THE KNIGHTS OF THE SOUTHERN CROSS

Submission

Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005

Conducted by,
Senate Community Affairs Committee

Prepared and submitted by:
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Submission to the Senate Community Affairs Committee – Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005

The Committee Secretary,
Community Affairs Committee,
Department of the Senate
Parliament House,
Canberra, ACT 2600.

Dear Senators,

It is my pleasure to endorse the enclosed submission to the Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005 prepared by the Knights of the Southern Cross (Victoria) Inc.

The KSC was inaugurated in 1921 as a national organisation of Catholic men dedicated to works of charity and social welfare within the community, and to the promotion of the Christian way of life in Australian society. In Victoria it represents 2000 members, whose activities include care for the aged, support for education and various charities, as well as activities that support local communities throughout metropolitan and rural areas.

Our interest in the inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill stems from our following concerns:

- That fetal abortion has very little to do with female reproductive health; in other words pregnancy should not be viewed as some sort of 'disease'.
- That the use of the RU486 drug poses very serious health risks to Australian women.

We believe that the current system where the Federal Minister for Health has responsibility for approval of the RU486 drug is preferable to this responsibility being transferred to the Therapeutic Goods Administration. This is because RU486 does not have a therapeutic application but instead interrupts a normal and healthy physiological process, and is therefore unlike the medicines, medical devices, blood and tissues that the TGA evaluates.

I commend the submission to your careful deliberations and remain available should you wish to discuss it further.

Yours sincerely,

Jim Morrissy
State Chairman.

16th January 2006

HOW RU486 IS USED TO CAUSE AN ABORTION

In support of our case the following explanation of how RU486 causes an abortion to occur is based on information taken from the National Right to Life Website in the United States of America www.nrlc.org.

RU486 (generic name mifepristone) is an artificial chemical that disrupts the action of progesterone, which is an important hormone in the early stages of pregnancy. It does this by taking the place of progesterone in chemical receptor sites in the woman. Progesterone is important because it stimulates the growth of the lining of the uterus in which the embryo is implanted and from it receives nourishment, as well as limiting contractions of the uterus that could cause the embryo to dislodge from the lining.

Without the continued action of the progesterone, the growth of the uterine lining will stop and the natural menstrual process will begin soon after. The action of the RU486 is intended to cause the embryo to die from starvation, as it no longer receives nutrients from the uterine lining. The baby will then be expelled from the woman's body with the decayed uterine lining during the induced menstrual cycle.

According to information in a study by Sophie Christin-Maitre, Philippe Bouchard, and Irving Spitz, "Medical Termination of Pregnancy," (*New England Journal of Medicine*, Vol. 342, No. 13 (March 30, 2000), p. 951) RU486 is able to induce an abortion only between 64% and 85% of the time. This rate of successful termination is considered by researchers as "inadequate for general clinical use".

Because of this reason, the chemical abortion process requires the woman to be given a second drug two days after taking the RU486, a woman is given a prostaglandin, usually misoprostol, to cause powerful uterine contractions with the aim of expelling the embryo from the uterus.

There is a then a third visit to the doctor required after another week or two to determine if there has been a complete abortion. If there has not been a complete abortion, the abortionist generally advises the woman to have a surgical abortion to prevent the woman giving birth to a baby that has been harmed by the drug or suffering an infection because a dead embryo has not been expelled from the uterus.

THE APPROPRIATE RESPONSIBILITY AUTHORITY

When making a decision on whether the responsibility for approval of the use of the RU486 drug should remain with the Federal Health Minister or be transferred to the Therapeutic Goods Administration, it is helpful to examine the role of the TGA. The following information has been taken from the current website for the Therapeutic Goods Administration **www.tga.gov.au/docs/html/tga/tgaginfo.htm**

About TGA

The Therapeutic Goods Administration (TGA) is a unit of the Australian Government Department of Health and Ageing. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

What is a therapeutic good?

A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989).
Therapeutic use means use in or in connection with:

- *preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;*
- *influencing inhibiting or modifying a physiological process;*
- *testing the susceptibility of persons to a disease or ailment;*
- *influencing, controlling or preventing conception;*
- *testing for pregnancy; or*
- *replacement or modification of parts of the anatomy.*

From examining the above definition of a “therapeutic good” taken from the TGA website, it is our view that the RU486 drug is not a therapeutic good**.** It cannot be classified as a medicine because it does not prevent, cure or alleviate any disease or ailment. It could be argued that as RU486 inhibits the physiological process of pregnancy, its use might satisfy the above definition. However there are other chemicals, such as pesticides, which can inhibit physiological processes but these are definitely not classed as therapeutic goods. This is because the use of such chemicals does not have the objective of having a positive effect on the health of the recipient. In the same way, RU486 does not have positive health benefits for the women who use it. The objectives of chemical abortion relate more to social than physiological reasons.

The following information from the same TGA website details the risk management approach used by the Therapeutic Goods Administration when evaluating therapeutic goods:

The TGA's risk management approach

The TGA's role is to develop and implement appropriate national policies and controls for medicines, medical devices, chemicals, gene technology, blood, blood products and tissues.
In undertaking its regulatory roles, the TGA adopts a risk management approach by identifying, analysing, evaluating and treating the risks posed by medicines, medical devices, chemicals, gene technology, blood, blood products and tissues.
The approach to risk management is detailed in three documents, one for each of the regulators within the TGA group.

(The three regulators being the Therapeutic Goods Administration, the Office of Chemical Safety, and the Office of the Gene Technology Regulator.)

(a) Risk management approach to the regulation of therapeutic goods

The TGA's risk management approach to the regulation of therapeutic goods is available below. This document describes the TGA's role in the management of risks associated with medicines, medical devices, blood and tissues.
The document also provides details of how the TGA communicates both internally and with external stakeholders on risk management issues.

(b) The Office of Chemical Safety

The Office of Chemical Safety is part of the TGA Group of Regulators, within the Australian Government Department of Health and Ageing (DoHA).
The Office of Chemical Safety undertakes risk assessment and provides advice on potential public health risks posed by chemicals used in the community. The Office comprises:

- *the national industrial chemicals regulator - National Industrial Chemicals Notification and Assessment Scheme (NICNAS);*
- *chemicals assessment for public health risk assessment for veterinary chemicals, pesticides and other environmental chemicals;*
- *public health controls/standards setting (secretariat for poisons scheduling); and*
- *compliance and monitoring responsibilities to effect Australia's obligations under UN Treaties and the Customs Act and supports the National Drug Strategy for the legitimate end use of controlled substances.*

(c) The Office of the Gene Technology Regulator (OGTR)

The TGA also supports the Gene Technology Regulator in administering statutory responsibilities under the Gene Technology Act 2000. The Gene Technology Act 2000, which came into force on 21 June 2001, describes a national scheme for the regulation of genetically modified organisms in Australia, in order to protect the health and safety of Australians and the Australian environment by identifying risks posed by or as a result of gene technology, and to manage those risks by regulating certain dealings with genetically modified organisms.

From the above information, it can be argued that the TGA has a risk management plan well suited for assessing the risks associated with medicines, medical devices, blood and tissues. As RU486 cannot be classified under any of these categories, it therefore should not be assessed by the TGA.

If RU486 is classified as a chemical, it could be argued that it should be assessed according to the risk management plan of the Office of Chemical Safety. However this organisation generally assesses poisons, agricultural chemicals, pesticides and the like. Its risk assessment process is not suited to the evaluation of a chemical such as RU486 which has the stated aim of interrupting the normal process of a healthy pregnancy.

In summary, it appears that there is no specific authority that has the legal responsibility for assessing the suitability of a chemical such as RU486, which has a stated non-therapeutic objective in disrupting a healthy physiological process (pregnancy). In this circumstance, the responsibility cannot be transferred to the TGA but should remain with the more general authority. The more general authority in this case is the Commonwealth Department of Health and Ageing, which is the Responsibility of the Minister for Health.

HEALTH RISKS TO AUSTRALIAN WOMEN RESULTING FROM THE USE OF RU486

We are very concerned that members of Parliament are moving towards getting the RU486 drug approved for use in Australia in light of reports from other countries where previously healthy women have died after using the drug for chemical abortion. There have been reports of RU486 use resulting in deaths of women in Britain, Sweden and the United States of America. Particularly disturbing are reports of the deaths of teenage girls.

Increased risk of bacterial infections:

An example of the health risks that Australian women may be exposed to is highlighted in an article dated 26th November 2005 "RU 486 Deaths Probe" taken from the website for the *Weekend Australian* www.theaustralian.news.com.au. This article states that health authorities in the United States of America are investigating the safety of RU486 after four women who died after taking the drug were all found to have suffered from clostridium sordellii, a rare form of bacteria that causes blood poisoning. The investigation will seek to find out if RU 486 impairs the immune system. All four deaths have occurred since the drug was approved for use in the USA in September 2000.

Dangers from heavy bleeding:

One of the most serious side effect of chemical abortions is heavy and prolonged bleeding. It has been reported that a chemical abortion using RU486 results in an average blood loss of nearly four times the average blood loss from a standard suction abortion. A Swedish teenager is reported to have bled to death in June 2003 after receiving RU486 at her local hospital.

In the United States, Doctor Mark Louviere from Iowa reported that in November 1994 he had treated a woman, a participant in trials of RU486, who had lost between half and two thirds of her blood volume two weeks after taking RU486. This woman required emergency surgery and a blood transfusion of four units to survive. (Statement of Mark Louviere, MD, FDA Mifepristone (RU486) Hearing, 7/19/96, pp. 223-227.)

Dangers to women with other medical conditions:

The website of the National Right to Life in the USA www.nrlc.org/RU486/ru486info has a list of conditions that researchers considered sufficient grounds to exclude from clinical trials of the RU486 drug. Some of these conditions include:

- High blood pressure.
- Bronchitis.
- Use of IUDs or oral contraceptives in the past three months.
- Pelvic inflammatory disease.
- Allergies.
- Epilepsy.
- Recent intake of steroids or anti-inflammatory medication.
- Having a history of liver, stomach or intestinal disease.

It has also been reported that the trials were conducted only on women between the ages of 18 and 35.

As some of these medical conditions are reasonably common throughout the population, it is concerning that researchers found it necessary to exclude such a sizeable number of people from the trial of RU486. If this drug is only considered suitable to trial on women with perfect health, then there are important questions to be raised on how safe this drug is for use by women in the Australian community generally and how realistic and accurate the trials of RU486 were in the first place.

Psychological concerns:
In the trials of RU486 in the United States of America in 1994 and 1995, it was reported that 49% of the women aborted their baby within the four hours they were waiting at the doctor's clinic after taking the prostaglandin drug (to cause contractions to expel the baby from the uterus). Another 26% of women aborted the baby over the next 20 hours, which would likely be at their home or workplace or when travelling. At least 8% of the women did not have a complete chemical abortion and required surgery to abort the baby.

This means that nearly half of the women in the trial face the discomfort, nausea, bleeding and other side effects of a chemical abortion without trained medical professionals at hand, and perhaps when they are all alone. Assuming that this proportion would be similar to women in Australia who would use RU486 if it is approved, there is a very high chance that a large number of women may suffer psychological trauma from this experience.

As the RU486 drug is intended for use in ending pregnancies up to nine weeks after conception, the embryo would be quite well developed inside the uterus. It may be up to 6 cm long with its internal organs almost fully formed and facial features such as eyes, nose and mouth visible. In other words, it will be clearly identifiable as a little human being.

We have very grave concerns about the mother's psychological well-being from the experience of a chemical abortion, particularly if she is at home or alone. Issues of guilt and other stresses may arise as there is a good chance that she will be able to see the little human being that has been terminated as it is expelled from her uterus.

We also refer your attention to the following quotes from an article by prominent biologist and social scientist Renate Klein, associate professor in women's studies at Deakin University, on 23rd December 2005 on the website www.onlineopinion.com.au/view.asp?article=3991.

"I oppose the abortion drug RU486. I am a long-time feminist and health activist who is committed to women's access to safe and legal abortion, and I am getting exasperated with the pro-choice movement's simplistic message about RU486. It is not safe and it will not expand women's choices."

“A well-tried and simple abortion method exists: suction abortion. It is done in a doctor's surgery, and is over in minutes. If complications occur, emergency treatment is at hand. Compared with this, RU486 is messy and unpredictable. RU486 tablets and prostaglandin, taken two days later, can draw out the abortion process to two weeks or more, with bleeding, nausea, vomiting and painful contractions. One in ten women will then need a dilation and curettage to complete the abortion.”

“As Australians are increasingly turning to organic food to limit the poisons we put into our bodies, how can anyone suggest that it is a good choice for women to do exactly the opposite with an RU486-prostaglandin abortion?”

The concerns raised by women such as Renate Klein about women being asked to put a poisonous and dangerous substance such as RU486 into their bodies show clearly that this is not a standard issue that can be examined by a body such as the Therapeutic Goods Administration. The TGA has a clear focus on assessing medicines, medical devices and the like which have the aim of a positive health outcome for the person using the product. Therefore we strongly recommend to the Senate Committee that any decision about the approval of the RU486 drug should remain the responsibility of the Federal health Minister.