

Questions & Answers on RU-486

RU-486: RU asking the right questions?

Should the ban be lifted on the controversial abortion drug RU-486? Caroline De Costa and Lyn Allison say yes, claiming it is safe and effective and would increase women's options. But are they missing the point? Are they even asking the right questions? In order to bring about a fully informed public debate we need to consider some of the following facts.

What is RU-486 and how does RU-486 work?

Mifepristone, commonly marketed as RU-486, is a drug used to induce a chemical abortion. It is an artificial steroid that blocks progesterone, a hormone needed to continue a pregnancy. A second drug, misoprostol, is given 48 hours later. This drug, a prostaglandin, causes uterine contractions to help expel the embryo. Mifepristone has never been registered for use in Australia.

How is RU-486 different from the "Morning-after" Pill (MAP)?

RU-486 is used in combination with a prostaglandin to induce a chemical abortion. It is officially used to end pregnancies up to 49 days. MAPs although marketed as "emergency contraceptives" can also work as potential abortifacients. The supplier of the MAP in Australia advises that should be taken in the first 72 hours after sexual intercourse and that it can work in three different ways. (1) It can prevent ovulation. (2) It can attempt to slow down the transport of the egg and sperm in an attempt to prevent fertilization. (3) It can discourage implantation of an embryo in the lining of the uterus. This means that RU-486 nearly always acts to induce a chemical abortion and that MAPs can induce a chemical abortion.

What does the US Food and Drug Administration (FDA) say about mifepristone? www.fda.gov/cder/drug/infopage/mifepristone

In the US, post-marketing reports from 2000 through to the end of October 2004, have recorded 676 adverse events following 350,000 applications, ranging from minor symptoms such as nausea and dizziness to more serious adverse events, including hospitalization and death.

- 3 women have died
- 17 women have had ectopic pregnancies
- 72 women have experienced blood loss requiring transfusions
- 7 women have had serious bacterial infections

"FDA and Danco Laboratories have received reports of serious bacterial infection, bleeding, ectopic pregnancies that have ruptured, and death, including another death from sepsis that was recently reported to FDA. These reports have led to the revision of the black box labelling." [FDA Statement, Nov 2004]

The FDA Patient information sheet advises that after using mifepristone:

- 5-8 out of 100 women will need a surgical procedure to end the pregnancy or to stop too much bleeding.
- Women need to be able to access emergency medical help in the 2 weeks after taking the drug.
- Vaginal bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days.

Some of the symptoms of a ruptured ectopic pregnancy may mimic the expected symptoms of a chemical termination of pregnancy. [FDA Statement, Nov 2004] Since its approval in the US in Sept 2000, 4 Californian women have died from sepsis following medical abortion with mifepristone and misoprostol. [FDA Alert, July 2005] See also www.RU486Facts.org

Is RU-486 a panacea?

No. New methods of abortion will not solve Australia's abortion problem. Abortion by any means remains a sad and tragic choice. It is estimated that around 100,000 abortions occur each year in Australia. Whichever way it is done, abortion is a reflection that as a society we are not addressing the real needs of women. Few women really want an abortion, much less a do-it-yourself-at-home chemical one.

Is it really providing better choices?

How will RU-486 expand the list of options women have? How will it solve the child versus continuing education/career problem many women face? All too often women are only given half the information and are panicked, threatened, and abandoned into abortion, by parents, partners and husbands. Often abortion is the only choice they are offered by counsellors and abortion clinic staff. For many women the "right to choose" has become an obligation to choose. Lifting the ban on RU-486 will not address these issues.

How will a new method of abortion improve women's lives?

One in five women report being coerced into sex (*The Sexual and Reproductive Health of Victorians 2005*), sometimes under the influence of drugs and alcohol. In an increasing climate of violence against women how will RU-486 help tackle this difficult issue? How will it help us argue against the idea that women are only playthings and against the objectification of women? Is giving them an abortion pill the best and most compassionate thing we can do for these women? How will this encourage Australian men to treat all women and their children with the dignity and respect they deserve?

In whose best interest?

For over 30 years advocates of abortion have told women that surgical abortion is a simple procedure that allows them to get on with their life. Yet, many women describe being left shattered and alone after abortion. We now know that at least 10% of women suffer some kind of severe and prolonged psychological distress as a result of an abortion. Abortion is not the answer.

Now we are being told that RU-486 is a simple and safe method of terminating a pregnancy. But chemical abortion involves a number of visits to the doctor. Will this drawn-out procedure add to a woman's trauma? Will coming face-to-face with foetal remains traumatise a whole new generation of Australian women? Will it bring the violence of abortion too up close and personal? Abortion does not liberate women; it traps and isolates them in a world of pain and grief.

Isn't RU-486 just like inducing a miscarriage?

Women who have experienced a miscarriage describe the pain and anguish they suffer after this event. Now advocates of RU-486 are trying to tell women that induced miscarriage helps them.

What is the French experience of RU-486?

Catherine Euvrard, formerly a spokeswoman for Roussel-Uclaf (the French company which developed RU-486) who now holds the same position for the new French manufacturer of RU-486, Exelgyn, said: "When [women] take a pill, they have the feeling they are truly responsible for the abortion... [There can be more] psychological pain."

Edouard Sakiz, former chairman of Roussel-Uclaf, told the French newspaper *Le Monde*: "As abortifacient procedures go, RU-486 is not at all easy to use... True, no anaesthetic is required. But a woman who wants to end her pregnancy has to 'live' with her abortion for at least a week using this technique. It's an appalling psychological ordeal."

How and why did the US FDA approve RU-486?

Under pressure from Congress and the Clinton Administration the FDA approved the use of RU-486 in 2000. This occurred despite warnings that procedural and scientific requirements to prove the safety and effectiveness of RU-486 had been by-passed. Researchers warned that adequate clinical trials had not taken place, that RU-486 did not fit the category of "accelerated approval regulations" which were only meant to be used for life threatening diseases like AIDS and cancer. The FDA went ahead, despite the fact that Searle the manufacturer of the second drug required in the process, misoprostol, was objecting because it had created and marketed misoprostol to treat ulcers and not to end pregnancies. It could not be sure of its safety in abortion. The FDA also relaxed the conditions and safeguards used in the original clinical trials, leading to a situation where women do not have the protection of an ultrasound to determine gestational age or confirm if the pregnancy is ectopic or not. (NYT 19/11/2004)

Are there additional instances where women's health is put at risk?

The US experience shows that abortion providers are prescribing RU-486 beyond the recommended 49-day limit, putting women's health at risk. They are so confident that they will not be prosecuted, that they are advertising the availability of RU-486 after 49 days on the web.

If RU-486 is dangerous wouldn't we expect more reports of complications?

Yes, if it was compulsory to report complications to the FDA. But reporting of any adverse reactions to the FDA is entirely voluntary, even if the adverse reaction results in death. So it is very likely that true numbers of adverse reactions remain unknown and it is entirely possible that RU-486 is not as safe as many would have us believe.

How many deaths have there been from RU-486 overseas?

There have been at least 10 deaths associated with the use of RU-486 overseas.

One:	France April 1991
One:	Canada 2001
Brenda Vise:	USA Sept 2001
Holly Patterson 18:	USA Sept 2003
Vivian Tran 22:	USA Dec 2003
Rebecca:	Sweden June 2003
Two:	UK Jan 2004
Chanelle Bryant 22:	USA Jan 2004
Oriane Shevin 34:	USA May 2005

What is "Holly's Law"?

Holly Patterson's sobbing father told reporters that "there is no quick fix for pregnancy, no magic pill," two days after she died as a result of taking RU-486. Following her death in California in 2003, Congressmen Jim DeMint, Roscoe Bartlett and Senator Rick Santorum introduced bills that became known as "Holly's Law" to suspend FDA approval of RU-486 pending a review of its safety. Congress is still to vote on Holly's Law.

Is the US FDA going to review its guidelines on RU-486?

Yes. *The New York Times* (23/11/2005) reports that after the recent deaths from RU-486 "stumped officials from FDA and the federal Centre for Disease Control and Prevention have decided to convene a scientific meeting early next year to discuss this medical mystery, according to two drug agency officials who spoke on the condition of anonymity because of the sensitivity of the topic." Just as the US is reviewing the use of RU-486 due to safety concerns, advocates are attempting to pressure the Australian government into lifting the ban on this controversial abortion drug.

Will the Manufacturer (Danco) face lawsuits?

Yes. *The New York Times* (23/11/05) reports, that "the families of Ms Patterson, Ms Tran, and Ms Bryant have all filed suit against Danco, claiming the company failed to warn patients of the drug's dangers."

Is RU-486 safe to use long term?

There have been no long-term studies carried out. There is increasing concern that apart from blocking progesterone receptors RU-486 interferes with glucocorticoid receptors, which in turn affect the immune system and may make women more vulnerable to infection.

Why is RU-486 being promoted?

Promoters of RU-486 aim to make abortion more acceptable to the general public and increase the number of doctors willing to be involved in abortion. Caroline Westoff an obstetrician and gynaecologist told the *New York Times* (11/7/1999) that "One of my real, and I think realistic, hopes for this method is that it will help get abortion back into the medical mainstream and out of this ghettoised place it's been in."

What are women saying about RU-486?

Germaine Greer, Prominent Australian Feminist

In 2002 Germaine Greer was asked to speak at a gynaecologists and obstetricians conference "Best for Women" to help promote RU-486. Instead she shocked her audience by drawing the line at RU-486. She described abortion as being like amputation. "Of course we need access to amputation but we need even more to make sure that as few people are in a situation where they need amputations as possible." She said that "these are violently active chemicals and they have violent reactions on the organism." and went on to ask "What is it that's brought us to a situation where a woman who is pregnant doesn't want to be?" and what is the "situation in which a woman would undergo that kind of assault?"

Annette MacDonald, Women for Women's Health (*Vancouver Sun*, 18/9/1992)

"Dumping chemical into women's bodies – especially into their reproductive systems- has generated billions of dollars in profits for multinational pharmaceutical companies. In the second half of the 20th century these giant companies have created a reproductive technology 'market' which they have inundated with 'Products' such as the contraceptive pill, the Dalkon Shield, Norplant, Depo-provera, VES, DES and ritrodine (to name just a few). All of these drugs and appliances have two things in common: (1) they were not properly tested before they were marketed, and (2) they damaged the health of literally millions of women... Enter RU-486, the "abortion-pill," the latest chemical innovation in fertility-control technology."

Serrin Foster, Feminists for Life, USA

"How anyone can suggest to women that RU-486 is an easy fix to society's lack of resources for women and children is simply irresponsible and degrading."

Dr Brigid Vout, Life Office Sydney

"RU-486 is a chemical response to the complex problems facing a woman who is pregnant in difficult circumstances. But it's not the solution. A drug which ends a new human life and endangers a woman's health is never a 'safe and effective' solution."

Is abortion the best we can do for pregnant women?

Arguing that we should leave women to make their own decisions sometimes translates to don't bother us with your problem. No one wants to see women chained to the sink. Nor do we want to see single women struggling alone to bring up a child. But no one wants to see women forced into submitting to unwanted abortions either. We should be working together to systematically eliminate the obstacles that prevent pregnant women from continuing with their pregnancy. Babies aren't the enemy. Society needs to change to make room for women and our life giving potential instead of demanding that we become just like men. We need to work to make society, workplaces, schools, universities, and hospitals, even parliament, more friendly, supportive and welcoming of women with children. This would really be empowering of women.

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