CATHOLIC WOMEN'S LEAGUE AUSTRALIA INC

Member Organisation of the World Union of Catholic Women's Organisations
'NGO in Consultative (Roster) status with the
Economic and Social Council of the United Nations'

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11th January, 2006

Community Affairs Legislation Committee
Department of the Senate
Parliament House
CANBERRA ACT 2600

Dear Secretary,

Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005.

On behalf of Catholic Women's League Australia Inc. I herewith forward a Submission concerning the abovenamed Bill.

Yours sincerely,

Maureen Clark
National Secretary
CWLA Inc.

Submission to Community Affairs Legislation Committee

Title of Bill: **Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005**

Catholic Women's League Australia Inc. urges the rejection of the Therapeutic Bill to repeal Ministerial responsibility for approval of RU486, thereby transferring responsibility for drugs approved, from the Minister for Health to the Therapeutic Goods Administration. This would place RU486 in a different category from the current law, agreed to by both sides of Parliament in 1996, that allows the importation of RU486 for purposes other than abortion (e.g. when treating a rare form of cancer) where its use is appropriate.

The debate surrounding the approval of RU486 for abortion is complicated since the aim and effect of its use, in conjunction with a prostaglandin, is to take life from and expel a developing baby.

Catholic Women's League Australia Inc. deplores the move to approve RU486 as an abortifacient. The 8,000 members of Catholic Women's League Australia Inc. are concerned, NOT ONLY FOR WOMEN WHO MAY FALL VICTIM TO SEPSIS, OR TO ONE OF THE OTHER 676 ADVERSE EFFECTS OF RU486 LISTED BY THE US FOOD AND DRUG ADMINISTRATION, (current public health advisory attached, with another due early in 2006) but also for the loss of their children and all that these 'lost' children could have contributed to society.

Since RU486 is now being considered as a means of medical abortion it is not enough to focus entirely on the medical dimension and the possibility of unwanted complications arising from its use. The proposal to allow the prescription of RU486 as an abortifacient is a matter for moral, social and political judgement extending beyond the Therapeutic Goods Administration. **It is a serious matter that must involve the Minister for Health, the Parliament and widespread public debate.**

The Australian Institute of Health and Welfare states that young women aged 20 – 24 have more than one abortion for every two live births. (Mercury 16.12.'05). National figures show that one in four pregnancies are aborted each year. It is as if we no longer value human life – yet we are truly compassionate and supportive of victims of war and natural disasters.

A civilised society respects the sanctity of human life from the moment of conception until natural death. Jewish author, Chaim Potok writes: 'He who destroys a child destroys a nation' and he is right. Today nearly one in four Australian women of

childbearing age will never become mothers and the number of one-child families has tripled since 1985. The current Australian fertility rate is only 1.77 compared with 3.6 in 1961. (A fertility rate of 2.1 is needed for replacement.) One in six Australian couples are infertile. There are couples desperate to have a child, and women who repeatedly expose themselves to the serious health risks of super-ovulatory drugs in order to have a child. Humanity requires that adoption be both encouraged and accepted as a viable option for the nurture of children.

Adverse effects for the mother

Despite the makers of Misoprostol issuing a serious warning about its use in conjunction with Mifepristone, FDA reports the death of at least four women from sepsis following the killing of the baby with Mifiprex (Mifepristone) and the incomplete expulsion of the dead baby with the aid of Misoprostol. (attachment 1.)

The U.S. Food and Drug Centre for Drug Evaluation and Research states that **"It is not known which antibiotic and regimen (what dose and for how long) will be effective in cases of infection such as the ones that have occurred" following the use of RU486**. The number of women left sterile following abortion is not known. However it is known that many women have suffered serious bleeding requiring blood transfusion and some ectopic pregnancies have ruptured following medical abortion brought on by RU486. How safe can the drug be when women with any of the following conditions are excluded from tests for fear that the drug might prove dangerous or deadly for them - women suffering asthma, glaucoma, high blood pressure, liver, respiratory, renal or heart problems, diabetes or cardiovascular disease (Spitz, NEJM, 4/30/98). RU486 is known to cross the blood follicle barrier and enter a woman's ripening eggs. The long term consequences on the reproductive system of the mother's later children is unknown. (Raymond, *et al*, RU486: Misconceptions (1991).
Abortion brought about by RU486 could prove lethal for rural women who have little or no help available should problems arise. Finally the woman is faced with the trauma of disposing of the identifiably human foetus she passes at home. Babies begin to form identifying features at about 5 weeks and at seven 7 weeks (just after the second missed period) the foetus is clearly identifiable as human. There is no question that a mother's physical and mental health could be endangered if the self-administered drug becomes commonplace. Women using RU486 would be placing their lives at serious risk.

Long term effects of abortion

Miscarriage and abortion are both stressful events and a study from Norway suggests that abortion may be associated with long-term psychological distress. (WebMD Medical News, 12.12.'05) Researchers interviewed 40 women who had miscarriages and 80 women who had abortions and followed them for 5 years. Women who had

miscarriages suffered more anxiety and depression immediately after the event and six months later. But abortion was associated with more stress and anxiety two and even five years after the event. At five years, both groups had few intrusive thoughts about the event. But the women who had abortions were seven times as likely to report that they actively avoided thinking about it. When compared with the general population, women who had abortions had higher anxiety scores at all measured time points – from 10 days after the pregnancy termination to five years later. Women who had miscarriages had higher than normal anxiety scores at only one of the measured time points – 10 days after their pregnancy ended. (BMC Medical Journal Dec. 2005). Ample evidence of post abortion trauma has been available since the '70's.

When using RU486, a woman has to live with the abortion for up to two weeks before it is completed – this is an acknowledged psychological burden according to Sydney based psychiatrist Louise Newman. A Christchurch New Zealand study has found elevated rates of depression, anxiety, suicidal behaviour and substance abuse in women who have undergone abortion - not surprising since there has been an expanding body of information available since the 70's highlighting these long term effects.

CONCLUSION: Members of Catholic Women's League Australia Inc deplore the bid to approve RU486 as an abortifacient. We grieve the generations lost to abortion, and hold concern for women who may fall victim to sepsis or to one of the other 676 adverse affects of the drug if it is prescribed to kill abort a child from the nurturing environment of its mother's womb. CWLA rejects any decision to transfer responsibility for the approval of RU486 from the Minister of Health to the Therapeutic Drugs Administration. This awesome responsibility rightly belongs to the Minister for Health, the Parliament and the people.

Betty Roberts OAM
Social Issues Convenor
CWLA Inc
11th January 2006

<u>Attachment:</u> Public Health Advisory for Mifepristone

The FDA is investigating recently reported serious adverse events associated with Mifeprex (mifepristone), also known as RU-486. As a result, the FDA has issued a public health advisory highlighting the risk of sepsis, or blood infection, when undergoing a medical abortion using Mifeprex and misoprostol in a manner that is not consistent with the approved labeling. There are now four cases of deaths from infection from September 2003 to June 2005 after a medical abortion with these drugs.

The bacteria thought to have caused the fatal infection have been identified in two of the cases, and the other two cases are under investigation by the FDA, along with the Centers for Disease Control and Prevention, state and local health departments, and Danco Laboratories LLC, the manufacturer of Mifeprex. Doctors are urged to have a higher level of suspicion for sepsis in their patients taking Mifeprex.
Previously, the FDA had received reports of serious bacterial infection, bleeding, ectopic pregnancies that have ruptured, and death. Those reports led to the revision of the black box labeling for Mifeprex, approved by the FDA in 2000. The drug is approved as part of a regimen that calls for at least three visits to a doctor's office or clinic, according to the labeling. On the first visit, the woman receives counseling and a medication guide. Then she takes 600 milligrams of mifepristone by mouth while at the doctor's office. Two days later, she returns to the physician and, if she is still pregnant, takes 400 micrograms of misoprostol by mouth while in the doctor's office. Misoprostol, a prostaglandin, causes the uterine muscles to contract and end the pregnancy.

"The FDA is committed to sharing emerging drug information with the public and we believe it is important to share with health care providers and patients the latest serious reports of infection associated with this drug that we have received," says Steven Galson, M.D., Director of the FDA's Center for Drug Evaluation and Research.

Visit www.fda.gov/cder/drug/infopage/mifepristone for more inform

The following passage is taken from “notes on abortion by medical rather than surgical means” from a paper by Beth Kruse printed in the American Journal of Obstetrics and Gynaecology 2000;183:S65-S75.

Drugs used
Mifepristone (RU486 is not approved for use in Australia) or Methotrexate
followed by misopristol (a prostaglandin)

The following deals with the use of methotrexate.
Methotrexate causes the abortion or death of the foetus and the misopristol causes the uterus to contract to complete the process.

In the US the misopristol is taken by the patient at home.
The time taken for the process to be complete varies – from several hours to several days, sometimes longer.
Unlike surgical abortion, medical abortion occurs outside the surgery - distanced from trained medical help and within an unknown time frame.
Intervention is common after medical abortion and doctors need particular training, experience and skill.

Pain.
Described as greater than menstrual pain
Psychological factors like fear and ambivalence play a part.
The pain begins as the misopristol starts to take effect and an analgesic like ibuprofen (Nurofen) is recommended.
Continuing pain, how much is unclear, points to an incomplete abortion, an ectopic pregnancy or infection.

Bleeding
"Bleeding during and after abortion typically constitutes the greatest concern for both women and their care providers" The amount will be more than experienced at any time previously and with more clots.

Re length of bleeding
One study……. average 9 days ……range 1 – 32 days
Another ……average 14-17 days……..range 1 – 69 days

Women may require blood transfusion and/or surgery.
It is very important to recognise the occurrence of excessive bleeding and take action quickly.
One measure given is if it soaks through 2 thick pads per hour for 2 consecutive hours.
The woman may be alone at home trying to make this judgment.
It is very important to have well trained medical help at hand for a quick response for women experiencing this at home.
She is at risk of hypotension, tachycardia, hyperventilation, anxiety, restlessness, confusion leading to dullness and stupor. You are then facing a medical emergency.

Failed abortion.
In 90-98% of women these methods achieve an abortion. Since it can be very slow and troublesome for the women, surgical abortion often follows.
If there is still a heartbeat after 2 weeks a surgical abortion would be done.
99% of abortions occur by 36 days after methotrexate is used.
Those who have not aborted will no longer feel pregnant or have symptoms induced by the medication. It will be like waiting for a period.

Gastrointestinal side effects
Nausea – fairly common - difficult to distinguish from the usual pregnancy sickness.

Headache, dizziness, hot flushes are fairly common.

Infection may occur.

Abnormalities in the foetus.
The misopristol (the prostaglandin) can cause abnormalities in a baby who survives.

Follow up after medical abortion is very important.
In 2-10 % the pregnancy will continue, the abortion will be incomplete or there will be serious blood loss.

- End of “notes on medical rather than surgical abortion”