

Submission

to the

Senate Community Affairs Committee

**Inquiry into Therapeutic Goods Amendment
(Repeal of Ministerial responsibility for
approval of RU486) Bill 2005**

From Salt Shakers
A Christian Ethics Group

Salt Shakers produces a monthly journal and an email news bulletin on a range of ethics issues, and has several thousand subscribers to these across Australia.

Jenny Stokes
Research Director

13 January 2006

Ph: (03) 9800 2855
PO Box 6049, Wantirna, Vic, 3152.

Submission

Introduction

The current inquiry into who should have the authority to decide if RU 486 – the Health Minister and the parliament or the Therapeutic Goods Administration – needs to be considered in terms of the effect and purpose of the drug as well as the technical question of who approves it.

The effect on the woman and on the unborn child both needs to be considered. The wider issues of ethics relating to abortion need to also be considered. The parliament is morally responsible for decisions relating to abortion. This is beyond the scope of the TGA, which operates to evaluate and assess drugs for their beneficial worth. The main purpose of RU 486 is the destruction of the child. However it also has severe consequences for the mother.

Recommendation

The proposal of the current Bill under Inquiry, that is the purpose of the Act as expressed in Section 3 of the proposed Bill is:

The purpose of this Act is to remove the responsibility for approval of RU486 from the Minister and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration.

Salt Shakers recommends that the Committee decline the recommendation proposed in the Bill. Salt Shakers recommends that the responsibility for approval of RU486 remain with the Health Minister.

Submission

The points made in the following submission initially focus on why the responsibility for approval should remain with the Minister for Health.

However it is impossible to properly consider that without considering the nature and application of the actual drug RU 486, so some points will address that as well.

1. RU 486 is restricted

The use of RU 486 in procuring an abortion is the primary reason the drug has a restricted classification. It is not simply a therapeutic drug that provides benefits to the consumer, such as aspirin.

Whilst the drug's helpfulness or therapeutic nature for women could possibly be debated, the effect of the drug on the unborn child is without dispute. It causes the death of the child.

The fact that a drug has such an outcome puts it in a totally different category and warrants the particular attention of the Health Minister and the Parliament who are accountable to the people through elections.

2. Therapeutic use of RU 486

If RU 486 is desired to be used by a doctor for a therapeutic purpose, such as the treatment of cancer, then that doctor can easily apply to use the drug and have the Minister consider whether approval should be given.

If it is genuinely for a therapeutic purpose that can be evaluated openly and be subject to public scrutiny rather than within the TGA.

3. Role of Parliament in deciding on abortion matters

If the purpose of giving responsibility for the approval to the TGA is to allow the drug's use for abortion when it is currently NOT allowed for that purpose, then this matter should be debated and voted on by the parliament.

Abortion has always been, and continues to be, a controversial matter. It is often given a conscience vote in the parliament due to the sensitivity of the issue.

It is not acceptable for the issue of whether abortions should be allowed using this drug to be dealt with merely by considering who gives 'approval' for its use.

4. The Health Risks of RU486 for the woman

The matter of who approves the use of RU 486 cannot be considered without considering the dangers of the drug. The health risks and dangers of using RU 486 have been well documented. These include severe bleeding, infection and death.

At least TEN deaths have occurred through the use of RU 486.

Since the drug has been allowed in the USA the FDA has documented at least 4 deaths.

a) FDA Patient Notice and warning

The FDA upgraded their warnings relating to the drug in July 2005.

They added this note to their Patient Information Sheet:

FDA ALERT– [07/2005] FDA is aware of four women in the United States who died from sepsis (severe illness caused by infection of the bloodstream) after medical abortion with Mifeprex and misoprostol. Sepsis is a known risk related to any type of abortion. The symptoms in these cases were not the usual symptoms of sepsis. We do not know whether using Mifeprex or misoprostol caused these deaths. Patients should contact a healthcare professional right away if they have taken these medicines and develop stomach pain or discomfort, or have weakness, nausea, vomiting, or diarrhea with or without fever, more than 24 hours after taking misoprostol. These symptoms, even without a fever, may indicate sepsis. Make sure your healthcare practitioner knows you are undergoing a medical abortion. “

This is posted on their website:

The US Food and Drug Administration Patient Information Sheet

Mifepristone (marketed as Mifeprex) or RU 486

<http://www.fda.gov/cder/drug/InfoSheets/patient/mifepristonePIS.htm>

This FDA “Patient Advice” also lists the major risks...

“What Are The Risks?

The following are the major possible risks and side effects of Mifeprex therapy. This list is not complete.

Cramping and Bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes, you can get cramping and bleeding and still be pregnant. This is why you must return to your healthcare professional on Day 3 and on about Day 14. See the [Medication Guide](#) for more information on when to return to your healthcare professional. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take on Day 3. Bleeding or spotting can be expected for an average of 9–16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of ending the pregnancy.

Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Prompt medical attention is needed in these cases.

Be sure to contact your healthcare professional right away if you have any of the following: *Heavy Bleeding.* Contact your healthcare professional right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical abortion/D&C) to stop it.

Abdominal Pain or Feeling Sick. If you have abdominal pain or discomfort, or you are feeling sick with symptoms including weakness, nausea, vomiting or diarrhea, with or without fever, more than 24 hours after taking the misoprostol, you should contact your healthcare professional right away. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).

Fever. In the days after treatment, if you have severe abdominal pain or a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your healthcare professional right away. Fever may be a symptom of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).”

b) An article by Dr John Wilkes lists 10 deaths from the use of RU 486.

RU-486 Has Killed Ten Women by John Wilke, on Life Issues...

This documents the deaths from RU 486.

See <http://www.lifeissues.org/ru486/deaths.htm>

He also had an article published in the New York Times on Nov 25, 2005, listing these deaths. (see www.nytimes.com/2005/11/23/national/23pill.html).

c) The RU 486 Files and other sources document the severe medical risks of the drug.

See <http://www.ru486.org/>

d) Study published in Annals Feb 2006

A major report published in the February 2006 edition of *Annals* journal, cites major adverse effects of RU 486 and calls for a review of the drug by the FDA.

The report is titled “**Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient**”

The authors Gary and Harrison analysed 607 unique adverse events, and concluded:

“The AERs discussed above relate to the use of mifepristone in otherwise healthy young women and document a significant risk of severe, life-threatening, or even lethal adverse events. The most common of these adverse events are hemorrhage, infection, and missed diagnosis of ectopic pregnancies. The most commonly fatal adverse event is sepsis, which may present without fever and progress rapidly to death.

Although neither the manufacturer nor the FDA recognizes a causal link between the use of mifepristone and the adverse events reported, it is undeniable that these women were healthy before the use of mifepristone and became very sick or died shortly after its use. Before any medication is used, a prudent practitioner weighs carefully the risks of the medication with the potential benefits. Medications, such as chemotherapy agents, with life-threatening or potentially lethal adverse effects are acceptable in treating conditions that are themselves debilitating or lethal such as cancer, HIV, sepsis, and others. In these cases, alternative treatments are limited and, without treatment, the disease is rapidly lethal. The use of mifepristone as an abortifacient, however, is radically different. Pregnancy in most instances is a benign, self-limited condition, with duration of approximately 8 months from diagnosis for most women. It generally occurs in otherwise healthy young women. The choice of mifepristone termination over surgical termination is based mainly on patient perceptions of safety, convenience, and privacy, but these perceptions do not accurately reflect the realities of the regimen.

Furthermore, complete, accurate data concerning the public health risk posed by the mifepristone/misoprostol regimen currently in use are not being gathered through the FDA’s Adverse Event Reporting System. After reviewing over 600 AERs, we believe that the FDA must promptly conduct a thorough review of this aspect of its postmarketing surveillance system to determine whether the failures described above are peculiar to mifepristone reports or are systemic to all drug reports.

See the Report Abstract at <http://www.theannals.com/cgi/content/abstract/aph.1G481v1>

Full Report at <http://www.theannals.com/cgi/reprint/aph.1G481v1>

5. Use of the drug for ‘rural women’

Those promoting the use of the drug in Australia often refer to the lack of availability of abortion in rural areas and suggest that this might provide an alternative.

However, the drug requires repeated medical treatments and at least three visits to a doctor. This is detailed on the FDA patient sheet.

“You must have 3 visits to your doctor’s office during the treatment procedure. It is *extremely important* that you attend all three visits.”

If rural women have difficulty getting to a doctor – or obtaining medical appointments – this will not be a suitable treatment for them.

Doctors commenting in an article in *The Age*, noted that it would be very unsuitable relating to privacy concerns – many people including the doctor, nurses, emergency services and pharmacists all knowing what you are doing.

In addition, at least 10% of abortions done using RU 486 require a surgical procedure to 'complete' the abortion and remove material from the womb.

The concept of encouraging women to 'have a miscarriage at home' using RU 486 discounts the horror and trauma suffered by many women when they see the aborted identifiable baby that is 'expelled' after taking these drugs.

Conclusion:

We encourage the Committee to recommend that the process of approving the use of RU 486 remain with the Health Minister in order to ensure openness and accountability on this sensitive issue.