

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

15 January 2006

Dear Sir

**Submission from the Respect Life Office Catholic Archdiocese of Melbourne
to the inquiry into Review of Therapeutic Goods Amendment
(Repeal of Ministerial responsibility for approval of RU-486)
Bill 2005**

Introduction

Calls are being made by some in our community to lift the Ministerial responsibility for approval of RU-486 and give it to the Therapeutic Goods Administration (TGA). Proponents aim to make this controversial drug RU-486 widely available in Australia, claiming that it is safe and effective and would increase the range of options open to women for pregnancy termination.

Any such moves to repeal Ministerial responsibility for approval for RU-486 are shortsighted and should be rejected by Federal Parliament for a number of important reasons.

RU-486 cannot be divorced from broader issue of abortion

While proponents of RU-486 would prefer to limit this debate to narrow technical questions about its safety and effectiveness of RU-486 no one can hide the fact that this drug is designed to cause an abortion and therefore it must be viewed in the context of a much broader community debate over abortion.

The last few years have seen community disquiet grow over abortion and RU-486 cannot be viewed in isolation from this.

Parliament should decide important issues of public policy not the TGA

The TGA has considerable professional expertise in determining the safety or otherwise of certain medications and this is not in dispute. However the issue of whether or not RU-486 should be generally prescribed and made widely available also falls into the area of social concern and public policy. It is ultimately an issue for society and for political leaders to decide as our community representatives.

Continuing Safety Issues

Although the United States of America Food and Drug Administration (FDA) approved the use of RU-486 in 2000 the decision was highly controversial and remains far from settled. Approval was given, despite warnings that procedural and scientific requirements had been by-passed and that adequate clinical trials had not taken place. The FDA was said to be under pressure from Congress and the Clinton Administration and relaxed safeguards used in the original clinical trials. This meant for instance, that women are not required to have an ultrasound to determine if a pregnancy is ectopic or not, a situation which could cause life-threatening complications.

From 2000 to October 2004, the FDA recorded 676 adverse events following 350,000 applications. These ranged in severity from minor symptoms such as nausea and dizziness to serious complications such as blood loss, ectopic pregnancy, and rare bacterial infections which have been fatal in some cases. But the true number of adverse reactions remains unknown as reporting to the FDA is not mandatory but is entirely voluntary— even if that adverse reaction results in death.

At least 10 deaths have been associated with the use of RU-486 around the world.

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|---------------------|-------------------|
| One: | France April 1991 |
| One: | Canada 2001 |
| Brenda Vise: | USA Sept 2001 |
| Holly Patterson 18: | USA Sept 2003 |
| Vivian Tran 22: | USA Dec 2003 |
| Rebecca: | Sweden June 2003 |
| Two: | UK Jan 2004 |
| Chanelle Bryant 22: | USA Jan 2004 |
| Oriane Shevin 34: | USA May 2005 |

The parents of Ms Patterson, Ms Tran, and Ms Bryant are all suing Danco, the US manufacturer of RU-486, claiming that the company failed to warn their daughters of the dangers.¹

There may in fact be more deaths and complications associated with the use of RU-486 but we have no way of knowing the true number. It is entirely possible that RU-486 is not as safe as many would have us believe.

As recently as 23/11/2005, the *New York Times* (NYT) reported that recent deaths associated with RU-486 have forced the FDA to plan another review for early 2006. The NYT reports “stumped officials from the FDA and the federal Centre for Disease Control and Prevention have decided to convene a scientific meeting early next year to discuss this medical mystery, according to two drug agency officials who spoke on the condition of anonymity because of the sensitivity of the topic.”

Given the current controversy in the USA it would seem extremely imprudent for Federal Parliament or the TGA to rush into allowing or encouraging the widespread use of RU-486 in Australia.

Ultimately RU-486 is not just any drug

Mifepristone or RU-486 is not just any drug but is designed to induce a chemical abortion by blocking progesterone, a hormone required for the continuation of pregnancy. A second drug, misoprostol is given 48 hours later to cause uterine contractions to help expel the embryo.

This action places it in a special class of drug as it brings about a do-it-yourself abortion. It is not truly therapeutic in action, as it is not given to cure or treat disease but rather to end life, in this case the life of a human embryo or fetus and is therefore an abortifacient. It is therefore appropriate that it continues to be classed amongst "restricted goods" in subsection 3(1)

Increasing community concern about abortion

Over the last 30 years abortion has become a very common surgical procedure and yet there is growing community concern over whether it is really a pro-woman option. Increasingly we are hearing from women who have experienced an abortion that abortion only exacerbated their problems and in some cases, triggered severe and prolonged psychological distress.

A long-term study of New Zealand women published this month by Professor Fergusson, a psychologist and epidemiologist at the Christchurch Schools of Medicine and Health Sciences, found that abortion was not without severe long term psychological consequences. Professor Fergusson said the study was conducted to address the lack of reliable evidence on the mental health effects of abortion."The issue is not a trivial one," he said. "Abortion is the most common medical or surgical procedure young women undergo, by far, (and) there are potential adverse reactions. "²

By the age of 25, the study found 42 per cent of those who had had an abortion had also experienced major depression during the previous four years.³ They also found that those having an abortion had elevated rates of subsequent mental health problems including anxiety, suicidal behaviours and substance use disorders. This association persisted after adjustment for confounding factors.⁴

The results surprised the authors who described themselves as "pro-choice." Yet other studies also show that abortion can undermine women's health and well-being. A new 13- year study of the entire population of women in Finland found that deaths from suicide, accidents and homicide are 248% higher in the year following an abortion compared to women who have not been pregnant in the prior year.⁵

Abortion and broken relationships

High rates of abortion in Australia also have other dramatic impacts and often-unforeseen consequences. Researchers and counsellors are learning that abortion can adversely affect relationships between couples⁶ and that many couples are unable to maintain a relationship once there has been an abortion. Vicki Thorn, psychologist and counsellor (Project Rachel USA) estimates that as many as 70% of relationships end after an abortion.⁷ Researchers are also finding that women with a history of abortion are also significantly more likely to go through subsequent divorces.⁸ Australia is also witnessing a high rate of relationship break-up and abortion may be one of the factors undermining the establishment of successful long-term relationships.

Abortion as first resort rather than a last resort?

Abortion has become so common that it is often the first thing women are offered. Sadly sometimes it is the only thing women are offered. The “right to choose” has almost become an “obligation to choose” abortion. Yet more abortion is not what the community wants.

A major study carried out in 2005 by the *Southern Cross Bioethics Institute (SCBI)* into Australian’s attitudes to abortion found around 63% to 73% of Australians believe that the current rate of abortion - around 1 in 4 pregnancies - is too high. And 87% believe that it would be good if the numbers of abortions could be reduced while maintaining existing legal rights to freely choose abortion.⁹

Caroline Westoff, an obstetrician and gynaecologist told the *New York Times* that “one of my real, and I think realistic, hopes for this method (RU-486) is that it will help get abortion back into the medical mainstream and out of this ghettoised place its been in”¹⁰ Yet in the light of the *SCBI* research it seems likely that most Australians would be concerned about the introduction and widespread use RU-486 especially if there was any likelihood that it would maintain or even increase or the current numbers of abortions, or “normalise” abortion. It seems likely that also that they would not want decisions of such importance left to the TGA.

The Catholic Church, along with many Australians is also concerned about the high incidence of abortion. The Catholic Church has always taught and continues to teach that no reason, no matter how sad or tragic can ever justify that taking of the life of an innocent unborn child. The Church teaches that every life from the moment of conception much be respected, defended and welcomed.¹¹

Yet the Catholic Church also reaches out to all who have been wounded by abortion and offers them healing and help¹² through programs such as Project Rachel. The Church does not want to see the destructive effect of abortion continue to have such a profound impact on women and on our society. The Catholic Church believes that pregnant women need the help and support of the community to allow them and encourage them to continue with their pregnancies and establish families.

High rate of abortion a failure of public policy

New methods of abortion will not solve Australia’s abortion problem. Abortion by any means remains a sad and tragic choice. Whichever way it is done, abortion is a reflection that as a society we are not addressing the real needs of women and men. Few women really want an abortion, much less a do-it-yourself one.

Widespread availability of RU-486 will do nothing to reduce the numbers of abortions taking place. It will not solve the child versus the continuing education/career problem many women face. It will not make abortion easier. It will not make relationships healthier. It will still leave women grieving. Abortion is not a panacea nor is RU-486.

It is time that our nation faced the difficult and unpleasant fact that abortion by any means harms men, women and children.

The whole area of abortion deserves renewed thought and effort in order to come up with new initiatives and better public policies which are supportive of vulnerable women and children. Efforts to make RU-486 widely available will only add to our problems not solve them. If we are to truly improve the lives of the next generations of Australians and

find new ways of reducing numbers of abortions that occur each year then we must all work together in a spirit of good will. This is the only way to truly strengthen the bonds between couples and within families and to build a healthy society.

Thank you for your invitation to make a submission to the Australian Senate Community Affairs Legislative Committee. I would be happy to discuss my submission further should that be helpful. I can be contacted on (03) 9412 3373 or mriordan@jp2institute.org

Yours sincerely,

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Endnotes

¹ *New York Times* 23/11/05

² Julie Rowbottom, "Abortion linked to mental risk" *The Age* 3/1/06

³ Greg Tourelle, "Abortion raises depression risk, say NZ researchers" *The New Zealand Herald* (4/1/06)

⁴ Fergusson, David M., John Horwood, L. & Ridder, Elizabeth M., "Abortion in young women and subsequent mental health. (2006)" *Journal of Child Psychology and Psychiatry* **47** (1), 16-24.

⁵ M.Gissler et al., "Injury deaths, suicides and homicides associated with pregnancy, Finland 1987-2000," *European J. Public Health* 2005 15(5): 459-63

⁶ Burke T, "Forbidden Grief: The Unspoken Pain of Abortion," 2002 (Springfield: Acorn Books), Belsey EM et al, "Predictive Factors in Emotional Response to Abortion: King's Termination Study –IV," *Soc. Sci & Med.*, (Chap 3, no 2)

⁷ Vicki Thorn, in 1984 founded *Project Rachel* USA, & National Office of Post-Abortion Reconciliation and Healing, the Catholic Church's Healing Ministry for women who have had abortions- see aftermath of abortion <http://www.noparh.org/>

⁸ Teresa Burke *op cit* p 203, J.R Cogle, DC Reardon, and PK Coleman, "Depression associated with abortion and childbirth: A long term analysis of the NLSY cohort,' *Arch. Women's Mental Health* (2001)3(4) Suppl. 2:105

⁹ Fleming J I, Ewing S. "Give Women Choice: Australia Speaks on Abortion," Southern Cross Bioethics Institute, 26 April 2005 also <http://www.bioethics.org.au/>

¹⁰ *New York Times* 11/7/1999

¹¹ Catechism of the Catholic Church, 1994 (Homebush: St Paul's) # 2270-2276, John Paul II. *Evangelium Vitae*: Encyclical Letter on the Value and Inviolability of Human Life, (Homebush: St Paul's), 1995, # 62

¹² John Paul II. *Evangelium Vitae*: Encyclical Letter on the Value and Inviolability of Human Life, Homebush: St Paul's, 1995, especially see # 99 "Special words to Women who have had an abortion"