

SUBMISSION TO THE INQUIRY INTO THERAPEUTIC GOODS AMENDMENT  
(REPEAL OF MINISTERIAL RESPONSIBILITY FOR RU-486) BILL 2005

Professor Caroline de Costa  
Department of Obstetrics and Gynaecology  
James Cook University School of Medicine  
Cairns Campus, PO Box 902  
Cairns QLD 4870

I am an obstetrician and gynaecologist practising in Far North Queensland, with responsibility for the care of women in remote and rural areas throughout Cape York. I also teach medical students in James Cook University School of Medicine, many of whom it is hoped will become rural doctors. I have practised obstetrics and gynaecology for 32 years, much of that time in remote rural areas. I have performed abortions, both early and late, and counselled many women considering abortion, and believe I have a very good understanding of the feelings of women faced with making the difficult decision about abortion for themselves.

Over the past few years I have become aware from the overseas literature of the increasing use of the mifepristone/misoprostol regimen for induced abortion. In May this year I attended the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists in San Francisco where this subject was discussed in depth (including the matter of the four deaths in California from *Clostridium sordellii* infection.) I became more fully aware of the safety and effectiveness of mifepristone/misoprostol and of the acceptability of the regimen to a large number of women. I have now read every study on this subject available in the medical literature in English and French and published since 1983 (well over 200 articles) and I am convinced of the usefulness and safety of the drug.

It was for this reason that I published in the *Medical Journal of Australia* of 3 October this year the article calling for the availability of mifepristone for Australian women, which has been largely responsible for re-igniting this debate.

Immediately the article appeared, the Australian Medical Association, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Rural Doctors' Association, the National Association of Specialist Obstetricians and Gynecologists and

many other individual members of the medical profession re-examined the scientific evidence and also came to the conclusion that the drug should be available to Australian women. It is also felt by many medical practitioners especially those with some experience of rural practice that the drug, used under appropriate medical supervision, would provide increased access to abortion for rural women who currently experience difficulty accessing safe legal surgical abortion.

(An example is in Far North Queensland – surgical abortion is available only in Cairns, where a small number are done in the public system, and the remainder in a private clinic. Women from Cape York or the Atherton Tablelands need to travel vast distances to access the service and are required to pay \$750 up front for a surgical abortion. However excellent hospital facilities for the care of women suffering spontaneous miscarriage or other complications of pregnancy, including the availability of ultrasound, exist in all the small towns throughout the region, including Atherton, Mareeba, Innisfail, Mossman, Cooktown, Weipa and Thursday Island, and hence the necessary back-up for the small number of women needing medical intervention in medical abortion could potentially be provided in all these places.)

I am well aware that all drugs licensed for use in Australia require rigorous assessment by the TGA and I believe strongly that mifepristone should undergo this objective process. There are indeed many drugs already in use in Australia as abortifacients, including misoprostol, gemeprost, Syntocinon, methotrexate and ergometrine, which have TGA approval. However mifepristone is the most efficient and has the least side effects.

It is essential that this inquiry be limited to the subject of the current ban on the drug, and not be extended into an argument about abortion per se. Abortion is legal, and safe, in all Australian states and territories; in most cases, abortions are carried out using surgical techniques but a significant proportion, as already stated, are by medical means. The debate should be about removing the very unusual power of the Federal Minister for Health to deny access for Australian women to this drug, and this drug alone, thereby limiting their health choices. This ban must be lifted and the opportunity given to the TGA properly to assess the drug.

Caroline de Costa