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1.5 Although the title and stated purpose of the Bill refer only to RU486, the provisions to be repealed by the Bill deal with abortifacient drugs, not specifically RU486.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

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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

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.
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> 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.
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> 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

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

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

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

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

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

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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

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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

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

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

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

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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