



# **WHNSW**

**Women's Health NSW**

Non Government

Feminist Health

Services

## **SUBMISSION TO THE INQUIRY INTO THERAPEUTIC GOODS AMENDMENT (REPEAL OF MINISTERIAL RESPONSIBILITY FOR APPROVAL OF RU486) BILL 2005.**

### **Introduction**

Women's Health New South Wales is the peak body for 23 women's health centres throughout New South Wales. These member centres (including the Bessie Smyth Foundation, a specialist pregnancy termination and counselling service) have provided a range of health services to women around the state since the early 1970s. The collective knowledge of the women's health sector relating to women making pregnancy choices including abortion, is vast, covering thousands of client services over 30 years or more. We, the peak body, understand from the experience of our member centres, that the best decisions regarding pregnancy termination are those made by a woman in consultation with her medical practitioner. Similarly, we believe that a decision regarding the approval of RU486 is best made by the qualified body, the Therapeutic Goods Administration (TGA), the appropriate body to address the safety and efficacy of all drugs to be used in Australia.

### **Submission**

We are all entitled to our opinion and beliefs. However medical decisions should be made on the basis of rigorous and up-to-date medical evidence. And who better to evaluate the medical evidence than the Therapeutic Goods Administration (TGA)? A recent research note by the federal parliamentary library service says that given that the current debate over RU 486 is "essentially over questions of risk management" and that management of the risks associated with

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Funded by NSW Health Department

medicines is an “explicit function of the TGA”, that the Government should step back and let the TGA do its job: "The TGA is regarded by the Government as being qualified to manage the risks associated with any therapeutic good that is used (or proposed for use) in Australia. From this, one could reasonably assume that it is also qualified to manage the risks associated with abortifacients such as RU486". (see: <http://www.aph.gov.au/library/pubs/RN/2005-06/06rn19.htm>)

We offer the following key points for your consideration:

### **1.0 The vast majority of Australians support a woman’s right to choose and believe that abortion is a matter between a woman and her doctor.**

The 2003 Australian Survey of Social Attitudes conducted by the Australian National University found that 81% of Australians support a woman’s right to choose and only 9% are against. A recent call for Australian voter’s signatures on a petition supporting the removal of the effective ban on RU486 has collected nearly 6000 signatures in its first week. (See: [http://www.getup.org.au/campaign.asp?campaign\\_id=19](http://www.getup.org.au/campaign.asp?campaign_id=19)).

### **2.0 The evidence is in and it’s clear: RU 486 is safe and effective**

An impressive roll-call of Australian, International and World Health Bodies support the availability of RU 486. They include:

- The World Health Organisation
- The Royal Australian New Zealand College of Obstetricians and Gynaecologists
- The Public Health Association of Australia
- The Royal College of Obstetricians and Gynaecologists (UK)
- The Australian Medical Association
- The American Medical Association

- American Association for Advancement of Science
- Federal Drug Administration (US)
- The Rural Doctors Association of Australia
- Federation of International Gynaecology and Obstetrics (FIGO)
- American College of Obstetricians and Gynecologists
- Cochrane Collaboration

### **3.0 No medication or medical procedure is risk-free. But the experts say that the health risks associated with RU 486 fall well within acceptable limits**

RU 486 has been used by over 21 million women around the world in more than 30 countries, including the United Kingdom, New Zealand and the United States. According to the Royal Australian New Zealand College of Obstetricians and Gynaecologists, the risk of mortality and serious complications with abortion are “rare” and in some cases may be lower with medical abortion. (see: <http://www.ranzcog.edu.au/womenshealth/pdfs/Termination-of-pregnancy.pdf>).

Indeed, the adverse drug event rate for RU 486 is very low at .137%. This compares with the over-the-counter drug Claratyne which has an adverse event rate of 12% (87 times higher than Mifepristone).

RANZCOG also notes that infection using medical abortion “may be less frequent than with suction curettage method of abortion”. This is relevant to discussions surrounding the recent deaths of four American women from an unusual bacterial infection. In the December 1 st Edition of the *The New England Journal of Medicine* Dr Robert Greene, a Professor of obstetrics, gynecology, and reproductive biology at Harvard Medical School, Boston and the Director of obstetrics at Massachusetts General Hospital, Boston, has argued that the overall mortality rate associated with medical abortion is small (1:100,000) and no different to that posed by surgical abortion. Given that it remains unclear if the infection was associated with abortion using RU 486, and RU

486 has been used by millions of women in Europe and China with no reported instances of the infection, Greene argues against regulators restricting or banning the drug, though he stresses the importance of women being informed about the small risk of this infection before giving consent (see:

<http://content.nejm.org/cgi/content/full/353/22/2317?query=TOC>).

#### **4.0 The US FDA recently affirmed the safety of medical abortion for American women and authorised its continued use.**

#### **5.0 Making a non-surgical option available to women will not increase the abortion rate**

Medical abortion, like surgical, requires appropriate medical supervision and women in most states will still need to persuade a medical practitioner their abortion is “necessary” for them to comply with relevant state criminal codes regulating the procedure.

Overseas experience shows that that the availability of medical abortion does not increase the overall number of abortions that take place, as was recently acknowledged in a recent briefing paper by the Australian Christian Lobby. (See: [http://www.acl.org.au/pdfs/load\\_pdf\\_public.pdf?pdf\\_id=437&from=](http://www.acl.org.au/pdfs/load_pdf_public.pdf?pdf_id=437&from=))

The introduction of RU 486 in Germany 1999 has seen a steady rise in the number of women choosing a medical abortion, but a relatively steady rate of abortion over all. Increasing numbers of American women are also choosing medical over surgical abortion, but the US recently recorded its lowest overall rate of abortion in 30 years. In Sweden, abortion rates actually declined after medical abortion was introduced (See: <http://www.agi-usa.org/pubs/journals/3415402.pdf>)

**6.0 The Therapeutic Goods Administration - not politicians, religious leaders, academics or political activists - should decide if RU 486 poses an unacceptable level of risk to Australian women**

The upcoming vote is not about abortion, or the safety of RU 486. It is about *who will decide* if RU 486 is safe and effective enough for Australian patients and we uphold that the Therapeutic Goods Administration - not politicians, religious leaders, academics or political activists - should decide if RU 486 poses an unacceptable level of risk to Australian women.

We iterate that medical decisions should be made on the basis of rigorous and up-to-date medical evidence. And who better to evaluate the medical evidence than the Therapeutic Goods Administration.



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20 January 2006

**End of submission**