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SUBMISSION

Committee Secretary
Community Affairs Committee
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RU486 was designed specifically to end an innocent human life. This makes it unique. It is not simply another drug, and should not be treated as just another drug.

Arguments for amending the Therapeutic Goods Administration Act to remove responsibility for the importation of this drug from the Health Minister and the Parliament should be firmly resisted.

RU486 kills. It is designed to kill innocent, defenceless, unborn babies. It has also killed some of their mothers and has injured many more.

RU486 is a two drug regimen consisting of mifepristone and misoprostol. Mifepristone works by blocking progesterone receptors. Progesterone is the hormone which sustains the life of the baby in the womb. Without it, the lining of the womb breaks down and the baby detaches and dies through lack of sustenance. Misoprostol is a prostaglandin which causes uterine contractions, expelling the now dead baby from the womb. This is the stuff nightmares are made of.

According to the Food and Drug Administration in the USA, there have been over 800 reported adverse reactions to RU486 in the United States since the drug was approved for use there in 2000. The FDA has also stated that only about ten percent of cases are actually reported, so the number of women adversely affected by RU486 could number in the thousands. More serious than the injuries, are the deaths of at least four young women in California since 2003. Their deaths have been directly attributed to mifepristone-induced septic shock due to a serious bacterial infection, Clostridium sordellii.

Doctor of pharmacology and researcher, Professor Ralph P Miech, wrote in the September 2005 issue of *The Annals of Pharmacology* that mifepristone causes changes in the cervix that allow C. sordellii, a common vaginal bacteria, to enter the cervical canal. Dr Miech explained, "C sordellii thrives in this low-oxygen environment and derives nutrition from the decaying fetal tissue". He

added that C. sordellii infections are "rare outside of mifepristone use."

As a result of these deaths in California and another in Canada, also as a result of a C. sordellii infection, a Congressional Subcommittee has begun a major investigation into the safety of RU-486 (mifepristone). The Chair of this Subcommittee, Congressman Mark Souder (R.-Ind), wrote to the US Food and Drug Administration (FDA) on December 21st regarding FDA's investigation into the RU-486 deaths:

"Each of the four women who died from septic shock were infected by Clostridium sordellii, a potent anaerobic bacteria. It is also known that a Canadian woman died from septic shock linked to C. sordellii after taking RU-486. These women did not possess other risk factors or underlying medical conditions that would have predisposed them to sepsis. In general, they were young and healthy….although these women complained of weakness, nausea and vomiting, these symptoms are consistent with the medical abortion procedure, and they had no fever to indicate an infection. Nevertheless, each woman died soon after being hospitalized."

In his letter, Congressman Souder referred to an article published in the New England Journal of Medicine summarizing the results of an investigation into the fatalities by the FDA and the Centers for Disease Control (CDC). (Marc Fischer, M.D. et al., *Fatal Toxic Shock Syndrome Associated with Clostridium sordellii after Medical Abortion*, 353 N. Engl. J. Med. 2352 (2005). He wrote, "An article accompanying the New England Journal of Medicine Report notes that RU-486 abortions present patients with a ten times greater risk of death than surgical abortions done early in pregnancy."

The FDA is expected to respond to a series of questions posed by Congressman Souder on behalf of the Subcommittee no later than 12.00pm, Monday, February 6th 2006. US Senator Jim DeMint (R.-S.C.) told the Baltimore Sun that the FDA had told him that RU486 could be pulled from the market. He said, "Increasingly, they are aware that it is a dangerous drug."

The families of three of the Californian victims are suing the manufacturers of RU-486, Danco Laboratories, because the company failed to warn patients of the drug's dangers.

Here in Australia, the Women's Electoral Lobby (WEL) are singing the praises of a Briefing paper on RU-486 put out by Reproductive Choice Australia. This briefing paper makes for chilling reading.

Totally disregarding the French Health Departmental warning about the use of prostaglandins with RU-486, the Reproductive Choice Australia briefing paper casually reports that "In other countries, the women are provided with the prostaglandin tablets to take at home." Compare this with the French directive, issued by a joint committee of the French Republic signed by the Director of General health, the Director of Hospitals, and the Director of Pharmacy and Medicine after the RU-486 death of French mother, Nadine Walkowiak, in 1991. This directive states that whenever prostaglandins are given, cardiopulmonary resuscitation equipment and electrocardiographic machines be at standby, a defibrillator be available, calcium channel blockers drawn up in a syringe and vital signs be monitored over a period of several hours. (The French Republic. French Official Warn on Use of RU-486. *Child & Family* 21:102,1992)

The briefing paper referred to above lists several side effects, but there is no mention at all of the risk of death. A similar situation occurred ten years ago when Family Planning NSW and Family Planning Victoria were conducting trials of RU-486 in Australia without the knowledge of the then Health Minnister, Senator Graham Richardson. The trials were halted because, among other

irregularities, the consent forms were inadequate, failing to warn of the serious side-effects, eg death.

Those who advocate removal of responsibility from the Health Minister and Parliament, boast that "millions of women worldwide have safely used mifepristone regimens". Not true. Millions of unborn babies have been killed by this human pesticide, and no one knows for sure just how many of their mothers have died or been seriously harmed as well.

What abortionists and their allies want is unrestricted access to abortion. If RU-486 is approved for the Australian market, it will take abortion out of separate clinics, operated by relatively few abortionists in the country, and into every medical practice and pharmacy in Australia.

Approval of RU-486 could also result in fast-forwarding the dream of pro-abortionists, the total decriminalization of abortion around the country. Existing laws in Queensland, NSW and Victoria carry penalties for anyone who gives a woman a noxious substance with the intention of causing her miscarriage. There are few substances as noxious as mifepristone.

It is ironic that the push for greater access to abortion should come at a time when more and more evidence is coming to light about the harm abortion causes women in particular. Apart from the growing recognition of post abortion trauma, there is the mounting evidence of the increased risk of breast cancer associated with abortion. Only this month results of a long-term study in New Zealand were released. The study showed that abortion raised the risk of women developing later mental health problems, including depression, anxiety, and drug and alcohol abuse. The leader of the New Zealand study was reported as saying that the results of the study could undermine the legal basis for access to abortion in jurisdictions, including NSW, in which termination is legal only if continuing the pregnancy would threaten the woman's physical or mental health.

Australia, like other Western nations, faces a serious problem of an ageing population. It is absolute madness to make available yet another method of killing off future generations of Australians.

Say NO to RU-486.