition, 52-3, n.235.
- 42 Many abortionists do not have admitting privileges at hospitals. For example, one Supreme Court justice noted in 1999 that Leroy Carhart, M.D., a notorious partial-birth abortionist, “lack[ed] admitting privileges at any hospital.” *Stenberg v. Carhart*, 530 U.S. 914, 956 (2000) (Kennedy, J., dissenting). One would want an RU-486 prescriber to have admitting privileges at a nearby hospital to protect the health of the patient because “dumping” the patient into the local emergency room is dangerous. In general, emergency room (“ER”) physicians are not trained to perform D&C’s. Handling emergency hemorrhage caused by retained products of conception or severe uterine infection requires the performance of a D&C or, even, a hysterectomy. The physician would have to admit the patient to the hospital where he/she would have operating privileges; however, the physician needs to have admitting privileges at that hospital. There would be a dangerous delay in having the ER physician locate an “on-call” OB/GYN to come to the hospital to treat a bleeding emergency.

- 43 Citizen Petition, 53, n. 237. Normally, such behavior by a drug company during the FDA approval process would get a company's drug application buried – if not killed.
- 44 Citizen Petition, 53, n. 239.
- 45 Sheryl Gay Stolberg, "F.D.A. Adds Hurdles in Approval of Abortion Pill," *New York Times* (June 8, 2000). Note the paper's bias in characterizing the proposed restrictions as "hurdles" rather than as safety precautions.
- 46 Ibid.
- 47 Citizen Petition, 54, n. 240 (*see* Letter, Senator Barbara Boxer to Dr. Jane Henney, Acting FDA Commissioner, June 9, 2000: 1).
- 48 Ibid. (*see* Letter, U.S. Representative Lynn Woolsey to Dr. Jane Henney, Acting FDA Commissioner, June 22, 2000: 1).
- 49 Ibid. (*see* Letter, Mark Green, Public Advocate for the City of New York, to Dr. Jane Henney, Acting FDA Commissioner, Sep. 22, 2000: 1).
- 50 Citizen Petition, 9, n. 24.
- 51 Citizen Petition, 54-57.
- 52 21 C.F.R. § 314.500.
- 53 Ibid.
- 54 Citizen Petition, 21-22 (citing and quoting Jeffrey T. Jensen, Susan J. Astley, Elizabeth Morgan, and Mark D. Nicols, "Outcomes of Suction Curettage and Mifepristone Abortion in the United States: A Prospective Comparison Study," *Contraception* 59 (1999): 153-159). Jensen *et al.* noted that RU-486 abortion patients "reported significantly longer bleeding" and "significantly higher levels of pain . . . , nausea . . . , vomiting . . . , and diarrhea" than the surgical abortion patients. Ibid.
- 55 Rachel Zimmerman, "Clash Between Pharmacia and FDA May Hinder the Use of RU-486," *Wall Street Journal* (Oct. 18, 2000): B1. Hutt added that the agency is in an "embarrassing and uncomfortable position."
- 56 All confidential or patient-identifying information is stripped from these reports by the FDA before release under the Freedom of Information Act.
- 57 Frontline, "Dangerous Prescription," FAQs & Links, posted Nov. 13, 2003 (*see* "How does the FDA find out about adverse events?" at: <http://www.pbs.org/wgbh/pages/frontline/shows/prescription/etc/links.html>).
- 58 In May 2006, the FDA's Janet Woodcock testified before a House subcommittee that, based on numbers provided by Danco, 575,000 women had been "exposed" to RU-486. At the time the FDA had received approximately 1,000 unique AERs related to RU-486's use as an abortifacient. In a March 2004 filing Planned Parenthood and the National Abortion Federation, responding to the Citizen Petition, admitted that five per-cent of women needed surgical intervention to complete an RU-486 abortion. Five per-cent of 575,000 equals 28,750. One thousand (received reports) divided by 28,750 (expected failures given total abortions) equals three and a half per-cent—a generous estimate. *See* Statement of Janet Woodcock for the Souder Hearing (May 17, 2006). Dr. Woodcock's statement and other documents pertaining to the Souder Hearing except for the staff report are available at: (<<http://reform.house.gov/CJDPHR/Hearings/EventSingle.aspx?EventID=43922>>).
- 59 Janice G. Raymond, Renate Klein, and Lynette J. Dumble, *RU 486: Misconceptions, Myths, and Morals* (Cambridge, Mass.: Institute on Women and Technology, 1991), 31-47 (go to: <<http://www.spinifexpress.com.au/non-fict/ru486.htm>>).
- 60 The AERs had been filed with the FDA between September 2000 and September 2004. *See* Margaret M. Gary, M.D., and Donna J. Harrison, M.D., "Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient," *Annals of Pharmacotherapy* (published online Dec. 27, 2005) (www.theannals.com).
- 61 It appears that all of the women used a 200 mg RU-486 (oral), 800 mcg misoprostol (vaginal) regimen. The Canadian died as part of a clinical trial for RU-486. The Canadian mifepristone trial was ended after this 26 year-old woman's death in August 2001. RU-486 has still not been approved by Canadian drug authorities.
- 62 For the advisory, go to: <<http://www.fda.gov/cder/drug/advisory/mifeprex.htm>> (updated 11/04/05).
- 63 Go to: <<http://www.fda.gov/cder/drug/infopage/mifepristone/mifepristone-qa20050719.htm>>.

- 64 Two scientists have independently offered similar analyses of a relationship between RU-486 and septic shock. R.P. Miech, M.D., Ph.D., "Pathophysiology of Mifepristone-induced Septic Shock due to *Clostridium sordellii*," *Annals of Pharmacotherapy* 39 (Sep. 2005): 1483-8; Letter to the Editor, James A. McGregor, M.D., *Contraception* 72 (2005): 393.
- 65 Chairman Souder was told of 88 infection cases over a longer period of time. Letter from David W. Boyer, Assistant Commissioner for Legislation, FDA, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, House of Representatives (May 2, 2006), 8 ("Boyer May 2, 2006 Letter").
- 66 Gary and Harrison, 2.
- 67 Information and papers related to the workshop may be found on the webpage: <http://www.fda.gov/cder/meeting/clostridia_disease.htm>. Doctors Miech and McGregor gave presentations at the CDC workshop.
- 68 Lazar *et al.*, "Modification of Septic Shock in Mice by the Antiglucocorticoid RU-38486," *Circulatory Shock* 36(3): 180-4 (1992).
- 69 Boyer May 2, 2006 Letter, 8.
- 70 Life-threatening cases were defined by active hemorrhaging with hemoglobin less than 7 g/dL and the transfusion of 2 or more units of packed red blood cells (PRBCs).
- 71 Lo Woei Chung *et al.*, Letter to the Editor, "Thrombotic thrombocytopenic purpura secondary to mifepristone in a patient of medical termination in early pregnancy," *Annals of Hematology* (webposted Dec. 18, 2006) (DOI 10.1007/s00277-006-0237-7). The patient died of active gastrointestinal tract and *intracranial* hemorrhage. This death report may lend weight to the hypothesis that mifepristone can produce excessive hemorrhage in some patients.
- 72 In fact, the FDA's Medical Officer noted the results of one methodologically poor but damaging study for RU-486. The Officer observed that RU-486 abortion patients experienced "significantly more blood loss than did surgical patients." See Staff Report, "The FDA and RU-486: Lowering the Standard for Women's Health?"

Hearing before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, House of Representatives, Representative Mark Souder, Chairman (October 2006): 14, n. 68 (go to: <<http://reform.house.gov/UploadedFiles/RU486%20Final%20Report%20PDF%20Version.pdf>>).

- 73 Raymond *et al.*, 39. The prostaglandin used was gemprost not misoprostol.
- 74 *Ibid.*, 32.
- 75 Spitz *et al.*, 1243.
- 76 *FDA Mifepristone Hearings Transcript*, 223-7. Dr. Mark Louviere, M.D., told the panel at the 1996 FDA hearing of his encounter with a woman in his hospital's emergency room in November 1994. She had taken RU-486 two weeks earlier and presented to the ER with hemoglobin equal to 5.8, hematocrit at 17.3, blood pressure at 90/60 and a pulse of 120. After receiving 2 units of packed red blood cells her hemoglobin level rose only to 6.8, and she was given 2 more units. Louviere became famous when he wrote a news story for the *Des Moines Register* exposing blatant lying in a Planned Parenthood press release claiming no RU-486 complications in 238 women who took the drug in Iowa.
- 77 E. Hakim-Elahi, M.D., Letter to the Editor, *Ob.Gyn News* (Feb. 15, 2005): 6.
- 78 *Ibid.*
- 79 Gardiner Harris, "Some Doctors Voice Worry Over Abortion Pills' Safety," *New York Times* (April 1, 2006).
- 80 *Ibid.*
- 81 *Ibid.*



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