

Dear Community Affairs Committee,

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

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. As cited in the 2003 Australian Survey of Social Attitudes conducted by the Australian National University, 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).

Whilst everyone is entitled to hold their own opinions and beliefs, medical decisions should be made on the basis of rigorous and up-to-date medical evidence. The Therapeutics Goods Administration (TGA) has the responsibility of ensuring that therapeutic goods available in Australia are of an acceptable standard through appropriate assessment and monitoring processes. Therefore, it is appropriate that the Therapeutics Goods Administration (TGA) evaluate the medical evidence in relation to RU486. 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 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>)

Whereas no medication or medical procedure is risk-free, experts say that the health risks associated with RU486 fall well within acceptable limits. RU486 has been used by over 21 million women world-wide 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>). The adverse drug event rate for RU 486 is very low at .137% compared 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 1st 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, 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>). It should also be noted that RU486 has been used by millions of women in Europe and China with no reported instances of the infection. The US FDA recently affirmed the safety of medical abortion for American women and authorised its continued use.

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 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=)

The introduction of RU486 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>)

The Therapeutics Goods Administration - not politicians, religious leaders, academics or political activists - should decide if RU486 poses an unacceptable level of risk to Australian women. The upcoming vote is not about abortion, or the safety of RU486. It is about ***who will decide*** if RU486 is safe and effective enough for Australian patients. It is about ensuring that the Therapeutic Goods Administration can continue to do the job that it has been mandated to do in assessing and evaluating therapeutic goods. It is about ensuring that the decisions about the availability of therapeutic goods in Australia are made on the basis of rigorous and up-to-date medical evidence.

We maintain that the Therapeutics Goods Administration - not politicians, religious leaders, academics or political activists - should decide if RU 486 poses an unacceptable level of risk to Australian women.

Yours sincerely,

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