



PUBLIC SUBMISSION

**Inquiry into Therapeutic Goods Amendment (Repeal
of Ministerial responsibility for approval of RU486)
Bill 2005**

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Contents

Contents	2
Executive Summary	3
RU486 in Australia	4
Access	4
Therapeutic use of RU486	4
Accountability.....	5
Safety.....	7
More real choices, not more abortion methods	8
Conclusion.....	10
The Australian Christian Lobby	11

Executive Summary

The Australian Christian Lobby (ACL) considers that the Health Minister should maintain ministerial responsibility for the abortion drug RU486 and, therefore, that the Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005 should be rejected.

The primary reason for retaining Ministerial responsibility for RU486 is:

- ❖ *Political accountability for moral policy* – The Therapeutic Goods Administration (TGA) regulates all drugs in Australia, but its mandate only relates to the safety, efficacy and quality of the drug. RU486 is no normal drug as its purpose is to take a human life. The TGA does not consider moral issues. Abortion policy is a serious social issue, which should rest with elected and accountable representatives. It should not and cannot be determined by an unelected body that considers only the technical aspects of a drug. On something as grave as medical abortion it is important for the Health Minister to maintain the ability to decide on RU486.

In addition there exist:

- ❖ *Concerns about the safety of RU486* – RU486 is not as safe as a surgical abortion. When comparing RU486 with surgical abortions in early pregnancy (a true comparison), RU486 carries nearly ten times more risk to the mother. About 5%-8% of women need additional interventions to complete the abortion. Overseas experience shows that 10-20% of women fail to attend their follow up visits. Serious complications can follow. A surgical abortion is over relatively quickly and pain relief is available. A medical abortion takes place over many days, usually in the woman's home, with bleeding lasting for several weeks. It is not a safer or easier method of abortion.
- ❖ *A need for more choices, not more abortions* – Research by the Southern Cross Bioethics Institute shows that approximately 73% of Australians think the abortion rate is too high and 87% support reducing the abortion rate. Making RU486 available would simply provide women with a choice between different abortion methods; a real choice would be an alternative to abortion.

RU486 in Australia

Access

In 1996, the Therapeutic Goods Act 1989 was amended with bi-partisan support, to include a new class of 'restricted goods', which required ministerial approval, over and above the usual Therapeutic Goods Administration (TGA) evaluation processes. These 'restricted goods' were placed in this unique category because of their unique purpose – to end human life in the womb.

It is important to note that RU486 is not banned in Australia: the 'restricted goods' category applies to drugs intended for use in women as abortifacients. RU486 has non-abortifacient purposes in cancer and hormonal treatment, and the TGA, in its public testimony to the Senate Inquiry on 15th December 2005, stated that the current arrangements had not caused any barrier to the non-abortifacient use of RU486. As with other products not on the Australian Register of Therapeutic Goods, applications can be made for its use in medical research under the clinical trial exemption (CTX) scheme and the clinical trials notification (CTN) scheme.

However, the requirement for written permission from the federal Health Minister should be retained as RU486 is not always for therapeutic use – it can be used to destroy, not to heal, a human life.

Therapeutic use of RU486

It is legally dubious whether or not the TGA is legislatively empowered to examine RU486 when its intended use is to end human life in the womb. Under the Therapeutic Goods Act 1989, the TGA is required to regulate goods that have a 'therapeutic use':

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- or
- (c) testing the susceptibility of persons or animals to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons or animals.

Quite clearly, RU486 does not fall under definitions (a), (c) and (e). Regardless of the definition of conception taken (at fertilization of the egg by the sperm or at implantation of the embryo in the uterus wall), it is reasonable to accept that (d) does not apply to RU486.

It is doubtful that (f) could apply to RU486 as the developing foetus, with its separate heartbeat and own blood type, is not part of the woman's anatomy.

RU486 is most likely to fall under paragraph (b), although this too is contestable. The key words in the paragraph are 'influencing, inhibiting or modifying.' An argument may be made that those words 'inhibiting etc.' must be read as a group in accordance with the legal rule of statutory construction: *noscitur a sociis*. That rule provides that the meaning of a word or phrase may be ascertained from the words accompanying it. 'Killing' or 'destroying' is of quite a different class to 'inhibiting', 'modifying,' or 'influencing'.

ACL acknowledges that interpretation of legislation in this area will be contested and that expert legal advice may assist in resolving this dispute, but believes that RU486 does not have a therapeutic use if intended for ending pregnancy and may not actually be a therapeutic good when used for this purpose.

Accountability

The Australian Christian Lobby believes it is crucial that decisions about the use of RU486 to ultimately rest with the elected Government. The government of the day has a mandate from the Australian population to make policy decisions on its behalf. It is also accountable to the Parliament and the people for its actions. Decisions on the value of human life and the means (if any) by which it can be ended should rightly rest with elected representatives.

The key question before the Senate Inquiry is whether RU486 is just like every other drug and should therefore be assessed by the TGA or whether it is indeed a unique product that requires additional public scrutiny.

The TGA exists to assess the quality, safety and efficacy of therapeutic goods but it has no mandate to make decisions on the complex moral and social issues surrounding an abortion drug. Any TGA review will focus solely on the technical aspects of the drug, as laid down in

the legislation (and the safety considerations will only apply to the mother, not the child for whom the drug will be lethal). There is no consumer representation on the Australian Drug Evaluation Committee and its processes are closed due to commercial-in-confidence considerations. Such arrangements mean there would be no scope for any public input to its deliberations. This is unacceptable given the unique implications of decisions on abortion.

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A technical review of a drug's quality, safety and efficacy is simply not enough in the case of abortifacient drugs. Abortifacient drugs rightly belong in a separate category to other drugs in the Therapeutic Goods Act. They are designed to kill a developing life, not to restore health or ease pain. As uniquely contentious drugs, they require a higher level of scrutiny, which is appropriately placed in the hands of elected representatives who can consider the wider social and ethical issues of human life. This position received bi-partisan support in the parliamentary debates of 1996. As noted by Senator Neal of the Australian Labor Party:

“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 the government and addressed with absolute and direct accountability and absolute and complete transparency...We wish to ensure that, in circumstances where this drug is to be imported into Australia, the minister be required to approve the drug and that notification of this approval be given in this chamber.¹”

If the proposed amendment has come about because of concerns that the current arrangements do not allow for suitable accountability because the judgement rests solely with the Health Minister, then the most logical option is to strengthen this accountability, not to discard it. There may be advantages in making the responsibility for such a politically contentious matter more explicitly a whole-of-government decision, by making the setting of policy on abortifacients a joint decision of Cabinet. This would allay concerns that the ideological predisposition of any Health Minister would drive decisions on abortion, instead increasing the level of accountability and transparency.

¹ Hansard, Senate 9th May 1996 p. 624

Handing full responsibility for RU486 to the TGA would be an effective endorsement of abortion on demand by the Government. Few Australians are supportive of abortion on demand: recent research showed that 85% of Australians believed that abortion was unacceptable if the foetus was healthy and there was no abnormal risk to the mother².

Safety

The Australian Christian Lobby has grave concerns about the safety of RU486.

1. *More dangerous than surgical abortion*

There is emerging evidence to show that a medical abortion is not as safe as a surgical abortion. Previous comparisons have been between a medical abortion in early pregnancy and a surgical abortion at any stage of pregnancy. However, a recent article in the New England Journal of Medicine compared medical and surgical abortions at the same stage of pregnancy (up to 8 weeks gestation). This study found that the risk of death from an RU486 abortion was approximately 1 in 100,000 whereas the risk from a surgical abortion at less than 8 weeks gestation was just 0.1 in 100,000³. These results indicate that the risk of death from an RU486 abortion is approximately ten times greater than the risk from a surgical abortion at the same stage of pregnancy.

At least 5 North American women have died in recent years from taking RU486. The drug weakens the immune system, allowing *Clostridium sordellii* bacteria to enter the cervix where they may multiply and cause a massive infection resulting in sudden death - a mifepristone-induced septic shock due to *Clostridium sordellii*⁴. The symptoms of this infection are at first identical with the pain and bleeding expected from an RU486 abortion so medical aid may be sought too late or not at all.

This fact makes a mockery of the pro-drug campaign's claims this abortifacient is necessary to give rural women more abortion options. Women isolated from access to surgical abortion would be most at risk with this drug. Access to surgical abortion is a vital emergency safety procedure and RU486 should not be prescribed where surgical abortion is not available.

² Southern Cross Bioethics Institute, *Give women choice: Australia speaks on abortion*, 2004

³ Michael F. Greene, "Fatal infections associated with mifepristone-induced abortion", *New England Journal of Medicine*, 353:22, 01/12/2005.

⁴ R.P. Miech, "Pathophysiology of Mifepristone-Induced Septic Shock Due to *Clostridium sordellii*," *Annals of Pharmacotherapy*, 2005, 39, pp.1483-1488.

2. High follow-up intervention rate

Unlike surgical abortion, a medical abortion requires several visits to the doctor. After the initial administration of the drug and later administration of a prostaglandin, women must return to their doctor to check the abortion has been successful. In 5% - 8% of cases, the abortion is incomplete and an emergency surgical abortion needs to be performed. This is a high intervention rate. Without this emergency surgical abortion, a woman is at risk of septic infection, lower abdominal pain, fever, nausea and death as a result of the dead foetus still in her womb. Unfortunately, experience in the USA shows that 10% – 20% of women fail to attend this follow-up visit.

3. A protracted, lonely experience

Media discussion of RU486 seems to present it as a simple pill that offers women a much easier way to procure an abortion than surgery. Many people would prefer medical to surgical treatment in other areas of their health and make the same assumption about abortion choices. However, RU486 is not the easier method of abortion. It requires multiple visits to a doctor and the administration of two drugs over several days causing powerful contractions endured without anaesthesia. The prolonged abortion is a lonely, painful experience that takes place away from medical supervision. The remains of the child may be visible to the woman who must then suffer the additional trauma of packaging up the dead foetus for disposal by the clinic. Bleeding continues for a further 2-3 weeks⁵. A surgical abortion is a much more straightforward process.

More real choices, not more abortion methods

As the pro-choice lobby often states, women do not choose an abortion lightly. It is a difficult decision that women and couples will usually have agonised over.

A recent New Zealand study has analysed the linkages between abortion in young women aged 15 – 20 and subsequent mental health to the age of 25⁶. This compared the mental health of women who had never become pregnant, women who had given birth and women who had had an abortion. The study adjusted for any association between mental health

⁵ Rachel Jones & Stanley Henshaw, "Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden", *Perspectives on Sexual and Reproductive Health*, 2002, 34:3, pp. 154-161.

⁶ David M. Fergusson, L. John Harwood & Elizabeth M. Ridder, "Abortion in young women and subsequent mental health", *Journal of Child Psychology and Psychiatry*, 2006, 47:1, pp 16-24.

outcomes and pregnancy status group by factoring in pre-pregnancy aspects such as social background, childhood and family history, mental health and personality factors.

The authors concluded that, “women who had had an abortion had elevated risks of subsequent mental health problems including depression, anxiety, suicidal behaviours, and substance use disorders. This association persisted after adjustment for confounding factors.” Pro-abortionists often claim that the harm is not from abortion itself but from pre-existing mental health factors or other stresses surrounding a pregnancy. The authors of the New Zealand study note these common criticisms but have tried to address them in their study design by adjusting for such confounding factors. They conclude that, “it is difficult to disregard the real possibility that abortion amongst young women is associated with increased risks of mental health problems.

Similar conclusions were drawn by a 1996 study of Finnish women, which found that women who had had an abortion were much more likely to commit suicide (34.7 per 100,000) than women in the general population (11.3), those who had given birth (5.9) or those who had suffered a miscarriage (18.3). They concluded that the increased risk of suicide after an induced abortion indicated either common risk factors for both or the harmful effects of induced abortion on mental health⁷.

As a society, we need to do everything possible to ensure that women are not faced with such a terrible choice; a choice that both sides of the abortion debate agree is traumatic. Some women choose abortion against their better judgement because they perceive a lack of societal support for parents. If this is the case, both pro-choice advocates and pro-life lobbyists can agree that there should be more done to support women who would much rather keep their baby than abort it.

The proposed amendment has focused the debate solely on offering women a choice between abortion methods. A real choice would be one that provided women with an alternative to abortion should they wish it. Australia needs to provide more options to help women who would like to give birth to their babies.

The previously quoted recent research is evidence enough that the public attitude to abortion is changing (73% of Australians think the abortion rate is too high and 87% support

⁷ Mika Gissler, Elina Hemminki, and Jouko Lonnqvist, “Suicides after pregnancy in Finland, 1987-94: register linkage study,” *British Medical Journal*, 1996, 313, pp.1431-1434.

reducing the abortion rate⁸). The personal and social harms of the ideological campaign for abortion are at last being recognized.

Conclusion

It is impossible to conclude that there is no moral aspect to this debate. The question of removing ministerial responsibility for RU486 is a morally loaded question. For this simple reason alone ministerial responsibility should be maintained, because the TGA can only consider technical aspects of drugs, not serious social and moral questions. If there exist concerns that the Health Minister is not suitably accountable, options such as expanding accountability to the Cabinet or increased reporting requirements should be explored.

It is also questionable whether RU486 when intended for use as an abortifacient actually meets the criteria of a therapeutic good. The legality of this should be considered by the Committee. Furthermore, as this question is intricately linked to the issue of abortion, it is also important to note that medical abortion is more dangerous and traumatic than surgical abortion. While allowing abortion to occur, governments have traditionally shunned 'abortion on demand', but removing ministerial responsibility would be a significant step in that direction. Legislators should be focusing on finding genuine alternatives to abortion, not more ways to carry it out. To provide more ways to procure an abortion is out of step with the Australian public.

⁸ Southern Cross Bioethics Institute, *Give women choice: Australia speaks on abortion*, 2004

The Australian Christian Lobby

The Australian Christian Lobby (ACL) is a non-party partisan, non-denominational political lobby group that represents the views of hundreds of churches and thousands of supporters Australia wide. The Christian constituency reflects a sizeable percentage of the broader community. 68% of the Australian population declared themselves Christian in the 2001 ABS Census and about 2 million Australians attend a church regularly. As such, while ACL does not claim to speak for all these people, its policy suggestions may resonate with large numbers of them.