Community Affairs Committee

RU486 Submission

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Hills Parents and Friends Group (SA) would like to advise the Community Affairs Committee that it strongly opposes any introduction of the drug RU486 in Australia.

Whilst proponents of the RU486 argue that women have the right to access safe and efficient non surgical abortion, the findings of countries such as the United States, Canada and other European countries clearly demonstrate the drug is far from being "safe" and "efficient".

This short discussion paper will endeavour to highlight the problems of safety and effectiveness, as well as the litigious and moral dilemma associated with the use of RU486; and will conclude with a brief summary of potential benefits and risks.

RU486 is not safe

One of the major selling points for RU486's supporters is that a woman having a chemical abortion could avoid the risks associated with surgical abortion. When it was setting up the initial American trials of RU486 in 1994, the Population Council, the U.S. sponsor of the pill, highlighted the fact that with a "successful" chemically induced abortion that featured RU486 and a prostaglandin (PG) to trigger contractions, "There are no risks of anaesthesia or uterine perforation or cervical canal injury, [which are] rare complications of surgical termination of pregnancy."

But the truth is that the chemical method is not safer. Women are simply trading one set of risks for another.

For example: Provided the woman is not part of the over 1-9% for whom the chemical method fails (meaning a surgical abortion is required), the woman using the RU486/PG combination simply faces a whole new set of risks and dangers, ranging from haemorrhage to heart failure.

It has been well documented that women bleed nearly <u>four times more</u> from a RU486 abortion as they would from a standard first trimester suction curettage abortion. Bear in mind, at least one out of every fifty women who took it in U.S. trials bled so badly they required some form of surgical intervention (see Complications and side effects associated with the use of RU486).

Distributors of the drug admit that they have seen more pelvic infections in women who taken RU486 than they did during trials (*Los Angeles Times*, 10/1/01).

However, regarding the various RU486 trials around the world; these alone have raised grave concerns for women safety. The 2005 Italian trials were suspended

soon after commencing because reports showed one in twenty women taking the drug were having partial abortions at home followed by excessive bleeding⁽¹⁾. In the U.S trails a woman almost died and required hospitalisation after developing serious complications. And it is well known that in the Canadian 2001 trials a woman died of the drug (see **References** #13) . The list could go on, but the fact remains the RU486 method may be different from the surgical method, but it is not safer.

RU486 is not efficient

12 years before the US approved RU486 *Mademoiselle* magazine (November 1988) dubbed RU486 the "miracle pill." *Ms.* magazine (April 1987) rhapsodised about RU486 as if it were magic: "Imagine being pregnant, swallowing a pill, and presto! not being pregnant any longer."

The image of RU486 as some sort of magic pill that makes the baby "go away" has caused many desperate women to inquire about the abortifacient. However, many baulk when they learn the reality is quite different⁽²⁾. As bad as surgical abortions are, many have come to realise chemical abortions as something worse.

<u>Unpredictable</u>

The unpredictability of RU486 is also a real problem. With RU486, doctors have no way of determining when the abortion will occur, how rough and bloody it will be, or whether it will even take place at all.

Instead of the impersonal, mechanical, abrupt, invasive trauma of the standard 15-minute surgical procedure, the woman having an RU486 abortion faces a long, bloody, arduous, physically and psychologically taxing abortion that takes days or even weeks to complete. This drawn-out affair requires a minimum of three doctor visits over a two-week period, and necessitates her keeping her doctor's number or the address of the nearest emergency hospital next to her phone. And it still may not "work."

This is a dangerous situation and it is hardly what any rational person would call an *improvement*, let alone a *good* health practice.

It is worthwhile pointing out here, at present, the US Food and Drug Administration (FAD) indicated that at least 5 women have died from infections resulting from RU486. (3)

RU486 and litigation

Whilst advocates of RU486 promote it as a quick fix, many women will be more than disappointed when they find out RU486 is a lot more complicated than swallowing an aspirin. Over the years our society has witnessed a burgeoning of litigation cases against various companies and corporations who rigidly professed their products were safe (eg cigarettes, asbestos, silicon breast implants, etc) when the opposite was in fact the case.

And regarding litigation against RU486 companies:

The family of Hoa Thuy Tran, a student who died from using RU486, has filed a lawsuit against Danco Laboratories, claiming the company failed to disclose the pills could cause infections leading to death and posed other risks.

While the FDA is investigating these deaths, Ralph P Miech, professor emeritus, department of molecular pharmacology, physiology, and biotechnology at Brown University, provided clear evidence that the drug caused conditions in which bacterial infections could flourish and cause deadly septic shock.

(This was part of an article written by Babette Francis Herald Sun 27/10/05)

Myth of moral neutrality

Promoters of the pill have repeatedly forecast that RU486 would "change the debate" over abortion. But what does RU486 really change? The issue has never been when, where, or how an abortion was performed, but rather the fact* that abortion involves the destruction of innocent human life. And none of that changes with RU486. In short: an RU486 abortion is still an abortion.

(* A human embryo is a *human* life, this is an undisputable biological fact. The terms embryo, fetus, baby, toddler, child, adolescent, adult, simply refer to the various stages of human development.)

Summary of benefits and risks

Supporters of RU486 cite the following as benefits:

- safe and efficient way to end a pregnancy
- women are in control of their own bodies
- non-invasiveness of the drug in contrast to surgical abortions ie
- avoids risks (physical and emotional) normally associated with surgical abortion
- can be carried out in privacy of own home

Complications and side effects associated with the use of RU486:

- heart attacks and strokes⁽⁴⁾ -- in two of 20,000 patients⁽⁵⁾ -- attributable to the prostaglandin administered with RU486⁽⁶⁾
- inflammation of the fallopian tubes⁽⁷⁾
- excessive bleeding, for up to two weeks (5-9% of patients)⁽⁸⁾, possibly up to 40 days⁽⁹⁾
- need for blood transfusion⁽¹⁰⁾ -- 18 in one study of 2,040 women⁽¹¹⁾; in 1% of patients, according to another report⁽¹²⁾ -- due to loss of blood
- maternal death (13)
- possible fetal deformity (survival of fetus in 1% of cases)⁽¹⁴⁾
- incomplete abortion -- 2.1%⁽¹⁵⁾ -- retention of placental fragments -- in 43 of 2,040 patients⁽¹⁶⁾, leading to surgery.⁽¹⁷⁾
- ineffectiveness in ending tubal ectopic pregnancies. (18)
- failure to interrupt pregnancy in 1% of cases⁽¹⁹⁾ -- 20 of 2,040 women⁽²⁰⁾ -- for unknown reasons⁽²¹⁾
- need for surgical procedure -- in 81 of 2,040 women, or 4% (22)
- delay in follicular maturation and disturbance in periodicity⁽²⁴⁾
- abdominal cramps⁽²³⁾, requiring narcotics in 30% of cases
- nausea, vomiting, diarrhea, headache⁽²⁵⁾
- psychological problems⁽²⁶⁾

REFERENCES

(1) Redorbit 22/9/05 http://www.redorbit.com/news/health/248562/minister_halts_italys_first_abortion_pill_trial/

 $^{^{(2)}}$ San Francisco Chronicle, 9/24/01; Virginian-Pilot, 9/24/01

⁽³⁾ http://www.mccl.org/news/nr072105.htm

⁽⁴⁾ Amer Fam Phys [American Family Physician] Sept 90

⁽⁵⁾ Med Ltr on Drugs & Therapeutics Dec 14 90 p 112

⁽⁶⁾ Without PG, however, the drug's failure rate is 20%.

⁽⁷⁾ Amer Med News Oct 26 90

⁽⁸⁾ Med Ltr on Drugs & Ther Dec 14 90 The mean duration is 8.9 days, according to the Amer Fam Phys Sept 90. However, data from the UK indicate "very heavy bleeding" in 9% of patients.

- (9) Amer Med News Oct 26 90
- (10) New Eng Jour of Med Mar 8 90
- (11) Amer Fam Phys Sept 90 p 781
- $^{(12)}$ Med Ltr on Drugs & Ther Dec 14 90
- (13) CNSNews.com 19/11/01 'Canadian woman dies in RU486 trial' http://www.cnsnews.com/ViewCulture.asp?Page=%5CCulture%5Carchive%5C200109%5CC UL20010919a.html
- (14) New Eng Jour of Med Mar 8 90; Amer Fam Phys Sept 90; Lancet Sept 21 91
- (15) New Eng Jour of Med Mar 8 90
- (16) Amer Jour of Ob & Gyn Aug 90 p 543; Amer Fam Phys Sept 90
- (17) Amer Jour of Ob & Gyn Aug 90
- (18) Amer Fam Phys Sept 90; Amer Jour of Ob & Gyn Aug 90. In the case of a 27-year-old with simultaneous pregnancies in the uterus and ovary, the uterine pregnancy was ended but the fertilized egg implanted in the fallopian tubes survived the abortion and had to be surgically removed. (When beta human chorionic gonadotropin remained elevated after the abortion, the second pregnancy was discovered."
- (19) New Eng Jour of Med Mar 8 90
- (20) Amer Fam Phys Sept 90
- $^{(21)}$ Amer Jour of Ob & Gyn Apr 90 p 91 One study seemed to tindicate a correlation between body weight and abortion failure.
- (22) Amer Fam Phys Sept 90
- (23) Network News Sept-Oct 92
- $^{(24)}\,\mathrm{Amer}$ Fam Phys Sept 90; Med Ltr on Drugs & Ther Dec 14 90
- (25) New Eng Jour of Med Mar 8 90; med Ltr on Drugs & Ther Dec 14 90
- ⁽²⁶⁾ Pyschological risks; see: Debra Rosenberg, Michelle Ingrassia, and Sharon Begley, "Blood and Tears," *Newsweek*, p. 68. Louise Levanthes, "Listening to RU486," *Health*, January/February 1995, p. 88. *Boston Globe*, May 8, 1995, p. 1.; "Prepare now to counsel patients on RU486.