

Submission relating to the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU-486) Bill 2005

by Martin Shanahan

The simple fact that large numbers of surgical abortions, estimated variously at between 60,000 to 80,000 per year depending on interpretation of information made available by State Government authorities and the Health Insurance Commission with respect to Medicare claims against certain Item Numbers, are already performed in Australia does not of itself provide justification for facilitating easier access to a chemical, or “medicine”, such as RU-486.

Contrary to assertions made by Dr Christine Tippet representing the RANZCOG on the first day of public hearings of this Committee,¹ world-wide maternal death rates when RU-486 is administered in accordance with the manufacturer’s instructions – that is in the first 49 and up to not later than 63 days of a pregnancy – are ten (10) times higher than maternal morbidity for surgical abortion. So dangerous and costly does the Government of the People’s Republic of China believe this drug to be that it halted access through pharmacies whether or not it is prescribed by a medical practitioner – this decision is in the context of China’s highly regulated, rigidly enforced and intensely anti-human rights population control program.²

RU-486 is a “medicine” that has a primary purpose, the ending of a human life. That is a matter of public policy and continuing scrutiny by Parliament, not an administrative body with statutorily prescribed and precisely delineated powers of assessment, review and control.

The Therapeutic Goods Administration (TGA) is established to ensure that medicines (and medical devices) meet stringent standards with respect to efficacy, safety, distribution and marketing. Given the primary purpose for which RU-486 is designed and intended, there is no way that the TGA can find that chemicals such as those incorporated in RU-486 are safe for unborn children and thus permit its use, unless Parliament directly or indirectly says that the TGA may in fact do so.

The amendments to the Act contained in this Bill ensure that the TGA is invited to sanction access to a drug with a chemical formulation explicitly designed to end the life of an unborn child.

RU-486 or similar “medicines” made from chemicals of the same class as those found in current formulations of RU-486 are more dangerous than chemicals associated with teratogenic “medicines” such as Thalidomide. Refer Appendix 1

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Substantial research now exists demonstrating a high correlation between the level of abortion rates and the incidence of child abuse.^{3,4}

Abortion is directly associated with significant and substantial increases in the incidence of depression⁵ and a variety of self-destructive behaviours including alcohol abuse, addiction to prescription and non-prescription (though lawfully obtained) medicines and use of damaging so-called “street drugs”.⁶

Abortion, whether undertaken by surgical or medical (RU-486) means, incurs a significant economic burden on the whole community. Abortion directly harms a substantial number of women.⁷ Abortion is always fatal for the unborn child, a human individual at perhaps the most defenceless time of its life.

Use of RU-486, a progesterone inhibitor designed to halt maternal capacity to keep an unborn human being alive in utero, also requires use of a second powerful chemical. Misoprostol, a prostaglandin, is administered typically three (3) days after administration of the initial dose of Mifepristone, to force a woman to commence contractions to expel the dead child from her body.

Pfizer manufactures and markets Misoprostol, under the brand name Cytotec. This product was developed for the treatment of ulcers. Originally, Cytotec was manufactured by Searle and Searle explicitly refused to recommend this drug for use in relation to abortion and opposed its use for these purposes.

In a letter to 200,000 healthcare professionals and doctors in the United States dated 23rd August 2000, Searle included the following warning:

“Serious adverse events reported following off-label use of Cytotec in pregnant women include maternal or fetal death; uterine hyperstimulation, rupture or perforation requiring uterine surgical repair, hysterectomy or salpingo-oophorectomy; amniotic fluid embolism; severe vaginal bleeding, retained placenta, shock, fetal bradycardia and pelvic pain.”⁸

Searle is now part of the Pfizer pharmaceutical group. The patient product information sheet included with Cytotec currently states that “Cytotec can cause abortion (sometimes incomplete which could lead to dangerous bleeding and require hospitalization and surgery), premature birth, or birth defects. It is also important to avoid pregnancy while taking this medication and for at least one month or through one menstrual cycle after you stop taking it. Cytotec has been reported to cause the uterus to rupture (tear) when given after the eighth week of pregnancy. Rupture (tearing) of the uterus can result in severe bleeding, hysterectomy, and/or maternal or fetal death.”⁹

The objective of the *Therapeutic Goods Act 1989*, which came into effect on 15th February 1991, is to provide a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices. This is clearly set out in Section 4 (1) (a) of the Act.

Section 4 (1) (b) of the same Act specifies that the Parliament also seeks to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

Section 3 of this Act defines a “poison” as “an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury”. RU-486 is unequivocally a poison. The TGA is, if the Bill being considered becomes law, being granted powers to permit access to a chemical formulation that is, in absolute terms, more dangerous to unborn children than the teratogenic Thalidomide.

Therapeutic Goods Administration (TGA) is a unit of the Australian Government Department of Health and Ageing and is responsible for administering the provisions of the legislation.

The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. At the same time the TGA is structured to ensure that the Australian community has access, within a reasonable time, to therapeutic advances. It is difficult to see how a drug formulation that is 100% fatal to unborn children and 1000% more likely to cause maternal death when administered as specified by its manufacturer can in any way be considered a “therapeutic advance”.

This Committee is considering a legislative change intended to facilitate access to a drug designed to kill.

Please, advise that the Bill be withdrawn. Please, recommend that the Bill be defeated if put to a vote in the Senate.

Members of this Committee have an opportunity to protect many Australian women and many more unborn Australians.

Initial proponents of this legislative change argued that it was required to assist women without access to medical services such as those available to people in Australian cities. It was also argued however that this so-called “medicine” would still be administered under appropriate medical supervision. It was said that after the initial dose of Mifepristone, patients would return to their doctor and have the dose of Misoprostol administered and that fourteen (14) days after the initial dose of Mifepristone, patients

would be examined to ensure that the uterine contractions had indeed expelled the whole of the dead child.

Yet in January 2006, three doctors who work at the hospital in the Victorian regional town of Mildura indicated that they were seeking approval from their hospital's ethics committee to use RU-486. If approved by that committee, they would make application to the TGA for approval to access RU-486 knowing that this would lead to a referral to the Minister under the existing provisions of the Act.

The three doctors argued that as hospitals in the Christmas / New Year period are too crowded to provide abortion services to those who want them, RU-486 offers a way to get women out of hospitals, free up medical facilities – the drug would be used at home and women will be able to manage the process with less assistance and intervention than is required by a surgical abortion. The woman will just experience a “miscarriage”.¹⁰

Dr. Pettigrew, one of the three Mildura applicants, is quoted as saying that “apart from giving the women an option to have either medical or surgical termination, the use of RU-486 would enable most women to have the option of having the miscarriage at home and hence save all the travel time”.¹¹

Regrettably, many years of psychiatric research show conclusively that this is flawed thinking.

Abortion, whether medical or surgical, is **contra-indicated** where there is an adverse existing psychological or psychiatric condition in the patient.¹² The detailed reports published annually in South Australia stipulating the reasons for a pregnancy termination, an abortion, consistently show that more than 90% of abortions in South Australia are carried out for psychological or psychiatric reasons.¹³ Given the evidence this is cause for great concern.

The psychological and psychiatric detritus of an abortion frequently appears many years after the abortion takes place. Exposing Australian women to yet one more complication in a healthcare system that has now exposed hundreds of thousands of Australian women to the perils of unrecognized mental health illnesses is unreasonable and bad medicine.

Why has an organization such as “beyondblue” been established? Why is depression now seen as the greatest risk to health in Australia? The link from increased abortion rates in the early 1970s through to the explosion in diagnoses of clinical depression across, in particular the female part of, the Australian community is direct. Associated with that is the widespread increase of violence in domestic relationships and appalling increases in the rates of child abuse.

Ours is a violent society. We do not imbue members of our community with a sense of responsibility for those in need when we tolerate the deliberate killing of 60,000 to 80,000 Australian children every year.

Taking the lower number to establish an Australia-wide base-line, the chilling reality is that since approximately 1972, some 1,980,000 abortions (60,000 by 33 years) have adversely affected abortion survivors: the mothers who survived the trauma of participating willingly or unwillingly, in the death of their child; the fathers who either knowingly and willingly supporting, or unable to stop, the actions of the mother of their child, have participated in the destruction of that child.

While a proportion of women have had repeat abortions, it is truly a disheartening reflection when one realizes that more than one million, and probably closer to one and a half million, Australian women have had at least one abortion.

This epidemic needs serious attention if it is to be slowed. Introducing yet one more killing tool to the assembly line of techniques already available to cause childhood death in this country just makes no sense. It is poor medicine, poor economics, poor mental health, and plain poor science.

Please do not recommend support for the proposed changes to the Therapeutics Good Act that are intended to remove Ministerial responsibility for direct control of what is now quite properly, on medical, psychiatric, psychological and economic grounds, a barred substance.

Martin Shanahan
14th January 2006

Appendix 1: Definition of Teratogenic Drugs

Teratogenic drugs: A teratogen is an agent that can disturb the development of the embryo or foetus. Teratogens can halt a pregnancy or more commonly produce a congenital malformation (a birth defect). Classes of teratogens include radiation, maternal infections, chemicals, and drugs.

Drugs capable of acting as teratogens include:

ACE (angiotensin converting enzyme) inhibitors such as:

- benazepril (Lotensin);
- captopril (Capoten);
- enalapril (Vasotec);
- fosinopril sodium (Monopril);
- lisinopril (Zestril, Prinivil);
- lisinopril + hydrochlorothiazide (Zestoretic, Prinzide)
- quinapril (Accupril); and
- ramipril (Altace);

Acne medication isotretinoin (Accutane, Retin-A);

Alcohol ingested chronically or in binges;

Androgens (male hormones);

Antibiotics: tetracycline (Achromycin), doxycycline (Vibramycin) and streptomycin;

Anticoagulant (blood-thinner): warfarin (Coumadin);

Anticonvulsants (seizure medications) such as:

- phenytoin (Dilatin);
- valproic acid (Depakene, Valproate);
- trimethadione (Tridione);
- paramethadione (Paradione); and
- carbamazepine (Tegretol);

Anti-depressant drug: lithium (Eskalith, Lithob);

Antimetabolite / anticancer drugs: methotrexate (Rheumatrex) and aminopterin.

Antirheumatic agent and metal-binder (chelator): penicillamine (Ciprimene, Depen).

Antithyroid drugs such as:

- thiouracil/propylthiouracil; and
- carbimazole/methimazole;

Cocaine;

DES (diethylstilbestrol): a hormone; and

Thalidomide (Thalomid): approved by the FDA for the treatment of a complication of leprosy (erythema nodosum leprosum).¹⁴

¹ Dr. C.G. Tippet, CA38, Senate Legislation, 15th December 2005

² Beijing Morning Post, 9th October 2001

³ Ney, P. Fung, T., Wickett, A.R., "Relationship between Induced Abortion, and Child Abuse and Neglect: Four Studies," *Pre- and Perinatal Psychology Journal* 8(1):43-63

Psychiatr. J. Univ. Ottawa., Fall 1993; Benedict, M., White, R., and Cornely, P., "Maternal Perinatal Risk Factors and Child Abuse" *Child Abuse and Neglect* 9:217-224 (1985); Lewis, E., "Two Hidden Predisposing Factors in Child Abuse," *Child Abuse and Neglect* 3:327-330 (1979); Ney, P., "Relationship between Abortion and Child Abuse," *Canadian J. Psychiatry* 24:610-620 (1979).

⁴ Coleman, P.K., Maxey, C.D., Rue, V.M., and Coyle, C.T., "Associations between voluntary and involuntary forms of perinatal loss and child maltreatment among low-income mothers", *Acta Paediatrica*, Vol. 94, 10:1476-1483, October 2005

⁵ Fergusson, D.M., Horwood, J.L., Ridder, E.M., "Abortion in young women and subsequent mental health", *Journal of Child Psychology and Psychiatry and Allied Disciplines*, Vol. 47, 1:16-24, (January 2006). The Abstract accompanying this article includes the following note:

"Data were gathered as part of the Christchurch Health and Development Study, a 25-year longitudinal study of a birth cohort of New Zealand children.

Information was obtained on:

- a) the history of pregnancy/abortion for female participants over the interval from 15–25 years; b) measures of DSM-IV mental disorders and suicidal behaviour over the intervals 15–18, 18–21 and 21–25 years; and
- c) childhood, family and related confounding factors.

Results: Forty-one percent (41%) of women had become pregnant on at least one occasion prior to age 25, with 14.6% having an abortion. **Those having an abortion had elevated rates of subsequent mental health problems including depression, anxiety, suicidal behaviours and substance use disorders.**" (Emphasis added)

⁶ Ney, P.G. and Wickett, A.R., "Mental Health and Abortion: Review and Analysis", *Psychiatr. J. Univ. Ottawa*, Vol.14, 4:506-516 (1989)

⁷ Gissler M., Berg C., Bouvier-Colle M.H. and Buekens P., "Pregnancy-associated mortality after birth, spontaneous abortion or induced abortion in Finland, 1987-2000", *Am. J. Ob. Gyn.*, 2004; 190:422-427

⁸ <http://www.fda.gov/medwatch/safety/2000/cytotec.htm>

⁹ http://www.pfizer.com/pfizer/download/ppi_cytotec.pdf

¹⁰ <http://www.abc.net.au/news/newsitems/200601/s1543562.htm>

¹¹ <http://www.theage.com.au/news/national/doctors-apply-to-prescribe-abortion-pill/2006/01/07/1136609985238.html>

¹² Ney, P.G. and Wickett, A.R., refer Endnote 5 above

¹³ The most recent Annual Report contains information relating to 2003 and was published in June 2005. The Report is prepared by the Adelaide based Pregnancy Outcome Unit, Epidemiology Branch, in the South Australian Government's Department of Health, www.dh.sa.gov.au/pehs/pregnancyoutcome.htm

¹⁴ <http://www.medterms.com/script/main/art.asp?articlekey=9334>

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