

RU486

The Abortion Pill

Risks and Dangers

Despite heavy publicity by the pill's promoters claiming that the RU486/prostaglandin method is a safe and effective alternative to surgical abortion,^{1,5} controlled testing has offered a very different picture.

Is it Dangerous?

In France, a woman suffered heart failure and died after taking RU486 in combination with its accompanying prostaglandin.² In America, one of the women participating in the U.S. trial of RU486 nearly bled to death after taking the abortion drugs (see reverse).

Every RU486 abortion involves at least two drugs, RU486 (also called "mifepristone") and a prostaglandin (PG), usually misoprostol. These drugs are dangerous for a number of reasons.

RU486 is a complex chemical molecule effecting multiple systems of the body.³ This is why it has effects not only on a woman's reproductive system, but her cardiovascular, digestive, and central nervous systems as well.³ Misoprostol, the prostaglandin ordinarily used in conjunction with RU486, has its own side effects, triggering the painful, often nauseating, contractions that expel the dead baby.⁴

Because of the pain, bleeding, nausea, fevers, and other side effects, these drugs are often further supplemented by additional drugs such as antispasmodics,⁵ antibiotics, narcotic analgesics, etc.,³ each of which comes with its own attendant risks and side effects and potential interaction problems.

In England, one of just four countries where the drug is allowed, all pills are numbered to ensure that they are not released to untrained personnel.³ In France, the country with the most experience with the drug, the government requires that any facility dispensing the drug have an electrocardiograph and emergency resuscitative equipment nearby.⁶

Does it sound safe and simple to you?

● SAFETY WARNING ●

Women with any of the following conditions have been kept out of tests of RU486 for fear that the drug might prove dangerous or deadly for them.

- Presence of cardiovascular risks, including high blood pressure, obesity, cigarette smoking, and diabetes §, ¹⁷
- Asthma and bronchitis ‡
- Age over 35 or under 18 §, ¹⁷
- Anemia or blood clotting disorders §
- Menstrual irregularity, fibroids or endometriosis §
- Use of IUD or oral contraceptive less than 3 months prior to conception §, ¹⁷
- History of problem pregnancy, current ectopic pregnancy, or pelvic inflammatory disease *, ¹⁷
- Allergies, epilepsy, or adrenal insufficiency ‡
- Recent intake of steroid or anti-inflammatory medications ‡
- Long term administration of cortisone or similar drugs ‡, *
- History of liver, stomach, intestinal, or kidney disease *, ¹⁷

If only women in perfect physical condition can endure the drug...

How safe can it be?

1/00

§ Raymond, *RU486: Misconceptions* (1991); ‡ Silvestre, *NEJM*, 3/8/90; * Couzin, *NEJM*, 12/18/86

Complications

There are over 1.3 million abortions performed in the U.S. each year.⁷ We are told that 20-33% of abortions performed in France are chemical abortions.^{8, 18} If U.S. use mirrored French use, and U.S. abortion rates remained stable, one could expect the following numbers of complications based on current clinical data:

	<u>COMPLICATION</u> ^{5, 17}	<u>EXPECTED U.S. RANGE</u>	<u>RESULTING #'s of COMPLICATIONS</u>
8%	failure to complete abortion	X 273,146 - 450,691 =	21,852 - 36,055 "failures" per year
2%	hemorrhaging	X 273,146 - 450,691 =	5,463 - 9,014 hemorrhaging per year
2%	surgical intervention to stop bleeding	X 273,146 - 450,691 =	5,463 - 9,014 surgical interventions/yr
1%	require hospitalization	X 273,146 - 450,691 =	2,731 - 4,507 hospitalizations per year
(4)	transfusions	X 273,146 - 450,691 =	515 - 850 transfusions per year

Nasty Side Effects: Part of the Package

Pain

79%-96% of women taking the RU486/PG combination reported pain,^{4,17} so bad that as many as half required some form of analgesia, whether an opiate or some other injectable painkiller.^{3,4,5,17}

Three researchers who reviewed much of the data on RU486 say "many of the women in these studies experienced pain for several days/weeks until the abortion was complete. Thus we are talking about prolonged, not transient pain, although this is rarely noted."³

Nausea, Diarrhea, and Vomiting

Between 24% and 61% of RU486/PG patients experience nausea as part of the procedure. About one in five of all women struggle with diarrhea, while 15.3%-26%, or up to a quarter, vomit.^{3,5,17}

Infection

In one trial, as many as 5%, or 1 in 20, showed signs and symptoms of infection.⁹ Fevers and chills, often indications of infection, are not unexpected side effects of the process.⁵ Antibiotics often must be prescribed for suspected infections.¹⁰

If and when an RU486/PG abortion is unsuccessful (anywhere from 5% -20% of the time^{11,12}), and there is an incomplete abortion, the risk of infection is much greater.^{13,14} Whatever supposed benefit chemical abortion has over surgical abortion is then lost when a woman undergoes the surgical procedure with its attendant risks.

Other Side Effects

Fatigue,¹³ fainting, skin conditions, anemia, asthenia, hot flashes, heart palpitations, breast conditions,⁵ mood changes, thirst.¹⁴

Long Term Consequences

Unknown. Few independent studies. RU486 does cross the blood follicle barrier and get into a woman's ripening eggs.³ Could this effect the reproductive systems of a woman's later children, as DES did?

NOTES: 1. Baulieu, *The "Abortion Pill"* (1991); Baulieu, in *Clinical Applications of Mifepristone . . .* (1993); Lang, *Vogue*, August 1988. 2. Riding, *NY Times*, 4/10/91. 3. Raymond, et al, *RU 486: Misconceptions* (1991). 4. McKinley, *Human Reproduction* (1993), pp. 1502-5. 5. FDA, Mifepristone Hearings, 7/19/96. 6. French Government Letter, April 12, 1990. 7. Henshaw, "Abortion Services in the United States 1995-1996," *Family Planning Perspectives*, (Nov/Dec 1998) 8. Gianelli, *American Medical News*, 4/12/93. 9. Birth Control Trust, Conference, 4/22/93. 10. WHO Study, *Fertility & Sterility* (1991) 11. Aubeny and Baulieu, *C.R. Acad. Sci. Paris (III)*, (1991), pp. 539-545. 12. Jouzaitis, *Chicago Tribune*, 8/30/95. 13. Sitruk-Ware, *Contraception* (1990), pp. 221-243. 14. Li, *Fertility & Sterility* (1988), pp. 732-742. 15. *Ob.Gyn.News* (1989), No. 24, p. 1. 16. Speroff, *Clinical Gynecological Endocrinology & Infertility*, 3rd ed. (1983). 17. Spitz, *NEJM*, 4/30/98. 18. Population Council, Website, www.popcouncil.org, 1/98. 1/00

An Iowa Doctor gives a first hand account

The woman who took RU486 . . . and nearly died

Between October of 1994 and Labor Day of 1995, a nationwide trial of RU486 was conducted. A Planned Parenthood clinic in Des Moines was one of the testing sites. News accounts said the trial went well without any problems. One Iowa doctor who saw the story said he knew better.

I could hardly believe my eyes when I read the first paragraph of an article in the Sept. 2, Des Moines Register, "The clinical test of the 'abortion pill' has ended in Iowa, with no complications among 238 women who ended unwanted pregnancies without surgery."

This is untrue, and I can only surmise that the reason must have to do with the political volatility of the abortion issue. Regardless, it is imperative from a scientific standpoint that if Planned Parenthood is to be part of a nationwide clinical trial, it must report the facts

whether they agree with them or not. . . (A)

In November of 1994, I was called to the Alan Hospital Emergency Room in Waterloo, Iowa, for a woman who was bleeding due to a miscarriage and was in obvious shock. A blood test showed that she had lost between one-half to two-thirds of her blood volume. For those of you who understand this, her hemoglobin was 5.8 and her hematocrit was 17.3. Her blood pressure was 90 over 60, her pulse was 120, she was in obvious shock.

I had thought she was having an incomplete miscarriage, but her husband took me into the hall and told me that she had taken RU 486 approximately 2 weeks before. It was my clinical opinion that she would die soon if she did not have an immediate D&C.

Without even doing the routine preparation we normally do for surgery, I realized that I had to take her immediately to surgery to save her life. I took her to the operating room and removed the contents of her uterus surgically. I gave her two units of packed red blood cells intraoperatively. Even later

that evening, 2 hours post-transfusion of those two units, her hemoglobin was still 6.8 and her hematocrit was 20 something. She required two more units of blood because she was still orthostatic and symptomatic . . . (B)

To report to the people of Iowa, the Population Council, and to the FDA that there were "no complications" in Iowa is simply not true. . . (A)

If near death due to the loss of half of one's blood volume, surgery, and a transfusion of four units of blood do not qualify as a complication, I don't know what does. (A)

"If near death due to the loss of half of one's blood volume, surgery, and a transfusion of four units of blood do not qualify as a complication, I don't know what does."

- Mark Louviere, M.D.

How did the clinic and the trial sponsor respond?

[President of Planned Parenthood of Central Iowa Jill] June said "no complications" refers to the trial -- that the trial was conducted successfully -- and not to the condition of the participants.

However, Sandra Waldman, a spokeswoman for the New York based Population Council, which sponsored the trial, said the trial resulted in "no deaths or serious complications." When asked whether Louviere's patient's experience qualifies as a serious complication, Waldman said it would be "within the context with what happened before [in France]." (C)

Sources:

A. Dr. Mark Louviere, *Waterloo Courier*, 9/24/95.

B. Statement of Mark Louviere, MD, FDA Mifepristone (RU486) Hearings, 7/19/96.

C. Tom Carney, *Des Moines Register*, 9/21/95



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Researchers regard heavy, prolonged bleeding as the chief problem and most serious side effect of chemical abortions.³ The average blood loss from an RU486 is reported to be 70ml, nearly four times the average blood loss from a normal suction curettage abortion¹⁵ and very close to the 80ml menstrual blood loss level doctors consider "abnormal."¹⁶ This is hardly the "heavy period" spoken of by some of the pill's promoters.¹⁸

In a 1990 British study, five out of 579, or nearly 1%, bled so much they required both transfusions and curettage to stop the bleeding.³ In U.S. trials with a new prostaglandin (misoprostol) that was supposed to resolve such problems, "excessive bleeding" was noted in 4 out of 230 women who participated in the Des Moines part of the study.¹² What "excessive bleeding" means is unclear, but we do know one of those women almost bled to death (see above). Several women in the U.S. trial had to be given uterotonic agents to stop the bleeding.¹⁷

How Bad is the Bleeding?

It is not merely the amount of blood lost but how long a woman bleeds that is a medical concern. Normally, the bleeding may last one or two weeks, but there are records of women bleeding as much as two months or more.^{3,5,17}

There is additional concern because only about half of women who take RU486 actually abort at the doctor's office, meaning 50% or more face their bleeding and aborting without medical supervision.¹⁷