



16 January 2006

Mr Elton Humphery
Committee Secretary
Community Affairs Committee
Department of the Senate
Parliament House
Canberra ACT 2600

Dear Committee Secretary,

Attached is the Australians Against RU486 submission to the Senate Inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005.

We would appreciate the opportunity to appear before the committee for further discussion regarding our submission.

A full list of the membership of Australians Against RU486 will be provided to the Senate Committee in the coming days.

Please feel free to contact me on 0417 656 668.

Regards,

Simone Holzapfel
Executive Director
Australians Against RU486

**It's Not Safe, It's Not Simple,
It's Not Right for Australian women**

National Office of AARU486

225 Glenmore Road
Paddington NSW 2021
Phone: 02 9357 1684

Email: info@aarU486.org.au

Web: www.aaru486.org.au



Submission to the Senate Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

Introduction

Australians Against RU486 (aa RU486) is concerned with the inherent medical, social and ethical affects of RU486.

This submission highlights that those who oppose changing the current approval process surrounding RU486 are pro-life and pro-choice.

From the outset of this debate, those supporting the changes have tried to paint all those who may oppose RU486 as anti-abortionists. This submission confirms that you can be pro-choice and anti RU486, a feminist and anti RU486, pro-life and anti RU486. These are not contradictions.

Their reasons are varied but their focus is singular.

The broad coalition of individuals and organisations within aa RU486 have differing views: some believe that abortion is wrong; while others view abortion as a viable option but worry about the signals a pill promoted by its advocates as a 'simple solution' sends; still others believe that the RU486 debate isn't about a woman's right to choose but rather that it's about women's health.

The aa RU486 submission attempts to distill the arguments against changing the current approval circumstances in a simple and easy to understand way. aa RU486 believe there are a number of arguments to retain the existing scrutiny and accountability surrounding the approval of RU486. These are outlined below.

**It's Not Safe, It's Not Simple,
It's Not Right for Australian women**

National Office of AARU486

225 Glenmore Road
Paddington NSW 2021
Phone: 02 9357 1684

Email: info@aar486.org.au

Web: www.aaru486.org.au



Scrutiny and accountability for a drug 'like no other'

- aa RU486 agree that RU486 should remain in its TGA 'restricted goods' category given its role as an abortifacient and that the current restrictions surrounding its approval should remain.
- The current level of scrutiny and accountability associated with RU486 is right and appropriate given medical, social and ethical concerns surrounding the drug.
- aa RU486 believes that the approval of RU486 must be something the Australian Parliament, through the Minister for Health, takes responsibility for given the higher criteria of ethics and social responsibility related to this drug.

TGA suitability for Approval

- aa RU486 believe that the TGA is not a suitable body to approve RU486.
- While, aa RU486 recognises the experience and good standing of the TGA, whatever your view, the TGA is not designed to deal with morality any drug.
- In evaluating an application for registration and listing of a 'therapeutic good' the Therapeutic Goods Administration is bound to consider "whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established" (Therapeutic Goods Act 1989, Section 25). There is no provision in the legislation for the TGA to consider broad social and ethical issues related to a 'therapeutic good'.
- The TGA is an organisation solely designed to look at any drug on its safety, efficacy and quality. Ethical and social criteria are not considered.
- aa RU486 contends that it is unsuitable for the TGA to approve RU486, on the grounds that it is a drug that is designed with an ethical dimension like no other drug.
- In addition, the TGA approval process is most often based upon research developed by the drug companies. aa RU486 shares the view of prominent bioethicists, like Renate Klein that RU486 research to date has been less than adequate in its controls and its reach.

**It's Not Safe, It's Not Simple,
It's Not Right for Australian women**

National Office of AARU486

225 Glenmore Road
Paddington NSW 2021
Phone: 02 9357 1684

Email: info@aarU486.org.au

Web: www.aaru486.org.au



Other research

- Recent New Zealand research highlights the psychological impacts that abortion may have on women.
- At this early stage, however, no one has any way of knowing the full extent of any harm.
- How can we ask the TGA to approve a drug, the psychological impacts of which are not fully known?

Signals to the Community

- A recent survey by the Southern Cross Bioethics Institute concluded that over 70 per cent of Australians think the abortion rate is too high and over 80 per cent think that it would be a good idea if the number were reduced while ensuring existing legal rights were protected.
Giving Women Choice: Australia Speaks on Abortion
Southern Cross Bioethics Institute, 2004
- aaRU486 believes the messages advocated by those who promote RU486 as a safe and easy fix, one designed for minimum fuss, are wrong and irresponsible especially considering Australian society may accept abortion but is clear in its desire to reduce the number of abortions that take place.
- 94 per cent of Australians believe that alternatives should be seriously considered before exercising the choice to have an abortion. Are advocates of RU486 in their promotion of this pill irresponsibly making abortion seem too easy?

**It's Not Safe, It's Not Simple,
It's Not Right for Australian women**

National Office of AARU486

225 Glenmore Road
Paddington NSW 2021
Phone: 02 9357 1684

Email: info@aarU486.org.au

Web: www.aaru486.org.au



Health Risks of RU486 raise questions that can't be ignored

- **Advocates of RU486 say it's safe, but evidence suggests the opposite**
 - The American Food and Drug Administration (FDA) **is investigating recently reported serious adverse events associated with mifepristone** (trade name Mifeprex, also known as RU-486). As a result, the FDA is issuing a public health advisory today highlighting the risk of sepsis or blood infection when undergoing medical abortion using Mifeprex and misoprostol in a manner that is not consistent with the approved labeling. **There are now four cases of deaths from infection from September 2003 to June 2005 following medical abortion with these drugs.**
FDA Website, 19 July 2005
 - These deaths have important implications both for the care of individual patients and for public policy. Disturbing aspects of the cases described by Fischer et al. in this issue of the Journal (pages 2352 – 2360) include the following: **all the women were young and healthy; they had apparently successful procedures (there was no evidence on autopsy of retained products of conception); their clinical presentations were somewhat cryptic because they had cramping, which is very common after the procedure, and no fever; and they all died remarkably rapidly after presentations.**
The New England Journal of Medicine; 1 December, 2005
 - RU486 has been linked to the deaths of at least ten women across Europe and the US since its introduction.
 - After a woman died during a trial of RU486 in Canada the trial was stopped and RU486 is not licensed there.
 - The drug is currently under review by the Centers for Disease Control (CDC) and the Food and Drug Administration in the United States after the recent deaths of five American women.
 - For up at least 8 per cent of women RU486 will result in an incomplete abortion. These women will be required to undergo a surgical abortion.
 - Up to 5 per cent of women will have blood loss so severe that it will require medical intervention.
 - In the US alone, there have been over 600 'adverse events' voluntarily reported to the Food and Drug Administration (FDA) as a result of RU486.

**It's Not Safe, It's Not Simple,
It's Not Right for Australian women**

National Office of AARU486

225 Glenmore Road
Paddington NSW 2021
Phone: 02 9357 1684

Email: info@aarU486.org.au

Web: www.aaru486.org.au



- **Advocates of RU486 its simple to use but it's not simple**
 - "RU 486 is not at all easy to use. In fact it is much more complex to use than the technique of vacuum extraction. True, no anaesthetic is required but a woman who wants to end her pregnancy has to 'live' with her abortion for at least a week using this technique. **It's an appalling psychological ordeal.**"
Edouard Sakiz, Chairman of Roussel Uclaf (The French Company developed and manufactures the RU486 drug in France) in 1989.
 - **"This is a very high rate of intervention compared to other medications.** I think that is one of the reasons it could only be used under a completely tied-down framework."
Dr Ross Maxwell, National President, Rural Doctors Association of Australia.

The RU486 Regime

The reality of **medical surveillance is not physician oversight from a distance but a highly-medicalised, multi-step, time-consuming procedure which, for many women, involves continuous suffering and pain.**

RU486 Misconceptions, Myths and Morals: Klein, R; Raymond J; Dumble L

1. Initial consultation, physical examination and pregnancy test. This will include a pelvic exam and possible ultrasound. Women should also be checked for contraindications (age, weight, medical history, medications, non-smoker). If contraindications are present, RU486 is not administered.
2. 24 hours later the initial drug is administered. The pill is taken in the presence of a nurse or doctor. In this initial period, most patients will bleed heavily. 1 in every 100 patients will require medical intervention to manage the blood loss.
3. 48 hours after the initial drug is administered, a prostaglandin is administered. This is again taken in the presence of the medical practitioner.
4. After the administration of the second drug, clinics often keep women there for up to 3 or 4 hours in the hope that the embryo will be expelled before sending them home. Other women wait longer; hours, days, sometimes weeks.
5. Between 7 and 14 days later, a patient must return for another pelvic examination to confirm the abortion is complete.
6. If the abortion is incomplete, then a conventional abortion is performed. Up to 10 per cent of women endure double abortion jeopardy.

**It's Not Safe, It's Not Simple,
It's Not Right for Australian women**

National Office of AARU486

225 Glenmore Road
Paddington NSW 2021
Phone: 02 9357 1684

Email: info@aarU486.org.au

Web: www.aaru486.org.au



- **Advocates of RU486 say it brings a level of privacy to the process but it's not private**
 - **Many of the researchers and physicians readily admit that RU486 is not safe enough to administer without close medical supervision.**
RU486 Misconceptions, Myths and Morals: Klein, R; Raymond J; Dumble L
 - Many states have laws which require that the physician examine the fetal remains whatever is passed," Nathanson said. "Now the question is how is a young girl of 17 going to go plowing through a toilet bowl full of blood clots and other nasty things to try to find this tiny little fetus and bring it to the doctor?
In 1969, Dr. Bernard Nathanson was co-founder of National Association for the Repeal of Abortion Laws, later renamed National Abortion Rights Action League. He was also the director of what was then the largest abortion facility in the world New York City's Center for Reproductive and Sexual Health.
 - The RU486 regime requires at least 3 trips to a clinic or physician with at least 3 invasive internal vaginal examinations over an 8 to 14 day period.
 - The entire regime must be taken under strict medical supervision and close to emergency medical assistance.
- **Advocates of RU486 say that RU486 will expand the choices for Australian women, but it's not good for Australian women**
 - **"It's not safe and it will not expand women's choices."**
Renate Klein, The Australian, 9 December 2005
 - "RU486/prostaglandin abortion could be considered a modern version of the backyard abortion: unsafe, painful and scary, not something that those of us who support a woman's right to choose could endorse."
Renate Klein, The Age, 25 November 2005
 - **The RU486 abortion should not be either a Pro Life or Pro Choice issue.** The most primary concern here must be the health and welfare of our children and young women.
Monty and Helen Patterson - Parents of 18 year old Holly Patterson who died in 2004 from complications arising from RU486.
 - Australian women already have access to Medicare-funded abortion.

**It's Not Safe, It's Not Simple,
It's Not Right for Australian women**

National Office of AARU486

225 Glenmore Road
Paddington NSW 2021
Phone: 02 9357 1684

Email: info@aarU486.org.au

Web: www.aaru486.org.au



- 84,000 abortions are performed each year. It will put the lives of women in Australia at greater risk by introducing a drug with serious side effects.
- The RU486 pill makes more demands on an already well over stretched health dollar.
- RU486 causes severe malformations to babies that survive including fused limbs, brain malformations, kidney problems and genital malformations.

Australians Against RU486

Australian Against RU486 is a coalition of concerned groups and individuals including pro-choice people campaigning on medical, ethical or moral grounds to keep ban on RU486. The coalition includes eminent doctors, physicians, academics, and community leaders from all over Australia.

aa RU486 supports positive outcomes for Australian women and believes that advocates of RU486 are endangering the lives of Australian women in the name of choice. **aa RU486** is a trust established specifically and solely to campaign to keep the ban on RU486.

Contact Us

For further information contact the **National Office of Australians Against RU486** at:

225 Glenmore Road
Paddington NSW 2021

02 9357 1684
info@aar486.org.au
www.aaru486.org.au

**It's Not Safe, It's Not Simple,
It's Not Right for Australian women**

National Office of AARU486

225 Glenmore Road
Paddington NSW 2021
Phone: 02 9357 1684
Email: info@aar486.org.au
Web: www.aaru486.org.au