The Senate

Community Affairs Legislation Committee

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

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TABLE OF CONTENTS

Membership of the Committee .... *iii*

INTRODUCTION 1

THE BILL 1

THE INQUIRY 2

THE APPROVAL PROCESSES 3

THE DRUG RU486 (MIFEPRISTONE) 5

Medical terminations 5

Non-abortifacient uses of mifepristone 7

Misoprostol use in conjunction with mifepriston 8

The definition of 'therapeutic good' 9

Factually flawed claims 9

ARGUMENTS IN SUPPORT OF THE BILL 11

Abortion in Australia 12

Women's Right of Choice 13

Ministerial v Therapeutic Goods Administration responsibility 15

The Minister for Health 15

The Therapeutic Goods Administration 16

The 1996 amendments to the Act and their impact 17

RU486 and International evidence and approval 19

Approval and use as a safe and effective drug 19

Mental health issues raised by the Christchurch Health and Development Study 22

Availability of RU486 should it be approved 23

No evidence that abortion rates would increase 23

Medical practitioners 24

Rural Issues 25

Queensland 27

Tasmania 27
Victoria 28
Western Australia 28
Working to reduce unwanted pregnancies 28
ARGUMENTS OPPOSED TO THE BILL 29
Effect of the Bill broader than stated purpose 29
Accountability 30
RU486 is unique 30
TGA assessment limitations and the moral dilemma 30
Concerns at TGA research and public safety 31
Minister should retain responsibility 32
Responsibility should be broadened to involve cabinet and/or Parliament ... 33
A Committee of Experts 33
Abortion in Australia 34
Safety of RU486 34
Can be pro-choice and anti-RU486 34
Complications arising from RU486 procedure 35
Adverse events, associated deaths and FDA concerns 35
Use and Monitoring if made available 37
Psychological issues 38
Impact on medical practitioners and medicine 39
Use of RU486 for other medical indications 39
Rural issues 40
1996 Amendments to TGA Act 42
History of the ‘restricted goods’ provisions in the 1996 Amendments 42
Availability of RU486 and increased abortion numbers 44
Addressing issues associated with unwanted pregnancies 44
CLOSING COMMENT 46

ADDITIONAL COMMENTS – Senators Adams, Allison, McLucas Moore, Nash, Nettle, Webber 47

ADDITIONAL COMMENTS – Senators Humphries, Barnett, Fielding Polley, Joyce 53

FAMILY FIRST ADDITIONAL COMMENTS 57

APPENDIX 1 – Submission and Correspondence received by the Committee .. 71

APPENDIX 2 – Public Hearings 87

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

INTRODUCTION

1.1 The Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 (the Bill) is a private Senators' bill that was introduced into the Senate on 8 December 2005 by Senator Nash and also on behalf of Senators Troeth, Allison and Moore. On the same day, 8 December 2005, the Bill was referred on the motion of Senator Troeth to the Committee for inquiry and report by the second sitting day in 2006 (effectively 8 February 2006).

1.2 A majority of the Committee (Senators Adams and Moore dissenting) agreed that a short extension to the reporting date should be sought. Following the receipt of advice relating to Senate business programming, the Committee subsequently agreed (Senator Fielding dissenting) that it would not formally seek an extension from the Senate.

THE BILL

1.3 The Bill expresses as its purpose 'to remove the responsibility for approval of RU486 from the Minister and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration'.[1]

1.4 The Bill achieves this purpose through the amendment of the *Therapeutic Goods Act 1989* by repealing subsection 3(1) (definition of restricted goods), section 6AA (importation of restricted goods), section 6AB (exempt goods), section 23AA (ministerial approval of evaluation, registration or listing of exempt goods) and subsection 57(9) (delegation).

1.5 Although the title and stated purpose of the Bill refer only to RU486, the provisions to be repealed by the Bill deal with abortifacient drugs, not specifically RU486. Subsection 3 (1) of the *Therapeutic Goods Act 1989* states that:

> **restricted goods** means medicines (including progesterone antagonists and vaccines against human chorionic gonadotrophin) intended for use in women as abortifacients.

1.6 The Bill will repeal this definition and remove the requirement for Ministerial approval before restricted goods can be imported (section 6AA), evaluated, registered or listed (section 23AA). Besides RU486 (Mifepristone) the following medicines are currently listed as restricted goods which cannot be imported without Ministerial

1 The Bill, clause 3.

approval: Alprostadil, Carboprost, Dinoprost, Dinoprostone, Gemeprost, Misoprostol, Prostaglandins and Vaccines against human chorionic gonadotrophin.[2]

1.7 Evidence was received that medicines on the list are used in Australia under approval. Dr Edith Weisberg advised:

> The hCG vaccine has stopped being developed. That is what it says in the legislation—'such as vaccines'. The human chorionic gonadotrophin vaccine could be used as a contraceptive but it has not proved to be effective and is no longer being developed, so that is not relevant anymore. Gemeprost is on the market. If you look at MIMS, Gemeprost is actually approved for use to induce labour, but it is also approved in MIMS for use for induction of second trimester abortion. Misoprostal is also on the market as Cytotec for the treatment of gastric ulcers. So these drugs are not really restricted as such, and prostaglandins are available for the induction of labour. They are not totally restricted.[3]

THE INQUIRY

1.8 The Committee acknowledged that in accordance with Senate procedures the inquiry should be restricted to the stated purpose of the Bill, which is to remove the responsibility for approval of RU486 from the Minister and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration. However, the Committee was of the view that it was inevitable that the nature of the debate on the subject would open the issue to the wider consideration of RU486 and abortion generally.

1.9 While accepting that the debate would become wider than the specific purpose of the Bill, in accordance with Senate procedures the Committee processed and received as public submissions only those that were relevant to the Bill. However, the Committee agreed to receive and publish all correspondence it received that expressed opinions on the general subjects of RU486 and abortion that did not refer to the Bill or were not relevant to the actual Bill that had been referred to the Committee.

1.10 The Committee received 2496 submissions and 2292 additional pieces of correspondence, a total of 4788 public contributions to the inquiry. A listing of the individual submissions received and a statistical breakdown of the submissions and correspondence received is at Appendix 1. The Committee considered the Bill at public hearings on 15 December 2005, 3 and 6 February 2006. Details of the public hearings are referred to in Appendix 2. Submissions and the Hansard transcript of evidence may be accessed through the Committee's website at http://www.aph.gov.au/senate_ca Complete volumes of submissions and correspondence received by the Committee are available in CD format from the Committee secretariat.

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2 http://www.tga.gov.au/docs/html/bringmed/apendixa.htm Appendix A, subsection (d). TGA information on drugs subject to import controls, dated 6.2.06.

3 *Committee Hansard* 6 February 2006, p.78 (Dr Weisberg, SHFPA).

1.11 In undertaking this inquiry the Committee has been mindful that it is in circumstances where the political parties have given their Senators a ‘free vote’ on the Bill when it is considered by the Senate. Thus, in conducting the inquiry and in the preparation of its report, the Committee considered that its primary role was to gather information to assist Senators to make an informed decision on the Bill. The report has been prepared by describing the approval processes in question and the pharmacological properties of RU486, and then providing an outline of the issues and arguments raised in evidence by those groups and individuals supporting the Bill and those opposing the Bill.

1.12 The Committee has not been requested nor will it be making a judgement on the particular drug. The single issue for the inquiry as contained in the Bill was whether the Minister for Health or the TGA should have the responsibility for making that judgement. As was the case with the Committee's previous inquiry into a Bill for which Senators had been given a 'free vote',[4] the report does not formulate conclusions or make recommendations because the Committee considers that should be the prerogative of individual Senators in exercising a 'free vote'.

THE APPROVAL PROCESSES

1.13 The explanatory memorandum describes the current approval process for RU486 and the change that is proposed by the Bill:

> In 1996 amendments to the Therapeutic Goods Act were passed that placed medications such as RU486 in a special group of drugs known as 'restricted goods'. According to the 1996 amendments restricted goods cannot be evaluated, registered, listed or imported without the written approval of the Minister for Health and Ageing. In addition, any such written approval must be laid before each House of the Parliament by the Minister within 5 sitting days of being given. RU486 is the only medicine that is subject to the restricted goods condition.[5]
>
> Medicines used for any purpose other than abortion are evaluated and regulated by the Therapeutic Goods Administration (TGA) alone and do not require additional approval from the Minister for Health and Ageing…
>
> Removal of the restricted goods provisions in the Act would mean that RU486 could be evaluated within the same framework as applies to all other medicines.[6]

1.14 In a recent Research Note the Parliamentary Library explained that:

> the restricted goods provisions do not amount to a direct ban on RU486 or other abortifacients. A sponsor seeking approval to market an abortifacient can apply through the same process as exists for all prescription medicines

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4 Report on the Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002, October 2002.

5 Paragraph 1.6 notes that RU486 is just one of the class of medicines defined as restricted goods.

6 Explanatory memorandum, p.1.

> in Australia—that is, an application would need to be submitted with supporting data to demonstrate the quality, safety and effectiveness of the drug. The key difference as a result of the restricted goods provisions is that, in addition to the supporting data, written ministerial approval is required before a restricted good, such as RU486, can be evaluated by the TGA.[7]

1.15 Dr David Graham, National Manager of the TGA, explained to the Committee the approval process used by the TGA for therapeutic goods, other than restricted goods.[8] Therapeutic goods must be entered onto the Australian Register of Therapeutic Goods (ARTG). Goods on the ARTG are entered at different levels, depending on the risk associated with the product. Prescription drugs, which have the highest level of control, are evaluated on the basis of quality, safety, and efficacy.

1.16 The entry and categorisation of therapeutic goods on the ARTG is determined by the Secretary of the Department of Health (or his or her delegate), on the basis of advice provided by expert advisory committees within the TGA. In the case of prescription drugs the relevant expert advisory committee is the Australian Drug Evaluation Committee (ADEC). The expert advisory committees provide the advice to the Secretary on the basis of an evaluation by the TGA, which in turn is based on submissions made by the sponsor of the therapeutic good.

1.17 If the Secretary decides that the therapeutic good is suitable for marketing, then the good is entered into the ARTG. The Secretary may determine that the marketing of a therapeutic good is subject to certain conditions.

1.18 The Parliamentary Library made the following conclusion in relation to the two approval processes:

> Removal of the restricted goods provisions would mean that RU486 could be evaluated within the same framework as applies to all other medicines. It is reasonable to assume that this may provide potential sponsors of the drug with greater confidence that an application for approval would be worth pursuing—in that the determining factor in the process would be an evidence-based evaluation by the TGA of the merits and risk profile of the drug.
>
> At the same time, removal of the restricted goods provisions would mean that the additional layer of scrutiny (that is, the requirement for Ministerial approval and notification of Parliament) that currently exists in relation to applications for marketing of RU486 would no longer exist.
>
> However, this is not the same as saying that the process for evaluating applications for abortifacients would become less transparent or accountable. Under current arrangements, the Minister is simply required to notify the Parliament of a decision to approve an application for evaluation

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7 Luke Buckmaster, 'RU486 for Australia?', *Research Note*, no. 19, Parliamentary Library, 28 November 2005, p.2. http://www.aph.gov.au/Library/pubs/rn/2005-06/06rn19.pdf

8 *Committee Hansard*, 15 December 2005, pp 20-21 (TGA).

> by the TGA. Given the fact that such a decision would not be disallowable by the Parliament, this does not amount to a significant level of parliamentary scrutiny. Further, the Minister is not required to table decisions not to approve such applications, meaning that the Parliament is neither necessarily informed of these, nor does it have the capacity for any oversight of such decisions.
>
> Essentially, current arrangements mean that the Minister for Health alone decides whether applications for evaluation of abortifacients such as RU486 can proceed through the usual processes of the TGA. It could be argued that this situation is at odds with the evidence-based framework generally used to assess other medicines in Australia.
>
> While it could also be also be argued that special arrangements are necessary in the case of RU486, given community sensitivity to the issue of abortion, it should be noted that the current arrangements do not necessarily provide for significant parliamentary scrutiny of applications to evaluate, register, list or import RU486 for use in medical abortion. Rather, this power currently resides entirely with the Minister for Health.[9]

THE DRUG RU486 (MIFEPRISTONE)

1.19 The Committee received submissions and evidence on the operation and functions of mifepristone (the generic name for RU486). The generic and common names for the drug are used almost interchangeably in submissions. Mifepristone, also known by the trade name Mifeprex in the USA and Mifegyne in Europe and New Zealand, was developed in the early 1980s by the French pharmaceutical Roussel Uclaf.

Medical terminations

1.20 The hormone progesterone is made in large quantities during pregnancy. Progesterone stimulates and maintains the development of the endometrium – the lining of the uterus. Mifepristone is a synthetic anti-progesterone – it blocks the action of progesterone in the body by occupying progesterone receptors on cells. By blocking the action of progesterone, mifepristone causes the endometrium to degenerate so that a pregnancy cannot be sustained.[10]

1.21 In medical terminations (as distinct from surgical terminations), mifepristone can be used in conjunction with prostaglandin, a drug that stimulates uterine contractions. The combination of mifepristone and prostaglandin is the most effective method of termination for pregnancies of less than 7 weeks.[11] Mifepristone is mainly

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9 *Research Note*, no. 19, Parliamentary Library, 28 November 2005, pp.3-4.

10 *Committee Hansard* , 15 December 2005, p. 4 (AMA); *Committee Hansard* , 15 December 2005, pp. 54-55 (RANZCOG); *Submission* 401, p.3 and Attachment 4 (RANZCOG).

11 *Submission* 401, p. 3 (RANZCOG).

used during the first nine weeks of pregnancy, though is also effective for second trimester termination up to 20 weeks, again in conjunction with a prostaglandin.[12]

1.22 While Mifepristone is widely used internationally, including in the United Kingdom, the United States, Europe and New Zealand, protocols for its use vary between countries. However, the process can briefly be summarised as follows: a specified dose of mifepristone is administered orally under medical supervision in a licensed facility, after which in most cases the woman is able to return home. Two to 3 days later she returns to the facility and prostaglandin is administered under medical supervision, usually misoprostol, which causes the uterus to contract thereby expelling the products of conception that consist of the tiny embryo, placental tissue, membrane and blood clot.[13]

1.23 Witnesses also stressed to the Committee the importance of ultrasound prior to administering mifepristone to establish how far advanced the pregnancy is and that the pregnancy is not ectopic.[14]

1.24 Reported severe adverse effects of RU486 include infection and septic shock, haemorrhage and ruptured ectopic pregnancies. Other side effects include abdominal pain and nausea. In clinical trials in the United States surgical abortion was needed after medical abortion with mifepristone and misoprostol failed in 6-8 per cent of cases.[15]

1.25 There have been eleven known fatalities associated with the use of RU486 as an abortifacient. One in France, one in Sweden, one in Canada, three in Britain, and five in the United States. Five of these fatalities were due to septic shock following Clostridium sordellii infection, two resulted from haemorrhage (one of which was from a ruptured ectopic pregnancy) and one from coronary thrombosis. The maternal mortality rate for an RU486 abortion has been estimated to be ten times the rate for a surgical abortion carried out at the same period of gestation.[16] The number of these fatalities needs to be viewed against Mifepristone having been used by some twelve million women worldwide.[17]

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12 *Submission* 401, Attachment 2, p. 16 (RANZCOG).

13 *Committee Hansard* , 15 December 2005, pp.3-4 (AMA). *Submissions* 3, pp.1-3 (Prof de Costa); 930, pp.6-9 (Istar Ltd).

14 *Committee Hansard* , 15 December 2005, p.5 (AMA), 37 and 40 (RDAA).

15 MM Gary and DJ Harrison *Analysis of severe adverse events related to the use of Mifepristone as an abortifacient* Annals of Pharmacotherapy Vol 40 (February 2006). I.M. Spitz et al. *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States* New England Journal of Medicine Vol 338 (1998)1241-1247. *Submissions* 401, Attachment 2, p. 17 (RANZCOG); 930, p. 4 (Dr Renate Klein).

16 M.F. Greene Fatal infections associated with mifepristone-induced abortion. New England Journal of Medicine Vol 353 (2005)2317-2318.

17 *Committee Hansard* 3 February 2006, p.39 (PHAA); *Submission* 401, p.3 (RANZCOG).

1.26 Submissions and correspondence received by the Committee indicated considerable confusion by many who thought that mifepristone was the 'morning after pill'. Dr Page of the Rural Doctors Association of Australia clarified the difference between mifepristone and the morning after pill:

> The morning-after pill is a medication that needs to be taken within 72 hours of unprotected intercourse. So, for example, if somebody has used a condom for contraception and the condom broke, they need to be able to purchase the medication quickly and to take it.
>
> It is basically a dose of medication that is very like the contraceptive pill, but you take it in a higher dose and then repeat the dose 12 hours later…
>
> The intent of the morning-after pill is to change the lining of the womb so that, when the egg is trying to implant, the uterus is not of the right hormonal nature to allow implantation to happen and so the fertilised egg flushes out with the normal period for that woman...[18]

Non-abortifacient uses of mifepristone

1.27 The Committee received submissions and heard evidence on non-abortifacient uses for mifepristone.

1.28 Mifepristone can be used to prevent pregnancy by inhibiting ovulation or preventing implantation, depending on the time in a woman's menstrual cycle the drug is administered.[19] As well as being a means of emergency contraception, mifepristone can be used as a regular method of contraception for women unable to use contraception containing oestrogen. Aside from contraceptive uses, mifepristone can be used to manage gynaecological conditions such as endometriosis and uterine fibroids.[20]

1.29 Mifepristone has also been used in the treatment of breast and prostate cancer, meningiomas (a type of brain tumour), and Cushing's Syndrome (a disorder of the adrenal gland). There are indications that mifepristone may be useful in the management and treatment of glaucoma, depression, HIV/AIDS and dementia.[21]

1.30 These uses are all investigational/unlabelled as specified in the Mifepristone Drug Information for the United States.[22] Under the current restricted goods provisions the Minister has given approval for the importation and use of RU486 for

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18 *Committee Hansard*, 15 December 2005, p. 51 (Rural Doctors Association of Australia).

19 *Committee Hansard* , 15 December 2005, p. 4 (AMA).

20 *Submission* 907, pp.2-3 (Sexual Health and Family Planning Australia); *Committee Hansard*, 15 December 2005, p. 2 (AMA).

21 *Committee Hansard*, 15 December 2005, p. 2 (AMA); *Submission* 712 (name withheld); *Submission* 907, p. 3 (Sexual Health and Family Planning Australia); *Submission* 1004, p. 2 (RACP Australasian Chapter of Sexual Health Medicine); *Submission* 603, p. 2 (Monash University Department of Obstetrics and Gynaecology); 704, p.3 (RCA).

22 Mifepristone: Drug Information at www.uptodate.com

some of these uses. The investigational/unlabelled status of these uses would not be affected by the passage of the Bill.

Misoprostol use in conjunction with mifepriston

1.31 In the United States, Europe and New Zealand the prostaglandin most commonly used to bring about the expulsion of the fetus following the use of RU486 in a medical abortion is misoprostol (Cytotec ®).

1.32 A spokesman for Pfizer Australia, the Australian distributor of Cytotec ®, has reportedly said that "We would not recommend use outside TGA-endorsed indication and at this stage that just involves stomach ulcers. To get any other use of the drug would involve major clinical trials and that can take years."[23]

1.33 The Medical Director of Searle, the previous manufacturer of Cytotec ® since acquired by Pfizer, warned in a "Dear Health Care Provider" letter dated 23 August 2000 that “Cytotec is not approved for the induction of labor or abortion. Serious adverse events reported following off-label use of Cytotec in pregnant women include maternal or fetal death; uterine hyperstimulation, rupture or perforation requiring uterine surgical repair, hysterectomy or salpingo-oophorectomy; amniotic fluid embolism; severe vaginal bleeding, retained placenta, shock, fetal bradycardia and pelvic pain.”

1.34 The Cytotec: Product Information states that "Congenital anomalies sometimes associated with fetal death have been reported subsequent to the unsuccessful use of misoprostol as an abortifacient… Several reports in the literature associate the use of misoprostol during the first trimester of pregnancy with skull defects, cranial nerve palsies, facial malformations, and limb defects."

1.35 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists noted in its November 2005 statement on the "Use of Misoprostol in obstetrics and gynaecology" that "the company which markets an oral formulation of Misoprostol (Cytotec) has not researched and does not support its use in pregnancy, nor does it intend to do so". The RANZCOG statement also observes that studies of Misoprostol in obstetrics and gynaecology “have not been large enough to exclude low risks of serious adverse events".

1.36 Dr Elvis Seman gave evidence that medical defence organisations would not indemnify doctors for the off-label use of misoprostol.[24]

1.37 Dr Edith Weisberg gave evidence that a lot of drugs are used off-label with peer support:

> I think off-label prescribing is very common because the companies often do not believe that it is worthwhile changing the indication for a drug

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23 The Australian, 31 January 2006, p.3.

24 *Committee Hansard* 3 February 2006, p.48 (Dr Seman).

> through the TGA if a new indication becomes apparent through research. It is very expensive for a company to do that and they often do not think the commercial gain from it would be adequate to make that worthwhile.[25]

The definition of 'therapeutic good'

1.38 A number of submissions and correspondence argued, based on common dictionary definitions of 'therapeutic', that therapeutic goods are those which remediate or prevent an illness, and that mifepristone should not be classed as a therapeutic good, and not be monitored or regulated by the TGA.[26]

1.39 It needs to be clarified that in the legislative context the relevant definition is that contained in the Therapeutic Goods Act. Section 3 of the Act defines a 'Therapeutic good' to include goods for (or presented for) a 'therapeutic use'. Therapeutic use is also defined in section 3 of the Act to mean use in or in connection with:

> (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
>
> (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
>
> (c) testing the susceptibility of persons or animals to a disease or ailment; or
>
> (d) influencing, controlling or preventing conception in persons; or
>
> (e) testing for pregnancy in persons; or
>
> (f) the replacement or modification of parts of the anatomy in persons or animals.

1.40 Some submissions noted that this comprehensive list of 'therapeutic uses' makes no specific reference to causing an abortion.

Factually flawed claims

1.41 Claims made in several submissions by supporters of the Bill were admitted to be without substance during the public hearings.[27]

1.42 Three of these claims originated in a pro forma submission placed on the website of Reproductive Choice Australia. Submissions substantially utilising this

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25 *Committee Hansard* 6 February 2006, p.72 (Dr Weisberg, SHFPA).

26 *Submission* 413, p. 1-2 (Australian Family Association (NSW)); *Submission* 975, p. 2-3 (Mr Geoffrey Bullock); *Submission* 1111, p.2-3 (The Australian Catholics Bishops Conference, The Bishops Committee for the Family and for Life (ACT)).

27 For example, re Claratyne "It may be an unfortunate analogy. I can see your point: I can see that that particular analogy is not a good one" Dr Taft, Public Health Association, Public Hearing, Melbourne, 3 February 2006 CA 39; "Senator BARNETT—Is it a fair comparison? Ms Crozier [Women' Health NSW]—On the way you are presenting it, I would say no, and I accept that-", Public Hearing, Sydney, 6 February 2006 CA19.

material included those from the Public Health Association (Submission 10), the National Union of Students (Submission 1000), Women's Health NSW (Submission 402) and the Bankstown Women's Health Centre (Submission 95). The misinformation in these submissions also appears on the Public Health Association website on a page headed "USE AND SAFETY OF RU486: THE INTERNATIONAL EVIDENCE"
[at:http://www.phaa.net.au/sig/Women's_Health/useandsafetyofru486.htm]

1.43 The submissions presented by the groups mentioned above were developed in good faith based on information and evidence represented by Reproductive Choice Australia and NARAL Pro Choice America.

1.44 The claims include:

1. The adverse drug event rate for RU486 is very low at 0.137%. In the USA, the adverse drug event rate for mifepristone is very low – only 0.137%. This includes minor complications such as headaches and nausea (NARAL 2004). Claritin (sold over the counter at pharmacies as Claratyne in Australia) has an adverse drug event rate of 12% - over 87 times higher than mifepristone (NARAL 2004).

2. In the December 1st Edition of the New England Journal of Medicine Dr Robert Greene, a Professor of Obstetrics, Gynaecology, 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.

3. The US FDA recently reaffirmed the safety of medical abortion for American women and authorised its continued use.

1.45 Each of these claims is factually incorrect.

1. The figures given for adverse drug event rates improperly compare serious adverse events requiring hospital treatment for RU486 with all reported adverse events for Claratyne, including minor side-effects such as dry mouth and headache. The figure of 0.137% for adverse events rate for mifepristone is referenced by the PHA to NARAL 2004. However, the bibliography refers to: NARAL Pro-choice America. Mifepristone is a Safe Choice, Fact Sheet 20 December 2005. Available at: http://www.prochoiceamerica.org (accessed Nov 2005). This Fact Sheet uses the standard Physicians Desk reference 2003 to derive the adverse events rate for Claratin as 12%. However, it derives the adverse events rate for mifepristone (which it gives as 0.022%, presumably a typographical error for 0.22%) from Henderson et al. "Safety of Mifepristone Abortions in Clinical Use" published in Contraception in October 2005 which gives a figure of 2.2 per 1,000, which is of course 0.22%, for "reportable complications requiring inpatient or outpatient hospital treatment, most commonly heavy bleeding". This, of course, leads to a misleading and totally inappropriate comparison. Comparing all reported adverse events for each drug would give a 96%

rate for RU486, based on the US Clinical trials[28] which is 8 times higher than the12% adverse event rate for Claratyne. The claim that Claratyne has an adverse event rate 87 times higher than Mifepristone is that incorrect by a factor of 696.

2. Dr Michael [not Robert] Greene in fact states in the NEJM article that the overall mortality rate associated with medical abortion is 10 times higher than the mortality rate for surgical abortions at 8 weeks' gestation, the most appropriate comparison.

"The overall maternal mortality rate associated with induced abortion in the United States is approximately 1 per 100,000. That overall rate is a "blended" rate including all the procedures performed in the United States at all gestational ages. The gestational-age–specific rate increases exponentially from 0.1 per 100,000 at 8 weeks' gestation to 8.9 per 100,000 at 21 or more weeks' gestation. Mifepristone is approved for the termination of pregnancies at less than seven weeks' gestation. Therefore, the appropriate comparison is with a risk of 0.1 per 100,000 for surgical abortions performed at less than eight weeks' gestation."[29]

3. The US Food and Drug Administration has in fact increased its warnings about the risks of medical abortion, most recently on 4 November 2005, in response to the series of deaths from RU486 abortions. As these claims have been widely promoted and quoted it is important to record that they have been demonstrated to be factually flawed.

ARGUMENTS IN SUPPORT OF THE BILL

1.46 Many submissions supporting the Bill noted that in considering the Bill the Committee was only being asked to consider whether the Minister for Health or the TGA should have the responsibility for approval of RU486. They stressed that the Committee was not being asked to consider whether a woman should be able to receive medical assistance to terminate a pregnancy nor was the Committee being asked to make a determination about the efficacy and relative medical risks associated with RU486. It was their view that the issue in question was essentially a question of good governance arrangements. Dr Cockburn wrote:

> The Bill before the Parliament is about governance. However it is contentious because of its relation to abortion. There is a vocal minority who seek to reduce access to all abortions and they cloud this Bill with emotive anecdotes, and unscientific arguments…Those in favour of the Bill believe in principles of good governance and accountable, transparent, scientific drug evaluation in Australia.[30]

1.47 Dr Seth-Purdie provided a detailed outline of the governance argument:

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28 Mifeprex Product Label at: http://www.fda.gov/cder/foi/label/2000/20687lbl.htm

29 M.F. Greene, Fatal infections associated with mifepristone-induced abortion. New England Journal of Medicine Vol 353 (2005)2317-2318.

30 *Submission* 701, p.3 (Dr Cockburn).

> Transparency, accountability and probity are well accepted features of good governance. When governments are faced with decisions that require expert consideration of technical matters, it is common practice to establish bodies that operate at arm's length. By selecting widely respected experts for these bodies, and by ensuring that they use clearly articulated criteria and processes for decision-making - as well as for the detection and handling of any conflict of interest that might arise - these bodies can make decisions on complex matters in a manner that can generate a high level of public confidence in the outcomes. Making the process highly accountable – with a clear decision-trail – increases this level of confidence…
>
> Ministerial discretion does not necessarily have the same characteristics. A minister is not necessarily an expert on the subject matter of the portfolio. The advice received by a minister, or the considerations used to reach a particular decision, are not necessarily transparent. Where electoral sensitivities are involved a minister may be tempted to, or rather expected to, take these considerations into account. Ministerial decisions influenced in this way may well result in different outcomes from those reached by disinterested experts making decisions on the basis of publicly stated criteria…
>
> The Committee needs to consider whether the public interest in good governance is better served in this instance by maintenance of the Ministerial discretion, or by its removal. Removal would appear to permit a more transparent and directly accountable process of deliberation on the medical indications and contra-indications for the use of RU486.[31]

1.48 Some submissions argued that as Australia is a democratic, secular society and not a theocracy, public policy decisions including medical decisions must be based on rational, scientific and independent inquiry isolated from the potential for individuals in political power to subvert such decisions to political and religious belief.[32]

Abortion in Australia

1.49 While the Bill and the inquiry are not about abortion many submissions both supporting and opposed to the Bill made reference to the issue. Those supporting the Bill argued that access to an abortion is a settled issue in Australia noting that abortion is a legal and safe procedure in all Australian States and Territories.[33] However, it was also noted that there are legal variations operating across jurisdictions and this remains a concern for those performing the procedure:

> It needs to be remembered that whilst abortion is legal in all states and territories (either by common law ruling or by statute) there are still provisions in the respective state/territory Crimes Acts or Criminal Codes

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31 *Submission* 919, pp.1-2 (Dr Robyn Seth-Purdie). Also *Submission* 4, p.1 (NFAW).

32 *Submissions* 707, p.1 (PHAA); 1086, p.3 (Liberty Victoria).

33 Eg *Submissions* 3, p.2 (Prof de Costa); 601, p.3 (ARHA); 902, p.1 (Dr Wainer); 1004, p.2 (ACSHM).

> (with the exception of the ACT – the ACT is the only state which has repealed provisions from its Crimes Act) which relate to abortion.
>
> The existence of these provisions, even though they and their interpretation have been clarified either by common law ruling (Victoria, NSW and Qld) or by statute (NT, SA, WA and Tasmania) make doctors nervous. The possibility of being arrested and charged with performing a so-called 'unlawful' abortion is still present for all doctors who perform abortions in Australia, except doctors in the ACT.[34]

1.50 Most abortions are performed in Australia using surgical techniques. Submissions argued that because abortion is a legal procedure in Australia, both surgical and medical options to provide this procedure should be available in Australia, as they are in many countries of the world. Every drug which has an abortifacient effect, in terms of their approval process, should be evaluated like all other drugs are. There is no case for the continued singling out of abortifacient drugs. As the Australasian Chapter of Sexual Health Medicine said 'It is anomalous that current restrictions mean that surgical abortion is available and legal, while medical abortion, while legal, is not available'.[35]

1.51 This issue was summarised by Professors Rogers, Ankeny and Dodds:

> Induced abortion is a legal, albeit heavily regulated, procedure in Australia; the licensing of RU486 will not alter this situation. What will change if RU486 is licensed is that Australian women and their medical practitioners will have an increased range of options from which to select the safest and most efficacious treatment for any particular patient.[36]

Women's Right of Choice

1.52 Many submissions strongly advocated women's right of choice; firstly that all women should have access to safe and affordable pregnancy termination services should this be their chosen option and secondly, that women should be entitled to choice in regard to pregnancy termination options.

1.53 The view that women do not give sufficiently serious consideration in making these decisions was strongly refuted. It was emphasised that women do not make such decisions lightly and give great deliberation to reaching an informed decision – and they certainly do not need interference from external sources. It was considered 'highly inappropriate' that 'the current legal situation means that the Health Minister of the day has power over aspects of women's reproductive choices'.[37]

> Women are fully human and capable of fully moral decisions. They do not require the oversight or supervision of Parliament (or anyone else) to ensure

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34 *Submission* 905, p.10 (WAAC).

35 *Submission* 1004, p.2 (ACSHM).

36 *Submission* 202. p.2 (Professors Rogers, Ankeny and Dodds).

37 *Submission* 916, p.2 (WHV).

> that they make ethically sound decisions about mothering. It is an old ethical principle that decisions should be made by those most directly affected by them… Women who are mothers are the same women who have abortions. They do not require a public debate or Parliamentary or ministerial oversight regarding their decision to mother, and neither do they for their decision to terminate a pregnancy.[38]
>
> In our experience women are very careful in the consideration of their choices with regard to a pregnancy, and the availability of RU486/Misoprostol will not change how they view these choices. We envisage that the same degree of counselling and discussion would be involved in providing a woman with an RU486/Misoprostol termination as a surgical termination, and the same legal requirements will presumably apply.[39]

1.54 The RANZCOG and the AMA expressed the opinion that if a woman has chosen to have an abortion, she should not only have available to her accurate and appropriate information about abortion, but she should also be provided with sufficient information to make an informed choice about having a safe medical abortion rather than a surgical abortion if that is her preference.

1.55 The medical groups emphasised the need for legal terminations to be performed safely and to the highest possible standard to ensure that women who choose this option do not suffer unnecessary harm. RANZCOG indicated that 'there is clear evidence that some women would prefer not to have a surgical procedure if that could be avoided and also clear evidence that this is a safe if not safer option for pregnancy termination up to nine weeks gestation'.[40] The Royal Women's Hospital also expressed a belief that:

> for many women a medical abortion, which can be performed earlier in pregnancy than surgical abortion, would be preferable... Some women undergoing a termination of pregnancy want a safe alternative to surgery and to avoid being anaesthetised, which can cause a sense of a loss of control… Nevertheless, some women will continue to want surgery, and both options should be made available. Several other studies have shown that women value choice, have a strong preference for one or other approach, and are more likely to be satisfied with a method they choose.[41]

1.56 The AMA advised that its review of the present literature:

> ead us to the same position as the [RANZCOG], that non-surgical forms of abortion based on the use of RU486 are sufficiently safe that they should be made available to Australian women within, of course, a therapeutic relationship and with all necessary services and support. There is no expectation that the rigorous service provision that ensures surgical

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38 *Submission* 902, p.1 (Dr Wainer).

39 *Submission* 608, p.1 (WCFGP Rich). Also *Submission* 905, p.9 (WAAC).

40 *Submission* 401, p.2 (RANZCOG)

41 *Submission* 903, p.2 (RWH, Melbourne).

> abortions are very safe would be relaxed when the medical option is available…[42]

1.57 The fundamental role of a medical practitioner in assisting a woman reach an informed decision was referred to in a number of submissions. Reference was made to survey findings that the overwhelming majority of Australians support a women's right to choose and believe that abortion is a matter solely between a woman and her doctor.[43] Many emphasised this point including WHNSW who, as the peak body representing women's health centres throughout NSW, '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'.[44]

1.58 In addition to the other medical groups, the RACGP also noted that 'General practitioners are trusted members of the health care community who are well placed to provide advice on options available to women contemplating a termination and management of a termination, counselling, ongoing care and contraception'.[45]

Ministerial v Therapeutic Goods Administration responsibility

1.59 Supporters of the Bill raised a number of arguments as to why they considered that the TGA should have responsibility for the approval of RU486 rather than the Minister for Health.

The Minister for Health

1.60 While a number of submissions included an argument against the Minister based on the particular beliefs of the current Minister, others argued against the position of the Minister rather than a particular individual retaining the responsibility. They argued that Ministerial responsibility for approving RU486 was inappropriate on a number of grounds:

- The Minister for Health does not have the capacity for or specific expertise in assessing the safety and efficacy of therapeutic agents;
- Singling out abortifacients for Ministerial approval does not improve the safety of drug regulation and prescribing in Australia. The democratic political process requires that the government act in the interest of the constituency it represents and should not rely on the decision of one person, while denying the advice of a properly constituted expert body. It is not

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42 *Submission* 1003, p.2 (AMA).

43 *Submission* 402, p.2 (WHNSW); 419, p.2 (Hobart WHC); 917, p.5 (Children by Choice); 1000, p.3 (NUS).

44 *Submission* 402, p1 (WHNSW). Also *Submission* 4, p.4 (NFAW); 922, p.1 (WIRE)

45 *Submission* 908, p.3 (RACGP).

appropriate that the availability of any drug should rest on the decision of a single individual. This process is in conflict with evidence based medicine;[46]

- Seeking Ministerial approval for each use of the drug potentially breaches the confidentiality of the patient for whom its use is sought. There are no other medical procedures or treatments for which such an approval process is required, and as it is essential to avoid breaches of patient confidentiality, it is not morally acceptable and potentially discriminatory to require such approval for RU486.[47]

The Therapeutic Goods Administration

1.61 The central argument asserted by the supporters of the Bill is that the Therapeutic Goods Administration is the specialist statutory body in Australia authorised to evaluate, approve and regulate therapeutic drugs in the public interest, after a rigorous and robust assessment of scientific evidence and an examination of the risks inherent in any drug proposed for marketing in Australia. The TGA has been provided through legislation with all the necessary powers, authority and resources to evaluate and assess research results regarding the quality, safety and efficacy of a specific drug and to advise practitioners and the community on its safe and effective use.

1.62 It was pointed out that the TGA's approval process is subject to clear standards of accountability and transparency for evaluating clinical evidence. The approval process is based on scientific evidence, and examines and evaluates the quality, safety and effectiveness of drugs on this evidence. The TGA takes a risk management approach to drug evaluation. Its risk assessment procedures provide clarity and transparency of process and ensure that decisions about access to unproven drugs are protected from vested interests, whether from consumers with chronic or life threatening illnesses, or manufacturers mindful of profit margins, who may seek to influence decisions on access to drugs. The public's interests are also protected by the TGA's governance structure and accountability process, which require reporting through the Minister to parliament.[48]

1.63 Given the role and assessment processes of the TGA in delivering a considered judgement about the risk/benefit profile of a drug, the question was rhetorically posed: '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?'[49]

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46 *Submissions* 706, p.4 (IFPACA); 708, p.1 (RWH&FPV); 901, p.5 (Dr Stone); 907, p.2 (SH&FPA).

47 *Submission* 202, p.1 (Profs Rogers Ankeny and Dodds).

48 Eg *Submissions* 701, p.2 (Dr Cockburn); 708, pp.1-3 (RWH&FPV); 907, pp.1-2 (SH&FPA); 916, pp.1-2 (WHV); 1085, p.2 (VCOSS).

49 *Submission* 704, p.1 (RCA).

1.64 Within the TGA, an expert advisory committee, the Australian Drug Evaluation Committee, undertakes assessments and provides independent, scientific advice on all drugs to the TGA. ADEC is entrusted with making significant decisions and has provided sound judgements that have served Australia well over many years.

1.65 Those supporting the Bill hold the view that Australia is well served by the professional competence and integrity of the TGA. With an evidence based, risk management approach to the consideration of therapeutic goods, they consider that the TGA is the appropriate body to address the safety and efficacy of all drugs to be used in Australia. The supporters argue that the TGA should be the approving body for ALL medicines and medical devices. There is no reason to exclude one group of therapeutic agents from the Act by having a separate process for the drug RU486.

> SH&FPA believes that ADEC's advice constitutes an appropriate, objective, apolitical conclusion based on the efficacy, quality and safety of a drug and its suitability for use by Australians. That this expert body is not trusted to provide adequate advice on this matter seems to refute the whole proposition of evidence based scientific scrutiny in the provision of appropriate drug supply to the Australian community.[50]

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1.67 Istar Ltd, the company formed specifically to import mifepristone into New Zealand, provided information about the use of the drug in New Zealand including the approval process and tightly restricted distribution and access arrangements, operation of protocols for early medical abortion and the oversight of abortion procedures by an Abortion Supervisory Committee. Istar advised that:

> In New Zealand mifepristone has been assessed and its use monitored by Medsafe, the New Zealand equivalent of the TGA. The drug has been satisfactorily regulated using the same procedures and controls that are available for other prescription medicines.[52]

The 1996 amendments to the Act and their impact

1.68 Submissions argued that the 1996 amendments to the Therapeutic Goods Act created a significant inconsistency in the administration established under the Act for the evaluation, approval and regulation of therapeutic goods. They imposed an exception to the agreed standards and criteria for assessing drugs for use in Australia

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50 *Submission* 907, p.1 (SH&FPA). See also *Submission* 4, p.1 (NFAW); 1004, p.1 (ACSHM).

51 *Submission* 907, p.1 (SH&FPA). See also *Submission* 4, p.1 (NFAW); 1004, p.1 (ACSHM).

52 *Submission* 602, p.5 (Istar Ltd).

thereby undermining the integrity of the system established by the TGA to protect and promote public health through safe and effective use of high quality, therapeutic drugs in Australia.[53]

1.69 By reducing the powers of the TGA and shifting the absolute power over access to these drugs, the amendments to the Act meant that the safety and efficacy of these drugs could not even be evaluated without the Minister's written approval. The Act does not require the Minister to seek advice, give any reasons or follow any protocol, when making a decision regarding an application relating to these drugs. Dr Cockburn noted that:

> No other drugs have this layer of ministerial micromanagement. Every other drug is evaluated solely on its scientific merits by the TGA, free from ministerial interference, using accountable methods to assess its safety and efficacy.[54]

1.70 Some submissions noted that there were wider medical implications because the Act has effectively banned the entry of RU486 into Australia not only for use as an abortifacient but also for the number of other possible uses such as an emergency contraceptive, in the treatment of some breast and brain tumours, and as treatment for endometriosis and irregular bleeding.[55] Others put the impact of effectively banning RU486 in stronger terms:

> It is unconscionable to indicate (by effectively banning the scientific examination of a therapeutic agent in Australia) that Australia’s scientific and medical community are not capable or responsible enough to use a drug appropriately. There is no evidence to believe that Australian doctors would act in an irresponsible manner with this, or any other therapeutic agent.[56]

1.71 Professor David Healy, Chairman of the Monash University Department of Obstetrics and Gynaecology, described his decades of experience in the medical use of Mifepristone including studies commenced in 1988 and 1994 in conjunction with the World Health Organisation. Professor Healy commented that:

> Therefore, before the 1996 amendment to the Therapeutic Goods Act, it seems that Mifepristone had already been approved twice by the Australian Government, including on one occasion by the TGA.
>
> It therefore is bewildering to me, that medication such as RU486 and other restricted goods cannot be evaluated, registered, listed or imported without the written approval of the Minister for Health and Ageing in 2006.
>
> The 1996 amendment has damaged the health of Australian women by creating a climate of reproductive hostility. This has resulted in a lack of

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53 *Submissions* 708, p.3 (RWH&FPV); 1085, p.2 (VCOSS).

54 *Submission* 701, p.1 (Dr Cockburn).

55 *Submission* 907, p.3 (SH&FPA); 1003, p.2 (AMA).

56 *Submission* 1004, p.1 (ACSHM).

> interest by pharmaceutical companies in applying for sponsorship and registration of such medicines in Australia.[57]

RU486 and International evidence and approval

Approval and use as a safe and effective drug

1.72 Submissions supporting the Bill, while recognising that no medication or medical procedure is risk-free, referred to the substantial body of literature establishing the safety and efficacy of RU486 when used in conjunction with a prostaglandin (usually misoprostol) to induce early abortion. With the evidence reporting extremely low levels of adverse incidents, the health risks associated with RU486 are considered to fall within acceptable limits, which has enabled an extensive list of prestigious Australian, International and World Health Bodies to formally support RU486 including:

- The World Health Organisation
- The Royal Australian New Zealand College of Obstetricians and Gynaecologists
- The Australian Medical Association
- The Rural Doctors Association of Australia
- The Public Health Association of Australia
- The Royal College of Obstetricians and Gynaecologists (UK)
- American College of Obstetricians and Gynecologists
- The American Medical Association
- American Association for Advancement of Science
- US Federal Drug Administration
- Federation of International Gynaecology and Obstetrics
- Cochrane Collaboration.[58]

1.73 It was argued that the safety of RU486 could be demonstrated by the 35 countries that had approved the use of the drug as an alternative to surgical abortion most commonly in the first 49 days of pregnancy. These countries include the UK, USA, many in Europe and Scandinavia, India, South Africa and New Zealand. There have been an estimated 500 000 early medical terminations in North America since the drug was approved as an abortifacient in 2000 and over one million in Europe.[59]

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57 *Submission* 603 (Professor David Healy). These trials were referred to in other submissions including 601, p.2 (ARHA)

58 *Submissions* 10, p.1 (PHAA); 402, pp.2-4 (WHNSW); 917, p.3 (Children by Choice Association); 1000, p.3 (NUS);

59 *Submissions* 10, p.2 (PHAA); 401, p.3 (RANZCOG); 601, p.2 (ARHA); 701, p.2 (Dr Cockburn).

1.74 As noted, submissions recognised that no intervention is without risk and drugs do have side effects.[60] It is important to determine that associated health risks fall within acceptable limits. RANZCOG argued that 'as surgical termination is accepted as a safe procedure, it is pertinent to compare the side effects and maternal mortality of medical termination with surgical termination'. The College noted that there had been few randomised trials comparing early medical and surgical termination but the data they presented was a compilation of the best available evidence.

- Serious complications are rare and occur in approximately 4/1 000 procedures with either method. Mortality and serious morbidity occurs less frequently than if a pregnancy went to term;
- Maternal mortality rates relating to surgical termination in Australia and North America are of the order of 0.3-0.8/100 000 and most recent data indicates the commonest cause was related to anaesthesia;
- Serious complications with medical terminations are rare with overall rates due to haemorrhage infection of 2.7-3.0/100 and 2.0/100 requiring surgical evacuation of retained tissue.[61]

1.75 The risk of death from any cause associated with attempting to carry a pregnancy to term is 8 to 10 times the risk of death from a termination.[62] Pregnancy related deaths in Australia still occur at the rate of 8.2 per 100 000 confinements.[63]

1.76 The Association of Reproductive Health Professionals stated that:

> From 1993 to 2000, the U.S. Food and Drug Administration received over 4,000 adverse event reports, including 55 reports of death, involving loratadine [sold over the counter at pharmacies in Australia as Claratyne] a drug which recently gained over-the-counter status. Among users of sildenafil [Viagra], there have been approximately five deaths for every 100,000 prescriptions provided. According to the manufacturer, Pfizer, more than 23 million men worldwide have been prescribed the erectile dysfunction medication Viagra and more than 1 billion prescriptions have been written.[64]

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60 Reproductive Choice Australia noted that RU486 is not 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). *Submission* 704, p.3.

61 *Submission* 401, pp.3-4 (RANZCOG).

62 Green, See also *Committee Hansard* 15 December 2005, p.38 (RANZCOG).

63 Slayter EK, Sullivan EA & King JF, *Maternal Death in Australia 1997-1999*, AIHW Cat. N. PER 24, Sydney 2004: AIHW National Perinatal Statistics Unit, p.xiv.

64 *Submission* 1001, pp.4-5 (The Association of Reproductive Health Professionals).

1.77 A number of submissions commented upon the recent deaths in the USA associated with the use of RU486. The women had died from infection of the uterus by clostridium sordellii. Dr Christian Fiala, FIAPAC, commented that:

> As tragic as these cases are, one has to see them in perspective. Nothing of this kind has been reported in Europe in the last 15 years and more than 1.5 million women being treated. And it is safe to assume that tragic cases like these ones would have been reported, given the high public awareness on this topic.[65]

1.78 Clostridium sordellii infections have also occurred following childbirth (vaginal delivery and caesarean section) and pelvic and abdominal surgery. All such cases have been fatal. Additionally, this infection is not restricted to women of reproductive age. Other known cases of Clostridium sordellii have occurred in males and females of varying ages and under non-obstetric conditions, including umbilical infection, deep skin infection, tendon transplant surgery, orthopaedic surgery and following motor vehicle accidents. No causal link has been established between the US deaths and infection and the use of RU486.[66] While the FDA has clarified its warnings on the use of RU486, the FDA has not withdrawn RU486 from sale in the US and it continues to be available for use for medical abortions.

1.79 The information about death rates in the US for surgical abortion in the first 8 weeks and the death rate from infection associated with RU486 contained in a recent review article by Dr Michael Greene and an accompanying editorial in the New England Journal of Medicine was referred to in many submissions. The editorial noted that in either case these are extremely rare events and do not justify banning the drug. The author goes on to warn about overreacting to scant data, although he recognises that this is difficult in relation to any discussion that touches on abortion.

> As tragic as the deaths of these young, healthy women are, they remain a small number of rare events without a clear pathophysiologic link to the method of termination. Patients should be informed of this risk before they consent to the procedure and should be vigilant for symptoms after the procedure. Providers must be aware of this potential complication and not be reassured by the absence of fever. Regulators should keep this rare complication in perspective and not overreact to scant data by prematurely

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65 *Submission* 706, p.3 (Dr Fiala, FIAPAC).

66 *Committee Hansard* 6 February 2006, p.76 (Sydney Centre for Reproductive Health Research, Sexual Health and Family Planning Australia). See also Hogan SF, Ireland K, 'Fatal acute spontaneous endometritis resulting from *Clostridium sordellii', American Journal of Clinical Pathology* 1989; 91:104-106; McGregor JA, Soper DE, Lovell G, Todd JK, 'Maternal deaths associated with *Clostridium sordellii* infection, *American Journal of Obstetrics and Gyneocology* 1989; 161:987-995; Abdulla A, Yee L, 'The clinical spectrum of *Clostridium sordellii* bacteraemia: two case reports and a review of the literature', *Journal of Clinical Pathology*, 2000; 53:709-12; Omphalitis. Patrick G Gallagher, MD, Samir S Shah, MD <http://www.emedicine.com/ped/topic1641.htm> accessed Jan 2006-02-07; Kainer, MA, Linden, JV, Whaley DN, Holmes, HT, Jarvis, WR, Jernigan, DB Archibald LK, 'Clostridium infections associated with Musculosketetal-Tissue Allografts', *New England Journal of Medicine*, Vol 350 (25) 2564-2571.

> foreclosing the only approved medical option for pregnancy termination. It may be difficult, however, to maintain equipoise on this issue in the wake of recent perceived regulatory lapses and amid the turbulence created by any discussion about abortion.[67]

1.80 The Parliamentary Library Research Note made the following comment in relation to the debate over the efficacy and possible side-effects of RU486:

> Broadly, this Note suggests that there has been very little dispute in the current debate over the substantive 'clinical facts' of RU486 (such as its efficacy and possible side-effects). Rather, much of the debate has involved alternative characterisations of the risk associated with this form of medical abortion. This suggests that one of the key questions in the debate over RU486 is about who is the appropriate authority to evaluate the risk associated with this medicine and determine its appropriateness for authorised use in Australia.[68]

Mental health issues raised by the Christchurch Health and Development Study

1.81 Dr Robyn Seth-Purdie referred to the Christchurch study on abortion and subsequent mental health problems published in January 2006 and commented on what relevance the CHDS study had for the Committee's consideration of the Bill. The study was also referred to by some opposing the Bill. Dr Seth-Purdie, who had been provided with analysis of the CHDS data during the course of the study, submitted that it is important to appreciate the limitations on the study published and to be aware that the paper published by CHDS on its web site is careful to make the following points:

> First, the study did not collect the data that would permit comparison of the personal circumstances or the attitudes towards their own pregnancy of the two groups of young women who were identified as having been pregnant... [Factors that] might be expected to have some impact on decisions about pregnancy, and on subsequent mental health…
>
> Second, based on whole population figures, the incidence of terminations reported in the study group was too low – only 80% of the expected level. Given that the group that reported never having been pregnant exhibited much lower rates of mental illness than both pregnant groups, under-reporting could have had a significant impact on the results...
>
> Thus, the elevated risk associated with pregnancy termination reported by the CHDS cannot be unequivocally attributed to the termination. However, the paper certainly highlights the need for further study in this area. It also indicates the need to ensure adequate support for young women who

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67 Greene M, 'Fatal Infections Associated with Mifepristone-Induced Abortion', *New England Journal of Medicine,* 353:22, 2317-2318. See also an interview with Dr Greene at transcript http://www.abc.net.au/rn/talks/8.30/helthrpt/stories/s1521375.htm

68 *Research Note*, no. 19, Parliamentary Library, 28 November 2005, p.1.

> become pregnant, regardless of whether they decide to proceed with or to terminate their pregnancy.[69]

Availability of RU486 should it be approved

1.82 A number of submissions responded to comments that should RU486 be approved the drug would become easily available and its use uncontrollable. Dr Cockburn reflected many expressed views when she wrote:

> Maybe you are concerned that passing this Bill will automatically make abortifacients available to the general public. This is not the case. The drugs still need to be fully evaluated by the TGA whose experts who will employ the same accountable criteria and protocols that all other medications in this country are put through. Only then, if these drugs pass the tests; and, after appropriate clinical protocols and restrictions are put in place would they be licensed for prescription use by Medical Practitioners in appropriate clinical and legal circumstances. It is inconceivable that there would be any intention of over the counter or unrestricted supply of these drugs. RU486 is NOT Postinor (commonly called the Morning After Pill.).[70]

1.83 Submissions and correspondence received by the Committee indicated considerable confusion by many who thought that RU486 was the 'morning after pill'.

No evidence that abortion rates would increase

1.84 Concern at the number of abortions performed every year in Australia was expressed in many submissions supporting the Bill. However, they argued that there is no evidence to support the contention that making RU486 available will result in an increase in the number of women seeking an abortion, nor will it have a significant impact on the number of abortions performed. Rather, it was anticipated that the availability of RU486 would provide women and the medical profession with an additional choice in the method of termination resulting in medical abortions replacing a proportion of the surgical abortions currently undertaken.[71]

1.85 It was noted that medical abortion, like surgical, would require appropriate medical supervision and women in most States will still need to persuade a medical practitioner that their abortion is 'necessary' for them to comply with relevant State criminal codes regulating the procedure.

1.86 Submissions cited overseas experience and studies which had demonstrated that the availability of medical abortion does not increase the overall number of abortions that take place. Reference was made to the introduction of RU486 in the UK, USA, Germany and Sweden where the proportion of abortions performed using this method steadily increased while the overall abortion rates remained stable or

69 *Submission* 919,pp.2-3 (Dr Seth-Purdie).

70 *Submission* 701, p.5 (Dr Cockburn). Also *Submission* 901, p.2 (Dr Stone).

71 *Submissions* 401, p.3 (RANZCOG); 903, p.3 (RWH Vic); 922, p.1 (WIRE); 1003, p.3 (AMA).

actually declined.[72] Istar Ltd provided New Zealand statistics which indicated that 'since the introduction of medical abortion there has not been an increase in the number of abortions, in fact in 2004 there was a small decrease for the first time in seven years'.[73]

Medical practitioners

1.87 Comments by opponents of the Bill portrayed a possible situation where a patient could be left on their own while undertaking a medical termination procedure. This was countered by the supporters who argued that, with the introduction of RU486, women undertaking a medical termination will still require appropriate medical supervision as is currently required with a surgical termination. Furthermore, in order to comply with relevant State laws regulating the procedure, many women will still need to explain to a medical practitioner why a pregnancy termination is 'necessary' in their situation, and must still receive detailed information regarding the procedure and its associated risks in order to provide informed consent.[74]

1.88 Medical practitioners emphasised that they have the expertise and would be involved with all stages of the medical procedure. The RACGP noted that if a woman chooses a medical termination, this service should be provided in accordance with evidence based guidelines and protocols when the risk to the woman is small. Many women internationally have chosen medical terminations, especially those who want to avoid anaesthetics or surgery. The RACGP expressed confidence that Australian general practitioners have adequate training and capacity to care for patients, including support for women who choose a medical termination if this becomes available in the future.[75]

1.89 The RWH noted that gynaecologists are suitably trained to supervise medical abortion and to recognise and manage any complications. Care may be delivered in partnership with midwives, counsellors and General Practitioners according to appropriate protocols. Protocols would be established regarding all of the steps required for medical abortion.[76]

1.90 Submissions argued that as with many other medical procedures, protocols can be developed to ensure that women have access to medical care, according to the level of risk, following administration of the drugs. RANZCOG advised that a doctor must be trained to undertake a surgical termination safely and, for mifepristone to be used safely, training and education of practitioners and the development of best practise guidelines is essential. RWH indicated that it would establish protocols and train relevant staff to make this treatment available to women, as appropriate.

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72 *Submissions* 1003, p.3 (AMA); 402, p.4 (WHNSW); 917, pp.4-5 (Children by Choice).

73 *Submission* 602, p.5 (Istar Ltd).

74 Eg *Submissions* 917, p.4 (Children by Choice); 922, p.2 (WIRE).

75 *Submission* 908, pp.3-4 (RACGP).

76 *Submission* 903, p.3 (RWH).

Approaches to counselling and decision-making about abortion would not change. Clinical practice, information and support would be informed by international evidence about best practice.[77]

1.91 Reference was made to international guidelines and protocols that are already operative, for example New Zealand has developed comprehensive guidelines for the use of mifepristone for medical abortion.[78] Both RANZCOG and the British Royal College of Obstetricians and Gynaecologists have developed position papers for the use of RU486, the latter being evidence-based as they have access to the drug.[79]

1.92 Many of the medical representatives, women's hospitals and groups indicated that they would wish to be involved in the development of Australian guidelines and protocols.

1.93 Doctors from the Women’s Clinic and Family General Practice on Richmond Hill who currently offer a range of family planning and other medical services including, termination of pregnancy stressed that:

> If the drug was to be introduced there are issues to be addressed around the training and experience of the practitioners prescribing and monitoring it. For instance it is imperative, when performing a surgical TOP, that the possibility of an ectopic pregnancy be considered and excluded in the course of management. Ectopic pregnancy is a life-threatening emergency and is a significant cause of maternal deaths if undiagnosed and not treated. Experience in the diagnosis and management of ectopic pregnancy is thus essential and protocols for the use of RU486 must have interruption of the pregnancy and exclusion of an ectopic pregnancy as an assured end point.[80]

Rural Issues

1.94 Many submissions were received representing views from regional, rural and remote areas of Australia. The argument common to these submissions was summarised by a group of doctors working in Broome, WA:

> As doctors practising in a remote part of Australia, we regularly witness the disadvantage of rural and remote women in accessing early and safe termination of pregnancy compared with their urban peers.[81]

1.95 The disadvantage described in submissions covered issues such as lack of choice in accessing services, difficulties imposed by distance travel, transport and accommodation costs away from home, and loss of family support and other assistance. The submissions argued that the limited access to timely legal termination

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77 *Submissions* 401, p.5 (RANZCOG); 903, p.3 (RWH)

78 *Submissions* 602, pp.3-5 (Istar Ltd); 708, p.2 (RWH&FPV).

79 *Submission* 204, p.1 (Professor Pettigrew).

80 *Submission* 608, p.2 (Women’s Clinic and Family General Practice on Richmond Hill, Vic).

81 *Submission* 606, p.1 (Broome Regional Aboriginal Medical Service)

services in rural and remote Australia could be safely addressed by supporting access to RU486 used under appropriate medical supervision. The RDAA noted:

> Currently surgical abortion is unavailable in many rural and remote areas. Women who have to travel to larger centres for this service may lose both the personal emotional support and the continuity of medical care they would have in their own community. It could be argued that medical termination under the supervision of their local doctor would be the safer alternative for many of them and they should have the right to this option.[82]

1.96 The Association for Australian Rural Nurses noted that nurses and midwives are the major group of health professionals outside metropolitan cities providing health care to rural and remote women. The AARN asserted that:

> The availability of a range of reproductive choices is especially important for rural and remote women. Time delays in gaining a safe abortion can have a dramatic impact on rural women's health and wellbeing. The medical complications of a delayed termination of pregnancy are the direct result of a dearth of services being available in rural and remote areas. The long distances women need to travel must be taken into consideration when making decisions about women's reproductive health.
>
> In supporting the amendment it is anticipated that rural and remote women will cease to be disadvantaged in relation to available, accessible, appropriate and affordable reproductive choices.[83]

1.97 Many submissions took strong exception to the argument that the use of RU486 in rural areas would place women at significant risk because the argument disregards the fact that the drug would always be administered under medical supervision. The RDAA stated that:

> The concern that this supervision may not be available to women in rural Australia is unfounded. Doctors in rural and remote Australia are keenly aware of their duty to ensure that their patients are provided with the safest treatment options possible. They have the advanced skills needed to manage complex conditions and to deal with medical emergencies without the support systems available to their urban colleagues. They know the range of treatment they and their nearest hospital can provide, and they are used to assessing which treatment options are safest for their patients in a wide range of conditions.[84]

1.98 The argument was also seen to contain inferences about medical capability with one submission asserting that 'these arguments, in essence, are an attack on the integrity of the rural and remote medical workforce'.[85] The RDAA emphasised that rural doctors have the expertise and experience to offer women who decide on the

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82 *Submission* 911, p.4 (RDAA). Also *Submission* 901, p.3 (Dr Stone); 905, p.8 (WAAC).

83 *Submission* 921, p.1. (AARN).

84 *Submission* 911, p.4 (RDAA).

85 *Submission* 905, p.6 (WAAC).

termination of a pregnancy the option of safe medical abortion under their supervision. The Association also noted that the specialist obstetricians and generalist and procedural GPs who provide reproductive care are required to maintain and enhance their skills by Continuing Professional Development through courses such as those offered by the Australian College of Rural and Remote Medicine.

1.99 It was further noted that many rural areas have small hospitals equipped to deal with pregnancy and spontaneous abortion and these hospitals could also provide back up for women needing assistance with medical abortions.[86]

1.100 A number of submissions gave detailed examples of the issues faced within rural and remote communities in a number of States. These are described below:

Queensland

> In Far North Queensland – surgical abortion is available only in Cairns, where a small number are done in the public system, and the remainder in a private clinic. Women from Cape York or the Atherton Tablelands need to travel vast distances to access the service and are required to pay $750 up front for a surgical abortion. However excellent hospital facilities for the care of women suffering spontaneous miscarriage or other complications of pregnancy, including the availability of ultrasound, exist in all the small towns throughout the region, including Atherton, Mareeba, Innisfail, Mossman, Cooktown, Weipa and Thursday Island, and hence the necessary back-up for the small number of women needing medical intervention in medical abortion could potentially be provided in all these places.[87]
>
> TGA approval of RU486 is an important issue in Queensland because there's very limited access to surgical termination for regional women. Provision of RU486 would provide a way for medical abortions to be provided without the great disruption to women's lives and the cost of having to travel to centres such as Brisbane, Rockhampton, Townsville and Caboolture where surgical termination services are available. The latest abortion figures released by the Australian Institute of Health and Welfare showed that Queensland women are more likely to travel interstate for an abortion than women in other states… These figures highlight the geographical disadvantage thousands of Queensland women face when obtaining abortions… It is clear from the statistics provided by the Australian Institute of Health and Welfare that women living in regional Queensland are seeking termination services but are disadvantaged in terms of time and cost by issues of distance.[88]

Tasmania

> Of particular significance to Tasmania is the history of irregularity of access to and provision of surgical abortion in our state. For decades, Tasmanian

86 *Submission* 419, p.2 (Hobart Women's Health Centre).

87 *Submission* 3, p.2 (Professor de Costa).

88 *Submission* 605, pp.2-3 (FPQ). Also *Submission* 917, p.2 (Children by Choice Qld).

> women seeking to terminate an unwanted pregnancy have been subjected to the whim of public hospitals and individual surgeons as to whether they can access this procedure or not. Similarly, there has been very limited access to private services, which are often prohibitively expensive or inaccessible from outside of the capital. As a consequence, hundreds of women over this time have had to travel to mainland cities to access this service, resulting in significant expense, time away from work or families, lack of support at the time of the procedure, a delay in accessing the procedure and lack of aftercare in the weeks following… Having access to a medical alternative to surgical abortion, such as RU486 would eliminate this disadvantage, by allowing women to access this service via a general practitioner in their local area.[89]

Victoria

> VCOSS members in regional Victoria have reported that women living in regional and rural areas face restricted access to abortion services due to limited service providers, the financial cost of seeing a private practitioner, the lack of public transport, and the lack of privacy that can exist in smaller communities. Many women in regional and rural Victoria must currently travel to access safe termination services, which generally entails two to three days away from their family, friends and work – from their support networks... Access to RU486, or a medical abortion, would significantly assist in removing these barriers for women, as well as enabling them to access their support networks.[90]

Western Australia

> Currently, women requesting a termination of pregnancy in the Kimberley are often required to wait several weeks for the procedure to be performed locally or when unable to be accommodated on our limited surgical lists, required to travel up to 3000 km to Perth… Obviously, the decision to terminate an early pregnancy is a difficult and emotional one for most women. Despite this many women are having to endure this procedure alone, far from home and supports and liable for extra financial expenses.[91]

Working to reduce unwanted pregnancies

1.101 Many groups and individuals supporting the Bill acknowledged the high rate of abortion and urged the implementation or enhancement of a range of programs and services aimed at reducing unwanted pregnancies. These included putting more resources into improved sex education with expanded programs for better education of boys and girls on responsible human relationships, wider availability of information about and access to contraception and other fertility control techniques, and appropriate counselling. The AMA and National Foundation for Australian Women summed up the views expressed by many:

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89 *Submission* 703, pp.1-2 (People for Choice Tasmania).

90 *Submission* 1085, p.3 (VCOSS).

91 *Submission* 606, p.1 (Broome Regional Aboriginal Medical Service).

> The AMA supports actions the government is proposing and should consider to take others to reduce the demand for abortions, such as better sex education in primary and secondary schools, improving access to effective modern contraception and emergency contraception on the PBS, making the work environment more conducive to having children by increasing the availability of child care and making it more affordable by allowing childcare costs to be claimed as an expense and therefore paid pre-tax and mandating 6 months paid maternity leave and a whole raft of other supports that are not relevant to this inquiry.[92]

> [NFAW called upon the Commonwealth to] develop and provide funds, in consultation with the governments of States and Territories, health professionals, education professionals and representatives of women's organisations, for a national program of sexual health education which includes relationships counselling, ready affordable access to appropriate means of contraception including emergency contraception, an appropriate range of independent professional counselling for girls and women considering termination of a pregnancy, counselling after a termination, and counselling for relinquishing mothers.[93]

ARGUMENTS OPPOSED TO THE BILL

Effect of the Bill broader than stated purpose

1.102 Opponents of the Bill argued that the very purpose of the drug RU486 meant that the debate over the Bill could not only be restricted to the question of who should have responsibility for making a decision concerning the drug's approval, it must also be viewed in the context of a much broader community debate over abortion. The last few years have seen community disquiet grow over abortion and RU486 cannot be viewed in isolation from this. The argument was summed up by the Queensland Bioethics Centre:

> It is well nigh impossible to comment upon this Bill without raising the question of abortion. After all the legislation as it stands is primarily concerned with RU486 as an abortifacient. The use of RU486 for other genuine medical purposes is, all things being equal, not problematic. A particular feature of RU486 is that it can be used for a non-therapeutic purpose, namely the ending of a new human life.[94]

1.103 The Australian Federation of Right to Life Associations contend that the Bill has a much broader legal effect than the short title and purpose clause would suggest by stating that the Bill's only effect would be to remove Ministerial responsibility for approval of RU486. The Bill proposes to repeal section 6AA of the Act that deals with the importation of restricted goods and repeal the definition of restricted goods in subsection 3(1) which currently states 'restricted goods means medicines (including

92 *Submission* 1003, p.3 (AMA).

93 *Submission* 4, p.4 (NFAW).

94 *Submission* 207, p.1 (QBC). See also *Submission* 720, p.1 (RLOCAM.

progesterone antagonists and vaccines against human chorionic gonadotrophin) intended for use in women as abortifacients'. AFRTLA argued that the repeals mean that if the amendment Bill is passed, it would remove from Ministerial responsibility approval of the importation of all abortifacient drugs/vaccines, not only of RU486, and therefore the short title and purpose clause were 'seriously misleading'.[95]

Accountability

RU486 is unique

1.104 Opponents of the Bill spoke with a single voice that RU486 is not like any other drug. They argued that because the drug is designed to end the life of a human being, it thereby makes this drug a matter of unique public concern demanding a unique level of public scrutiny and accountability. The nature of this drug and its intended use has profound social and ethical significance. For this reason the Catholic Archdiocese of Sydney and others argued that:

> The 1996 amendments to the [TGA Act] placed substances such as RU486 in a special group of drugs known as 'restricted goods' on grounds that they are drugs which are intended for use in women as abortifacients. This is an appropriate designation for abortifacient drugs. A substance is 'therapeutic' if it relates to the treatment or curing of disease. Abortifacients, however, are not administered to women with the intention of treating or curing a disease. Abortifacients are administered with the intention of ending the life of a human embryo or foetus... As abortifacients are not genuine 'therapeutic goods', drugs intended for use in women as abortifacients should continue to be regarded as 'restricted goods'.[96]

1.105 Dr Klein developed a further argument beyond specifically referring to the purpose of the drug:

> The inevitable combination of RU486 with [prostaglandin] is one reason why RU486 is not like any other drug and cannot simply be assessed (eg by the TGA) on its quality, safety and efficiency. *RU486 does not work on its own, it needs the prostaglandin component*.[97]

TGA assessment limitations and the moral dilemma

1.106 Submissions drew attention to the legislative requirement that in evaluating an application for registration and listing of a therapeutic good the Therapeutic Goods Administration is bound to consider 'whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established'. There is no legislative authority or other requirement for the TGA to consider or assess the deeper social and ethical issues related to a therapeutic good.

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95 *Submission* 421, p.3 (AFRTLA).

96 *Submission* 628, p.2 (Catholic Archdiocese of Sydney). Also *Submissions* 411, p.1 (CWLA); 420, p.1 (FoL); 627, p.4 (RTLA).

97 *Submission* 930, p.4 (Dr Klein).

The TGA is quite simply not equipped nor intended to deal with the morality of any drug and its resultant action. It is these issues that for opponents of the Bill are at the heart of concerns about RU486 and its availability.[98]

1.107 The extensive, and costly, research that would be required in assessing RU486 in association with the prostaglandin by or on behalf of the TGA was also questioned:

> It is clear that drugs are assessed only based on their quality, safety and effectiveness. Interactions of two drugs - Mifepristone and Misoprostol - let alone the myriad of regimens, complications, contradictions, multiple sites of actions, as well as social and ethical components of chemical abortion would be a considerable challenge for the TGA. Of course, long-term research studies, originated in Australia - clinical trials as well as laboratory studies - could be requested by the TGA. However the problem arises as to who would fund the extensive work that is required. *The TGA could not fund it because since 1998-99 the Australian Government has required the TGA to operate on a full cost-recovery basis*.[99]

1.108 A further concern raised in many submissions was that the Bill proposes to shift responsibility to an unelected, and therefore unaccountable, group of anonymous bureaucrats and scientists in the TGA who have no statutory role to deal with complex social and ethical matters.

> There is no reason to doubt that the TGA has sufficient medical knowledge and expertise to conduct the evaluation of RU486 and other abortifacients for quality, safety and efficacy.
>
> However, drugs such as RU486 do not only carry the usual medical risks associated with standard 'therapeutic goods'. Because they are designed to end very young human lives, allowing or disallowing access to abortifacients has serious social implications. The TGA does not have the knowledge, expertise or the mandate, to make a judgment about the ethical and social impact of abortifacient drugs. Judgments and decisions about 'restricted goods' call for an additional level of scrutiny and accountability by elected community representatives.[100]

Concerns at TGA research and public safety

1.109 Although many submissions recognised the experience and good standing of the TGA, others raised concerns relating to its approval processes and research performance, noting that the robustness of its processes had been questioned in recent times.

> TGA approval process is most often based upon research developed by the drug companies. aa RU486 shares the view of prominent bioethicists, like

98 *Submissions* 931, p.3 (aaRU486); 933, p.5 (CDAV); 1111, pp2-3 (ACBC)

99 *Submission* 930, p.12 (Dr Klein).

100 *Submission* 628, p.2 (Catholic Archdiocese of Sydney). Also *Submissions* 720, p.1 (RLOCAM); 938, p.2 (Lutheran Church of Australia).

> Renate Klein that RU486 research to date has been less than adequate in its controls and its reach.[101]

1.110 The Australian Federation of Right to Life Associations referred to problems which have featured in a series of audits of the TGA conducted by the Australian National Audit Office in the last decade into the efficiency, effectiveness and accountability of the TGA's performance in evaluating and approving prescription and non-prescription drugs for public use. The Federation argued that 'the outcomes of these audits do reveal the need for substantial improvement in TGA processes for the sake of public safety'.[102]

Minister should retain responsibility

1.111 Submissions opposing the Bill argued that the serious social and ethical issues which surround abortion and the use of abortifacients, which make them unsuitable for evaluation within the same TGA framework as therapeutic goods, require that the Minister for Health and Ageing should retain ultimate responsibility for decisions in relation to the importation, trial, registration and listing of RU486 and other abortifacients in order to ensure that regulation is via the appropriate scrutiny and accountability of elected community representatives. The Australian Catholic Bishops Conference referred to the social policy issues:

> Abortion is a sensitive and complex community issue. It is not appropriate for any consideration of abortion to be merely about the technicalities or the efficiency of different methods of abortion. It is for that reason that it is not appropriate for the TGA to be the sole body to consider an abortifacient such as RU486. The social policy aspects of such a product must be taken into account.
>
> Currently, consideration of the social policy implications of RU486 is undertaken by the relevant Minister. There is no reason for that arrangement to change.[103]

1.112 A number of submissions also quoted Senator Christabel Chamarette during the debate on the 1996 amendments to the Act:

> There is not only a health issue in the narrow sense – that is, whether the drug is safe – but also a question of whether the availability should be limited for ethical or policy reasons in the context of social policy. This debate is yet to be heard…I affirm the right of this parliament to have scrutiny over such issues.[104]

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101 *Submission* 931, p.3 (aaRU486). See also *Submission* 240, p.3 (Dr Seman).

102 *Submission* 421, p.5 (AFRTLA).

103 *Submission* 1111, p.3 (ACBC).

104 *Submission* 420, p.1 (Festival of Light).

Responsibility should be broadened to involve cabinet and/or Parliament

1.113 Some submissions noted that concerns had been expressed about a particular Minister having responsibility for making the policy decision on RU486 and proposed that the matter could become one for Cabinet rather than the individual Minister for Health.[105] This would ensure that the decision remained in the hands of elected politicians accountable through the ballot box. Others, such as the CWLA who concluded that 'this awesome responsibility rightly belongs to the Minister for Health, the Parliament and the people',[106] broadened the options for responsibility to include Parliament:

> There are alternative methods by which parliamentary scrutiny for approval of abortifacient drugs could be achieved that might ensure more objective, considered debate... [including] approval by a panel of Ministers holding relevant portfolios; approval by Cabinet; approval given in a disallowable instrument. The Association submits that the essential principle is to retain parliamentary accountability for approval of this particular class of drugs…[107]

A Committee of Experts

1.114 Dr Renate Klein proposed the establishment of a Committee of Experts consisting of informed community members including social and natural scientists, doctors, pharmacists and ethicists whose research should go beyond aspects of quality, safety and effectiveness of these restricted goods and investigate their complex interactions with Australian women’s lives. The Committee of Experts would have an important role in aiding the Minister for Health in her/his deliberations. Even if the Bill is passed Dr Klein suggested that such an independent Committee of Experts should nevertheless be established immediately, and, parallel to the TGA, conduct its own broader investigation into the question of the availability of RU486 as an abortifacient in Australia. Dr Klein explained:

> I make this suggestion…because the brief of the TGA does not enable it to fully canvass the range of social and ethical issues emanating from RU486 abortions. Further, as the TGA is financed on a full cost-recovery basis, it is unreasonable to believe that it has the capacity – and indeed the RU486 licensee who is applying for registration would be willing to pay for it – to perform an in depth inquiry into all aspects of chemical abortion.
>
> I suggest that in fact independent of whether the Bill is rejected or accepted, such a multidisciplinary Committee of Experts may be essential to alleviate community concerns about either the wisdom of an individual’s (the

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105 *Submission* 5, p.5 (WFDRHL).

106 *Submission* 411, p.3 CWLA).

107 *Submission* 421, p.10 (AFRTLA). See also *Submissions* 636, p.2 (Salt Shakers); 931, p.2 (aaRU486)

> Minister for Health) decision, or the narrowness of the TGA's investigation that assesses RU486 as if it were a drug like any other.[108]

Abortion in Australia

1.115 As noted earlier opponents of the Bill argued that it is impossible to comment upon this Bill without raising the question of abortion. Abortion remains an issue of grave moral and social significance and is still governed by legal constraints in all Australian jurisdictions with the exception of the ACT. In three States at least abortion remains a criminal offence and is 'legal' only under the conditions set forth by the decisions of a few individual judges in what have become landmark, but untested, judgments.[109]

1.116 Submissions emphasised that although abortion is widely practised in Australia, it is a mistake to think that Australians favour abortion on demand and argued that passage of the Bill would send conflicting messages about the practice:

> It is one thing for legislators to accept the legal status quo on abortion, but it is another thing altogether to ignore the fact that Australians are deeply conflicted about the status quo, with fewer than one in four people believing that abortion is morally justified outside of certain 'hard cases' involving disability or a danger to the mother's health, and only 15% believing that abortion is morally acceptable when the foetus is healthy and there is no abnormal risk to the mother. To legislate for the removal of the current special status of RU486 as a drug requiring ministerial approval sends the message that our federal representatives are intent on consolidating and strengthening abortion practices despite the views of the community.
>
> Rather than basing a decision on the fact that surgical abortion is currently available, any decision should reflect the reality that abortion itself is of great moral concern to the Australian public.[110]

Safety of RU486

Can be pro-choice and anti-RU486

1.117 A number of submissions highlighted that those who oppose changing the current approval process surrounding RU486 can be pro-life and pro-choice. Dr Klein who is in full support of a woman's right to have access to safe and legal abortion argued strongly against the introduction of RU486.[111] Australians Against RU486 said that it is erroneous to simply label all those who may oppose RU486 as anti-abortionists:

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108 *Submission* 930, pp1-2 (Dr Klein).

109 *Submissions* 207, p.1 (QBC); 420, p.5 (FoL); 421, p.9 (AFRTLA).

110 *Submission* 1012, p.2 (SCBI).

111 *Submission* 930, p.2 (Dr Klein). See also *Submission* 240, p.1 (Dr Elvis Seman).

> This submission confirms that you can be pro-choice and anti RU486, a feminist and anti RU486, pro-life and anti RU486. These are not contradictions.
>
> Their reasons are varied but their focus is singular.
>
> The broad coalition of individuals and organisations within aaRU486 have differing views: some believe that abortion is wrong; while others view abortion as a viable option but worry about the signals a pill promoted by its advocates as a 'simple solution' sends; still others believe that the RU486 debate isn't about a woman's right to choose but rather that it's about women's health.[112]

Complications arising from RU486 procedure

1.118 Issues of safety were argued in many submissions by referring to the complications that can arise from undertaking an abortion using a procedure involving RU486 and prostaglandin. Some submissions referred to this as chemical abortion rather than medical abortion. The procedure, as described earlier in the report, is a drawn out multi-step procedure that involves a number of visits to a licensed practitioner's premises.

1.119 The complications that occur with abortions that arise from the use of RU486 have been documented in research and include, but are not limited to: heavy and often prolonged bleeding including the need for blood transfusions, incomplete abortions necessitating surgical intervention, moderate or severe physical pain, and considerable mental anguish.[113]

Adverse events, associated deaths and FDA concerns

1.120 Many submissions raised fears over the safety of RU486 referring to adverse events and deaths associated with the use of the drug and concerns within the United States Food and Drug Administration (FDA). They considered that a medical abortion was not safer than, or even as safe as, a surgical abortion.

1.121 Submissions argued that although the FDA approved the use of RU486 in 2000 the decision was highly controversial and remains far from settled. Approval was given, despite warnings that procedural and scientific requirements had been bypassed and that adequate clinical trials had not taken place. They pointed to the FDA reporting in November 2004 that it had received 676 adverse events, following 350 000 applications from 2000 to October 2004, ranging in severity from minor symptoms such as nausea and dizziness to serious complications such as blood loss, ectopic pregnancy, and rare bacterial infections which have been fatal in some cases.

1.122 Reference was made to at least 10 deaths having been associated with the use of RU486 across Europe and the US since its introduction, though submissions

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112 *Submission* 931, p.1 (aaRU486).

113 *Submissions* 240, pp.2-3 (Dr Seman); 930, pp.7-11 (Dr Klein)

focussed on the death of four young women in California over the past two years. They each died within a week of taking RU486 of the same overwhelming infection of the uterus (*clostridium sordellii*). Three of the families are suing the manufacturer, Danco. The company says it has 'no answers' as to how this has occurred.

1.123 A death of a third British woman in association with a mifepristone/misoprostol abortion was confirmed in January 2006 by the United Kingdom's Medicines and Health Products Regulatory Agency.[114] Senator Joyce asked about the Australian context:

> **Senator JOYCE**—So it would be a fair statement that women who otherwise would have had a surgical abortion but who take RU486 will—if these things play out in Australia—die.
>
> **Dr Piercy**—Yes.[115]

1.124 A recent review article published in The New England Journal of Medicine on 1 December 2005 described these four deaths of previously healthy women due to fatal toxic shock syndrome and called for "further study of its association with medical abortion". An accompanying editorial noted that while the death rate in the US for surgical abortion in the first 8 weeks is around 0.1 in 100,000 the death rate from infection associated with RU486 for similar early abortions is close to 1 in 100,000 or ten times higher.

1.125 The FDA is investigating recently reported serious adverse events associated with RU486 (trade name Mifeprex in the US) and, as a result, issued a public health advisory on 19 July 2005 highlighting the risk of sepsis or blood infection when undergoing medical abortion using Mifeprex and misoprostol in a manner that is not consistent with the approved labelling. The FDA is reportedly convening a high-level scientific meeting with the Centre for Disease Control early in 2006 over these recent deaths linked to RU486.[116]

1.126 The United States Congressional Subcommittee on Criminal Justice Drug Policy and Human Resources is currently investigating the handling of the approval process for RU486 by the FDA, as well as its response to the five deaths and other adverse events related to RU486 abortions.[117]

1.127 On 1 February 2006 Congressman Roscoe Bartlett announced that he had seventy nine (79) co-sponsors for the RU486 Suspension and Review Act, a bill that would require the Food and Drug Administration to suspend sales of RU486 until a

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114 *Committee Hansard* 3 February 2006, p. (Mr Richard Egan, Festival of Light).

115 *Committee Hansard* 3 February 2006, p.28 (Dr Piercy, RTLA).

116 *Submissions* 5, pp.6-7 (WFDRHL); 421, p.8 (AFRTLA); 627, pp.7-8 (RTLA); 628, p.5 (Catholic Archdiocese of Sydney); 636, pp.2-4 (Salt Shakers); 720, p.2 (RLOCAM); 722, pp2-5 (Dr Lennon); 931, p.5 (aaRU486); 933, pp.2-4 (CDAV);

117 Letter to the U. S. Food and Drug Administration on Mifeprex, aka "RU-486"

At: http://reform.house.gov/CJDPHR/News/DocumentSingle.aspx?DocumentID=38547

complete review of its safety is conducted following the deaths of five American women after RU486 abortions. The Bill is also known as "Holly's Law" with the support of Monty and Helen Patterson, the parents of 18 year old Holly Patterson one of these five women.[118]

1.128 On 30 January 2006 the Italian Minister for Health Francesco Storace announced that the Italian Government was restricting imports of RU486. "From now on doctors will have to justify every individual request on precise clinical and epidemiological grounds" he said.[119] This move follows the suspension of a trial use of RU486 in Turin last September after one in twenty women being given RU486 were having partial abortions at home followed by excessive bleeding.

1.129 In Canada, a trial of RU486 was suspended after a 26 year old Canadian woman died of toxic shock syndrome on 1 September 2001.[120] RU486 has never been licensed for use in Canada despite it being a nation with extremely liberal abortion laws.[121]

1.130 Submissions argued that, given these emergent safety concerns, at this point in time it would be premature and imprudent for any Australian authority to make a determination about the safety of RU486. As Dr van Gend noted 'the the jury appears to have been sent out again on the safety aspects of RU486'.

Use and Monitoring if made available

1.131 Submissions argued that given the high risk of medical complications associated with RU486 it is important to consider how this drug would be monitored if it were to be made available through the TGA. Reference was made to different procedures in Europe and the US. Of particular issue was that trends seen in American since the introduction of RU486 demonstrate that there is little or no follow up care for women. Whilst it is recommended that women have access to medical treatment for a period of time after taking RU486, it is left up to the discretion of the individual who is taking the drug. The Council for Marriage and the Family addressed this issue:

> There is therefore reason for serious concern regarding how women will be protected and cared for after taking this drug if it becomes readily available through the TGA… If this drug were to be made accessible through the TGA it is recommended that there ought to be some strict regulation regarding its use such as supervised administration of the drug in a hospital setting and appropriate follow up (as is conducted in some countries in Europe). It is also recommended that RU486 be accessible only through a

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118 Rep. Bartlett Wins Support to Ban Abortion Pill,Thursday, February 02, 2006 By Elissa Petruzzi at: http://www.foxnews.com/story/0,2933,183520,00.html

119 The Times (London), 1 February 2006.

120 Sinave et al *Toxic shock syndrome due to* Clostridium sordellii Clinical Infectious Diseases Vol 35 (2002) 1441-1443

121 *Committee Hansard* 3 February 2006, p.73 (Mr Richard Egan, Festival of Light).

> specialist such as a gynaecologist, who is able to take responsibility for the follow up care involved.[122]

Psychological issues

1.132 Many submissions commented on psychological issues associated with determining to have and then carrying through with an abortion. Drs Stephen and Dianne Grocott, consultant psychiatrists described the issues raised in many submissions:

> The fact that the vast majority of Australian abortions are performed for social reasons implies that many women would bear and raise their child, if they had financial and relationship support instead of perceiving that the child threatens the survival of their individuality, their relationship, their career or the wellbeing of their other children. Women frequently decide to keep their children if they believe that they will have the support they need to do so. A medical abortion, marketed as an easy option, would have the effect of making it harder for women to ask for help when they are in crisis about their pregnancy…
>
> Dianne has first-hand experience of the psychological consequences to women, men, grandparents and siblings of abortion decisions. Many researchers have documented increased rates of depression, suicidal behaviour, substance abuse and relationship dysfunction that have variously been labelled "post-abortion syndrome"... There is a great need for public recognition of the psychological consequences of abortion so individuals can be correctly diagnosed and treated. There is also need for research in this area.
>
> RU486 is marketed as "easier" than surgical abortion. The initiation of a medical abortion is easier, but the consequences of delivering a dead foetus at home, or of pain and bleeding for up to weeks would further increase psychological trauma to women and their families. There is a need for independent research into the true psychological consequences of RU486, especially the consequences for women who decline to attend for follow-up.[123]

1.133 A number of submissions also referred to the recently published Christchurch Health and Development Study undertaken by Professor Fergusson in New Zealand on abortion and subsequent mental health problems. Professor Fergusson found that women who had had at least one abortion were twice as likely as others to drink alcohol at dangerous levels and three times as likely to use illicit drugs. The study reportedly found that at age 25, 42 per cent of women in the study group who had had an abortion also experienced major depression at some stage during the previous four years. This was nearly double the rate of those who had never been pregnant and 35 per cent higher than those who had chosen to continue a pregnancy. They also found

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122 *Submission* 410, p.3 (CMF).

123 *Submission* 623, pp.1-2 (Drs Stephen and Dianne Grocott).

that those having an abortion had elevated rates of subsequent mental health problems including anxiety, suicidal behaviours and substance use disorders.[124]

Impact on medical practitioners and medicine

1.134 It was also argued that the introduction of RU486 will negatively impact on medical practitioners and the practice of medicine:

> The introduction of RU 486 will extend the reach of abortion and its culture and ethos further into the mainstream of medical practice, involving more and more doctors, healthcare workers and medical students. Bringing abortion into the domain of primary care will further erode the practice and values of authentic healthcare which is founded on respect and care for all human beings and the principle of "first do no harm"… If it is successful it will have a profoundly negative effect on medical practice and medical practitioners alike.[125]

Use of RU486 for other medical indications

1.135 A number of submissions acknowledged the potential medical benefits of RU486 other than as an abortifacient. Dr Klein noted that, contrary to some comments, the 1996 amendments to the TGA Act did not ban RU486 and advised:

> it is indeed being trialled in Australia for other indications including as emergency contraception, and, since 2003 in conjunction with the contraceptive implant Implanon, to counter unacceptable bleeding and study RU486s action on ovulatory function and cervical mucus. Cancer research is also ongoing. The rejection of [this Bill] would not jeopardise these projects, nor indeed preclude further research. *However, it is precisely these many other sites of actions of RU486 that make it eminently unsuitable as an abortifacient as it is not specific enough in its action to stop a developing pregnancy*.[126]

1.136 Dr van Gend proposed that if RU486 is found by the TGA to be safe, then valid medical indications for its use, including certain cancers, hormonal diseases and medically essential termination of pregnancy, should be authorised. He argued:

> What the Government should be doing, in consultation with medical authorities, is to establish valid medical indications for RU486 – whether in certain cancers, hormonal diseases, or medically essential abortions – and approve the drug for those uses…
>
> RU486 is already available for certain medical conditions. Further, if medical authorities can define situations where abortion is medically essential, and where RU486 is safe and preferable to surgical abortion, then the drug should be authorised for such situations. In this way, RU486 could be accessed readily for these approved conditions through the current

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124 *Submissions* 420, p.2 (FoL); 720, p.3 (RLOCAM); 934, p.2 (NCC).

125 *Submission* 933, p.5 (CDAV).

126 *Submission* 930, p.11 (Dr Klein).

> system of Authority prescriptions, used for many special drugs (such as narcotics) where strict prescribing conditions must be met for their use.
>
> But the Government will have set the policy limits of this Authorisation – not on the elementary criteria of 'safety and efficacy' which the TGA exists to assess, but on more complex and significant criteria including the issue of justice to the unborn child. That is why the Government needs to keep a policy watch over the lower levels of administration like the TGA, which quite properly make their assessment on simpler technical criteria, appropriate for most drugs, but ethically inadequate for RU486.[127]

Rural issues

1.137 Many of the submissions opposing the Bill argued against the view that making RU486 available in Australia could possibly alleviate problems of unequal access to abortion by women in rural areas and those for whom privacy is an issue for religious, ethnic or other reasons.

> Those promoting the use of the drug in Australia often refer to the lack of availability of abortion in rural areas and suggest that this might provide an alternative. However, the drug requires repeated medical treatments and at least three visits to a doctor… If rural women have difficulty getting to a doctor – or obtaining medical appointments – this will not be a suitable treatment for them.
>
> Doctors commenting in an article in The Age, noted that it would be very unsuitable relating to privacy concerns – many people including the doctor, nurses, emergency services and pharmacists all knowing what you are doing.[128]

1.138 The submissions referred to reviews which suggest that safe medical abortion, like surgical abortion, requires the availability of an appropriate level of back-up medical care to address possible complications arising from the procedure. They noted that in cases where there has not been a successful medical abortion, the abortion will need to be completed surgically by a qualified physician and in some cases, women will require urgent medical care for side-effects such as internal bleeding and infection of the retained products of conception. Access to such urgent medical care is not readily available in many rural areas. A pharmacist in rural NSW described her situation:

> I am a rural pharmacist, who works in larger rural centres such as Wagga Wagga and Albury. I also work in smaller communities, and my most recent placement was at Condobolin, a town of about 3,500 thousand people, with one pharmacy and a small hospital. Although there are currently 4 doctors in Condobolin, there are no facilities for women to have their babies there. So they must go at least an hour away to Parkes or Forbes, where there is not always an obstetrics specialist available, or to Orange, Dubbo or Wagga Wagga, which are a minimum of 2 hours away.

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127 *Submission* 5, p.5 (WFDRHL).

128 *Submission* 636, p.5 (Salt Shakers).

> These larger, more distant centres could deal with a medical emergency at any time; however a patient may live as far as one and a half hours away from Condobolin. So the best case scenario would be a minimum of two hours for townsfolk, or three and a half hours, for some Australians, to reach emergency care.
>
> How do we place the supply of RU486 in this context?[129]

1.139 The issue of distance in rural areas was also referred to by Dr Buist from Women's Hospitals Australasia and Dr Piercy of RTLA:

> **Senator Barnett** - In your submission you stress the need for ready access to hospital facilities and include the ability to conduct an emergency surgical evacuation of the uterus. I would like to know how close to a fully equipped hospital would a woman need to be and for how long before being able to get to such a facility after she takes mifepristone or misoprostol?
>
> **Dr Buist** - I do not think I used the word 'hospital', but I accept the point. I did not specifically say 'hospital' and I am not necessarily suggesting that. Nonetheless, I am talking about within four hours or less—and perhaps even a shorter time—of being able to get to such a facility. That is why I have been very clear, hopefully, that I do not see this as a solution for a woman who is a long way from at least a district general standard facility.[130]
>
> **Senator JOYCE**—We seem to have problems at the moment getting doctors out into regional areas of Australia because of the debacle in the health system. Nonetheless, do you think RU486 has a special application to regional Australia that is going to be of great advantage to those people?
>
> **Dr Piercy**—I think it would be far more dangerous in regional areas.[131]

1.140 Submissions argued that the implications of such a scenario for women in rural and remote Australia is what was envisaged within the written advice from the Chief Medical Officer to the Health Minister dated 15 November 2005, which stated inter alia:

> Professor Child believes the introduction of medical abortion using mifepristone would require extensive coordination and backup arrangements, and would be appropriate only in circumstances in which there was an established relationship with an obstetric service that could deal with emergency complications outside normal clinic hours. It[s] use more broadly, for example by GP's in rural and remote areas, would substantially increase the risks to women undergoing termination…
>
> For some women seeking pregnancy termination a medical abortion may be preferable, but is unsafe in circumstances in which appropriate supervision and follow-up may not be available. It is therefore unsuitable for women in

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129 *Submission* 635, p.1 (Ms Jenny Madden).

130 *Committee Hansard* 6 February 2006, p.44 (Dr Buist).

131 *Committee Hansard* 3 February 2006, p.29 (Dr Piercy, RTLA).

> rural and remote areas who may have limited access to obstetric facilities.[132]

1.141 Opponents to the Bill concluded their argument that, as women in rural areas and those for whom privacy is an issue for religious, ethnic or other reasons are more likely to be unable or unwilling to access urgent medical care than women in urban areas, RU486 could seriously endanger the health of these women. As the Catholic Doctors Association of Victoria argued: 'There is a considerable risk to women in rural and isolated areas because of the lack of emergency surgical and medical backup that is necessary to deal with the known complications of RU486 use'.[133]

1996 Amendments to TGA Act

1.142 A number of submissions referred to the background and parliamentary debate when in 1996 Senator Brian Harradine's amendments to the TGA Act received bipartisan support. They argued that for the same reasons of public accountability, parliamentary scrutiny and monitoring these amendments should be respected and retained by the current Parliament.[134] The Catholic Archdiocese of Sydney noted that:

> [The 1996 amendments ensured] that abortifacients were subject to an additional layer of scrutiny. These amendments were supported by both the Liberal-National government and the Labor opposition, and based upon specific concerns about the safety of the drug RU486, as well as broader concerns about the ethical and societal impact of abortifacient drugs. Those who spoke in support of the amendments suggested that it is not sufficient to assess the appropriateness of such drugs only in relation to scientific criteria such as safety and efficacy because abortion is a sensitive community issue.
>
> Abortion continues to be a ‘sensitive community issue’ in 2006. New research suggests that there exists a significantly high degree of disquiet within the community over the acceptability of abortion on demand.[135]

History of the ‘restricted goods’ provisions in the 1996 Amendments

1.143 An account of the history of the 'restricted goods' provisions being placed into the Act in the 1996 Amendments was given in the submission from Women’s Forum Australia.

> The current requirement for Ministerial scrutiny can only be understood in light of events which were precipitated by the decision of an unidentified official within the TGA to authorise the importation of RU486 in 1994 for clinical trials in Australia. That action set in train a series of events culminating in the halting of a Victorian trial of the drug and four separate

132 Media release, Minister for Health and Ageing, 15 November 2005, ABB140/05.

133 *Submission* 933, p.4 (CDAV). See also *Submission* 628, pp.4-5 (Catholic Archdioceses of Sydney).

134 *Submissions* 5, p.4 (WFDRHL); 207, p.2 (QBC); 627, p.4 (RTLA).

135 *Submission* 628, p.3 (Catholic Archdiocese of Sydney).

departmental investigations into the trials ordered by the then Minister for Health and Human Services, the Hon Dr Carmen Lawrence MP.

As an abortifacient, RU486 was a prohibited import unless exempted by the Department of Human Services and Health pursuant to the Customs (Prohibited Imports) Regulations. It was understood that no such exemption would be given unless the Minister was consulted. Neither the Minister for Human Services and Health nor the Minister for Family Services, who had responsibility for the Therapeutic Goods Authority (TGA), were consulted prior to the exemption by the departmental delegate…

Senator Graham Richardson, the Health Minister at the time the exemption was granted, acknowledged that official parliamentary undertakings had been "breached" and said the Government would see whether it could rectify the situation…

Despite claims that the TGA had rigorously scrutinised and strictly evaluated the drug prior to authorising approval3 during Senate Estimates hearings on May 25, 1994, Dr Malcolm Wright, head of the Drug Evaluation Branch of the TGA, demonstrated that this was not correct.

“We do not evaluate …TGA has not carried out an assessment to the quality, safety and efficiency of this product in connection with this notification...The only brake on the system is that the trial cannot commence until we send them, in effect, a receipt saying that we have had their letter. There is no evaluation carried out and it is not built into the process…That is why the fee is $90. It is just the clerical fee for doing it, fixing it, keeping the record.”

The TGA hadn’t rigorously scrutinised anything. It had merely sent out a receipt. There was no independent control or scrutiny of drug trials on human subjects…

When asked for information about the trials and the approval process, the researchers involved in the trials complained to the National Health and Medical Research Council (NHMRC) that parliament's demands for trial details and consent forms were a threat to academic freedom. Health Minister Dr Carmen Lawrence responded, saying private ethics committees had "a very, very substantial responsibility , and we have to get past the time … where it's left to medical experts”. “It is incumbent upon us all to ensure that women are fully informed about drugs [they volunteer to trial]."

There had been no independent assessment of legality and questions were raised about whether the trials were actually within the law.

The Melbourne trial was halted after questions were raised about the adequacy of the consent form given to women… The forms failed to mention cardiovascular risks and the fact that if the chemical abortion failed, there was the possibility of birth defects and a surgical termination was required…

Trials were suspended August 16, 1994.

This was the background against which the amendment to the TGA Act was introduced and passed, requiring ministerial scrutiny over any application for the importation of RU486 or any other prostaglandin antagonist. Then ALP Senator Belinda Neal, said:

> “We acknowledge that this issue raises large concerns within the community. It raises issues beyond purely health issues. These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability.”
>
> Then Greens Senator Christabel Chamarette said:
>
> “We deserve to have parliamentary scrutiny of decisions. We deserve to have a voice on issues and not simply leave them to boards of experts.”[136]

Availability of RU486 and increased abortion numbers

1.144 Many submissions commented critically upon the very high number of abortions that are known to be performed in Australia each year. Arguments were made in submissions and correspondence that the availability of RU486 and 'easier' medical abortions would result in an increase in the number of abortions performed:

> Pre-Abortion counselling is often provided by representatives of abortion providers who minimize the research evidence about long-term physical and psychological effects on women, and relationship effects with their partners and subsequent live children. As mainstream Australian society has yet to acknowledge and address this research, the consequences of providing an additional abortion method which is marketed as making abortion easier may increase further the rate of abortions and subsequent individual and societal damage.[137]
>
> At present, there is no substantial evidence that the availability of abortifacients increases, or decreases, a nation's overall abortion rates. However, it is hard to see how access to medical abortion will do anything to address public concern about the high incidence of abortion in Australia. Prima facie, the more methods of abortion and the greater the access, the more 'mainstream' abortion may seem and the more likely the abortion rate is to increase. Social arguments in favour of abortifacient use in Australia, on grounds that women should have a 'choice of abortion methods' would seem to support the current culture of high abortion rates.[138]

Addressing issues associated with unwanted pregnancies

1.145 Submissions argued that the availability of RU486 would not address the many social and personal issues that are at the root of Australia's abortion problem. It would merely offer young healthy Australian women a less-safe abortive solution to the profound social, moral, economic and financial problems that women face when choosing how to deal with unplanned, unwanted or difficult pregnancies.

1.146 There is a need to focus on offering counselling and support for women with unwanted pregnancies. The Southern Cross Bioethics Institute noted the Government's recent plan to provide Medicare funding for pregnancy counselling and establish an

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136 *Submission* 920, pp.4-6 (WFA).

137 *Submission* 623, p.1 (Drs Stephen and Dianne Grocott).

138 *Submission* 628, pp.3-4 (Catholic Archdiocese of Sydney).

independent national pregnancy counselling hotline and referred to its research showing that the Australian public is nearly unanimous in its support for the provision of counselling to pregnant women and for ways of reducing the overall abortion rate.[139]

1.147 The SCBI also referred to the recent 'Christchurch study' which found that abortion increases the likelihood of young women developing mental health problems and concluded that this research 'implicitly supports the need for independent counselling for pregnant women. It also provides impetus for reducing the abortion rate and strengthening alternatives, rather than providing more ways of having an abortion.'[140]

1.148 Drs Elvis Seman and David van Gend were hopeful that the debate on RU486 would have one very positive outcome:

> The RU486 debate has allowed us to “take stock” of where we are with abortion in Australia. The only people who dislike terminations more than the doctors doing them are the 90,000 Australian women who each year feel they have no other alternative. After this inquiry, and irrespective of the outcome, we need to focus our attention on the pressures causing Australian women to seek abortion & start providing viable alternatives. Selena Ewing’s 2005 evidence-based review of termination of pregnancy proposes a research agenda worthy of our attention.[141]
>
> The debate on RU486 provides an opportunity for the profession to reaffirm the ethical distinction between medically essential termination of pregnancy and abortion for non-medical reasons. RU486, if considered safe, should be authorised for the former, while for the latter the [medical] profession must join with Government in the urgent policy task of reconstructing social supports for women distressed by unplanned pregnancy.[142]

1.149 Broader social supports were discussed in a number of submissions, for example:

> Australian women, men and children deserve more choices other than abortion. Effort should be invested in education, couple counselling and support of pregnant women. When families or communities in which an unplanned pregnancy occurs can support the mother so that she can support her child, they allow that child an opportunity to be born and raised to attain his or her potential and contribute to the wellbeing of Australian society, rather than instead becoming yet another abortion statistic.[143]

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139 *Submission* 1012, p.2 (SCBI). See also *Submissions* 628, p.4 (Catholic Archdiocese of Sydney); 722, p.9 (Dr Lennon); 933, p.6 (CDAV).

140 *Submission* 1012, p.3 (SCBI).

141 *Submission* 725, p.2 (Dr Seman).

142 *Submission* 5, p.7 (WFDRHL).

143 *Submission* 623, p.2 (Drs Stephen and Dianne Grocott).

CLOSING COMMENT

1.150 As noted earlier, the Committee is not making any recommendations relating specifically to the Bill. However, it notes that a number of groups and individuals both supporting and opposing the Bill expressed concern over the number of abortions in Australia and the critical need to address wider personal and social problems. They urged the implementation or enhancement of a range of programs and services aimed at reducing unwanted pregnancies and supporting women through pregnancy.

Recommendation 1

1.151 The Committee recommends that increased financial support be provided to improve sex education, including better education on responsible human relationships; wider availability of information about and access to contraception and other fertility control techniques; ensure independent professional counselling for women considering a termination of pregnancy, counselling post termination and counselling for relinquishing mothers as required; greater social support for women who choose to continue with their pregnancy; and increasing the availability and affordability of child care.

Senator Gary Humphries
Chairman

February 2006

Additional comments on the Inquiry into the Therapeutic Goods Amendment (repeal of Ministerial responsibility for approval of RU486) Bill 2005

Senator Judith Adams
LIB, Western Australia

Senator Lyn Allison
AD, Victoria

Senator Jan McLucas
ALP, Queensland

Senator Claire Moore
ALP, Queensland

Senator Fiona Nash
NAT, New South Wales

Senator Kerry Nettle
AG, New South Wales

Senator Ruth Webber
ALP, Western Australia

"If the Parliament wishes to stop terminations from happening then it should legislate to stop them. If it is not prepared to do that, it should not limit the options that women may have when they make the terrible decision to have the pregnancy terminated."

Ian Pettigrew.
Associate Professor of Rural Obstetrics and Gynaecology,
Monash School of Rural Health,
MILDURA. (204)

It is our view that issues concerning the legality, morality and desirability of abortion in Australia are outside the terms of reference of this inquiry, being the responsibility of the various state and territory governments to decide. Of the remaining submissions received into the inquiry – those which address the terms of reference – opposition to the removal of Ministerial veto can be summed up by five main arguments:

- That the drug does not have "therapeutic value"; hence it does not come under the jurisdiction of the TGA (eg. 93, 420, 635);
- That the drug is unsafe, and that conflicting reports on the safety of the drug suggest that it is better to keep the drug out of the country until further research is done (eg. 74, 210, 1014);
- That the use of RU486 in the termination of a pregnancy is more traumatic for the woman than surgical abortion (eg. 11, 975, 1083);
- That allowing the drug to be made available will lead to an increase in the abortion rate (eg. 950, 975, 1012); and
- That the Health Minister should be responsible for making the decision because it encompasses more than just the safety of the drug (eg. 412, 628, 720).

That the drug does not have "therapeutic value", as pregnancy is not a disease; hence it does not come under the jurisdiction of the TGA

Ms Jill Michelson of Marie Stopes International writes (918):

"The Therapeutic Goods Administration (TGA) has to date overseen the evaluation and approval of over 50,000 therapeutic goods and therapies in Australia, making it the most experienced and qualified entity in the country.

The TGA is well resourced and positioned to make an evidence-based assessment based on clinical and professional criteria as to the efficacy of, as well as any risks pertaining to, the use of RU486.

As a member of the World Health Organisation (WHO) Collaborating Centre the TGA has access to counterpart bodies throughout the world, including in countries where RU486 has been approved and is currently in use, ensuring that the TGA has access to the most up-to-date information when making an assessment in relation to RU486.

Australia is well served by the TGA and the integrity and competence of their world's best practice standards."

The TGA assesses and monitors therapeutic goods that are available in Australia, to ensure that they are of an acceptable standard. Its purpose is to ensure that the Australian community has access to therapeutic

advances. It is a highly respected body, and as a member of the World Health Organisation (WHO) Collaborating Centre, the TGA has access to counterpart bodies in countries where RU486 has been assessed and approved for use.

The role of the TGA is to monitor the safety, quality and efficacy of medicines coming into Australia; its function does not rely on everyday usage of the word "therapeutic". Rather, the role of the TGA is defined by the Therapeutic Goods Act. From the TGA's own website:

> A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989).
>
> Therapeutic use means use in or in connection with:
>
> - preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
> - **influencing inhibiting or modifying a physiological process;**
> - testing the susceptibility of persons to a disease or ailment;
> - **influencing, controlling or preventing conception;**
> - testing for pregnancy; or
> - replacement or modification of parts of the anatomy.

The TGA is responsible for assessing the safety, quality and efficacy, and this role is not limited only to medically essential treatments. The TGA has a role in approving such goods as breast implants and some cosmetics, neither of which is used to prevent or treat disease.

Furthermore, it is clear that the decision to terminate a pregnancy is often taken for medical reasons. In the interests of these women, it is important that they should not be denied alternative methods of doing so, should they be deemed safe.

That the drug is unsafe, and that conflicting reports on the safety of the drug suggest that it is better to keep the drug out of the country until further research is done

The evidence that has been presented has demonstrated that, while no medical procedure is without risk, the risks of this particular drug are minimal. However, we assert that it should be the qualified professionals at the TGA that make the final assessment.

More importantly, that the evidence that has been provided by both sides of the argument is coming from the same sources, suggests to us that

this is in fact a question of interpreting the data and assessing the risks – a job we are confident in leaving to health professionals at the TGA.

It is important to acknowledge that the Australian Medical Association (AMA) (1003), The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) (401, 401a, 401b, 401c, 401d) and Rural Doctors Association of Australia (RDAA) (911) all endorse the use of RU486 for medical termination of pregnancy.

Further questions about the circumstances under which RU486 may be administered should also be determined by the relevant professionals. In recommending that the Health Minister's veto power be removed we do not assert that there should be any less regulation of this drug than with any other.

Therefore, we support the move to remove the Health Minister's veto power, so that the safety of the drug, and recommendations for its correct use, can be determined by those most qualified to do so. In doing so, we do not make any claims as to the safety or otherwise of this drug. Rather, we recognise that this is a technical question that should remain outside the realm of politics.

That the use of RU486 in the termination of a pregnancy is more traumatic for the woman than surgical abortion

Some submissions have argued that this method of termination is more traumatic for the woman, while others have argued that this is a preferable option.

From the research we have been presented with, it seems that the choice between surgical and medical abortion is a matter of personal preference and control. Despite the varying results of research into the effects of abortion on the woman, there seems to be a universal recognition of the fact that abortion is always more traumatic when it is not freely chosen and fully informed.

For this reason alone, it is clear that, should the TGA declare the drug safe, providing women with another option for her to consider will be a positive move.

Furthermore, it has been argued that for women who cannot get access to surgical abortion, and those for whom privacy and control are primary considerations, being forced to make costly and conspicuous visits to abortion clinics, often being accosted by protestors, is in itself a highly traumatic experience (204, 606, 901, 911).

That allowing the drug to be made available will lead to an increase in the abortion rate

This claim has been made in a number of the submissions to the inquiry, however no supporting evidence has been provided to show that this has been the case in any of the many countries where RU486 has been made available. Evidence was presented that suggested that the introduction of RU486 in countries such as the UK, US, Germany and Sweden, the overall abortion rates remained stable or actually declined (402, 917, 1003).

The evidence also indicates an increase in the number of early terminations, as medical abortions can be performed earlier in the pregnancy than surgical abortions can. Some countries have recorded a steady rise in the numbers of medical abortions, however this has coincided with a decrease in the number of surgical abortions being performed, suggesting that for many women this is the preferred option.

There is no evidence, however, to suggest that allowing RU486 into Australia will in any way conflict with the important policy goal of reducing the total number of terminations.

Further to this, it remains our view that if the concern is for women's physical and mental health, then making it more difficult to obtain appropriate medical care is not an acceptable response.

That the Health Minister should be responsible for making the decision because it encompasses more than just the safety of the drug

Questions of the legality and availability of abortion fall to the state and territory governments. Allowing the Federal Government to exert control over the availability of RU486 for reasons other than safety gives is allowing it to override the laws of the majority of states and territories, which have ruled that abortion be allowed under certain circumstances (705, 1005).

It has been argued that the Federal Government should not be required to "rubber stamp" the decisions made by state and territory governments (729). However this is not the question that we are being asked to address. Although the current Health Minister has made it clear that he will not allow abortifacients into the country, the Ministerial veto will continue to apply to all subsequent Health Ministers.

There are many medications the uses of which have social and ethical implications, for example Viagra, birth control pills and medications involved in IVF. However, the need for ministerial approval is limited to abortifacients, and it is our view that this additional level of scrutiny

provides the Health Minister with a level of power that should be outside of his or her role.

Conclusion

To summarise, while there have been plenty of reasons offered as to why RU486 should not be made available in Australia, we remain unconvinced that the Health Minister should have the unique power to make that decision. In order to determine the safety of the drug, it is clear that the health of Australian women depends on appropriately qualified professionals making such decisions based on an ongoing, careful assessment of the evidence-based research, and therefore we recommend the Bill be passed to allow this to take place.

Senator Judith Adams
LIB, Western Australia

Senator Lyn Allison
AD, Victoria

Senator Jan McLucas
ALP, Queensland

Senator Claire Moore
ALP, Queensland

Senator Fiona Nash
NAT, New South Wales

Senator Kerry Nettle
AG, New South Wales

Senator Ruth Webber
ALP, Western Australia

Additional comments

Senator Gary Humphries

Senator Guy Barnett

Senator Steve Fielding

Senator Helen Polley

Senator Barnaby Joyce

1. The nature of the Chair's Report is to provide a description of "the approval processes in question and the pharmacological properties of RU486" along with "an outline of the issues and arguments raised in evidence by those groups and individuals supporting the Bill and those opposing the Bill."

2. These additional comments go further. As full or participating members of the Committee who have considered all the evidence in the 4788 submissions and correspondence received and given at the public hearings we would like to state our conclusions.

3. The central claim of the supporters of the Bill is that RU486 is simply another drug, not essentially different from any other drug, and that therefore there is no justification for the 'restricted goods' provisions in the existing legislation.

4. After considering all the evidence we conclude that this central claim is without foundation because it ignores the fundamental fact that RU486 is a drug intended to cause abortion.

5. It is used as the first drug in a two drug regimen administered during the first 9 weeks of pregnancy for the purpose of ending the life of the developing child and bringing about its expulsion from the mother's body. RU486 has also been used in abortions up to 20 weeks gestation. Even if the TGA approved it solely for abortions up to 9 weeks once it was registered there would be nothing to prevent its off-label use for mid-trimester abortions.

6. This use does not correspond to any of the meanings of "therapeutic use" given in Section 3 of the Therapeutic Goods Act 1989.

7. Opinions in the community on abortion are divided and conflicted. Recent opinion polls indicate that Australians think there are too many abortions and that they disapprove of abortion for financial and social reasons.

8. Supporters of the Bill argued that, given that the States and Territories are responsible for the legal status of abortion in their jurisdictions, the Federal

Parliament has no right to retain legislation that can be construed as limiting the methods of abortion available in Australia. We strongly reject this argument. The Federal Parliament has constitutional responsibility for imports and other matters reflected in the very existence of the Therapeutic Goods Act 1989. In voting on the provisions dealing with abortifacients as "restricted goods" Senators and Members are necessarily voting on the question of abortion. To vote to treat that class of drugs intended for use in abortion as simply equivalent to genuinely therapeutic drugs would be to state that these drugs do not raise any particular ethical or social issues connected with abortion itself.

9. The Therapeutic Goods Administration is empowered by the Act to consider the safety, quality and efficacy of a drug. It has no power or competence to consider the broader social and ethical impact that may follow if a drug is registered for import and use in Australia. Under the existing 'restricted goods' provisions the Minister can consider the social and ethical impact of an abortifacient drug. If this Bill is passed, and these provisions are removed, then the social and ethical implications of introducing RU486 to Australia cannot be taken into consideration. We hold that allowing the abortion drug RU486 into Australia is a major social policy change that therefore should only be able to be made by a Minister accountable to the Parliament and the people.

10. We believe that there is strong evidence of serious risk to women associated with the use of RU486 in abortions, evidence which could properly be assessed by the TGA in considering the safety and efficacy of the drug.

11. Given the requirements of close consultation with the administration of RU486 and the difficulties in many regional areas with an appropriate level of access to medical facilities and supervision we have grave concerns for the health and lives of women in regional areas and specific disadvantaged groups who would use the drug.

12. Supporters of the Bill were of one voice in claiming the safety of RU486. Many claimed that a medical abortion was as safe or safer than a surgical abortion. Several claimed that RU486 had a higher adverse event rate than the over the counter allergy drug Claratyne ® . These comparisons are demonstrably false. Medical abortion carries with it a ten fold higher mortality rate than surgical abortion. RU486 is certainly far more dangerous than Claratyne ® .

13. Many supporters of the Bill were also distressingly cavalier in their attitude to the eleven deaths of women officially acknowledged to have occurred in association with RU486 abortions. One witness stated that the difference between 10 women out of 100,000 dying from an RU486 abortion compared to 1 woman per 100,000 dying from surgical abortion at the same gestational stage was like the difference between 10 grains of sand and one grain of sand – imperceptible to the human eye. As Senators entrusted with making laws for the peace, order and good government of this Commonwealth of Australia we utterly reject this cavalier approach to the lives of Australia women. We cannot

support any diminution of the checks currently in place before a drug which may take the lives of healthy young Australian women is allowed into this country.

14. There have been a total of 11 known deaths associated with RU486 abortions. Three British women have died, five women have died in the United States, one in Canada, one in Sweden and one in France. In August 2001 a 26 year old, previously healthy woman was admitted to Sherbrooke University Hospital in Quebec, Canada with abdominal pain, vomiting and foul-smelling vaginal discharge. Seven days earlier she had had abortion medically induced by RU-486 and misoprostol. Despite treatment in the intensive care unit the woman died within 3 days of admission. Her uterus was found to be infected with a bacteria *Clostridium sordellii* and she was found to have died of toxic shock. As a result of this tragic death the trial of RU486 in which the woman had participated was halted and RU496 has never been approved in Canada.

15. Four American women, all otherwise healthy before submitting to an RU486/misoprostol abortion, have also died from toxic shock syndrome caused by *Clostridium sordellii* infection. These women were Holly Patterson (18), who died September 17, 2003; Hoa Thuy Tran (21), who died 29 December 2003; Chanelle Bryant (22), who died 14 January 2004 and Oriane Shevin (34), mother of two, who died 14 June 2005. According to Professor Ralph Miech, MD, Ph.D., the abortion drug **triggers a bacterial infection in a woman's cervical canal that doesn't normally occur**. **The bacteria thrive on the decaying tissue from the dying unborn child and impairs the woman's ability to fight off the infection.** Officials from the Food and Drug Administration and the Centers for Disease Control and Prevention have decided to convene a scientific meeting early 2006 to discuss this medical mystery, according to two drug agency officials who spoke on the condition of anonymity because of the sensitivity of the topic.

16. The death of 16 year old Swedish girl Rebecca Tell Berg on 3 June 2003 after an RU486 abortion resulted from blood loss six days after taking misoprostol to complete the abortion process. She was found by her boyfriend having bled to death in her shower.

17. An analysis of adverse events following RU486 abortions demonstrates that for every woman who dies in association with an RU486 abortion there are seventy women who suffer life-threatening complications, including severe haemorrhage, sepsis and ruptured ectopic pregnancy. Sixty eight American women have required blood transfusions after RU486 abortions with 42 of these cases classified as life threatening. Up to 8% of women who are undergo an RU486 abortion fail to abort. They may undergo a second surgical abortion further increasing the overall health risks. If the woman chooses not to have this second abortion and carries the pregnancy to term the risk of fetal malformation is 23%.

18. Governments and legislators in several other jurisdictions have taken steps to prevent or cease the use of RU486 for abortion. The Italian Government has just announced a ban on any general import of RU486 into Italy. This follows the suspension of a trial of RU486 in Turin last September after serious health concerns. The United States Congress has before it the RU486 Suspension and Review Act (also known as Holly's Law after Holly Patterson, an 18 year old woman who died after an RU486 abortion). This Act would suspend all sales of RU486 while the comptroller general investigates the Food and Drug Administration's handling of the approval process for RU486. A Congressional Subcommittee is also investigating the handling of the approval process for RU486 by the FDA, as well as its response to the five deaths and other adverse events related to RU486 abortions.RU486 remains unlicensed in Canada after the suspension of a trial following the death from toxic shock syndrome of a 26 year old woman on 1 September 2001.

19. Given these moves in other jurisdictions, the serious health risks to Australian women, and above all the necessity to consider the social and ethical implications of a drug intended to produce abortion, we conclude that the 'restricted goods' provisions for abortifacient drugs should remain in place and the Bill be rejected.

Senator Gary Humphries
LP, Australian Capital Territory

Senator Guy Barnett
LP, Tasmania

Senator Steve Fielding
FFP, Victoria

Senator Helen Polley
ALP, Tasmania

Senator Barnaby Joyce
NATS, Queensland

Family First Additional Comments

Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005

Executive Summary

During the debate in 1996 on the *Therapeutic Goods Amendment Bill 1996 (No.2),* then Labor senator Belinda Neal said:

> These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability.[1]

Then Greens senator Christabel Chamarette said:

> We deserve to have parliamentary scrutiny of decisions. We deserve to have a voice on issues and not simply leave them to boards of experts.[2]

The onus is on those who seek to repeal that Bill to show there has been sufficient change since 1996 to warrant such action. Not only have they failed to do so, but they have not even attempted to do so.

The issue before Senators back in 1996, and before us now, was made by a number of submissions and by Monique Baldwin, a regulatory associate with a pharmaceutical company and somebody who is very familiar with the role and operations of the Therapeutic Goods Administration (TGA). Writing in *The Australian* last month, Dr Baldwin said:

> In my professional experience, RU486 is not like any other drug. It is not designed to prevent, treat or diagnose an illness, defect or injury. It is not therapeutic. It is designed to cause an abortion that will end a developing human life. RU486 has serious ethical and social concerns that go far beyond scientific analysis.[3]

The TGA has told this Committee it is not competent to address these concerns. On December 15 last year the TGA said that it confines itself to technical questions of quality, safety and efficacy - it does not consider ethical issues.[4] The reason the TGA is not able to make these decisions is because it is our responsibility – the responsibility of elected leaders – not theirs.

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1 *Senate Hansard* May 9, 1996 p 624

2 *Senate Hansard,* May 21, 1996, p 821

3 Probe a prescription for social concern, The Australian, 31 January, 2006, p.12

4 Dr Graham and Ms Halton, Department of Health and Ageing, CA Hansard, 15 December 2005, pages 30-31.

In discharging this responsibility, elected leaders must consider community attitudes. For this reason the research of the Southern Cross Bioethics Institute, which is current and which was done professionally, is important. It found that 87 per cent of Australians thought the number of abortions performed in Australia was too high. While the community does not want laws changed, they do want governments to take initiatives to reduce the number.[5]

The Southern Cross Bioethics Institute is not alone in its view. On January 4, the *Sydney Morning Herald* editorialised:

> A substantial majority (sic) supports abortion on demand — but at the same time an even greater majority (sic) is uneasy with the number of procedures carried out and wants the abortion rate cut somehow.[6]

If the Senate passed this Bill, it would be doing the opposite of what the community wants. The Parliament would be sending a message that RU486 is just another drug and abortion is just another medical procedure. Elected leaders would be sending the message that they are not prepared to deal with the real issues that women face when deciding whether or not to proceed with their pregnancies.

In this context, it is worth noting an issue last year in the Victorian electorate of Murray, whose Member, Dr Sharman Stone, is a strong supporter of this Bill because of her concern for rural women. An agency which had provided practical help to pregnant women for almost 30 years, faced closure due to a lack of funds. Given the enormous help it has given to hundreds of rural women, Dr Stone did virtually nothing to help.[7]

During the committee hearings it has become clear there are other reasons why it would be wrong to give the TGA the power to approve this drug. The Committee has heard about the possible medical and psychological effects of RU486, both short term and long term.

We have been also learned that the TGA does not require medical practitioners and pharmacists to report adverse effects of a drug.[8] Consequently the TGA cannot properly monitor the effects of a drug. This is a serious issue given that RU486 has caused deaths and that we do not know what long-term psychological effects it will have.

A Minister, on the other hand, could make mandatory monitoring a condition of approval, by a body such as the Adverse Drug Reactions Assessment Committee

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5 Submission 1012, Southern Cross Bioethics Institute.

6 Editorial: No excuse for wilful ignorance. *The Sydney Morning Herald*, 4 January 2006.

7 Christie Peuker, We will fight for service: senator. *Shepparton News*, 3 November 2005.

8 Submission 920, Women's Forum Australia, page 21.

(ADRAC). Even if the TGA could impose such conditions, there is no guarantee they would maintain them or that they would be accountable if they removed them.

The submission of a rural pharmacist, Jenny Madden[9], highlighted the fact that the morning-after pill is now available over the counter at pharmacists. At the time of the original application, the manufacturer said:

> It is only to be used as an emergency contraceptive and one of the reasons it is available on prescription only is so doctors can regulate how patients use it.[10]

A TGA committee removed this restriction 12 months after the original approval and were not held accountable for this backflip. Had the Minister been responsible, there would have been much greater public accountability.

Women's Forum Australia has pointed out that the TGA is funded by the industry because it is required to recover its operating costs from application fees and charges.[11] A body responsible for approving contentious drugs, such as RU486, must not only be impartial but be seen to be impartial. If perceptions of bias, as distinct from actual bias, are an issue, the perception of bias of an ongoing, unelected body is of greater concern than the perception of bias of a Minister who happens to have a particular portfolio at a particular time.

Supporters of this Bill have not made a case for change. Relying on unfounded conspiracies or untested allegations of bias is insufficient reason to change the law. RU486 is a unique drug which raises major social, ethical and policy issues. These issues must be addressed by us, as Australia's elected leaders, and not passed off to unelected expert committees.

For these reasons, Family First opposes this bill.

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9 Submission 635, Jenny Madden

10 Byden-Brown, Sarah, Morning-after pill on sale. *The Australian*, 1 July 2002.

11 Submission 920, Women's Forum Australia

Introduction

The *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005* would allow abortion-causing drugs like RU486 (Mifepristone) to be imported into Australia without the need for the Health Minister's approval.

The debate is complex and involves a wide range of issues, including:

- Principally, who should make such important policy decisions – the Health Minister as an elected community representative, or unelected bureaucrats in the Therapeutic Goods Administration;
- Whether abortion drugs like RU486 are suitable for women in rural areas, given the availability of abortion in rural areas was the initial impetus for the current debate ;
- Limitations of the Therapeutic Goods Administration in approving and monitoring abortion drugs; and,
- Concerns about the safety of the drug and the risks it would pose to women's health.

The explanatory memorandum says that the bill only deals with RU486, but in fact it would affect a whole range of abortion drugs including "Alprostadil, Carboprost, Dinoprost, Dinoprostone, Gemeprost and Misoprostol … [and] vaccines against human chorionic gonadotrophin."[12]

Another submission noted that passing the bill "… would mean there would also be no ministerial scrutiny over anti-fertility vaccines."[13]

Conduct of the inquiry

The Committee was only allowed time to hold hearings in Canberra, Melbourne and Sydney, which made it difficult to consult with people in rural areas. This was particularly disappointing given the initial impetus for the current debate over RU486 was to increase abortion access for women in rural areas. The policy of the Committee to select witnesses closer to these three cities, even if people who made submissions lived in the same state, meant that some rural people missed out on appearing as witnesses.

12 Ms Mongan, Australian Federation of Right to Life Associations, CA Hansard, 3 February 2006, page 23.

13 Submission 920, Women's Forum Australia, page 16.

The Committee was only given one day after the last hearing day to finalise the report on this important issue. Hansard for the Sydney hearing was not to be made available until late on the same afternoon the report had to be finalised. This meant that evidence given at the Sydney hearing was less likely to be reflected in the final report.

Senators are expected to have less than one day to consider the report once it is tabled, before they debate and vote on the bill. This is why Family First has labelled the process a farce. Despite all the hard work of the Committee and those who provided submissions and appeared as witnesses, Senators cannot be expected to properly consider the report in less than one day. They need at least a week to be able to make an informed decision on the bill.

Ministerial accountability for RU486

The current legislation was passed in 1996 with bipartisan support for making the Health Minister responsible and accountable for an issue of great community concern.

> Former ALP Senator Belinda Neal, said: “We acknowledge that this issue raises large concerns within the community. It raises issues beyond purely health issues. These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability.” (*Senate Hansard* May 9, 1996 p624)
>
> Former Greens Senator Christabel Chamarette said: "We deserve to have parliamentary scrutiny of decisions. We deserve to have a voice on issues and not simply leave them to boards of experts."(*Senate Hansard,* May 21, 1996, p821)

Research shows the community is concerned about the high number of abortions and wants it reduced.

The research, by the Southern Cross Bioethics Institute in Adelaide, found:

> While 62%-69% of Australians support abortion on demand as a general principle, 64%-73% think the abortion rate is too high (depending on whether the figure of 90,000 abortions or the ratio of 1 in 4 pregnancies aborted is used), and 87% think that it would be a good thing if it could be reduced without restricting access to legal abortion.
>
> To legislate for the removal of the current special status of RU486 as a drug requiring ministerial approval sends the message that our federal representatives are intent on consolidating and strengthening abortion practices despite the views of the community.
>
> Rather than basing a decision on the fact that surgical abortion is currently available, any decision should reflect the reality that abortion itself is of great moral concern to the Australian public. [14]

14 Submission 1012, Southern Cross Bioethics Institute, page 3.

The thousands of submissions to the committee inquiry reflect that concern.

RU486 is different to other drugs because it is an abortion drug which could see 'do-it-yourself' abortions in the home. For example, in New Zealand "… a woman might be given the drug to take at home …"[15] and the Rural Doctors Association of Australia said some women "… may well safely be able to administer at home."[16]

Even if administered in a surgery or hospital, RU486 would cause many women to abort at home.[17] One submission noted that "the process is less predictable & gives women less control, anonymity & privacy, as the abortion can occur anywhere & at any time."[18]

It is clear this social policy issue is not settled.

This is a serious social policy issue, as well as a major moral and ethical issue. That is why elected members have been given a conscience vote.

The question is: should policy decisions be made by elected leaders or unelected bureaucrats?

One witness commented that:

> … politicians are unavoidably concerned about medical issues because they are concerned about the common good. The good of our community requires that we have a good health system. If politicians wash their hands of concern of medical issues, we would not have Medicare, for instance, we would not have public hospitals, we would not have universities to train our health professionals and so on …
>
> … all of our political leaders [need] … a certain courage, a willingness to lead at the moment, because the temptation would be very strong to pass this to somebody else – to some bureaucrat or to some group such as the TGA – to worry about.[19]

The TGA admits that it confines itself to only technical questions of quality, safety and efficacy. The TGA does not consider ethical issues.[20] Questions of ethics and values in major social policy issues are for elected leaders to decide. That is their job; what the community elects, and expects, them to do. When politicians make

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15 Dr Tippett, CA Hansard, 15 December 2005, page 39.

16 Dr Page, CA Hansard, 15 December 2005, page 28.

17 See discussion with the AMA, the Rural Doctors Association and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists about how a woman aborting at home could dispose of her foetus. CA Hansard, 15 December 2005.

18 Submission 240, Dr Elvis Seman, page 2.

19 Bishop Anthony Fisher, CA Hansard, 6 February 2006, page 11, 13.

20 Dr Graham and Ms Halton, Department of Health and Ageing, CA Hansard, 15 December 2005, pages 30-31.

decisions, they must consider community attitudes and they are accountable to the people at elections. Unelected bureaucrats do not represent the community and are not accountable to the community.

The great advantage of the current system is that it is clear the Health Minister is responsible and he or she must report to Parliament if they approve importing an abortion drug into Australia. I agree with Professor Charles Franks' statement that "responsibility must be allocated to identifiable persons before they can be held accountable."[21]

Family First believes the Federal Parliament would be setting a dangerous precedent if we were to give unelected bureaucrats the power to make policy decisions.

Women in rural areas

The current debate over RU486 was initiated when Professor Caroline De Costa published an article in the *Medical Journal of Australia* calling for RU486 to be made available, saying it "… is critical for many women in rural areas and women in some ethnic groups whose access to surgical abortion is limited."[22]

Member for Murray, Dr Sharman Stone, has also lobbied for the introduction of RU486 in Australia, specifically for rural women.[23] Family First is disappointed that Dr Stone did not take a much stronger stand last year when a pregnancy support service in her electorate faced closure due to a lack of funds. Family First lobbied the Federal Government to provide funding to keep open the Goulburn Valley Pregnancy Support Service which, for almost 30 years, has been providing practical help to women to continue with their pregnancies.[24] Fortunately, on the day the centre was due to close its doors, November 18 last year, the Government announced a one-off $40,000 grant, ensuring it can remain open until June 2006. Given the organisation has made such an enormous difference to the lives of so many women in her electorate, it is disappointing Dr Stone failed to take a much stronger stand.

In response to calls to introduce RU486, the Health Minister sought advice from his Department. On the issue of whether the drug was suitable for women in rural areas, the Department advised "RU-486 or mifepristone is a method for inducing an abortion that is associated with an increased risk of adverse outcomes over conventional surgical termination, and requires similar and in some cases greater levels of backup.

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21 Franks, CES (2004), Putting accountability and responsibility back into the system of government. *Policy Options*, October. Page 64.

22 De Costa, CM (2005) Medical abortion for Australian women: it's time. *Medical Journal of Australia*, Vol 183(7), pages 378-380.

23 Submission 901, Dr Sharman Stone.

Melissa Polimeni, Chance of abortion backdown. *Herald Sun*, 14 October 2005

24 Christie Peuker, We will fight for service: senator. *Shepparton News*, 3 November 2005.

[It is]… unsuitable for women in rural and remote areas who may have limited access to obstetric facilities."[25]

Abortion supporters share these concerns. The Women's Abortion Action Campaign has said:

> Ensuring, if you are not set up to perform a suction curettage, that you have a back up system of where to refer women to, if the possibility of retained products after administration of RU486 eventuates – these are huge practical problems which are not easily overcome, particularly if one is working in a rural or remote area.[26]

A number of other submissions highlighted the difficulty of accessing health services in rural areas to reduce the risk to women of using RU486.

> I am a rural pharmacist, who works in larger rural centres such as Wagga Wagga and Albury. I also work in smaller communities, and my most recent placement was at Condobolin, a town of about 3,500 people, with one pharmacy and a small hospital. Although there are currently 4 doctors in Condobolin, there are no facilities for women to have their babies there. So they must go at least an hour away to Parkes or Forbes, where there is not always an obstetrics specialist available, or to Orange, Dubbo or Wagga Wagga, which are a minimum of 2 hours away.[27]

Dr David Gawler expressed concern that:

> the manufacturer's protocol for the "safe" use of RU486 stipulates that a woman having such an abortion must see a medical practitioner on day 1, 3 and 14. In many areas of Northern Australia, serviced by itinerant doctors, this would not be possible. In addition, continuous medical cover is often not available.[28]

Dr Elvis Seman discussed the practical problems of administering RU486 in a rural setting:

> I am from Broken Hill originally. I have practised as an obstetrician in Woomera, Lameroo and lots of country places, so I am quite familiar with the system and the patient assisted transport scheme. I know this is expensive. It is very inconvenient for those women to travel to the city, but mark my words: this is money well spent if fewer women are going to die from it. So that is where I would like to see my money spent: sticking to the safer, albeit at times less convenient, option.

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25 RU-486 (Mifepristone) – Medical Abortion. Minute to the Minister. Department of Health and Ageing, November 2005.

26 Women's Abortion Action Campaign, submission 905, page 10.

27 Submission 635, Ms Jenny Madden, page 1.

28 Submission 1, Dr David Gawler, page 1.

> Consider this as well, because of all the adverse things that can occur: women will come back haemorrhaging severely—not a lot, but they will. This is a real panicky sort of situation for doctors in the country. They have got to summon a colleague who can give the anaesthetic, then urgently deal with the haemorrhage. Worse still, there is ectopic pregnancy. It is terrifying to see a young woman come in hematonic shock from a ruptured tubular ectopic pregnancy. This is an emergency. They may or may not be able to deal with it up there. They will have to evacuate these particular women to Perth; they may die along the way. And this is an important point: with surgical termination you can confirm you have terminated a pregnancy from inside the womb at the time. You have got an early warning system of an ectopic pregnancy.
>
> This does not exist with chemical abortion, because the tissue that is passed by the woman is never analysed—but that is the nature of it—and, furthermore, the drugs induce symptoms that can mimic an ectopic pregnancy.
>
> This is why in the adverse event report 11 out of 17 of the ectopics that were reported had ruptured. So you are going to have a delay in diagnosis of ectopic pregnancy. This is uncommon, but we are talking about uncommon things, because our safety is so good at the moment we must not compromise it. To reiterate, I would rather see my money spent more expensively sending some of these isolated women to the city to have a safer procedure.[29]

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) admits that it confines itself to only technical questions of quality, safety and efficacy. It does not consider ethical criteria.[30]

The TGA, which is currently part of the Department of Health and Ageing, will become part of a new statutory authority being established on 1 July 2006 to regulate therapeutic products in Australia and New Zealand, making it even more arms length from the Government. [31]

Dr Monique Baldwin, a regulatory associate with a pharmaceutical company who is very familiar with the role and operations of the TGA, wrote last month in *The Australian*:

> … in my professional experience, RU486 is not like any other drug. It is not designed to prevent, treat or diagnose an illness, defect or injury. It is not therapeutic. It is designed to cause an abortion that will end a developing

29 Dr Seman, CA Hansard, 3 February 2006, page 51-52.

30 Dr Graham and Ms Halton, Department of Health and Ageing, CA Hansard, 15 December 2005, pages 30-31.

31 See: http://www.tga.gov.au/docs/html/recruit/empcond.htm

> human life. RU486 has serious ethical and social concerns that go far beyond scientific analysis.[32]

A number of submissions also raised concerns over the TGA being fully funded by the industry it is supposed to regulate:

> The fact that the TGA is dependent on the industry it is charged with regulating for its operating costs raises the issue of whether or not the TGA must not only be independent but be seen to be independent. The TGA risks the perception that it may exhibit a bias towards the drug industry, rather than serving the Australian community which contributes little to its budget. Given the controversial nature of RU486, Women's Forum Australia believes that the risk of this perception is a further reason why it would be inappropriate for the TGA to be responsible for approving this drug.[33]

The person or group responsible for RU486 must be independent and seen to be independent. This cannot be said of the TGA, which is in the financial clutches of the industry and depends on money from pharmaceutical companies.

There was also concern that doctors and pharmacists are not obliged to report problems with RU486 and that reporting is voluntary:

> Further, while manufacturers and distributors of registered medicines must report evidence of adverse events, medical professionals and pharmacists are not required to do so. Yet, in the case of RU486, it is the medical professionals and pharmacists who are likely to be made aware of adverse effects. Experience in the USA demonstrates that it is essential that reporting of adverse effects of RU486, a drug which has caused deaths, must be mandatory and that whoever approves the use of RU486 must able to require such reporting regardless of whom becomes aware of adverse events. Since the imposition of such a requirement is beyond the scope of the TGA, it is more appropriate that the Minister approve this drug. [34]

Availability of RU486 over the counter at pharmacies

One rural pharmacist raised a concern about dispensing RU486 as a pharmacist, linking it to a concern about dispensing the morning-after pill Postinor-2.[35]

The morning-after pill was first made available in Australia in July 2002, on prescription after consulting a GP. There was concern reported in the media at the time that the company would move to make Postinor-2 available over the counter at

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32 Probe a prescription for social concern, The Australian, 31st January, 2006, p.12

33 Submission 920, Women's Forum Australia, page 21.

See also submission 930.

34 Submission 920, Women's Forum Australia, page 21.

35 Submission 635, Jenny Madden, page 2.

pharmacies. This was denied in an article in *The Australian* on 1 July 2002, which said:

> A Schering spokesperson said it had no intention of applying to Australia's Therapeutic Goods Administration to sell Postinor-2 without a prescription. "It is only to be used as an emergency contraceptive and one of the reasons it is available on prescription only is so doctors can regulate how patients use it."[36]

Schering's Product Information documents recommended that women consult their doctor to rule out a list of conditions that may be aggravated by taking the drug and endangering their health.

However, in June 2003, not even 12 months after the pill was made available by prescription-only, the National Drugs and Poisons Schedule Committee (a committee of the TGA) announced that Postinor-2 should be made available over the counter at pharmacies.[37], without prescription. This happened from 1 January 2004.

Furthermore, despite assurances that pharmacists would follow a voluntary protocol, there have been reports of pharmacies routinely flouting the protocols, the drug being handed over by a beauty consultant and girls as young as 15 buying it.[38]

Proponents of RU486 say it will be used under medical supervision, but if it is allowed into Australia, how long will such a restriction last? Experience with Postinor-2 suggests any dispensing restrictions will not last or be ineffective.

A system of voluntary reporting of adverse drug events is inadequate. It is likely, given the experience with Postinor-2 that, if RU486 is allowed into Australia, conditions would change.

Risk to women

There has been a significant amount of information presented to the committee about the dangers of RU486 for women. While this information is not central to the issue of who should decide on this important policy issue, it is relevant given the general view that RU486 would more likely be allowed into Australia if the decision is left to the TGA.

The physical risk of using methods of chemical rather than surgical abortion is greater for women. An editorial in *The New England Journal of Medicine* from late last year "… noted that while the death rate in the USA for surgical abortion in the first 8

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36 Byden-Brown, Sarah, Morning-after pill on sale. *The Australian*, 1 July 2002.

37 National Drugs and Poisons Schedule Committee (Therapeutic Goods Administration), Record of reasons 38th Meeting 17-19 June 2003 - http://www.tga.gov.au/ndpsc/record/rr200306.htm.

38 Price, Sarah, Morning-after pill sold by a beauty consultant. *Sun-Herald*, 30 May 2004. Spagnolo, Joe, Morning after pill. *The Sunday Times* (Perth), 8 January 2006.

weeks is around 0.1 in 100,000, the death rate from infection associated with RU486 for similar early abortions is close to 1 in 100,000."[39]

Feminist academic Dr Renate Klein, who supports abortion but is strongly opposed to RU486 because of the health risks to women, notes that

> … instead of terminating a pregnancy in 10 minutes [by surgical abortion] with a minimum recovery time of only hours, especially if a local anaesthetic is used, an RU 486/PG abortion is a drawn out multi-step procedure that can last for weeks.[40]

Head of the Urogynaecology Clinic at the Flinders Medical Centre, Dr Elvis Seman, agrees that chemical abortion is much more difficult than surgical abortion

> A woman having a surgical abortion is usually in hospital for a few hours, she experiences variable cramping & vaginal loss for a few days, & usually returns to work & normal activities after 2 days. In contrast chemical abortion takes an average of 9-16 days, with 9% of women bleeding over 30 days. Thus with chemical abortion women are sicker for longer & will need more help at home, & more time off work. The process is less predictable & gives women less control, anonymity & privacy, as the abortion can occur anywhere & at any time.[41]

An RU486 abortion also involves the use of a prostaglandin drug called Misoprostol to complete the abortion. This is despite the drug not being approved for that purpose and despite the fact that the manufacturer has advised against its use for abortion.

> The use of misoprostol in gynaecology is "off label" .In other word it is not licensed by its manufacturer to be used gynaecologically, not even for dealing with miscarriages. Thus whilst the use of misoprostol in chemical abortion is legal, it is unethical, & the TGA would be asked to approve a drug for an indication for which it is unlicensed.[42]
>
> … a spokesman for Pfizer Australia, said the company did not think it should be used after RU486. 'We would not recommend use outside TGA-endorsed indication and at this stage that just involves stomach ulcers," the spokesman said.'[43]

One submission noted major problems with the use of RU486 (Mifepristone) and Misoprostol:

> An investigator for the National Research Institute for Family Planning in Beijing wrote in a 2000 issue of the *Journal of the American Medical*

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39 Submission 628, Life Office, Catholic Archdiocese of Sydney, page 5.

40 Submission 930, Dr Renate Klein, page 7.

41 Submission 240, Dr Elvis Seman, page 2.

42 Submission 240, Dr Elvis Seman, page 3.

43 Patricia Karvelas, Abortion warning by drug's producer. *The Australian*, 31 January 2006.

Women's Association: "The common complications ... are profuse bleeding and allergy ... Allergic reactions to Mifepristone and misoprostol were not uncommon, manifesting in facial edema, skin rash and itching, numbness of feet and hands, and even a serious case of allergic shock." The investigator wrote that mifepristone/misoprostol abortions are falling into disfavor among staff at larger hospitals in China: "The staffs were too busy to handle the procedure (more counseling, more visits and observation), and they also have to manage the referred cases with serious side effects and complications."[44]

The psychological risks of an RU486 abortion were discussed in a number of submissions:

A medical abortion, marketed as an easy option, would have the effect of making it harder for women to ask for help when they are in crisis about their pregnancy. It is a natural reaction when in a crisis for people to seek a perceived quick and easy option. It takes time and dialogue to work out what will be best for all parties for the long term.

…the consequences of delivering a dead foetus at home, or of pain and bleeding for … weeks would further increase psychological trauma to women and their families.[45]

Another quoted studies which reveal chemical abortions are more stressful and painful:

Two recent UK studies have compared women having surgical abortions with women having chemical abortions. The researchers found that women having chemical abortions rated the procedure as more stressful & painful, & they experienced more post-termination physical problems & disruption to their lives. Women may not expect, or are not told, that they may see the foetus, & this was associated with more intrusive events – nightmares, flashbacks & unwanted thoughts related to the procedure. [46]

Such concerns were contrasted in one of the hearings with this bland and removed comment, apparently not recognising the reality of abortion for women:

"… women are used to dealing with menstrual loss all the time. She can make a choice of what she wants to do. She needs to know that she may pass a foetus."[47]

Another quoted the head of the company that created RU486:

Even Edouard Sakiz, the former chairman of Roussel-Uclaf, the French company that developed RU486, has said: "As abortifacient procedures go,

44 Submission 920, Women's Forum Australia, page 13.

45 Submission 623, Drs Dianne and Stephen Grocott, pages 1 and 2.

46 Submission 240, Dr Elvis Seman, page 2.

47 Dr Andrew Pesce, Australian Medical Association, CA Hansard, 15 December 2005, page 9.

> RU486 is not at all easy to use ... a woman who wants to end her pregnancy has to live with her abortion for at least a week using this technique. It's an appalling psychological ordeal."[48]

Conclusion

Supporters of this Bill have not made a case for change. RU486 and other abortion drugs are part of a unique class of drugs and their distribution raises complex social, ethical and policy issues. They are different to other drugs in that they could see 'do-it-yourself' home abortions and women aborting at home. Questions of ethics and values in major social policy issues are for elected politicians to decide. Family First believes the Federal Parliament would be setting a dangerous precedent if we were to give unelected bureaucrats the power to make policy decisions.

Senator Steve Fielding

Leader of the Family First Party

Family First Senator for Victoria

48 Submission 920, Women's Forum Australia, page 15.

APPENDIX 1

Submissions and Correspondence received by the Committee

1 Gawler, Dr David M (NT)
2 Joseph, Ms Rita (ACT)
3 de Costa, Professor Caroline (QLD)
Supplementary information
Supplementary submission received 20.12.05
4 National Foundation for Australian Women (NFAW) (ACT)
5 World Federation of Doctors Who Respect Human Life Queensland Branch (QLD)
Supplementary information
Articles tabled at public hearing 15.12.05:
C De Costa: *Medical abortion for Australian women: it's time*
MF Greene: *Fatal Infections Associated with Mifepristone-Induced Abortion*
Adelson, Frommer &Weisberg: *A survey of women seeking termination of pregnancy in NSW*
6 Hickey, A/Professor Martha
7 Staley, Ms Louise (VIC)
8 Name withheld
9 Name withheld
10 Public Health Association of Australia (ACT) [related submission No. 707]
11 Endeavour Forum Inc (VIC)
12 Kulikovsky, Mr Andrew (SA)
13 Focus on the Family Australia (VIC)
14 Women's Electoral Lobby Victoria (WEL Vic) (VIC)
15 Alp, Mr Ashley (VIC)
16 O'Dwyer, Ms Anne (VIC)
17 Pettiford, Mrs C (QLD)
18 Louie, Mr David
19 Dudley, Mr Jonathan
20 Kemp, Mr Michael (WA)
21 Williams, Ms Kay
22 Downie, Mr Peter (QLD)
23 Bearham, Mr Earl & Ms Valmai (QLD)
24 Teale-Sinclair, Mr Tom (NSW)
25 Punch, Ms Gillian (ACT)
26 Wilson, Rev Peter (NSW)
27 Jones, Ms Marla & Mr Mark (WA)
28 Woolley, Ms Erin (TAS)
29 Chaffey, Mr Ian (VIC)
30 Bernard, Mr David (VIC)
31 McInerney, Br Patrick (SA)
32 Condon, Ms Simone
33 Vaiano, Mr Sam & Ms Wendy
34 Perrin, Mr David
35 Overton, Mr Nick (TAS)
36 Wulff, Mr Robert (NSW)
37 Christian Adult Social Institute (VIC)
38 Simpson, Mr Thomas John (WA)
39 Smyth, Mr John (VIC)
40 Orton, Mr David (VIC)
41 Peagam, Mr Kevin
42 Peet, Mr Geoff (NSW)
43 Buthgieg, Mrs Jane (NSW)
44 Feonandes, A (NSW)
45 Drennan, Mrs J (NSW)
46 Berecry, Mrs Yvonne (NSW)
47 Graham, Mr Eli (TAS)
48 McMaster, Ms Cathie (VIC)
49 Dolan, Mr Peter (NSW)
50 Marman, Mr Patrick
51 Gear, Mr Spencer (QLD)
52 Vermeulen, Ms Rene (WA)
53 Lisle, Ms Rebecca (NSW)
54 Wolf, Mr Darron (QLD)
55 Mackenzie, Ms Janet (VIC)
56 Mahlab, Ms Eve (VIC)
57 Lippiatt, Mr Matthew (QLD)
58 Dale, Ms Carol (QLD)
59 McGarity, Ms Barbara (NSW)
60 Strauss, A/Professor Jennifer (VIC)
61 Secomb, Mr David (QLD)
62 Creedy, Mr Terry
63 Winter, Mr Tim (VIC)
64 Hamill, Mr Tim (QLD)
65 Ninnes, Mrs Frances
66 Orth, Ms Peita (QLD)

67 Fay, Mr Richard & Ms Judy
68 Robinson, Mr Philip
69 Welch, Mr Alistair (NSW)
70 McCormack, Mr John (VIC)
71 Songailo, Mr Peter (SA)
72 Kiraly, Ms Judi
73 Prater, Mr Michael (VIC)
74 Francis, Mr Charles (VIC)
Supplementary information
Tabled at public hearing 3.2.06
National Lawyers Association Review, Winter 2003, by Charles Francis, *Personal Injury Law Suits: against abortionists and the A*.B.C. *link*
Herald Sun, 29.09.98, article titled *The price of grief*
Superior Court of the State of California for the County of Los Angeles, complaint filed 17.09.04, Bryant v Danco Laboratories
Web extracts relating to RU486
75 Miranda, Mr Melville (VIC)
76 Weymouth, Mr John (VIC)
77 Micklethwaite, Ms Beth (ACT)
78 Stocks, Mr Bernie (VIC)
79 Houston, Ms Bridget
80 Darnell, Mr John & Ms Glenys (ACT)
81 Oakroot, Mr Richard (NSW)
82 Bagguley, Ms Mariane
83 Denney, Mrs Celia
84 Welna, Mrs Barbara (NSW)
85 Hilton, Mrs Melissa (NSW)
86 Xuereb, Mrs M (NSW)
87 Spits, Ms Susanne (WA)
88 Ryan, Ms Margaret (VIC)
89 Wilson, Ms Kerry (VIC)
90 Pitt, Mr Ed & Ms Ann (QLD)
91 Crouch, Mr Peter
92 Coulson, Mr John & Ms Rowena (QLD)
93 Lynch, Dr Johanna (QLD)
94 Knight, Mr Peter & Ms Harini (VIC)
95 Bankstown Women's Health Centre (NSW)
96 Griffiths, Mrs Margaret (QLD)
97 Women's Health Loddon Mallee (VIC)
98 James, Mr Gabriel (NSW)
99 Vink, Mr J M (QLD)
100 MacLean, Mr Hillas & Ms Rhoda (ACT)
101 Phillips, Major General Peter R (ACT)
102 Collins, Mr Keith (WA)
103 O'Meara, Mr Peter (WA)
104 Oram, Mr Joe & Ms Helen (QLD)
105 Vanderwal, Ms Gerrie (TAS)
106 Dinel, Ms Yves (NSW)
107 Brennan, Mr Col (QLD)
108 Bekker, Mr Steve & Ms Jan (VIC)
109 Kuilenburg, Mrs Marianne (TAS)
110 Elliott, Mr Evan (NSW)
111 Salkin, Ms Vicki (ACT)
112 Graham, Miss Hannah Marie (TAS)
113 Tremain, Ms Audrey (NSW)
114 Townsend, Mr Anthony (VIC)
115 Davis, Mr Mike & Ms Sarah (TAS)
116 Lee, Ms Margie (VIC)
117 Nicholson, Mr Don (QLD)
118 Saillard, Ms Pauline (WA)
119 Chesson, Ms Joy (NSW)
120 Calneggia, Mr Frank (WA)
121 Elliott, Reverend Peter J (VIC)
122 Costa, Mrs Frances M (NSW)
123 Lean, Dr Murray (QLD)
124 Haggett, Mrs Rose (WA)
125 McDonald, Mrs J (NSW)
126 Bennett, Ms Catherine (NSW)
127 Nightingale, Mr Lee (QLD)
128 Rowe, Mrs Brenda (WA)
129 Micheelsen, Ms Inge (QLD)
130 Johnson, Ms Maree (VIC)
131 Simms, Mrs Doreen (QLD)
132 van der Linden, Mrs Maureen (VIC)
133 Cowell, Ms Margaret C (ACT)
134 Welch, Ms Doris R (WA)
135 MacDonagh, Mrs (WA)
136 Wenzel, Mr Des & Ms Junita (NSW)
137 King, Mr Gary (VIC)
138 Guinane, Mr Kevin (VIC)
139 Dignan, Mrs Yvonne (VIC)
140 Lawrence, Mr Steve (VIC)
141 Whately, Reverend Jenny (WA)
142 Longfield, Mrs Heather (NSW)
143 Lowe, Ms Judy A (VIC)
144 Mullins, Ms Beverley (WA)
145 Quinn, Mrs Doreen (NSW)
146 McMillan, Ms Audrey (QLD)
147 Butler, Mr M F (NSW)
148 Casanova, Mrs Helen (VIC)
149 Walker, Mrs P M (TAS)

150 Herbert, Mrs Margaret (NSW)
151 Ivatts Family (WA)
152 Hill, Mrs A P (QLD)
153 Tait, Mr B (QLD)
154 Roche, M J (NSW)
155 Brown, Mrs Robyn (NSW)
156 Padgett, Mrs Rosalie (NSW)
157 Padgett, Mr Denis (NSW)
158 King, Mrs Gillian (VIC)
159 Brydon, Mr Raymond (VIC)
160 King, Mrs Simone (NSW)
161 Charles, Mr Owen & Ms Kathleen (VIC)
162 Lawrence, Mrs Dorothy (VIC)
163 Townsend, Mr B & Ms N (TAS)
164 Buck, Mrs Kerry (NSW)
165 MacDonagh (WA)
166 Prentice, Mr Laurie & Mrs Glad (ACT)
167 Gill, Dr John A (VIC)
168 Hart, Mr George (VIC)
169 Hodgson, Ms Joy (VIC)
170 Beecroft, Mr Geoffrey (VIC)
171 Stewart, Mr Craig K (WA)
172 Fabry, Ms Janet A (WA)
173 Waite, Mr Paul (VIC)
174 Giffard, Dr P (ACT)
175 Bignold, Mrs Marie (NSW)
176 Murray, M G (NSW)
177 Grieshaber, Mr James & Ms Patricia (QLD)
178 Jones, Mrs J (WA)
179 Moynahan, Ms Maureen (VIC)
180 Moynahan, Mr Greg (VIC)
181 Coelho, Ms Celine (VIC)
182 Warrener, Mr Vincent & Ms Helen (WA)
183 Grace, Mr A A & Mrs R M (SA)
184 Thompson, Ms Eileen (NSW)
185 Fisher, Mrs Moira (TAS)
186 Venn, Mrs Kath (TAS)
187 Kobelke, Mr Stephen (WA)
188 Gallacher, Mrs S (QLD)
189 McGinnity, Mr Brian (WA)
190 Broomhead, Mr Chris (VIC)
191 Hartley, Mr Dunstan & Ms Margaret (WA)
192 Banks, Mr John (VIC)
193 Robins, Mr Keith & Ms Val (WA)
194 Trevor, Mr Pryce D (QLD)
195 Cozijnsen, J (WA)
196 Healy, Mr J P & Ms M J (WA)
197 Pleming, Ms Jill (NSW)
198 Field, Ms Felicity (VIC)
199 Anglicare South East (NSW)
200 Newton, Mrs Margaret (QLD)
201 Campbell, Ms Rochelle (VIC)
202 Rogers, A/Professor Wendy
Ankeny, Dr Rachel A
Dodds, A/Professor Susan (NSW)
203 Weber, Ms Brigitte
204 Pettigrew, A/Professor Ian (VIC)
205 Forster, Mr David (VIC)
206 Catholic Women's League of Victoria & Wagga Wagga (VIC)
207 Queensland Bioethics Centre (QLD)
208 Presbyterian Church of Victoria (VIC)
209 Hills Parents and Friends Group (SA) (SA)
210 Evangelicals for Life (NSW)
211 Larkin, Mr W B (NSW)
212 Meade, Ms Christina (VIC)
213 Cain, Ms Sharolyn
214 Breen, Mr Gavan (NT)
215 Donker, Mr Robert (VIC)
216 Meade, Dr Brian & Mrs Elizabeth (VIC)
217 Blandford, Ms Anita (TAS)
218 Doyle, Ms Phyllis & Mr John (NSW)
219 Wood, Ms Marie (VIC)
220 Moore, Mr Neville (VIC)
221 Moore, Mrs Elizabeth (VIC)
222 Nibbs, Mrs Marie (TAS)
223 Alejandrino, Mr Michael & Ms Rachel (VIC)
224 Harding-Davis, Ms Annette & Mr Paul (NSW)
225 Cannard, Mrs Patricia (QLD)
226 Haber, Ms Deborah (VIC)
227 Owens, Ms Julie Anne (NSW)
228 Prinzen-Wood, Mr Robert & Ms Sabina (QLD)
229 Kirk, Mr Jon & Ms Susan (QLD)
230 Morrissy, Mr Jim (VIC)
231 Nyhuis, Mr Rob (VIC)
232 Manuell, Mr Guy (VIC)
233 O'Brien, Mr Ben (VIC)
234 McDonald, Mrs Jenny
235 Harrold, Mr Scott & Ms Anne
236 Manganaro, Ms Carmelo
237 Simard, Mr Joseph (QLD)
238 Lamb, Mr Andrew (QLD)

239 Holman, Mr Graham (VIC)

240 Seman, Dr Elvis (SA) [related submission No.725]
Supplementary information
Additional information provided following public hearing 3.2.06 received 6.2.05

241 Groves, Mr Paul (QLD)

242 Hurney, Mr John (NSW)

243 Entwistle, Mr Harry (WA)

244 Harrold, Mrs Helena (QLD)

245 Nicholls, Ms Melanie

246 Wise, Fr Andrew (VIC)

247 Zeakis, Mr Lee (WA)

248 Green, Mr Troy (NSW)

249 Grierson, Ms Noela (QLD)

250 Holmes, Ms Susan (NSW)

251 O'Connell, Mr Toby (NSW)

252 Maliphant, Ms Jenny (NSW)

253 Phillips, Ms Linda (QLD)

254 McDonald, Mr Ewan & Ms Rebecca (VIC)

255 Nicholls, Ms Meredith

256 Stanfield, Mr David (QLD)

257 McManus, Ms Louise (NSW)

258 Nelson, Ms Margaret (VIC)

259 Vella, Mr Steven (NSW)

260 Day, Mr John & Ms Joy (VIC)

261 Wright, Mr Peter & Ms Mary (TAS)

262 Dingwall, Ms Marion (QLD)

263 Heenan, Mrs Mary (VIC)

264 Woollam, Mr Brendan & Ms Melanie (NSW)

265 Twinn, Rev Christopher C (QLD)

266 Madden, Mr Gerard (NSW)

267 Turnbull, Mr Robert & Ms Daisy (NSW)

268 Dwyer, Ms Wendy (QLD)

269 Close, Ms Johanna (QLD)

270 Australian Family Association (TAS)

271 Waugh, Mr Geoff (QLD)

272 Sylvester, Ms Rechaelle (NSW)

273 Thompson, Ms Judith (NSW)

274 Tang, Mr Yong & Ms Fui

275 Donaldson, Mr Ken (WA)

276 Snell, Ms Clare (VIC)

277 Ward, Mr James (VIC)

278 Rau-Wig, Ms Melinda (VIC)

279 McInnes, Mr Peter (NSW)

280 Scheele, Mr Frank (QLD)

281 Verkerk, Ms Michelle

282 Foo, Ms Kelinda

283 Carolan, Ms Mary (NSW)

284 Dowse, Ms Catherine (NSW)

285 Robinson, Mr Phillip (VIC)

286 de Vos, A & A (WA)

287 Parker, Mr John (QLD)

288 Donnelly, Mr Rachel (VIC)

289 Bull, Ms Marie & Mr Peter (ACT)

290 Kornaczewski, Alex

291 Allison, Mrs Ruth

292 Lentsment, Mr Wayne (VIC)

293 Steckfuss, Ms Teresa

294 Kyabram Evangelical Uniting Church Council of Elders (VIC)

295 Knell, Mr Nevil & Mrs Gloria (VIC)

296 Clark, Ms Michelle (QLD)

297 Long, Mr Michael

298 Clarke, Ms Val

299 Wotherspoon, Mr Danny (NSW)

300 Swire, Mr William & Ms Teresa

301 Kaufmann, Ms Jill

302 Rodgers, Ms Sarah (VIC)

303 Kline, Mr Colin (VIC)

304 Meads, Ms Lin

305 Berg, Sumner

306 Murphy, Ms Liz (VIC)

307 Hoy, Ms Carolyn (NSW)

308 Atheist Foundation of Australia Inc (SA)

309 Poole, Ms Jennifer

310 Rodgers, Ms Ruth (ACT)

311 Martini, Ms Tamsin

312 Burgess, A & F

313 O'Brien, Fr Joachim (VIC)

314 Cobcroft, Mr Greg

315 Murphy, Ms Jo-Ann

316 Macdonald, Ms Wendy (VIC)

317 Leahy, J & T & Family (QLD)

318 Sullivan, Ms Marie & Mr Kevin (NSW)

319 Saunders, Ms Sue (TAS)

320 Nahm, Ms Mia (NSW)

321 Matthews, Ms Margaret

322 Groves, Mr Paul (QLD)

323 Coret, Mrs Margaret (TAS)

324 Stubbs, Mrs Margaret (QLD)

325 Prior, Mr Alan (NSW)

326 Hunter, Mr Neville (VIC)

327 Wilson, Ms Margaret
328 Wolf, Ms Liz
329 Lee, Mr Douglas George (QLD)
330 Panting, Ms Jan & Mr Bryan
331 Osten, Mrs Vicki (QLD)
332 Berry, Ms Lesley
333 Kelly, Mr James (QLD)
334 Leong, Khuan Harn (NSW)
335 Muller, Ms Susan (QLD)
336 Cornish, Mrs Pamela
337 Bowman, Mr Victor (QLD)
338 Shaw, Mr Ron & Ms Jenny (QLD)
339 Mann, Ms Alison (NSW)
340 Stille, Mr John (QLD)
341 Honner, Ms Genevieve (SA)
342 Wotherspoon, Ms Annette (NSW)
343 Gonzalez, Ms Gillian (WA)
344 Geluk, Mr M P
345 Turner, Mr Adrian (QLD)
346 Heggers, Mr Bill
347 Knudson, Mr Dexter and family
348 Hales, Ms Norma (VIC)
349 O'Connell, Mr Leo (QLD)
350 O'Connell, Ms Carol (QLD)
351 Slucki, Mr Stefan (SA)
352 Rankins, Ms Ronda
353 Cappello, Mr Anthony (VIC)
354 Michel, Mr Gerard (SA)
355 Weekes, Ms Jenni
356 Kerrutt, Ms Brigitte (VIC)
357 Hilbig, Mr Max (SA)
358 Wilkie, Ms Judy & Mr Rob (VIC)
359 Rasmussen, Mr Ivan (QLD)
360 Suter, Mr Ron (VIC)
361 Lasker, Mr Danny (VIC)
362 Marstaeller, Mrs Esma (NSW)
363 Miller, Mr Stewart (WA)
364 Griffioen, Mr Gerrit & Ms Ineke (WA)
365 Smith, Ms Jeannette
366 Amery, Mr Geoff (VIC)
367 Turner, Mr Adrian (QLD)
368 Heesh, Dr John (NSW)
369 Ryan, Mr Taylor
370 Bourne, Ms Norma
371 Myree, Ms Dawn (NSW)
372 Parker, Mr James & Ms Catherine
373 Rees, Ms Desiree
374 Chira, Florin (VIC)
375 Bell, Ms Christine
376 Symons, Ms Julia (NSW)
377 White, V P
378 Hinton, Ms Elizabeth (NSW)
379 Bennett, Mr Bruce
380 Auchterlonie, Mr Don (VIC)
381 Esdaile, Mr David (NSW)
382 Bennett, Mrs Catherine
383 Etherton, Ms Trish (QLD)
384 Drum, Ms Nola
385 Grounds, Mr Geoffrey (QLD)
386 Chigwidden, Mrs Barbara (NSW)
387 Coleman, Mr Paul (ACT)
388 Collins, Ms Petina (QLD)
389 Kennedy, Mr Chris
390 Ross, Fra Christopher (WA)
391 McDonald, Mrs Jenny
392 Nivet, Ms Marianne (VIC)
393 Coleman, Mr Harry (QLD)
394 Canning, Ms Aileen & Mr Leo (VIC)
395 Tremain, Ms Audrey (NSW)
396 Juffs, Ms Gabrielle (QLD)
397 Templeton, Chris
398 Harrold, Ms Cheryl & Mr Dennis
399 Scott, Ms Susan
400 Shiosaki, Ms Debora (WA)
401 Royal Australian and New Zealand College of Obstetricians and Gynaecologists (VIC)
402 Women's Health NSW (NSW)
403 Baird, Dr Barbara (TAS)
404 Howie, Ms Mary-Lou
405 Leichhardt Women's Community Health Centre staff (NSW)
406 Mullins, Ms Rosemary (NSW)
407 Hoskisson, Mr Ronni (NSW)
408 Worth, Ms Kate
409 Right to Life Australia, Queensland Office (QLD)
410 Council for Marriage and the Family, Catholic Archdiocese of Melbourne (VIC)
411 Catholic Women's League Australia Inc (SA)
412 Catholic Women's League Tasmania Inc (TAS) [related submission 1125]
413 Australian Family Association (NSW) (NSW)
414 Jones, Ms Mary (NSW)
415 Clezy, Dr J K A (TAS)
416 McMillan, Pastors Stuart & Ros (NT)

417 Clarke, Ms Marialouise
418 Darnell, Ms Glenys (ACT)
419 Hobart Women's Health Centre (TAS)
420 Festival of Light Australia (SA)
421 Australian Federation of Right to Life Associations
(ACT)
Supplementary information
Tabled at public hearing 3.2.06
TGA list of substances subject to import controls – permit only required
New England Journal of Medicine, Perspective, Dec 05, Imichael Greene, *Fatal Infections Associated with Mifepristone-induced Abortion.*
422 Family Life International Australia Ltd (NSW)
423 Smith, Gregory (NSW)
424 Window, Mrs Anne (QLD)
425 Wigan, Ms Liz (QLD)
426 Rauch, Mr Mark & Ms Kathy (NSW)
427 Meehan, Ms Pamela (WA)
428 Roberts, Mr David
429 Catholic Women’s League Australia, NSW Inc, Armidale Diocese (NSW)
430 Whiting, Ms Gabrielle (VIC)
431 Townend, Mr Don & Ms Gwen (TAS)
432 Spinks, Mrs Jenny (NSW)
433 Darcey, Mr Pat (NSW)
434 Setionago, Ms Marilyn (NSW)
435 Long, Mr Michael (VIC)
436 Arnold, Dr Barbara (QLD)
437 Farley, Ms Margaret (QLD)
438 Letchford, Dr Peter (WA)
439 Sullivan, Mr Damien & Mrs Jane (VIC)
440 Milliken, Mr David
441 Bokma, M
442 Wegener (SA)
443 Padjen, Ms Margaret & Mr Neno
444 Meilak, Mrs Alison
445 Miller, Mr Ian (NSW)
446 Wilson, Mr Ron (TAS)
447 Beasy, Mr Graham (VIC)
448 Duncan, Ms Cassandra (VIC)
449 Gilmour, Mr John (WA)
450 Thorsen, Mr Martin (WA)
451 Flynn, L R (NSW)
452 Marks, Mr R A (VIC)
453 Cherry, Ms Margaret (TAS)
454 Vigilante, Ms Sally
455 Stout, Ms Ginny
456 Spee, Mr John (VIC)
457 Spee, Mrs Joan (VIC)
458 McKinley, Ms Marie (VIC)
459 Haire, Mr David (NSW)
460 Brosnan, Mrs Louise (QLD)
461 Brandis, Ms Rachael (QLD)
462 Friend, Ms Rita (VIC)
463 Chant, Ms Margaret
464 Noy, Ms Dianne (VIC)
465 Bare, Mr Nick (VIC)
466 Santamaria, Dr Joseph (VIC)
467 Uulf, Mrs Grace (VIC)
468 Sweeny, Ms Shannon (VIC)
469 Southern, Mr Gordon
470 Brandt, Mrs Veronica (NSW)
471 Mitchell, Ms Melissa (NT)
472 Uulf, Mr Rufus (VIC)
473 Yates, Ms Evelyn & Mr Jim (TAS)
474 Mackin, Mr Bernie
475 Pryor, Ms Rosemary & Mr Malcolm (VIC)
476 Brosnan, Mr Paul (QLD)
477 Dendle, Mr Paul & Ms Catherine (QLD)
478 Hunter, Mr Ian & Ms Glenice (VIC)
479 Munro, Ms Jane (VIC)
480 Hosking, Ms Roma (ACT)
481 Wilson, Mr Nathan (VIC)
482 Morrissey, Mr John J (VIC)
483 Prior, Ms Judith (TAS)
484 Ryan, Dr Neil E (VIC)
485 Wagner, Mr Walter (TAS)
486 Clements, Mr Robert (ACT)
487 Teo, Adeline
488 Dowd, Fr Christopher (VIC)
489 Songailo, Mr Peter & Ms Kerri (SA)
490 Leonard, Ms Laura (VIC)
491 Grierson, Mr Ross & Ms Lorraine (QLD)
492 Kersten, Ms Andrea (WA)
493 Gillam, Mrs Gloria (TAS)
494 Glasgow, Mr Ken (NT)
495 Johnson, Ms Margaret (VIC)
496 Hamilton, Dr Tim (VIC)
497 Knox, Ms Lynne (QLD)
498 Knox, Mr Noel (QLD)
499 Meade, Mr Damian (VIC)
500 Pirie, Mr Ron & Ms Barbara (NSW)

501 Eves, W A (WA)
502 Haynes, Ms Rhonda (WA)
503 Holmes, Mr E J (TAS)
504 Lovedee, Ms Y (WA)
505 Sullivan, Ms Anneliese (NSW)
506 Graham, Ms Geogina m (NSW)
507 Heyhae, G (WA)
508 Hawley, Ms Sheryl (WA)
509 Casanova, Mr John (VIC)
510 Colley, Mr Kevin (ACT)
511 Burgstaller, Mrs Barbara (VIC)
512 McKenzie, Mrs Maureen (SA)
513 Thomas, Ms Denise (VIC)
514 Streckfuss, Mrs Doreen (VIC)
515 Vickers, Mr Allan & Ms Judith (NSW)
516 Toohey, Mr Jack (VIC)
517 Van der Plas, Mr Laurence (WA)
518 Leicester, Mr Gerald S (VIC)
519 Colreavy, Mr Maurice F & Eileen M (NSW)
520 Harman, Mr Greg & Ms Susan (WA)
521 O'Brien, Mr Peter (VIC)
522 O'Brien, Paul J (TAS)
523 Nichols, Mr Robert A (WA)
524 Cozynsen, Mr Gerard (WA)
525 Parker, Miss Jo (NSW)
526 Knox, Mrs Helena (NSW)
527 Guinane, Ms Jennifer (VIC)
528 Hedgecoe, Ms Betty (ACT)
529 Beriman, Ms Margaret (VIC)
530 Beriman, Mr Bernard (VIC)
531 Manning, Ms Jean (NSW)
532 Ferwerda, Dr Peter (VIC)
533 McCutcheon, Mrs N L (NSW)
534 Frost, Mr Andrew & Ms Liza (NSW)
535 Peters, Mr Roland & Ms Sonia (SA)
536 Allport, Mrs A (NSW)
537 Moriarty, Mr Mark & Ms Cathy (NSW)
538 McCutcheon, Mr David (NSW)
539 Graham, Ms Christine I (NSW)
540 Clifford, Mr Brendan (WA)
541 Dale, Mr M H (WA)
542 Watt, Mr Ian & Ms Deirdre (WA)
543 Donegan, Mr Peter (WA)
544 Kelly, Mr Mark & Ms Alma (QLD)
545 Probert, Mr Chris & Ms Gwen (WA)
546 National Woman's Christian Temperance Union of Australia Ltd (WA)
547 Ginnivan, Mr Bernard (NSW)
548 Kirkpatrick, Ms Juliet (NSW)
549 Hancock, Mr Bill & Ms Milly (QLD)
550 Mitchell, Mr Bruce & Ms Helen (VIC)
551 Beaty, Mrs Pam (VIC)
552 Mumane, Mrs Irene (VIC)
553 Fitzpatrick, Mr Patrick (VIC)
554 de Bruyn, Mr Leo & Ms Bernadette (VIC)
555 Vanderburgh, J L (ACT)
556 Chase, Ms Ruth (WA)
557 Bakes, Mrs Ione J (TAS)
558 Burgstaller, Mr Heinrich D (VIC)
559 McConnon, Ms Joyce (TAS)
560 King, A J (NSW)
561 Barber, Mrs Jean (TAS)
562 Rayney, Ms Yolanda (WA)
563 Palmer, Mrs Veronica (TAS)
564 Fong, Ms Lois (NT)
565 Tallon, Ms Sue (QLD)
566 Tallon, Mr Tony (QLD)
567 White, Mrs Audrey (TAS)
568 Graham, Ms Catherine A (VIC)
569 Jarvis, Mr A (NSW)
570 Pezzelato, Ms Ellen (QLD)
571 Geyer, Ms Aya (SA)
572 Grinter, Mrs Noelle (VIC)
573 Carrigan, Ms Barbara (NSW)
574 McCray, Mr Douglas B (NSW)
575 Griffin, Miss Margherita (VIC)
576 O'Donnell, Sister Marie (NSW)
577 Gibbins, Mr Rob (QLD)
578 Abbott, Mr Peter (VIC)
579 Murphy, Ms Jo-Ann (VIC)
580 Mitchell, Mr Ernie (NT)
581 Carter, Mrs Joy (TAS)
582 Barden, Mr Malcolm (NSW)
583 Curtain, Ms Carmel (VIC)
584 McCarthy, Mrs Marie (VIC)
585 Goldsmith, Mrs Leonie (VIC)
586 Pearce, Mrs Kathleen (TAS)
587 Cavanagh, Mrs Colleen (NSW)
588 Millie, Mr David (VIC)
589 Hayes, Mr John G (NSW)
590 Fuimara, Mrs Alice (NSW)

591 Coghill, Ms Karin (NSW)
592 Jackson, Mr Patrick (VIC)
593 Walker, Mr Gerard (NSW)
594 Wintle, L (VIC)
595 Groenewold, Mr John & Ms Maria (TAS)
596 Shortill, Mr Dermot (VIC)
597 Stratford, P J (QLD)
598 Speirs, Mrs Jan (NSW)
599 Storrs, Mr Phillip (QLD)
600 Caswell, Mr Evan & Ms Kerri-Ann (QLD)
601 Australian Reproductive Health Alliance (ACT)
602 Istar Ltd (NEW ZEALAND)
603 Monash University Department of Obstetrics & Gynaecology (VIC)
604 Family Planning Tasmania Ltd (TAS)
605 Family Planning Queensland (QLD)
606 Broome Regional Aboriginal Medical Service (WA)
607 Women's Electoral Lobby Vic (VIC)
608 Women's Clinic and Family General Practice on Richmond Hill (VIC)
609 Dent, Ms Melissa (VIC)
610 Dower, Dr Jo (QLD)
611 Smallwood, Ms Rosalind (VIC)
612 DeBats, Ms Rosanne (SA)
613 Pro-Life Victoria (VIC)
614 Shanahan, Mr Martin (NSW)
615 Bampton, Mr Daniel
616 Strangman, Mr Denis
617 Ross, Ms Merle (QLD)
618 Morrison, W F (NSW)
619 Breden, Rev Roger (NSW)
620 Andrew, Fr Mick W Mac (NSW)
621 Macdonald, Mr Alistair & Ms Cathryn (NT)
622 Hynard, Mrs I B (NSW)
623 Grocott, Dr Dianne & Dr Stephen (NSW)
624 Jones, Mr John (NSW)
625 Christian Democratic Party (WA Branch) (WA)
626 Survivors of Abortion Ltd (QLD)
627 Right to Life Australia (VIC)
Supplementary information
Tabled at public hearing 3.2.06
The Annals of Pharmacotherapy, Feb 2006, M. Gary & D. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*
Article by L. Leeman & E. Espey, July 04, *"You can't do that 'round here" a case study of the introduction of medical abortion care at a University Medical Center*
628 Catholic Archdiocese of Sydney (NSW)
629 Hamill, Mr Tom (QLD)
630 Carden, Mr Timothy (QLD)
631 Ely, Ms Jacqueline (NSW)
632 Hamilton, Ms Elizabeth (VIC)
633 Wood, Dr Graeme (VIC)
Supplementary information
Additional information provided following public hearing 3.2.06 received 6.2.05
634 Ransom, Ms helen (VIC)
635 Madden, Ms Jenny (NSW)
636 Salt Shakers (VIC)
637 Wilks, Mr John (NSW)
Supplementary information
Tabled at public hearing 6.2.06
Erratum to submission
Copy of letter to ADEC dated 15.9.98
638 Wyborn, Ms Helen (NSW)
639 Piercy, Dr Eloise & Dr Mathew
640 Dreger, Mr Randall (VIC)
641 O'Loughlin, Ms Carolyn (NSW)
642 McEwen, Mr John (NSW)
643 Gallagher, Ms Jill (SA)
644 Stuparich, Mr Nick & Ms Helen (ACT)
645 Bagguley, Mr Charles (VIC)
646 McLennan, Mr David (ACT)
647 Porter, Mr Neil (NSW)
648 Ashkar, Mr Eugene (VIC)
649 Chatterton, Mr Andrew & Ms Wendy (QLD)
650 Campbell, R W & P R (TAS)
651 La Bonne, Mr Eric & Ms Natalie (VIC)
652 Ridley, Pastor John & Ms Elizabeth (SA)
653 Appleby, Mr Jerome (SA)
654 Clarnette, Dr D (VIC)
655 Cumming, Mr David & Ms Joyce (TAS)
656 Coorey, Ms Norma (NSW)
657 Stevens, Mr Andrew (WA)
658 Stevens, Ms Katharine (WA)
659 Blackley, Ms Ruth (WA)

660 Blackley, Mr Philip (WA)
661 Fisher, Ms Shirley (SA)
662 Ross, Mr Alexander (QLD)
663 Schafer, Mr Carl (NSW)
664 Perez, Mr Luis (NSW)
665 Powell, Ms Mary (NSW)
666 O'Connell, Ms Cecilia & Mr Michael (NSW)
667 Wagner, Ms Amy (TAS)
668 Drake, Ms Lynne (NSW)
669 Harvey, Mr Trevor (WA)
670 Hawkins, Mr & Mrs (WA)
671 Stewart, Mr Alexander & Mrs Dora (NSW)
672 Vachon, Fr Richard (VIC)
673 Kirk, Ms Olga & Mr David (QLD)
674 Mobbs, Ms Anne (NSW)
675 Pelekani, Dr Con (SA)
676 Horsfall, Mr Simon (NSW)
677 Sutherland, Ms Mary (NSW)
678 Hancock, Mr Gary (ACT)
679 Carlyle, Ms Amanda (SA)
680 Oxley, Mr Benjamin (NSW)
681 Joakimidis, Yuri (SA)
682 Wroblewski, Mr Henry (VIC)
683 Rendell, Mr Matthew
684 Boast, Ms Veronica (SA)
685 Curtis, Mrs Leanne (QLD)
686 Duffield, Mr Richard & Ms Betty (VIC)
687 Sebastianelli, Ms Josephine (QLD)
688 Charlesworth, Ms Natarsha (TAS)
689 Horsfall, Ms Kathleen (NSW)
690 Dinham, Mr Andrew (SA)
691 Ross, Mr Malcolm & Ms Ingrid (ACT)
692 Sylvester, Ms Carmen (SA)
693 Shirley, Mrs Alison
694 Polak, Dr Max (VIC)
695 Schroeder, Mrs Lorraine (WA)
696 Schylder, Kris (QLD)
697 Leonard, Ms Alison (VIC)
698 Magree, Mr Brian (VIC)
699 Hope, Ms alison (VIC)
700 Mardon, Chris (SA)
701 Cockburn, Dr Sally
702 ACT Ministerial Advisory Council on Women (ACT)
703 People for Choice Tasmania (TAS)
704 Reproductive Choice Australia (VIC)
705 Curry, Dr Steven (VIC)
706 International Federation of Professional Abortion and Contraception Associates (FIAPAC) (AUSTRIA)
707 Public Health Association of Australia (ACT) [related submission No. 10]
708 Royal Women's Hospital & Family Planning Victoria (VIC)
709 McCullagh, Dr Peter (NSW)
710 Women's Department Monash Student Association (VIC)
711 Association for the Legal Right to Abortion (WA) Inc (WA)
712 Name withheld
713 Gippsland Womens Health Service (VIC)
714 Dent, Ms Charlotte (VIC)
715 NSW FPA Health Foundation (NSW)
716 Ramsay, Ms Maggie (NSW)
717 Catholic Women's League Australia Inc, National Bioethics Working Party (NSW)
718 Catholic Women's League Weston Creek Branch (ACT)
719 Catholic Women's League SA Inc (SA)
720 Respect Life Office Catholic Archdiocese of Melbourne (VIC)
721 Guild of Saint Luke Queensland (QLD)
722 Lennon, Dr Catherine (NSW)
723 Obeid, Dr John (NSW)
724 Little, Dr Deirdre (NSW)
725 Seman, Dr Elvis (SA) [related submission No. 240]
726 Stephenson, Dr Rodney (VIC)
727 Lynch, Dr Peter & Lynch, Mrs (QLD)
728 Utley, Dr Doug (VIC)
729 Ford, Mr Justin (VIC)
730 Thomas, Dr Adrian (VIC)
731 Christian Covenant Community Inc (QLD)
732 Cavicchi, Ms Ruth & Mr Alex (VIC)
733 Deeming, Mr Andrew
734 Radford, Professor Anthony (SA)
735 O'Brien, Ms Anna (VIC)
736 Stone, Ms Cath (VIC)
737 Waldock, Ms Helen
738 Pilgrim, Mr Don & Ms Annette (NSW)
739 Peck, Ms Elizabeth (QLD)
740 Ryan, Mr Francis (TAS)

741 Meaney, Mr Frank (SA)
742 van de Paverd, Mrs Anna (VIC)
743 Pickering, Mr Brian & Ms Robyn (NSW)
744 von Marburg, Ms Anna (NSW)
745 Langeneck, Mr Wolfgang (NT)
746 Sutherland, Ms Jane (NSW)
747 Kotlowski, Ms Elizabeth (QLD)
748 Nicholls, Dr Ruth (WA)
749 Jones, Mr Gordon (WA)
750 Byl, Mr Paul & Ms Lisa (WA)
751 Boyd, Mr Phil (TAS)
752 Spezzano, Ms Heidi (SA)
753 Musch, Ms Gail (QLD)
754 Cotton, Ms Kathy (TAS)
755 Zollo, Mr Steven (SA)
756 Ryan, Mr Chris (NSW)
757 Greenwood, Ms Caroline (TAS)
758 Loscher, Dr Jennifer (QLD)
759 Shaw, Mr John (TAS)
760 Shaw, Ms Janene (TAS)
761 Ison, Ms Barbara (NSW)
762 Doran, Mrs Patricia (QLD)
763 Grimer, Mr Marc (NSW)
764 Clougher, Ms Margaret (TAS)
765 Hewson, Ms Marian (NSW)
766 Horgan, Mr Michael (NSW)
767 Morey, Ms Vivianne (TAS)
768 Magill, Ms Sharon (QLD)
769 Goonewardene, Mrs Shelagh (VIC)
770 Woolley, Ms Erin (TAS)
771 Musgrave, Mrs L (WA)
772 Kirchner, Ms Robyn (NSW)
773 Name withheld (VIC)
774 Mitchell, Ms Sue (QLD)
775 Hagan, Mrs Therese (QLD)
776 Orton, Ms Patricia (ACT)
777 Palma, Mr Michael & Ms Maria (VIC)
778 Grainger, Mr Andrew & Ms Carol (QLD)
779 Herdman, Ms Frances
780 Calihanna, Mr Gerard (NSW)
781 James, Dr John (NSW)
782 Hong, Dr Janet
783 Stronach, Mr David (TAS)
784 Wiltshire, Ms Mary (VIC)
785 Landini, Mr David (NSW)
786 Westbury, Ms Heather (ACT)
787 Fulop, Ms Diane (ACT)
788 Pember, Mr Brian (NSW)
789 Corbett, Dr Andrew (TAS)
790 Ford, Mr Daniel (ACT)
791 Harvey, Rev Fr (VIC)
792 Byrne, Mr Norman (QLD)
793 Murphy, Mr Matthew (NSW)
794 Ferguson, Ms Lynette (NSW)
795 Westbury, Mr Rodney (ACT)
796 Marsh, Ms Alison (NSW)
797 Ward, Ms Sherrin (TAS)
798 McKay, Mr Peter (ACT)
799 Robson, Mr Greg (NSW)
800 McIntyre, Ms Sabina (NSW)
801 Sebastianelli, Ms Josephine (QLD)
802 Fagan, Mr Mike & Ms Sylvia
Dulhunty, Mr James & Ms Anne
Browne, Ms Katie
deVille, Ms Veronica
Johnson, Mr Ross
Healey, Ms Sally (NSW)
803 Hutton, Ms Catherine A (QLD)
804 Janssen, Mr A A & Ms B (VIC)
805 O'Connor, Mrs Mary (VIC)
806 Barnes, Mr Peter (WA)
807 McKelvie, Mr David (QLD)
808 Hunt, Mrs P M (NSW)
809 Groves, Mr Paul (QLD)
810 Preece, Ms Eleanor (VIC)
811 Atkins, Mr Robert & Ms Kathleen (VIC)
812 Kelly, Mr D J (VIC)
813 Goldsmith, Mrs Leonie (VIC)
814 Bentley, Mrs Sue (VIC)
815 Gothmann, Mrs Cheryl (QLD)
816 McGrath, G (QLD)
817 Farmer, Ms Melinda (WA)
818 Tilley, Mr P & Ms G (TAS)
819 Young, Ms Norma (NSW)
820 Donaldson, Mrs M R (WA)
821 Wesley, Mr John (WA)
822 Petrucci, M (VIC)
823 Bresnehan, Mr Brian (TAS)
824 Butterworth, Ms Sue (VIC)
825 Hallahan, J G (NSW)
826 Plier, Mrs Maria (VIC)
827 Elliott, Ms Marjorie (VIC)
828 Scott, Ms Patricia (NSW)
829 Hughes, Ms Helen (NSW)

830 Ilesich, Ms Helen (NSW)
831 O'Connor, Ms Anne ()
832 Shiel, Mr Gerald (VIC)
833 Armstrong, Mr P & Ms M (WA)
834 Forestor, Mr Vern (VIC)
835 Roberts, Ms Judie (VIC)
836 Marr, Mr Max & Ms Alison (VIC)
837 Bagguley, Mr Chas (VIC)
838 Gillie, Mr Ron & Ms Margaret (VIC)
839 Tibbetts, Mr Jim & Ms Gwen (NSW)
840 Mason, Ms Linley (QLD)
841 Bezzina, Mrs Lyn (VIC)
842 Smyth, Ms Eris (TAS)
843 Catholic Women's League Australia New South Wales Inc (NSW)
844 Stockings, Mr Ross & Ms Jennifer (NSW)
845 Morton, Ms Cynthia (WA)
846 Rodricks, Mr Jude & Ms Crystal (NSW)
847 Donaghey, Ms Ida (SA)
848 Vincent, Mr Phillip (TAS)
849 Zaccari, Mr Vincent (VIC)
850 Chambers, J (TAS)
851 Van Galen, Mr Diny & Ms Cecily (TAS)
852 Burrell, Mr Robert & Ms Barbara (NSW)
853 Wise, Mrs Marie (TAS)
854 Bishton, Mr Barrie (NSW)
855 Quinn, G (NSW)
856 Robertson, Mr B & Mrs C (QLD)
857 Carden, Ms Christine (ACT)
858 Toohey, Mr D & Ms U (VIC)
859 Phillips, Mr Peter (VIC)
860 Hocking, Mrs Barbara (QLD)
861 Elliott, Mr Matthew & Ms Amanda (VIC)
862 Stedman, Ms Kerry (WA)
863 Edwards, Ms Annabelle (WA)
864 Plumridge, Mr Richard (WA)
865 Rose, Mrs Mary (WA)
866 Hanrahan, Mrs Eileen (VIC)
867 Holohan, Dr Aidan T (WA)
868 Quinn, Mrs P (NSW)
869 Flynn, J M (NSW)
870 Cini, Mr Ron (NSW)
871 Reardon, Mr Richard (VIC)
872 McGavin, Dr P A (ACT)
873 Casanova, Mrs Leanne (VIC)
874 Harrold, Ms Mary (NSW)
875 Pregnancy Help Australia (ACT)
876 Society of Traditional Catholics (QLD)
877 Doctors for Life (NSW)
878 Dalmolin, Ms Jeanette (WA)
879 Daley, Mr Robert (NSW)
880 Goddard, J M (NSW)
881 Worlands, Mr Darren (VIC)
882 Campbell, Mr J & Mrs E M (NSW)
883 O'Shea, Dr Robert (SA)
884 O'Kane, Philomena (TAS)
885 Reardon, Mrs Katherine (VIC)
886 McLaren, Mr John (NSW)
887 Stewart, J (QLD)
888 Packman, Mrs Rosetta (NSW)
889 Bishton, Ms Margaret (NSW)
890 Orton, Ms Patricia (ACT)
891 Carden, Ms Sarah (ACT)
892 den-Bakker, Mrs Denise (VIC)
893 Forsyth, Mr Graham & Ms Dianne (WA)
894 Moss, Ms Mary T (NSW)
895 Doonan, Ms Alison (TAS)
896 Wurst, Mr Norman & Ms Joy (QLD)
897 Bellamy, M J (NSW)
898 Mills, Ms Patricia (VIC)
899 Poland, Mr James (TAS)
900 Goss, Mr James (WA)
901 Stone, Hon Dr Sharman, MP (ACT)
902 Wainer, Dr Jo (VIC)
Supplementary information
Additional information received following public hearing 3.2.06, received 7.2.06
903 Royal Women's Hospital, Melbourne (VIC)
904 Women's Electoral Lobby Australia (WEL) (ACT)
905 Women's Abortion Action Campaign (NSW)
906 Bessie Smyth Foundation (NSW)
907 Sexual Health & Family Planning Australia (NSW)
908 Royal Australian College of General Practitioners (VIC)
909 Royal Australasian College of Physicians (NSW)
910 National Association of Obstetricians and Gynaecologists (NASOG)
911 Rural Doctors Association of Australia (ACT)

912 Women's Department, Students' Association of the University of Adelaide (SA)

913 Pregnancy Advisory Centre, Central Northern Adelaide Health Service (SA)

914 Fraser, Ms Helen

915 Family Planning Welfare Association Northern Territory (FPWNT) (NT)

916 Women's Health Victoria (VIC)
Supplementary information
Additional information received following public hearing 3.2.06, dated 7.2.06

917 Children by Choice Association Inc (QLD)

918 Marie Stopes International

919 Seth-Purdie, Dr Robyn (ACT)

920 Women's Forum Australia (WFA) (NSW)

921 Association for Australian Rural Nurses Inc (VIC)

922 WIRE Women's Information (VIC)

923 Women's Rights Action Network Australia (VIC)

924 Fentiman, Ms Shannon (QLD)

925 Pettigrew, Professor Ian (VIC)

926 Betts, Dr Katharine (VIC)

927 Emmerson, Ms Abigail

928 Wyborn, Ms Helen (NSW)

929 Wolstenholm, Petar (NSW)

930 Klein, Dr Renate (VIC)
Supplementary information
Supplementary submission received 21.12.05
Opening Statement tabled at public hearing 3.2.06

931 Australians Against RU486 (NSW)

932 Knights of the Southern Cross, Victoria (VIC)

933 Catholic Doctors Association of Victoria (VIC)

934 National Civic Council (VIC)

935 National Civic Council New South Wales (NSW)

936 Australian Christian Lobby (ACT)
Supplementary information
Supplementary submission received 19.1.06

937 Australian Family Association (South Australian Branch) (SA)

938 Lutheran Church of Australia (SA)

939 Queensland Right to Life (QLD)

940 McAuley, Mr Michael (NSW)

941 Knights of the Southern Cross (NSW) Inc (NSW)

942 Adrian Fortescue Chapter of Lay Dominicans

943 Women's Action Alliance (Australia) Inc (VIC)

944 Fogarty, Dr Gerald
Cusi, Dr Mel
Cullen, Dr Martin
Stephens, Dr Peter (NSW)

945 American Association of Pro Life Obstetricians and Gynecologists (AAPLOG) and the Family Research Council (FRC) (USA)

946 Respect Life Office Catholic Archdiocese of Perth (WA)

947 Catholic Women's League Sydney Archdiocese (NSW)

948 O'Keefe, Hon Barry (NSW)

949 New Testament House Churches (ACT)

950 Fatherhood Foundation (NSW)

951 Family Council of Queensland (QLD)

952 Dewell, Ashley (SA)

953 Flood, Mr Gerald (VIC)

954 Smith, Mr Roy & Ms Kathleen (WA)

955 Harwood, Ms Jenny (NSW)

956 Blackmore, Dr Kim (ACT)

957 Kellaway, Mr Shann & Ms Jennifer (NSW)

958 Boncales, Ms Grace (NSW)

959 Healy, Ms Dorothy (NSW)

960 Duckett, Mr David (VIC)

961 Trott, Ms Carmen

962 Schlager, Ms Bronnie

963 Deppe, Mr Anthony & Ms Olga
Deppe, Mr John & Ms Maire
Deppe, Mr John & Ms Sharon
Turner, Mr David & Ms Mary (NSW)

964 Wall, Ms Linda (NT)

965 Coates, Mr Neil & Ms Meridith (QLD)

966 Grinter, Mr Matthew (VIC)

967 Glynn, Mr Joseph (QLD)

968 Shelton, Mr Lyle & Ms Wendy (QLD)

969 Barnes, Mr Steve (QLD)

970 Siow, Mr Arthur (SA)

971 Curtis, Mr Tim (NSW)

972 Marsh, Ms Jodi (NSW)

973 Newell, Dr Patricia (VIC)

974 Sidhu, Mr Sarjit (VIC)

975 Bullock, Mr Geoffrey (QLD)

976 Briscoe-Hough, Mr Greg (NSW)
977 Craven, Mrs Patricia (NSW)
978 MacKenzie, Mr John (TAS)
979 Mongan, Ms Carolyn (ACT)
980 Cole, Mr Michael (ACT)
981 Bosotti, Mr Max & Ms Cathy (NSW)
982 Devlin, Ms Elizabeth (NSW)
983 Healy, Mr Patrick (VIC)
984 White, Ms Marcel (NSW)
985 Clough, R V & Ms Joan D (VIC)
986 Carden, Ms Catherine (ACT)
987 Carden, Mr Peter (ACT)
988 Moore, Mr Daryl (NSW)
989 Moore, Ms Margaret (NSW)
990 Jones, Mr Eric (NSW)
991 Foreman, Ms Jane (WA)
992 Lesta, Dr Ken (NSW)
993 Law, Mr Robert (ACT)
994 Lopez, Dr Karen (NSW)
995 Dijkstal, Mr Pieter (NSW)
996 Reen, Ms Barbara
997 Davies, Mr Roy & Ms Bronwyn
998 Tenkate, Mr Craig (QLD)
999 Cox, Mr Michael
1000 National Union of Students (VIC)
1001 Association of Reproductive Health Professionals and the Feminist Majority Foundation (USA)
1002 Jolley, Dr Daniel (VIC)
1003 Australian Medical Association Limited (ACT)
1004 The Royal Australasian College of Physicians Australasian Chapter of Sexual Health Medicine (NSW)
1005 EMILY'S List Australia (VIC)
1006 Women's Network (NT) Inc (NT)
1007 Humanist Society of Queensland (QLD)
1008 Dean, Dr Margaret (NSW)
1009 Hargreaves, Jane
Lemon, Kerry
Tarry, Robin
Statton, Lyn
DeGeest, Emily
Sketton, Grace
Tarry-Smith, Kirsten
Nelson, Renata (VIC)
1010 Woods, G
1011 McKaskill (VIC)
1012 Southern Cross Bioethics Institute (SA)
1013 Brethren Christian Fellowship (NSW)
1014 World Federation of Doctors who respect Human Life (Vic Div) (VIC)
1015 Usher, Ms Maryse (VIC)
1016 Lock, Mr Nicholas & Ms Rita (VIC)
1017 Watson, Dr Martin (VIC)
1018 Ventura, Ms Therese & Mr Vince (VIC)
1019 Page, Mr Peter
Page, Ms Svetlana
Page, Mr Daniel (NSW)
1020 Harding, Mr Nathan (QLD)
1021 Guilfoyle, Mr Alan
1022 Curtis, Ms Emma
1023 DuBern, Mr Peter & Ms Carole (NSW)
1024 Althaus, Mr A G (QLD)
1025 Vanderpoll, Mr Wally (NSW)
1026 Herbert, Mr Neil (VIC)
1027 Burrow, Mr Barrie (NSW)
1028 Farrell, Ms Danielle (NSW)
1029 Gunton, Ms Jane (QLD)
1030 Hoffmann, Ms Ann
1031 Zappavigna, Ms Luisa (WA)
1032 Morse, Mr Rick (NSW)
1033 Sheeran, Mr Paul (NSW)
1034 Howlin, Mr Phillip (NSW)
1035 Xeros, Mr Geoffrey (NSW)
1036 Rawson, Mr Stephen (NSW)
1037 Ruseler, Ms Caroline (VIC)
1038 Althaus, Ms Anne-Maree (QLD)
1039 Marsh, Mr Jonathan (NSW)
1040 Weaver, Mr Vicki (NT)
1041 Name withheld
1042 Marsh, Mr Nathaniel (NSW)
1043 Marsh, Mr Israel (NSW)
1044 Webster, Mr Alasdair (NSW)
1045 Bourne, Mr Scott
1046 Klenthis, Ms Rebekah
1047 Fernandez, Ms Donna
1048 Morris, Mr Jeff & Ms Lanell
1049 Del Rosario, Ms Del
1050 Crouch, Dr Stephen
1051 Bosch, Mr Harvey & Ms Helen
1052 Hughes, Mr Peter
1053 Rosario, Mr Gordon
1054 Ferravant, Ms Anne
1055 Maunders, Ms Jean & Mr Ron
1056 Lamont, Dr Amanda

1057 Ms Scardina
1058 Hurley, Mr Brett
1059 Austin, L
1060 Fitzgerald, Mr Robert & Ms Lynette (WA)
1061 Cauchi, Mr Aaron
1062 Brown, Mrs Suzanne (WA)
1063 Hutton, Ms Samantha (WA)
1064 Bell, Mr Ian (NSW)
1065 Sullivan, Mr Kevin & Ms Marie (NSW)
1066 Bouffler, Ms Bernice (NSW)
1067 Vaughan, Mrs Erica (TAS)
1068 Prichard, Ms Carol (TAS)
1069 Murphy, Mrs Frances (NSW)
1070 Revell, Ms Phyllis (TAS)
1071 Heazlewood, Ms Pauline (TAS)
1072 Dyer, Mrs Mary (NSW)
1073 Parkin, Mr Ken & Ms Kath (VIC)
1074 Meade, Dr Brian & Mrs Elizabeth (VIC)
1075 Duggan, Mr James (VIC)
1076 Bonney, Ms Evelyn (WA)
1077 Dennis, Ms Margaret (TAS)
1078 Bourke, Miss Sheila (TAS)
1079 Lee, Mr Frank (VIC)
1080 Williams, Ms Dorothy (VIC)
1081 Mullone, Mr Barry (VIC)
1082 Booth, Mr Trevor (WA)
1083 Sherston, Ms Anne
Shannon, Ms Allegro
Triffett, Ms Maree (TAS)
1084 Nash, Ms Marie (VIC)
1085 Victorian Council of Social Service (VIC)
1086 Liberty Victoria – Victorian Council for Civil Liberties Inc (VIC) [related submission 1112]
1087 Fox, Ms Stacey (WA)
1088 Barbero, R V & P J (NSW)
1089 Flowers, Mr John (VIC)
1090 Heffernan, Mrs Wanda (NSW)
1091 Grimer, Mr Marc (NSW)
1092 Matthews, Mr Haydn & Ms Kym (WA)
1093 Francis, Miss Loretta (NSW)
1094 Santoro, Mr John (VIC)
1095 Laman, Mr Dane J D (QLD)
1096 Penhalluriack, Mr Frank (VIC)
1097 Malin, Ms Margaret
1098 Beattie, Mrs E M (WA)
1099 Peake, Ms Veronica (WA)
1100 Truchanas, Rima & Gaechter, Terry
1101 Walsh, Ms Jean (NSW)
1102 Hickey, Mr Paul (NSW)
1103 D'Souza, Ms Joan
1104 Pintado, Ms Stephanie
1105 O'Reilly, Dr Richard (NSW)
1106 Buist, Ms Elizabeth
1107 Lenehan, Mr Joseph (NSW)
1108 Kennedy, Mr Tim (WA)
1109 Russell, Mr David (QLD)
1110 Lausberg, Mr Eric (VIC)
1111 The Australian Catholic Bishops Conference, The Bishops Committee for the Family and for Life (ACT)
1112 Women's Hospitals Australasia (ACT)
1113 Shaw, Dr John (ACT)
1114 Koontz, Ms Marilyn
1115 Portelli, Kim (NSW)
1116 Hilder, Mr Colin (NSW)
1117 Men's Health and Wellbeing Association (NSW)
1118 Liberty Victoria – Victorian Council for Civil Liberties Inc (VIC) [related submission 1086]
1119 Baldwin, Dr Monique (NSW)
1120 Clemson, Ms Nina (NSW)
1121 Lambert, Mr Gilbert (QLD)
1122 Gordon, Fr Bernard (NSW)
1123 Sequeira, Mr Andre & Ms Neicha (WA)
1124 Hearne, Ms Julie (NSW)
1125 Catholic Women's League (Tasmania) Inc (TAS) [related submission 412]
1126 Council of Australian Humanist Societies Inc (VIC)
1127 Klar, Mr Bernard
1128 North Canberra Baptist Church (ACT)
1129 Shreenan, Mr Peter (VIC)
1130 de Vos, Mr Gerrit and Ms Marlene
1131 Ellis, Ms Susan (QLD)
1132 Young, Mr Peter (NSW)

Additional information

Department of Health and Ageing – response to questions on notice following public hearing 15 December 2005, received 1.2.06

Therapeutic Goods Administration – information relating to substances subject to import controls received 6.2.06

Senator Barnett – Copy of Reproductive Choice Australia information for submissions, tabled by Senator Barnett at public hearing 6.2.06

Senator Boswell – Letter from Dr David Gawler to Senator Boswell dated 5.12.05, tabled by Senator Boswell at public hearing 15.12.05

Summary of submissions and correspondence received

Submissions	
Individual submissions	1132
In support of Bill	125
Not in support of Bill	1007
Form letter submissions (none support Bill)	1364
Total submissions	**2496**

Correspondence	
Class 1 - Oppose Bill or a bill to approve or introduce RU486 into Australia	
Individual letters	161
Form letters	419
Class 2 - No reference to Bill	
A - Against or oppose approval of RU486	467
Form letters	221
B - Pro life; anti abortion comments	679
C - Combination of arguments A+B	335
Class 3 - Pro choice, no reference to Bill	10
Total correspondence	**2292**

Total of all submissions and correspondence received	**4788**

Note:

The correspondence received by the Committee has been divided into 3 categories.

Category 1 includes letters that may oppose the Bill by name or oppose the Bill to legalise RU486 (or similar wording). However, these letters misunderstand the Bill by making comments that do not address the purpose or subject of the Bill and are not relevant to the actual Bill under inquiry.

Category 2 letters make no reference to the Bill at all and the comments in them are not relevant to the purpose or subject of the Bill. This category has been divided into 3 general classes:

A – letters expressing opposition to RU486, wanting the ban on RU486 continued, or are opposed to the legalisation of or introduction into Australia of RU486.);

B – letters that provide strongly held views against abortion or provide pro-life or right to life comments;

C – letters that provide a combination of both A and B comments.

Category 3 express general pro choice comments without any reference to the Bill.

APPENDIX 2

Public Hearings

Thursday, 15 December 2005
Parliament House, Canberra

Committee Members in attendance

Senator Humphries
Senator Adams
Senator Allison
Senator Boswell
Senator Fielding
Senator Joyce
Senator McGauran
Senator McLucas
Senator Moore
Senator Nash
Senator Nettle
Senator Polley

Witnesses

Australian Medical Association (AMA)

Dr Mukesh Haikerwal, President

Dr Andrew Pesce, Executive Councillor

Dr Margaret Chirgwin, Director, ama Public Health and Ethics Department

Department of Health and Ageing

Ms Jane Halton, Secretary

Professor John Horvath, Chief Medical Officer

Dr David Graham, National Manager,Therapeutic Goods Administration

Mr Richard Eccles, Assistant Secretary

Rural Doctors Association of Australia

Via teleconference

Dr Ross Maxwell, President

Dr Sue Page, past President

Ms Susan Stratigos, Policy Advisor

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Dr Christine Tippett, Senior Vice President

Catholic Health

Mr Francis Sullivan, Chief Executive Officer

Australian Reproductive Health Alliance

Ms Christina Richards, Chief Executive Officer

Ms Marie Coleman, Patron

Ms Lesley Vick, recent Acting President

Women's Electoral Lobby Australia (WEL)

Ms Roslyn Dundas, ACT Convenor

Friday, 3 February 2006
Parliament House, Melbourne

Committee Members in attendance

Senator Humphries
Senator Adams
Senator Allison
Senator Barnett
Senator Fielding
Senator Joyce
Senator McLucas
Senator Moore
Senator Nash
Senator Nettle
Senator Polley
Senator Webber

Witnesses

Dr Jo Wainer – Monash Institute for Health Services Research

The Royal Women's Hospital & Family Planning Victoria

Ms Dale Fisher, Chief Executive, The Royal Women's Hospital

Ms Lynne Jordan, Chief Executive Officer, Family Planning Victoria

Professor Jeremy Oats, Clinical director Women's Services, The Royal Women's Hospital

Dr Chris Bayly, Associate Director Women's Services, The Royal Women's Hospital

Mr Charles Francis QC

Ms Babette Francis, Endeavour Forum Inc****

Right to Life Australia

Ms Margaret Tighe, President

Dr Mathew Piercy

Australian Federation of Right to Life Associations

Ms Kath Woolf, Spokesperson

Ms Carolyn Mongan, Councillor, ACT Right to Life Association

Public Health Association of Australia

Dr Cathy Mead

Dr Angela Taft

Dr Julia Shelley

Reproductive Choice Australia

Dr Leslie Cannold

Women's Health Victoria

Ms Marilyn Beaumont, Executive Director

Ms Kerrilie Rice, Policy & Research Officer

Dr Graeme Wood

Dr Elvis Seman

Dr Sally Cockburn

National Union of Students
Ms Sarah Wickham, National Women's Officer

Women's Department, Monash Student Association
Ms Rhiannon Platt, Women's Officer

Dr Renate Klein

Southern Cross Bioethics Institute
Dr Greg Pike, Director

Festival of Light
Mr Richard Egan, Member

Monday, 6 February 2006
Parliament House, Sydney

Committee Members in attendance

Senator Humphries
Senator Adams
Senator Barnett
Senator Fielding
Senator Heffernan
Senator Moore
Senator Nash
Senator Polley
Senator Webber

Witnesses

Catholic Archdiocese of Sydney
Dr Brigid Vout, Executive Officer, Life Office

The Australian Catholic Bishops Conference, Bishops Committee for the Family and for Life
Bishop Anthony Fisher

Catholic Archdiocese of Melbourne, Respect Life Office
Ms Marcia Riordon, Executive Officer

Women's Health NSW
Ms Denele Crozier, Executive Officer

Women's Abortion Action Campaign
Bessie Smyth Foundation
Ms Margaret Kirkby

Bankstown Women's Health Centre
Ms Sue McClelland, Coordinator

Leichhardt Women's Community Health Centre staff
Ms Isabelle Potter, Manager
Ms Jo Perks, Women's Health Nurse

Ms Rita Joseph

Australians Against RU486
Ms Simone Holzapfel, Executive Director

Women's Forum Australia (WFA)
Ms Katrina George, Director
Ms Melinda Tankard-Reist, Director

Ms Anne Sherston

Women's Hospitals Australasia
Dr Robert Buist, President

The Royal Australasian College of Physicians, Australasian Chapter of Sexual Health Medicine
Dr Therese Foran

Dr Catherine Lennon

Dr Dianne Grocott

Dr John James

Mr John Wilks

Sexual Health & Family Planning Australia
Dr Edith Weisberg, Director of Research
Mr Cameron McLean, Acting Chief Executive Officer

A/Professor Susan Dodds