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Committee Secretary
Community Affairs Committee
Department of the Senate
Parliament House
Canberra ACT 2600

Submission to the Senate Community Affairs Legislation Committee Inquiry into A Bill for an Act to Repeal Ministerial Responsibility for approval of RU486 and for related purposes.

Background

For many years the Therapeutic Goods Administration (TGA) of Australia had been responsible for the pre-market evaluation, approval and monitoring of all therapeutic goods intended for supply in Australia.

Between 1991 and 1996 there had been two approvals for RU486 to be trialled as an abortifacient in Australia under the Clinical Trial Notification Scheme (CTN), and it would appear that 6 trials had been approved for non-abortion related research. (Senator Bob Woods, Senate Hansard p 814, 21 May 1996).

In May 1996 Senator Harradine successfully moved an amendment to the Therapeutic Goods Act 1989 (TGAct) to define RU486 and other abortifacient drugs as *restricted goods* (TGA 2.3) and to ban their trial, importation, registration or listing without the written approval of the relevant Minister (TGAs 6AA; s.23AA).

Senator Harradine was careful to insist that his amendment was not intended to ban the drug RU486, and the Senator's intentions were repeated in the parliamentary debate in speeches made by Michael Lee, MP (House of Representatives, 29 May 1996), the summing up speech by the Minister for Health, the Hon Michael Wooldridge, (House of Representatives, 30 May 1996) and others (eg Neil Andrews, House of Representatives, 30 May 1996). The Hon Dr Michael Wooldridge stated in relation to the Harradine amendment:

> "*this really does not change anything except that the delegated authority will not now be exercised by a public servant, but rather by the Minister responsible. The Senate will have some oversight of this.*" (p920 House Hansard, 30 May 1996).

Despite the stated intent of those supporting the amendment, however, Senator Meg Lees and some fellow senators predicted this amendment would effectively lead to a ban on the drug. She said:

> *"I obviously accept the right-indeed in this country we appreciate the right-to all have individual views, but I believe that by making this particular drug subjected to this second test, (i.e. Ministerial approval) it will simply deter manufacture. It will deter those people who have developed these drugs overseas from ever seeking approval in this country."* (Senate Hansard, p 576, 8 May 1996)

It seems that Senator Lees was right. Since 1996 no pharmaceutical company has applied for approval for the trialling, access or distribution of the now "restricted" drug, presumably anticipating that their (very costly) application would not succeed. Consequently, since 1996 Australian doctors and their patients have not had the option of access to Mifepristone, also known as RU486. It is effectively banned.

In the decade since the 1996 Harradine amendment, two things have happened.

Firstly, RU486 has become well established as a safe, non-surgical option for women requiring an abortion, in countries including France (where the drug was developed) in New Zealand, UK, USA, Israel, China, Sweden and in many other Western European nations.

Medical research carried out in these countries, and after more than one million episodes of the drug's use has found that the drug is non-invasive, avoids surgical and anaesthetic risks and is as safe as surgical abortions. However, unlike surgical abortions, this drug can be used from the earliest stages of pregnancy.

It is important to note that the drug, RU486 or Mifepristone is not an "over the counter" product, like the so called "morning after pill". RU486 can only be prescribed and its use supervised by a doctor. Protocols for the drug's use have been mandated in all countries requiring a doctor to, amongst other things, first obtain the patient's informed consent, (and ensuring the termination is lawful according to that country's legislation) the conduct of an ultrasound to check for ectopic pregnancy etc, and close supervision, including access to hospital admittance in the (unusual) event that this be required.

The World Health Organisation has now designated RU486 as an essential drug for developing countries. The Royal College of Obstetricians and Gynaecologists in the United Kingdom recommends non-surgical in preference to surgical abortion for women with pregnancies of 49 days or less. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, The National Association of Specialist Obstetricians and Gynaecologists, The Australian College of Rural and Remote Medicine, The Australian Medical Association and The Public Health Association of Australia are amongst those who ask that RU486 should also be made available for Australian doctors to prescribe.

The second major change since 1996 is that while the Australian Government supports the concept that comprehensive, affordable and confidential reproductive health services are reasonably available to all Australians, an unintended consequence

of the 1996 Harradine Amendment of the Therapeutic Goods Act 1989 has been to make a rural woman, and their doctor's decision to terminate a pregnancy, much more traumatic, costly and less timely. This is a very serious consequence.

In fact, access to any reproductive health related medical procedure, for example the implantation or removal of a contraceptive under the skin, the insertion of an IUD, a vasectomy, or a pregnancy termination, is today far less likely to be available in a rural medical clinic, compared to a clinic in a capital city. As more private hospitals are being purchased by church-based organisations which do not approve of contraception and some other reproductive health related procedures, the availability of any reproductive health services is further contracting. Over much of regional Victoria and Tasmania, for example, virtually no Reproductive Health procedures are available.

It is not just in small country towns where access to medical procedures is limited, or non-existent. For example none of the doctors (or specialists) in the city of Bendigo, with a population of over 100,000 will carry out a surgical pregnancy termination.

Most rural doctors recommending or supporting pregnancy termination direct their patients to find an abortion clinic in a capital city. Patients are warned that protestors may photograph them entering the clinic, and they may encounter abuse from placard carrying protesters. In Victoria the patient will need to have at least $250 (some of which will be rebated), private or public transport to the clinic, and an overnight stay. In Queensland the clinic costs will exceed $700. A teenager with little support, or a low income woman or someone from a minority culture who is urgently in need of anonymity often finds it very hard to make the complex, costly arrangements, which in turn delays the timing of the termination, causing additional trauma.

I have been contacted by or have consulted numbers of doctors in regions where no surgical terminations are locally available. Some tell me they do not offer to carry out surgical abortions because of their own faith positions. I respect these doctors' rights to refer their patients elsewhere. However, the majority of doctors tell me they do not carry out surgical abortions themselves because they no longer perform any surgical procedures of any description any more for a number of reasons. These doctors believe access to a drug like RU486 would better guarantee their patient's anonymity, and be a safe, and more affordable outcome for their patient. They would prescribe and supervise the drugs use. Should an emergency arise, their patients would have the same hospital/emergency access as any of their other patients. Rural doctor organisations have made these same points clear.

As Professor Ian Pettigrew, Monash University, and provincial Obstetrics and Gynaecology representative on NASOG is quoted as saying: "Women in rural areas wanting terminations faced problems that women in the city did not encounter. There are fewer places performing abortions, increased privacy concerns and many women had to travel long distances to see a doctor." The Age, Page 1, January 8th 2006.

Two applications for individual practitioner authorised use of RU486 have recently been forwarded to the Government for assessment. These applications are under the Scheme which allows approved individual medical practitioners to prescribe for their own patients. Both applications are from doctors in clinics serving regional areas

(Mildura and Cairns). A third application is expected to be received from Albury. This special application process is time consuming and onerous. Approval to initially apply is also required from local medical ethics committees, however, such is the concern about the contracted options for best practice in regional areas that these doctors have persisted with the process. Obviously, they hope to succeed in their applications, to give at least some women in some areas better outcomes.

Like most Australians, I am concerned that too many women, especially teenagers, find themselves in the traumatic situation of needing to consider an abortion. We urgently need to address all the factors that, sadly, lead to an abortion, with the aim of changing the current situation. I will do all I can to see these issues are addressed.

Meanwhile if all Australian doctors, including country doctors, had the option of prescribing, and supervising a medical termination using a drug like RU486, some women could, at an earlier stage, and more safely, confidentially and affordably have a non-viable pregnancy terminated. Currently there is no other option but a surgical procedure anywhere. It should also be noted that there is no reported evidence, world wide, of access to medical abortions increasing the long term rate of all terminations performed.

The current lack of a range of reproductive health options for rural women is significant and affects their well-being. RU486 access is just one of, but an important option for rural doctors and specialists to be able to prescribe and administer to those needing an abortion.

It is also important to note that restricting access to RU486 in no way addresses the rates of abortion in any country, it simply makes Australian women's reproductive health services less safe. On the basis of the impact on rural women alone, I believe we need to repeal the amendment which has effectively blocked access to RU486 in Australia over the last 10 years.

Obviously, there were no references to rural population consequences during the 1996 debate. Instead there were several main arguments advanced by those supporting the Harradine amendments. The first argument was that the drug RU486 had unique characteristics being an abortifacient. This "uniqueness" had already been recognised by the drug's inclusion on schedule 8 of the Customs (Prohibited Imports Regulations) 1956. It was then claimed because of its unique properties decisions about whether or not this drug should be trialled, evaluated, or made available to Australian women should not be made by bureaucrats (i.e. the Departmental Secretary) who base their decision on independent evaluation and advice from the TGA, but rather it should be determined by "the Minister" of the day using other unspecified criteria.

In relation to this argument, the fact is that the termination of a woman's pregnancy by properly qualified medical practitioners is legal in all Australian states and territories according to that jurisdiction's psycho-social and medical criteria including reference to the stage of the pregnancy. It is therefore inappropriate for the Australian government to use anything other than scientific, medical evidence-based information to evaluate a drug access application for what is intended for a lawful medical use. Australian patients should be able to expect at least the equivalent of world best

reproductive health support and practice, and doctors should be able to prescribe what is best for their patient when their needs indicate an abortion is necessary and complies with the relevant law. Decisions about the safest and best way to procure the pregnancy termination should be left to the doctor and his or her patient.

The second argument in the 1996 debate was that the drug was "so unsafe" that its introduction to Australia required extra scrutiny and transparency. Thus they contended that the process for evaluating RU486 in Australia would become more effective, transparent and accountable if the Minister's discretion replaced the evidence based TGA process which had the Departmental Secretary acting on the advice of the TGA.

In fact, however, the Harradine amendments could not and have not provided any extra levels of efficacy, scrutiny or transparency. As the Research note of 28 November 2005 no. 19 of the Department of Parliamentary Services, Parliamentary Library states:

> "Under current arrangements, the Minister is simply required to *notify* the Parliament of a decision to *approve* an application for (RU486) evaluation by the TGA. Given the fact that such a decision would not be disallowable by the Parliament, this does *not* amount to a significant level of parliamentary scrutiny. Further, the Minister is *not* required to table decisions *not to approve* such applications, meaning the Parliament is neither necessarily informed of these, nor does it have the capacity for any oversight of such decisions." (original emphasis)

The Harradine 1996 amendment does not require the Minister to justify why a request for a trial, evaluation by the TGA or importation, might be denied. No guidance is given as to what criteria the Minister may use in coming to his/her decision. Clearly this has not added an extra layer of evidence based scrutiny at all. The opposite effect has been realised.

I therefore strongly support the proposed new amendment which would remove the Minister's discretion and place any applications for the consideration or use of RU486 (and any other abortifacients) under the scrutiny of the TGA. The TGA has been established to scientifically evaluate and monitor all legal drug access and use in Australia.

The TGA is a World Health Organisation Collaborating Centre, a designation which can only be achieved after consider of the following:

- The scientific and technical standing of the institution concerned at the national and international levels with particular reference to its recent record of achievement and its ongoing activities;

- The place the institution occupies in the country's health, scientific and educational structures and its relations with the national authorities concerned, in terms of both its contribution to national health development programmes and the governmental support it receives;

- The quality of its scientific and technical leadership, the number and qualifications of its staff, and the adequacy of its equipment, laboratory or teaching premises and other facilities;

- The institution's prospective stability in terms of personnel, activity and funding;

- The working relationship which the institution has developed with other institutions in the country as well as the intercountry, regional and global levels;

- The institution's ability, capacity and readiness to contribute, individually and within networks, to WHO programme activities, whether in support of country programmes or by participating in international collaborative schemes;

- The technical and geographical relevance of the institution and its activities to WHO's mandate and programme priorities; the institution's will, where appropriate, to develop its potential with the scientific and technical support of WHO; the ability and readiness of the institution to provide services over a sufficient period of time and not only for a single, limited task.

The TGA is an internationally respected body capable of good, independent evidence based research.

The States and Territories have already considered the social policy implications of access to abortions in Australia. They have done this in response to overwhelming and persistent public support for the rights of women to be able to safely and legally terminate a pregnancy, (and this is consistently shown in polls for example: Australian Election Study 2001, The Australian Survey of Social Attitudes of 2003 and ongoing, various Newspolls). It is important that the Commonwealth's processes do not continue to inadvertently restrict the medical profession's capacity to help these women.

I support this 2005 amendment as I acknowledge Australian women's reproductive health needs, as expressed by our peak medical associations, and on the evidence of the extra trauma and hardships now faced by some rural women needing, and indeed deserving, safe, affordable, confidential and accessible reproductive health services.

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