SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Inquiry into

Therapeutic Goods Amendment

(Repeal of Ministerial responsibility for approval of RU486) Bill 2005

SUBMISSION:

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RU486: POLITICAL RESPONSIBILITY, MEDICAL INTEGRITY

1. Government should retain policy responsibility for contentious social and ethical questions.

2. The medical profession should retain the ethical distinction between medically essential abortion and abortion for non-medical reasons.

3. RU486 should be made available for genuine medical indications, including medically essential abortion, but not in cases of abortion for non-medical reasons.

Summary Points

- Abortifacient drugs such as RU486 (mifepristone) are unique in that no other drugs are designed to end a human life, and therefore their use demands a unique level of public scrutiny and accountability.

- The current regulatory arrangements in Australia for abortifacient drugs were instituted in 1996 with bipartisan support to ensure proper accountability by Government on a matter of public concern, and should remain.

- Doubt remains over the safety of RU486, especially in rural settings, and Australia must await the findings of investigations into recent deaths overseas.

- If RU486 is found by the Therapeutic Goods Administration (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 by Government.

- Other uses for RU486 which are medically unjustifiable, such as taking the life of healthy offspring to relieve the social distress of parents, should have no place in Government policy or medical advocacy.

- Instead, the compelling policy task for both Government and the medical profession is to strengthen social supports for women distressed by unplanned pregnancy.

Sections

1. The Bill: a proposal to abandon proper Government accountability

The central question facing MPs and Senators is this: why should RU486 require special approval by Government, when all other drugs are simply assessed by the TGA?

The answer is that abortifacients like RU486 are unique, as drugs designed to take life. That fact is of obvious public concern, and explains why this drug demands the special attention of those elected to deal with such matters of public concern.

Australians will differ on whether the life of a very young human being matters, but there is no dispute that after using RU486, where there once was a dynamic living creature and an unfolding human destiny, there is now death.

So RU486 is uniquely contentious in its action, raising serious moral issues, and obviously requiring a special level of scrutiny and accountability by our elected representatives.

The current regulation of RU486 was established in 1996 on exactly this principle of accountability, and with bipartisan support. On behalf of Labour, former Senator Belinda Neal spoke with a moral seriousness lacking in the current debate:

> "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." (Hansard 9/5/96).

The Parliament in 1996 thereby aimed to prevent recurrence of the debacle in 1994 where an anonymous official in the Health Department approved the importation of RU486 without the Minister's knowledge. As Senator Neal concluded:

> "We wish to ensure that, in circumstances where this drug is to be imported or supplied in Australia, the minister be required to approve the drug and that notification of this approval be given in this chamber."

A decade later, and Parliament is again to debate the regulation of RU486, but this time the stated aim is to remove this accountability, so once more a departmental official can approve RU486 without the Minister taking policy responsibility or the Parliament knowing.

With the *Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005* the Parliament is being asked to support an amendment which undermines, for ideological reasons, proper Ministerial accountability on a matter of public importance. It would be a triumph of underhandedness over transparency in our public life.

If this Bill is passed, it would be an abandonment by Parliament of their responsibility to grapple with difficult social and ethical questions, instead hiving the issue off to unelected scientists and bureaucrats who are not accountable for contentious decisions. The Therapeutic Goods Administration (TGA) has the vital but secondary role "to ensure the quality, safety and efficacy of medicines"; it has no brief to take

into account the moral status of the life to be ended by RU486, and without such ethical considerations no serious and responsible decisions can be made.

If this Parliament votes to dodge responsibility, it will by timid default give its imprimatur to the current practice of abortion on demand for non-medical reasons. The Federal Government has never had to commit itself one way or the other on the question of abortion for non-medical reasons; now that is unavoidable, even if the commitment is by merely washing its hands of the lives in question.

**** A note concerning attempts to discredit the current arrangements:***

As a footnote to this process of 'undermining' of an entirely professional and proper level of regulation, let the record be corrected on one false and misleading claim. It is often stated or implied in the media that the current regulatory arrangements on RU486 are somehow 'illegitimate' because they were instituted by the former pro-life Senator, Brian Harradine, and apparently only supported by Prime Minister Howard in exchange for Harradine's vote on the partial sale of Telstra.

Let the facts speak for themselves.

Senator Harradine acquired the balance of power unexpectedly in August 1996 upon the defection from the ALP of Senator Mal Colston. At that point his vote became vital to the passage of the Telstra Bill, which went through later that year. Prior to August his vote was not of importance, he had no leverage with which to do deals, but it was prior to August – in May 1996 – that the Senate passed his amendments with bipartisan support.

As Senator Harradine stated later:

> "I had no particular influence when my amendments were accepted, other than reasoned argument. My amendments to the TGA Bill concerned important matters of public accountability, parliamentary scrutiny and monitoring - that's why they received the support of the Senate."

His amendments received the respect of both parties in 1996, and for the same reasons of "public accountability, parliamentary scrutiny and monitoring" they should be respected and retained by the current Parliament.

It appears, from the perspective of a member of the public, that the same animus directed against the pro-life Catholic Harradine is now being used against the pro-life Catholic Abbott in order to discredit further the current regulations of RU486. That sort of personality politics is a poor basis for a change in legislation.

The Parliament need not toss out the baby with the bathwater; if there is a personal issue with the current Health Minister, there must be a way to bypass that short of throwing out entirely proper and responsible legislation. As one

observer, well aware that the workings of the political process are outside my experience, may I still suggest that itt would be possible to get around this problem in a constructive way by simply making any policy decision on RU486 a matter for Cabinet rather than the individual Health Minister?

I leave that for the consideration of those who would like to find a way forward that does not involve jettisoning good legislative arrangements.

2. The need to permit RU486 for authentic medical indications

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.

The AMA has always known that RU486 would remain available for valid medical uses – which is evident in the trials currently under way in cancer therapy. AMA representatives met in 1996 with Senator Bob Woods (Parliamentary Secretary to the Minister for Health) who then told Parliament:

> "In terms of the AMA's perception that we are in some way banning a drug from coming to Australia, that is not the case. We are making the minister sign off, if you like, and making sure that public accountability is raised." (Hansard 21/5/96)

So 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 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.

3. Failure of advocates to make a medical case for abortion using RU486

It is puzzling that, to date, advocates for RU486 have failed to propose a single case where abortion is medically necessary, which might then justify its use. More expert advice is clearly needed to define such situations, rare though they undoubtedly will be.

Also puzzling is that advocates choose as their 'trump card' in public debate the scenario of abortion for rural and remote women - the one situation in which RU486 should obviously not be used, since it would be considerably more dangerous than a surgical curette.

Dr Carolyn De Costa, an advocate for RU486, opened her recent article in the *Medical Journal of Australia* with one such rural scenario, and her case study is significant in that it gives a social rather than medical justification for the abortion, and does not consider the risks that would be faced if the woman had used RU486. [1]

In her case study a rural woman requests abortion on social grounds because her partner was "unsupportive". She finds the local doctor sympathetic, but unable to arrange termination at the small local hospital. The cost of the bus fare to a major centre and abortion clinic fees was sufficiently high that she reluctantly continued the pregnancy. She had suffered pre-eclampsia with both earlier babies, who had been born before 32 weeks with no reported problems, and therefore she should have been under close antenatal supervision. However, she presented to the doctor at 26 weeks, not with early signs of oedema or proteinuria, but "severely ill" in advanced pre-eclampsia. She was flown to the major centre for emergency caesarean section too late to save the baby, and after several days recovery in the high dependency unit she returned home.

De Costa argues that "this woman's story could have been very different if Australian women had access to mifepristone". Indeed. How would this doctor, unable to detect pre-eclampsia in a timely manner, detect and deal with toxic shock from RU486-related *clostridium sordellii*? If the doctor was unable to do an elective curette in his small country hospital to terminate pregnancy, how would he do an emergency curette in a distressed and hypotensive woman haemorrhaging after medical abortion, or septic from retained products? How would he perform an emergency transfusion? And even more basic, how would he have performed the routine ultrasound to exclude ectopic pregnancy, a condition otherwise masked by the symptoms of medical abortion?

These are the sort of sober questions which led the Chief Health Officer, Dr John Horvath, to advise Health Minister Tony Abbott that RU486 would be "unsuitable for women in rural and remote areas who may have limited access to obstetric facilities".[2]

It seems premature, even complacent, for medical groups to declare that RU486 is safe. The Food and Drug Administration (FDA) in the United States is reportedly convening a high-level scientific meeting with the Centre for Disease Control early in 2006 over recent deaths linked to RU486. Four fit young women in California alone, in the past two years alone, have 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. [3]

A new review of this fatal syndrome in *The New England Journal of Medicine* on December 1st 2005 calls for "further study of its association with medical abortion"[4] while an accompanying editorial notes 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*.[5] Editorial and article attached.

That observation is not included in the material supporting RU486 sent to all MPs and Senators by the AMA and RANZCOG on November 29th, as the NEJM is a more recent publication.

So the jury appears to have been sent out again on the safety aspects of RU486, and those who jump to premature conclusions on its safety seem to be motivated more by political impatience than by a desire for scientific objectivity.

4. The joint policy task for Parliament and the medical profession

RU486 is a uniquely complex social challenge and its fate should be decided by those elected to judge on matters of public concern – not by unaccountable bureaucrats dealing only with sterile technical matters of safety and efficacy.

Safety is only one consideration in the decision about the use of RU486. If the TGA were to consider it safe enough, then other medical authorities would have to define clinical indications for its use, whether in cancer, Cushing's syndrome, or medically essential abortion. Provided these indications were medical in nature, they would be authorised by Government as a matter of course. But current proposals for RU486 are being justified more on ideological than on clinical grounds, and we need the responsible scrutiny of Government to prevent the use of RU486 degenerating into a mere human pesticide serving social abortion on demand.

The profession should not be capitulating to a degraded utilitarian ethic which supports social abortion in the rhetorical language of 'increasing choice', as AMA President Mukesh Haikerwal put it,[6] where there is no pretense of medical necessity, and no apparent concern whatsoever for the life of the unborn child. 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 profession must join with Government in the urgent policy task of reconstructing social supports for women distressed by unplanned pregnancy.

5. Summary Recommendations

- That the Parliament reaffirm its proper accountability on difficult social questions, especially those touching on life and death and justice, and reject the attempt of the proposed Bill to shift responsibility to an unelected group of bureaucrats and scientists in the TGA who have no statutory role to deal with complex social and ethical matters.

- That the Government resolve this debate by permitting the use of RU486 for authentic medical indications as defined by medical authorities, and subject to

safety approval by the TGA. Such conditions will include certain cancers, hormonal disorders, and abortion which is essential to prevent grave physical harm to the mother.

- That RU486 be accessed readily for these approved conditions through the current system of Authority prescriptions, used for many special drugs (such as narcotics) where strict prescribing conditions must be met for their use.

- That the Government limit the availability of RU486 to authentic medical situations, not permitting its use for abortion on non-medical grounds such as financial or emotional stress, sex-selection, or as a backup to failed contraception.

- That both Government and the profession undertake comprehensive policy work on reconstructing social supports for women distressed by unplanned pregnancy.

6. References and attachments

[1] De Costa C. Medical abortion for Australian women: it's time. *Medical Journal of Australia* 2005; 183: 378-380
[2] Horvath comments reported at http://www.abc.net.au/pm/content/2005/s1509375.htm
[3] Harris G. Deaths after abortion pill to be studied by officials. *New York Times* 23/11/05. http://www.nytimes.com/2005/11/23/national/23pill.html
[4] Fischer M et al. Fatal Toxic Shock Syndrome Associated with *Clostridium sordellii* after Medical Abortion. *The New England Journal of Medicine* 2005; 353: 2352-60
[5] Green M. Fatal Infections Associated with Mifepristone-Induced Abortion. *The New England Journal of Medicine* 2005; 353: 2317-18
[6] Haikerwal M. Interview with Fran Kelly, ABC radio – posted 8/11 to http://www.ama.com.au/web.nsf/doc/WEEN-6HX2LE

- ATTACHED: Green M. Fatal Infections Associated with Mifepristone-Induced Abortion. *The New England Journal of Medicine* 2005; 353: 2317-18

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