

An edited version of the CSBQ submission of 13 January 2006 to the federal Senate committee

INQUIRY INTO THERAPEUTIC GOODS AMENDMENT BILL (REPEAL OF MINISTERIAL RESPONSIBILITY FOR APPROVAL OF RU486) BILL 2005

On 16 February 2006 our federal House of Representatives voted 95 – 50 to pass the RU 486 bill. While this was a conscience vote, a brief analysis of the second reading vote reveals that over 90 per cent of Labor MPs voted in favour of the bill. In contrast, the Coalition vote was 52 per cent against the bill. In South Australia, 88 per cent of Liberal MPs voted against the bill.

A majority of community opinion sought a delay in the vote for more public discussion.

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RE – INQUIRY INTO THERAPEUTIC GOODS AMENDMENT BILL (REPEAL OF MINISTERIAL RESPONSIBILITY FOR APPROVAL OF RU486) BILL 2005

relating to the use of RU486 (mifepristone) as an abortifacient in Australia

I read that RU486 was developed in the early 1980s by the French drug company Roussel-Uclaf and belongs to a class of steroid compounds called antiprogestins. These block the action of the natural hormone progesterone which is needed to sustain a pregnancy. RU486 causes changes in the uterine lining that lead to the detachment of the pregnancy sac. When used to terminate a pregnancy RU486 is given in combination with a prostaglandin (PG), usually Misoprostol. This causes the uterus to contract and helps to expel the dead embryo / fetus.

Pro-abortion groups claim that RU486 is a “private, woman-controlled, safe and effective” alternative to surgical (suction) abortion, and that RU486 would make “de-medicalised” abortion services more accessible to women in rural, regional and remote areas. However, there is considerable evidence to the contrary.

These groups argue that decisions on the use of RU486 as an abortifacient in Australia should be made by the officers of the Therapeutic Goods Administration (TGA).

RU486 is already available in Australia for the treatment of certain cancers and hormonal conditions. In 1996 the Federal Parliament determined (with bipartisan support) that RU486 should only be released as an abortifacient with the written approval of the Minister of Health, with that approval to be notified to the Parliament.

The function of the TGA is to consider the “safety, efficacy and quality” of any drug. In 1996 both sides of Parliament recognised that the use of abortifacients raises more complex social and moral issues that concern the Australian community, and

agreed that Parliament should retain its proper powers to examine such difficult questions. It can be argued that the unelected officers of the TGA have no role in balancing such complex social and ethical matters. In contrast, the Minister of Health can be held accountable for his/her decisions.

Returning to the efficacy and safety of RU486 -

Overseas studies indicate that RU486 is about 90 per cent effective in inducing the abortion of a pregnancy of up to 7 weeks gestation (49 days after the first day of the last menstrual period). This is too soon for many women to recognise an unplanned pregnancy. In clinical trials in the USA the failure rate climbs to 23 per cent by 9 weeks. Small numbers suggest that the failure rate may reach 40 per cent by 11 weeks.

Where chemical abortion is very slow and troublesome, surgical abortion (dilatation and curettage) may be needed to remove the pregnancy sac. Where pregnancy continues, the RU486 / PG combination can cause abnormalities in babies who survive.

Prof Michael Green, chair of the Ob & Gyn faculty at Harvard University, in the New England Journal of Medicine of December 1st 2005, reports a ten-fold increase in maternal deaths with RU486 when compared with suction (surgical) abortion at 6 to 8 weeks of pregnancy. This is contrary to the claims of many pro-choice doctors that RU486 is a safe form of abortion.

There have been at least 10 deaths of women overseas after receiving RU486. The exact figure is unknown because in many countries abortion deaths are not attributed to the procedure. Factors in the known deaths have included major bleeding, rupture of ectopic (tubal) pregnancies, major infection (with a specific toxic shock syndrome in which the bacterium *Clostridium sordelli* from the vagina infects the dead tissue in the uterus), and major allergic reactions associated with RU486/PG. Some physicians suggest that RU486 as a potent steroid can lower the ability of even young and healthy women to fight infection.

The Food and Drug Administration (FDA) in the USA has received reports of over 600 serious adverse reactions to RU486. In the USA reporting is not mandatory, and the FDA estimates that only 10 per cent of adverse effects of any drug are reported.

The dangers of RU486 are continuing to become apparent –see the major article “Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient”, by Margaret M Garry MD and Donna J Harrison MD, published in the December 28th 2005 issue of the Annals of Pharmacotherapy.

There may also be long-term effects, as traces of RU486 remain in the ovaries and egg follicles of women consumers. Some physicians have expressed concern that these residual traces of RU486 may be a causative factor in infertility or miscarriages or birth defects. The analogy to potent chemicals damaging the environment is obvious.

Because of these health concerns some leading pro-choice feminists such as Dr Renate Klein and Dr Germaine Greer are opposed to the use of RU486 as an abortifacient. Dr Klein of Deakin University describes RU486 as “messy and unpredictable. RU486 and PG can draw out the abortion process for two weeks or more, with bleeding, nausea, vomiting and painful contractions. One in ten women will then need a dilatation and curettage to complete the abortion.”

Given that the risks of major complications with RU486 are so unpredictable, this form of abortion is clearly unsafe for women in rural/remote areas where immediate access to medical and hospital care is unavailable.

Since the embryo of 6 to 8 weeks gestation is visibly human, a woman viewing such an abortion at home would appear at increased risk of emotional distress, anxiety and depression. An embryo aborted intact at this stage can have a visibly beating heart, decerebrate limb movements, and be seen to be male or female. A major New Zealand study by Prof D Fergusson published in January 2006 in the UK Journal of Child Psychiatry and Psychology confirms the greater risks of mental health problems in women who have had abortions.

Many women suffering post-abortion complications insist that they were not fully informed of all these risks in the consent process. This is a continuing problem in Australia, given the lack of Medicare-funded access to unbiased counselling by experienced counsellors who are not working for abortion providers. Failure of disclosure of all material risks may open the way for a successful damage claim in negligence against the doctor or health service concerned.

Pro-choice people sometimes appear to forget that to exercise genuine choice women need to have correct and complete information to empower them to make the choice that they perceive to be right for them. Genuine choice also requires that each option receive adequate levels of community support including government funding. A December 2005 study showed that only 25 per cent of Australian women were aware of RU486. When given information about the safety issues, over 60 per cent were opposed to RU486 being introduced here.

The national government of China may not have a world-best reputation in human rights and safe medical practice. RU486 was widely used for abortions in China from 1992, and health officials became so concerned about the many complications that in 2001 China banned all use of RU486 as an abortifacient.

Similarly Canada and Italy are reported to have ceased the use of RU486 on safety grounds. In the USA the FDA has a ‘black label’ warning on RU486, and is currently having a major inquiry that may lead to a similar ban on RU486.

Given the risks involved in the use of RU486 as an abortifacient, I would respectfully urge the Committee to maintain the 1996 decision, that the Minister of Health retain his/her oversight of applications to use RU486 and retain the power of veto.”

Signed
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