

MEDICAL ABORTION AND THE LAW

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I INTRODUCTION

‘Medical abortion’ implies the use of approved drugs to induce expulsion of a pregnancy from the uterus, the procedure taking place under medical supervision. It is thus distinguished from surgical abortion, in which instruments are used to extract the pregnancy.

‘Late’ medical abortion (usually from 13–21 weeks of pregnancy, but occasionally later) is practiced widely in Australia, usually in cases where a diagnosis of severe foetal abnormality has been made; such diagnoses are not yet technically possible earlier in pregnancy. Late medical abortion is mostly performed in hospitals or clinics using the drugs gemeprost, misoprostol and others. These drugs are synthetic forms of prostaglandins, substances occurring naturally in the body whose functions include causing contractions of the uterus.

More recently, methotrexate, a drug licensed for use in Australia for treatment of psoriasis and certain cancers, has been used in combination with the prostaglandin misoprostol, and misoprostol has been used alone, to bring about earlier abortions (5–9 weeks of pregnancy). In this situation, the methotrexate is administered by injection in a clinic or surgery; subsequently (usually about two days later) the misoprostol is administered vaginally, either by the doctor or by the woman herself. The abortion then occurs at home some hours later, in a process resembling a natural miscarriage. While misoprostol is licensed for use in Australia (as elsewhere overseas) only for the treatment of stomach ulceration, both misoprostol and methotrexate are used ‘off-label’ for abortion. The use of drugs ‘off-label’ is a widely accepted practice in the medical profession and is recognised as such by the Therapeutic Goods Administration (‘TGA’) and similar overseas bodies, such as the United States Food and Drug Administration. The cost of making multiple applications for licensing discourages pharmaceutical companies from doing so.

Now widely used overseas for medical abortion is the drug RU 486 (mifepristone), available in France since 1988 and in many other countries since

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the early 1990s. RU 486 is an anti-progesterone: it opposes the action of progesterone, the hormone that supports a pregnancy. RU 486 is used in conjunction with misoprostol. It is given orally in a clinic or doctor's surgery and 48 hours later misoprostol is administered vaginally by the doctor or the woman herself. The RU 486/misoprostol combination brings about abortion in more than 95 per cent of cases; it is more effective, and has less side effects, than methotrexate/misoprostol. At up to nine weeks of pregnancy the abortion can occur at home, although there must always be immediate access to medical care for the small proportion of women who need it. Around 80 per cent of all abortions are performed before nine weeks in countries where legal abortion is easily accessible, and 90 per cent are performed before 13 weeks. The use of RU 486/misoprostol has meant that early abortions can take place even earlier in pregnancy, resulting in increased safety for women. The RU 486/misoprostol combination has proved highly acceptable to women, is much cheaper and easier to provide than surgical abortion, and is now available in more than sixty countries.

II AMENDMENTS TO THE *THERAPEUTIC GOODS ACT*

The *Therapeutic Goods Amendment Act 1996* (Cth), known as the 'Harradine Amendment', effectively prevented the use of RU 486 by Australian women by specifically requiring the additional approval of the Minister of Health for the import and use of the drug, over and above such approval from the TGA. This amendment had the incongruous effect of prohibiting RU 486 as an abortifacient in Australia, whereas other substances such as methotrexate and misoprostol continued to be readily available on prescription.

In February 2006, following sponsorship of a Private Members' Bill by four women Senators across party lines and a wide public campaign, the *Therapeutic Goods Amendment Act 2006* (Cth) was passed. This amendment overturned the Harradine Amendment, making the personal permission of the Minister of Health no longer necessary for approval of the import and use of RU 486 for the purpose of abortion.

In December 2005, one of the authors and a colleague made an application to the TGA to become Authorised Prescribers of RU 486 for early abortion. The Authorised Prescriber provisions in section 19(5) of the *Therapeutic Goods Act 1989* (Cth) allow individual medical practitioners to gain TGA approval to use drugs not licensed in Australia, but licensed overseas. Such drugs may only be used in specific situations for particular patients and only within the private practices of the applicant(s). It would appear that when the 1996 Harradine Amendment was drafted the instigators were unaware of the existence of the Authorised Prescriber regulations and, therefore, of the possibility that the process could be used to apply for approval to import and administer RU 486.

In April 2006, permission to use RU 486 for abortion was granted to us by the TGA, who thus effectively declared its use to be safe for Australian women. In June 2006, the TGA issued us an import permit for RU 486 and, at the time of writing, it is anticipated that the drug will shortly be used, on a case-by-case

basis, in Cairns. It is also anticipated that more medical practitioners will apply to become Authorised Prescribers and that, in the near future, one or more pharmaceutical companies will apply to the TGA to market RU 486 in Australia. Approval for such distribution should have the potential, for Australian doctors who choose to do so, to provide medical abortion for women requesting it in most parts of the country. At present, surgical abortion services are difficult to access for many women, especially those in rural areas or belonging to certain ethnic groups.

It is timely, then, to examine how the use of medical abortion will comply with the current laws regarding abortion, in Queensland, as in other states.

III MEDICAL ABORTION AND THE STATES

A Queensland

Section 226 of the *Criminal Code Act 1899* (Qld) appears unambiguous in the imposition of criminality for unlawfully supplying any thing (whether substance or instrument) with the intention of procuring an abortion. Liability for the practice of abortion in Queensland has traditionally been avoided by the defence in section 282 of the same act, which allows for ‘surgical operations’ on the child or mother ‘for the preservation of the mother’s life if the performance of the operation is reasonable, having regard to the patient’s state at the time and all the circumstances of the case’.

A broad interpretation of the section was applied by Maguire JDC in what appears to be the only prosecution made under this section: *R v Bayliss and Cullen*.¹ The concept of ‘reasonableness in the circumstances’ is sufficiently ambiguous as to allow practitioners a degree of flexibility in interpreting the legislation.

It would seem, though, that the section 282 defence would not extend to the administration of RU 486, as it is clearly not a ‘surgical operation’. In April this year, the Queensland Branch of the Australian Medical Association wrote to the State’s Attorney-General requesting clarification of this matter. After seeking advice from the Solicitor-General, the Premier, and the Attorney-General, the Queensland government issued a joint statement which took the view that where the TGA has approved use of a drug, prescription of that drug is lawful in Queensland pursuant to the *Health (Drugs and Poisons) Regulation 1996* (Qld), and that further amendment to Queensland legislation is not required.² Because a prescription is *lawful*, it is not an *unlawful supply* and, therefore, there is no application of section 224 or section 226 of the *Criminal Code Act 1899* (Qld).

With such changes to the landscape of the provision of abortion services in Queensland, it is argued that this is an opportune time for amendments to be made to Queensland legislation to remove the ambiguity around appropriately

1 (1986) Qld Lawyer Reps 8.

2 Joint statement by Premier and Attorney-General of Queensland, ‘Queensland Doctors and the Prescription of RU486’ (Media Statement, 24 April 2006) <<http://statements.cabinet.qld.gov.au>> at 18 July 2006.

administered surgical abortion. This was certainly the approach recommended by the Taskforce on Women and the Criminal Code in their report submitted to the Queensland government in November 1998.³

It would also appear from the Cabinet joint statement that late medical abortion for foetal abnormality, when performed using drugs approved by the TGA, is similarly covered by the *Health (Drugs and Poisons) Regulation 1996* (Qld). This practice has, for years, been of concern to doctors performing such abortions in Queensland hospitals since, though there have been no prosecutions, there was belief that section 282 might not adequately cover the clinical indications for these procedures.

B New South Wales

The *Crimes Act 1900* (NSW) establishes criminality for inducing an abortion, including for the woman herself, in sections 82, 83 and 84. There is no defence to the offences, other than the interpretation of what is 'lawful'. Justice Levine, in *R v Wald and Ors*,⁴ determined that abortions in NSW are lawful where 'the accused ... had an honest belief on reasonable grounds that what they did was necessary to preserve the women involved from serious danger to their life, or physical or mental health, which the continuance of the pregnancy would entail, not merely the normal dangers of pregnancy and childbirth, and that in the circumstances the danger of the operation was not out of proportion to the danger intended to be averted'.⁵

With the eventual introduction of RU 486 in New South Wales, similar issues will arise as in Queensland, as criminality only attaches to *unlawful* administration or procuring of substances or instruments to induce an abortion. As in Queensland, the prescription of RU 486 would likely be lawful in New South Wales because of the approval given for the use of drugs by the TGA. The result is a difference in the lawful requirements for medical abortion compared to surgical abortion: medical abortion is not subject to the test outlined in *R v Wald and Ors*.

Furthermore, a complicating feature may arise in the context of section 82, which creates a crime for a woman who 'unlawfully administers to herself' substances to induce abortion. While RU 486 is administered to a woman in a hospital or clinic, misoprostol which is the second drug required in the process, can be safely administered by the woman herself at home. While the position is unclear, the writers are of the view, however, that where RU 486 and misoprostol have been *lawfully* prescribed to the woman, if she administers misoprostol to herself, it will not contravene section 82.

3 Queensland Government, *Report of the Taskforce on Women and the Criminal Code*, Recommendation 81 (2002) <<http://www.women.qld.gov.au>> at 18 July 2006.

4 (1971) 3 NSWDCR 25.

5 Ibid 29.

C Victoria

The situation in Victoria is almost identical to that in New South Wales, although the sections in the *Crimes Act 1958* (Vic) are set out a little differently. The crime of unlawfully administering a drug or using any instrument to procure an abortion (including by a woman herself) is set out in section 65, and that of unlawful supply of such drug or instrument is in section 66.

The decision of *R v Davidson*⁶ set out the conditions in which abortion is lawful in Victoria, in similar terms to the later decision in NSW of *R v Wald*.

Tasmania has similar legislation, but there is no judicial authority on point to give any indication as to how these sections would be interpreted.

D South Australia

While sections 81 and 82 of the *Criminal Law Consolidation Act 1935* (SA) maintain general prohibitions on performing abortions or providing substances or instruments to procure an abortion, South Australia also maintains a statutory definition of lawful abortion in section 82A of that Act. This section establishes in some detail who can decide that an abortion is the appropriate treatment (in some cases two treating doctors), who can be treated with an abortion, under what circumstances, and in what physical environment.

The sections do not appear to distinguish as to how the abortion is effected, whether through surgical or medical means. As a result, the legislative situation in South Australia does seem to adequately cater for the provision of medical abortion in that state.

E Western Australia

In Western Australia, in 1998, following an attempted prosecution of two doctors and a major public campaign, a new section 199 was inserted in to the *Criminal Code* (WA). In combination with amendments to the *Health Act 1911* (WA), Western Australia now has a fairly comprehensive statutory system dealing with the performance of abortions, including late abortions. As in South Australia, these sections would appear to apply equally to both surgical and medical abortion.

F ACT and the Northern Territory

The legislative situation in the ACT and Northern Territory is similar to that in Western Australian and South Australia, although the details are certainly different. For example, the *Health Regulation (Maternal Health Information) Act 1998* (ACT), designed to clarify requirements for abortion and to decriminalise the procedure, specifies that abortions must only be performed by appropriately qualified persons 'in suitable premises.' South Australia and the Northern Territory also have regulatory frameworks that restrict abortion practice to 'prescribed' hospitals or clinics.

6 [1969] VR 667.

A detailed discussion of the intentions and effects of such legislation is beyond the scope of this article, but the requirement that an abortion be performed in an 'approved facility' does have implications for the practice of medical abortion. Such a stipulation is appropriate for surgical abortions, but will need to be defined or revised when medical abortion becomes more widely available if doctors are to be lawfully able to administer RU 486 in private surgeries and prescribe misoprostol for use at home. It would be inappropriate if these recent measures, designed to liberalise abortion law and provide clear guidelines for practice, in fact worked to restrict women's access to medical abortion.

IV CONCLUSION

In 2004, de Crespigny and Savulescu, writing in the *Medical Journal of Australia*, called for a concerted effort at State and Federal level to clarify and make uniform Australia's abortion laws.⁷ The introduction of safe and effective medical abortion regimens makes the need for these changes even more urgent. It is clear that medical abortion can currently be practiced lawfully in the Eastern States, and in certain circumstances in the remainder. However, if Australian women are to have equity of access to both medical and surgical abortion, it is essential that state regulatory frameworks for abortion be further revised to clarify the situation, and desirable that this revision results in uniform legislation across the country. It is time for our laws to catch up with modern abortion practice.

7 Lachlan de Crespigny and Julian Savulescu, 'Abortion: time to clarify Australia's existing laws' (2004) 16 *Medical Journal of Australia* 201.