



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

A Question of Good Governance

The sponsors of this Private Member's bill have made clear that their concern is *not* the morality of abortion, or its legality. Under certain conditions, abortion is lawful and safe in all Australian states, though regulation of provision does vary. Rather, to paraphrase Prime Minister John Howard, the vote slated for February 2006 is about whether a single member of Parliament or the Therapeutics Goods Administration (TGA) should decide on the safety of the drug. (Hudson 2005)

Arguments in favour of the TGA making the decision are both numerous and strong. The first is the need to avoid Federal interference with State laws on abortion. In Australia, the States regulate abortion. The curtailment of the legitimate regulatory scope of the TGA by the Commonwealth improperly interferes with State policy and law in this area.

The second is the importance of keeping politics out of medical decision-making. Rather, decisions about the health of all Australians need to be made on the basis of the medical evidence by the experts charged by government with precisely this risk assessment role. Drugs like RU486, those 1996 amendments to the Therapeutic Goods Act classify as intended for use in women as abortifacients, are the only medications the TGA does not have authority to evaluate and regulate. Yet, since its establishment in 1989, the TGA has fulfilled its responsibility to both "assess and monitor" the almost 50,000 other drugs on which Australians rely for their health. As well, the Howard government has relied on the TGA to assess and manage the risks associated with contentious pharmaceuticals like the NSW Government's proposed trial of cannabis for pain relief. (Department of the Parliamentary Library 2003-04) Why should RU486 be different?

One possible reply to this question put forward by supporters of the effective ban is that RU486 is an especially risky pharmaceutical. However, this claim is illogical. The TGA is the body charged to assess the risk of drugs. On what expertise and process have those who claim the drug is too risky for the regulator to assess relied? How can an evidence-based evaluation of the drug's safety put women at risk? What sense does it make to deem a drug too unsafe to have its risks properly and impartially evaluated? Isn't the point of such an expert assessment to weigh the medical evidence and deliver a considered judgment about the risk/benefit profile of the drug? If the evidence exists to support claims that the drug is unsafe, shouldn't those expressing concern about risk welcome the vindication likely to come from a proper evidence-based evaluation by the TGA?

As it happens, the evidence does not support claims that RU486 is a particularly risky pharmaceutical. All drugs have risks and benefits, but 15 years of experience of the drug in European countries like France, the UK, Germany and Sweden have produced a large body of evidence that clearly demonstrates the drug's safety and efficacy for use in inducing early miscarriage. Notes the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (the RANZCOG): "There is a substantial body of literature establishing the safety and efficacy of mifepristone when used in conjunction with a prostaglandin analogue, usually misoprostol, to induce abortion." (The Royal Australian and New Zealand College of Obstetricians and Gynaecologists 2005) The World Health Organization concurs. In July 2005 it placed RU486 on its list of "essential medicines", and described abortion – by surgical or medical means – as "one of the safest medical procedures." (World Health Organization 2003; World Health Organization 2006)

The widespread consensus amongst qualified medical professionals and medical researchers about RU486/Mifepristone's safety and efficacy may be why, according to a recent research note from the Parliamentary Library in Canberra, ban-supporters and those opposed to the ban are not in dispute about basic facts about the drug's efficacy and possible side-effects. (Buckmaster 2005) What *is* in contention is the acceptability of the risk/benefit profile for Australian patients. On one side of this dispute are all the major Australian medical organizations, including the Australian Medical Association (AMA) and the RCANZOG, as well as key professional organizations and peak bodies overseas including the World Health Organisation, the Royal College of Obstetricians and Gynaecologists (UK), the Federation of International Gynaecology and Obstetrics (FIGO) and the American College of Obstetricians and Gynecologists. These groups conclude on the basis of the medical evidence that the risks posed by the drug fall well within acceptable limits, and are outweighed by the benefits. On the other are largely opponents of all abortion – whether induced surgically or medically – who suggest that because the drug has no benefits, it's risks are overwhelming and incapable of being managed by appropriate medical protocols, proper prescriptive practices or informed patient consent. That the central issue in the current debate is risk management is a "key point", according to a recent Parliamentary Library research note: evaluating and managing the risks associated with medicines is an "explicit function of the TGA". This then raises the question: why when it comes to this class of drugs – and this class of drugs alone – is the capacity of the TGA to carry out its prescribed function being called into question?

One answer to this question is that this class of drugs is different to all others. Dr David van Gend, from the Queensland Branch of the World Federation of Doctors Who Respect Human Life, is one of those who argue that drugs like RU486 are "unique" as no other drugs are "designed" to end human life. (Hansard 2005) But this is incorrect. RU486 was designed by its healthcare company-creator Roussel Uclaf as a treatment for serious endocrine conditions like Cushings Syndrome. The discovery that the compound could induce very early abortions was an unexpected outcome of this investigation.

Perhaps what Dr van Gend meant was that drugs like RU486 are unique because they have the *effect* of ending human life. This certainly seems to be the gist of recent reported comments by Ms Simone Holzapfel, a former employee of Health Minister Tony Abbott's, and coordinator of the newly-formed Australians against RU486, who said the drug "was in a league of its own". (Morris 2006)

But such claims are also incorrect. There are a number of pharmaceuticals that are both registered in Australia by the TGA and used in a broad range of healthcare settings that can end human life, including morphine sulfate. (Therapeutic Goods Administration 1999) Nor can it be said that RU486 is the only medicine capable of harming an embryo/fetus or causing miscarriage. Currently, the TGA lists around 55 drugs or categories of drugs that either “cause, are suspected to have caused or may be expected to cause an increased incidence of human fetal malformations or irreversible damage” (Category D) or have “a high risk of causing permanent damage to the fetus” (Category X). These include the anti-malarial Quinine, several vaccinations, numerous anti-epileptics and the mental illness treatment Lithium salts. (Therapeutic Goods Administration 2000)

RU486 is not the only drug designed or capable of ending human life, and its anti-progesterone action may allow it to improve and save the lives of seriously ill Australians. RU486 is indicated as therapy in a variety of serious and, in some cases, life-threatening medical conditions. These include inoperable meningiomas; Cushing’s Syndrome; breast and prostate cancer; glaucoma; depression; endometriosis, and uterine fibroids. In addition, the drug has shown promise in the treatment of HIV/AIDS, dementia and progesterone-dependant uterine and ovarian cancer.

So if RU486 is a pharmaceutical agent like all others, with a range of risks and benefits for a wide variety of patients, and the capacity to both induce miscarriage and to save lives, there appears to be no rational argument to support the retention of the 1996 amendments to the Therapeutics Goods Act (1989) which have effectively banned the drug in Australia. Rather, rational consideration suggests that in the same way as the TGA fulfils its mandate with regard to other drugs – ensuring they are of an acceptable standard and that Australian patients have access to them within reasonable time frames – it should be politically unshackled so it can undertake this work with regard to RU486.

If arguments in favour of retaining the effective ban on RU486 are not grounded in logic, what is their source? One candidate is faith. Eighty-two per cent of Australians support a woman’s right to choose whether or not she has an abortion. This figure declines only slightly for religiously identified Australians, 77% of whom support a woman’s right to choose. However, the small minority of Australians (9%) who oppose a woman’s right to choose – and presumably favour a retention of the ban – are predominantly people of “faith.” (Betts 2004)

Yet, Australians of all religions and cultural backgrounds have good reason to oppose the influence of faith rather than logic-based arguments in policy decisions that affect all of us. This is because in pluralist democracies the religious and cultural rights and freedoms we enjoy depend on the refusal of government to favour one’s group’s religious or cultural outlook over another. As has been shown in many countries across the globe, the State’s imposition of the values of one religious or cultural group on the whole can undermine national cohesiveness and sabotage democracy. Australians must hold to our principles that religion has no place in politics (Parliament of Australia 1900) and politics has no place in medicine. Upholding this conviction does not make our democracy values-neutral but a unifying repository for values shared by most of the world’s religions and subscribed to by the people of all successful democracies: justice, equity, respect, tolerance, honesty, integrity, personal responsibility and trust.

This makes the solution to the dispute between those opposed to the effective ban on RU486 and those who support it – a dispute about the acceptability of the risks associated with RU486 – precisely the sort that should be decided by the expert government authority in an impartial evidence-based manner. Let the TGA decide. And let responsible politicians and citizens alike respect and abide by the experts' ruling, whatever it is.

For inquiries regarding this submission please contact:

Dr Leslie Cannold
LCannold@unimelb.edu.au

References

- Betts, K. (2004). "Attitudes to Abortion in Australia: 1972 to 2003." *People and Place* **12**(4): 22-28. <http://elecpress.monash.edu.au/pnp/view/abstract/?article=0000010218>
- Buckmaster, L. (2005). "RU486 for Australia?" *Research Note* **19**(2005-6). <http://www.aph.gov.au/library/pubs/rn/2005-06/06rn19.htm>
- Department of the Parliamentary Library (2003-04). "The Use of Cannabis for Medical Purposes." *Research Note* **13**. <http://www.aph.gov.au/library/pubs/rn/2003-04/04rn13.pdf>
- Hansard (2005). Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval for RU486) Bill 2005. *Senate Community Affairs Legislation Committee*. Canberra, Hansard. <http://www.aph.gov.au/hansard/senate/committee/S8992.pdf>
- Hudson, P. (2005). More Tax Cuts on the Way: PM. *The Sunday Age*. Melbourne: 1.
- Morris, L. (2006). Abortion pill's enemies unite. *Sydney Morning Herald*. Sydney. <http://www.smh.com.au/news/national/abortion-pills-enemies-unite/2006/01/13/1137118970048.html>
- Parliament of Australia (1900). The Australian Constitution. <http://www.aph.gov.au/senate/general/constitution/chapter5.htm>
- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (2005). *Mifepristone (RU486)*. College Statement. <http://www.ranzcog.edu.au/publications/statements/C-gyn14.pdf>
- Therapeutic Goods Administration (1999). Gazettal Notice Therapeutic Goods Act 1989 Australian Drug Evaluation Committee Recommendations. *ADEC 207th Meeting Recommendations*. Canberra, Department of Health and Ageing, Therapeutic Goods Administration. <http://www.tga.gov.au/docs/html/adec/adec0207.htm>
- Therapeutic Goods Administration (2000). *Prescribing Medicines in Pregnancy*, 4th Edition. Canberra, Therapeutic Goods Administration. <http://www.tga.gov.au/docs/html/mip/medicine.htm>
- World Health Organization (2003). *Safe Abortion: Technical and Policy Guidance for Health Systems*. Geneva, World Health Organization. http://www.who.int/reproductive-health/publications/safe_abortion/safe_abortion.pdf
- World Health Organization (2006). *Goal 8: Essential Medicines*. *Millennium Development Goals*, World Health Organization. http://www.who.int/mdg/goals/goal8/essential_medicines/en/