THERAPEUTIC GOODS AMENDMENT (repeal of Ministerial responsibility for approval of RU486) BILL 2005

SUBMISSION TO SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

from

DR SALLY COCKBURN, MBBS

I **strongly support** the *Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005* in its purpose to remove political interference from the evaluation of safety and efficacy of all medications intended for use in Australia, and restore the full powers of the Therapeutic Goods Administration (TGA). The vote is not about whether RU486 is safe but who is qualified to decide. I urge all parliamentarians to **vote in favour** of the Bill.

Terms Of Reference (TOR):

I have been informed that the TOR for this Inquiry are encompassed in the purpose of the Bill ie "*to remove the responsibility for approval of RU486 from the Minister and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration*". My submission is restricted to these TOR. However, having seen other submissions and read the transcript of the first day of proceedings, I note that some of this goes beyond the scope of the TOR to cover more general issues of abortion. I am more than happy to appear before the Committee to discuss my submission and these other issues.

Reasons Why The Responsibility For Ru486 Should Be Removed From The Minister:

In its current form, the TGA Act requires that any drug in the "restricted goods" class "*must not be evaluated or registered or listed without the written approval of the Minister [for Health]."* (This class contains only drugs intended to induce abortion) .The Act does not require the Minister to seek advice, give any reasons or follow any protocol, when making a decision regarding an application relating to these drugs. The only requirement afterwards is that any approval document must be placed before Parliament "*within 5 sitting days of being given*". The same does not apply to a rejected application.

No other drugs have this layer of ministerial micromanagement. Every other drug is evaluated solely on its scientific merits by the TGA, free from ministerial interference, using accountable methods to assess its safety and efficacy. In appropriate clinical settings women can access an abortion under state and territory laws in Australia (http://www.mja.com.au/public/issues/181_04_160804/dec10242_fm.html). It is not right that the personal opinion of one Commonwealth Minister should be able to deny the evaluation of a drug that may be an appropriate clinical and lawful option for those Australian women who require it. All drugs should be evaluated the same way :- by the TGA, the organisation set up specifically for that purpose.

Some people argue drugs that induce abortion are "unsafe" and somehow "different" or "special" and should be kept separate from other drugs. These were the notions Senator Brian Harradine told his colleagues he based his 1996 amendments to the TGA Act upon. That 1996 legislation reduced the powers of the TGA by hiving off abortifacients into the "restricted goods" class and shifted the absolute power over any access to these drugs to the Minister for Health. The changes meant that safety and efficacy of these drugs could not even be evaluated without his or her written approval. This legislation was based on opinion, not scientific data. It is ludicrous, and a classic "catch 22", to consider that any drug is *too unsafe* to allow proper evaluation of its *safety* by the TGA. Until the power is returned to the TGA we must continue to rely on opinion, not scientific evaluation, about the safety of these drugs.

No group or person, not even the Minister for Health, is more qualified than the TGA to assess the safety and efficacy of drugs in this country. After all, we trust the TGA to decide on the fate of all other drugs. Those who oppose this Bill undermine the integrity of the drug evaluation system in Australia.

Allowing one person to hold total responsibility for a drug or group of drugs also paves the way for application of personal bias. This is intolerable in matters pertaining to health where best practice is based on evidence, not morals and good clinicians keep their personal bias out of the consulting room. The current Minister for Health, Tony Abbott, has declared his views on abortion and RU486 publicly: He is not in favour of either. On 15 November 2005 Mr Abbott said, on ABC radio's PM program, "*I conclude that there is no reason, based on the report from the Chief Medical Officer, to change longstanding practice in*

regards to RU-486". He went on to say, " *My reading of that report is that there are significant additional health risks associated with medical terminations, and that the safest way to have a termination is a surgical termination*" (http://www.abc.net.au/pm/content/2005/s1507408.htm)

On that same day Mr Abbott's office circulated a copy of that memo from his Chief Medical Officer (CMO) in PDF form by email to members of the media. I have seen a copy of this document and my reading of the report is that the Mr Abbott's interpretation was incorrect. So too, was that of his parliamentary secretary, Christopher Pyne, who on the ABC's 7:30 report a few days later, he said "*The medical advice from the chief medical officer puts beyond any doubt that RU-486 would be a dangerous drug to register*"(http://www.abc.net.au/7.30/content/2005/s1513109.htm) (How is Mr Pyne qualified to comment on registration when the TGA hasn't even evaluated it yet ?)

In that same ABC report Mr Abbott told the Australian People "*to take a cold shower*" over the issue. The office of the CMO subsequently made a statement to the media to the effect that Mr Abbott (and Mr Pyne) did misinterpret, or at least inappropriately extrapolate, from the advice given by the CMO on the matter of RU486 and its safety (http://www.abc.net.au/am/content/2005/s1508653.htm).

Mr Abbott also said on ABC radio "*I don't hold myself out as being an expert when it comes to particular medical procedures*." http://www.abc.net.au/pm/content/2005/s1507408.htm. Taking this statement, together with his apparent difficulty in interpreting medical advice, Mr Abbott tells us exactly why the responsibility for decisions about RU486 and related drugs should be removed from his personal portfolio and returned to the TGA.

I respect Mr Abbott's conviction to his faith and his right to hold his personal views, but by his own admission, he is not an expert in drug evaluation. As an elected Member of Parliament in Australia it is not his personal or religious beliefs that should be driving him when he is making decisions that affect the health of our community. A Minister for Health is not required or expected to have any scientific or medical credentials and so should leave matters of a clinical nature to those who do. Pass the Bill. Let the TGA do its job.

Reasons Why The Responsibility For Ru486 Approval Should Be Returned To The TGA:

The TGA came into being in 1991 following an act of Parliament in 1989. According to the TGA's website "*The Australian community expects that medicines and medical devices in the marketplace are safe and of high quality, and of a standard at least equal to that of comparable countries. The objective of the Therapeutic Goods Act 1989 is to provide a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices. (*http://www.tga.gov.au/docs/html/tga/tgaginfo.htm)

At the time the TGA was set up it was responsible for evaluating all drugs. As mentioned earlier, in 1996 this changed with the passing of amendments to the TGA Act proposed by Senator Brian Harradine. The politics involved in passing the 1996 changes are understandable. Senator Harradine held the balance of power in the Senate and his vote was needed on another issue. However, the morality of the deal is highly questionable and, even if any basis for the amendments ever existed, it does not now. If any political debt was owed to Senator Harradine it has been paid. In 2006, 35 countries have approved RU486 as a safe alternative to surgical abortion (APPENDIX 1). These include USA, UK and New Zealand. The TGA must now have its full powers returned so it can fulfil its own objectives. If comparable countries are any example, Australia is well overdue for RU486 to be evaluated.

The TGA takes a risk management approach to drug evaluation. Its protocols take into account special circumstances and it has scope to place restrictions on the way drugs are prescribed even after licensing. It also has the option not to license a drug at all (http://www.tga.gov.au/about/tgariskmnt.htm#pdf). Many drugs have potentially serious side effects but this does not mean they cannot be prescribed responsibly, and it certainly does not mean they should be ineligible for evaluation. These are clinical issues, which are best assessed by the experts at the TGA, not a senate inquiry and certainly not one Minister.

The TGA exists within the Minister for Health's own department and if the Minister had concerns about safety of another drug he could ask the TGA to give him their evaluation data on it. However, since Senator Harradine's amendment came into law in 1996, the TGA has not been able to freely gather local data on RU486 safety in abortion because research was effectively stopped. So, considering the Minister

has said that understanding the safety of the drug is pivotal to whether he could approve an application for RU486, he is stuck. He can't turn to the TGA for advice because, as the law stands, they would need to seek his written permission first before they could evaluate the drug in order to answer his question! And he's already said he doesn't feel qualified…..It's a rather confusing, circular process, but something that can be fixed by reinstating the full power of the TGA.

The TGA is Australia's expert body for evaluation of drug safety. It was set up to evaluate all drugs and there should be no exceptions. Patients are asking why they cannot access a drug that is available in the UK, USA and NZ. Doctors cannot turn to the trusted TGA to find out if RU486 meets Australian safety standards because it has not been evaluated. This Bill must be passed so we may all know the facts.

Conclusion (Including Personal Note To Parliamentarians):

The Bill before the Parliament is about governance. However it is contentious because of its relation to abortion. There is a vocal minority who seek to reduce access to all abortions and they cloud this Bill with emotive anecdotes, and unscientific arguments. The Bill is not about abortion and does not require discussion of RU486's safety profile. Those who wish to see this Bill fail are either against abortion, or do not properly understand the role of the TGA and the impact of the 1996 amendment in effectively banning RU486.Those in favour of the Bill believe in principles of good governance and accountable, transparent, scientific drug evaluation in Australia.

In appropriate clinical situations a woman can access an abortion within the law in Australia. When a woman has made an informed decision to access a legal abortion based on her particular circumstances, no politician, religious zealot or moral extremist has any place in deciding what mode of abortion is more appropriate for her. This is a clinical issue and the patient's decision should be based on scientific evidence, which should be presented in an unbiased way so that she can weigh up the risks and benefits of her options. Currently her only abortion option is surgical. It is wrong that her rights are so disrespected that other clinical options, which are available in comparable countries, are not even been allowed to be evaluated here. The Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 must be passed to ensure that doctors can be comfortable we are offering a patient her best clinical options and that she has the opportunity to decide her most appropriate alternative.

I recently visited my local Member and asked him about his views on this Bill. During our conversation some issues came to light that I think warrant addressing here since other parliamentarians may have similar concerns.

Maybe you are thinking some members of the community could perceive the conscience vote as being about abortion. You may have concerns about how a vote in favour of this Bill may be seen by those in your electorate, worried that it may be seen as condoning abortion. Over 80% of Australians believe that a woman should have the right to choose an abortion. Less than 10% disagree with this statement**.** (The Australian Survey of Social Attitudes 2003 http://assda.anu.edu.au/studies/D1070.html)Even if they mistakenly thought the Bill was about abortion (which it is not), most Australians would support a vote in favour, given community views on abortion and choice. Also, as stated earlier, in Australia, under appropriate clinical circumstances, a woman can access an abortion within the law. Whether you pass this Bill or not, women will still be seeking and obtaining abortions. New Zealand is only a short flight across the Tasman for a woman determined to access a medical abortion, but New Zealand's proximity is no justification for delaying evaluation of the drugs here.

Some may try to tell you that passing this Bill could "make it easier" for women to choose to terminate a pregnancy. It is insulting to suggest that the decision to abort is ever easy. Even if the TGA licensed RU486, women would still have to qualify under clinical and legal criteria before accessing the procedure. It is even more insulting to treat women as if they cannot think for themselves by restricting their options with bureaucratic and political red tape that is nothing more than a thin veil for extremist moral views.

Some may argue that RU486 should be kept out of the hands of the TGA because of harm that would come to embryos if it were licensed for use in abortion. This is implicit in the act of abortion, and an embryo has no legal rights. If it is deemed relevant to this Bill APPENDIX 2 covers this in more depth.

If you are concerned that there are already too many abortions in this country, then please look at ways to help prevent unwanted pregnancies by putting more resources into improved sex education and contraception availability, rather than restricting the evaluation of potentially safe alternatives to existing legal abortion options.

Maybe you are concerned that passing this Bill will automatically make abortifacients available to the general public. This is not the case. The drugs still need to be fully evaluated by the TGA whose experts who will employ the same accountable criteria and protocols that all other medications in this country are put through. Only then, if these drugs pass the tests; and, after appropriate clinical protocols and restrictions are put in place would they be licensed for prescription use by Medical Practitioners in appropriate clinical and legal circumstances. It is inconceivable that there would be any intention of over the counter or unrestricted supply of these drugs. RU486 is NOT Postinor (commonly called *the Morning After Pill.).*

Any member of the public who wishes to read Hansard online can see that when Senator Brian Harradine proposed his TGA Amendment Bill in 1996, his intention was to prevent access to this form of abortion. Safety factors and risks to women's health were, at best, secondary concerns. It is amazing that Senator Harradine's amendment received such smooth passage through both Houses. However, the reason may become clearer when it is pointed out that around that time in 1996, Senator Harradine's deciding vote was allegedly needed to pass another controversial Bill relating to Telstra. It is openly said by many that this was no coincidence. If Australians' health options were sold out in 1996, isn't it time to right that injustice?

While the subject of the current Bill may be RU486, the issue in the conscience vote is **governance**. The moral issue at the core of this conscience vote is whether you believe it is right to continue to support a piece of legislation that your colleagues put in place in 1996, under questionable circumstances, which is now at odds with accepted principles of good governance, expert opinion and clinical practice in comparable countries (APPENDIX 3), and public opinion.

Make no mistake, the people of Australia know the real issues and are watching to see, now that Senator Harradine with his special influence has left the Parliament, if you have the fortitude to govern for the people and not for an extremist minority. Please show us that we elected you for the right reasons. Or at least show us which of you believe in reproductive choice, so the 80+% of Australians who hold this view might know who to vote for at the next election should abortion continue to be an issue.

Biographical Note:

I am a graduate in Medicine from Monash University and a registered Medical Practitioner in Victoria with over 22 years clinical experience. I currently work in General Practice in suburban Melbourne and also as a tertiary teacher, public health educator and patient advocate. I have worked extensively as a health writer and presenter on radio, television, and in print for over 15 years. My special interests are medical communications, counseling, as well as sexual and reproductive health. I have held the post of Senior Lecturer at Monash University, taught communication skills and was involved in development of the medical undergraduate curriculum in the 1990's. I currently teach Medical Journalism in the Faculty of Medicine Nursing and Health Sciences at Monash. I consult to various business and government organisations on health policy, education, communication and media. I have extensive experience on community and government committees including Ministerial Advisory Committee for Women's Health, and Metropolitan Ambulance Service in Victoria. I currently sit on the board of Family Planning Victoria and the Medical Advisory Committee of Marie Stopes International. I am an ambassador or patron of several of community organisations including Marie Stopes International Australia, Royal District Nursing Service, and Reach Out Southern Mental Health. I have been an appointed Australia Day Ambassador in Victoria for the last 5 years.
I recently visited a sexual health clinic in London where Medical Abortions are common procedure. I sat in and observed a clinical session.
I do not represent any particular organisation in my submission. The opinions expressed in this submission are entirely my own.

Dr SALLY COCKBURN, MBBS. Bayside, Victoria. 12th January 2006

APPENDIX 1 CHRONOLOGY OF MIFEPRISTONE (RU486) APPROVAL

1988 FRANCE
CHINA

1991 UK

1992 SWEDEN

*(**1996** AMENDMENT PASSED IN AUSTRALIA REMOVING RU486 FROM TGA AUTHORITY)*

1999 AUSTRIA
BELGIUM
DENMARK
FINLAND
GERMANY
GREECE
ISRAEL
LUXEMBOURG
NETHERLANDS
SPAIN
SWITZERLAND

2000 NORWAY
RUSSIA
TAIWAN
TUNISIA
UKRAINE
USA

2001 NEW ZEALAND
SOUTH AFRICA

2002 AZERBAIJAN
BELARUS
GEORGIA
INDIA
LATVIA
UZBEKISTAN
VIETNAM

2003 ESTONIA

2004 GUANA
MOLDOVA

2005 ALBANIA
HUNGARY

Reference : http://www.gynuity.org/documents/mife_approval_2005_list.pdf

APPENDIX 2 DOES AN EMBRYO HAVE A "RIGHT TO LIFE"?

Dorland's Illustrated Medical Dictionary defines the term "embryo" in humans as "the developing organism from the fourth day after fertilization to the end of the eighth week". The term "foetus" is used from then until birth. Medical abortions usually take place at or before 7 weeks at which time the embryo is about the size of a thumbnail. See actual size picture, right, of 48 day embryo. (More info: http://embryology.med.unsw.edu.au/wwwhuman/Stages/CStages.htm) Unfortunately some people use emotive language, distorted images and anecdote to try to make their point. Their desire to protect the unborn is so strong they refuse to believe that anyone else's point of view is acceptable. They are absolutely entitled to their view on abortion and for it to govern their own lives. However, in Australia they are not entitled to impose their beliefs on those who may not hold the same religious or moral views as them because, according to the law that governs us, an embryo has no legal rights and a woman can, in appropriate circumstances, access abortion within the law.

Many believe "right to life" is the nub of the so-called "abortion debate" and spills over into the RU486 issue. However the question is whether any proposed "rights" of an embryo override those of the woman who has decided to abort it (assuming she has given with informed consent, it is clinically appropriate and she is legally entitled to access that abortion under state law). Although laws on abortion maybe confusing, it is clear that unborn embryos (and foetuses) have no legal right to prevent a woman having an abortion. In 2004 respected Australian medico legal expert , Prof. Loane Skene stated in a commentary on the subject in the British Medical Journal, "*The mother is the only person whose consent is relevant for abortion… her consent is sufficient legal authority for it to be done, provided that the abortion is not unlawful under the criminal law. No one can prevent her having an abortion, including the baby's father*". She goes on to say "*The fetus certainly does not have an enforceable "right to life" because, as noted earlier, no one can intervene to prevent the mother having an abortion, even well into in the pregnancy",* and she concludes "*the law approaches abortion from the viewpoint of the mother—it is lawful if her life or health would be seriously at risk if the pregnancy continued, (including by the birth of a child with a serious abnormality); and if she provides informed consent."*

http://jme.bmjjournals.com/cgi/content/full/30/4/408

The law aside, and harsh as it may sound to those who believe that life begins at conception, it seems that it is not a "Human Rights" argument. Dr Thomas Faunce who lectures at the Australian National University in both the school of Medicine and Law published a paper in 2003 in response to a proposed ACT bill of human rights. In it he discusses the debate on the definition of the beginning of human life and states that "*the record of drafting negotiations (travaux preparatoires) leading to the creation of the "right to life" in the human rights document known as Article 6 of the International Covenant of Civil and Political Rights (ICCPR), indicate that the proposal by Belgium, Brazil, Mexico and Morocco to make the protection apply "from the moment of conception" was rejected by a vote of 31 to 20 with 17 abstentions."*

Canberra Times 29 Sept 2003 p 11 http://acthra.anu.edu.au/articles/Faunce_Abortion_and_Bill_of_Rights4.pdf

The "right to life" issue and the unborn is eloquently discussed by Scottish Professor of Law and Ethics Sheila AM McLean and Kerry Peterson in their 1996 article "Patient Status and the Pregnant Women" published in the Australian Journal of Human Rights. In it the authors state " *it is well established that the foetus has contingent legal interests but it has no rights until live birth. Baker P's oft-quoted dictum on this point bears repeating. In Paton v Trustees of BPAS he said: The foetus cannot, in English law, in my view have any right of its own at least until it is born and has a separate existence from its mother. That permeates the whole of the civil law of this country ... and is, indeed, the basis of the decisions in those countries where law is founded on the common law, that is to say, America, Canada, Australia, and, I have no doubt, in others."* The Authors thoughtfully conclude their paper with this statement:
"We may all desire that every pregnant woman acts in an unimpeachable manner - many, if not most, do – but we cannot enforce this. To seek to do so would entail an unwarranted intrusion into all aspects of a woman's life solely because of the fact of her pregnancy. It would logically entail that the clinical information we have (not all of it unarguable) concerning what has the potential to harm the foetus would become not information or advice but an authoritarian regimen, removing freedom of choice for the duration of the pregnancy. It engenders, or perpetuates, discrimination against women based on their biological capacities. To adopt this approach, purportedly in order to show respect for the foetus, would be a monumental misunderstanding of the concept of respect and a perverse interpretation of the value of human rights. It is the law's shame that it has in the past colluded in this to the detriment of women."

Australian Journal of Human Rights June 1996 http://www.austlii.edu.au/au/journals/AJHR/1996/6.html

APPENDIX 3 HEALTH AND MEDICAL PEAK BODY STATEMENTS ON MEDICAL ABORTION

World Health Organisation (WHO)

"At the Special Session of the United Nations General Assembly in June 1999, Governments agreed that "in circumstances where abortion is not against the law, health systems should train and equip health-service providers and should take other measures to ensure that such abortion is safe and accessible. Additional measures should be taken to safeguard women's health."

Safe abortion - technical and policy guidelines for health systems – WHO, 2003
http://www.who.int/reproductive-health/publications/safe_abortion/

Cochrane Collaboration

" There are several different surgical techniques for early termination of pregnancy (abortion in the first three months). Several drugs can also be prescribed alone or in combination to terminate early pregnancy. This is called medical abortion, and uses the hormones prostaglandins and/or mifepristone (an antiprogesterone often called RU486), and/or methotrexate. The review of trials found that medical methods for abortion in early pregnancy can be safe and effective, with the most evidence of effectiveness for a combination of mifepristone and misoprostol (a prostaglandin). Almost all of the trials were done in well-resourced hospitals where women returned for check-up."

Medical methods for first trimester abortion, Kulier et al *The Cochrane Database of Systematic Reviews* 2005
Plain English explanation **http://www.cochrane.org/reviews/en/ab002855.html**

World Health Organisation (WHO)

14th Edition (March 2005) ESSENTIAL MEDICINES WHO MODEL LIST (revised 2005)

Explanatory Notes

"The core list [of essential medicines] *presents a list of minimum medicine needs for a basic health care system"*
"The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed"

http://whqlibdoc.who.int/hq/2005/a87017_eng.pdf

WHO ESSENTIAL MEDICINES LIBRARY

The WHO Essential Medicines Library is based on the 14th WHO Model List of Essential Medicines. It is primarily intended for national, hospital and institutional essential medicines selection committees.

http://mednet3.who.int/EMLib/

Medicine use(s): Mifepristone - Misopristol
Formulation : tablet 200mg - tablet 200micrograms
Rationale and Use : A Cochrane review of 39 trials showed that sequential administration of oral single dose mifepristone oral 200 mg tablet followed by vaginal single dose misoprostol 800 micrograms in 36 to 48 hours is effective and safe in inducing medical abortion of up to 9-weeks of pregnancy.Requires close medical supervision.
Note: Where permitted under national law and where culturally acceptable.
ATC Code(s) 0
Listing: Complementary List

http://mednet3.who.int/EMLib/DiseaseTreatments/MedicineDetails.aspx?MedIDName=443@mifepristone-misoprostol

Australian Medical Association (AMA)

RU-486 has been effectively banned in Australia since 1996. It is available in many countries including the USA and the UK.AMA President, Dr Mukesh Haikerwal, calls on the Federal Government to remove restrictions on the use of the drug in Australia.Dr Haikerwal said the AMA Federal Council made the change to its position statement to reflect current medical and clinical opinion on the drug, and to give women a safe and effective alternative to surgical abortion

AMA Media release 7 11 2005 : AMA Supports Use of RU-486 for Termination of Pregnancy
http://www.ama.com.au/web.nsf/doc/WEEN-6HW5DZ

Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)

9 Nov 2005 Media release : that RANZCOG gives
"support to the Australian Medical Associations' position on endorsing the use of non-surgical forms of pregnancy termination such as mifepristone (RU486). The College states that mifepristone (RU486) has a proven role in fertility control. It is widely available throughout Europe and the USA. It is now available in New Zealand, but not Australia. "RANZCOG believes that best practice in this field includes the option of using mifepristone when termination of pregnancy is to be performed", RANZCOG President, Dr Kenneth Clark said today. Mifepristone's use in conjunction

with prostaglandins provides the option of medical termination of pregnancy, which is an option preferred by many women."RANZCOG Media release 9 November 2005 http://www.ranzcog.edu.au/media/pdfs/MR-Mifepristone_9-November05.pdf

Federation of International Gynaecology and Obstetrics (FIGO)

Women have the right to make a choice on whether or not to reproduce and should therefore have access to legal, safe, effective, acceptable and affordable methods of contraception.
In summary, the Committee recommended that after appropriate counseling, a woman had the right to have access to medical or surgical induced abortion, and that the health care service had an obligation to provide such services as safely as possible.

From Ethical Aspects of induced abortion for non medical reasons (p65)
http://www.figo.org/content/PDF/ethics-guidelines-text_2003.pdf

Federal Drug Administration (FDA - USA)

The Food and Drug Administration today approved mifepristone (trade name Mifeprex) for the termination of early pregnancy, defined as 49 days or less, counting from the beginning of the last menstrual period.
Under the approved treatment regimen, a woman first takes 600 milligrams of mifepristone (three 200 milligram pills) by mouth. Two days later, she takes 400 micrograms (two 200-microgram pills) of misoprostol, a prostaglandin. Women will return for a follow-up visit approximately 14 days after taking mifepristone to determine whether the pregnancy has been terminated. Because of the importance of adhering to this treatment regimen, each woman receiving mifepristone will be given a Medication Guide that clearly explains how to take the drug, who should avoid taking it, and what side effects can occur.
"The approval of mifepristone is the result of the FDA's careful evaluation of the scientific evidence related to the safe and effective use of this drug," said Jane E. Henney, M.D., Commissioner of Food and Drugs. "The FDA's review and approval of this drug has adhered strictly to our legal mandate and mission as a science-based public health regulatory agency." FDA based its approval of mifepristone on data from clinical trials in the United States and France.
The labeling for mifepristone emphasizes that most women using the product will experience some side effects, primarily cramping and bleeding. Bleeding and spotting typically last for between 9 and 16 days. In about one of 100 women, bleeding can be so heavy that a surgical procedure will be required to stop the bleeding

FDA Media release 28 September 2000
http://www.fda.gov/bbs/topics/news/NEW00737.html

American College of Obstetricians and Gynecologists (ACOG) - *(USA)*

Medical abortion is a lengthier process with more steps than surgical abortion, so this method will not be chosen by every woman needing an early abortion," she says. "The evidence shows that most women who choose medical abortion do so because of a desire to avoid surgery if at all possible. We want to aid physicians wishing to help these women."

ACOG news release march 31 2001
http://www.acog.org/from_home/publications/press_releases/nr03-31-01-2.cfm

Royal College of Obstetricians and Gynaecologists (RCOG) - (UK)

"that abortion services should 'provide high quality, efficient, effective and comprehensive care that respects the dignity, individuality and rights of women to exercise personal choice over their treatment'"
and their president stated "Abortion is a safe procedure that should be funded by the NHS and seen as an integral part of a reproductive and sexual health care service. It is a basic health care need for women and should be regarded as such by those who purchase and provide services. We hope this Guideline will stimulate local services to review whether they are able to meet the needs of women with unwanted pregnancies."

From News release 13 march 2000 Royal College of Obstetricians and Gynaecologists Launches Abortion Guidelines
http://www.rcog.org.uk/index.asp?PageID=880&PressReleaseID=44

RCOG

Medical abortion is the most effective method for women who are less than 7 weeks pregnant. It is also a possible choice at any stage of pregnancy.

A doctor or nurse has the right to refuse to take part in abortion on the grounds of conscience, but he or she should always refer you to another doctor or nurse who will help. The General Medical Council's Duties of a Doctor says that doctors must make sure that their "personal beliefs do not prejudice patient care". The Nursing and Midwifery Council's Code of Conduct provides similar guidance to nurses.

From Abortion Care – What You Need to Know (patient info sheet)
http://www.rcog.org.uk/resources/Public/pdf/aboutabortioncare.pdf

RCOG

Induced abortion is one of the most commonly performed gynaecological procedures in Great Britain, with around 186 000 terminations performed annually in England and Wales and around 11500 in Scotland. The Abortion Act does not apply in Northern Ireland and no official abortion statistics are collected. At least one-third of British women

will have had an abortion by the time they reach the age of 45 years…… The provision of abortion as an integral part of broader sexual health services is reflected in the proposal within the strategy [The National Strategy for Sexual Health and HIV] to "develop managed networks for sexual health services with a broader role for those working in primary care settings and with providers collaborating to plan services jointly so that they deliver a more comprehensive service to patients". Sexual health strategies developed by the National Assembly of Wales and by the Scottish Executive include similar targets for abortion care.

From The Care of Women Requesting Induced Abortion
http://www.rcog.org.uk/resources/Public/pdf/abortion_summary.pdf

Planned Parenthood (USA)

"Since its approval in France in 1988, mifepristone has proven to be a safe, effective, acceptable option for women seeking abortion during the first several weeks of pregnancy"……

Mifepristone: Expanding Women's Options for Early Abortion ; Planned Parenthood
http://www.plannedparenthood.org/pp2/portal/files/portal/medicalinfo/abortion/fact-early-abortion-mifepristone.xml