

**SUBMISSION**

**ON THE INQUIRY INTO THE**

**THERAPEUTIC GOODS AMENDMENT (REPEAL OF MINISTERIAL  
RESPONSIBILITY FOR APPROVAL OF RU486) BILL 2005**

**TO THE**

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**FROM**

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### 1. Introduction

The Bill seeks to remove the authority for decisions of the use of RU486 (mifepristone) from the Minister for Health and Ageing, and give it to the Therapeutic Goods Administration (TGA).

This submission addresses the use of RU486 as an abortifacient, not its possible uses in treating cancer. All references to it should be read in this context.

It is my contention that:

- RU486 is not a therapeutic drug, and therefore should not come under the auspices of the TGA;
- RU486 is not safe, in that it can be fatal, and it has other side-effects that deem it unsuitable for use by women;
- RU486 enhances the risks of mental illness following its use as an abortifacient;
- Because abortion is a social as well as a health issue, the use of RU486 should be determined by an accountable, policy-making body or person;
- The use of RU486 could lead to the introduction of abortion-on-demand, in defiance of state laws that deem the killing of an unborn child a criminal offence.

Because of these reasons, the Bill should not be voted into legislation, and decisions about the use of RU486 should remain under the authority of the Health Minister.

### 2. RU486 is not a therapeutic drug.

“Therapeutic” means “of or having to do with treating or curing of disease”(1). RU486 is designed to kill a growing human being. This places RU486 in a different category to all other drugs assessed by the TGA.

Pregnancy is not a disease or a disorder or an illness. It is the natural way that people come into the world. To say that RU486 is therapeutic is to change the meaning of the word. Even in the definitions of “therapeutic use” given in the Therapeutic Goods Act 19989, there is no mention of the TGA being authorised to assess as therapeutic, drugs which are designed to kill unborn human beings.

Not only does it cause death to the unborn child, but evidence is mounting of its harmful effects on the women who take it.

### **3. RU486 is not safe**

RU486 is fatal for unborn children. There are also physical health risks for women associated with its use.

The USA Food and Drug Administration (FDA), the equivalent of our TGA, is investigating the adverse effects of RU486 between September 2000 when it was introduced in the USA, and September 2004. There were 607 separate adverse events produced from various sources. Concerns about the safety of the drug, and of the poor reporting of adverse incidents, are expressed in a report in *The Annals of Pharmacotherapy* Volume 40 February 2006.

In their report on the FDA's Adverse Event Reports (AERs) re use of RU486, Margaret M Gary & Donna J Harrison concluded that "...poor AER documentation almost certainly resulted in the underestimation of the severity of some adverse events."(2). They also wrote: "Medications, such as chemotherapy agents, with life-threatening or potentially lethal adverse effects are acceptable in treating conditions that are themselves debilitating or lethal such as cancer, HIV, sepsis, and others. In these cases, alternative treatments are limited and, without treatment, the disease is rapidly lethal. The use of mifepristone (RU486) as an abortifacient, however, is radically different. Pregnancy... generally occurs in otherwise healthy young women. The choice of mifepristone termination over surgical termination is based mainly on patient perceptions of safety, convenience, and privacy, but these perceptions do not accurately reflect the realities of the regimen." (3)

Margaret M Gary was also reported as saying "The FDA reports that only about 1% to 10% of adverse events for any given drug are ever reported. And in this case women may be even less likely to report problems because they may be ashamed." (4)

From this, it may be concluded that:

- \* the severity of the reports of adverse effects from the use of RU486 is under-reported;
- \* the actual number of adverse affects from the use of RU486 is greatly under-reported;
- \* RU486 actually causes illnesses in patients who don't have a disease.

China introduced RU486 in 1992. In 2001, it decided to withdraw the drug from sale at pharmacies due to the adverse effects on women and concerns about fertility rates.

### **4. RU486 enhances the risk of mental illness**

Not only does RU486 cause unnecessary ill-health physically, but abortion has been shown to cause mental illness.

Research by Dr Dennis Fergusson of New Zealand, published in January 2005, highlights this fact (5). This study found that a causal link between mental ill-health and abortion was undeniable, even taking into consideration confounding factors. It found that the mental illness following abortion was twice as much as for those who had never been pregnant, and 35% more than those who had continued pregnancies to birth. He concluded that the mental illness followed from the abortions, not as a result of the pregnancies. Despite Dr Fergusson's pro-choice beliefs and acclaim by the medical fraternity for his previous studies, this study was refused publication by three major medical journals and by the Abortion Supervisory Committee of New Zealand on the grounds that it was too controversial.

Dr Fergusson's results compare favourably with the Finnish study (6) which found that abortion increased the risk of suicide in women by 600% when compared with those who continued pregnancy to birth.

There is increasing evidence of this link world-wide. In Australia, the stories of mental illness following abortion recorded by Melinda Tankard Reist in her book *Giving Sorrow Words* (Duffy & Snellgrove 2000) give lie to the idea that abortion is a relatively minor procedure designed to bring women peace of mind.

With the use of RU486, the risks of mental illness are increased. The procedure is prolonged, painful, and not always private. The induced miscarriage can occur at home or work. The foetus can be seen, and the woman can know that this child died at her own hand. These factors can easily add to the trauma already experienced.

## **5. Abortion is a social issue also**

The TGA may have an ability to assess the drug's side-effects, its efficiency, and quality, but because abortion is a major social issue, decisions on its use must be made by a publicly-accountable person or body like the Health minister, Cabinet or Parliament.

In 1996 Senator Christabel Chamarette spoke for those who agreed with the decision to have RU486 under the control of the Health Minister. She said "There is not only a health issue in the narrow sense – that is, whether the drug is safe – but also a question of whether the availability should be limited for ethical or policy reasons in the context of social policy...I affirm the right of this parliament to have scrutiny over such issues." (7)

The findings of the Southern Cross Bioethics Institute in a 2005 study on abortion confirm Senator Chamarette's wisdom. In the study, some 85% of Australians expressed their belief that abortion is wrong if the unborn child is healthy and there is no health risk to the mother.

Because of the social implications of abortion, the idea that RU486 should be assessed for use by an unelected and unrepresentative body like the TGA is hardly a democratic ideal. The decision needs to be made by a body or person who is accountable to parliament and hence to the people. At present, the Health Minister is that suitable

person. The thought that cabinet or parliament should decide can also be entertained, because these are also publicly-accountable bodies.

## **6. RU486 leads towards abortion on demand**

Once in use, RU486 can lead to abortion on demand. Once we have found a reason for the use of RU486 (for example, for rural women who may not be able to have surgical abortion), there can be found reasons for extending its use to other situations.

Indeed, if rural women can use it, isn't it discriminatory to prevent women in other areas from using it if they find it difficult to attend an abortion clinic, or if they believe it to be offensive or dangerous to undergo surgical abortion? Access to the drug should then be made available on a wider scale. Indeed, services should be provided for any woman who wants to take it as an alternative to surgical abortion.

It may also be possible, under certain circumstances, for a capable woman to administer the drugs herself, and supervise her chemical abortion at her own home. Certainly, it would be more convenient. For example, a woman doctor, nurse or mid-wife could effectively argue that her competency levels are sufficient for self-administration.

Consider this possible scenario then. A woman believes that she would be mentally harmed by continuing a pregnancy, and she decides to choose abortion by the RU486 process. She believes her competency is such that she can assess her own situation correctly. She approaches a couple of sympathetic doctors who agree to support her decision if it is taken to court. She conducts the abortion herself. She surrenders herself to the police because she has broken the law, in not getting written assessment from two doctors. In court the woman explains that she relieved the burden of abortion from doctors and nurses and rightly placed the burden on herself. All else remained the same as any other abortion.

A sympathetic judge or jury could easily rule in her favour. If so, she has achieved a defacto abortion-on-demand. The laws against abortion protecting the life of the unborn are forced to retreat once more. The child in the womb has become a non-person. The world mourns our loss of dignity.

## **7. Conclusion**

RU486 is not therapeutic for unborn children who are protected by states' laws. It cannot be classed as 'safe' or therapeutic for use by women because pregnancy is not a disease or disorder. The mental illness caused by abortion is enhanced by use of RU486. A publicly-accountable body or person should decide on the use of RU486 because abortion is a social as well as a health issue. Allowing use of RU486 as an abortifacient leads towards abortion on demand, in defiance of laws designed to protect unborn children.

The Therapeutic Goods Amendment (Repeal of Ministerial responsibility for RU486) Bill 2005 should be rejected because of these reasons.

## References

(1) *World Book Dictionary* 1978 p.2174

(2) “Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient”, *The Annals of Pharmacotherapy* February 2006 Volume 40 [online edition].

(3) *ibid.*

(4) WebMD Medical News 29-12-05

<http://www.webmd.com/contents/Article/116/112325.htm> .

(5) Fergusson, David M, Horwood, Ridder, L John and Elizabeth, “Abortion in young women and subsequent mental health”, *Journal of Child Psychology and Psychiatry*, Vol 47 (1), January 2006, pp 16-24.

(6) Gissler, M, et al, “Injury deaths, suicides and homicides associated with pregnancy, Finland 1987 – 2000”, *European J Public Health*, 15(5): 459-63, 2005.

(7) Australian Senate Hansard, 21/5/1996, page 824