Elton Humphrey
Committee Secretary
Community Affairs Committee
Department of the Senate
Parliament House
CANBERRA ACT 2600

15 January 2006

Dear Sir

Re: Submission from the **Catholic Doctors Association of Victoria,** to the inquiry into **Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU 486) Bill 2005**

In this submission we wish to argue that the Federal Parliament should reject proposals to transfer the current Ministerial responsibility for approval of the drug RU 486 to the Therapeutic Goods Administration (TGA). Because of the issues of safety concerning this drug, especially to women in rural and isolated settings and because of the serious ethical and social issues and unique public concern that pertains to the use of RU 486 as an abortifacient, it should continue to be regarded as a 'restricted good' and subject to the responsibility, accountability and scrutiny of elected representatives of the community.

Introduction

RU 486 is not the solution to the real problems of abortion

The introduction of RU 486 will not reduce the number of abortions in Australia nor will it address the underlying issues that lead women to abortion nor alleviate the post-abortion effects experienced by many women undergoing abortion.

Worldwide there are around 53 million abortions per year[1]. This equates to 1 billion abortions since 1980. This recent phenomenon is of an unprecedented scale in human history and will have many serious and far reaching effects on the fabric of our society, the meaning and values of our culture and the future well being of inter-generational relationships.

In Australia there are already too many abortions occurring with approximately 100,000 abortions per year. This number is considered unacceptable on all sides of politics as well as by a large majority of the Australian public according to recent research[2].

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[1] Henshaw SK, Singh S, Haas T. *The incidence of abortion worldwide.* Int Fam Plann Perspect 1999;25(Suppl):30–38. and WHO Technical Report Series: 871. Geneva: WHO, 1997.

[2] Fleming J I, Ewing S. *Give Women Choice: Australia Speaks on Abortion,* Southern Cross Bioethics Institute, 26 April 2005. Can be viewed at www.bioethics.org.au This is the most extensive and in depth research yet undertaken on the opinions Australians have about abortion.

This research into Australian's attitudes to abortion was conducted by the Southern Cross Bioethics Institute and is to date the most extensive research on this subject. It revealed that 63% of Australians either oppose or are not strongly supportive of abortion on demand and 64% to 73% of Australians think that the abortion rate is too high while 87% believe that it would be a good thing if the number were reduced while at the same time protecting existing legal rights.

A. RU 486 is *not* a safer form of abortion.

1. ***A recent editorial in the New England Journal of Medicine suggests a 10-fold increase in mortality for RU-486 mediated medical abortion as compared with surgical abortion for similar gestational age.*** [3]

2. ***There is no evidence to support the notion that medical abortion is safer than, or even as safe as, surgical abortion. The onus should be on those proposing the introduction of RU 486 as an alternative means of abortion to offer evidence of at least its equivalent safety profile compared to surgical abortion.***

Contrary to evidence that Dr Haikerwell and the A.M.A. gave to the senate committee in December that the "safety profile [of RU486] is not dissimilar to that of surgical procedures" [4]there is in fact very little evidence to support this statement and little basis for such reassurance.

The Cochrane Collaboration in 2002 states that there is in fact very little evidence in the literature comparing the adverse events related to surgical and medical abortion. The limited number of studies (six in total) considered eligible by the Cochrane study group involved small sample sizes and lacked the power to analyze the less common rates of severe adverse events. [5]

There were only two studies that compared RU 486 with surgical abortion (Henshaw, 1994 and Ashkok, 2002) and only one of them, Ashkok, used the common regimen of Mifepristone 200mg/Misoprostol 800ug while Henshaw used Mefipristone 600mg/ gemeprost 1mg.[6],[7]

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[3] Greene,M. *NEJM*, Dec. 1, 2005, Vol. 353, No. 22, p 2318

[4] Proof Committee Hansard Senate Community Affairs Legislation Committee
Reference: Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005 Thursday 15th December 2005 Canberra

[5] Say L, Kulier R, Gulmezoglu M, Campana A. Medical versus surgical methods for first trimester termination of pregnancy. *The Cochrane Database of Systematic Reviews* 2002, Issue 4. Art. No.: CD003037.pub2. DOI: 10.1002/14651858.CD003037.pub2. prepared and maintained by The Cochrane Collaboration and published in The Cochrane Library 2005, Issue 4 http://www.thecochranelibrary.com

[6] Ibid., see also Ashok PW, Kidd A, Flett GMM, Fitzmaurice A, Graham W, Templeton A. A randomized comparison of medical abortion and surgical vacuum aspiration at 10-13 weeks gestation. Human Reproduction 2002;17(1):92–8.

Both involved small numbers. Henshaw: 363 pts and Ashkok: 486 patients.

Nevertheless, the Ashkok study found that the RU-486 group was associated with a longer duration of bleeding, increased rates of vomiting and diarrhoea, more severe pain following the procedure and a lower preferred option for future abortions.[2] The Henshaw study also showed a longer duration of bleeding and a lower preferred option for future abortions with the RU 486 group.[8]

3. ***Many serious adverse events have been reported with the use of RU486. These adverse events are all the more significant considering that it is a drug given to otherwise healthy young women with normal early pregnancies.***

A recent report of 'FDA Severe Adverse Events', including deaths, related to the use of RU-486 as an abortifacient showed:

a. 237 cases of haemorrhage. There was one fatal haemorrhage, 42 life-threatening and 168 serious cases of haemorrhage, with 68 cases requiring a blood transfusion.

b. 66 cases of infection There were 7 cases of septic shock reported (3 fatal and 4 life-threatening), and 43 cases requiring parenteral antibiotics. Surgical interventions were required in 513 cases (235 emergent, 278 non-emergent). Emergent cases included 17 ectopic pregnancies, 11 of which had ruptured.

c. There have been a total of 8 known deaths to date, including 5 due to septic shock, 3 of which have been linked to *Clostridium sordellii* and 2 infection-related deaths which are currently under investigation. [9]

4. ***The rates of serious adverse events may be even higher than previously thought due to under-reporting***

It is now recognized that there has been a likely under-reporting of serious adverse events related to RU 486, including deaths. The Centre for Disease Control in the US is currently considering the recent RU-486 related deaths due to infection and has required that any suspected cases be reported to the FDA[10]. Until now adverse event reporting to the FDA about RU 486 was entirely voluntary. "Complete and accurate data concerning the public health risk posed by RU 486 are not being gathered through the FDA's Adverse Event Reporting System."[11]

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[7] Ibid., see also Henshaw RC, Naji SA, Russall IT, Templeton AA. A comparison of medical abortion (using mifepristone and gemeprost) with surgical vacuum aspiration: efficacy and early medical sequelae. Human Reproduction 1994;9(11):2167–72.

[8] Ibid.,

[9] Gary M, Harrison D. *Ann Pharmacother* 2006; 40:xxx, Published Online, 27 Dec 2005, *www.theannals.com*, DOI 10.1345/aph.1G481

[10] www.cdc.gov/mmwr/preview/mmwrhtml/mm5429a3.htm; accessed 5 Jan 2006

[11] Margaret M Gary and Donna J Harrison *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient* Annals of Pharmacotherapy 2006, Feb, Volume 40, Published Online, 27 Dec 2005, www.theannals.com, DOI 10.1345/aph.1G481

5. ***The current practice of using RU 486 for late trimester and early second trimester is now common overseas and is putting women at even higher risk of complications.***

RU 486 is *not* being used only for early trimester abortion (<49 days or 7 weeks) despite more than "49 days ... since your last menstrual period began" being cited as a contraindication for its use by both the FDA and the manufacturer. It is already being used, under medical supervision, in countries such as the UK and US, for inducing abortions up to 91 days (13 weeks) and beyond[12],[13], [14] thereby increasing the risks of complications from this drug and further endangering the health of women.

6. 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 RU 486 use.

5-8% of women using RU 486 for medical abortion will require surgical intervention. These interventions are usually of an emergent rather than an elective nature.

Contrary to the reassurances given by Dr Haikerwell to the Senate Committee in December, such interventions require much more than " access to a remote hospital with a doctor able to perform curettage"[15]. Dr Haikerwell seems unfamiliar with the actual requirements of emergency surgical backup in a rural setting which include access to an anaesthetist, a nursing theatre team, laboratory and transfusion facilities and pre-hospital ambulance transfer capabilities. Therefore the task of assembling all the elements needed to deal with an urgent complication of RU 486, especially in an after hours situation would be very difficult if not impossible and would put many women at serious risk.

The reassurance of 'Authority' requirements based on location or otherwise would also be of little value considering the variable level of medical locum cover in many areas.

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[12] U. KIRAN, P. AMIN and R. J. PENKETH Journal of Obstetrics and Gynaecology (February 2004) Vol. 24, No. 2, 155–156,

[13] Haitham Hamoda, MBChB, Premila W. Ashok, MD, Gillian M. M. Flett, BCh, and Allan Templeton, MD: *Medical abortion at 64 to 91 days of gestation: A review of 483 consecutive cases* Am J Obstet Gynecol 2003;188:1315-9

[14] Ashok PW, Kidd A, Flett GMM, Fitzmaurice A, Graham W, Templeton A. A randomized comparison of medical abortion and surgical vacuum aspiration at 10-13 weeks gestation. Human Reproduction 2002;17(1):92–8.

[15] Proof Committee Hansard Senate Community Affairs Legislation Committee
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B. Safety is not the only issue.

1. *It is the ethical and social dimensions and not merely the safety profile of this drug that are the real issues to be addressed.*

RU 486 is not like any other drug. It is designed to end the life of a human being. It thereby makes this drug a matter of unique public concern. The nature of this drug and its intended use has profound social and ethical significance as can be told by the current level of debate about changes to federal legislation and the possibility of this drug being made widely available.

The Therapeutic Goods Administration is strictly concerned with the safety and efficacy of therapeutic goods. It is not equipped nor intended to be able to assess the deeper moral and social issues concerning this drug and its intended use. It is these issues that are at the heart of concerns about this drug and its availability.

2. *RU 486 will further diminish the respect for nascent human life in our culture*

The disrespect and disregard for nascent human life diminishes the dignity of all human beings and further erodes the concept of the inviolability of human life which is the foundation of a civilized society and the basis of sound and ethical healthcare.

The erosion of these fundamental concepts inevitably coarsens our response to the weak and vulnerable members of the human family, diminishing our humanity and the fabric of our society.

The recent prevalence of the abortion culture in our society has had, and will continue to have, many profound negative consequences. Some of these consequences, such as the extent and degree of post-abortion depression, are only now being revealed despite consistent efforts by many to suppress or deny such realities.

3. *The introduction of RU 486 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". Changing the culture of medicine and healthcare in this way is one of the main objectives of the proponents of the abortion industry regarding the introduction of RU 486 [16],[17]. If it is successful it will have a profoundly negative effect on medical practice and medical practitioners alike.

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[16] Caroline Westoff an obstetrician and gynaecologist told the New York Times (11/7/1999) that *"One of my real, and I think realistic, hopes for this method (ie RU 486) is that it will help get abortion back into the medical mainstream and out if this ghettoised place it's been in'.*

[17] Lawrence Leeman, Eve Espey *"You can't do that 'round here" : a case study of the introduction of medical abortion care at a University Medical Center"* Contraception 71 (2005) 84– 88

Conclusion

With the increasing evidence of serious adverse events related to the use of RU-486 and the unfavorable comparison with surgical abortion based on available evidence it is difficult to see why legislation should be changed that will likely lead to RU 486 being made available for the facilitation of less safe abortions.

When the safety of this drug for women is currently being investigated in the US by the Food and Drug Administration and Centre for Disease Control because of a recent spate of deaths and adverse events and while three families are currently suing the drug company *Danco* for its responsibility in three respective deaths, it is difficult to understand why the government hastening to alter legislation which will likely make available such a controversial and unsafe drug which does not address the real issues concerning the problems of abortion.

RU 486 does not address the many social and personal issues that are at the root of Ausrtalia's abortion problem. It merely offers young healthy Australian women a less-safe abortive solution to the profound social, moral, economic and financial problems that women face when dealing with unplanned pregnancies. [18], [19]

In view of the serious issues and concerns discussed in this submission we believe it is appropriate that the Federal Parliament maintain the current legislation regarding the Ministerial responsibilities for approving evaluation, registration, listing and importation of restrictive goods in Australia, such as RU 486, and continue to define medicines intended for use in women as abortifacients as 'restrictive goods' as. It is only with these current arrangements that the appropriate and necessary level of accountability and scrutiny for this drug can be ensured.

Thank you for the opportunity to make a submission to the Australian Senate Community Affairs Legislative Committee.

I would be happy to meet with your staff to discuss this issue should that prove useful. I can be contacted at committee@catholicdoctors.asn.au

Yours sincerely,

Dr Eamonn Mathieson
President of the Catholic Doctors Association of Victoria
On behalf of the Executive Committee of the CDAV

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[18] Adelson PL, Frommer MS, Weisberg E.: *A survey of women seeking termination of pregnancy in New South Wales.* Med J Aust. 1995 Oct 16;163(8):419-22.

[19] Abortions are rarely undertaken for a specified medical condition (0.3%). See Parliament of South Australia, *1st Annual Report of the South Australian Abortion Reporting Committee for the Year 2003.*