

16<sup>th</sup> January 2006

Committee Secretary  
Community Affairs Committee  
Department of the Senate  
Parliament House  
Canberra ACT 2600

Dear Members of the Community Affairs Committee,

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

Thankyou for the invitation to make a written submission to this Inquiry. I write to you in my capacity as an academic in a medical faculty, with a life-time interest in reproductive health matters, and as someone who has been involved in the public deliberations about the provision of essential abortion services for the past 37 years. I organised the first medical meeting to discuss mifepristone, in Melbourne in 1985, and with my late husband set up Australia's first publicly operating abortion service, in Melbourne in 1972. In the late 1980s I traveled to London, Edinburgh and Paris to visit clinics in which women were having medical abortions so that I could understand their experience, as well as that of the doctors who supervised the abortion.

I have edited a book, titled *Lost*, that is about to be published in which Australian women recall their experiences of illegal abortion and what they were forced to endure in order to access this essential reproductive service. Reading their stories makes one thing absolutely clear. Women cannot be coerced into mothering and will take whatever risks they have to, including death, when they have concluded that they cannot continue with a pregnancy. If it is the case, and it is true throughout the world, that laws and regulations cannot prevent abortion but can only influence the conditions in which they are provided, then it is the highest duty of the State to ensure that abortion services are provided in the safest way possible. And I submit that the body with the expertise and remit to establish this is the Therapeutic Goods Administration, not the Minister for Health, or indeed, the Parliament.

I want to make a number of points.

1. 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 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, and in the instance of pregnancy, that means the pregnant woman and her partner (unless the pregnancy resulted from coerced or violent sex). 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. Having an abortion is part of the normal experience of sexually active, heterosexual, fertile women and in Australia at least one in three women will have that experience.
2. Access to safe, legal and affordable abortion is a settled issue in Australia. More than 80% of Australians support access to safe abortion, between 4-9% oppose it, and the rest are undecided. Surgical abortion services are available in private clinics, private hospitals and some public hospitals.

Difficulties of access exist in rural Australia and women from those areas travel to obtain services. Australians have had access to safe, legal and affordable abortion since the early 1970s and there has been no evidence of a moral decline in the fabric of the nation as a consequence.

3. There is no escalation in the abortion rate, despite attempts to create a moral panic about abortion numbers. According to a report by Women's Health Victoria, there were 18,713 Medicare-funded abortions in Victoria and Tasmania over the 12-month period from July 2003 to June 2004. This is 2,719 fewer than the 21,432 procedures reported 10 years earlier. The number of procedures has reduced in the 0-24 year age group and the 25-34 year old group. However, there has been a slight increase in abortive procedures in women aged 35+ over the past decade.

The Royal Commission on Human Relationships, held in 1975-6, found that its best estimates of abortions at that time and earlier were 90-100,000 each year. It seems the population has increased substantially since then, but not the number of abortions, which are estimated to be approximately 80,000 annually. This may reflect an increased capacity for women to influence with whom and when they have sex, as well as more ready access to reliable contraception.

4. Attempts to generate anxiety about abortion make it even more necessary that decisions about the best available medical technology for delivery of this essential reproductive service are kept away from politicians and placed in the hands of technocrats and scientists, who at the very least are skilled at assessing evidence and leaving their personal feelings to one side. The reproductive fate of millions of Australian women should not be left at the whim of the most well-organised or well-healed professional lobbyist, or those with the ear of the minister or prime minister, whoever they happen to be.

5. Women are very experienced at vaginal bleeding. They do a lot of it in a life-time. They have menstrual periods and miscarriages and post-birth bleeding and when asked whether medical or surgical abortion is preferable, 80% of women who have experienced both prefer medical abortion, although the priority is a safe abortion, whether medical or surgical. With their doctors looking after them, more than one million women in Europe and 500,000 in North America have demonstrated that they can manage the challenges of medical abortion. Medical abortion is new technology to Australia but not to the rest of the world, and vaginal bleeding is not new to women.

6. Australian women are entitled to believe that their government governs on their behalf. It is anomalous that a medication that is specifically for women's use, and has been demonstrated to be safe and effective, is the only one selected to receive the unique treatment of being classified as a 'restricted good'. One wonders what the Parliament is afraid of, to pass a bill just for one class of medication.

7. Australia has an enviable reputation around the world for its National Medicines Policy (2000) and Pharmaceutical Benefits Scheme and is quoted by the World Health Organisation as an example that other countries should follow in establishing the regulatory regimes for medicines.

**Box 3 Example of the essential medicines concept in a developed country**

In Australia the Pharmaceutical Benefit Scheme ensures full or partial reimbursement of over 80% of all medicines prescribed in primary care settings. Over the years the scheme has developed a very systematic procedure to decide which medicines will be reimbursed, including systematic reviews of efficacy, safety and comparative cost-effectiveness. As a result, only around 650 active ingredients in around 1100 dosage forms (1600 products) are reimbursed under the scheme. <http://www.who.org>

The Policy has as its central objective to ‘provide quality care responsive to people’s needs’ and ‘timely access to the medicines that Australians need’. Presumably those Australians include women who need timely access to the best available care in providing abortion services. If that is the case, then the Policy leads directly to assessment of that quality by the Therapeutic Goods Administration, rather than a politicised process in which ‘quality’ may be lost in the debate.

8. The National Medicines Policy also requires that ‘All partners (ie State and Federal governments) consider that the quality, safety and efficacy of medicines available in Australia should be equal to that of comparable countries. To this end:

nationally standardised regulation of medicines should be managed through rational and transparent criteria and processes;’

and

‘regional and international harmonisation of regulatory requirements should be pursued vigorously to reduce duplication and unnecessary restrictions and to facilitate early availability of therapeutic advances;’

Rational and transparent criteria and processes are to be found in the procedures of the Therapeutic Goods Administration. That is its function and purpose. These two aspects of the National Medicines Policy point strongly to two outcomes of the Senate Inquiry. The first is to provide the policy framework within which the proposed Bill lies, and the second is to support an immediate consideration of the usefulness of mifepristone and other similar compounds in the Australian context, in order to harmonise regulatory requirements with those of other countries such as India, China, New Zealand, Europe and North America and to facilitate early availability of therapeutic advances.

8. The World Health Organisation (WHO) has recently added mifepristone to its list of essential medicines for developing countries. Australia does not fit into that category, but it is useful to consider the definition of ‘essential medicines’ and how such a list might be developed. The WHO defines essential medicines as

**those that satisfy the priority health care needs of the population.**

**They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.**

Australia has a functioning health system, including a process of evaluating new medicines. Access to safe and affordable abortion care is a high priority health care need for Australian women and their families and if a company were to apply to provide medicines for therapeutic abortion, then these principles suggest that such an application should be considered by the processes in place for all other medicines.

According to the WHO, a key factor for successful implementation of an essential medicines list, such as the one maintained through the Pharmaceutical Benefits Scheme, is to ‘establish a transparent process for creating and updating the list of essential medicines, provide a voice for key stakeholders, but ensure a scientific, evidence-based process’. This scientific process lies within the TGA, not the political process.

9. Finally, I want to introduce the Inquiry members to the findings of the recent 15 country WHO study on intimate partner violence. It finds that this is the most common form of violence in women’s lives and takes an enormous toll on the health of women around the world. Women who reported physical or sexual violence by a partner were also more likely to report having had at least one induced abortion or miscarriage than those who did not report violence. In most countries studied between 4% and 12% of women reported being beaten during pregnancy. More than 90% of these women had been abused by the father of the foetus. These are the realities within which women make the decision to mother or not,

and if the Senate Inquiry can come to a conclusion that helps them do that safely, respecting their human dignity and moral worth, then I urge you to do so.

Yours Sincerely,

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