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

11 January 2006

Dear Sir

Submission from the **Catholic Archdiocese of Sydney,** to the inquiry into **Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU 486) Bill 2005**

In my position as Executive Officer of the Life Office, and drawing upon my professional qualifications and experience as a medical doctor and bioethicist, I am pleased to make this submission on behalf of the Catholic Archdiocese of Sydney.

The Life Office is an agency within the Catholic Archdiocese of Sydney, established to extend the research, policy and educational activities the Church undertakes in life and related issues. Currently there are some 589,000 Catholics in the Archdiocese of Sydney, constituting 32.3% of the general population living within the geographical boundaries of the diocese. Over one million Catholics live in the greater Sydney area.

The Catholic Church has a long and ongoing tradition of directly caring for the health of women and children, as well as advocating for social policy that seeks to promote and protect the life and health of every member of the human family. We sponsor the oldest and largest network of healthcare institutions in the world and are the largest non-government provider of healthcare in Australia.

Catholics hold strong beliefs about the dignity of the human person, as well the intrinsic value of bodily life and health, procreation and parenthood, human rights and responsibilities. However these beliefs are not exclusive to Catholics. Of particular relevance to this submission, the Catholic Church's opposition to abortion is based upon the principle of the inviolability of human life which is shared by all the great religious traditions and cultures of the world. Our opposition to abortion is not a sectarian idiosyncrasy. Catholic ethical and social teaching, while confirmed by Christian faith, is also based upon sound reasoning which can be understood and appreciated by all people irrespective of any religious belief. Revelation leads us to reverence human life, but so too does reason.

1. Concerning the definition of *restricted goods* in Subsection 3(1).

1996 amendments to the *Therapeutic Goods Act 1989* 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 (*Therapeutic Goods Act 1989*, section 3).

This is an appropriate designation for abortifacient drugs. A substance is 'therapeutic' if it relates to the treatment or curing of disease.[1] 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 fetus.

Even in cases where abortion is judged to be medically necessary to preserve or restore the health of a woman (i.e. circumstances where abortion is the means to treating or curing of disease) abortifacients are never 'therapeutic' for both the woman and the embryo/fetus. At any rate, given that the majority of abortions in Australia are carried out for social, not maternal health reasons,[2] even in a secondary sense, abortifacient drugs are rarely 'therapeutic' for women.

As abortifacients are not genuine 'therapeutic goods', drugs intended for use in women as abortifacients should continue to be regarded as 'restricted goods'.

2. Concerning requirements for Ministerial approval for the importation, evaluation, registration or listing of restricted goods

As the *Explanatory Memorandum* to the Bill states, the Therapeutic Goods Administration (TGA) is 'specifically charged with identifying, assessing and evaluating the risks posed by therapeutic goods that come into Australia, applying any measures necessary for treating the risks posed, and monitoring and reviewing the risks over time.'

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.

The Parliament of Australia allowed amendments to the *Therapeutic Goods Act 1986* to ensure 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.[3]

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.

A major in-depth investigation of Australian's attitudes to abortion has found that 63% of Australians either oppose or are not strongly supportive of abortion on demand. Although supportive of legal access to abortion, Australians are deeply ambivalent about the morality of abortion and apart from 'hard cases' involving danger to the mother's health or foetal disability, fewer than 1 in 4 Australians think that abortion is morally justified.

In fact, this study reveals strong community support for a reduction in abortion numbers, without restricting access. 64% to 73% of Australians think that the abortion rate is too high. 87% believe that it would be a good thing if the number were reduced while at the same time protecting existing legal rights to freely choose abortion. [4]

In line with these findings, it is reasonable to assume that the community is significantly concerned about the broader ethical and social issues surrounding abortifacients such as RU486. It is unlikely that the majority of Australians believe that decisions about the importation and registration of abortifacients should be based solely upon a bureaucratic decision about the medical safety and efficacy of these drugs.

In line with general community attitudes, Catholics are certainly concerned about the high incidence of abortion in Australia. The Catholic Church has taught from its earliest days, and continues to teach that the direct and voluntary killing of the unborn, at any stage and by what ever means, is gravely immoral. No reason, however serious or tragic can ever justify the deliberate killing of an innocent human being. [5] Science has now put beyond doubt that life begins at fertilization, thus reinforcing our duty to protect and respect human life at all stages of development

At present, there is no substantial evidence that the availability of abortifacients increases, or decreases, a nation's overall abortion rates.[6] 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.

Practically, what is required is not another method of abortion, but positive strategies which address the social circumstances that cause women to choose abortion over childbirth in the first place. Abortifacients like RU486 are not an adequate answer to the complex needs of women facing a difficult pregnancy. The answer lies in building a culture where law, social policy, institutions, communities and individuals respect and serve the dignity of every human person by providing women with the emotional and practical support necessary to continue a pregnancy in difficult circumstances.

Serious ethical and social considerations surround RU486 and similar abortifacient drugs. It would be a mistake to remove the restricted goods provisions in the Act so that RU486 would be evaluated within the same framework as all other drugs. 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.

3. Additional considerations

Whichever authority decides, the task of assessing the safety and efficacy of abortifacients will remain beset with difficulties so long as ideological bias affects the interpretation of research, and sometimes, the collection of the raw research data itself. With this in mind, the following points are presented with the hope of making an objective contribution to current debate over the safety profile of the drug RU486.

a. *Access to RU486 could seriously endanger the health of at-risk rural and isolated women.*

Those wanting to make RU486 available here in Australia have emphasized the possibility that it could 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. [7]

A recent *Parliamentary Library Research Note* states, however, that most reviews of the available evidence about RU486 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." In the 5 to 8% of cases in which there has not been a successful 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. [8]

The Chief Medical Officer, Professor John Horvath, in written advice to the Health Minister, stated that the use of RU486 by GPs in situations where there was not an ‘established relationship with an obstetric service that could deal with emergency complications outside normal clinic hours…would substantially increase the risks to women undergoing termination.”[9]

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.

b. *RU486 may not be as safe as some advocates of the drug claim.*

A recent article in *The New England Journal of Medicine*, (December 1st 2005), described four deaths of previously healthy women due to fatal toxic shock syndrome associated with *Clostridium sordellii* after medical abortion. The authors have called for further study of this syndrome’s association with medical abortion. [10] A related editorial noted that while the death rate in the USA 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. [11]

The Food and Drug Administration (FDA) in the United States is convening a high-level scientific meeting with the Centre for Disease Control early in 2006 over deaths linked to RU486.

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.

c. *Abortion poses important psychological, as well as physical, risks to women’s health.*

When assessing medical ‘risk’, insufficient consideration is paid to the psychological risks of abortion. One hopes that the recent attention given to the findings of a reputable major New Zealand study will begin to correct this oversight. Data collected as part of the *Christchurch Health and Development Study* found that having an abortion was associated with elevated rates of subsequent mental health problems including depression, anxiety, suicidal behaviours and substance abuse disorders. This association persisted after adjustment for confounding factors.[12]

With respect to the specific issue of medical abortion, I draw the Committee’s attention to a prospective comparative study conducted at a UK teaching hospital which investigated whether medical and surgical abortion patients differ, before and after pregnancy termination, in their degree of emotional distress. The study found that one quarter of women in both groups remained anxious at 4 weeks

post-abortion. Women undergoing medical abortion, however, reported higher levels of severe pain, bleeding and disruption of daily activities; moreover, women who saw the foetus were most susceptible to psychological distress, including nightmares, flashbacks, and unwanted thoughts related to the procedure.

This study also found that exercising choice of abortion method is unrelated to post abortion emotional distress or satisfaction with care. [13]

4. Summary

The Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU 486) Bill 2005 should be rejected for the following reasons:

- RU486 and other drugs intended for use in women as abortifacients are not 'therapeutic goods,' but constitute a specific group of drugs whose purpose is to end the life of human embryo/foetus. Drugs intended for use in women as abortifacients should continue to be regarded as 'restricted goods'.

- There are important ethical and social concerns surrounding abortifacient drugs which make them unsuitable for evaluation within the same framework as therapeutic goods. 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 appropriate scrutiny and accountability by elected community representatives.

- There are important safety concerns about the impact of the drug RU486 on the physical and psychological health of women that require objective consideration.

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 on 02 9390 5290 or lifeoffice@sydney.catholic.org.au.

Yours sincerely

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Endnotes

[1] *Heinmann Australian Dictionary*.

[2] 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.*

One Australian study found that the factors most frequently contributing to the decision to seek a termination are concerns about finances (60%), change in lifestyle, single parenthood and being too young. See Adelson, P, Frommer, M and Weisberg, E. 'A survey of women seeking termination of pregnancy in New South Wales,' *The Medical Journal of Australia* Vol 163 Oct 1995, pp. 419-422.

[3] Parliamentary Library, *Research Note: RU486 for Australia,* 28 November 2005, no. 19, 2005-06.

[4] Fleming J I, Ewing S. *Give Women Choice: Australia Speaks on Abortion,* Southern Cross Bioethics Institute, 26 April 2005.

[5] John Paul II. *Evangelium Vitae: Encyclical Letter on The Value and Inviolability of Human Life.* Homebush: St Pauls, 1995, n.62.

[6] In France, England, and Wales, the overall abortion rate remained stable from the year prior to mifepristone's approval to 2000 (a total of 8 – 12 years depending on date of licence). While the overall abortion rate in Sweden fell following mifepristone approval (the abortion rate in Sweden fell from 21 per 1,000 in 1990 to 18 per 1,000 women in 1999) Scotland's abortion rate increased following mifepristone approval (the overall abortion rate in Scotland rose between 1990 and 2000, from 9 to 11 per 1,000 women. See Jones, Rachel & Stanley Henshaw. 'Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden', *Perspectives on Sexual and Reproductive Health*, 2002, 34(3), 154-161.

[7] de Costa, C., 'Medical abortion for Australian women: it's time', *Medical Journal of Australia,* vol 183, no. 7, 2005, pp 378-80.

[8] Parliamentary Library. *Research Note: RU486 for Australia,* 28 November 2005, no. 19, 2005-06.

[9] Department of Health and Ageing. *RU-486 (mifepristone) – medical abortion,* Minute to the Minister, November 2005.

[10] 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

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

[12] Fergusson D, Horwood L. J, Ridder E. 'Abortion in young women and subsequent mental health', *Journal of Child Psychology and Psychiatry* 2006; 47(1):16.

[13] Slade P, Heke S, Fletcher J, Stewart P. 'A comparison of medical and surgical termination of pregnancy: choice, emotional impact and satisfaction with care', *British Journal of Obstetrics and Gynaecology* 1998 Dec; 105(12):1288-95.