Submission to the Senate Community Affairs Committee

By the Adrian Fortescue Chapter of Lay Dominicans

Concerning the

Therapeutic Goods Amendment (Repeal of Ministerial

***responsibility for approval of RU486) Bill* 2005**

I: THE PROPOSED AMENDMENT AND ITS PURPOSE

According to the *Explanatory Memorandum* to the *Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill* 2005 (**"the Bill"**):

> *"The purpose of this 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.*
>
> *In 1996 amendments to the Therapeutic Goods Act were passed that placed medications such as RU486 in a special group of drugs known as 'restricted goods'.*
>
> *According to the 1996 amendments* ***restricted goods cannot be evaluated, registered, listed or imported without the written approval of the Minister for Health and Ageing****.*
>
> *In addition,* ***any such written approval must be laid before each House of the Parliament by the Minister within 5 sitting days of being given****.*
>
> *RU486 is the only medicine that is subject to the restricted goods condition.*
>
> ***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****.*
>
> ….
>
> ***Removal of the restricted goods provisions in the Act would mean that RU486 could be evaluated within the same framework as applies to all other medicines****. …this may provide potential sponsors of the drug with greater confidence that an application for approval would be worth pursuing….."* (Emphasis added)

II: REASONS AGAINST THE BILL

A: Dignity of the person

1 Dignity of the embryo

1. We and many Australians consider the embryo a human person from the moment of conception, for sound philosophical reasons, including the genetic and biographical continuity of the self directing human entity which begins at conception and continues until natural death, in some cases at a very advanced age.

2. For us, this is a sufficient reason to repudiate RU486 which is sought for no purpose other than the supposedly easy destruction of the human embryo by the mother taking the RU 486, usually privately and away from medical supervision of its operation and effects.

3. We acknowledge that not all Australians share our view of the status of the human embryo. The remainder of this submission, however, is based on propositions which all Australians do share.

2 Dignity of the mother

4. All Australians agree that the women who may take RU 486 if the Bill is passed are human persons whose dignity must be respected.

5. RU 486 does not respect the dignity of women who take it. Legislative change to allow RU 486 does not even begin to deal with the fact that any abortion is a bad outcome for the woman. It attempts to evade the question: "*How can we better help women?"* by disguising abortion as a private matter of a drug at home instead of surgery at a clinic or hospital. The result, as Renata Klein has said, is that many abortions will be backyard abortions – They will at best be solitary and fearful experiences of defeat and grief by women who will now feel an additional and very unsympathetic pressure to treat a pregnancy as a problem, and to bear the sole responsibility to solve the problem without bothering anyone else.

6. This is to put the physical and psychological health of Australian women at great risk. Women will be told that RU 486 is safe to take at home. In some cases it will very clearly not be safe.

(a) Psychological harm to women caused by RU 486

7. It is now clear that abortion can be followed by a significant incidence of depression. This is born out by the recent published results of research by Professor Fergusson in New Zealand. (He is not a member of the "right to life" movement; indeed he identifies himself as "pro-choice"). If abortion carries a heightened risk of depression, then RU 486 can be expected to increase this risk even more, as the solitary taking of the drug by a woman at home will lead her to feel totally responsible for the decision, even though pressure by other persons, or the unsympathetic reaction of society to her pregnancy, will have played a large part in the decision, indeed may have made her part in the process very lacking in freedom.

8. Apart from this grave psychological damage, there may also be serious physical harm following the use of RU 486. Associate Professor Renata Klein has written concerning this risk of physical harm from the use of RU 486 :

> *"I am not a Catholic. I am not a man. I am not a right-to-lifer. But 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.*
>
> *…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 10 women will then need a dilation and curettage to complete the abortion.*
>
> *Ironically, as Australian pro-RU486 lobbying is reaching fever pitch, discussions in medical circles about the deaths of five women in the US and Canada after an RU486-prostaglandin abortion are increasing (there were two additional deaths in Britain and one in Sweden). No one is sure why these deaths occurred.*
>
> *The Canadian woman's death in 2001 was explained by pointing to the antiglucocorticoid effect of RU486, which weakens a woman's immune system, making it impossible for her to fight bacteria and leading to septic shock and rapid death. Canada stopped the trial and RU486 (Mifeprix) is not licensed.*
>
> *Conversely, in California, the four deaths were first attributed to contaminated prostaglandin tablets (in contravention of the approved US Food and Drug Administration protocol, a woman is given the prostaglandin tablets to insert into her vagina instead of returning to a doctor's surgery and taking them orally). But this hypothesis has been disregarded; the tablets were tested and were not contaminated.*

So the experts are back to the drawing board. All they can offer is a warning to women that an RU486-prostaglandin abortion may incur an infection. (One wonders if they will tell them that healthy women have died.) But the symptoms of infection are exactly the same as those that follow an RU486-prostaglandin abortion: nausea, vaginal bleeding, cramping and back pain. How is a woman to know if she is simply going through the drawn-out stages of the abortion or if her body is developing a life-threatening infection?

Three lawsuits are in progress.

And another worrying fact has come to light: as the cause of death of one of the Californian women the coroner stipulated cardiac arrest. Only when her family ordered a private autopsy was sepsis discovered as the cause of death. How many other deaths remain unattributed to RU486-prostaglandin abortion?

And how many adverse effects remain unreported? In the US, reporting is not mandatory and the FDA considers that only 10 per cent of adverse effects of any drug are reported. As of October last year, official figures for RU486-prostaglandin abortion were 676 adverse effects, 17 ectopic pregnancies and 72 women requiring blood transfusions. If that is only 10 per cent, then the real figures are substantial.

As Australians are increasingly going organic to limit the poisons we put into our bodies, how can anyone suggest that it is a good choice for women to do exactly that in an RU486-prostaglandin abortion? ….. Surely those using their conscience should vote against exposing Australian women to abortion drugs that can kill."

(Renata Klein, a biologist and social scientist, is co-author of *RU486 Misconceptions, Myths and Morals.* She is an associate professor in women's studies at Deakin University in Melbourne. See also *NEW ENGLAND JOURNAL of MEDICINE* 1 December, 2005, "*Fatal Infections Associated with Mifepristone-Induced Abortion"* by Michael F. Greene, M.D.)

9. Neither Professor Fergusson nor Professor Klein have positions based on, or remotely connected with the "right to life" lobby; their academic integrity compels them to publish their concerns relevant to this debate, despite their "pro-choice" views.

10. In the interests of the dignity of the human person, and of women's health, the Bill should not pass.

B: The Rule of Law

11. Proponents of the Bill want RU 486 to be available with the same, and only the same controls as other drugs. Yet abortion is widely treated as a special case by Australian legislatures. Abortion is regulated by law. E.g. in Victoria by common law, and in South Australia by statute, abortion is restricted to situations where it is judged necessary to preserve the (physical or mental) health of the mother. In other words, the legislative arm of

government provides an additional check on abortion beyond the private judgement of an individual woman and her personal medical advisors. Good reason for this can be seen in the risks to women's health associated with abortion. (See, eg. the notorious recently published results of the research by Professor Fergusson into depression after abortion.) It is for this reason that it is prudent, and necessary for women's health, and consistent with the existing legislative and judicial restriction of abortion to situations where it is thought that a woman's health requires it, that RU 486 should continue to be subject to controls beyond those required for other drugs. The present requirement of Ministerial approval should be retained for this reason also.

C: Compassion

12. Finally, compassion for women urges that Australian society should continue to regard every abortion as a sad and undesirable solution to distress or problems suffered by a particular woman. Compassion requires that a woman's distress be aided, not that she be urged to allow the rest of us to pretend that there is no pregnancy, no problem, no risky miscarriage, no risk of lasting distress or depression or feeling of defeat. We should want to help every woman for whom her pregnancy is a burden, and not in an awkward, embarrassed and unfeeling way tell her to go out into the back yard, where we can't see her and fix it up alone.

III: CONCLUSION

13. For all these reasons, the Bill should not pass.

16 January, 2006

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(Adrian Fortescue Chapter of Lay Dominicans,
represented by Anthony Krohn, Prior of the Chapter)