CAROLINE DE COSTA

RU-486

THE ABORTION PILL

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RU 486.

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LIST OF COMMON ABBREVIATIONS USED IN THIS BOOK

ACOG – American College of Obstetricians and Gynecologists

AMA – Australian Medical Association (also American Medical Association, abbreviation not used in this book)

FDA – Food and Drug Administration (United States)

FIGO – International Federation of Obstetricians and Gynaecologists

MIMS - Monthly Index of Medical Supplies

MJA – Medical Journal of Australia

NHS – National Health Service (United Kingdom)

PC – Population Council

RANZCOG – Royal Australian and New Zealand College of Obstetricians and Gynaecologists

RCOG – Royal College of Obstetricians and Gynaecologists

TGA – Therapeutic Goods Administration

WHO – World Health Organisation

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INTRODUCTION

On a bright winter's day at the beginning of July, 2006, I walked from my office in the JCU School of Medicine in Cairns and across the three city blocks to the rooms of my colleague Dr Mike Carrette. Waiting for me with Mike was a woman I will call Joanne. I had met Joanne the previous week when I had shared a three way consultation with herself and Mike.

Joanne was 43 years old and had recently discovered that she was six weeks pregnant. The pregnancy was unplanned. In a previous pregnancy Joanne had suffered an episode of thrombo-embolism – a blood clot had formed in her leg and migrated to her lungs. Fortunately this life-threatening condition had not been fatal for her, although she required anti-coagulant medication for the ensuing six months. The physician caring for her at the time had also given her some strongly worded advice – she should avoid further pregnancy, which posed a serious threat to her life.

In addition to her medical problems Joanne, as a divorced single mother, felt quite unable to proceed with another pregnancy at her age. She had consulted her general practitioner, who talked sympathetically with her about all her options. After thinking long and hard, Joanne decided that she should undergo an abortion. She was also interested in the possibility of a medical abortion, in order to avoid an anaesthetic.

At her first consultation with Mike and myself, the procedure of induced medical abortion using the drugs mifepristone (RU486) and misoprostol was explained. Joanne brought with her a friend, Doreen, to act as support person throughout the process, which

would take place in Joanne's home. Exactly what Joanne could expect to feel, the various risks that were involved, and what she should do in any kind of emergency, were all outlined. She was supplied with written information about the world-wide experience of medical abortion and a detailed consent form to take home and read. The appointment for the following week was pencilled in.

We met again as planned. Joanne was quite sure of her decision and had brought with her the signed consent form. Mike unwrapped the package of mifepristone and as we both watched Joanne took a sip of water and swallowed it down. Would she feel any side effects that afternoon? she asked. Not likely, we replied, RU486 itself has few side effects. But she had contact numbers for both of us in case of any problems.

Two days later we met for the third time. On this occasion Joanne had four tablets of the drug misoprostol inserted vaginally. She had already been given prescriptions for antibiotics and painkillers. She was driven home by Doreen who stayed in close touch with us by phone. Two hours later Doreen reported that Joanne was experiencing some contractions and bleeding; within half an hour the abortion process was complete and bleeding and pain were settling.

Joanne had just become the first woman in twelve years to undergo a legal abortion using RU486 in Australia, and one of the very few ever to use the drug in this country.

Why is this event in any way remarkable? RU486, as mifepristone[1] continues to be more widely known, has been available in France and Switzerland since 1988, the United Kingdom since 1991, most other European countries since the early-mid 90s, and the United States since 2000. It is used legally in Russia, India, China, Israel, Turkey, Tunisia and New Zealand, amongst many other countries. In almost all these places its use evokes little in the way of controversy. Its actions, side effects and potential risks have been widely studied, and the evidence shows that it is safe, effective,

1 Throughout this book the names RU 486 and mifepristone will be used interchangeably – they are the same thing.

and highly acceptable to women, both for early abortion – usually implying up to nine weeks of pregnancy – and for the much less common procedure of late abortion. However in Australia the drug, after initial (promising) trials directed by Professor David Healy of Monash University, became the focus for political manoeuvring that had nothing to do with the health or human rights of Australian women. Under an extraordinary piece of legislation known as the Harradine Amendment, the use or import of the drug was prohibited without the personal permission of the Federal Minister of Health. This had the effect of discouraging pharmaceutical companies from applying to the Australian Therapeutic Goods Administration (TGA) for approval to import and market the drug – which is the normal pathway by which drugs developed and manufactured overseas enter the country. It also meant that Australian women have been poorly informed about something quite familiar to their sisters in Europe, North America and elsewhere, and denied a choice that is widely available in so many other countries.

This situation was partly remedied by the overturning of the Harradine Amendment by a conscience vote in both Houses of Parliament in February 2006. This unique event occurred because a cross-party group of women senators introduced a Private Members' Bill in the Senate, which was passed in that House and a week later in the Lower House, the House of Representatives. The bringing of this piece of legislation to the Parliament, and the events that preceded it, demonstrated an extraordinary unity of purpose between women from all shades of the political spectrum and from a huge range of different backgrounds. There was clear recognition from these women- and of course from many men – that access to safe, legal abortion must be a fundamental right of Australian women and that this is the opinion of a majority of the population. Allowing access to RU486 extends that right, increasing the choices available to women having to make the difficult decision about terminating an unwanted pregnancy. Widespread availability of RU486 in this country also offers the possibility of improving

access of some Australian women to abortion, particularly rural women and women from certain ethnic groups.

However the overturning of the Harradine legislation did not immediately result in widespread access to the drug for Australian women. All drugs licenced for use in Australia and made available for prescription by doctors must first pass through a rigorous process of approval by the TGA. The TGA acts to ensure that drugs used by the Australian public have been widely and appropriately tested, that they are safe, or at least that any side effects or contra-indications are well known, and that they are effective. The TGA continues to monitor drugs after they have been approved for use in Australia, keeping a register of severe adverse effects, and it has the power to withdraw drugs from the Australian market. It is to the benefit of all of us that the TGA acts in this way.

The TGA can generally only assess a drug when a drug company makes an application to manufacture and/or market that drug in Australia. At the time of writing this book, no such application for mifepristone has been approved by the TGA, and it is believed that no such application has yet been lodged. Drug companies are not usually so reluctant to bring overseas drugs to Australian consumers, and the reasons why this hasn't yet happened for RU486 are far from clear, although it seems certain that the political controversy surrounding the drug in Australia has played a major role.

However within the extensive legislation governing the role of the TGA there is provision for private doctors to apply to import and use particular drugs for their own patients, in certain serious medical conditions. This is called the Authorised Prescriber legislation. In late 2005 Dr Mike Carrette and I lodged an application under this legislation to be permitted to use mifepristone – RU486 - for the purpose of medical abortion in early pregnancy, in our own practices in Cairns. This was a complex process involving much paperwork but six months later (and two months after the overturning of the Harradine Amendment) this permission was granted to us. We were able to obtain a small supply of RU486 from New Zealand

colleagues and we have been using the drug in Cairns under the Authorised Prescriber guidelines for a year now.

In that time several other Australian doctors have made similar applications to the TGA but at the time of writing I am not aware of any others having been granted approval. Dr Carrette and I continue in the bizarre position of being the only medical practitioners in Australia able to use a drug that is widely prescribed and recognised overseas as the most appropriate choice for medical abortion.

I am hopeful that in the near future a drug company will lodge an application with the TGA – given the huge amount of overseas evidence in favour of the drug I believe it is likely that such an application would be granted. I very much look forward to the day when RU486 is simply a non-controversial option for women in this country, one of many choices for reproductive health that currently include most forms of contraception, emergency contraception, surgical abortion and sterilisation. Meanwhile I have written this book to provide accurate information about RU486 and its actions to Australian women (and men), as well as to outline the history of the drug's development, including its prolonged and unnecessary entanglement in the politics of the Howard government.

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SOME BASIC FACTS ABOUT RU 486

RU 486 was initially RU38486, and was just one of many sample drugs in the French laboratories of the company Roussel Uclaf -hence "RU". It was first synthesised in April 1980, then lab-tested in France in 1981 before undergoing trials in patients (women volunteers) in France and Switzerland in 1981-82. Although it has since been formally named mifepristone – RU486 being the laboratory name only – and this is the name used by the medical profession, to the public it is still known and quickly recognised as RU486.

The drug is a synthetic steroid, meaning it has a chemical structure somewhat similar to the naturally-occurring sex hormones oestrogen and testosterone, but it is made in the laboratory, and does not occur in nature. It acts by opposing the action of the naturally-occurring hormone progesterone. Progesterone is normally produced by one or other of a woman's ovaries in the second half of the menstrual cycle. If a woman becomes pregnant progesterone production by the ovary increases and is supplemented by progesterone produced by the developing placenta. Progesterone is essential to the continuation of the pregnancy. When a pregnant women takes a single dose of RU486 the drug locks onto the chemical receptors in the lining of the uterus that normally bind with progesterone, thereby preventing natural progesterone from acting. This effectively ends the pregnancy because the placenta cannot develop.

RU486 has been found to have a number of potential uses in medicine (these are discussed further in Chapter 6). However its

best known and most widespread use at present is for the purpose of induced abortion. For this it is usually used together with another drug, misoprostol. Misoprostol is a synthetic form of prostaglandin. Like steroids, prostaglandins are substances some of which occur naturally in the human body, although misoprostol itself is made in laboratories. Misoprostol has a number of effects but the most important is to bring about contractions of the pregnant or recently pregnant uterus. This property has made it an effective treatment for post-partum haemorrhage – the heavy bleeding that can sometimes follow normal childbirth and threaten women's lives. It also makes misoprostol useful in induced abortion as it brings about the expulsion of the contents of the uterus after mifepristone has ended the pregnancy. Misoprostol acts quickly – usually within four hours of being administered – and it does so generally with little blood loss. It is also very effective – the abortion process is usually complete after a single dose of misoprostol. The action of misoprostol on the uterus is increased by previously administering the mifepristone.

It needs to be made clear that medical abortion using mifepristone/misoprostol is not a 'magic bullet' that simply melts the pregnancy away. All the products of conception – which in the first trimester (the first twelve weeks of pregnancy) are mostly made up of placental tissue and membrane – need to be expelled from the woman's body. This is a process that of necessity involves some bleeding and some pain – both of which are usually manageable by the woman concerned. Bleeding tailing off to a discharge takes a number of days to disappear completely following medical abortion. For most women this is no problem, women are used to vaginal bleeding, it's scheduled to happen to them every month between the ages of 12 and 50, and is normal for several weeks following childbirth. Medical abortion properly conducted also requires – usually –two or three visits to a doctor or clinic, and sometimes more. Surgical abortion properly conducted has similar requirements.

Various regimens are used in different countries but the principle of orally-administered mifepristone followed by orally or vaginally

administered misoprostol is common to all. When the abortion is performed before nine weeks of pregnancy (what is referred to medically as nine weeks' gestation) this process can occur either in a clinic or hospital situation or in the woman's own home. In the latter case the woman must initially be under medical care and must have access to emergency help in the event of a complication of the abortion, although complications are infrequent. Women experience early medical abortion much like a natural miscarriage. Crampy pain and vaginal bleeding are an intrinsic part of the abortion process as they are with miscarriage. Some tissue, which is visibly partly placenta and partly membranes, is passed, together with the fetus which is generally not recognisable as such. At six weeks of pregnancy the fetus (technically still called an embryo) is about 2 mm long, at seven weeks 5mm, and at eight weeks about 10 mm (one centimetre) long.

Various studies have shown that with mifepristone-misoprostol regimens in recommended doses 95-99% of women will abort completely. The remainder will require uterine aspiration (or curettage, 'D&C') to complete the abortion, in a clinic or hospital situation.

Mifepristone can also be used for later abortion, again in conjunction with misoprostol. Medical abortions performed later than nine weeks are best performed in a hospital or clinic as there may be a need for strong analgesics (pain relief) and there is a greater risk of heavier bleeding than with early medical abortion. Nevertheless only a small percentage of late medical abortions actually incur these complications.

In the United Kingdom, early medical abortion using mifepristone/misoprostol has been available since 1991. It is now widely accessed by women – up to a third of early abortions in many centres in the UK are performed this way. Women have found the method highly acceptable – it is often described as less invasive, and allowing women to feel more in control, by those who have undergone the procedure. The Royal College of Obstetricians and Gynaecologists (RCOG), with headquarters in London, has

published detailed guidelines, based on the evidence of up-to-date research, about how the drugs should be used. Similar guidelines have been published by the American College of Obstetricians and Gynecologists (ACOG). In drawing up this information for doctors and for the women under their care, these Colleges have made clear their beliefs that RU486 is a safe, effective option for women who have made this choice of abortion for themselves.

All women considering termination of pregnancy should be provided with full information about all their options as well as available procedures and alternatives. Appropriate counselling and assessment by a doctor is vital. They should be offered other aspects of health care for women including follow-up contraception, Pap smear screening and screening for sexually transmitted infections, and they should be fully supported emotionally through the abortion process. It is important to make sure that the pregnancy is in the uterus and not an ectopic pregnancy e.g. in the fallopian tube, and that the abortion has caused all the products of conception to be expelled from the uterus. These considerations are as true of medical abortion as they are of surgical abortion. Surgical abortion is legal in all states of Australia under varying circumstances and is widely available but there are inequities of access to abortion services, and in some states although a Medicare rebate is payable abortions are generally performed in private clinics. Mifepristone and misoprostol are cheap to produce; misoprostol is currently available in Australia and is widely used in obstetric practice for conditions other than induced medical abortion (for example for women bleeding after normal vaginal births) although it is not licenced for these purposes. Numerous overseas studies have shown that the majority of women undergoing medical abortion have been "satisfied" or "very satisfied" with the procedure.

These are the basic facts. Why then if this safe option exists does medical abortion using RU486 continue to be, for all intents and purposes, unavailable to Australian women?