

RU 486/ Mifepristone

A factual guide to the issues in the Australian Debate



Introduction

A Private Member's bill, the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill is now before Parliament. The bill seeks to remove responsibility for approval for abortifacients like RU486 from the Minister for Health and Ageing and return it to the Therapeutic Goods Administration (TGA). The Reproductive Health Alliance and Reproductive Choice Australia have produced this briefing paper to articulate the variety of robust arguments in favour of giving regulatory oversight of RU486 to the TGA; to document the scientific and medical community's support for access to the drug in Australia and to counter a range of misrepresentations of the drug's uses, effects and safety record.

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A Question of Good Governance

States' Rights, Politics and Medicine

The sponsors of the Private Member's bill Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 have made clear that their concern is not the morality of abortion, or its legality. Abortion is currently safely available in Australia with the regulation of provision varying from state to state. 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, abortion is regulated by the states. 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 separating politics from medical decision-making. Rather, decisions about the health of all Australians need to be made on the basis of medical evidence by the experts charged by government with precisely this risk assessment role: the TGA. Medicines intended for use in women as abortifacients, like RU486, are the only ones 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. 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?

‘ If concerns being expressed about the drug’s safety are evidence-based, those voicing them should welcome the vindication likely to come from a scientific evidence-based evaluation by the TGA. ’

Let the TGA decide

One possible response to this question put forward by supporters of the effective ban is that RU486 is an especially risky pharmaceutical. The TGA is the body charged to assess the risk of drugs. What expertise and process have been relied on for the claim – made by ban supporters – that RU486 is too risky for the TGA to assess? 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? The point of such an expert assessment is to weigh the medical evidence and deliver a considered judgment about the risk/benefit profile of the drug.

If concerns being expressed about the drug’s safety are evidence-based, those voicing them should welcome the vindication likely to come from a scientific evidence-based evaluation by the TGA.

The International Experience with RU486

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 Europe has produced a large body of evidence that clearly demonstrates the drug’s safety and efficacy for use in inducing early miscarriage. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (the RANZCOG) notes: “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 agrees. In July 2005 it placed RU486 on its list of “essential medicines”, and described abortion – by either surgical or medical means – as “one of the safest medical procedures.” (World Health Organization 2003; World Health Organization 2006)

‘The central issue in the current debate is risk management. This is a key point, because evaluating and managing the risks associated with medicines is an explicit function of the TGA. Why has the TGA’s capacity to carry out its prescribed function been called into question when it comes to RU486?’

The widespread international consensus amongst qualified medical professionals and researchers about RU486’s safety and efficacy may be why, according to a recent research note from the Parliamentary Library in Canberra, few dispute the 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 major Australian medical organizations, including the Australian Medical Association (AMA) and the RANZCOG, who argue that the drug’s risks 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 its risks are overwhelming and incapable of being managed by doctors observing appropriate medical protocols, proper prescriptive practices and informed patient consent. That the Australian debate is about risk management is a key point because evaluating and managing the risks associated with medicines is an “explicit function of the TGA”. (Buckmaster 2005) This raises the question: why when it comes to this class of

drugs – and only this class of drugs – has the capacity of the TGA to carry out its prescribed function been called into question?

A Drug Like No Other?

The Queensland Branch of the World Federation of Doctors Who Respect Human Life says approval for RU486 should not lie with the TGA because no other drugs are “designed” to end human life. (2005) But this is incorrect. RU486 was designed by its healthcare company creator Roussel Uclaf as a treatment for serious endocrine disorders. The discovery that the compound could induce very early abortions was an unintended outcome of this research.

It is also wrong to claim that RU486 is unique because it is the only drug capable of ending human life. There are a number of pharmaceuticals 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 the fetus or causing miscarriage. The TGA lists

Myth

The death of 4 American women who aborted using RU486 has led the US Food and Drug Administration (FDA) to ban the drug.

Fact

The FDA has not banned on RU486. So far, the agency has identified the infection that caused the four tragic deaths as *Clostridium sordellii*, though the source of that infection remains unclear. Prior to these four cases, only ten cases of *Clostridium sordellii* have been identified in the literature and most are unrelated to (medical or surgical) abortion: 8 occurring after delivery of live-born infants, 1 after a medical abortion and 1 not associated with pregnancy. (Fischer 2005) Because this infection has not been observed in other countries despite over a decade of medical abortion; because pregnancy and childbirth as well as abortion may put a small group of women predisposed to the infection at risk, and because infection is a small but known risk associated with any type of abortion, the FDA has not moved to restrict access to the drug. (US FDA 2005)

However, even if the FDA does eventually establish a link between the infection and medical abortion, the risk of mortality associated with medical abortion will still be low (around 1:100,000). This is comparable to the very low mortality associated with surgical abortion at comparable gestational ages (0.1 per 100, 000). (Fischer 2005; Greene 2005).

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)

The anti-progesterone RU486 is also capable of improving and saving the lives of seriously ill Australians who for the past decade have been denied ready and affordable – and in some cases any – access to treatment for 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.

Australian Democracy and the Constitutional Requirement to Separate Religion and Politics

Eighty-one 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)

The religious and cultural rights and freedoms Australians enjoy depend on the refusal of government to endorse any group’s religious or cultural values and impose it on the entire community. In many countries, the state’s imposition of the values of one religious or cultural group has undermined national cohesiveness and sabotaged democracy. Australians must hold to our principles that religion and politics don’t mix. (Parliament of Australia 1900) Upholding this conviction does not make our democracy values-neutral but enables shared democratic values like justice, equity, respect, tolerance, honesty, integrity, personal responsibility and trust to flourish. This is why the TGA must decide, on the basis of an impartial evaluation of the medical and scientific evidence.

Myth

Making RU486 available will enable “Do-It-Yourself” (DIY) terminations that will make abortion “too easy” for women and increase the abortion rate.

Fact

There is nothing DIY about medical abortion. To be safe, and to comply with state laws abortions - whether procured medically or surgically – require medical oversight and approval. If a state requires that a woman satisfy physical and mental health tests before qualifying for a surgical abortion, she will be required to satisfy the same tests to have a lawful termination using medical methods.

If women need to suffer when they have an abortion, similar logic suggests we should deny them pain relief during labour so they can suffer – as was once believed just and necessary – when they give birth. As the WHO has noted, even if couples use contraception correctly 100% of the time, there will be close to six million accidental pregnancies each year. It takes two to make an unplanned pregnancy, but the when fertility control methods fail, it is women who are held responsible.

RU486 Will Not Increase the Abortion Rate

More than one factor will contribute to a woman’s evaluation that a pregnancy is unwanted and her decision to seek an abortion. Most reflect a woman’s considered view that she would be unable to be a good mother to a(nother) child while meeting her existing obligations to herself, her partner, her parents her community and/or existing children. (Bankole, Singh et al. 1998; Cannold 2000)

There is no evidence to suggest that providing women with another means of procuring a safe and legal abortion increases the abortion rate. The introduction of RU486 for early induced abortion in France, Great Britain and Sweden in the late 1980s/early 1990s has either seen abortion rates remain stable, or in the case of Sweden, decline. (Jones and Henshaw 2002) In fact, the introduction of medical abortion in Europe has seen a dramatic increase in the proportion of abortions taking place earlier in pregnancy. In France, the proportion of abortions performed at or before seven weeks from the last menstrual period increased from 12% in 1987 to 20% in 1997, while in Scotland, the proportion of all abortions that occur before 10 weeks gestation has increased from 51% in 1990 to 67% in 2000. Similarly, in Sweden, the proportion of abortions performed before nine weeks increased from 45% in 1991 to 65% in 1999. (Jones and Henshaw 2002) This should not be surprising as quality studies show that women often choose medical methods because they are available earlier than surgical, and being able to terminate as early as possible is important to them. (Slade 1998 and Weibe 1993 as cited in Say, Kulier et al. 2005)

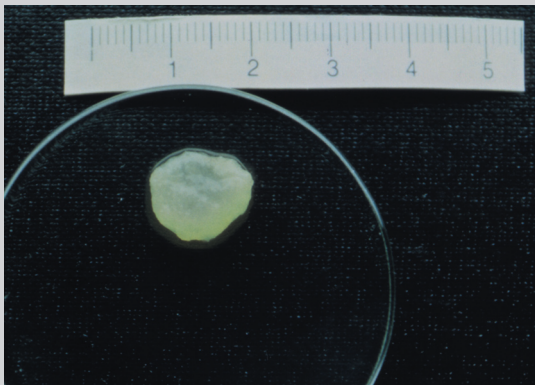
Myth

RU486 takes up to three days to terminate a pregnancy, and puts women's emotional health at risk by enabling them to terminate an identifiable "fetus" at home.

Fact

RU486 works by blocking the hormone progesterone, and by so doing halting the changes in the female body that support pregnancy. The withdrawal of progesterone, a process that begins shortly after the woman ingests the tablets, results in a breakdown and shedding of the lining of the uterus similar to what occurs in a normal menstrual cycle. Around 48 hours later, women are administered a prostaglandin, and 6 hours later, around 90% will have completed their miscarriage. This makes the 3-day claim nonsense, as the vast majority of women have terminated their pregnancy well before this time. (Childbirth by Choice Trust 1996)

One of the things women like about medical abortion is the capacity to miscarry in the privacy of their own home. Spontaneous miscarriage is a common occurrence up to 12 weeks of pregnancy, and many such miscarriages will occur at home. About 50% of all fertilized eggs die and are aborted spontaneously, usually before the woman knows she is pregnant while 1 in 10 known pregnancies will spontaneously miscarry, usually between 7 and 12 weeks after the woman's last menstrual period. (Medline Plus 2005) The World Health Organisation notes women experience spontaneous abortion and medical abortion similarly: "the effects of medical methods of abortion are similar to those associated with spontaneous abortion and include cramping and prolonged menstrual-like bleeding". (World Health Organization 2003)



A gestational sac at five weeks after
Last Menstrual Period (LMP)

The RANZCOG says that women who chose medical abortion do not usually cite the passage of a sac as a concern. (The Royal Australian and New Zealand College of Obstetricians and Gynaecologists 2005) This may be because up to 9 weeks pregnancy, the time frame in which RU486 is medically indicated, the only products a woman will see are placental tissue and blood. The embryo/fetus is still at the earliest stages of development. At 5 weeks (or 35 days) pregnancy, the embryo is 2-3.5mm long (about half the size of a grain of rice) and is not identifiably human. At 8 weeks of pregnancy the embryo/fetus is 13-17mm. (Larson, 1998) According to Dr Lennart Nilsson, the medical and scientific photographer whose photographs have appeared in *Life*, *Time* and *National Geographic*, its organs have not fully formed, and it has neither face, bones, hair or nails. Says Dr Nilsson, at this time the embryo's brain and brain functions are "very underdeveloped, and there cannot yet be any real consciousness...". (Nilsson 1990, 91; Larson 1998).

Women's sanitary requirements when miscarrying at home, whether spontaneously or as a result of medical abortion, are no different to those they face during a heavy monthly bleed.

The Australian Debate about RU486: What Counts as Evidence

Reliable evidence is the result of recognised and transparent research methods. Such methods ensure that researchers' findings conform to accepted academic or professional standards and what is claimed to be "data", "findings", "fact" or "evidence" is worthy of the name.

Ethical Research Produces Valid Results

The NHMRC issues ethical guidelines for medical researchers as well as social and behavioural scientists. These include the expectation that research questions be designed to contribute to knowledge; that researchers show a clear commitment to the pursuit and protection of truth; that they rely on research methods appropriate to the discipline and demonstrate both personal and professional honesty. Universities and other organisations that receive funding from the NHMRC are obligated to establish Institutional Ethics Committees (IECs) to review all research involving humans. IECs scrutinize all aspects of a proposed research project, including the suitability and effectiveness of the proposed methodology.

This is because it is considered unethical to involve people in research so poorly designed it has no capacity to generate valid data.

Research-consumers are indirectly protected by this policy, which ensures that projects with methods incapable of delivering valid findings will be stopped from proceeding by the denial of ethics approval.

Research from Independent Institutions Lacks Quality Guarantees

When independent institutions conduct research there are no quality guarantees to either research participants or research-consumers: including journalists and political decisionmakers. Indeed, unless the findings from independent institutions are reported in a peer refereed journal, the data is unlikely to have been subject to any recognised verification procedures.

The Debate about RU486: Some Key Facts

Public Opinion

Australians are highly supportive of RU486. In a 2006 poll conducted by Newspoll and funded by the Australian Reproductive Health Alliance, 68% told researchers they favoured RU486 being made available in Australia for use by qualified medical practitioners. Only 21% opposed the drug's availability and 9% were unsure.

The 2003 Australian Survey of Social Attitudes (AuSSA) conducted by the ACSPRI Centre for Social Research at the Australian National University shows 82% of Australian adults support a woman's "right to choose". A review of polling trends published in the peer reviewed journal *People and Place* shows that over the past 34 years, support for reproductive freedom has "moved strongly in a pro-choice direction". (Betts 2004) A 2005 Systematic Review of randomised controlled trials comparing surgical and medical abortion by The Cochrane

Collaboration concluded: “medical methods for abortion in early pregnancy can be safe and effective, with the most evidence of effectiveness for a combination of mifepristone and misoprostol”. (Say, Kulier et al. 2005)

Induced Abortion Does Not Cause Breast Cancer

Yet, in what is claimed to be an “evidence-based review of abortion”, the faith based organisation Women’s Forum Australia (WFA) cites the Cochrane Review in its case against medical abortion without ever referring to this conclusion. Similarly, the WFA’s “evidence-based review” claims that induced abortion may be a risk factor for breast cancer despite such a link being definitively ruled out by the US National Cancer Institute in 2003 on the basis of an extensive review of the population-based, clinical and animal studies. (National Cancer Institute 2003) This definitive conclusion about the absence of any link between induced abortion and breast cancer was echoed by the RANZCOG in their 2005 *Termination of Pregnancy: A resource for health professionals*. (RANZCOG 2005, 4)

The Cost to Politicians, Journalists and the Public of Unethical Research

The author of the WFA “evidence-based review” is a staff member at the Southern Cross Bioethics Institute (SCBI). The SCBI describes itself as an “independent, non-sectarian” institution (Southern Cross Bioethics Institute 2005), but is actually an initiative of Southern Cross Care (SA). Southern Cross Care is a product of the Knights of the Southern Cross: an “Order of Catholic men committed to promoting the Christian way of life throughout Australia”. (Cannold 2005; Mannix 2005) While the SCBI declines to reveal its link to the Knights, the Knights are more candid. Their website identifies – and links to – the SCBI as a Knights branch. (Knights of the Southern Cross 2004)

It may be that frustration with the failure of legitimate research and polling to deliver data useful in restricting women and couples’ reproductive dignity and freedom has led those committed to this goal to set up organisations with feminist or academic-sounding names to conduct and self-publish their own “research”. Instead of disseminating results through accepted channels like peer-reviewed journals, the media is used to give such “findings” profile.

The Problem of Push-polling and the Importance of Accurate Credentials

But policy-makers and journalists who rely on such “data” are at risk of significant exposure. The failure of such research – and researchers – to conform to basic ethical and academic standards throws doubt on the credibility of any findings. Early in 2005, a scandal erupted when several academic researchers attempted and failed to obtain the questions used by the SCBI to generate public opinion “data” about abortion. (Cannold 2005; Cox 2005; Mannix 2005) The repeated refusal of SCBI to release their questions made it impossible for academic researchers to rule out the possibility that the results had been generated by the disreputable practice of providing false information to participants and soliciting their views using leading questions: a practice known colloquially as “push-polling.” It also lent weight to the suspicion that the “researchers” were deliberately trying to conceal the use of illegitimate research methods like push-polling from journalists, decision-makers and the public.

As the National Council on Public Polls argues in the 3rd edition of “20 Questions a Journalist Should Ask About Poll Results”, accurate reporting on poll findings requires journalists to ascertain the “exact wording of the poll questions” because the wording of questions “can make major differences in the results.” (Gawiser and Evans Witt 2002) Journalists who report poll data without this information risk being used by those who seek to mislead decision-makers and the public.

It is also imperative that full and accurate disclosure of authors’ or organisations’ credentials is attached to all published information and opinion. While everyone is entitled to express their opinion, whatever it may be, on the political issue of the day, journalists, decision-makers and the general public rely on credentialing information to make sense and accord weight to the information and opinion presented. (Cannold 2005)

Myth

An abortion with RU486 is too hard on women.

Fact

The evidence is not on the side of those who claim that the process of aborting using RU486 will be too hard on Australian women. This regimen has been used by millions of women worldwide and has been shown to be “safe and effective” in two Cochrane Systematic Reviews. (Kulier, Gulmezoglu et al. 2005) (Say, Kulier et al. 2005) RU486 is on the WHO’s list of essential medicines, and is endorsed as safe and effective by the WHO, the RANZCOG, The Public Health Association of Australia, The Royal College of Obstetricians and Gynaecologists (UK), The American College of Obstetricians and Gynaecologists, The Australian Medical Association, The American Medical Association, The American Association for Advancement of Science and the Federation of International Gynaecology and Obstetrics (FIGO), among others.

Why Women Choose RU486

Millions of women choose medical abortion over surgical every year in countries where they are given the choice. Their reasons include the desire to avoid anaesthetic; the sense that medical abortion feels more “natural” (i.e. like a miscarriage); fear and expectation of pain caused by surgery; as well as a desire to terminate earlier than is possible with surgical methods. (Slade 1998 and Weibe 1993 as cited in Say, Kulier et al. 2005; The Royal Australian and New Zealand College of Obstetricians and Gynaecologists 2005) Studies suggest that what women really want is choice. (The Royal Australian and New Zealand College of Obstetricians 2005) Like all adults they value being treated like rational, competent patients capable of understanding disclosures about the risks and benefits of medical interventions and – in the context of their particular needs and personal values – giving or withholding their informed consent to mooted medical procedures. Australian women are capable decision-makers. If they judge medical abortion as too risky or difficult compared to surgical abortion, they won’t choose it. Yet currently Australians have no pregnancy termination options despite international agreements made by successive Australian governments that commit to supporting reproductive health choices. In 1996 Australia was a signatory to the International Conference on Population and Development (ICPD) Program of Action which amongst other things has a stated goal of ‘the provision of universal access to a full range of reproductive health care and family planning services’. The Prime Minister reaffirmed this commitment in October 2004.

The Effective Ban on RU486: The Moral Issues at Stake

Unsafe Abortion

Prior to decriminalisation in Western nations and Australia, the central moral issue in the abortion debate was the degradation, injury and death of young healthy women from unsafe, illegal abortion. While decriminalisation has led to very low mortality rates from induced abortion in the West, 20 million unsafe abortions are performed each year around the globe. One third of these will result in serious complication. One in five women will suffer a reproductive tract infection that may leave them sterile, and 67,000 will die from complications of unsafe abortion. (World Health Organization 2003)

Australians tend to believe the days of backyard abortions are over. Yet continuing uncertainty about the legal status of the procedure in some states, and the refusal of some regional health authorities, hospitals and/or staff to meet any or most of the demand for surgical terminations has created a provision crisis in some parts of rural and regional Australia. (NHMRC 1996)

This crisis has been exacerbated in recent years by religious providers – who are opposed to safe, legal abortion in all or most circumstances – taking control of a growing number of public health services, and the re-opening of the political debate about the procedure's legitimacy. It is well known that when safe termination services are unavailable, maternal morbidity and mortality rates rise. (World Health Organization 2004)

Rural and Regional Disadvantage

Women who live and work outside of major metropolitan centres suffer more disadvantage than those in the cities when confronted with the crisis of an unplanned or unwanted pregnancy. To access abortion, these women must travel to urban areas for services, leaving behind support systems and obligations. Because typical abortion-referral pathways render women ineligible for federal travel assistance, rural women and their families are faced with travel and accommodation costs that metropolitan women are not forced to bear. (NHMRC 1996)

Unmet need for safe abortion services in rural and regional Australia has meant the effective ban on RU486 in Australia has disproportionately disadvantaged country women. This is because while there are few reproductive health clinics outside metropolitan areas, some rural and regional practitioners would welcome the opportunity – where appropriate and when desired by the woman and her family – to prescribe and oversee a medical abortion using RU486 and to organise surgical back-up for the small percentage of women who fail to miscarry. (Radio National 2005)

‘ Where effective contraceptive methods are available, the abortion rate declines sharply. When safe termination services are unavailable, maternal morbidity and mortality rise. ’ – The World Health Organisation

The Costs to Women, Children and Society of Unwanted Births

People usually agree on the desirability of reducing the abortion rate through a reduction in the number of unplanned and unwanted pregnancies. Where effective contraceptive methods are available, the abortion rate declines sharply. (World Health Organization 2003) But even if all contraceptive users were to use methods perfectly all the time, there would still be close to six million accidental pregnancies every year. (World Health Organization 2004)

The costs to women, children and society of unwanted pregnancies and births cannot be overstated. Women who carry unwanted pregnancies to term are more likely to smoke, drink, to delay obtaining prenatal care and to give birth to low-birth weight infants who they are less likely to breast-feed. They are more likely to be depressed and unhappy after the birth than mothers with wanted children, and to spank and slap their children more frequently.

Unwanted children have lower quality relationships with their mothers, show poorer social adjustment, school performance, and as adults appear more likely to have poor self-esteem, to engage in criminal behavior, to be on welfare, and to obtain psychiatric services. (Baydar 1995; Kubicka, Matejcek et al. 1995; Barber 1999; Korenman, Kaestner et al. 2002; D’Angelo, Colley et al. 2004) The negative consequences of unwanted births are a major cost to both families and taxpayers. In 1997, the State of Colorado estimated this burden at \$USD 28 million. (Boonstra and Sonfield 2000; Colorado Department of Public Health and Environment ND)

The Cost to Seriously Ill Patients

The effective ban appears to have curtailed research into the drug's non-abortifacient uses. Several legitimate clinical trials of RU486 for other purposes have been plagued by administrative delay, and an unprecedented degree of regulatory audit and ethics committee scrutiny, including some researchers being visited at home and questioned by police in order to ensure the drug was not being imported to induce abortion. (Foran 2005)

The extensive red tape surrounding the import of RU486 for such clinical trials, and the high level of government scrutiny of such trials may explain the dearth of Australian research into the drug's other uses, despite the promise it has shown in the treatment of a range of debilitating diseases. The Secretary of the Commonwealth Department of Health and Ageing acknowledged that only "a very small number" of cancer patients had gained access to the drug. (Hansard 2005)

One reason for this may be the TGA's Special Access Scheme (SAS) when it comes to RU486. The scheme is designed to allow registered medical practitioners to request approval to import unapproved therapeutic goods into Australia to treat individual patients, with applications evaluated on a case-by-case basis. Anecdotal evidence suggests that at least some patients attempting to import RU486 under the SAS have found the experience invasive of their privacy, stressful, time-consuming and expensive. Some have experienced lengthy delays, while others – despite being classified as Category A ("very seriously ill") patients – have been unable to successfully import the drug.

These problems have been caused by the 1996 amendments to the TGA despite the clear intention of the legislation to avoid penalizing seriously ill patients. In part this is because the relatively small number of such patients, combined with intense bureaucratic scrutiny and the uncertainty caused by the legislation, means pharmaceutical companies have not seen it in their interest to market the drug in Australia. Only a complete repeal of the 1996 amendments will provide pharmaceutical companies with the certainty they need to provide all Australian patients with the drug.

Bankole, A., S. Singh, et al. (1998). "Reasons Why Women Have Induced Abortions: Evidence from 27 Countries." *International Family Planning Perspectives* 24(3). <http://www.guttmacher.org/pubs/journals/2411798.html>

Barber, J. (1999). "Unwanted Childbearing, Health and Mother-Child Relationships." *Journal of Health and Social Behaviour* 40: 231- 257. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10513146&dopt=Abstract

Baydar, N. (1995). "Consequences for Children of Their Birth Planning Status." *Family Planning Perspectives* 27(6). <http://www.guttmacher.org/pubs/journals/2722895.html>

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>

Boonstra, H. and A. Sonfield (2000). "Revisiting Public Funding of Abortion for Poor Women." *The Guttmacher Report on Public Policy*. http://www.agiusa.org/pubs/ib_funding00.pdf

Buckmaster, L. (2005). "RU486 for Australia?" *Research Note* 19(2005-6). <http://www.aph.gov.au/library/pubs/rn/2005-06/06rn19.htm>

Cannold, L. (2000). *The Abortion Myth: Feminism, Morality and the Hard Choices Women Make*. Foreword by Rene Denfeld. Hanover, London, Wesleyan University Press, University Press of New England.

Cannold, L. (2002). "Understanding and responding to anti-choice women-centred strategies." *Reproductive Health Matters* 10(19): 171-179. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12369322&dopt=Abstract

Cannold, L. (2005). "The Cell or the Sizzle?" *The Walkley Magazine* 31: 25-26.

Cannold, L. (2005). Madness in the Method. *The Age*. Melbourne: 12. <http://www.theage.com.au/news/Education-News/Madness-in-themethod/2005/05/13/1115843369081.html>

Childbirth by Choice Trust (1996) *RU486: The Abortion Pill*. <http://www.cbctrust.com/ru486.php>

Colorado Department of Public Health and Environment (ND). Unintended Pregnancy Why it Matters. *Secondary Unintended Pregnancy Why it Matters*. <http://www.cdphe.state.co.us/pp/womens/pdf/UPWebDoc2002.pdf>

Cox, E. (2005). "The Politics of Research." *On Line Opinion*. <http://www.onlineopinion.com.au/view.asp?article=3469>

D'Angelo, D., B. Colley, et al. (2004). "Differences Between Mistimed and Unwanted Pregnancies Among Women who Have Live Births." *Perspectives on Sexual and Reproductive Health* 36(5). <http://www.guttmacher.org/pubs/journals/3619204.html>

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>

Fischer, M. (2005). "Fatal Toxic Shock Syndrome Associated with *Clostridium sordellii* after Medical Abortion." *New England Journal of Medicine* 353(22): 2352-2360. <http://content.nejm.org/cgi/content/short/353/22/2352>

Foran, T. (2005). Debating the 'Abortion Pill'. *Australian Doctor*. <http://www.australiandoctor.com.au/news/04/0c038604.asp>

Gawiser, S. and G. Evans Witt (2002). 20 Questions a Journalist Should Ask About Poll Results. *Secondary 20 Questions a Journalist Should Ask About Poll Results*. Place Published, National Council on Public Polls. <http://www.ncpp.org/qajsa.htm#12>

Green, M. (2005). "Fatal Infections Associated with Mifepristone-Induced Abortion." *New England Journal of Medicine* 353(22): 2317- 2318. <http://content.nejm.org/cgi/content/short/353/22/2317>

Guttmacher Institute (2005). State Facts About Abortion. *State Facts About Abortion*. Secondary Guttmacher Institute. Place Published, Guttmacher Institute. <http://www.guttmacher.org/pubs/sfaa/georgia.html>

Hudson, P. (2005). More Tax Cuts on the Way: PM. *The Sunday Age*. Melbourne: 1.

Jones, R. K. and S. K. Henshaw (2002). "Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden." *Perspectives on Sexual and Reproductive Health* (34): 3. <http://www.agi-usa.org/pubs/journals/3415402.pdf>

Knights of the Southern Cross (2004). *Knights of the Southern Cross Weblinks: Knights of the Southern Cross Links*. <http://www.kscsa.org.au/links.html>

Korenman, S., R. Kaestner, et al. (2002). "Consequences for Infants of Parental Disagreement in Pregnancy Intention." *Perspectives on Sexual and Reproductive Health* 34(4). <http://www.guttmacher.org/pubs/journals/3419802.html>

Kubicka, L., Z. Matejcek, et al. (1995). "Children from unwanted pregnancies in Prague, Czech Republic revisited at age thirty." *Acta Psychiatrica Scandinavica* 91: 331-369.

Kulier, R., M. Gulmezoglu, et al. (2005). Medical Methods for First Trimester Abortion (Review). *The Cochrane Database of Systematic Reviews*, John Wiley & Sons. http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD002855/pdf_fs.html

Larson, W. (1998). *Essentials of Human Embryology*. New York, Churchill Livingstone.

Mannix, K. (2005). Abortion survey lacks credibility. *Online Catholics*. 51.
<http://www.onlinecatholics.com.au/issue51/index.php>

Medline Plus (2005). Miscarriage. Secondary Miscarriage. Secondary Medline Plus. Place Published, US National Library of Medicine and the National Institute for Health.
<http://www.nlm.nih.gov/medlineplus/ency/article/001488.htm>

Mifegyne (2005). Mifegyne - patient information leaflet (mifepristone): 2.

National Cancer Institute (2003). Abortion, Miscarriage, and Breast Cancer Risk. National Cancer Institute Fact Sheet. <http://www.cancer.gov/cancertopics/factsheet/Risk/abortion-miscarriage>

NHMRC (1996). An Information Paper on Termination of Pregnancy in Australia. Canberra, National Health and Medical Research Council.

Nilsson, L. (1990). *A child is born*. New York, Dell.

Radio National (2005). Rural doctors disappointed by Abbott's abortion pill decision. *PM*, Sydney. <http://www.abc.net.au/pm/content/2005/s1509375.htm>

Say, L., R. Kulier, et al. (2005). Medical versus Surgical Methods for First Trimester Terminations of Pregnancy (Review). *The Cochrane Database of Systematic Reviews*. Cochrane Library, John Wiley & Sons. http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003037/pdf_fs.html

Southern Cross Bioethics Institute (2005). Welcome to Southern Cross Bioethics.
<http://www.bioethics.org.au/>

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>

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (2005). *Termination of Pregnancy*. College Statement. <http://www.ranzcog.edu.au/publications/statements/C-Gyn17.pdf>

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (2005). *Termination of Pregnancy: A resource for health professionals*. Melbourne: 38. <http://www.ranzcog.edu.au/womenshealth/pdfs/Termination-of-pregnancy.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> US FDA (2005). *Mifeprex (mifepristone) Information*. <http://www.fda.gov/cder/drug/InfoSheets/HCP/MifepristoneHCP.pdf>

World Health Organization (2003). *Safe Abortion: Technical and Policy Guidance for Health Systems*. Geneva, World Health Organization. http://www.who.int/reproductivehealth/publications/safe_abortion/safe_abortion.pdf

World Health Organization (2004). *Unsafe Abortion: Global and regional estimates of the incidence of unsafe abortion and associated mortality in 2000*. Geneva, World Health Organization. http://www.who.int/reproductivehealth/publications/unsafe_abortion_estimates_04/estimates.pdf

World Health Organization (2006). *Goal 8: Essential Medicines. Millenium Development Goals*, World Health Organization. http://www.who.int/mdg/goals/goal8/essential_medicines/en/



AUSTRALIAN
REPRODUCTIVE
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ALLIANCE

AHRA

The Australian Reproductive Health Alliance's mission is to promote public support for enhanced reproductive and sexual health in Australia and internationally, and promote the advancement of the status of women and girls.



RCA

Reproductive Choice Australia is a coalition of over 20 organisations including Sexual Health & Family Planning Australia, Children by Choice, the Public Health Association of Australia, the Australian Women's Health Network, the Women's Electoral Lobby, and all state based pro-choice coalitions.

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