The Secretary, Community Affairs,
Senate Committee Inquiry into RU 486
Parliament House,
Canberra ACT 2600

(Total - 8 pages)

SUBMISSION ON RU 486

Dear Senators,

As senior counsel with over 50 years experience as a barrister and having acted in numerous personal injury cases, I am writing to draw your attention to the fact that there are already several legal cases pending against Danco Laboratories in the USA for death and/or injury caused by RU 486.

Until these cases are resolved, it is my opinion that the Australian TGA should not be authorised by our Parliament to determine the safety of the abortion drug RU 486 as all the facts will not be known until the evidence is heard in the US cases and the outcome has been judicially determined.

I have acted for and obtained damages for women psychologically traumatised by abortion, including a case where a woman passed recognizable fetal parts. She was so severely traumatised that she suffered gross psychological damage and was still unable to work when her case was settled at mediation. It was not anticipated she would be able to work in the foreseeable future. Her quality of life was minimal. Such trauma is likely to occur more frequently with the use of RU 486 where the woman will often be aborting at home. With surgical abortion ordinarily care is taken to ensure that the woman does not see any parts of the fetus because of the known traumatic effect of the sight of identifiable fetal parts.

I have also acted in other abortion-related damages cases for women: I would appreciate the opportunity to appear as a witness before your inquiry and outline the physical and psychological trauma experienced by women following abortion. Such trauma will be exacerbated with the prolonged RU 486 procedure which takes a week or more, compared with surgical abortion which is relatively swift.

Because of what is already well documented about the possible effects of RU 486, it seems to me many legal actions for negligence are likely to be brought against medical practitioners prescribing its use, when there is resulting injury to the patient, nor would I rule out the possibility of legal action against the TGA if its decision leads to making the drug available in Australia. Depression leading to suicide is amongst the possible adverse reactions. See attached note.

Also attached is background information from Concerned Women for America on Danco Laboratories and the manufacture of RU 486.

Charles Francis

Charles Francis, AM, QC, RFD
12 Denham Place,
Toorak, Vic. 3142
Ph:(03) 9822 5218
Fax: (03) 9822 3069

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SUICIDE LINK TO ABORTION

Springfield, IL — A study published in the August edition of the Southern Medical Journal reveals that women who have abortions are at significantly higher risk of near and long term death than women who give birth. This contradicts the widely accepted opinion that abortion is safer than childbirth.

Researchers examined death records linked to Medi-Cal payments for births and abortions for approximately 173,000 low income Californian women. They discovered that women who had abortions were almost twice as likely to die in the following two years. They also discovered that the elevated mortality rate of aborting women persisted over at least eight years. Over the eight year period studied, women who aborted had a 154 percent higher risk of death from suicide, an 82 percent higher risk of death from accidents, and a 44 percent higher risk of death from natural causes.

This is the second large record based study to find elevated mortality rates among women following an abortion. In 1997, a government funded study of maternal deaths in Finland sent a tremor of worry through family planning agencies when it revealed that in the first year following an abortion, aborting women were 252 percent more likely to die compared to women who delivered and 76 percent more likely to die compared to women who had not been pregnant. Many of the extra deaths were due to suicide.

The new study confirms the trend found in Finland using a large sample of American women. In addition, where the Finland study was limited to a one year follow-up, the new study reveals higher mortality rates persist over at least eight years.

-- Another study has confirmed the fact that women who have abortions suffer from mental anxiety, guilt, shame, and distress years later. Those negative emotional feelings can last as long as five years after the abortion or even longer, the Norwegian study found.
The study, published in the journal BMC Medicine, in Norway compared 40 women who suffered a miscarriage and 80 women who had abortions. Researchers questioned them 10 days, 6 months, two years and give years after what happened.

The survey found that women who had miscarriages felt more negative emotions shortly after the event compared to women who had abortions. But long-term, women who had abortions experienced significantly more distress and anguish.

Women who had abortions were 10 times more likely to have negative long-term feelings about it compared with women who had miscarriages.

The Oslo University researchers said women who have abortions should be given information telling them of the adverse emotional reaction they will likely have to it down the road.

The study follows on the heels of a comprehensive study in Finland showing that those who have had abortions have higher rates of suicide than women who carry their pregnancies to term.

The comprehensive three-year study of the entire population of women in Finland found that, compared to women who have not been pregnant in the prior year, deaths from suicide, accidents and homicide are 248% higher in the year following an abortion.

The suicide rate among women who had abortions was six times higher than that of women who had given birth in the prior year and double that of women who had miscarriages.

The epidemiological study, published in the European Journal of Public Health, was conducted by Finland's National Research and Development Center for Welfare and Health.

Pro-life group said the new Norwegian study confirmed what they have been saying for many years -- namely that women will eventually severely regret their abortion decisions.

Richard Warren, from the Royal College of Obstetricians and Gynecologists, reacting to the new study, agreed that abortion "may bring with it long-standing feelings of anxiety and guilt."

RU-486: Killer Pills 9/10/2002
By Wendy Wright

The FDA broke its own rules in the fast-track approval of the "abortion pill." Sadly, women are paying with their lives.

Most people assume that advances made in medicine and science are helpful—and save lives. Regrettably, that is not always true. In the case of the abortion pill, RU-486, women are not helped—and lives are certainly not saved. Yet in September of 2000, the Food and Drug Administration (FDA) approved RU-486, or Mifeprex, for sale in the United States– a drug whose only purpose is to kill human beings.

POLITICS AND CONTROVERSY
There are reasons this chemical abortion is controversial. In 1993, President Bill Clinton overturned the ban on RU-486. He ordered the U.S. Department of Health and Human Services (HHS) to review ways to test, license, and manufacture the drug. HHS Secretary Donna Shalala compelled Roussel-Uclaf, the French manufacturer of RU-486, to hand the patent over for free— to the Population Council, a pro-abortion group. The Population Council used intense political pressure on the FDA to approve the drug without the necessary testing or restrictions to ensure patients' safety.

The Population Council created Danco Laboratories to market and distribute RU-486. Danco could not find a company in the United States willing to manufacture the drug, due to the risk that healthy women would be injured or have children born with abnormalities. So it contracted with a company in China, which was previously cited by the FDA for tainted drugs.

HOW RU-486 WORKS
In their campaign to promote RU-486, pro-abortion activists claimed that RU-486 makes abortion "easier," "safer" and "more private." But there is nothing easy or safe about RU-486.

The FDA limits RU-486 to women in the first seven weeks of pregnancy. After taking three tablets in the abortion facility or doctor's office, the woman goes home. This drug blocks progesterone from getting to the developing baby. Without this nutrient hormone, the baby starves to death.

Thirty-six to 48 hours later, the woman returns to the doctor to take a second drug, misoprostol, to expel the baby. Misoprostol is an ulcer drug that the manufacturer, Searle, has warned doctors should not be used in pregnancy-related conditions. It is at this time that the woman is most likely to suffer complications.

Seven days later, she returns for an exam to make sure the baby has been expelled and to monitor her bleeding. If the procedure failed, the woman then undergoes a surgical abortion.

The procedure requires three clinical visits and access to emergency medical facilities in the event of complications.

SIDE EFFECTS
Women who take RU-486 experience firsthand just how difficult it is. Common side effects include painful contractions, nausea, vomiting, diarrhea, pelvic pain and spasms, dizziness and headaches—as well as the trauma of potentially seeing their aborted baby. Some women have been hospitalized and required surgery and/or a blood transfusion. In most cases, women endured prolonged bleeding, anywhere from nine to 30 days.

It is not known what the potential long-term side effects might be on a woman's fertility, future pregnancies or immune system.

Since its approval, one woman died from a ruptured ectopic pregnancy. Two 15-year old girls suffered life-threatening infections. One 21-year-old had a heart attack. A woman in Canada died during the trials from bacterial infection, which caused the trials to be suspended. These were healthy women, who, after taking RU-486, ended up very unhealthy.

Edouard Sakiz, former president of Roussel-Uclaf, described RU-486 as "not at all easy to use." He explained, "The woman must live with this for a full week; this is an appalling psychological ordeal."

ABORTION BEFORE SAFETY

In June of 2000, the FDA notified the Population Council of the various restrictions under which RU-486 would be approved—all intended to ensure the safety of the patient. These restrictions reflected the limitations used in the trials and how it is used in Europe. For example, ultrasound must be used to determine the age and place of pregnancy, since the complication rate for RU-486 increases dramatically if used after 7 weeks, and it does nothing to treat an ectopic pregnancy, which has the same symptoms as common RU-486 side effects pain and bleeding.

The Population Council leaked the list of restrictions to pro-abortion groups and the media. The groups complained publicly and to the FDA that the restrictions would limit the accessibility of the drug. Newspapers ran editorials criticizing the FDA. The FDA buckled and dropped nearly all the guidelines intended to protect patients.

The remaining restrictions were weakened. For example, no longer could only physicians trained in dating pregnancies, managing complications or performing surgical abortions as a backup be allowed to administer RU-486. Instead, FDA allows RU-486 to be "provided by or under the supervision of a physician." No qualifications were established as to who can work "under the supervision of a physician."

ILLEGAL APPROVAL

Concerned Women for America, along with the American Association of Pro-Life Obstetricians and Gynecologists and the Christian Medical Association, filed a Citizen Petition with the FDA on August 20, 2002. This legal document outlines the numerous violations the FDA committed in its approval of RU-486 and how these violations resulted in the injury and death of women.

1. RU-486 was approved under a special "restricted distribution" approval process known as "Subpart H," reserved only for drugs that treat "severe or life-threatening illnesses." Even the Population Council complained that approval under this provision was "unlawful, unnecessary and undesirable." Pregnancy is not a severe or life-threatening illness. Other drugs approved under Subpart H treat fatal diseases, such as cancer or AIDS, and can have serious side effects —considered acceptable when the alternative is death. However, Subpart H allows the FDA to retain the right to oversee the drug's use after approval, and the right to pull the drug if it proves too dangerous or the manufacturer allows the drug to be used improperly.

2. The clinical trials to test the safety and efficacy of RU-486 were seriously defective. Neither the French nor the U.S. trials met FDA's standards. The data from the French trials suggest fraud, evidence tampering and under-reporting of complications. No data from the U.S. or French trials were obtained from blind testing, from randomized tests or from comparisons with control groups—FDA requirements to ensure unbiased trials. Yet even these biased trials are not reassuring about the safety or efficacy of this drug: 99 percent of the U.S. test subjects suffered some adverse event, and 23 percent of those were considered serious. Abortion was complete in only 92 percent of the test cases.

3. Nearly all the safety precautions the FDA recommended to protect women from being injured or killed by RU-486 were dropped from the final approval. These precautions included ultrasound diagnosis to verify the age and location of the pregnancy, and that the prescribing physician be able to treat an incomplete abortion and to have admitting privileges at a nearby hospital. These are all lower safety standards than required in other countries where RU-486 is used.

4. FDA ordered that a second drug, misoprostol, be used in conjunction with RU-486, since RU-486 is not effective in completing an abortion alone. However, misoprostol is an ulcer medication and its manufacturer, Searle Laboratories, warned doctors it does not want it used for abortion. The FDA has, in effect, mandated an unapproved "off-label" use of a drug, an action that is utterly without precedent or legal authority.

5. The FDA waived the "pediatric rule" with no explanation. Any drug given to adolescents must be tested on adolescents. Teenagers' bodies go through rapid hormonal maturation; their bodies are different from adults. No one under 18 (or over 35) was allowed to participate in the RU-486 clinical trials. Other countries have the same age restrictions. Yet the FDA did not limit the age of females to whom RU-486 could be given. Such prominent liberals as Sen. Hillary Rodham Clinton (D-New York) and Rep. Henry Waxman (D-California) have avidly championed the enforcement of the "pediatric rule" because they fear that pharmaceutical companies might endanger the health of children by cutting corners in the clinical trials.

6. Complications reported to the FDA demonstrate that RU-486 is a serious threat to the health and safety of women. These include two fatalities and 20 other near-fatal complications including a heart attack, two cases of systemic bacterial infection in 15-year olds and several hospitalizations for hemorrhaging. The FDA and Danco sent a letter to physicians in April 2002 warning of the complications reported since the FDA approved RU-486. This alone would cause an ordinary drug to be removed from the market immediately.

7. Danco, the distributor of RU-486, has a legal obligation to ensure that the drug be administered only in accord with the procedures approved by the FDA. Yet there are abortion providers who are advertising that they will administer RU-486 up to nine weeks of gestation (instead of the seven-week limit set by the FDA) and who have patients self-administer misoprostol, the second drug, at home. It is obvious that Danco is failing to live up to its post-approval obligations.

The Citizen Petition and related documents can be found at www.cwfa.org.

WOMEN AT RISK

Abortion is a difficult, traumatizing procedure that has ended the lives of millions of children and scarred the women who endured it. Chemical abortions like RU-486 will not advance women's health. They will only advance our national tragedy of abortion.

The FDA violated its own safety regulations when it approved RU-486 and put women's lives and health at risk. To protect further women from being harmed, it must pull its approval for Mifeprex.

Wendy Wright is senior policy director for Concerned Women for America.

RU-486: Don't Go There 12/12/2005
By Donna Harrison, M.D.

Members of Australia's Parliament need to know that RU-486's safety is now being heavily scrutinized in the U.S.

Editor's Note: This column first appeared on an Australian Web site, Onlineopinion.com.au. It is reprinted with permission.

As an American obstetrician-gynecologist, I have studied the U.S. administrative history and safety record of the abortifacient RU-486 for 10 years. As a result, I am dismayed that Australia's Parliament may overturn a system where the health minister is made responsible for approving abortion drugs. Before acting, the members of Parliament need to know that RU-486's safety is now being heavily scrutinized in the U.S. RU-486 is a dangerous drug which should not be approved in your country.

An RU-486 abortion consists of a two-drug regimen. Typically, 200 milligrams of RU-486 is taken orally followed, one to two days later, by the vaginal insertion of 800 micrograms of misoprostol. RU-486 starves the embryo of blood by blocking placental progesterone receptors; misoprostol induces uterine contractions to expel the dead embryo and other tissue.

Serious dangers can arise if a pregnant woman takes the first pill but fails to take the second, or if she or her clinic miscalculates dates, since the regimen's dangers substantially increase after 49 days from the date of the last menstrual period. Accurate pregnancy dating requires the use of ultrasound, but ultrasound use is not required in the U.S.

Since 2001, five North American women (four U.S., one Canadian) have died from septic shock after taking RU-486. In each case the infection was caused by a bacterial species, Clostridium sordellii, an anaerobe found rarely in the vaginal flora. In women of childbearing age, lethal infections caused by C. sordellii were rare prior to the Food and Drug Administration's (FDA's) approval of RU-486. Why are these deaths occurring?

Two scientists have independently offered similar analyses. Normally, the body's innate immune system destroys bacteria before they are able to multiply and secrete toxins into the bloodstream. However, RU-486's potent ability to block receptors for cortisol, a key signaling chemical in the immune system, causes it to malfunction. In some cases septic shock results.

As is the custom of the FDA, the agency is taking these deaths quite seriously. It updated the RU-486 labeling in November 2004 to include "new information on the risk of serious bacterial infections, sepsis, and bleeding and death that may occur following any termination of pregnancy, including use of Mifeprex." In July 2005, after two additional sepsis-related deaths were announced, FDA issued a national public health advisory that highlighted the risks noted previously. The New York Times reported this week that officials from both the FDA and the U.S. Centers for Disease Control and Prevention have decided to work together and convene a scientific meeting in early 2006 to analyze these cases in an effort to protect patients.

Unfortunately, RU-486's dangers do not end there. The FDA has received reports that more than a dozen American women have taken RU-486 while having an ectopic pregnancy, where the embryo is located outside the womb. In the U.S. this danger is magnified because the FDA regimen does not require ultrasound documentation of intrauterine pregnancy prior to the drugs' administration.

When an ectopic pregnancy ruptures, a woman will rapidly bleed to death internally unless she undergoes immediate surgery, and at least one American has died this way. Unfortunately, the signs and symptoms of ectopic pregnancy, like cramping and bleeding, mirror those a woman will experience while undergoing an RU-486 abortion. An endangered patient would reasonably expect her symptoms to stem from the RU-486 abortion and not from a life-threatening ectopic pregnancy. This danger will be heightened for women who do not have immediate access to surgical services, and this will be particularly so for women in rural areas.

One year ago, The New York Times reported that FDA was aware of 72 cases of blood loss so severe they required transfusions. I have examined over 850 adverse event reports that were submitted to the FDA. Bear in mind that these reports are filed voluntarily and that the agency receives submissions on only 1-10 per cent of all drug complications. That being said, the amount of blood loss in RU-486 abortions gone awry is staggering.

At least 80 women required emergency transfusions, with over half experiencing life-threatening hemorrhages requiring large amounts of blood. Several required the replacement of their entire blood volume. All would have died had they not received timely access to medical and surgical services. Therefore, rapid access to emergency services capable of providing transfusion and surgery is critical for patient survival.

Since 2000, the American medical community is now able to review "real world" RU-486 adverse event reports, and the data is alarming. RU-486 cannot be administered safely, and Australians will be ill-served by political efforts to hastily approve a drug whose true safety profile is only now being accurately discerned.

Dr. Harrison is the current Chairman of the Board of Directors of Americans United for Life, a public policy and public interest law firm. She also serves on the Board of Directors of the American Association of Pro-life Obstetricians and Gynecologists (AAPLOG). She is Chairperson of the AAPLOG subcommittee on RU-486, and coauthored the Citizen Petition filed with the FDA by CWA, AAPLOG and the Christian Medical Society to remove RU-486 from the market.