

13 January 2006

Elton Humphery
Committee Secretary
Community Affairs/Legislation Committee

Email: community.affairs.sen@aph.gov.au

Dear Mr Humphery,

RE: THERAPEUTIC GOODS AMENDMENT (REPEAL OF MINISTERIAL RESPONSIBILITY FOR APPROVAL OF RU486) BILL 2005

I write as Chairman of the Monash University Department of Obstetrics & Gynaecology.

I write with a unique perspective of this medicine, now generally known as Mifepristone.

I was the first author on the first international, peer reviewed, medical publication upon this medicine in 1985 (Journal of Clinical Endocrinology Metabolism 60: 1-4; 1985).

I was clinically involved in the medical care of the first American treated with Mifepristone – a young man with adrenal cancer, at the National Institutes of Health, USA.

As a specialist in Obstetrics & Gynaecology, I have had 20 years experience in the medical use of Mifepristone.

In 1986 I received approval through the Research & Ethics Committee, Queen Victoria Medical Centre, Melbourne to participate in a World Health Organisation Study of Mifepristone for treatment of a tragic obstetric complication where the fetus has died at the end of pregnancy but remains inside the uterus. This condition is called fetal death in utero.

This study was approved by the Australian Department of Health, Canberra. To my memory, this approval of Mifepristone, and its safety and efficacy by the Department of Health, Canberra, preceeded the formation of the Therapeutic Goods Administration branch of the Department of Health. Six pregnant women carrying a dead fetus at the end of their pregnancies were treated satisfactorily with Mifepristone and safely delivered.

I received a letter from the World Health Organisation (WHO), dated April 8, 1988, indicating that the pharmaceutical company Roussel-Uclaf headquarters in Paris had requested that I should not participate in further World Health Organisation multi centre trials using Mifepristone. WHO stated this request from Roussel-Uclaf was made following consultation with their representative in Australia who considered the political climate in 1988 unfavourable for carrying out such research.

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In 1994, I re-commenced studies with the World Health Organisation through Monash University and Family Planning Victoria of two WHO studies using Mifepristone.

These studies followed approval in May 1992 by the Therapeutic Goods Administration branch.

This work was subsequently published in various manuscripts (Medical Journal of Australia 167: 316-317; 1997 – The Lancet 353: 697-702; 1999).

Therefore, before the 1996 amendment to the Therapeutic Goods Act, it seems that Mifepristone had already been approved twice by the Australian Government, including on one occasion by the TGA.

It therefore is bewildering to me, that medication such as RU486 and other restricted goods cannot be evaluated, registered, listed or imported without the written approval of the Minister for Health and Ageing in 2006.

The 1996 amendment has damaged the health of Australian women by creating a climate of reproductive hostility. This has resulted in a lack of interest by pharmaceutical companies in applying for sponsorship and registration of such medicines in Australia.

Quite apart from emergency contraception and medical abortion, these medicines have also been used, not only for adrenal cancer and brain cancer, but also some forms of breast cancer and lung cancer.

I am unavailable on February 6. I would be privileged to assist the Committee if requested.

Yours sincerely,

PROFESSOR DAVID L HEALY
Chairman