# **FertilityCare**

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The Senate Community Affairs Committeee

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Dear members of the Senate Community Affairs Committee and parliamentarians,

I strongly recommend continuation of the ban on the "abortion pill" RU 486 which is lethal to unborn babies and hazardous to pregnant women. As a GP experienced in women's health problems I would urge your government to maintain the ban on RU486. There is strong medical evidence indicating that RU 486 has adverse medical outcomes for women including the deaths of at least eight women and 23% of users experiencing serious adverse effects. The adverse psychological effects of abortion have been documented in at least 24 studies and even the promoters of RU486 acknowledge using RU486 is an appalling psychological ordeal.

RU486 is like a human pesticide causing severe malformation to the babies that survive past nine weeks including fused limbs, brain malformations, kidney problems and genital malformations. The French government approved the marketing of RU 486 and held a 40% share in Roussel Uclaf the company that discovered this drug. Dr Jean-Michel Alexandre, president of the French government's Medical Sales Commission said that the "main drawback to the new drug is that it increases the risk of birth defects in babies who survive it". 1

1) There are significant problems with leaving the Therapeutic Goods

Administration to decide about RU486. The private members bill leaves the power and responsibility for allowing RU486 in the hands of the Therapeutic Goods

Administration through their National Drugs and Poisons Schedule Committee (NDPSC). This committee allowed the morning after pill over the counter despite overwhelming majority of submissions against this (mainly medical arguments.)

In April 2005 the ABC television reported that a best-selling pain reliever Vioxx had been linked by doctors to the deaths of about 300 Australians. Although records show the side effects of increased stroke and heart attacks were known for years the TGA did not act for several years and then finally warned doctors and the general community.

On the 4 Corners ABC April 11, 2005 ABC it was reported

"Australia's drug regulator (TGA) says it is underfunded and powerless to review a class of pain reliever that may have killed hundreds of Australians.

Medical director of Australia's Therapeutic Goods Administration, John McEwen, says his hands are tied as his office does not receive public funding and is dependent on the results of drug company trials and scientific studies.

Dr McEwen says his office is currently powerless to review a drug once it has been given market approval.

"It's in dispute that we would have [the] power to force those studies once a drug is on the market," he told the ABC.

Dr McEwen is still the chairman of the NDPSC committee despite reports in *Australian Doctor* (mid 2004 )that the government was considering disbanding the current committee in 2005 and setting up a committee with a larger representation of clinicians.

The committee in early 2004 had NO clinicians and even in 2005 only seems to have only one medical practitioner involved in clinical work out of the total committee of 18.Most committee members are bureauocrats, vets or toxicologists without clinical experience. How would this committee approving RU486 adequately monitor safety or enforce medical supervision?

## **Background of RU486**

RU-486 is the name commonly used for an artificial steroid that blocks progesterone, a hormone needed to continue a pregnancy.  $^{2\,3}$ 

# Mifepristone is the generic name for RU-486 An RU-486 abortion involves two drugs

When taken alone, RU-486 causes a complete abortion only about 60% of the time.<sup>3</sup> or up to 90% in some studies .Therefore a second drug, a prostaglandin ,usually misoprostol, is given 48 hours later to increase its effectiveness. The prostaglandin causes uterine contractions to help expel the embryo.

**Misoprostol** (brand name **Cytotec**) is the prostaglandin used with RU-486 in the U.S.

**Important Notice:** The manufacturer of Cytotec (misoprostol) has warned doctors that it recommends this drug not be used for abortion .Many doctors however ignore this advice and still give Misoprostol with RU486 to ensure that the abortion occurs in 98% of cases.

# 2) Adverse Events and Side Effects of RU486

Eight deaths have occurred in recent years related to RU-486 abortions: 4 in California, 1 in Canada, 2 in the United Kingdom and 1 in Sweden. In addition, a Tennessee woman died from a ruptured ectopic pregnancy after undergoing an RU-486 abortion. <sup>4</sup>

The death rate for women who have an RU-486 abortion is 1 per 100,000 compared with 0.1 per 100,000 according to Professor Greene from Harvard school of Medicine who discussed serious concerns about the dangers of RU486 in the New England Journal of Medicine in Dec 2005. In other words the death rate for women from RU486 is 10x greater than that of surgical abortions. <sup>5</sup>

On November 15, 2004, the FDA reported having received 676 "adverse event" reports concerning RU-486 abortions, including 17 ectopic pregnancies, 72 cases where blood transfusions were needed, and 7 serious infections. These women were healthy before the use of mifepristone and became very sick or died shortly after its use. 6 The most common fatal adverse event is sepsis which may present without fever and progress rapidly to death6

In U.S. trials of RU-486/misoprostol, at least 99% of patients experienced at least one of the following:

# abdominal pain (cramping) (97%)

- nausea (67%)
- headache (32%)
- vomiting (34%)
- diarrhea (23%)
- dizziness (12%)
- fatigue (9%)
- back pain (9%)
- uterine hemorrhage (7%)
- fever (4%)
- viral infections (4%)
- vaginitis (4%)
- rigors (chills/shaking)(3%)<sup>37</sup>

... Approximately 23% of the adverse events ... were judged to be severe."38

The **Cytotec (misoprostol) label** contains a "Special Note for Women" which states in part: "Miscarriages caused by Cytotec may be incomplete, which could lead to dangerous bleeding, hospitalization, surgery, infertility, or maternal or fetal death."

<sup>&</sup>quot;More than one adverse event was reported for most patients.

1. Hospitalizations. Patients in U.S. trials were carefully screened to be in good health, yet fourteen had to be hospitalized, eight for severe excessive bleeding.<sup>39</sup>

**Emergency room visits.** Another nineteen patients were treated in emergency rooms, but not admitted to the hospital.<sup>40</sup> Sixteen had excessive bleeding; the others were experiencing chest pain, cramping, and nausea and vomiting.<sup>41</sup>

#### 2. Pelvic Infections

A California teenager, Holly Patterson, died from septic shock in September of 2003 after taking RU-486. She went to the hospital several days after receiving the pills and according to the San Francisco Chronical she was told "her pain and bleeding were normal, and she was sent home with painkillers." Three days later, she returned to the hospital where she died of septic shock. Holly's father this week called on the AMA to stop RU486 entering Australia (The Daily Telegraph Mon 28/11/05) In the USA Federal drug regulators have discovered that all four women in the USA who died after taking an abortion pill suffered from a rare and highly lethal bacterial infection, a finding that is leading to new scrutiny of the drug's safety. Officials from the F.D.A. and the federal Centers for Disease Control and Prevention have decided to convene a scientific meeting early next year to discuss this.

Among other issues, the experts hope to explore whether the abortion pill, called Mifeprex or RU-486, somehow makes patients vulnerable to an infection with Clostridium sordellii, the lethal bacteria. Warnings about the drug's possible link with Clostridium sordellii were placed on Mifeprex's label in July, and the drug agency without announcement updated this information on its Web site on Nov. 4 it discovered that all of the deaths involved the lethal bacteria.

In each case, Clostridium sordellii infected the women's uteruses, flourished and then entered their bloodstreams. The bacterium can cause nausea, vomiting, diarrhea and weakness but may not induce fever, so victims often fail to realize how sick they are until it is too late and succumb to toxic shock. Antibiotics are often ineffective once an infection has flourished because even in death, the bacteria release toxins. <sup>7</sup> It would be extremely difficult for Australian doctors to detect or treat this rapid lethal infection.

Population Council's RU-486 drug trials in Canada were suspended in 2001 following the September 1, 2001 death of a woman participating in the trials, from septic shock due to a bacterial infection. The Canadian newspaper, *National Post*, reported that she took RU-486 pills on August 23 and returned two days later for misoprostol. By August 28 she was bleeding and suffering from cramps. She was hospitalized with unspecified side effects and died September 1, from a toxic-shock type syndrome brought on by a bacterial infection identified as *Clostridium sordelli*. The Vancouver abortion provider heading the Canadian drug trials, Dr. Ellen Wiebe, told the National Post that "The drugs caused the abortion and the infection is related to the abortion. ..."

# Studies on Infection Rates Following RU-486 Abortions

In a World Health Organization (WHO) study, 30% of women who had incomplete

RU-486 abortions developed pelvic/genital tract infections because one effect of the drugs combination is to suppress immune system response. In fact, the WHO study calls for women to receive antibiotics for six weeks following an RU-486 abortion.<sup>44</sup>

One review of RU-486/prostaglandin regimens around the world reports on a trial involving 2,000 cases.  $^{45}$  "The most common problems reported at follow-up were continued pain, vaginal bleeding, and offensive discharge. Antibiotics were prescribed for 5%

of the 1,322 women for presumed genital infection." 46

Four percent of the women in U.S. trials had RU-486-related fever, viral infection and vaginitis. <sup>47</sup> Ten cases of endometritis (inflammation of the uterine lining) also occurred. <sup>48</sup>

# 3. Excessive bleeding Near fatalities in U.S. and China.

*lowa.* An emergency room doctor, Mark Louviere, M.D., treated a woman from Waterloo, Iowa two weeks after she had taken RU-486 at the local Planned Parenthood clinic. When **she arrived at the ER, according to Dr. Louviere's testimony, she was "in obvious shock" having "lost between one-half to two-thirds of her blood volume. ... It was my clinical opinion that she would die soon. ... 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."** 

*China.* "Press reports from Henan province and Chengdu relate cases where women narrowly escaped death when excessive bleeding occurred after taking RU-486 without a physician's supervision," <sup>50</sup> according to the U.S. Embassy in Beijing. Some Chinese women had been able to obtain the drug from pharmacies or on the black market. Recently China banned all pharmaceutical sales of RU-486 in order "to guarantee patients' safety and protect their health." <sup>51</sup>

Severity of bleeding. Due to excessive bleeding, 25 women in the U.S. trials had to be hospitalized or treated in emergency rooms, 56 required surgery and 22 received intravenous fluids.<sup>52</sup>

Four patients in U.S. trials received blood transfusions; three of them had to be hospitalized.<sup>53</sup> One hundred forty-six patients (about 7%) were given uterotonic medications to help stop excessive bleeding.<sup>54</sup>

Up to 8% of patients had a decrease of more than 20% in hemoglobin or hematocrit levels.  $^{55}$ 

**Duration of bleeding.** Nine percent of women in U.S. trials bled for over 30 days, and one percent of women were still bleeding 60 days after taking RU-486. 56

In a Columbia University study, 20% of women bled or spotted for five to six weeks. 57

Two women describe bleeding. Two patients in Des Moines, Iowa RU-486 trials told a *TIME* magazine journalist that their bleeding was "like turning a jug of water upside down" and "like a faucet was turned on. There was a steady stream of blood. I

passed a golf ball size blood clot that scared me."58

#### 4. Allergic reactions

The FDA warns that mifepristone (RU-486) and misoprostol should not be given to women with known allergies to either drug,<sup>59</sup> but it doesn't explain how a woman would know she's allergic to either of these drugs before taking them.

"The common complications of medical [i.e., RU-486/ prostaglandin] abortion are profuse bleeding and allergy. ...

**Allergic reactions were not uncommon**, manifesting in facial edema [swelling], skin rash and itching, numbness of feet and hands, and even a serious case of allergic shock. The potential for such reactions is one reason to keep clients for observation. <sup>160</sup>

#### 5. Cardiopulmonary problems

After taking misoprostol, up to 1.4% of patients in U.S. trials had hypotension and up to 1.7% of patients had hypertension. A decrease in heart rate of more than 20% occurred in up to 21.3% of patients after taking misoprostol. An increase in heart rate of more than 20% after misoprostol occurred in up to 14.1% of patients. 61

Prostaglandins used with RU-486 for abortion have caused life-threatening cardiovascular complications, including 3 myocardial infarctions (1 fatal) and 3 cases of severe hypotension. 62

#### 6. Emotional and psychological reactions

The former chairman of Roussel-Uclaf (the French company which developed RU-486), Edouard Sakiz 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." <sup>63</sup>

Catherine Euvrard, formerly a spokeswoman for Roussel-Uclaf who now holds the same job for the new French manufacturer of RU-486, Exelgyn, has said: "When [women] take a pill, they have the feeling they are truly responsible for the abortion. ... [There can be more] psychological pain. "64

"During this critical two-week period [between 49 and 63 days] the tiny embryo in an amorphous sac begins to look very much like a baby, with a discernible head and limbs. ... Nurse Frenpzel remembers a day ... when she ... saw six surgical dishes with six embryos in them by the sink. 'It was upsetting,' she said. 'It was like looking at a little row of people. The women too were shocked when they looked at what they had expelled." 65

"You have to be very confident to choose this method. It may be physically more natural, but psychologically it hits you much harder. You preside over the killing of a baby, completely unblinkingly. For women who are confused or vulnerable, and of course, so many are in this position, it is really terrible."

One woman in U.S. trials was hospitalized for depression after attempting suicide. 67

**3) Serious physical and psychological damage** can be done to women through RU486. Although some argue an abortion at home may give a woman privacy it also burdens a woman with loneliness, isolation and the trauma of delivering tiny dead baby of 6-12 weeks development alone and at home.

Even the president of Roussel-Uclaf acknowledges that the RU486 procedure is traumatic. He described the RU486 procedure as " an appalling psychological ordeal because the woman .. has to "live" with her abortion for at least a week using this technique" 1

# 4) Serious medico-legal problems

RU486 related litigation would only add to the medical indemnity crisis that has occurred in recent years. The highest premiums are paid by individual obstetricians/gynaecologists up to \$140,00-\$160,000 per year. This is partly due to massive payouts because of babies born with abnormalities. Even a small number of cases related to RU486 could cause massive payouts.

# Lawsuits about RU-486

A Tennessee woman died from a ruptured tubal pregnancy five days after taking RU-486. A lawsuit alleges that clinic failed to diagnose her medical condition, resulting in her death. for more information.

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. (The New York Times 23/11/05)

Medical and women's groups join in petition to the Food and Drug Administration to halt the distribution and marketing of RU-486 pending review of the safety of RU-486. At least six women developed serious illnesses and at least two women have died after taking RU-486 to cause an abortion. **Few doctors offer RU-486** 

According to a September 24, 2001 Kaiser Family Foundation survey, only 1% of general practitioners and 6% of gynecologists gave RU-486 to a patient in the first year that it was available in the United States. Among doctors who specialize in abortion, only 12% have offered RU-486.<sup>70</sup>

Clinics which do a high volume of business are more likely to offer RU-486 abortions. The National Abortion Federation [NAF] estimates that half of NAF- member clinics offer mifepristone.<sup>71</sup>

Almost all college and university health centers will not dispense RU-486, because, they explain, "they can't meet FDA guidelines

for administering it safely."72

#### Reasons doctors don't offer RU-486

"In the Kaiser survey, discussed above, 37 percent of the gynecologists surveyed said they had not prescribed the drug because they personally opposed its use." While some doctors were concerned about protests or violence, others gave the following reasons: "lack of patient demand" (62%); "not interested in performing abortions" (49%); and "did not have office space to set aside for women taking the pill and awaiting its effects" (48%).

### RU-486 vs. surgical abortion

Dr. Mitchell Creinin conducts seminars for doctors who are considering giving RU-486 to their patients. The New York Times describes his experience this way:

[While] hundreds of doctors - family practitioners and obstetricians - have attended his seminars thinking that they could begin providing mifepristone to their patients seeking abortions, their eagerness to prescribe the pill often diminishes as they heard him talk.

He told them about the office visits a woman must make, the counseling a doctor must do, the backup medical services that must be provided and the state laws that must be followed.

"When you go through everything, they just say, 'Oh no. This is a lot more complicated than I thought. I have to think about it.'" Dr. Creinin said. "Most doctors who answered the surveys saying they are interested in offering this, change their minds when you tell them what's involved." "<sup>14</sup>

### **Cost a Factor**

Some news reports say that an RU-486 abortion may cost about US \$75 - \$100 more than a surgical abortion, but other providers say that they have to charge double the price of a surgical abortion because of the extra visits, counseling and monitoring involved. 75

A first trimester surgical abortion generally costs US\$300-\$375. Two clinics mentioned in press accounts said they charge US\$600 for an RU-486 abortion.<sup>76</sup>

#### What some doctors say about the cost:

Even among the 27% of gynecologists in the USA who already offer surgical abortion, many who had expected to use mifepristone have since backed away from it. In large part, that's because few anticipated the drug's manufacturer, Danco Laboratories, would charge as much as it does for the three-pill regimen: US\$270.

"The medication cost alone is so high, and when you add the physician fee and the cost of ultrasound, the price was prohibitive," said one Bergen County [N.J.] abortion provider who planned to offer it. "Once we presented it to our patients, they all said no." . . <sup>77</sup>

#### CONCLUSION

As a GP experienced in women's health problems I would urge you to maintain the ban on RU486. There is strong medical evidence indication that RU 486 has adverse medical outcomes for women including the deaths of eight women and 23% of users experiencing serious adverse effects. The adverse psychological effects of abortion have been documented in at lest 24 studies and even the promoters of RU486 acknowledge using RU486 is an appalling psychological ordeal. RU486 is used for abortions up to nine weeks. I have counselled many hundreds of women over the years and witnessed first hand the adverse psychological effects that abortion has on many women. RU 486 is lethal to unborn babies and is like a human pesticide causing severe malformation to the babies that survive.

We need to focus on offering counselling and support for women with unplanned pregnancies. We need positive prevention strategies for unplanned pregnancies NOT promoting RU486 abortions as the "quick-fix " solution which is a decision women may regret for the rest of their lives.

I request to appear in person to make a submission to your committee in early February '06.

Please contact me as soon as possible if I can appear in person to make a submission or provide any further details on this important matter.

Yours Sincerely

Dr Catherine Lennon MBBS FRACGP ICBCLC

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