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GENERAL,  
VASCULAR & ENDOVASCULAR SURGEON

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.**

Regarding RU486.

It is my belief that the present safeguards providing for the responsibility for approval for RU486 by the Minister for Health and Aging should remain in place, for the following reasons:-

I write as a medical practitioner and as a general/vascular surgeon working in Darwin. I regularly consult in remote Aboriginal communities as part of the Surgical Outreach Program of the Royal Darwin Hospital.

I am concerned that the abortifacient RU486 has been recommended for women in rural and remote locations. In fact it has been claimed that it will fill a gap in abortion services in these areas. There are a number of reasons why such a proposal is not only ill-considered, but dangerous.

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

Secondly, RU486 has some quite serious and potentially fatal complications, which have been well documented even by the manufacturer. Treatment of these complications may require urgent admission to a hospital. These complications include severe vaginal haemorrhage, haemorrhage from ruptured ectopic pregnancy, toxic shock syndrome and retained products of conception with infection.. (N.B. In the event of an ectopic pregnancy and retained products of conception, ultrasound assessment should be performed as part of medical best practice, and plainly, this service will not be readily available in rural and remote areas.)

In remote Northern Australia, the transfer of seriously ill women to hospital may take many hours even by Air-Med Evacuation flights. In the Wet season, with severe weather and flooded runways, the delay may be a day or more! Such delays could cost a woman prescribed RU486 her life. Even in urban U.S.A. with excellent transport and communication, there have been at least five deaths due to RU486. The risk of death due to complications in rural and remote Australia would be much higher.

Thirdly, there are major patient communication problems in the North, where many Aboriginal women speak little English. This may result in non-compliance due to inadequate understanding of instructions, leading to non-attendance at further medical appointments, and failure to recognise complications that may arise. N.B. The long and wordy patient agreement written by the manufacturer may not be understood by many Australian women whose first language is not English.

Furthermore, women who are very young and immature, intellectually impaired or psychiatrically disturbed may not understand or follow instructions. In these scenarios, RU486 could be a recipe for disaster.

RU486 is not a harmless universal panacea, akin to spontaneous miscarriage as some have suggested. Apart from its serious complications, 90% of women experience unpleasant side effects and perhaps a third have very unpleasant side effects. These side effects include bleeding, abdominal pain, nausea and vomiting, diarrhoea, headache, retained products of conception with the need for surgery.

In addition, the likelihood of post abortion depression and suicide is increased due to the prolonged process of RU486. The process goes on for days and it is possible that the woman will see the foetus in the toilet. The process can be very emotionally and physically traumatic, and this trauma is prolonged by 'flash back' visions of the dead foetus, albeit small. The psychological impact could well be worse than surgical abortion. Of course, as is often the case with such drugs, the research in this regard has not been done.

Importantly, there has been conjecture as to the cause of Toxic Shock Syndrome (following administration of RU486). Ralph P. Miech MD PhD, Associate Professor Emeritus, Department of Molecular Pharmacology, Physiology and Biotechnology of Brown Medical School, Brown University, U.S.A. has suggested that Mifepristone (used as part of RU486) may inhibit immunity which may enable infection, in particular by *Clostridium sordellii*.

In an article Published Online, 26 July 2005, [www.theannals.com](http://www.theannals.com), DOI 10.1345/aph.1G189 (**The Annals of Pharmacotherapy**). Prof. Ralph Miech writes:

*“The mechanisms of action of mifepristone were incorporated into the pathophysiology of septic shock due to C. sordellii. Mifepristone, by blocking both progesterone and glucocorticoid receptors, interferes with the controlled release and functioning of cortisol and cytokines. Failure of physiologically controlled cortisol and cytokine responses results in an impaired innate immune system that results in disintegration of the body’s defence system necessary to prevent the endometrial spread of C. sordellii infection. The abnormal cortisol and cytokine responses due to*

*mifepristone coupled to the release of potent exotoxins and an endotoxin from C. sordellii are the major contributors to the rapid development of lethal septic shock.*

*CONCLUSIONS; Theoretically, it appears that the mechanisms of mifepristone action favour the development of infection that leads to septic shock and intensifies the actions of multiple inflammatory cytokines, resulting in fulminant, lethal septic shock..”*

In fact the Federal Drug Authority and Centre for Disease Control in the U.S.A. are to hold a conference regarding the fatalities associated with RU486 in the new year (“New York Times” 23/11/05).

In the interests of Australian women’s health, surely the Australian Parliament should at least wait for the outcome of the aforementioned meeting before amending the Therapeutic Goods Act.

The Australian Government should be aware of the vested interests of drug companies who stand to make enormous windfall profits through the use of this drug that potentially endangers women’s health under the guise of ‘options for women’.

I therefore respectfully submit that the responsibility for approval for RU486 should remain under the most stringent control of the Minister for Health and Aging.

Yours faithfully.

David M. Gawler

12<sup>th</sup> December, 2005.