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Committee Secretary
Community Affairs Committee
Department of the Senate
Parliament House
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SUBMISSION TO THE INQUIRY OF THE THERAPEUTIC GOODS AMENDMENT (REPEAL OF MINISTERIAL RESPONSIBILITY FOR APPROVAL OF RU-486) BILL 2005

Members of the Community affairs committee:

Medical evidence indicates that RU-486 is unsafe:

More and more medical evidence is being cited which indicates that RU-486 is unsafe. It is clear that the extent to which RU-486 has affected the health and lives of women around the world is uncertain. According to the regulations established by the American Food and Drug Administration (FDA) Medical Doctors and abortion providers are not required to report adverse events of RU-486 to the FDA, only drug makers are. It has only been through the action of concerned family and friends of women and girls who have died after taking RU-486 that the degree of its many adverse effects is becoming more publicly known. It is reprehensible that multiple deaths have to occur in order for the safety of a product to be investigated. It is even more disappointing that the Australian government is considering making RU-486 readily available when there are well known and documented fatal complications associated with this drug.

Several deaths that have occurred in the USA and across Europe have all been linked to RU-486. A resent article published by Ralph P. Miech, M.D., Ph.D. (Associate Professor Emeritus, Department of Molecular Pharmacology, Physiology and Biotechnology, of Brown University's Medical School) in *The Annals of Pharmacotherapy* described two ways in which Mifepristone (generic name from RU-486) can interfere with the immune system, contributing to the development of an infection and ultimately leading to possible death.[1]

Clostridium sordellii is a bacterium that is part of the normal vaginal flora of about 10% of women. RU-486 can bring about a toxic bacterial infection as it causes cervical dilation and the loss of the mucus plug, which separates the uterus and cervix from the vagina during pregnancy. This then allows the bacterium (*Clostridium sordellii)* to enter the cervix and grow rapidly off the decaying embryonic tissue.

[1] Miech, Ralph. "Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium sordellii," *The Annals of Pharmacotherapy*, **39**:1483-8, September (2005).

At the same time RU-486 also interferes with the body's immune system, weakening it so that it cannot respond effectively to this new infection. The infection therefore spreads rapidly and once the toxins enter the blood stream, there is no cure.

One of the problems in diagnosing the presence of *clostridium sordellii* is that the symptoms are very similar to those of RU-486 such as excessive cramping and bleeding. Medical professionals have also highlighted such difficulties in accurate and timely diagnosis of the bacteria.[2] It is therefore extremely questionable how a young frightened teenager would be able to determine the difference and seek appropriate help. Particularly, when she may be choosing to have an abortion in secret as she feels that she cannot talk to her friends or family in this situation.

We only need to look at the number of documented cases of deaths[3] related to RU-486 and the supporting medical evidence to conclude satisfactorily that RU-486 is unsafe for use. The US medical authorities now have called for a review of RU-486 that will be held in early 2006. It seems that any action to introduce RU-486 here in Australia before the results of such an investigation are made public would be failing to look out for the best interests and health of women and girls in Australia.

If the drug is to be available through the TGA how will it be monitored?

Given the high risk of medical complications associated with RU-486 including-excessive bleeding, allergic reactions, infections, and death, it is important to consider how this drug would be monitored if it were to be made available through the TGA.

RU-486 abortions in France for example are performed at government-operated hospitals and clinics, typically with or adjacent to emergency room facilities. A 1990 directive jointly signed by the French Republic's Director General of Health, Director of Hospitals and Director of Pharmacy and Medication, states that whenever prostaglandins (e.g. mifepristone) are given "in association with RU 486" the "following technical conditions ... are indispensable and are to be followed: ... b) The doctor must ensure that diagnostic instruments and machines are close by, such as electrocardiogram equipment and particularly resuscitative cardiopulmonary equipment (including nitrous oxide and injectable calcium antagonists and a fibrillator)... c) Clinical observations and blood-pressure readings every half hour are indispensable for several hours following the administration of these drugs. d) Whenever there is chest pain, an electrocardiogram should be taken on the suspicion of rhythm troubles and in case of significant lowering of blood pressure" (April 12, 1990 letter from the French Republic, Department of Solidarity, Health and Social Protection, reprinted in *Child & Family* 21:102-103, 1990).

In Sweden, women are "supervised by the midwife for 4 to 6 hours at the outpatient clinic" (M. Bygdeman *et al*., "Medical Termination of Early Pregnancy: The Swedish Experience," *Journal of the American Medical Women's Assn.* ["*JAMWA*"], Supplement 2000, 55:3; 195, 196).

In China "the emphasis on close medical supervision is well accepted.... It is stressed that misoprostol should be taken in the clinic and followed by several hours of observation" (S. Wu, "Medical Abortion in China," *JAMWA*, Supplement 2000 at 197, 199). The long observation is one-reason staff in some large hospitals in China are growing reluctant to prescribe the drug

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[2] Fisher. M. *et al* "Fatal Toxic Shock Syndrome Associated with Clostridium sordellii after Medial Abortion," *New England Journal of Medicine*, **353**: 2352-60 (2005).

[3] According to the FDA in the United States 4 women have died as a result of taking RU-486. There have also been reported deaths in Sweden, United Kingdom, France and Canada. See www.RU486Facts.org.

combination: “The number of medical abortions has decreased recently in some of the large hospitals. The staffs were too busy to handle the procedure (more counselling, more visits, and observation), and they also have to manage the referred cases with serious side effects and complications”(*Id.* at 199).

Trends seen in American since the introduction of RU-486 demonstrate that there is little or no follow up care for women. Whilst it is recommended that women have access to medical treatment for a period of time after taking RU-486, it is left up to the discretion of the individual who is taking the drug. The inability of the medical profession to protect young and venerable women is grave failure of behalf of the medical profession whose first priority is to “do no harm”.

Further, one of the arguments which is being used to promote greater access of RU-486 is so that women can have their abortion at home in private. This argument however contradicts the recommended safe use of this drug and places the women at risk of further complications.[4] The follow up medical examination after taking RU-486 for example is essential as in at least 5-8% of cases the abortion is incomplete or unsuccessful and a surgical abortion will be required. There is therefore reason for serious concern regarding how women will be protected and cared for after taking this drug if it becomes readily available through the TGA. Of particular concern are girls who become pregnant who are under the age of legal consent and who seek to use RU-486 to have an abortion. Young girls in this situation may not understand the full consequences and effects of their actions and may be unwilling to consult with a parent or other adult for fear of the consequences. Strict regulations on the administration of RU-486 would be necessary in order to protect women in such demographics.

If this drug were to be made accessible through the TGA it is recommended that there ought to be some strict regulation regarding its use such as supervised administration of the drug in a hospital setting and appropriate follow up (as is conducted in some countries in Europe). It is also recommended that RU-486 be accessible only through a specialist such as a gynaecologist, who is able to take responsibility for the follow up care involved. For example a GP may not be suitably equipped and informed to manage care of a woman who has taken RU-486. It is irresponsible of the medical profession and the government if it were to make RU-486 available through the TGA and not provide such appropriate specialist care.

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[4]The Guidelines given with the drug mifepristone indicate that the woman needs to visit her medical provider on three occasions and have access to follow up care. The following is taken from the guidelines that come with the drug:

How should I take Mifeprex?

Day 1 at your provider’s office:

- Read this MEDICATION GUIDE.
- Discuss the benefits and risks of using Mifeprex to end your pregnancy.
- If you decide Mifeprex is right for you, sign the PATIENT AGREEMENT.
- After getting a physical exam, swallow 3 tablets of Mifeprex.

Day 3 at your provider’s office:

- If you are still pregnant, take 2 misoprostol tablets.
- Misoprostol may cause cramps, nausea, diarrhoea, and other symptoms. Your provider may send you home with medicines for these symptoms.

About Day 14 at your provider’s office:

This follow-up visit is very important. You must return to the provider about 14 days after you have taken Mifeprex to be sure you are well and that you are not pregnant.

Your provider will check whether your pregnancy has completely ended. If it has not ended, there is a chance that there may be birth defects. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy.

What about the long-term effects of taking RU-486?

Whilst there is many documented detrimental physical effects related to the use of RU-486, there has been little evidence to demonstrate the long-term effects of RU-486 on women. The psychological effects of RU-486 abortions on women for example may be considerable. As RU-486 is approved for use up to 49 days, women may deliver a foetus that looks like a tiny baby that she then must discard. It is questionable that this process in itself will have significant effects on a woman such as psychological distress, feelings of grief and regret. A resent study conducted by Dr. David M. Fergusson and published in the *Journal of Child Psychology and Psychiatry* found that compared to women who had never been pregnant and women who had been pregnant but never had an abortion, women who had abortions were at a higher risk for suicide, major depression, anxiety disorder and drug dependence.

More and more documented evidence indicates that women who have abortions can suffer from Post abortion syndrome, anxiety and depression.[5] The impact of RU-486 therefore may have long lasting effects on women. Through allowing the use of this drug to become widespread there may be significantly associated widespread social problems among women who choose to use it.

Summary:

It is false to assume that allowing RU-486 to be more widely accessible through the TGA is a better solution for all women. There is no doubt that use of RU-486 as a chemical abortifacient is dangerous. The current investigation into the use of this drug in the United States ought to encourage caution. RU-486 is dangerous to women's health. It is not an easy solution to the problem of unplanned pregnancy but potentially has long lasting and fatal effects. Woman facing an unplanned pregnancy deserve to have real options and supports. Women deserve better than RU-486.

This submission rejects the proposed Bill to remove responsibility for approval of RU486 from the Minister for Health and Aging and provide responsibility to the Therapeutic Goods Administration (TGA).

It recommends that the 1996 amendments to the Therapeutic Goods Act 1989 be maintained without any amendment.

Yours truly,

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[5] Common psychological problems include suicide, alcohol and drug abuse, eating disorders, relationship breakdown and repeat abortions. The following articles document and explain Post Abortion Syndrome. A. Speckhard & V. Rue, "Post Abortion. Syndrome: An Emerging Public Health Concern", *Journal of Social Issues*, **48**, 3, (1992). E.J. Angelo, "Psychological Sequelae of Abortion", Linacre Quarterly. **59**, 2, May (1992) and P. Ney *et al*., Mental Health & Abortion, *Psychiatric Journal of Ottawa*, **14**, 4, (1989).