

Submission to:

The Senate Community Affairs Committee –
Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial
responsibility for approval of RU486) Bill 2005.

Submission from:

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Catholic Women's League Australia Inc (CWLA Inc) is a national, non-government and non profit organization of women who believe in "promoting the spiritual, cultural, intellectual and social development of women" and who demonstrate a commitment to the dignity of women, the value of all human life and the maintenance of a caring and compassionate society.

Introduction

A. The stated purpose of the bill is to remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration.

B. There is recognition that there are underlying and concomitant issues relevant to and impacting on the purpose of this Bill. Some of these issues are

1. The existence and rights of an unborn child
2. The health of the mother – current and future and including access to the required medical assistance
3. The societal implications of an additional form of abortion

1. It is our opinion that there is no need to remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration.

Sections from Schedule 1—Amendment of the Therapeutic Goods Act 1989 for which repeal is requested

.a Subsection 3(1) (definition of *restricted goods*)

This definition should remain, as the definition is quite precise and does not limit the possibility for future uses of this type of material for a strictly therapeutic purpose.

.b Section 6AA

This section should remain as is - as it does not exclude a request being made to the Minister for approval of the import any restricted goods into Australia.

.c Section 6AB

This section should remain - Process issue

.d Section 23AA

and

.e Subsection 57(9)

These sections should remain – particularly in light of previous lack of consultation within the Department (1994)

Re transfer of responsibility from Minister to TGA

“Medicines used for any purpose other than abortion are evaluated and regulated by the Therapeutic Goods Administration (TGA) alone and do not require additional approval from the Minister for Health and Ageing”. The recalls of some drugs through the TGA in the past have only occurred after considerable time has elapsed between the initial notification of ‘side effect/harm’, alerts and assessments. This is a well documented process and a very positive one but how much ‘harm’ needs to occur before the recall of a drug previously approved by the TGA.

There is evidence that mistakes have been made in the past and drugs initially thought to be safe or with minimal side effects have needed to be removed from sale/availability.

B.1 The existence and rights of an unborn child

In the debate surrounding this proposed Bill there seems to be a distinct lack of consideration for the rights of the unborn child. Whilst not wanting to debate the issues of ‘when life begins’, ‘personhood’, sentience’ or ‘human’’, consideration is due to the intention of this drug, RU486 or Mifipristone or Mifegyne to kill the child of 49 days (frequently older). Many people throughout the world believe that “birth is not the start of a new human life--just a change of the baby's

environment". Nothing is added after conception except oxygen and nutrients (food and water), the same essentials that are needed to sustain human life after birth, Society for the Protection of Unborn Children (SPUC). The salient point is that all human life is of equal value. The life of the child in the womb is neither more nor less important than that of the mother.

The Convention on the Rights of the Child refers to the necessity of the state to protect children before as well as after birth, specifically because of their completely helpless circumstance. Other documents promoting similar concepts are

- the 1959 Declaration of the Rights of the Child, (1959) "*Whereas the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth*"
- the 1976 International Covenant on Civil and Political Rights. (*Part III, Articles 6 and 24*).

Disquieting information about RU468 reveals that the percentage of treatments that fail need to be followed by a surgical abortion. There is also evidence of abnormalities in babies for whom an RU486 abortion did not work and mothers have continued with the pregnancy. In other countries where abortion is sought later in the pregnancy, there is concern and growing unease among clinicians about the number of aborted babies born alive. The Society for the Protection of Unborn Children states, "SPUC's opposition to abortion is based on ethical principles that have received universal approbation, not on religious teaching. While all major world religions promote the value of life, and while SPUC's membership includes people of various religions, SPUC is not a religious organisation.

B.2. The health of the mother – current and future and including access to the required medical assistance

Procuring an abortion by the use of RU486 is not as easy and as simple as some would have us believe. Certainly there may be some advantages, however there are disadvantages well documented, effecting physical health and psychological health as has been identified by recent research.

Up to four visits to a doctor, hospital or clinic are necessary to complete the process. The success rate of RU486 alone is not high. Some studies have it as low as 54% and RU486 is therefore often used with a prostaglandin, which induces powerful contractions of the uterus and causes the dead baby to be expelled from the womb. If the treatment fails, the baby will be aborted by a surgical method either vacuum extraction or dilation and curettage.

In an article in the Michigan Daily (2000) as the drug Mifepristone was nearing approval by the USA FDA, Lindsey Alpert, it was noted that the drug will not be offered at the University Health Services because, "We feel that we do not have the ability to give 24-hour coverage". It is the necessity for access to follow up, medical help, diagnostic services (often ultrasonography), possible emergency services and support services that makes this drug unsafe for women who for whatever reason do not or can not easily access the required assistance. Rural and isolated women are particularly vulnerable in these circumstances - rather than the drug being 'ideal for the abortion to occur in the 'privacy of their own home'.

It is interesting to note that – Danco Laboratories announced on July 18th 2005 that it is modifying the labeling for Mifeprex® to include updated safety information. This information is in relation to and came out of reports of deaths from serious bacterial infection and sepsis following treatment with Mifeprex and misoprostol.

In 1992 Annette MacDonald, Women for Women's Health, noted that how giant companies have created a reproductive technology 'market' which they have inundated with 'Products' such as the contraceptive pill, the Dalkon Shield, Norplant and Depoprovera. All of these drugs and appliances

have two things in common: (1) they were not properly tested before they were marketed, and (2) they damaged the health of literally millions of women. Enter RU486, the "abortion pill," the latest chemical innovation in fertility control - essentially a dangerous drug.

The Canadian Adverse Reaction Newsletter, (current and online) has posted information about RU486 that includes, "Common adverse effects of the regimen include abdominal cramping and vaginal bleeding, headache, nausea and vomiting, and diarrhea. Rare but fatal cases of ruptured ectopic pregnancy have occurred. There is a discussion of possible *C. sordellii* infection and the steps that need to be taken to treat this infection. **It should be noted that the combination mifepristone (RU 486) and misoprostol is not currently approved for sale in Canada.**

Information available online about RU-486 from POISINDEX has the covering statement,

All POISINDEX(R) product information is CONFIDENTIAL, intended for use by healthcare professionals, and may not be released to nonmedical personnel.

Whilst there can be good reasons for the restriction of this information, it is interesting to note that there follows 17 pages of information about problems and side effects and strategies for possibly required emergency care and resuscitation.

B. 3. The societal implications of an additional form of abortion

In 1996, former Senator Belinda Neal when speaking in the debate said that, "We acknowledge that this issue raises large concerns within the community. It raises issues beyond purely health issues. These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability" (Hansard 9/5/96). Serrin Foster, Feminists for Life, USA has stated that, "How anyone can suggest to women that RU486 is an easy fix to society's lack of resources for women and children is simply irresponsible and degrading."

The research conducted by Sexton Marketing, a professional marketing company in Adelaide that polled 1200 randomly-selected Australian adults in December 2004, and reported by Fleming and Ewing in June 2005, indicated that there is strong community support for a reduction in abortion numbers without restricting access and that 87% believe it would be a good thing if the number were reduced while at the same time protecting existing legal rights to freely choose abortion. The research further indicated there was *near unanimous support for serious consideration of all the alternatives before choosing abortion* and that there was *strong community support for women who choose alternatives to abortion*. Sixty one percent to 74% of Australians feel positively towards women who choose alternatives to abortion, only 28% are positive towards women who choose to have an abortion. This is an indication that there is a recognition that not enough is being done to inform and support pregnant women (and fathers, of course), to provide education, and offer financial and other types of support when the choice is made to continue the pregnancy. The data also highlighted the *near unanimous support for information on abortion health risks*. Ninety-eight percent think that women should be advised of any health risks involved in abortion before choosing an abortion.

Overall the respondents are concerned about the physical health of women who desire termination, and they are not keen on an approach, which stigmatises women as criminals for choosing abortion. Although supportive of legal access to abortion, Australians are deeply ambivalent about the morality of abortion. Apart from 'hard cases' involving a danger to the mother's health or foetal disability, less than 1 in 4 thinks abortion is morally justified.

Recognising the right of women to have choice about their own health, sexuality and motherhood status embers of CWLA Inc nonetheless care about the health and dignity of all women, the value of all human life and the maintenance of a caring and compassionate society and so do not believe that repealing the current Legislation relating to the Amendment of the Therapeutic Goods Act 1989 would add any guarantee that those rights would be enhanced.