

Submission

on the Inquiry into the

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

to the

Senate Community Affairs Committee

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1. Introduction

Festival of Light Australia - a Christian community group promoting family values, with members in each state of Australia - welcomes the inquiry by the Senate Community Affairs Committee on the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005.

The inquiry provides an opportunity for members of the community to express their views on this important public policy matter.

When the Commonwealth Parliament passed the Therapeutic Goods Amendment Bill in 1996, to include a requirement for Ministerial approval for any importation of the drug known as RU486 (mifepristone), the Bill received bilateral support. It passed both second and third readings on the voices.

WA Greens senator Christabel Chamarette summed up the arguments for requiring special conditions (ie Ministerial approval) for RU486 when 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. This debate is yet to be heard I affirm the right of this parliament to have scrutiny over such issues.”¹

These arguments remain as valid now as they were in 1996.

2. RU486 is not therapeutic when used to procure an abortion

The Therapeutic Goods Administration (TGA) assesses - for safety, efficacy and quality - drugs used for therapeutic purposes. The TGA then grants or denies approval for their manufacture or importation into Australia.

However the drug RU486 (also known as mifepristone), when used to cause the death and subsequent miscarriage of humans in the first seven weeks of development, cannot be placed in the “therapeutic” category.

RU486 is not therapeutic because it does not benefit the unborn child - rather it causes the death of the child. Moreover recent overseas evidence indicates that the drug also poses health risks for the unborn child’s mother.

2.1 Mental health risks associated with abortion

There is growing evidence that mental health problems - in particular, major depression - are more likely to occur in women after they have undergone an abortion. Research on the computerised health records of all Finnish women of child-bearing age during a 13 year period

found that abortion increased the risk of suicide by 600% compared with a live birth. Miscarriage or ectopic pregnancy increased the risk by 200% compared with a live birth - about the same increased risk as not being pregnant at all. Women who had given birth to a live baby were least likely of all women to commit suicide within the next 12 months.²

Very recent research by Professor David Fergusson of New Zealand - part of his Christchurch Health and Development Study which has followed up 1265 children born in Christchurch in 1977 and investigated many aspects of their lives - has found similar results to the Finnish study. Published in January 2005, the Fergusson study³ looked at 500 women who were still in the study at age 25. By this age, 41% had become pregnant; 14.6% (over a third) had sought an abortion. A total of 90 women aborted their pregnancies.

Professor Fergusson found that women who had had at least one abortion were twice as likely as others to drink alcohol at dangerous levels and three times as likely to use illicit drugs. Forty two percent (nearly half) of women who had had an abortion had experienced major depression in the previous four years - twice as many as those who had never been pregnant and 35% more than those who had continued their pregnancies. Separate analysis showed that the mental health problems followed the abortions, not the other way around. Professor Fergusson said he was surprised by the results, but they were statistically strong.⁴ He said that the link between abortion and mental ill-health had persisted after adjustment for confounding factors.⁵

Professor Fergusson's research raises serious questions about the legal validity of abortions in states like South Australia and countries like New Zealand which allow abortion where continuing the pregnancy would threaten the mother's health. In both SA and NZ, about 98% of abortions are authorised on the grounds that the pregnancy is a threat to the mental health of the woman. Professor David Fergusson, who describes himself as "pro-choice", says his research could undermine the legal basis for access to abortion in New Zealand, since it indicates that aborting a pregnancy is more likely to result in mental ill-health for the mother than continuing the pregnancy.⁶

Professor Fergusson's research has impeccable methodology, but there have been attempts to cover up his findings because they undermine popular feminist dogma.

Despite acclaim from the scientific community for his many earlier studies based on the Christchurch child cohort, Fergusson said his abortion study had been rejected by three major medical journals before being accepted by a UK journal. "(This) is very unusual for us - we normally get accepted the first time," he said.⁷

Moreover the Abortion Supervisory Committee, which supervises all legal and compliance aspects of NZ terminations, examined Fergusson's findings in 2004 and concluded that they should not be published in their current form - because they were too controversial. Professor Fergusson was deeply upset by this suggestion that he cover up or water down the truth. He also expressed great concern that so few valid abortion studies have been published.

"It verges on scandalous that a surgical procedure performed on over one in 10 women has been so poorly researched and evaluated, given the debates about the psychological consequences of abortion," Professor Fergusson said.⁸

The extraordinary bias of medical journals was echoed in the Australian media, which rapidly published attempts to downplay the Fergusson findings by pro-abortion activists.⁹ Almost all opinion articles which newspaper editors chose to publish suggested that factors other than abortion had caused the mental health problems. Professor Fergusson pointed out that his research analysis had adjusted for the many different factors affecting the women involved,¹⁰ yet his remarks rebutting criticism were not published in any Australian newspaper.

None of the Australian abortion advocates has acknowledged the increasing amount of statistical as well as anecdotal evidence worldwide supporting the link between abortion and mental ill-health. Melinda Tankard Reist's book, *Giving Sorrow Words* (Duffy & Snellgrove, 2000) tells the personal stories of 18 women who had abortions and draws on the experiences of more than 200 others, many of whom are still suffering mental trauma such as depression, eating disorders and attempted suicide - risks they never expected and were never warned about.

2.2 Increased likelihood of mental health risks associated with RU486 abortions

Abortions performed via RU486 are more likely to be associated with depression than surgical abortions. The process is prolonged and more painful. RU486 slowly kills the unborn baby by means of its anti-progesterone action which prevents the foetus from receiving nourishment. The dead foetus is then expelled from the womb by the action of another drug, misoprostol. The mother later delivers her tiny foetus - possibly at home or at work. This delivery can be a traumatic experience, since a seven week foetus, while tiny, is nevertheless recognisable - as are parts of the placenta and umbilical cord. A woman suffering a miscarriage may have the same experience, but knows there is nothing she could have done to prevent it. A woman undergoing an RU486 abortion knows that her unborn child died by her own action, and this knowledge could exacerbate her trauma on seeing the foetus.

2.3 Physical health risks associated with RU486

RU486 is not as safe for women as surgical abortion. Excessive bleeding, painful cramps and retention of some tissue may require emergency medical treatment. At least five North American women have died in recent years from taking RU486, which weakens the immune system and allows *Clostridium sordellii* bacteria to enter the cervix where they may multiply and cause a massive infection resulting in sudden death. The symptoms of this infection are at first identical with the pain and bleeding expected from an RU486-misoprostol abortion, so medical aid may be sought too late.¹¹

China, which allowed the use of RU486 in 1992, withdrew the drug from sale in pharmacies in 2001 following concerns about its effect on future fertility and other complications.¹²

There have been at least ten deaths associated with RU486, detailed below from an article by Dr J C Willke in December 2004¹³ and an article in the *New York Times*, 23 November 2005.¹⁴

The first published case occurred in France in April 1991, but was widely dismissed because it was reported the woman had all three contra-indications to the use of the drug. She had been a heavy smoker, had heart problems and high blood pressure. However, in September 2001, a

Canadian woman died from septic shock eight days after taking the abortion pills. This was a result of a Clostridium infection in the uterus, possibly due to retained parts of the baby. A second woman, 21 years old, sustained a serious heart attack but survived. As a result, the Canadian trials of RU486 were temporarily halted.

On September 12, 2001, a 38-year-old woman in Tennessee died five days after taking RU486. She had a tubal pregnancy which, according to a warning from the US Food and Drug Administration, RU486 will not abort.

The abortion facility apparently failed to make the proper diagnosis, even though they did an ultrasound. She returned home and developed pain and bleeding. She placed multiple calls to the abortion facility as her condition worsened, but was advised that her symptoms were normal and routine. She was finally hospitalised and received legitimate medical care, but died from massive peritonitis from the ruptured tube. A major malpractice lawsuit was subsequently filed.

On June 3, 2003, a 16-year-old Swedish girl, Rebecca Tell Berg, died from an RU486 abortion. She was seven weeks pregnant. One week after being examined by a gynaecologist, she returned to the hospital and was given three RU486 abortion pills, a full dose. Two days later she returned and was given two Cytotec pills (a prostaglandin which is usually given as part of the abortion regime to increase the effectiveness of mifepristone). After a few hours, she was in severe pain, bleeding heavily and was given pain medication. After being kept in the hospital for eight hours, she passed a “big blob” and was sent home. Days later, still bleeding and in pain, her boyfriend encouraged her to go to the hospital. However, hospital officials told her she could bleed for as long as two weeks, so she stayed home. Eight days after the abortion she was found dead in the shower. A coroner's report confirmed that Rebecca bled to death. It noted, however, that the doctors had given an appropriate dosage, followed proper procedure and “followed all the rules”.

On September 17, 2003, the fifth victim, Holly Patterson, 18, of California, died after taking RU486. The Planned Parenthood clinic did not educate her on how to administer the medication, did not have her signature on a consent form and failed to report her death as an unusual occurrence. After taking the medication, she returned to a local hospital twice. The first time she was given painkillers and sent home. The second time she went to the hospital but died shortly afterwards. The Alameda County, California Coroner's official autopsy report stated that she died because retained foetal body parts caused a massive infection.

Another death in 2003 was that of a 21-year-old student, Hoa Thuy Tran, in California. According to the suit which was filed last October in Orange County Superior Court, Tran took the drug on December 23, 2003 at a Planned Parenthood clinic. She collapsed and died six days later.

In January 2004, the British Government announced that two women had died after taking RU486 for abortions. No details of the deaths or the victims were released. The deaths were described as “suspected fatal reactions associated with the use of RU486”.

On January 14, 2004, Chanelle Bryant, 22, of Pasadena, California, died six days after taking RU486. And on May 24, 2005, Oriane Shevin, 34, of Los Angeles, died five days after taking RU486.

Altogether, so far there have been 10 known deaths of women overseas as a result of RU486 - one in France, one in Canada, one in Sweden, two in Britain and five in the US. The risks of massive infection are linked with the anti-progesterone action of the drug.

Several US senators called for a US ban on RU486 in July 2005, and US health officials including the US Centers for Disease Control and Prevention have launched an investigation into the Californian deaths linked with the drug.¹⁵

3. Procuring an abortion remains a criminal offence for most Australians

Abortion remains a criminal offence in the three largest Australian states - NSW, Victoria and Queensland.

A NSW doctor, Suman Sood, is currently facing prosecution for manslaughter and administering a drug with intent to procure a miscarriage, after she initiated a late abortion and the baby boy was born alive but survived only a few hours.¹⁶

Some court judgements, such as *Menhennit* (1969, Victoria) and *Levine* (1971, NSW) have ruled that abortion is not an offence in certain narrowly defined circumstances, but these judgements have not been tested by a higher court. No parliament in NSW, Victoria or Queensland has voted to repeal the statutes which prohibit procuring an abortion.

Procuring an abortion is therefore an offence for the majority of Australian citizens. It is unethical for the Commonwealth Parliament to allow an unaccountable committee to assess and possibly approve the widespread use of a drug which could be used to perform a potentially criminal act.

4. Abortion is a social as well as a health issue

During the 1996 debate on Ministerial responsibility for the approval of RU486, Christabel Chamarette told the Senate that the issue was social and ethical as well as a health issue. She said, "If we were considering the importation of plutonium into this country, we would not leave it up to an expert committee or an ethics committee; we would demand that this parliament had a say. I am keen that we see the processes of scrutiny and public consultation not undermined ..."¹⁷

As this nation faces a declining population - the fertility rate is of the order of 1.73, significantly lower than the 2.1 needed to maintain current numbers without immigration - abortion is becoming an economic issue. Populations with too high a proportion of aged and infirm and too low a proportion of young workers become economically non-viable in the long term.

Federal health minister Hon Tony Abbott has said that Australia's high number of abortions - up to 90,000 every year, one and a half times the population of the city of Ballarat - is a tragedy. Research in 2005 by the Southern Cross Bioethics Institute found that a substantial majority of

Australians - some 85% - believe that abortion is not justified where the unborn child is healthy and there is no abnormal risk to the mother.¹⁸

As Christabel Chamarette has said, these are serious issues. Citizens deserve to have an input through their elected parliamentary representatives. An unelected group of people at the Therapeutic Goods Administration would not provide this representation. Making approval subject to Ministerial (and hence Cabinet) consent means that bad decisions can be reversed following the next election. A bad decision on such an important matter by the Therapeutic Goods Administration cannot readily be reversed.

5. Pro-abortion pressure on the Therapeutic Goods Administration

The revelation by Professor Fergusson that the NZ Abortion Supervisory Committee had concluded that his findings about mental health risks associated with abortion should not be published¹⁹ is a cautionary tale for Australia.

The Abortion Supervisory Committee, is, like the Therapeutic Goods Administration in Australia, a committee of supposed neutral experts. However as Professor Fergusson has revealed, even these “neutral” experts are vulnerable to pressure from pro-abortion ideologues - to the point of wanting to suppress information which could limit the availability of abortion.

There is no reason to believe that TGA members would be any different - therefore it is essential that the Commonwealth parliament retain its current power to scrutinise requests for the importation of RU486.

6. Conclusion

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

- abortifacient drugs like RU486 are specifically designed to destroy unborn human life, unlike other drugs, and are in contravention of the laws of three major Australian states. For this reason alone, the importation of RU486 should continue to be subject to parliamentary scrutiny through the requirement for approval by the Minister for Health.
- Research shows that abortion is linked with an increased risk of mental ill-health. RU486 is potentially more likely than other abortion methods to result in mental ill-health including depression and possibly suicide.
- The alleged safety of RU486 is currently being questioned following reports of serious complications and several North American deaths associated with its use in recent years. It would be premature to legislate to potentially widen the drug’s availability in Australia while RU486 remains under a cloud.

- The availability and accessibility of abortion for Australian women has implications for the future viability of the nation - and the Australian public, through its elected representatives, should have the freedom to debate and determine issues relating to abortion such as the availability of RU486.
- The Therapeutic Goods Administration may be subject to ideological pressure to approve the importation of RU486 and ignore potential problems, just as the NZ Abortion Supervisory Committee concluded that research linking abortion with mental ill-health not be published. The Commonwealth parliament should therefore retain the requirement for Ministerial approval for RU486.

References

1. Senate Hansard, 21/5/1996, page 824.
2. Gissler, M, et al, "Injury deaths, suicides and homicides associated with pregnancy, Finland 1987 - 2000", *European J Public Health*, 15(5): 459-63, 2005.
3. 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.
4. *The Sydney Morning Herald*, 3/1/2006, p 1.
5. Fergusson, David M, *loc cit*.
6. Hill, Ruth, "Abortion researcher confounded by study", *New Zealand Herald*, 5/1/2006.
7. *Ibid*.
8. *Ibid*.
9. For example, articles on Fergusson study in *Sydney Morning Herald*, *The Age*, *The Advertiser*, 4/1/2005.
10. Hill, Ruth, *loc cit*.
11. A statement by the US Food and Drug Administration (FDA) on 15 November 2004 announced new warnings on labels for RU486 (mifepristone) following "reports of serious bacterial infection, bleeding, ectopic pregnancies that have ruptured, and death, including another death from sepsis that was recently reported to FDA ... The new warnings to health care providers and consumers include changes to the existing black box on the product to add new information on the risk of serious bacterial infections, sepsis, and bleeding and death that may occur following any termination of pregnancy, including use of Mifeprex ... serious bacterial infection and sepsis may occur without the usual signs of infection, such as fever and tenderness on examination. Health care providers should be aware that prolonged, heavy bleeding may warrant surgical interventions. The label also warns that health care providers should be vigilant for patients with undiagnosed ectopic pregnancies (tubal pregnancies) as this condition may be missed by physical examination and ultrasound. Some of the symptoms of an ectopic pregnancy may mimic the expected symptoms of a

medical termination of pregnancy. Mifepristone is not effective for termination of these pregnancies.” (www.fda.gov/bbs/topics/news/2004/NEW01134.html)

12. Muehlenberg, Bill, “Let’s Not Return to the Dark Ages”, *Herald Sun*, Melbourne, 10/1/2006, p 18.
13. Willke, J C, MD, “RU486 Has Killed Eight Women”, Life Issues Institute, 1821 W Gilbraith Road, Cincinnati, Ohio OH 45239, USA, www.lifeissues.org .
14. Harris, Gardiner, “Deaths After Abortion Pill to be Studied by Officials”, *New York Times*, 23 November 2005.
15. See www.lifesite.net/ldn/2005/aug/05081507.html.
16. King, David and Box, Dan, “Abortion doctor to stand trial”, *The Australian*, 26/11/2005.
17. Senate Hansard, 21/5/1996, p 821.
18. “Give Women Choice: Australia Speaks on Abortion”, Southern Cross Bioethics Institute, Adelaide, 2005 (www.bioethics.org.au).
19. Hill, Ruth, *loc cit*.