COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Reference: Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

THURSDAY, 15 DECEMBER 2005

CANBERRA

BY AUTHORITY OF THE SENATE

INTERNET

The Proof and Official Hansard transcripts of Senate committee hearings, some House of Representatives committee hearings and some joint committee hearings are available on the Internet. Some House of Representatives committees and some joint committees make available only Official Hansard transcripts.

The Internet address is: **http://www.aph.gov.au/hansard**

To search the parliamentary database, go to:
http://parlinfoweb.aph.gov.au

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Thursday, 15 December 2005

Members: Senator Humphries *(Chair)*, Senator Moore *(Deputy Chair)*, Senators Adams, Barnett, Fielding and Polley

Participating members: Senators Abetz, Allison, Bartlett, Mark Bishop, Boswell, Bob Brown, George Campbell, Carr, Chapman, Colbeck, Coonan, Crossin, Eggleston, Chris Evans, Faulkner, Ferguson, Ferris, Forshaw, Hogg, Hurley, Joyce, Lightfoot, Ludwig, Lundy, McEwen, McGauran, McLucas, Milne, Nettle, O'Brien, Parry, Payne, Robert Ray, Siewert, Stephens, Watson, Webber and Wong

Senators in attendance: Senator Humphries *(Chair)*, Senator Moore *(Deputy Chair)*, Senators Adams, Allison, Boswell, Fielding, Joyce, McGauran, McLucas, Nash, Nettle and Polley

Terms of reference for the inquiry:

Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU485) Bill 2005.

WITNESSES

Committee met at 9.06 am

CHIRGWIN, Dr Margaret, Director, Public Health and Ethics, Australian Medical Association

HAIKERWAL, Dr Mukesh, President, Australian Medical Association

PESCE, Dr Andrew Francesco, Executive Councillor, Australian Medical Association

CHAIR (Senator Humphries)—Welcome. The Senate Community Affairs Legislation Committee is inquiring into the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005. The committee will be taking evidence on the bill, which proposes to move responsibility for approval of RU486 from the Minister for Health and Ageing to the Therapeutic Goods Administration. This inquiry will focus on the terms of the bill by seeking evidence on the issues that are relevant to the bill in order to inform the Senate in its deliberations.

I thank the witnesses for making themselves available to attend this hearing today at very short notice. It has been arranged for the committee to take evidence before submissions formally close in mid-January in order to give the committee an idea of the issues that it is facing and to inform the background to the later public hearings in February.

As you can see, we will have requests from the media today for footage to be taken. If there is no objection to that occurring, I will take it as agreed that we admit them to do that.

Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. I appreciate that we do not have a submission as yet from the AMA, but would you like to make an opening statement on the committee's terms of reference before we proceed to questions?

Dr Haikerwal—Thank you for asking the AMA to be your first presentation this morning. I hope that we will be able to reassure you that the proposed amendments to the Therapeutic Goods Act 1989 will benefit the Australian population as a whole and Australian women in particular. I know that there are a lot of groups lobbying you on this issue, and we are just one. You will hear from many today and on the further two days of your hearings. To be first is an honour, as it recognises that you value the AMA's input highly. As a body representing nearly 28,000 doctors, we take great care when developing policy on a wide range of issues, and we took great care while discussing and developing the policy relevant to today's discussion. Our membership is wide and reflects the same diversity as exists in the community.

Following the review of the literature we revised our own position statement on termination of pregnancy. The revised section of our position statement on reproductive health and reproductive technology of 1998 is short, and I will read it to you in total:

1. The AMA respects the rights of doctors to hold differing views regarding termination of pregnancy.

2. Where the law permits termination of pregnancy, the procedure and the associated anaesthesia should, as with any other medical intervention, be performed by appropriately trained medical practitioners, in premises approved by a recognised health standards authority.

3.—

and this is the one that was amended recently—

Where the law permits termination of pregnancy, non-surgical forms of termination (such as RU486/mifepristone) should be made available as an alternative to surgical abortion in cases where they are medically deemed to be the safest and most appropriate option based on the appropriate clinical assessment.

4. It is the doctor's responsibility to provide patients with information regarding the potential health risks and psychological consequences which can arise from continuation of and termination of pregnancy.

The revision we made was to replace a short section with 3., which stated that, where the law permits termination of pregnancy, non-surgical forms of termination—for example, RU486 (mifepristone)—should be made available as an alternative to surgical abortion in cases where they are medically deemed to be the safest and most appropriate based on appropriate clinical assessment. In this revision we took great care to make no judgment about the rights and wrongs of abortion as many of our members do not support abortion. However, we all support the need, where abortion is legal, for it to be performed safely and to the highest possible standard to ensure that women who choose this option do not suffer unnecessary harm.

The change to our position statement was made because we believe the necessary research on non-surgical forms of abortion has been done and has reassured us that the risks to women of using RU486 are acceptably low. There have been a few deaths, but sadly there are also a few deaths from surgical abortions as well. Indeed, reproductive health is fraught with danger. Our review of the present literature led us to the same position as the Royal Australian and New Zealand College of Obstetricians and Gynaecologists: that non-surgical forms of abortion based on RU486 are sufficiently safe and that they should be made available to Australian women within, of course, a therapeutic relationship, with all the necessary services and support. There is no expectation that the rigorous service provision that ensures surgical abortions are very safe would be relaxed when the medical option is made available.

We therefore call upon the government to remove the effective ban on RU486 by repealing the part of the TGA Act which was added in 1996 giving ministerial responsibility for approving evaluation, registration, listing or importation of restrictive goods in Australia and defining restrictive goods as medicines intended for use in women as abortifacients. These are the only drugs to require this kind of ministerial approval. This section of the act has effectively banned the entry of RU486 into Australia not only for use as abortifacients but also for the number of other possible uses, such as emergency contraception, treatment of endometriosis and treatment of some breast and brain tumours. We believe that the TGA is best suited to decide upon the safety of all medications and therapeutic products including RU486 and should be given the opportunity to judge the safety and efficacy of this medication as it does for all others. It is the best qualified authority to decide when and where and with what support services this drug should be made available. They must exert their judgment freely, fairly and away from undue pressure.

The AMA's judgment is that they will find the drug to be as safe as many others that are available in Australia and that the safety profile is acceptable. Women would of course need to be provided with sufficient information to make an informed choice between surgical and

medical abortion, once they have decided that abortion is required for them. It is certainly far safer to terminate a pregnancy with RU486 than to take the pregnancy to term but we will need to know about the rare possibility of death and the much more common issues of prolonged bleeding and possibly needing a surgical intervention to remove any retained products of conception, which happens in between five and eight per cent of cases. However, the AMA believes that the medical alternative to a surgical procedure, where legal, should be available to Australian women but should of course accept the verdict of the TGA on the safety of RU486, both for use of inducing an abortion and in the possible other areas mentioned above.

We understand there is concern about the number of abortions performed every year in Australia but we do not believe that RU486 will have a significant impact on the number performed. RU486 was introduced into the UK in the middle of 1991. The abortion rate per 1,000 women aged 15 to 44 in 1990 was 15.5. It was 15.04 in 1992 and went down to 14.59 after that. The rate of abortion pre the introduction of RU486 was not again reached until 1996.

Restricting access to RU486 in the unsupported expectation it will reduce the number of abortions is not reasonable. The AMA supports actions the government is proposing and should consider taking other actions to reduce the demand for abortion such as sex education in primary and secondary schools; improving access to effective, modern contraception and emergency contraception on the PBS; making the work environment more conducive to having children by increasing the availability of child care and making it more affordable by allowing child-care costs to be claimed as an expense and therefore paid pre-tax; and, mandating six-month paid maternity leave and a whole raft of other supports that we are not here to discuss today.

Our request is that senators consider the merits of the issues to hand and that restricting access to RU486 will not keep the numbers of abortions down. Women have always accessed abortions and unfortunately will continue to do so. By making RU486 available, you will remove the need for surgery for some. However, in reality most will probably continue to use surgical services. Thank you.

CHAIR—Thank you very much. Dr Pesce or Dr Chirgwin, do you wish to say anything at this stage?

Dr Pesce—No. I think we will leave the issues open.

CHAIR—Could you describe the procedure by which RU486 might typically be used, if there is a typical example, and what are its pharmacological effects?

Dr Pesce—Assuming the appropriate counselling and assessment of the patient has led to the decision that it is going to be used, it is used by giving an oral dose of mifepristone usually at the time of attendance at the clinic.

CHAIR—Is mifepristone and RU486 the same thing?

Dr Pesce—Yes. Roussel Uclaf was the company that developed RU486. That is its trade name. The generic name is mifepristone. It is given orally, usually on site, and the patient then is able to go home. Then, two days and three days later, a follow-up dose of a prostaglandin is

given. There can be various ones, but the most common one used overseas is misoprostol. Misoprostol is given either as an oral dose or a vaginal dose. Sometimes it is given, once again, with a patient returning to the site. It is administered under direct supervision of the staff of the clinic. Sometimes it is self-administered by the patient at home. There are several times when the patient needs to take a medication.

You asked about the mechanism of action. Mifepristone is a progesterone receptor antagonist, so it is chemically structurally similar to the progesterone molecule and therefore occupies a progesterone site on a cell. But it does not have the progesterone activity and therefore blocks the action of progesterone in the body and causes changes in the body because of the antiprogesterone effect. That will have various effects depending on the time it is used in the menstrual cycle. It may prevent ovulation, if it is given earlier than ovulation. It may cause premature failure of the follicle which produces the pregnancy-supporting hormones, if it is given later. It may induce a bleed, if given at the time of the expected missed period. These are the mechanisms by which it will have a reproductive effect.

CHAIR—The drug has the potential to have a contraceptive effect or an abortifacient effect.

Dr Pesce—That is correct.

CHAIR—As far as taking evidence is concerned, I propose to move around the table and invite senators to ask a couple of questions each. We will see how that goes in terms of being able to share the time available between all those who wish to ask questions. We will start with the deputy chair, Senator Moore.

Senator MOORE—Dr Haikerwal, in your opening statement, which was very fast, you did look at the issues of safety. I think that is something we are all interested in. We have received numerous emails about people's concerns, including concerns about alleged case studies from the United States. Whilst you did touch on the safety issues in your opening statement, I think it would be useful for the record to have some discussion about the particular issues of safety where this drug has been used and the knowledge you have about that. I will also put my second question on the record now. You have now changed your policy. Can you explain the process the AMA used to come up with that policy?

Dr Haikerwal—I will ask Margaret Chirgwin to reply to the second part in a moment. She is our public health director and manages that particular process. Regarding safety, I will make a few comments then Dr Pesce will also. The drug has been used in many parts of the world. In the UK it was introduced in 1991. Across the world there are over two million users of the drug. There are reports of infections that have been fatal in some instances. The particular bug that is involved in that is one that was around before RU486 and continues to be around. The problem with that particular bug is that it is hard to determine whether somebody is infected. There has been some talk about using the regime of medical abortion with antibiotics, but that has not been shown to be particularly beneficial either. If you look at figures for maternal mortality, in one particular triennium in Australia there were 90 deaths reported from normal pregnancies, whereas zero were reported from abortions. The other specific problems with RU486 are very much on a case-by-case basis and they are very small relative to the number of times that the drug has been used. All medications have risks

associated with them. All surgical procedures have risks associated with them. Indeed, continuing with a pregnancy also has risks associated with it. But it is important those risks are put into context.

Dr Pesce—The infection is caused by bacteria, which could be treated with antibiotics. Unfortunately, because the symptoms of infection are often very similar to the symptoms of what happens in a miscarriage—which is essentially what is being induced—it is not easy to pick which women have the infection. The other problem is that it is a toxic shock type syndrome. It is not just the active infection where the proliferation of the bacteria is causing the illness; it is the toxin, which is already preformed within the system, which then causes multiorgan failure. So you can be successfully treating the infection and it still may cause severe illness and death. Currently the understanding is that there have been five deaths associated with mifepristone use. Four of them have been classified as deaths from clostridium sordellii. There has also been a death from a ruptured ectopic pregnancy. This is where it is also important for any care providers to be aware that until the pregnancy is known to be intra-uterine there is a risk that it is an ectopic pregnancy in the fallopian tube or elsewhere, and mifepristone is not as successful in ending those pregnancies. Once again, the early symptoms of complicated ruptured ectopic pregnancies are similar pain and bleeding and the same sorts of symptoms that you would expect in a woman who is aborting or miscarrying. Therefore, unless it is something which is being carefully screened for, there is a risk associated with that.

Senator MOORE—I will not follow up on that; other senators have questions and I am sure they will be following up on that.

Dr Pesce—Basically we now have the benefit of hindsight. When this question was considered in 1995 and 1996 there may have been quite reasonable questions about the safety—as there are for any new medical or surgical procedures. Those deaths are extremely distressing and we would want to avoid any deaths, but there are no medical or surgical procedures which have no risk of death. From our overseas experience, comparatively speaking, on balance the rate is similar to deaths from surgical abortion and probably similar to direct obstetric deaths from complications of pregnancy.

Senator MOORE—Thank you.

Dr Chirgwin—You asked about the process. The process within the AMA is this: we have an Ethics and Medico-Legal Committee, and this issue obviously lies in their area. Earlier in the year my team put a paper to them which reviewed the literature. What we used to have was one short paragraph which said, 'The AMA acknowledges the need for further research into non-surgical forms of termination.' We replaced that with a new one which says 'Where the law permits termination of pregnancy, non-surgical forms of termination ...' et cetera. We only removed one very small line. We did a review of the literature and we also had conversations with the Royal College of Obstetricians and Gynaecologists, because they were also doing a review of the literature at the time. We presented that to the Ethics and Medico-Legal Committee, who discussed it. They then approved this change, which then went to federal council, who then had a further discussion about it before it was finally approved.

Dr Haikerwal—Our federal council is made up of 33 different people from varying specialties.

Senator MOORE—And they are elected, Doctor?

Dr Haikerwal—They are all elected.

Senator FIELDING—Thanks for that brief information. Family First is concerned about the health risks for women associated with this drug. Can you step me through the processes again that you outlined before about someone who has come to see a doctor. Can you roll through that again? You briefly went through it before.

Dr Pesce—From the point of view of maximising its safety?

Senator FIELDING—Just through the process, yes.

Dr Pesce—Of course it is not done in Australia at the moment, so I am going on what is done overseas. Basically, a woman usually would come having fairly certainly made up her mind by the time she gets to the health care providers. She has probably been through a lot of turmoil in making a very, very difficult decision. In my experience, by the time she has come, her mind is pretty well made up—although there are exceptions. There are women who come to me for counselling, as they should do. Once a decision has been made to terminate a pregnancy then a reasonable practitioner would talk about all of the available options which might be suitable for the woman—put to her the risks, put to her the advantages of various ways of doing it—and then hopefully, in a non-directive way, allow the woman to follow up with questions and then make a decision as to what she thinks is best for her. There is no doubt that, almost universally, a woman will be very heavily influenced by the information given to her by the practitioner. She will almost always follow the advice of the practitioner, but there are some women who are very determined to do things in a way that they have thought through, and go through with that.

If the decision is made to go through with a medical termination of pregnancy, the recommendations are that all of the risks are outlined to the patients, warnings given about the potential complications. I think those warnings would now be augmented compared to what they may have been before because of the United States FDA reports of the toxic shock related deaths. It is recommended that the woman be given 24-hour telephone access at least, so if there are any problems there has to be 24-hour availability of advice via the telephone. The advice would also be that, at a predetermined interval afterwards, the woman returned for screening to ensure that the process was proceeding and had been completed in a clinically satisfactory way and that the uterus was empty, the bleeding was settling and that things were settling down.

Dr Haikerwal—Prior to going to a specialist referral, the woman's first point of contact is usually the family doctor or GP, who will know what their particular situation is. They will discuss with them what options they have when they find themselves pregnant and whether that pregnancy is something that they want to continue with or not.

Senator FIELDING—Are you aware that in November the Italian health minister suspended Italy's experimental trials of RU486? This was only two weeks after a hospital had begun using the drug. There were 20 women who had used it; some had partial births at home,

some excessive bleeding. Are you aware of that situation at all and any reasons why they would suspend it?

Dr Haikerwal—We are certainly aware that was reported. I am not sure how the medication was used in the Italian context. Certainly that is not the experience of other countries where it continues to be used.

Senator BOSWELL—But surely there might be—

CHAIR—Sorry, Senator Boswell, but we have a very strict order of questioning today and I would prefer not to—

Senator BOSWELL—Yes, I know and I appreciate that, but as a point arises surely we can join in.

Senator ADAMS—None of us have done that.

Senator BOSWELL—Senator Adams, you have been here about three months. Just hang on.

CHAIR—We will be able to get to you very shortly, Senator Boswell. That was your second question Senator Fielding.

Senator FIELDING—I had a third.

CHAIR—We all have third questions, but we will have to take it in turns.

Senator FIELDING—What was the answer to that question?

Dr Haikerwal—We are certainly aware of that as a report of that discussion within the Italian context. It is not the same context as in other countries where the drug continues to be registered and used.

Senator NASH—Chair, I do not think it is appropriate behaviour for another senator to say to a senator that they should not comment because have only been here three months.

Senator ADAMS—We have only been here three months. We are not impressed about that.

CHAIR—Yes, indeed. Senator Boswell, with respect, we will take this on the approach that I have already indicated, which is that we will have turns when they come around and not otherwise.

Senator BOSWELL—Okay, I withdraw.

CHAIR—Members of the committee will certainly have priority as far as asking questions are concerned, irrespective of how long they have served on the committee.

Senator ADAMS—Dr Haikerwal, I would like to go back to the actual terms of reference of the bill. Could you tell me the AMA's opinion as to whether the minister should have the approval for the authority of this drug or the TGA? I would like to get your opinion on the record.

Dr Haikerwal—The view that we have expressed is that the TGA is the expert body that makes decisions about all therapeutic products used in the Australian context and indeed medications within Australia. It is an impartial body. It looks at evidence in the cold light of

day. It makes decisions based on what works, how well it works, how safe it is and whether it is a useful intervention within the Australian context. It should be allowed to continue to make those decisions for all medications and all therapeutic products.

Senator BOSWELL—Dr David Gawler, a surgeon at the Royal Darwin Hospital, has written a letter to all senators. I would like to table that letter. He has written to all senators outlining his concerns about RU486. He consults regularly in remote Aboriginal communities. Dr Gawler says:

RU486 ... in rural and remote locations ... is not ill-considered, but dangerous.

I take it that you do not agree with Dr Gawler?

Dr Haikerwal—In a context where there are no follow-up surgical facilities available it would not be used. RU486 is a medication which would be used under the same strict guidance as surgical terminations, because there is a need for surgical intervention in five per cent of women. Whereas 100 per cent of all women having surgical terminations need surgery, five to eight per cent of women who end up needing RU486 would require surgery. Therefore, it would never be prescribed in a setting without access to a remote hospital with a doctor able to perform curettage.

Senator BOSWELL—The first reason he gives is that the manufacturer's protocol says that a woman using RU486 must see a doctor on day one, three and 14. He also says that ultrasounds are not readily available in rural and remote areas. Do you agree with him on that?

Dr Pesce—There is no doubt that there are areas where the full backup facilities would not exist. Presumably, if the TGA performed its proper function, it could assess all of this and could place restrictions on the use of the drug as it does on many other drugs. It could be made an authority drug so that it would only be authorised to be used when certain prerequisite criteria were fulfilled. That would be a matter, quite properly, for the TGA to consider and it may well, quite properly, make recommendations along lines which would minimise the risks to women who do not have appropriate backup facilities to allow safe use of the drug.

Senator BOSWELL—I will keep to the script here, because we are pretty limited in time. Doctor Gawler says:

In many areas of Northern Australia, serviced by itinerant doctors, this would not be possible.

That is, to follow those procedures up.

In addition, continuous medical cover is often not available.

In those instances would you agree that it would not be safe to give RU486?

Dr Pesce—Where there is no appropriate medical backup, it would not be safe.

Senator BOSWELL—Thank you. If it was made legal—

CHAIR—Senator, I realise that you have a number of questions to ask, but I have indicated the procedure that we will use here. I will move to other senators and come back to you at the end, if we have time.

Senator FIELDING—Chair, I know as a committee that we discussed how much time we would need and there was a fairly lengthy debate about the time and already we are rushing on this issue. I heard last week a number of senators complaining about the amount of time we have to fully consider issues and here we are within four or five minutes already saying we have a time shortage.

CHAIR—I understand what you are saying, but we have agreed that we will have hearings today. We have 45 minutes provided for this set of witnesses. Dr Haikerwal, I understand, has to leave here to catch a plane at 9.45 am. We might consider this issue later. Let us get on with hearing these witnesses and perhaps in the break we might meet and discuss whether we need to change our hearing procedure.

Senator McLUCAS—Dr Pesce, you have talked about an 'on authority' drug. I want to ask you about the process by which the TGA approves medication and the likelihood of the TGA providing advice to a prescribing doctor about how the drug should be administered. I know that I am asking you to speculate on what might occur, but could you give the committee some indication of how that would work?

Dr Pesce—In normal circumstances, a company which is to introduce a drug into Australia could make an application or doctors who wish to use a drug for a clinical use can make an application.

Dr Haikerwal—Or, if there is a community good, it can be launched through a separate process.

Dr Pesce—The TGA would then designate appropriate experts to look at the evidence, both in terms of community need and data on safety and efficacy, make the relevant assessment and give a decision. In answer to your question, I think in a case such as this—given the very high profile, that the community is paying attention to this—I suspect their decision would be a very conservative one and would err on the side of emphasising safety rather than on rolling out a new therapy.

Senator McLUCAS—Do you imagine it would be an 'on authority' drug?

Dr Pesce—It would not surprise me. There are many authority drugs out there, a lot of the time just to contain costs but often also to make sure appropriate clinical use is followed. There are so many out there and doctors are so used to working within that system that I do not think it would be a logistical problem to use that system to enhance the safety of the introduction of the treatment.

Dr Haikerwal—Perhaps I can clarify the process a little more. The TGA obviously looks at the efficacy and the benefits of the drug and its safety profile based on Australian data but also data presented by the company and international data. The next step towards putting it onto the prescribing Pharmaceutical Benefits Scheme is done by the Pharmaceutical Benefits Advisory Committee. Any restrictions would pay heed to TGA's deliberations when putting restrictions on around prescribing and whether it goes onto authority. Yes, it is a continuing process.

Senator NASH—Dr Haikerwal, thank you for being here today. Going back to the terms of reference of moving the responsibility from the minister to the TGA, in your opening

statement you mentioned the benefit that would be brought to all Australians. I assume that your view is that moving from the current situation to the TGA having the responsibility would be of benefit to women in Australia. Can you expand on that a little further?

Dr Haikerwal—The need for expert opinion, consideration of data and the evaluation of products has to be done at arm's length from government because of considerations such as costs that would also preclude government from making certain decisions. We need to have an independent umpire, and we believe that the expert group that is the independent umpire is the TGA and that that group is the one most suited to make this sort of decision. I have no particular problems with the minister of health or with his beliefs. We know what they are and that is not the issue here. The issue is the TGA does every other drug and every other device we have in this country bar one.

Senator NASH—So to retain the current situation I guess would be to the detriment then of women? If it were going to be of benefit to move it to the TGA, retaining the current situation would then seem to be of detriment to women in Australia?

Dr Haikerwal—Indeed. It is not about this particular health minister. It was actually brought in under a different health minister anyway, so it is not just a matter of the minister or not the minister; it is a matter of the process and the reference to the independent umpire: the expert group.

Senator NASH—Finally, do you have complete confidence that the TGA have the ability to put an appropriate process in place to manage this drug safely in Australia, if they approved it?

Dr Haikerwal—Absolutely.

Dr Pesce—I think there is a well thought out, good, transparent arms-length system that has been put in place and it is acceptable for every other introduction of drugs into Australia. It would seem to me that this situation protects both the public and the government so that there can be no allegations or inference that there are decisions other than what the best public interest is at the heart of whoever is making the decision.

Dr Haikerwal—The TGA also act fearlessly. We saw that with Pan Pharmaceuticals and we saw that with vioxx, which was a very big-selling drug which worked but it had significant problems. They have worked independently of other statutory bodies, so they have the capacity, the ability and the wherewithal to do that if they need to.

Senator ALLISON—You have said, Dr Haikerwal, that the risks are acceptably low for RU486, mifepristone. There has been a lot of discussion about the four fatal cases in California. Can you tell us more about that? My understanding is that with that infection the outcome would have been the same had a surgical method of abortion been used or, indeed, the pregnancy carried to full term. Is that your understanding?

Dr Haikerwal—That is certainly my understanding. It is a genital infection that can cause problems, whichever part of the reproductive cycle we are talking about. Whether it was a miscarriage or ongoing pregnancy, it could still be an infection. The safety profile is not dissimilar to that of surgical procedures. Obviously, surgical procedures have associated with them the whole trauma of surgery, including the anaesthetic. Although they are all very low

risk, because we have such excellent services for anaesthesia and gynaecological procedures these days, there is still a risk involved with that sort of process.

Dr Pesce—In answer to your question, it can follow normal pregnancy. It can follow any gynaecological procedure of the uterus. Interestingly, in the post-mortem studies, the abortions had been complete. There was no retained tissue. It is certainly significant that you have this run of cases, but it is still unclear what connection there might be between the mifepristone being used to induce abortion and the cases that have led to deaths. But certainly these infections do occur and the majority of them occur outside this process and can occur in women who are pregnant and women who are not and who undergo surgery for other reasons. So it is not just restricted to this clinical setting.

Senator ALLISON—Would you spell out what you see as the benefits? What are the advantages? Why would it be that 50 per cent of women in the overseas experience chose a medical abortion as opposed to a surgical abortion? What is your perspective on that?

Dr Pesce—I think that in different contexts different women will make decisions that they feel most comfortable with. I underwent a vasectomy some years ago and, for some reason at the last minute, I decided I did not want a general anaesthetic and I had it done under local anaesthetic. I cannot tell you intellectually why I made that decision. I did not want a general anaesthetic and to go to sleep. I suspect that maybe this decision is the same. Maybe there is a sense of loss of control in a woman who has unexpectedly found herself pregnant. She has gone through a very difficult time—not of her choosing—and this may be a way of re-establishing some sort of control to say, 'I need to turn my life around, I want to make a decision; I am going to make this decision now.' Perhaps it is on that basis.

But, when you look at studies following up women who have undergone these procedures—and it may be a bit biased because it tends to be done earlier in pregnancy rather than later and therefore maybe the psychological sequelae of termination of pregnancy would be lower in women who have gone through the process earlier in pregnancy—they seem to have less psychological morbidity. It is postulated that possibly coming into the hospital, having an anaesthetic, having a surgical procedure and all that might actually have an effect on their psychological recovery.

Senator ALLISON—And the benefits of being able to have the termination—

CHAIR—Thank you, Senator Allison.

Senator ALLISON—I am sorry; it is the same question.

CHAIR—I am sorry, but we do have a procedure. We will come back for more questions at the end if we have time. Are you able to stay a little longer, Dr Haikerwal?

Dr Haikerwal—Yes.

Senator JOYCE—This would be a correct state, wouldn't it? There are people walking around today who, when we bring in RU846, mifepristone and misoprostol, through either clostridium sordellii or whatever, who will be dead after they take this drug.

Dr Pesce—Over a large number of years, it is probably inevitable.

Senator JOYCE—But it is inevitable, is it not? So it is a fact that there are people who will die from this?

Dr Pesce—They will die from complications of the termination of pregnancy.

Senator JOYCE—It will be from this drug though, just like it is in the United States?

Dr Pesce—I think it will be from the abortion. Whether it is due to the drug or not remains to be proven.

Senator JOYCE—But it actually antagonises and enhances the chance of infection through such things—or you do not think that is the case?

Dr Pesce—No, there is no evidence for a link between the actual drug and the type of infection that occurred. There is no doubt that it occurred after an abortion. There is no direct link between the drug and the choice of the medical abortion and this death, although perhaps one day that might be found. But there is no theoretical, clinical or scientific connection that has been established between this particular drug and the deaths.

Senator JOYCE—I have just two more questions.

CHAIR—One more question.

Senator JOYCE—One last question: in your ethics committee, how many people's lives did you consider in the use of this drug? Do you consider that it just affects one person's life or two and why did you come to that decision?

Dr Pesce—We particularly made a decision not to enter into whether abortion should be available, the morals of it. We wanted to make a clinical decision based on medical evidence and so very specifically we said where abortion is lawful then options should be made available to the woman. We did not go into the morals of whether abortion should be made available to women. We just made a comment that, if a country and a society have come to a decision that abortion is lawful in certain circumstances, in those circumstances where it is lawful, all of the options should be made available to the doctors and their patients.

Senator JOYCE—So there is a very specific reference as to who it is safe for.

Senator NETTLE—Thank you very much for being here to give evidence today. About a month ago, the AMA made some comments in relation to the advice that the minister had sought from the health department about this particular drug. Could you elaborate on that for the committee's benefit? Could you also comment on your views about how that process was done in relation to the minister seeking advice from the health department and how that might be different to a process where the TGA would be making a decision on the drug?

Dr Haikerwal—The ministerial advice was a specific question and was answered in a very specific way. The chief medical officer has made statements specifically around that issue himself. If there were an independent committee looking at this with all the evidence, I think the discussion would have been different. It is very clear that the use of medication such as RUA486 requires medical supervision and requires the access to surgical facilities in the five per cent of cases where surgery is required. Obviously, it is not something that is available where there is not a rural and remote location for surgery and where there is not medical

cover. The same rigour has to apply to the implementation and use of a medical form of abortion as would be there for a surgical form of abortion where it is legal.

Senator NETTLE—How do you think the advice would have been different if it had been advice sought by the TGA rather than by the health minister?

Dr Haikerwal—The TGA would consider the entire Australian context, not just the rural and remote context and would not make the inference that there was a potential for it to be used where there was no ongoing surgical facilities and no monitoring of the patient available.

Senator McGAURAN—Because of the possible health risks, which we all understand, particularly in the light of the fact that this is being sold as a take-home abortion procedure, we would all agree that the procedure and the counselling of the taking of the drug is critical—although I did notice you have been asked that question twice and have been quite evasive, if you go back over the *Hansard*. But we would agree on the principle of counselling and procedure. What advice or counsel would the AMA recommend to the patient as to what to do with the foetus when delivered alone at home?

Dr Haikerwal—It should not be a take-home product; there should be medical supervision. It has to be done with the same vigour and supervision as a surgical termination would be. We have not been evasive regarding counselling. Counselling is absolutely paramount. At every juncture, the woman has to take counselling and be helped through a very difficult time in her life—

Senator McGAURAN—My point was that, when asked twice, the doctor was evasive in explaining the full procedure. The question was: what counsel would you give the woman, under that circumstance, on what to do with the foetus once delivered at home?

Dr Haikerwal—The woman has the choice of how to dispose of the foetus. There are many ways that that can be done. That is something that can be taken to the hospital.

Dr Pesce—There is no statute to say what you have to do. The important thing is for the woman to be told that she is going to miscarry at home. It might come as a surprise to you, but women are used to dealing with menstrual loss all the time. She can make a choice of what she wants to do. She needs to know that she may pass a foetus. Depending on how many weeks pregnant she is, it may be an identifiable foetus. She needs to be prepared for that, but the choice is hers. There is no compulsory way to dispose of it.

Dr Haikerwal—The disposal issue is the same as when a woman has a miscarriage that is spontaneous. There are still products of conception that have to be removed and dealt with. Women grieve that, and they grieve it in various ways.

Senator BOSWELL—If RU486 were made legally available in Australia, how would you stop people buying it on the internet or from some form of black market? There will be people who get it and distribute it. Has the AMA—

Dr Pesce—We can do no more than we can now.

Senator BOSWELL—It is not in Australia now, so there cannot be a—

Dr Pesce—You could pass laws in Australia to make it illegal to supply it without prescription, and any company that does so would face penalties which would not make it

worth their while, but if women wanted to they could currently access things from overseas. You should ask Customs how you can stop it from coming into the country. I do not think that—

Senator BOSWELL—I am saying: once it is in the country, how would you stop it? You obviously have not considered it, so I will move on.

Senator MOORE—I think that is an unfair assertion.

CHAIR—It is an assertion which the doctors can respond to.

Senator BOSWELL—Have you considered it?

Dr Pesce—There are a lot of prescription-only drugs, and the problems of internet access and buying off the shelf without appropriate medical supervision are not high in this country for drugs which have very significant dangers and side effects if used inappropriately.

Senator BOSWELL—But this is a bit different, because women's lives are at risk. I am under the—

Dr Haikerwal—Senator, if a woman or man buys any drug over the internet without medical supervision and uses them inappropriately, their lives are at risk, whether it is aspirin, Nurofen, antibiotics, the works—this is one of them.

Senator BOSWELL—Doctor Gawler states:

RU486 has some quite serious and potentially fatal complications, which have been well documented even by the manufacturer. Treatment of these complications may require urgent admission to a hospital.

He cites complications including:

... severe vaginal haemorrhage, haemorrhage from ruptured ectopic pregnancy, toxic shock syndrome and retained products of conception with infection.

Do you agree that these complications exist, as admitted by the manufacturer?

Dr Pesce—Yes, we have made several references to it already.

Senator BOSWELL—Thank you. Dr Gawler goes on to say:

In remote … Australia, the transfer of seriously ill women may take many hours—

even a day or more—

even by Air-Med Evacuation flights … Such delays could cost a woman prescribed RU486 her life.

Is Dr Gawler correct in his assessment?

Dr Haikerwal—There are two things. First, if a pregnant woman has a spontaneous miscarriage in a rural or remote area she has the same risks as that. Second, if she asked for RU486 in a remote area she should not have been be prescribed it, because in a remote area you do not have access to medical supervision and you do not have access to surgical facilities.

Senator BOSWELL—Dr Gawler also cites 'patient communication problems in the North, where many Aboriginal women speak little English'. He says this may result in them not attending a further medical appointment or failing to recognise complications.

Dr Pesce—We deal with these issues every day. There are women who have exactly the same medical conditions, such as suspected ectopic pregnancies. If they do not understand English and do not live close to the hospital, I will admit them and manage them completely differently from women who live across the road, speak English and have lots of good social supports. Doctors make these decisions in rural and remote areas every day. Senator Boswell, you are probably aware—if not, you should be—that about one in six women who get pregnant miscarry, and about half of those will not completely miscarry and will require surgical therapy. It is a sad fact of life that women take extra risks when they live in rural and remote areas. There are risks from miscarriage as well as from surgical or medical abortion.

Dr Haikerwal—Rural practitioners are aware that they have to look after them, and therefore they make appropriate provisions for them. They prescribe to them and look after their care based on what is available in their locality.

CHAIR—Senator Boswell, we are going to have to move on because other senators have questions. Senator Fielding has a question.

Senator FIELDING—I can only say once again that Family First is concerned about women's health and the risks of this drug. You have used the analogy of taking aspirin. You mentioned earlier that people can take this drug at home. As far as I am concerned, that is stretching it a little too far. I must admit—

Dr Haikerwal—My point is that—

Senator FIELDING—Can I keep going? I have not interrupted you, so maybe I can keep going for a moment.

Senator ADAMS—You have made an allegation, Senator Fielding.

Senator FIELDING—I have not made an allegation. I am just saying that the mention of aspirin—

CHAIR—There will be an opportunity for Dr Haikerwal to respond.

Senator FIELDING—I am still concerned about women being confident of having access to medical supervision now and in the future. Quite clearly, you have stated that that would be mandatory for someone taking such a drug. Would the AMA draw up guidelines for women about how to dispose of their foetus at home, and what options do they have?

Dr Haikerwal—I would like to clarify my point about aspirin. My point was that every medication has its own dangers associated with it. I am not equating aspirin with RU486 or any other drug. I am saying that any drug used inappropriately has dangers.

Dr Pesce—I am an obstetrician and gynaecologist. I take about seven or eight women every week who book in for pregnancy and one or two of them turn up and have a miscarriage. Sometimes when they turn up they have had a miscarriage at home. I understand what you are saying. It must be very distressing to miscarry at home, planned or unplanned. We do not currently have any guidelines on what to do with foetal tissue that is miscarried. I do not think the AMA would involve itself in making recommendations across the board, and I suspect that it would probably be obligatory for the service provider to discuss the possibility of miscarriage, prepare the woman for the fact that miscarriage will happen and ask her what she would like to do. If the woman needs further advice, it can be given. The

advice might be given on the basis of her emotional response, on the basis of medical safety or on the basis of practicality. The woman might ask, 'Do I have to organise a funeral?' You can ask the woman what she feels and then respond appropriately to the answer she gives.

Senator McLUCAS—I want to go back to the role of the TGA. Once a new drug is able to be prescribed, how does the TGA, PBAC or whomever it is, tell doctors how it should be prescribed? What is that process?

Dr Haikerwal—When a drug has been registered, certain product information has to be provided with it. The product is available on the TGA web site and on the manufacturer's web site and that has some specific details of every aspect of the drug: how it works, what its chemical compound is, how to prescribe it, precautions, contraindications, side effects and drug interactions. There is separate consumer information, too. The consumer has specific information about the drug, when it should and should not be taken and more information to give to the doctor at the time of seeking that medication or being prescribed it, if they did not seek it specifically.

Dr Pesce—It can also have very specific information. For example, some medications can be used only after a certain test has been done. In the context of this drug, you could say that you can only give this drug once an ultrasound has documented an intrauterine pregnancy, because there are other medications you can give a patient only after you have measured their bone density for osteoporosis or had a tissue biopsy proving a certain diagnosis. It is well established within the current system to put very specific barriers around how a medication can be used, up to and including the diagnostic tests which have to be performed before it can be used and the things that are necessary for safety—blood tests, follow-up and all those sorts of things.

Senator McLUCAS—In your opinion, as doctors and as the AMA, does that process militate against the sort of inappropriate prescribing that Senator Boswell was alluding to?

Dr Pesce—I think a system could be put in place which, if followed, would be very satisfactory. You can never make guarantees for anything being done outside what is considered reasonable practice, and that is why doctors get sued. I think a combination of specific guidelines and the medico legal obligations that doctors have to their patients should they go outside those guidelines and something goes wrong augments the natural caution and sense of responsibility of doctors to their patients' wellbeing and welfare.

Senator JOYCE—You made the statement before about an 'identifiable foetus'. Can you explain to me what an 'identifiable foetus' is and, since the purpose of this drug is to stop the life of that 'identifiable foetus', the actual process of how that happens?

Dr Pesce—I meant by 'identifiable foetus' when you can see something which is obviously a very small developing baby. Often what is passed is just a blood clot and a bit of tissue that is not identifiable as a person, but sometimes it is. That is what I meant.

Senator JOYCE—What do you identify in it?

Dr Pesce—Anatomical structures.

Senator JOYCE—Such as?

Dr Pesce—Such as little limbs, perhaps other structures which are obviously identifiable.

Senator JOYCE—What is the process of how that 'identifiable foetus'—to give it another term for a person's life—dies?

Dr Pesce—It depends at what point in time the medication is used. If it is used early enough before implantation, implantation never occurs. A period occurs and the tissue is passed. If it occurs after implantation, the specific effect of the drug also induces a bleed, and during that bleed the tissue within the uterus is passed. Therefore, if the baby's heart was beating, it will not be after that.

Senator JOYCE—So it stops the heart beating?

Dr Pesce—Yes.

Senator JOYCE—I just wanted that on the record. It is good to know.

Senator FIELDING—Doesn't the TGA already provide advice on whether RU486 is an appropriate drug, regardless of whether the minister makes the final decision? Don't they already provide that advice?

Dr Pesce—If they were asked to provide the advice, they could make that opinion.

Senator FIELDING—Isn't your opposition to a final decision by the minister because you have already made a decision that the drug is appropriate and you think getting rid of the political accountability is the best way to get the drug into the country?

Dr Pesce—I think that the decision has been made on the basis of moves from our sister organisation—I guess it is appropriate to call it our sister organisation—the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, who have been extensively looking into this issue in response to requests from our members for us to address the issue. In standing back and looking at the evidence, we see no reason why the usual TGA approval principles should not be allowed to run their course. Of course, the thing that has not yet been said is that the company is not going to make an application to the TGA if it knows that ultimately it is going to upset the minister and (a) get knocked back, and (b) be in the minister's bad books. There is a very obvious disincentive for the proper process to be applied in this case, notwithstanding what the AMA thinks.

Senator ADAMS—I feel the rural doctors have been rather unjustly targeted with a lot of this focus on rural and remote. I know a lot of rural doctors are members of the AMA, so would you like to tell us exactly how these rural doctors are trained and whether they are appropriate practitioners to deal with such an issue?

Dr Haikerwal—Our rural and remote doctors are obviously a very highly skilled subset of our medical population. They have significant responsibility placed on their shoulders, being away from significant centres of population and having to work in very stretched circumstances. They know the limits of their own abilities, and they know the limits of the facilities around them. Many of them have access to facilities where they can do minor surgical procedures and other obstetric procedures, and others do not. They know what is there and what they can and cannot do. The training of doctors who work in rural areas is the same as for those who work in urban areas, with additional skill sets gained for that responsibility—that is, distance from quick and speedy help.

CHAIR—Thank you very much for your appearance today at such short notice and for longer than was expected.

Senator BOSWELL—I apologise to Senator Adams for what I said to her. Also, I want to make the point that the AMA are almost critical to this Senate inquiry. There are many more questions that I think all of us would like to ask of them. I wonder whether it would be possible to get them back, because I certainly would like to explore what Senator Fielding said about Italy and I have a similar inquiry about America having a convention or discussions coming up in the New Year to investigate RU486.

CHAIR—It is an issue that we will need to discuss. I suggest we have a private meeting now.

Proceedings suspended from 10.08 am to 10.18 am

ECCLES, Mr Richard, Assistant Secretary, Policy and International Branch, Department of Health and Ageing

GRAHAM, Dr David Trevor, National Manager, Therapeutic Goods Administration, Department of Health and Ageing

HALTON, Ms Jane, Secretary, Department of Health and Ageing

HORVATH, Professor John, Chief Medical Officer, Therapeutic Goods Administration, Department of Health and Ageing

CHAIR—Welcome. Thank you for appearing, particularly at short notice and in a period of the year when one would not normally be expected to take part in such things. The committee appreciates it. Information on parliamentary privilege and the protection of witnesses has been provided to you. I remind you that you are not required to answer questions on the advice you may have given in the formulation of policy or to express a personal opinion on matters of policy. We do not, of course, have a submission from you as yet because we have only just begun this process, but I now invite you to make an opening statement if you wish to make one before we proceed to ask questions.

Ms Halton—No, we do not wish to make an opening statement.

CHAIR—Okay. I start by asking for a very brief summary of the process whereby the decision was made for the minister to exercise control over a decision on the use or otherwise of RU486 in Australia. I understand that in about 1996 the procedures that had previously been used were changed to endow the minister with the power to make that decision. Is that the case? If so, can you explain how that came about?

Ms Halton—The change to the Therapeutic Goods Act, was in, I think, 1996, but I will stand corrected if I am wrong.

Dr Graham—Yes, it was.

Ms Halton—You are quite correct that two new provisions were inserted with respect to a new class of drug, making those drugs subject to a different provision. I cannot comment on the circumstances in relation to how those amendments to the act actually occurred. Indeed, I do not think any of the officers at the table were in our current positions at that time, so you would probably need to consult the historical record. I do not think we should speculate about the precise reasons. All I know is that the legislation that we in the department administer now has a different category in relation to this particular product.

CHAIR—Thank you.

Senator MOORE—I have two questions that are mainly focused on the therapeutic goods process. The first one follows on from your statement, Ms Halton: how many medications are in the particular category that was created in 1996? Secondly, when you look at the proposed legislation in front of us, you will see that we are recommending through the process that the TGA is the referral process for this medication. We need on record exactly what process the TGA puts in place when there is a referral to your authority of any medication for any

purpose. I would imagine that has to do with you, Dr Graham. As to the first question, Ms Halton, how many medications or products are in the new category?

Ms Halton—Because new drugs obviously come along all the time, it is rare—in fact, I do not think it is the case—that a particular product is actually specified in the legislation. In 1996 there were two amendments to have something called 'a restricted good'. A restricted good includes:

Medicines—

and this is where I will struggle with pronunciation, so I apologise in anticipation—

(including progesterone antagonists and vaccines against human chorionic gonadotrophin) intended for use in women as abortifacients.

The two sections of the legislation are section 6AA, which provides:

... a person must not, without the written approval of the Minister ...

and section 23AA, which provides:

... restricted goods must not be evaluated or registered or listed without the written approval of the Minister.

So it is not an item—

Senator MOORE—No—it is that group of items.

Ms Halton—Correct.

Dr Graham—I could go into the process. Under the Therapeutic Goods Act, the powers that we use are primarily the interstate trade corporation power and import powers. If a person wants to put a product onto the Australian market, the primary step is that they have to enter that onto the Australian Register of Therapeutic Goods. There are different levels of entry onto that Australian Register of Therapeutic Goods, depending on the risk with the product. Prescription drugs have the highest level of control and they go through a full premarket evaluation. The three pillars that are under the legislation are: quality—in other words, how the product is manufactured, consistency of manufacture and trueness to label; safety—that is, things such as evaluating potential side-effects, how those might occur in the marketplace and consideration of interactions with other drugs; and efficacy—that the drug in fact does work according to the claims that are proposed by the sponsor.

The sponsor is required to put in a submission to us and there are very defined guidelines about what is in that submission. We have a team of evaluators within the Therapeutic Goods Administration who carry out an evaluation of the information that has been provided. There might be a bit of toing-and-froing between the sponsor and TGA to collect further information. At the end of the day—and this is about the different levels of regulation—we have expert advisory committees of which we can ask advice on the outcomes of the evaluations that have occurred by the Therapeutic Goods Administration.

In the case of prescription drugs, this is the Australian Drug Evaluation Committee. The evaluation report, which at that stage would also have been sent back to the company for comment, would go the ADEC and they would provide advice. At the end of that process, the decision maker is the secretary of the department or whoever she has delegated that authority

to. If the recommendation is that the product is suitable for marketing—and there may be conditions to do with suitability—then that product is entered on the Australian Register of Therapeutic Goods. If it is a registered product—that high level for prescription drugs—it receives an AUST R number, which appears on the label, and it goes out into the marketplace.

There is another aspect of supply, and that is through the drug scheduling, which is a matter of retail supply at the state and territory level. There is another representative committee, called the National Drugs and Poisons Schedule Committee, that advises on what level of retail supply should apply to a product. For a new chemical entity, that would invariably be as a prescription product. So you would see 'Schedule 4, prescription only' on the label. That would imply that it can only be supplied on the prescription of a doctor. Then you have different levels of scheduling. Some are pharmacy only, some are pharmacist only—they have to be released by a pharmacist—and some are just open sale, which may appear in supermarkets or elsewhere.

Senator MOORE—I am sure that is something which other people will take up.

Senator FIELDING—We heard this morning from the AMA that people could be able to take the drug at home, which effectively means do-it-yourself abortions. If that were the case, has the TGA thought about what guidelines it would request that the AMA give women on how to take care of a foetus at home after taking the drug?

Ms Halton—I think it is important to understand that the role of the Therapeutic Goods Administration is to assess applications that come forward and to deal with issues, for example, in relation to adverse drug reactions and reports we get in that respect, and to assess new information about drugs that are listed. The Therapeutic Goods Administration has no role in speculative consideration in relation to drugs that are not listed and for which there have been no applications received.

Senator FIELDING—I raise the question because Family First are concerned about the health risks to women. There are genuine concerns from the medical profession concerning this drug. Early in 2006 the US Food and Drug Administration and the US Centres for Disease Control and Prevention will hold a joint public hearing into the five North American deaths that have followed the use of this drug. I am saying that there are definitely concerns out there. Given that we have heard this morning that people could take the drug at home—which is effectively do-it-yourself abortion—I am concerned about what guidelines the TGA may or may not be giving to the AMA.

Ms Halton—As I said, at the moment the TGA has no role in this area. In the event that there is an application from a sponsor in respect of this drug and in the event that there is an application from a practitioner under some of the other schemes, that would be considered. All of the circumstances and all of the evidence would be considered by the evaluators. As it currently stands that is not permitted without—as I have already pointed out—an agreement under the legislation that that evaluation occur. But at this moment the TGA has no role in doing any work of a speculative nature. That is not the role of the regulator.

Senator McLUCAS—I think we need to be very clear about what Dr Pesce, from the AMA, said. He said that the drug would be administered in surgery. He was very clear about that.

Senator FIELDING—I would have to look at the transcript, because I heard quite clearly that it could be taken at home after consultation.

CHAIR—I am not clear about what was said, so let us note that there is a question mark about that.

Senator ADAMS—I have a question for Professor Horvarth regarding the rural doctors and the question that the minister asked you to provide an answer to. Would you expand on the training of rural doctors?

Prof. Horvath—At the present time, rural doctors range in training from having general practice training and being vocationally registered, some with special interests, to a group that are not vocationally registered and have had less training. There is a very wide range of training and ongoing continuing education. It is clear that in the last decade there has been a lot of effort by the colleges, the professions and the government to enhance rural training and to enhance ongoing continuing education. But there is not a single template for the level of training, the level of educational support or the level of clinical support in rural or remote Australia. In fact, the same can be said for other communities.

Senator ADAMS—To follow on from that, would you consider that doctors practising in rural areas are capable of administering this drug and of being responsible for the administration and the care of the people they have under their care?

Prof. Horvath—I could not answer that generically. In looking at the literature and taking appropriate advice, it is obvious that the use of this drug requires a level of post-administrative support that will manage the consequences of its use, and that is approximately five to eight per cent requiring some evaluation and perhaps intervention following its use. That would need to be an important clinical component for its use, be it in remote or rural areas or in other areas.

Senator POLLEY—In the last decade, how many drugs have been approved and then had to be retracted from the market because of safety issues?

Ms Halton—We will have to take that on notice, but we have obviously had a couple of high-profile examples just in the last year.

Senator POLLEY—Could you elaborate on those—when they were approved, the reasons why they have been withdrawn from the market and what approval process they went through that would be different for RU486?

Dr Graham—One of the interesting examples of recent times is Vioxx, a Merck, Sharp and Dohme product, a COX-2 inhibitor, which was withdrawn from the market in 2004. That went through a premarket evaluation. I think it is fair to say that the premarket evaluation is very much based on clinical trials, and these are quite often done with fairly select groups where, although substantial, you have a limited number of patients that the products are tested on. The patients are fairly carefully selected, so sometimes it is apparent that, when a product gets into the marketplace more generally, side effects which might be of fairly low occurrence will start to show. That is why some of the post-marketing mechanisms are so important, such as pharmaco vigilance, which is really to monitor a product once it is on the market, identify such things as adverse reactions and collect that information together to see patterns. That can

lead to not just the withdrawal of a drug but perhaps a modification of how that drug is supplied into the market. So there would be examples of that, and that is an ongoing process. In fact, in the first three years of marketing approval companies in the prescription area have to supply us with ongoing reports about their marketplace experience.

Senator POLLEY—If this drug is approved, what processes would be put in place for the next 10 to 20 years to assess the different long-term effects of this drug so that the community would have confidence that this drug is safe?

Dr Graham—It would be a similar process—and this drug also has a history of use on overseas markets—where we would be monitoring the marketplace experience of that drug to identify if there were any consequences, and then there would be consideration of whether a response was necessary.

Senator POLLEY—What consideration is given to the concerns that have been raised in other countries where the drug has been administered and there has been loss of life?

Ms Halton—In what sense?

Senator POLLEY—How does that come into the process for assessment as to whether or not this is a safe drug to come onto our market?

Ms Halton—There are two issues there. The first is in respect of any initial application for registration. Obviously, the evaluators take account of all the international evidence and the evidence brought forward by a company in respect of a potential registration. Let us take the Vioxx example. Our evaluators took a slightly more conservative approach to these products in the first instance, but, as the international evidence became clear in this particular case, the company actually chose to withdraw the drug. So there would be a number of possible routes in respect of the consideration of international evidence.

Senator POLLEY—So the company actually made the decision before the department did about withdrawing that drug?

Dr Graham—That is the case.

Ms Halton—That is correct.

CHAIR—Senator, we have limits on the number of questions we can ask in these sessions, unfortunately—

Senator POLLEY—I apologise, my flight was delayed.

CHAIR—I had not told you about that. I am sorry.

Senator NETTLE—Since, 1996, what ongoing evaluation has the health department or the TGA done on the safety of RU486? I think, Professor Horvath, you mentioned a literature review. Can you outline for us what studies the health department or the TGA have done on the drug RU486?

Ms Halton—I will just make the point that the TGA is part of the department. It has a specific function in respect of regulation but it is the same enterprise. The answer is that we have not done any studies in respect of RU486.

Senator NETTLE—Is the literature review that the professor referred to previously the only—

Ms Halton—He is familiar with the literature.

Senator NETTLE—But the health department has done no studies in regard to RU486?

Ms Halton—We have done no studies on RU486. That is correct.

Senator NETTLE—Is the process for approval that the TGA uses for particular drugs a sound and appropriate one to be used for the evaluation of this particular drug?

Ms Halton—You are asking for an opinion. As was indicated in the first instance, we cannot provide you with an opinion. We can say that we administer the legislation as it is provided to us, and I believe that we administer it with due diligence.

Senator NETTLE—I will ask the question in another way: is there any reason why decisions about the availability in Australia of the drug RU486 could not be made in the same way that decisions are made about the availability of every other drug in Australia?

Ms Halton—Again, you are asking us for an opinion. I have to say that at the moment the legislation precludes that from happening, and we administer the legislation.

Senator JOYCE—Quality, consistency, safety and efficacy are the standards by which you judge a drug. At what stage in the in utero development of a person do you start considering the effects of a drug on their life?

Ms Halton—It depends on what the drug is. I am sorry, but you will have to be a bit more specific.

Senator JOYCE—Okay. In the development of a child before they are born, at what stage do you consider the effects of a drug on that child's life?

Ms Halton—In any application for the registration of a drug, the TGA evaluators take the data that is provided in respect of the actions of that drug. They consider it in respect of those particular criteria. We cannot provide you with an answer that goes to a particular point because, unless we are talking about a particular product or a particular circumstance, there is no blanket answer to that question.

Senator JOYCE—So the answer to that question is that you do not in fact consider the effects upon the unborn child?

Ms Halton—No, I did not say that. I said that there has to be a particular example given before we can answer that in a particular way.

Senator JOYCE—So if the question was 'Is this going to affect the life of this unborn child?' that would be a consideration that you would then have to take into account?

Ms Halton—It would depend on what the drug is and what the application is in respect of.

Senator JOYCE—RU486—there is a drug.

Ms Halton—We do not have an application for RU486 and the TGA has not put in place any speculative arrangements in that regard.

Senator JOYCE—I will change it around. Are there any other drugs that are currently under your auspices for which you have to consider the effects on the unborn child?

Prof. Horvath—Every drug that is considered—and I will answer this clinically and my colleague from the TGA can give you a technical answer—looks at the effects on the unborn child potentially, because there are some drugs that affect different growth pathways in a teratogenic effect. There are in fact a number of clinical guidelines, with different levels of warnings, depending on the previous evidence, as to the safety of the drug for an unborn child.

Dr Graham—Effects in pregnancy is a standard part of the product information—which is information that companies must supply with their products. In fact, there is a guideline around drugs and their effects on a pregnant woman, and that is guidance to the medical profession.

Senator JOYCE—Thalidomide and RU486, to give you an example: one considers a child and one does not.

Dr Graham—Yes.

Senator ALLISON—Dr Graham, could you describe the TGA's risk management approach to regulating medications?

Dr Graham—Yes. As I was saying earlier, the level of regulation is commensurate with the risk of the product. The primary point of regulation is through the Australian register of therapeutic goods so, in order for something to be supplied onto the Australian market, it has to enter that register, unless it is exempt. Very low-risk products—such things as antiperspirants are one example—would not be required to go onto the register. The next level up is the listable goods. These cover many of the herbal medicines and complementary medicines. There the rationale would be that, in terms of quality, the quality of a herbal medicine or a prescription medicine should be fairly similar—very similar. They should be manufactured consistently and should be true to label. A listable medicine still has to be manufactured, for instance, by a licensed manufacturer, as would a prescription medicine. In terms of safety, there is a list of permitted ingredients that are allowed in listable medicines. Rather than the products being evaluated, it is really the case that as long as the products contain these acceptable, permitted ingredients they are acceptable for listing. In terms of efficacy, the restriction there is that listable products can only be used for simple self-limiting illnesses. If anything more severe is claimed for a product it has to be evaluated in premarket evaluation.

So for listable medicines it really is a self-assessment procedure to a certain extent. Through an electronic system the makers can enter their information onto the register and gain entry onto the register quite quickly. There is a sampling process where samples of that information are taken off or selected for re-evaluation at times. We have got laboratories within the TGA that can carry out post-market sampling of those products. There are a number of other mechanisms that go into play post-market, to check the quality, safety and efficacy of listable medicines, but in general they are regarded as low risk. As long as there are limitations on their use and also on what they contain, they go in at that lower level. The next level up is the registrable class. There are two levels there. One is the lower level

registration of over-the-counter products—the Panadols and other products that you see in pharmacies. Those products go through a premarket evaluation, taking into account the fact that there usually is a long history of use and that they are not a prescription-only product. They are a lower schedule product so there is perhaps a lower degree of premarket scrutiny than there is for prescription products.

There is an expert committee against each of these levels that gives advice to the TGA. At the listable level we have got the Complementary Medicines Evaluation Committee, at the lower level of registrations there is the Medicines Evaluation Committee. Then we move up to prescription medicines, which I discussed earlier, an area which relies on a full premarket evaluation and very comprehensive information around quality, safety and efficacy. We do have expert evaluators internally that evaluate that information and seek advice from the Australian Drug Evaluation Committee—ADEC—and then a decision is made. At each of those levels the final decision maker is the secretary, but of course she would delegate most of those decisions to the TGA staff.

Senator ALLISON—There has been quite a lot of discussion in recent times about the non-abortifacient use of RU486 or mifepristone. Has the department done any work in this field and to what extent has the current veto which is available to the minister precluded or been a barrier to its use in research or clinical trials?

Ms Halton—Again, we have not done particular work. I am aware of the potential uses for alternative purposes. My observation—but Dr Graham can comment specifically—is that there has been no barrier for people wishing to do that kind of research and for those alternative uses, particularly in respect of the treatment of some of cancers. I am aware that the product has been imported and used for patients where that is clinically appropriate. Dr Graham may want to talk about the research side.

Dr Graham—There are a number of areas where a product that is not on the register can be used in this country. One of those areas, of course, is clinical trials. There are two areas of clinical trials where drugs can be used. One is called the Clinical Trial Notification Scheme. This is where, with an ethics committee supporting the trial, trialers can notify the TGA of the trial.

Senator ALLISON—But this process has not been used in relation to this product?

Dr Graham—It has, but not as an abortifacient use. What still applies in these cases is that, under the Customs (Prohibited Import) Regulations, abortifacients are regarded as a prohibited import unless they have permission for import. So in the case of clinical trials they not only have to notify us that the trial is occurring—and that notification occurs before the trial starts—but that it is occurring with ethics committee support. We certainly do check whether or not it is a non-abortifacient use of RU486. Approval also has to be given under the Customs (Prohibited Imports) Regulations for that material to be imported into this country.

Senator ALLISON—Chair, I have had my two questions, but I wonder if it would be possible for the TGA to provide the committee with a summary of the non-abortifacient use applications and the trial under way?

Dr Graham—We can do that. We probably have to respect the confidentiality of the information, but we can describe it, yes.

Ms Halton—I am aware that, in respect of some of the clinical uses for people with cancers, we are talking of a very small number of cases. With your indulgence, we will make sure that that is provided in a very non-identifiable way. I can tell you the number of cases, for example, over a particular period.

Senator ALLISON—And could you outline the issues to do with medical indemnity, which I gather are a problem in some of these cases?

Ms Halton—Not that we are aware of.

Dr Graham—Not that we are aware of.

Senator NASH—With regard to the process that needs to be undertaken, is the TGA better equipped to determine the quality, safety and efficacy of a drug than a parliamentarian?

Ms Halton—That is an opinion, which I think we have already indicated we are not permitted to provide.

Senator NASH—I understand that. I was merely talking about the process, but I accept that. It would be normal process for the TGA to determine that health risks were at an unacceptable level and therefore that they would not approve a drug?

Ms Halton—Certainly the process of evaluation takes account of the risks associated with a product which comes forward for potential registration. Yes, it is a fair summary that, if the risk of the use of a product effectively outweighs its benefit—and it has to be a significant benefit, obviously, before we even consider registering something—we will not register it.

Senator NASH—I have a quick question to Professor Horvath with regard to the practice in regional areas. Obviously there are situations that would preclude this drug being used. Would it be fair to say that rural and regional GPs would be capable of not prescribing this drug if they felt that the circumstances were inappropriate—and wouldn't they choose not to prescribe it if the circumstances were not appropriate?

Prof. Horvath—I cannot talk for individual clinician practice. But certainly nothing would preclude them, even if there were guidelines in place at the present time, unless the relevant state prescribing issues were to preclude it in some way. You really do need to have a lot of education and support mechanisms around any drug that is prescribed that requires some additional level of clinical support.

Senator NASH—So there could be state prescribing issues that would preclude it?

Prof. Horvath—I will have to refer to my colleague for the exact details on that.

Dr Graham—There are examples where drugs have been restricted to certain classes of prescriber, and I think the retinoins might be one example of that.

Prof. Horvath—That is correct.

Dr Graham—So that is one way that a drug can be restricted. As I was describing earlier, there are powers at the state and territory level where they can control certain channels of supply for drugs, and that would be one example where it has been restricted to a particular class of prescriber.

Senator McLUCAS—Dr Graham, you were describing the process by which a drug is approved. You were explaining that the drug scheduling gets to a point where it is a prescription-only drug. Can you explain the process that happens after a drug becomes a prescription-only drug? How does the TGA or the department—and there is potentially a PBS role here as well—get information to doctors about how the drug should be prescribed?

Dr Graham—There are two aspects to that: one is how it perhaps should be used by the medical profession and the other is how it is supplied through the supply chain. I might deal with the supply chain first. From that committee I referred to earlier, the National Drugs and Poisons Schedule Committee, there is a published schedule of classifications of drugs, according to S2, S3 or S4, which are different levels of supplier. That is published and it is picked up under state and territory legislation, and people in the supply chain have to observe that—that is, the sponsor, the wholesaler and the retailer have to observe how that product is supplied. So it would be illegal under state and territory legislation to supply a prescription drug over the counter, for instance.

In terms of medical practice, that is something that Professor Horvath may be able to comment on more, but it is really around professional guidelines. It is not the jurisdiction of the TGA. We certainly support the quality use of medicines and good professional practice through the way we underpin things such as the information that is going out with the product—consumer medicine information that is provided in lay English to patients and supplied by pharmacists and manufacturers to explain what the drug is and how it should be used correctly. Certainly one of our roles is to underpin the quality use of medicines, but we do not intervene on an individual patient basis between the doctor and the patient.

Prof. Horvath—From a professional point of view, firstly there are the publications as well as the drug information that comes out of the TGA, which is very highly regarded by the profession. Then there are guidelines that are published by bodies like the various professional colleges. The AMA from time to time publishes guidelines, and there are the various continued education components by universities and others. There is an attempt to ensure that the messages to the profession are reasonably homogenous and pretty clear-cut, and it depends on how widely dispersed in the profession the special interest groups are as to how that education is delivered.

Ms Halton—Turning to the question of the PBS, given that you have raised it, obviously the PBS is administered separately. So we basically have, as you are probably very well aware, a two-stage process. We have a process where a product seeks registration. That is an absolutely necessary prerequisite, obviously, before PBS consideration. Assuming a product is registered, if the sponsor wishes, it may come in and make an application for listing on the Pharmaceutical Benefits Scheme. As you would also be aware, if that application is successful, it may be in respect of a limited range of conditions—that is, we will not pay a subsidy in respect of a product unless it is in a certain number of categories. But ultimately that is about the subsidy attaching to the product, not necessarily the doctor's clinical practice.

Senator McLUCAS—When a drug is an on-approval drug, though, that on-approval can be applied to the drug for a range of reasons. Often it is to do with cost, but the approval process can also involve reasons other than cost. Could you explain that process as well?

Ms Halton—Yes, absolutely. There are a number of reasons we have drugs on approval, some of which are to do with the very narrow indications we have a drug listed for. Sometimes it is cost. So there are a number of reasons and you are quite right. The practitioner is required to ring for an authority to prescribe that product.

Senator BOSWELL—I will get back to my doctor questions, because they have much more experience than I do of these issues. I tabled a letter today from a Dr Gawler, who is a practising surgeon. He works with Aboriginal communities and remote communities. I understand that the US federal drug authority and the Centres for Disease Control and Prevention are to hold a conference in the new year regarding the fatalities associated with RU486. Senator Fielding made some reference to a similar sort of thing happening in Italy, which I wanted to pursue with the AMA, but my question was ruled out. Maybe he can follow up the question later. When the TGA is making the assessment of whether the benefits of the drug outweigh the losses, would you take into consideration the results of that US federal drug authority conference and those from whatever authority was responsible in Italy?

Ms Halton—Yes. Essentially, the TGA seeks to use the maximum amount of information available in taking its decisions. So if there is published evidence on a product—and with a product that has a history obviously there are more publications on it than perhaps there are for a new product—the TGA evaluators take account of all of that information.

Senator BOSWELL—I will yield to Senator Fielding if he wants to follow up the other question.

CHAIR—We might come back to that at the end, when we have all had a go.

Senator BOSWELL—Dr Gawler cites patient communication problems in the north, where many Aboriginal women speak little English. He says that this may result in them not attending a further medical appointment or failing to recognise complications. Would you take that into consideration when you were making the assessment?

Dr Graham—If that became apparent in the evaluation of the product there might be some consideration given to how we presented the product information. But in terms of the scientific evaluation of the evidence that is provided, we would be looking at the product by itself. As I said before, if there are issues in the supply chain that need to be taken into consideration, there are processes to do that.

Senator BOSWELL—In his letter, which I have tabled, Dr Gawler says that RU486 could be a recipe for disaster for women who are very young, immature, intellectually impaired, psychologically disturbed or who may not understand or follow instructions. Would you take all that into consideration when you were assessing this?

Ms Halton—It is important to understand that that is an opinion from a practitioner. As Dr Graham has indicated, the TGA evaluators would take account of all the published scientific evidence. That includes things that are published by the Food and Drug Administration or the corresponding organisations in Europe. The utilisation of a product is, as Dr Graham has explained, a matter which comes up in the management of the supply chain.

Senator BOSWELL—The answer to my question, then, is that you would not take any of those things into consideration. Who would take that into consideration? Who makes that assessment?

Ms Halton—You read to us an individual practitioner's opinion. I have tried to outline that the TGA takes decisions based on scientific evidence. What happens with a product, if it is safe to be registered, is that there are a range of issues around the use of that product—which Dr Graham has explained—such as information to practitioners, information to patients and indeed the process of working with the states in terms of the scheduling committees. It might well be that that kind of information would be germane to their considerations.

Senator BOSWELL—I will ask Dr Graham.

Ms Halton—He will tell you the same thing.

Dr Graham—Yes, that is the fact. We would certainly be looking at the scientific evidence and making a judgment on that. We would also use that information and other information to help other people to make decisions in the supply chain.

Senator BOSWELL—I will put it to you in this way: a drug may be safe but, if it falls into the hands of various people, it may become unsafe for those particular people—the ones I have just mentioned. Can you tell me how you make an assessment about which people may not be able to handle the situation?

Prof. Horvath—Virtually all drugs and all treatments fall into the category you have just described.

Ms Halton—Including Panadols.

Prof. Horvath—If not used according to appropriate clinical guidelines, they will in fact either be ineffective or may cause harm. I think the secretary just mentioned Panadol. Panadol is a particularly effective analgesic and is one of the more common drugs that is used for suicide attempts, especially in young women.

Ms Halton—And it causes death.

Prof. Horvath—Yes. And that is where the issues around education of the providers and the profession to ensure that any drug is used according to best practice and best guidelines come into it. If medical practitioners stray outside of best practice and best guidelines, the state registering authorities have very robust mechanisms for those to be brought to their attention and then to take appropriate action.

Ms Halton—And indeed there may be a medical indemnity issue if they stray.

CHAIR—I have a second question for the TGA. When a doctor administers a drug or a procedure to a patient there are, of course, ethical considerations which are part of that doctor's training. In your opinion, are there any ethical dimensions of the process that the TGA employs in assessing the effectiveness or suitability of a drug?

Dr Graham—What we try to do is evaluate the evidence that is given to us. In that sense, we are very objective about that evidence and make a judgment, as I said earlier, on the basis of the three principles: quality, safety and efficacy.

Ms Halton—I think it is important to understand that the TGA operates within the legislative framework that it is given. There are a number of places, for example, under the special access arrangements where a medical practitioner is required to have ethical clearance before they can actually use a product. But we require the TGA to make a technical assessment in respect of the criteria in the legislation.

CHAIR—And ethical considerations are not one of the criteria.

Prof. Horvath—No.

Senator MOORE—Ms Halton and Dr Horvath, I am asking your advice in terms of the process now with doctors and pharmacists. I know that your department oversees the pharmacy agreement as well. Individual practitioners have a choice about what services they can provide in both those groups within the medical facility and also the pharmacy. Is there anything in any legislation that forces a doctor or a pharmacist to prescribe anything that they do not want to or that they choose not to?

Ms Halton—Not that I am aware of, no.

Prof. Horvath—To be absolutely clear, under most state medical practitioners acts, a doctor must provide emergency care or make alternative arrangements.

Senator MOORE—That is under state legislation?

Prof. Horvath—Yes.

Senator MOORE—One of the questions we get asked a lot is about people not being able to access current services—things that are already in the system. It is my understanding that it is the decision of the individual practitioner or professional as to whether they want to prescribe or are prepared to prescribe—

Prof. Horvath—That is correct.

Ms Halton—Absolutely.

Senator MOORE—There is nothing in any legislation that we have currently that would force them to do that.

Ms Halton—No.

Prof. Horvath—That is correct.

Ms Halton—Obviously, there are some things you cannot provide if you do not have the technical competence to provide them.

Senator MOORE—That is another conclusion.

Senator FIELDING—Who are the experts who make the recommendations about drug approvals? Who chooses those experts? That leads to my next part: given there have been drugs approved by the TGA which have later been withdrawn from the market, do you accept that the TGA has made mistakes and gotten it wrong in the past?

Dr Graham—The evaluators within the TGA are people who have been selected because of their professional competence. They certainly get a lot of experience and training on site in terms of evaluation. As I said, there are external committees, such as ADEC, that they also use. The other thing I should mention is that we have a lot of MOUs and other arrangements

with our counterparts in other countries—such as Canada, America, Britain and those in Europe—so there is information sharing internationally. That is a continual activity which is another sounding board for us which helps us to see how our evaluations compare with those of other countries.

I have also mentioned that we do post-market monitoring, and I explained the reason for that. We do that because drugs are now coming onto the Australian market and the markets of many other countries pretty much simultaneously. In the past, companies put drugs into some markets before others and there was the opportunity to learn from experience about how those drugs were affecting those marketplaces. Now that companies are putting those drugs simultaneously into many countries, that previous experience is not there, so post-market monitoring is becoming more and more important. It is not a sign of failure that we are picking up some events that will only show up in the marketplace, where maybe several million patients are being exposed to a drug—the clinical trial might be based on 100 or 1,000 patients. It is just the fact that we are getting much more skilful in being able to use that information to identify events earlier. That is the challenge for the future.

Prof. Horvath—Wearing my previous hat as a clinician, the TGA is regarded nationally and internationally as one of the most robust and appropriate regulators in the industry. In recent years, it has made wide-ranging decisions ahead of the FDA. If we come back to the Vioxx story, there are a number of compounds in that class which, very wisely, the TGA did not approve and the FDA and the Europeans did approve. Those compounds in fact turned out to be far more of a problem and caused deaths quite early, and we were spared that. The Vioxx story was totally unpredictable in the early stages of registration. In fact, the causes of the difficulties with Vioxx were co-morbid conditions which came out over time, as those conditions in fact deteriorated. The profession has a very high regard for the level of work that the TGA does.

Senator FIELDING—One final point is that it has been raised with me that having the approval for this drug in the minister's hands means that the general population can vote one way or the other on the issue. If the approval is made by the TGA, it is a bit more difficult to hold someone publicly accountable so far as the electoral system is concerned.

Ms Halton—As the secretary of the department, I am accountable for regulatory decisions that we take. Regulatory decisions inside the department are actually my decisions, so I am the one who gets held accountable for them. But we operate very clearly within the context of the legislation we are given to administer. That is our responsibility.

Senator NASH—Is there any cause for this committee to not have complete confidence in the TGA to determine the quality, safety and efficacy of RU486?

Ms Halton—Again, you are asking me for an opinion. I can say that I believe that we administer our legislative responsibilities with earnest goodwill and a high level of technical competence.

Senator JOYCE—I acknowledge that you have not had RU486 brought before you, so you cannot actually make a decision about something, but I want to go down that track. If there were hormonal effects from a drug, say mifepristone, would that cause an antiglucocorticoid effect which, in essence, would affect the cytokine balance—the chemical

balance—in the body, affecting its ability to combat an infection? Would that be the case, and would you see that in other types of involvement of hormonal type drugs?

Prof. Horvath—Firstly, that is one of the effects of the drug. Again, I would need to talk to my colleague as to the full dossier on this drug. It does not come before me; it goes to the TGA.

Senator JOYCE—What about a broad reference to a hormonal treatment's effect on the capacity to fight an infection and how it can impair the balance?

Prof. Horvath—It depends on the hormonal treatment and it depends on what it affects. Virtually any drug can affect cytokines, and there are a range of cytokines going from one through to 16 or more and various subgroups. They are, in fact, merely messengers and transmitters. When you look at the evaluation of the literature as a clinician, you weigh up the risks and benefits of the drug or the procedure for the benefit that you wish it to achieve. The best example is anticancer drugs. They certainly interfere in a very large way with all the cytokine pathways you have mentioned. There is a major risk of side effects, but the benefits far outweigh the risk. As a clinician, all of us measure the benefits, the aim of what you are using the agent for, against the risks.

Senator JOYCE—That is the crux of my question, obviously. Couched in those terms, the benefit is the abortion of a child, which I think is abhorrent. But bearing that in mind, because we are using a drug which does affect the cytokine balance and the transmitters, there is more chance of an infection than there would be if we were not using that drug. Would that be a fair statement?

Prof. Horvath—I would have to take that on notice, because I would need to have a look at that part of the literature very carefully. I am not sure that the literature at the present time will in fact be able to answer it for you.

Senator JOYCE—I pose the hypothesis that, if it did affect the ability to combat an infection, there would therefore be more prevalence of people being affected in that way than if they had had an abortion in another form.

Prof. Horvath—When looking at the literature, those trials have not been done that I am aware of. I would certainly seek further advice from my colleagues and from the college as to whether those trials are under way anywhere.

Senator JOYCE—For your own reference, I refer you to *The Annals of Pharmacotherapy*, which is a leading peer review forum. It is an international journal for physicians, pharmacists and health care professionals who have actually done those studies and have come up with that position.

Senator POLLEY—I would like to know how many drugs are approved in Australia on an annual basis. Furthermore, in consideration of allowing the drug into the country, over a number of years people have raised concerns that there is, in some instances, overservicing in the administration of drugs by doctors. As I understand it, those considerations—that there is a risk of overservicing, of overusing drugs—are not taken into account, and this drug is actually used to abort a child. Can you assure me that I am correct in my understanding that those considerations are not taken into account in the approval of this particular drug. This is

in fact very different from Panadol; this is actually aborting a child. The issue is not about abortion or no abortion; it is about a drug that can be used readily and has the potential to be overused.

Dr Graham—There are other mechanisms within the department which use a lot of external stakeholder input to look at the quality use of medicines and overprescribing. There is a group called the National Prescribing Service, whose role is to monitor prescribing patterns of doctors and provide positive feedback about how to improve prescribing patterns where it may be necessary. There is also another committee within the department called the Pharmaceutical Health and Rational Use of Medicines Committee, which is a committee of experts whose sole purpose is to try to encourage the quality use of medicines. So, in a general way, there are a number of mechanisms to assist prescribers out there—and their prescribing patterns.

Ms Halton—But the framework that is applied by the TGA does not go to those issues. It simply goes to the evidence in respect of the utilisation of the product in respect of the application, if one is received.

Senator POLLEY—You can understand why there is obviously concern in the community in relation to handing over to a department as opposed to the minister the power to allow this to be administered in Australia.

Ms Halton—You are asking for our opinion again.

Dr Graham—In terms of the number of prescription medicines, I do not have the number for how many per year but at the moment on our register there are 6,655 prescription medicines.

Senator POLLEY—Could you then take it on notice to provide the figures for the amount of drugs that are actually approved for the market?

Ms Halton—Yes, we will give you that on notice.

Senator POLLEY—Thanks.

CHAIR—Going back to that issue of the origins of the decision to have the decision made by the minister as opposed to the TGA, we can of course read the *Hansard* of the debate at the time about the amendments to the TGA bill. Can you take on notice the tabling of any correspondence that you are able to release relating to that question?

Ms Halton—Again, this is nearly 10 years ago. I am not aware that we will actually have—

CHAIR—If you have none then that is fine but if you have any we would appreciate it.

Ms Halton—To the extent that I can find something which I am empowered to release, I am happy to go and have a look, but I have to say that, firstly, it is a long time ago, secondly, where any material might be I cannot swear to, and, thirdly, I have no idea what might exist. We will go and have a look.

CHAIR—I understand. We have a teleconference now.

Senator NETTLE—I do not know if there is an opportunity to ask questions now or whether we can see whether the department either can take questions on notice or is prepared to come to one of our subsequent hearings.

CHAIR—We have some people waiting on a teleconference interstate, so if you want to put those questions on notice, that would be great. I very much thank the department and the TGA for appearing today. We appreciate your time.

[11.18 am]

MAXWELL, Dr Ross, National President, Rural Doctors Association of Australia

PAGE, Dr Sue, Immediate Past National President, Rural Doctors Association of Australia

STRATIGOS, Ms Susan Mary, Policy Advisor, Rural Doctors Association of Australia

CHAIR—I invite Ms Stratigos to the table and we have Dr Maxwell and Dr Page on the line. Thank you very much for your patience in staying on the line. I am sorry we are running a little bit late. I realise you are both practising doctors and you may have patients in your waiting rooms that we are holding up, so I do apologise to them as well for this inconvenience. I think you have all been provided with information on parliamentary privilege and the protection of witnesses and evidence. I realise we have not had time for you to make a submission to the inquiry but I was wondering if you would like to make an opening statement to the committee before we proceed to questions. Dr Maxwell, did you wish to make a statement?

Dr Maxwell—Thank you very much. Just to contextualise who we are for the members of the committee, the Rural Doctors Association of Australia is basically a membership organisation. We have doctor members across the country who work in from what are known as interregional areas to very remote areas. So we cover a very wide breadth of rural and remote doctors within Australia.

We advocate on behalf of those doctors and on behalf of the community that they work in, and by and large their interests are very similar. One of the reasons we advocate is that there are poorer health outcomes in rural and remote environments and there are problems with access to services and equity of access to services. So, in some ways, that contextualises our submission to you.

We believe it is very important that any medication or any therapeutic intervention undergoes routine and rigorous scientific evaluation. We believe that a transparent process where this is done is the best way forward for Australia and for remote Australia. We think it is very important that remote Australians have equitable access to therapeutic interventions. We contend that the rural and remote medical work force is a highly trained work force. They operate an advanced scope of practice, dealing with a lot of emergencies and dealing with the ordinary sequelae of pregnancy where one in six ends in miscarriage. So they are already quite skilled in this area. They have advanced training to undertake that, and they undertake continuing professional development to retain their skills.

We contend that it is very reasonable that this anomaly in the legislation is removed. It is very important that people look at the evidence. Mifepristone is used for termination of pregnancies of less than seven weeks. It is usually used with another medication called misoprostol, which is either taken orally or vaginally, to actually complete the miscarriage. It has been widely used overseas. It has been used in the United Kingdom, the United States, France, Austria, Belgium, Germany, the Netherlands and Switzerland. There are extensive numbers around now about the safety of that medication. It appears to have an overall safety profile not dissimilar to surgical termination of pregnancy—like suction curettage.

It does appear to require some specific things. It requires that the practitioner and the woman have access to ultrasound. It is important to know exactly how many weeks the pregnancy is along. That may have some issues in rural and remote environments, but we contend that where there is access to ultrasound and to emergency services for resuscitation, and to suction curettage or curettage, it would be a safe procedure to have available in rural environments and even sometimes in remote environments.

The effectiveness is quite clear. I think the difficulty that people will have around it is that it may make access to termination of pregnancy somewhat more available. It is interesting that this week the figures for the current rate of termination of pregnancy in Australia have been published. When we are looking at a rate of one in four pregnancies ending in termination I would contend that the addition of another way to terminate pregnancy is probably not going to significantly alter that figure. The final part of our submission really is about the experience and the expertise of the doctors. I have already spoken about the fact that they already treat miscarriage frequently and that, by and large, they have extra skills in that area and undergo continuing professional development.

We would contend that the best way forward is that this medication goes to the Therapeutic Goods Administration for evaluation and that once it is through that evaluation, if it is going to be licensed, a program is developed between the professional colleges—the College of Rural and Remote Medicine, the Royal Australian College of General Practitioners and their National Rural Faculty and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists—to make sure that appropriate protocols are promulgated so that medical practitioners and health professionals understand how the medication would be used, what the safety parameters around it would be and what the settings would be where it would be safe to use. With that, I would like to invite Sue and Susan to make any further comments that they would like to and then ask for questions.

Dr Page—To my way of thinking, any treatment or medication option that is available in Australia should be available across the whole of Australia, and I was quite surprised at the thought that this medication might be quarantined to metropolitan areas only or that the whole of Australia would be denied access to it because it was not thought to be safe in a rural area.

On Ross's point that we currently manage complications of pregnancy, it is perhaps worth drawing to the committee's attention that fertility rates are higher in rural areas. Lots of rural families have three to five children per family, whereas it is quite common in a metropolitan environment to have between one and two children. Off the top of my head, I think the figure is that approximately 45 per cent of Australia's births take place in rural areas, although we constitute only 36 per cent of Australia's population. Because of that, rural units are well set up to deliver quality maternity services.

We have recently seen the report of the national perinatal mortality data sets, which show that the quality of services that are provided in rural areas for uncomplicated, low-risk type deliveries deliver outcomes that are not only as safe but actually have less intervention and, if you like, better outcomes than those in metropolitan areas. For every pregnancy that occurs, approximately one in 10 will end in miscarriage. So, for those high-volume numbers of pregnancies that are coming through, there are also a substantial number of miscarriages, with all the attendant risks of haemorrhage and so on, happening in rural areas, and rural doctors

and rural hospitals are well set up to deal with those complications already. To have an increase in that number through the use of medical termination would seem to me to be well within the capacity of rural health services to deal with.

There are clearly issues to be considered. For me, the issue around whether or not you have a termination is an entirely separate debate and not one that is for this arena today. But, having determined that a particular woman is to have a termination, in my mind it then comes down to: what is the safest and most cost-effective way of effecting that medical procedure, be it done through a medicinal process or through a surgical process? If you have a woman in a rural and remote area—and I will use an example from my recent clinical experience: a woman from an Aboriginal community with difficult access to transport and so on—you will not be performing a termination on that woman in her isolated setting because that will deliver an unacceptable risk. So the doctors who are prescribing this medication or who are organising surgical terminations will factor that into their choices about what is the best option. In this particular instance, the woman chose to travel a short distance up the coast to where there was a surgical termination facility. That journey to get to the nearest surgical termination facility took her about an hour and a half. Had misoprostol been available in Australia, she would have had to travel no more than approximately 20 minutes and could have stayed within her local community in order to be able to have a safe procedure done more locally.

In terms of the total number of terminations that take place in Australia, I think again another factor to be considered by the committee is the availability of psychological support services. What we see currently under the surgical support system is a compulsory requirement for women undergoing termination to have access to counselling to ensure that they are actually of the right mind to proceed with that process. If this medication were to be made available in Australia, after going through a pharmaceutical benefits advisory process, I would like to see consideration given to increasing the resources in rural areas for psychological support, to ensure that you have the same robust process for medical terminations as for surgical terminations. Having said that, there is research which again has come out just in the last month to say that the incidence of depressive illnesses, for example, is no higher in the group of women who have had terminations compared with the group of women who have not had terminations, so on its own it does not appear to be a risk factor for a significantly higher incidence of mental illness in that cohort.

As a nation, we certainly need to put much greater effort into safe sex advice and more accessible and more affordable versions of contraception. With every termination that takes place, there is the consideration of why it is taking place, whether it is the result of physical or mental illnesses, financial impost on the family or lack of social supports—all of those different reasons which feed into the decision as to whether or not somebody should appropriately have a termination. If we were better at providing affordable contraception in this country, wherever women are, to my mind we would have far fewer terminations happening in this country. That is where a much greater effort of the community needs to be delivered.

Certainly in rural areas we have inadequate pharmacy services. We have expenses added to every commodity that is available in a rural town, because of the travel and transport costs.

We have a lack of dedicated women's health services in rural and remote areas. It has been an enormous advantage to have an increase in the number of general practice nurses in rural communities, particularly with things like the introduction of the Pap smear items, because this provides women with greater choices, but I think we need to have a considered look at the availability of contraceptive services in rural and remote areas. For my patient, that was certainly a significant feature. Living in a community with poor access to public transport and being from a very impoverished family, she was not able to afford to buy her contraceptive medication in a consistent and without-gaps fashion.

CHAIR—Thank you very much. Do you have anything more to add, Ms Stratigos?

Ms Stratigos—No. Perhaps the committee would rather spend the rest of its time asking us questions that we will attempt to answer.

CHAIR—Indeed. Thank you very much to all three of you. Dr Maxwell, you mentioned that rates of abortion might be affected by availability of a drug like this. Would it not be the case that, with a drug which procured an abortion outside of a surgery or clinic, the numbers of abortions happening in Australia would not be easy to determine any longer? That is, a person might be administered a drug in a surgery, but the procured miscarriage would occur outside the clinic in almost every case. If that patient did not, say, return to the doctor, wouldn't it be harder to determine exactly how many abortions were occurring in Australia?

Dr Maxwell—That is a good question. It would really depend on how the service was delivered. If the service was delivered under the use of the current level B item numbers, then it would not be detectable from the point of view of data collection. It is a good question, because if we wanted to count it would be somewhat difficult. The only thing we would be able to count is the number of scripts written for mifepristone. That would give us some concept of how many terminations were occurring. One of the understood protocols for the use of this medication is that the women must be followed up after they have used it, because it is absolutely important that we make sure that, if they have used the medication, they have gone on to a completed termination of pregnancy. You may be aware that there are birth defects associated with using this medication and then going on to complete a pregnancy.

Ms Stratigos—Could I add that there is no evidence from countries where RU486 is already available that there has been an increase in the number of abortions by any method. I would also like to put this in the context that, as the National Perinatal Statistics Unit—which brought out that publication yesterday—points out, it is extraordinarily difficult to get accurate data on the number of terminations that take place in Australia today. Of course, there is no way of knowing the reason for which these terminations took place, so we are working in a very difficult area in an attempt to address the issue so rightly raised.

Dr Page—Can I add to that, though. If you wish to have the tracking, it clearly can be done through the script counting. It could perhaps be done under an authority prescription. It may even be that you consider the restriction of prescription of this medication to doctors who have done a dedicated training program—as we do, for example, for the use of methadone, where a requirement of that training program is to actually capture your data and do clinical audits. There are a number of ways that this can be done by using models that already exist for other medicines in Australia. I think the difficulty with this medication at the moment is

that it is kept in a category entirely outside the normal structures of how we deal with medications. But our normal Pharmaceutical Benefits Advisory Committee structures are robust and can deliver a variety of different data-capturing processes.

CHAIR—Thank you very much. Senator Fielding?

Senator FIELDING—I have a general question. How can Family First and the community be confident that the appropriate level of medical supervision and medical treatment will be guaranteed now and into the future, particularly in rural and regional areas?

Dr Maxwell—It is hard to absolutely guarantee something in each and every case, so it is quite a good question—how you would guarantee that. I think in my opening remarks I was trying to draw attention to the fact that this is much more than a medication for which you can whip in for five minutes and get a script and then be on your way. The protocols around it where it is being used overseas suggest that the women would normally have an average of three visits to the health care practitioner by the time the process is completed. And there are some very clear expectations about how the medication would be used, around the fact that the women would have had an ultrasound for very accurate dating of their pregnancy before they were offered the medication. They have to have counselling about how the medication will be used and what the effects of the medication will be, and there would have to be a very clear expectation that women are meticulously followed up to make sure that they have completed miscarriage or not. So that is the way it has to be used. I think that, however it moves forward, if it is going to go into widespread use then that would have to be a basic expectation.

Dr Page—May I add to that as well. Again coming back to the model that is already available in Australia: if we look at current terminations, there is a combination of state and Commonwealth legislation. For example, in the Northern Territory any termination can only be done by a specialist. That would mean that, should this drug be available in Australia, it actually would not be available for general practice use in the Northern Territory unless they were to change their state legislation.

Separate to that, once the medication has gone through its normal assessment processes—so that it is shown to have an evidence base for safety, quality and so on—then it is still up to the Pharmaceutical Benefits Advisory Committee as to things like access to the Pharmaceutical Benefits Schedule and the requirements for those eligible to prescribe it. Now, there are a number of medications which are currently available in a specialist-only model. Personally I would not recommend that for this, because my experience of that has been that any time any treatment or any medication is limited to a specialist-only model it significantly impacts the ability of rural communities to access that, because we have so few specialists in rural areas.

But you could, for example, use a model which is similar to the way that we deal with ultrasounds during pregnancy, where it is normal, accepted procedure to have an ultrasound which looks at the morphology of the infant and also confirms the dates, at approximately 17 weeks. If you have ultrasounds done in the first trimester, they are usually associated with the heightened risk for that individual patient of having an abnormality; for example, it might be following a small bleed in the first trimester of pregnancy. For you to be able to order these

additional ultrasounds under the subsidised system within Australia, you would have to have had dedicated training in obstetrics and gynaecology. So you could come up with a system that limited the use of this medication to particular doctors who have had additional training.

Again, I would not necessarily recommend that model for this drug. In rural and remote areas a number of our doctors have trained, for example, in the UK model or in Canada where the qualifications do not automatically fit into our structure, although the doctor may actually have considerable years of experience and training. You would probably want to look at a system whereby there was a dedicated training program just for this individual drug, similar to the methadone-prescribing model, so you could be sure that every doctor who was prescribing this medication was doing so with a really robust educational and support structure.

Senator FIELDING—We heard evidence earlier that the drug could be self-administered at home. If your association were approached, would you consider drawing up guidelines to help women take this drug at home and provide them with options for disposing of the foetus?

Dr Maxwell—We would probably see that as a role for—

Dr Page—The joint consultative committee.

Dr Maxwell—Yes—the academic colleges working between themselves to develop that sort of protocol. It is probably not our usual business to do that sort of work, but it is a piece of work that would need to occur.

Dr Page—Nationally there is a body called the Joint Consultative Committee of Obstetrics. It is a collaboration of the specialist College of Obstetricians and Gynaecologists, the Royal Australian College of General Practitioners and the Australian College of Rural and Remote Medicine. They already oversight, for example, the training of GP obstetricians. The standards, the level of training and curriculum and so on are set by that collaborative body. That seems to be an ideal body to be setting standards for the use of this particular medication.

In terms of self-administration at home, again, it would need to be a decision that was worked out between an individual doctor and a patient. But there are areas where, if the woman was going home, her actual home site may be quite isolated and it may not be in the best interests of that particular woman to be administering this at home where she may be far from emergency services. The same woman, if she were living in a centre and within a couple of hundred metres of the country hospital, may well safely be able to administer at home. You also need to look at things like the use of medications after hours, if you were going to have the bleeding complications after hours at weekends, when any hospital tends to have lower staffing levels, for example. But all of these things can be worked out on a case-by-case basis according to where the woman lives and what services are available at the hospital that is nearest to her.

Senator ADAMS—Thank you for being on the teleconference, Sue and Ross. I have been rather agitated about the adverse publicity for rural doctors. As you know, my background was with the National Rural Health Alliance, so I am certainly very supportive. Could you go through the training that is necessary for a GP to actually work in rural areas? I think a lot of people are not aware of the extensive training they have to do.

Dr Maxwell—A current graduate who comes into the training program at the moment will do a three-year program, which gets them to the general practice level, then they do advanced skills training on top of that. They will do three years where they are basically working in a supervised general practice and having discrete training within that practice. The Grad. Dip. Rural, which is a current qualification which is available, would then add in discrete skills on top of that. That is where they obtain obstetric skills, anaesthetic skills or other advanced skills.

If you are doing an obstetric diploma at the moment, it usually means 12 months of working in a dedicated obstetrics unit. It means doing normal deliveries and learning how to do operative deliveries with vacuum extraction and forceps, caesarean section and dilatation and curettage for the number of pregnancies which end in miscarriage. I remember that when I did mine my logbook showed that I had performed 192 of those procedures. The dilatation and curettage is in fact the procedure which would be called upon to deal with the sequelae of a partially completed medical termination of pregnancy. So people who have been through that process have actually done quite a lot of that work.

Dr Page—I think it also needs to be noted that somebody who is currently a GP obstetrician needs to have a hospital appointment, and the hospital itself looks at a credentialing process of that doctor in terms of the previous training they have had and their years of experience. For example, if you wanted a fellowship of the Australian College of Rural and Remote Medicine in addition to your FRACGP and Grad. Dip. Rural process, you would not be eligible for that fellowship until you have had a minimum of five years in a rural setting. It is not sufficient to have the training; you also need to have the rural experience. The dilemma for rural communities is that at the moment approximately a third of our doctors are overseas-trained, and the overseas qualifications do not necessarily map across identically to the Australian ones.

Perhaps I can give you an example from a town in southern central New South Wales. A GP obstetrician was going on a holiday and had arranged for a GP obstetrician colleague to be his locum. But his hospital refused to credential that doctor because he did not have his Australian diploma from the specialist college. Ironically, that same doctor was subsequently credentialled about six months later to replace a specialist colleague because in the intervening six months the hospital had reviewed his paperwork and found that while he did not have the Australian diploma qualification he actually had an enormous experience of obstetrics, including over 1,000 safe confinements. So sometimes you do need to look at the experience as well as the academic qualification, because of that mixed cohort of doctors that we have.

Ms Stratigos—Senator, if I could just add to that. As well as the basic training which Ross and Sue have outlined to you, ongoing continuing professional development is mandatory for medical practitioners in this country, including those in rural and remote areas. Yesterday, in preparation for coming here, I looked up the web site of the Australian College of Rural And Remote Medicine and found, I think, 24 courses designed for medical practitioners in rural and remote areas, to maintain and enhance their skills in reproductive health. There are—as you would all be aware—other organisations, notably Sexual Health and Family Planning

Australia, which organise extremely well-recognised courses to maintain and expand the skills of rural medical practitioners in this area.

Senator POLLEY—We already know—and I think it is an accepted fact—that we have a shortage of doctors in this country, particularly in rural and regional areas. Following on from Senator Fielding's question about the self-administration of this drug if it were to come onto the market, my concern would be that many of the doctors in my state have already got closed books. So what guarantee would there be that there would be the follow-up service that these women would require to ensure that there is adequate medical supervision after the event? Also, if somebody has to go in and have a surgical procedure, they are more likely to think about it on a number of fronts, in terms of cost and safety, because my understanding is that with every anaesthetic there is a risk. Wouldn't this drug, more than the surgical procedure, perhaps encourage women to have multiple abortions? It has been raised with me and I was alarmed to hear that this may be pushed onto the market because of a need for cost savings to the health system, in response to the huge cost of surgical procedures.

Dr Page—The first thing is that, with a surgical procedure, there is quite a significant cost to the mother, which is out-of-pocket expenses and is not covered by the Australian system. In that respect, the misoprostol would have the advantage in that there are lesser copayments, if you like. For example, with a number of the anaesthetics, if the woman wishes to have a general anaesthetic, that is a cost that the woman contributes to. In my experience of women who have terminations, I have yet to meet somebody who has had a termination who has regarded the process as trivial. My experience as a GP and obstetrician—and, Ross, I am sure your experience would be the same—is that for our local areas we do not just see our own patients; we also see patients who are referred to us by colleagues who do not do the obstetric process. I think that Australian women regard termination as a profound event. It is not like going shopping; it is something that they agonise over and it is a decision that they do not make lightly, because they are very aware that this is human life. When, for whatever reason, it is jointly determined that the termination is required—it is not a decision for the woman to make on her own or for the doctor to make on their own, and that is a requirement of every state legislation in Australia—I certainly think it is extremely unlikely that we would have a rapid growth in the number of people having terminations, because my experience is that women do not take it as a trivial matter.

Dr Maxwell—Just to add another point: I think your question of whether women would get the follow-up is a very good point. I think that you could not, in all ethics and legal responsibility, embark on a process where you prescribed mifepristone and misoprostol to procure a medical termination if you were not able to provide the follow-up. It is actually a vital part of that process that the follow-up does occur. I think that, when we are talking about how we would implement this if it were to become available, it is those sorts of issues that would have to be quite clearly spelt out by the joint consultative committee that Sue was talking about.

Dr Page—It is in the same way that, if someone comes in with a laceration, for example, you stitch them and automatically make the appointment for you to follow them up to remove the stitches. I would see this as a process that is likely to fit in the same context. You see the person, and you perhaps see them more than once in determining whether or not the

termination is the required procedure. Having made the decision, you would automatically put them in your book to follow up. In addition to that, there is an obligation on every doctor to see people in an emergency, so, even if the patient were not yours in the first place and you had not been involved in any way in the process of the medication being given, were they to present to the hospital with bleeding complications, they would be seen automatically as an emergency.

Senator POLLEY—With all due respect, what has been raised with me by the community is the concern that some doctors—not all doctors; I take that point—overservice. If we are looking at women's health, I think there would be evidence to suggest that some doctors in the past have been very quick to prescribe medication that was not necessarily needed on an ongoing basis but was a quick fix. The justification that has been put to me is that there is some genuine concern about that. If you are talking about follow-up services, I would like to put on the record information about pap smears and that fact that there have been instances in this country and overseas where doctors have not taken the responsibility of following up. There have been cases where women would have been spared their lives—or further surgery—if their pap smear results had been passed on to them, but they were not. So there are areas of concern for my community because there is a lack of doctors in rural and regional areas. There is genuine concern about the quick fix, overservicing and risk. You cannot guarantee that there will not be an increase because it is considered to be a less intrusive procedure.

Dr Maxwell—I think your points are reasonable concerns. It is very important that those things are addressed if this is introduced. One of the things that the legal cases around the pap smears has done is really change medical practice. If you look at current practice, results are invariably followed up quite tightly. The good side of some of those bad experiences has been that medical practice has changed enormously in that regard and hopefully we would simply take that on board. Some of the things that I have read about this actually suggested that one of the reasons to choose a surgical termination over a medical termination is that it is far quicker—it is over more quickly. The women's point of view, sometimes if they have good access to surgical termination, is that it is a shorter and sharper procedure. If you look at the data you will see that one of the things about a medical termination is that it can actually be quite drawn out, with regard to how many days it can take until the bleeding is finished and whatever. So your point about available services for follow-up is a good one. But I would still go back to the concept that, if this medication is going to be used, these are the sorts of questions that we must resolve rather than just put it out there as something that can be prescribed by anybody.

Senator ALLISON—Dr Page, you mentioned access to surgical terminations in rural areas. I understood that it was less likely now for women in even fairly major regional areas to be able to access surgical terminations at major hospitals or clinics or even with their GP. Is that the case? Is there any data on access to surgical terminations for rural women? If so, could you provide it?

Dr Page—The terminations, I guess, fit into the categories as to the reason for the termination—for example, if the reason for the termination is a serious health risk to the mother, such as her blood pressure is escalating quite rapidly. I use the example again of one

of my patients. By 12 weeks into the pregnancy, her blood pressure was 220 on 130. By the end of the pregnancy, people can have spontaneous strokes and die under those sorts of complications. Those types of terminations are treated as emergencies and they are done quite swiftly within the public hospital system in every state in Australia. Significant foetal abnormalities are treated similarly. However, if you are talking about first-trimester terminations, many women have not had an ultrasound by that time and so they would come to medical attention only if they had associated haemorrhaging. You might find, for example, that the actual embryo has not developed normally and so it is classed as being an inevitable miscarriage—that it will miscarry spontaneously. Again, those cases are usually dealt with quite swiftly within the public hospital system.

The so-called social termination is the category in which the reason for the termination taking place fits into issues of the woman's mental health, social support and her ability to deal with, for example, a single parenthood situation. These are the cases in which a much longer process of counselling usually takes place and where the indications for the termination to take place require a much greater extent of psychological services as a consequence. Those terminations effectively do not take place in rural areas at the moment, with very few exceptions. They tend to be dealt with by the woman travelling. In the case of my patient, the woman travelled for 1½ hours to the next nearest centre with a private termination facility. In that circumstance, the woman goes to—I hesitate to use the word—a one-stop shop for the entire day. It is a one-stop shop approach where they have medical counselling and social counselling and social workers and psychologists are in the building, and that is all provided as one discrete service.

Senator ALLISON—So there has been no trend over recent years for less access rather than more?

Dr Page—The reasons why women have terminations are not trivial. They are always well thought out and the decision is made with a certain amount of agonising of heart. In my experience, the woman who has decided to have a termination will travel if she needs to.

Senator ALLISON—That was not exactly my question. Perhaps you do not have the data.

Dr Maxwell—I do not know that there is any collection of data or mapping of the services, apart from quite anecdotal evidence that they are available in capital cities or large coastal centres. So women who live remotely do have to travel a long way to access those services. That makes a barrier. You have to have the wherewithal to decide you need a termination and have the monetary support to go ahead, organise it and be able to access it.

Senator ALLISON—My other question, Dr Page, was about your remark about contraception. In your view, is it a problem that no new oral contraceptions have been put on the PBS over the last 10 years and that there are no low-dose oral contraceptives on that list?

Dr Page—Yes, it is, particularly if you talking about teenaged girls. The most common strength of medication currently on the PBS often bears with it in that younger age group a level of nausea, bloating and weight gain which that younger group finds unacceptable. That would be a common reason for them to cease using oral contraceptives. It is also difficult in a rural area if you do not have a pharmacy in your town, so you have to travel to the next

nearest town to purchase your medication. Again, that becomes a barrier for that younger cohort to accessing reliable contraception in a manner that still keeps with it confidentiality.

Senator NASH—I want to focus on the purpose of the bill for a moment, which is, of course, moving the responsibility to determine the quality, safety and efficacy of RU486 from the minister to the TGA. In the Rural Doctors Association's view, is there benefit in doing that or not? Could you expand on that?

Dr Maxwell—As a general principle, I think it is a reasonable thing that it should be available through the TGA—that is, that the TGA should be making the appropriate recommendations around it. If we are going to put any sort of medication out into the public arena, it needs to be assessed on the basis of quality and safety. Obviously the government at some stage has a responsibility and a right to look at the cost-benefit implications of putting that medication into use. So if we have the medication go through that usual process then I think that is the appropriate way for its use to be determined. If that process comes up and says that either the benefits to women or the safety are not there or the costs involved are too great, then it is quite clear that that is where the decision should lie.

Senator NASH—Do you have confidence in the TGA's ability to do that appropriately?

Dr Maxwell—I would have no reason to doubt that they would have that ability. The TGA do that the rest of the time, and I think quality and safety in medications have been largely delivered to the country. Sue, do you have any other comment? You do a bit more work in this area.

Dr Page—Yes. Being familiar with the processes of how the therapeutic goods body works, I know there is an enormous amount of literature reviewed. They look at what has happened in countries overseas. If they are not happy with that amount of literature then they commission, with the pharmaceutical company, further studies to be done within Australia. I think that history has said that this is a robust structure, that we in this country do not have a lot of the problems that have been associated with more free access to medications in countries overseas. The quality and safety record of medications in this country is comparatively very good on an international level. I would personally have no problems with trusting the TGA to make the decision on my behalf.

Senator JOYCE—Thank you very much, Dr Ross and Dr Sue. I want to run past an issue and I want you to give me an answer about what would happen next. If a person presents to you, you administer Mifepristone and then you do not see her again so she now has either a mummifying or—hopefully not but possibly—a putrefying foetus in her body, tell me what would happen next.

Dr Maxwell—This is where it is very important that you have adequate follow-up mechanisms. It would be very important that you had a clear expectation about when the patient was going to come back to you or check back in with you. It would be vital that before you give this medication you make sure that you have the contact details—that you have the address, the phone number and the mobile phone number. With the patient's consent, obviously, it may even be worth while having the contact details of someone who she is close to.

Senator JOYCE—But my question was: what is going to happen to that patient next? They have not come back for the Misoprostol.

Dr Maxwell—Sorry, I misread the question. I thought it was: what are we going to do about it?

Senator JOYCE—No, what is going to happen to that person?

Dr Maxwell—If the patient has an incomplete miscarriage then there is a risk of them developing a septic abortion. That is a situation where this medication has some risk. But that appears to be quite rare, looking at the numbers.

Senator JOYCE—I just want to know what happens to that person when it becomes septic.

Dr Page—They would be admitted to the local hospital and treated.

Dr Maxwell—They would develop lower abdominal pain, a high fever and nausea and would need to seek urgent medical attention.

Senator JOYCE—And if they did not get it?

Dr Maxwell—The deaths associated with Mifepristone, of which I think there is a small number world wide—

Senator JOYCE—So they could die?

Dr Maxwell—are thought to be associated with a septic abortion.

Dr Page—Can I just clarify. The miscarriage process where the infant putrefies in utero is something that can occur with normal pregnancies as well. In a rural setting, for example, sometimes the first presentation for somebody is that they thought they had a continuing pregnancy, but they present febrile and with varying degrees of septic shock. There are two things associated with the risk of this happening: one is that you know to anticipate a miscarriage in this woman and that gives you a state of heightened vigilance, which may not be present in the spontaneous death in utero. That means, for example, that you would arrange that the woman attend for follow-up. If she does not attend for follow-up, it is a requirement of your general practice accreditation process that you have a system in place for following up people who fail to attend. In my instance, for example, that would mean that you would contact them by phone. Because we are in a small community, we actually do house visits and so on.

Senator JOYCE—I understand that. I just want to make sure that we get clearly on the record that, if a person in a regional area takes Mifepristone and does not come back for Misoprostol, they could die of septic shock—that is a definite possibility?

Dr Page—That is regardless of where they are; it is not just in a rural area.

Senator JOYCE—Finally, Dr Page, you said, 'It is a human life.' Could you please explain that statement to us all?

Dr Page—Sorry?

Senator JOYCE—In your previous comments you talked about there being another person involved in this. There is obviously the mother and there is also the 100 per cent

fatality rate for the child. You said, 'You have got to be careful, because it is a human life.' Could you please flesh that comment out and what that means to you?

Dr Page—If you have a pregnancy which has continued as long as eight weeks, which is towards the end of when this medication can be used, there is a 90 per cent chance that left to its own devices that pregnancy would continue and result in a birth, whether or not the child is born normally or abnormally or requiring operative intervention. I guess what you are talking about is: is this a human life, as defined? If the child were to be born at that eight-week mark, it would not be defined as being human life because it is not live born. The definition for a live born baby varies state by state according to whether it is 20 weeks or 24 weeks, for example, but the baby has to be able to draw a spontaneous breath after its birth. That is not possible for a baby of this gestation, because it has not yet grown its lungs.

I think what I was trying to put forward is that in the average woman's head, when she knows that she is pregnant—so it is not just that her period is late but she actually knows that she is pregnant—she has a sense of that pregnancy having the potential to be born as a live baby. So the decision that she makes that a termination must take place is not one that the average woman takes lightly. I do not have a concern that there would be a sudden escalation in terminations taking place because, in my clinical experience, the average woman is very profoundly aware of the consequences of having a termination.

Senator JOYCE—Finally, are you aware of the warning in the US that this drug can cause bacterial infection and sepsis and death may occur after use?

Dr Page—That holds true of any pregnancy that ends in a miscarriage.

Senator JOYCE—But the effects of your antiglucocorticoid actions and hormonal effects will actually increase the likelihood of infection because of its effects on the cytokines. Do you agree with that statement?

Dr Maxwell—I think that, if you compare the risks to the mother from termination of all sorts and the risks to the mother from going through to a normal delivery, in fact the risks are somewhat lower. If I can make a comment on your underlying point about termination: I appreciate exactly where you are coming from, because I personally find it an incredibly difficult thing and I am so grateful that I have never had to be in, or had a partner who has had to be in, the situation of having to make this choice. For better or worse, when you look at the number of terminations that have been performed surgically in this country, we have either tacitly or overtly made a decision that this service is going to be available. That is obviously a very big question, which has a lot of moral implications, and that is quite reasonable. As that decision appears to have already been made, our position is that we want to make sure that the options, the safety and the access to that service—assuming it is going to continue to be provided—are appropriate and suit the needs of women in rural and remote Australia.

Senator BOSWELL—One of your members, Dr David Gawler from the Royal Hospital of Darwin, has written to all senators. I have tabled his letter; unfortunately, you would not have been able to see it as yet. He goes on to make quite a number of assertions. I assume he is a member of your organisation, because he does deal in remote areas. He says:

In remote ... Australia, the transfer of seriously ill women to hospital may take many hours even by Air-Med Evacuation flights. ... the delay may be a day or more! Such delays could cost a woman prescribed RU486 her life.

Do you consider that Dr Gawler is correct, or wouldn't you prescribe RU486 to such a woman who has no access?

Dr Maxwell—I think it would be quite irresponsible to be prescribing this sort of medication to somebody who did not have fairly immediate access to resuscitation services and the ability to access a curette.

Senator BOSWELL—Can I run through a couple of other assertions that he makes. He cites:

... patient communication problems in the north, where many Aboriginal women speak little English. This may result in ... non-attendance at further medical appointments, and failure to recognise complications ...

He also goes on to say that RU486 could be 'a recipe for disaster' for women who are very young, immature, intellectually impaired or psychiatrically disturbed who may not understand or follow instructions. Do you think these women should be given RU486?

Dr Maxwell—I think it comes back to a matter of people being able to give informed consent—to be able to talk through with somebody what their options are and whether they understand the procedure that is going to occur. Part of the informed consent would be that there would be this undertaking from both parties that it would be a process that would only be completed once the woman had returned for follow-up and it was clear that a miscarriage had eventuated.

Senator BOSWELL—So you would not give RU486 to those women that I indicated there?

Dr Page—Can I speak to that as well. The first thing to say is that, in the Northern Territory, the current state legislation would preclude this being given other than through Darwin and Alice Springs, because those are the only places where you have specialist obstetricians, who at the moment are the only ones licensed to do terminations in that state.

Putting that aspect aside for the moment, one of the categories of whether or not somebody can give informed consent—and I am just trying to go by memory—is, for example, limited intellectual capacity. Somebody with limited intellectual capacity is not able to give consent for a surgical termination. Somebody needs to give that consent on their behalf because they are not clearly able to give informed consent. For example, somebody who was 14 or 15 would equally not be able to give their own consent for a surgical procedure. The categories of people whom you might regard as being most at risk are not able to give consent for their own medical treatments, for a whole variety of different reasons. If you have a 13-year-old or a 14-year-old who needs to have an antibiotic script, for example, you need to have her parent in the room. That is also in terms of the billing, for example, because somebody who is 13 cannot find their own Medicare docket.

In terms of whether or not somebody would be prescribed this when they were in a danger situation, I am obviously quite aware of the research that says that doctors make mistakes from time to time and patients are severely injured as a consequence—these events happen all

around Australia. So I am in no way suggesting that every doctor will get this right every time. But if the medication is determined to be safe and effective, if there are frameworks put in place about its use which may, for example, limit its administration to a cohort of doctors with additional training, and if there are guidelines set up by the Joint Consultative Committee on Obstetrics, then I would see that the safety frameworks are built into the system of administration, and it would be extremely foolhardy to prescribe this knowing that the woman was going to be a day-and-a-half air retrieval from the nearest emergency service.

Senator BOSWELL—What consultation—

CHAIR—Sorry, Senator. We are out of time.

Senator BOSWELL—I just have one more, if I could.

CHAIR—I know, but I am sorry: we just do not have time. We are already half an hour over time. We are not going to get any lunch at this rate. You can put a question on notice, if you want—that is fine.

Senator BOSWELL—It will take about two seconds, that is all.

CHAIR—To answer or to ask?

Senator BOSWELL—To ask and to answer.

Dr Page—Possibly both.

Senator BOSWELL—I just want to ask this: what consultation did you undertake with your members about your stand in support of RU486?

Dr Maxwell—The consultation with our members has been through the management committees of our organisation.

Dr Page—The executives of every state.

Dr Maxwell—Yes. The consultation, in some ways, was forced on us by being particularly singled out as the reason that you would not use it, which is somewhat of a red herring from many points of view. I think people have a wish to manage the access to termination services, and that is their own right and privilege. It is not anything to do with the skills of rural doctors.

Senator NETTLE—Thank you for being here to give evidence to us by the phone. We heard earlier from the Chief Medical Officer, Professor Horvath, that in five to eight per cent of instances of people using RU486 intervention would be required afterwards. I am wondering if you can tell us how that five to eight per cent compares with other drugs that you may use in terms of the safety and the need for intervention afterwards.

Dr Maxwell—That is a very high rate of intervention compared to other medications. I think that is one of the reasons it could only be used under a completely tied-down framework.

Senator McLUCAS—I have just one question. I put this question to you not as rural doctors but as doctors generally. There has been a bit of use of the word 'self-administration'. Senator Fielding and I are going to have another look at the *Hansard* to look very closely at what the AMA did say this morning. It is my recollection that they made it very clear that any

administration of this drug would be done with very close supervision. I think you have supported that today. The question I have is: do you perceive in the community a confusion between RU486 and the morning-after pill?

Dr Page—Absolutely.

Senator McLUCAS—Can you expand on that?

Dr Page—In the media queries that I have had on this issue—over, probably, a 12-month period, not just the most recent ones—there has certainly been confusion on behalf of the reporters who were interviewing me, which leads me to consider that there is confusion within the community itself. The morning-after pill is a medication that needs to be taken within 72 hours of unprotected intercourse. So, for example, if somebody has used a condom for contraception and the condom broke, they need to be able to purchase the medication quickly and to take it.

It is basically a dose of medication that is very like the contraceptive pill, but you take it in a higher dose and then repeat the dose 12 hours later. It has a high side-effect profile because it is a high dose, so you have lots of vomiting and nausea and so on. It is usually dispensed with anti-nausea medication for that reason. Its intent is to change the nature of the lining of the womb to trick the womb into thinking that it is at a different stage of the menstrual cycle. If the egg had been fertilised, it would normally take four days to travel down through the tube before it is ready to implant in the uterus. The intent of the morning-after pill is to change the lining of the womb so that, when the egg is trying to implant, the uterus is not of the right hormonal nature to allow implantation to happen and so the fertilised egg flushes out with the normal period for that woman. It is not a pregnancy that has started—it has not implanted. It only works if it does not implant, and therefore it is not a pregnancy.

Senator McLUCAS—So it is completely different to—

Dr Page—Completely different.

Senator McLUCAS—You are right—that is my perception as well—that there is confusion. The use of the term 'self-administration' grows that confusion, to be frank.

Dr Maxwell—The confusion arises because the protocol is that people take the RU486 and then a couple of days later they self-administer the misoprostol. They do that at home. That is the protocol of use in many situations. We self-administer medications all the time—that is what we do. We write prescriptions, give them to people and then they go home and take them.

Senator FIELDING—We could probably go back and forward about self-administration and do-it-yourself. I note Dr Page's concern that women in rural and regional areas have access to abortion and contraception. Are you also concerned to ensure that women do not feel forced by difficult circumstances to have an abortion they do not want because our community has not provided them with adequate support? What can we do in that particular area?

Dr Page—In rural and remote areas—as senators would be aware—there is an enormously difficult socio-economic circumstance. The average weekly earnings are lower. Rates of employment are somewhat lower, but when people are employed their average weekly

earnings are considerably lower. There are certainly different school completion rates and so on. There is an interplay between the social determinants of health, and health itself is one example. If you can keep Aboriginal girls in school for 12 months longer, then you drop the premature birth rate for that community by between seven per cent and 10 per cent. In many of our rural communities, not only do we not have pharmacists but the pharmacists that we do have may, for their own personal or ethical reasons, not dispense contraceptives—as we have seen in papers in the last 12 months.

These things all contribute to difficult circumstances for young women who are having pregnancies where there is either a medical reason for finishing it or a social circumstance reason of sufficient severity to impact on their mental health status such that it gives them the medical reason for termination, which is a legal requirement in this country. As a nation, we need to provide much greater support to our rural communities for their social aspects, economic aspects and their health aspects.

Senator POLLEY—You have already given evidence today that if this drug passed all scientific tests you would be in favour of it being administered, but you said that you believed that there needed to be services and counselling available for those women who unfortunately have to choose to make that decision to have an abortion. Would you be supportive of this drug being administered if there were not those counselling services available? You may have to take this one on notice: do you have any research which would clarify the situation about how many women in Australia are currently having multiple abortions, and the type of women who do so? It is not just young women or teenagers who are having these procedures, but a vast array of women. There are in fact some long-term issues about women who do. The people who I have spoken to who have had abortions still have great regret and suffer from depression and other psychological disorders 20 or 30 years after the event.

Dr Page—From a statistical point of view—and, again, this is research that has only been published in the last month—the rate of long-term depressive illnesses are no greater in the termination group than the no-termination group. That is certainly a common perception but, when they have actually studied the numbers, they have seen that that has not been the case. Perhaps what is happening there is that women who have depressive illnesses are looking for a reason for it, so they are hooking it onto that event, but women with terminations are no more likely to have long-term depressive illnesses than women without.

With regard to our psychiatric services in Australia, there is an enormous disparity in access for rural areas. If we look at psychiatrists, for example, we will see that something like 87 per cent of psychiatrists in this country are all in the capital cities, yet 36 per cent of Australians live in rural and remote areas. We need a much greater use of things like telepsychiatry to make those services available. Psychologists usually work in a private sector model. We have almost none of them in rural and remote areas, and we see things like the fact that rural men are statistically significantly less likely to have depression but significantly more likely to commit suicide. Clearly, they had the depression but they were not able to see somebody so it was not being diagnosed and they were not being offered treatment—and the treatments are very successful.

My concern with this medication is that, if it were embedded within the proper protocols, I would expect that the Joint Consultative Committee on Obstetrics would rightly say that part

of the protocol is that the woman has to have access to counselling services, and the decision to prescribe it or not prescribe it would then be determined by whether or not those services were accessible and affordable to that individual. If they were not accessible and affordable to that individual, it would seem to be, on available evidence, in her best interest to travel to where those services are available, in which case, she may choose to have a surgical termination as the alternative.

Ms Stratigos—To get back to the first part of your question, the data released this week by the National Perinatal Statistics Unit, which is a very highly regarded statistical body, suggests that, of the abortions that are counted in Australia at the moment—and I do emphasise my earlier point that the data is very rubbery, particularly in some jurisdictions—the highest rate of termination of pregnancy was in women in their early 20s. We can provide you with links so that you can see all that data, with perhaps a brief analysis of it insofar as we are able to go with what is known at the moment.

CHAIR—I thank you all for your time today. I appreciate the extended period for which you have been available to us.

[12.27 pm]

TIPPETT, Dr Christine Grace, Royal Australian and New Zealand College of Obstetricians and Gynaecologists

CHAIR—I welcome the next witness. Thank you for your time today and thank you for your patience in waiting for us to get to you. I suggest to committee members that, as we are running well over time, we limit ourselves to one question each for this witness and the following witness. If committee members have further questions, they can place them on notice. Dr Tippett, you have heard the information on parliamentary privilege. We do not have a submission from the college as yet, but would you like to make an opening statement before we proceed to ask you questions?

Dr Tippett—First of all, I would like to thank you for the invitation to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists to give evidence to your committee, which is considering the Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005. The RANZCOG is a training and standards setting organisation committed to pursuing excellence in the delivery of health care to women throughout their lives. We do not, nor would it be appropriate for us to, hold a position on the rights or wrongs of abortion. However, we are firmly of the opinion that, if a woman has chosen to have an abortion, she should not only have available to her accurate and appropriate information about abortion but also be able to choose to have a safe medical abortion rather than a surgical abortion if that is her preference.

There is clear evidence that some women would prefer not to have a surgical procedure if that could be avoided and that it is a safe option for pregnancy termination up to at least nine weeks gestation. Access to safe abortion is a health care issue and should be provided as an integral part of broader sexual health services. The politicisation of this issue is regrettable, although probably inevitable. We consider that it is no longer acceptable that RU486 be subject to the restricted goods provision. If the drug were to be made available to Australian women after evaluation by the Therapeutic Goods Administration, there is no evidence to support the contention that the availability of a medical termination will increase the number of terminations undertaken in this country. Medical terminations are available to women in New Zealand, North America, the United Kingdom, much of Western Europe, Russia, China, Israel and many other countries. We are strongly of the view that the therapeutic goods administration bill should be supported.

I will briefly present an overview of the drug, the evidence with regard to its safety and efficacy and the clinical application of the drug, as has been requested. Mifepristone is a synthetic antiprogesterone which has a proven role in women's health care. Progesterone is a hormone made in large quantities in pregnancy. It is essential to stimulate and maintain the development of the endometrium—the lining of the uterus—which enables the pregnancy to implant or establish itself in the uterus and to grow. By antagonising progesterone, mifepristone causes the endometrium to generate so that a pregnancy cannot be sustained. If a pregnancy is not in the uterus, if it is an ectopic or tubal pregnancy where there is not an established endometrium, mifepristone is not effective in interrupting the pregnancy. This is

an important consideration when the drug is used. It is important to establish that a pregnancy is in the uterus prior to the administration of mifepristone. I will elaborate on this further when I address the clinical use of this drug.

Safety and efficacy: there is a substantial body of literature established on the safety and efficacy of mifepristone when used in conjunction with a prostaglandin analogue, usually misoprostol, to induce early abortion. There has been an estimated 500,000 early medical terminations in North America and over one million in Europe since mifepristone was approved as an abortifacient in 2000. The Royal College of Obstetricians and Gynaecologists published in September 2004 national evidence-based clinical guidelines on the care for women requesting induced abortion. They evaluated the efficacy of medical and surgical termination. They included in their recommendations that ideally abortion services should be able to offer a choice of recommended methods for each gestation. Medical abortion using mifepristone plus a prostaglandin is the most effective method of abortion, taking into account safety and efficacy at gestations of less than seven weeks. Medical abortion using mifepristone and prostaglandin termination continues to be an appropriate method for women in the seven- to nine-week gestation band. Conventional suction terminations should be avoided at gestations below seven weeks. The reasons for these recommendations relate to the failure rate of early surgical terminations and an increased instance of women who have had medical terminations requiring surgical intervention to complete the evacuation of the uterus after late medical terminations. This is estimated to be between two to four per cent, increasing with gestational age.

The Royal Australia New Zealand College of Obstetricians and Gynaecologists ratified in November 2005 the document *Termination of Pregnancy: A resource for health professionals*. This is an extensively researched document, and both this and the Royal College of Obstetricians and Gynaecologists document address issues of side effects and complications.

As surgical termination is accepted as a safe procedure, it is pertinent to compare the side effects of maternal mortality of medical termination with surgical termination. Serious complications are rare and occur in about four per 1,000 procedures with either method. Mortality and serious morbidity occur less frequently if a pregnancy goes to term. There are few randomised trials comparing medical and surgical termination, but the data presented in both the documents I have cited is a compilation of the best available evidence.

A recent Danish study of 50,000 surgical procedures reported a complication rate of 3.4 per 100 within two weeks of the procedure, with bleeding, re-evacuation or precurettage or infection being the most common. Maternal mortality rates relating to surgical terminations in Australian and North America are of the order of 0.3 to 0.8 per 100,000, and the most recent data from North America suggests that the common cause related to anaesthesia. This compares with the maternal mortality from having a baby going to term of one per 10,000 in Australia—a 10 times greater risk. Serious complications with medical terminations are also of the order of four per 1,000 and are rare, with overall rates due to haemorrhage or infection of 2.7 per 100, and two per 100 requiring surgical evacuation of retained tissue. There have been four maternal deaths recently reported from North America, which I think have been referred to, where there was an association with medical termination of pregnancy, although mifepristone has not been cited as the causative agent. This gives an estimated mortality rate

in North America comparative with that of surgical termination. There have been no such reports of similar infections in Europe and there are eight other cases of similar deaths in women who have had pregnancies going to term.

No intervention is without risk. One cannot avoid risk. As I have said, maternal mortality associated with an ongoing pregnancy is 10 times higher than that associated with a termination of pregnancy. Contraception is advocated to prevent unwanted pregnancy. The risk of having a stroke related to taking the pill is about the same as the risk of dying of pregnancy termination. However, we consider the pill a safe drug, and quite rightly so. If we consider driving a safe form of transport we have to consider that there is a risk of dying equivalent to that of pregnancy in one year of driving 10 times greater than the risk of having a surgical or medical termination.

Medical termination using mifepristone is a safe procedure. Australian women should have a choice with regard to the type of termination they undergo. There is good evidence that women have valued choice and are more likely to be satisfied with the method if they can choose that method. The greatest risk of mifepristone is that it is potentially too easy to use. A doctor must be trained to undertake a surgical termination safely. For mifepristone to be used safely, training and education of practitioners and the development of best practice guidelines are essential. Useful information can be obtained from countries where this is already undertaken. However, we have to take into account our rather unique geographical distribution of population, and some of those problems have already been alluded to by prior speakers. The college would very much wish to be involved in the development of such guidelines.

In summary, the RANZCOG strongly supports the therapeutic goods amendment bill 2005. It is not appropriate that mifepristone continues to be subject to the restricted goods conditions. This has effectively denied Australian women the choice of a medical termination of pregnancy which is recognised as a safe alternative to surgical termination of pregnancy in early gestations. The appropriate body to evaluate and regulate this drug is the Therapeutic Goods Administration. It is, in fact, inconsistent and inappropriate for mifepristone to be evaluated or assessed by another body. We would be optimistic that were mifepristone to be subject to the same evaluation process as all other medications then application would be made to the TGA for approval. And we would hope that subsequently this medication would be available to Australian women. Thank you.

CHAIR—Thank you, Dr Tippett.

Senator MOORE—You referred to a document that your organisation produced in November which would include a lot of the scientific rationale. We will get a copy of that and if there are any questions arising out of that I will put them on notice. You also referred to the need for guidelines, and that has come up consistently in all the evidence so far. What kind of role would your professional group have in developing the usage documentation or guidelines that you would suggest should be in place if this drug, or any drug, was going to be referred for use in the community?

Dr Tippett—We would very much wish to have a very important role in the development of such guidelines, obviously in consultation with those groups that represent other doctors

who could be involved in administering the drug. I think the most important thing when considering this drug is that it should be considered in the context of an episode of care. There was discussion about self-administration. I think that puts the whole thing onto the wrong level. This is an episode of care when a woman goes to see a practitioner because she has a pregnancy which she is not sure she wishes to continue. I refute that women make this decision very easily. Almost universally, women go through a lot of grief and consideration when they decide to have a termination. It is not a decision they make easily.

Once they have made that decision and if they have a choice of options, they should be given good information on those. If they choose to have a medical termination—and a medical termination for many women is their choice, but it may in fact be more protracted and involve more pain, more bleeding, longer bleeding and more visits to a doctor—they should be able to have that choice. The guidelines will need to include whose going to be allowed to prescribe this medication. I believe that there should be some careful consideration of how that can be done safely, what context it can be prescribed under and what the requirements are for prescribing it.

For instance, ACRRM have discussed counselling services and the need to ensure that we have an accurate gestation of the pregnancy. I was somewhat disquieted when I initially heard some years ago that a third of women know when their last period is, a third think they do and a third have not got a clue—and it is probably, in my long experience, very true. Given that mifepristone is most valuable for pregnancies under seven weeks and between seven to nine weeks, it is very important that gestation is established, including ectopic pregnancies. So that may be one of the things included in the guidelines.

If you look at it as an episode of care, you do not look at mifepristone by itself: it is mifepristone plus misoprostol—those regimes. The two medications are integral to doing a medical termination, so they have to go together. The majority of women who undergo terminations are very responsible women. I believe that they are very unlikely to go off and have mifepristone and not return for the follow-up. In fact, women present very early if they have a spontaneous pregnancy and have some bleeding. They access medical help very readily. I cannot see any reason why, if they had a termination, that would change. The only reason that would change would be if the mifepristone were being given in an environment where a woman found herself being criticised for having a termination of pregnancy. So there has to be a way where she does have sympathetic people whom she can contact on a 24-hour basis.

Senator FIELDING—I put a question before to the Rural Doctors Association of Australia about drawing up guidelines on how women should take this drug at home—I will repeat that: some women are taking this drug at home; they are self-administering—and the options for disposing of the foetus. They responded by saying, 'We see that this is a role for the academic colleges.' And they added, 'It's a piece of work which would need to occur.' Will you be drafting guidelines on how women should dispose of the foetus?

Dr Tippett—Because we are advocating that this drug should be able, we have a responsibility to ensure that it be used safely, and using it safely means that there are good guidelines. I believe that we are one of the best bodies to be involved in developing those guidelines. We have great experience in the health care of women having a termination and all

the issues and problems related to it. So that would be very much a role that we would want to have and would intend to have.

There is now quite a lot of experience of the use of this drug in New Zealand, where it is used in very limited circumstances, in clinics. Self-administration is in some ways a bad term to use because, as I said, this is an episode of care. In the New Zealand context, a woman might be given the drug to take at home, but she comes back to the clinic where she has misoprostol within one to three days of having mifepristone. She will then usually miscarry in that setting. Whether or not that is appropriate in Australia with our different demographics is hard to know, but they are the things that will need to be talked about to make sure that there is minimal risk. But, as I said, no intervention—be it a surgical termination or a medical termination—is without risk. There is no guarantee that there will not be problems. We would always anticipate that there would be some. It is our responsibility to ensure that those risks and those problems are as small as can possibly be managed.

Senator FIELDING—So self-administering does happen in New Zealand. It is like do-it-yourself.

Dr Tippett—No, it is not like do-it-yourself. I take exception to that comment, Senator, with all due respect. This is an episode of care which is managed by a medical practitioner. To say that somebody who takes a medication and who then represents for the misoprostol is self-administering gives the wrong impression altogether. It should be done in a controlled environment where there is access to follow-up. In fact, it may be that, after discussion, misoprostol—a prostaglandin that causes the uterus to contract and evacuate the product of a conception—may occur in a controlled environment.

For instance, if you have a woman who is in a remote area, with some timing you may in fact—and this is hypothetical, because we need to sit down and really go through all the data and information—suggest she take her mifepristone 24 hours before and then present to a centre where she can have her misoprostol and stay there until she passes the tissue and can be checked to make sure everything is okay. In the New Zealand context that is usually within 12 hours, so it is doable within a day-case procedure in a centre that is not too remote from where she lives.

Senator FIELDING—We tabled a document before from Dr Gawler that says that there are many cases that—

CHAIR—Senator Fielding, we have agreed on one last question each.

Senator POLLEY—Can you explain to us here today how long it takes for a baby to die with a surgical procedure as opposed to dying with the medication RU486 and whether or not there is a risk that some women may be inclined to have multiple abortions through medication as opposed to surgical procedures?

Dr Tippett—The time from the initiation of a procedure to foetal death I cannot tell you precisely. Clearly, with a surgical termination it is fairly abrupt, because when a surgical termination is undertaken the pregnancy sac is disrupted, the foetus is destroyed and that happens very quickly. With a mifepristone termination, clearly it is going to be a more protracted period because effectively the endometrium withdraws the nourishment from the

foetus. As to over what period of time that exactly occurs, I would have to look at the literature to ascertain that for you.

Senator POLLEY—Would you provide that evidence?

Dr Tippett—I am not sure if that evidence is available. In my reading I have not seen that evidence to be available. If you give misoprostol, after 24 hours the pregnancy will usually go ahead and abort, so clearly by that time—24 hours—the pregnancy is no longer being supported. The reason why mifepristone is safer to use in earlier gestations is that that effect is going to be more effective in early gestations where there is less endometrium and less placental tissue present than in later pregnancies.

With regard to the concept that if there is a medical form of termination available women will have more terminations, there is no evidence to support that at all. Women do not choose lightly to have terminations. There have always been women in our community who have had a number of terminations. In fact, those women may well be more likely to access surgical termination because it is a quick fix: they can go to a clinic at 10 o'clock in the morning, they can have a termination at 11 o'clock, they can be out of there at 12 o'clock and they can be back at work the next day.

With a medical termination it is a much more protracted episode. If they are going to have some mifepristone, they will probably have some pain and maybe some bleeding at 24 hours. They will have misoprostol, with further pain and bleeding. We know from studies that that bleeding could go on for significantly longer than that with surgical termination. So in many ways that process could well be seen as a disincentive to women to have repeat terminations. What we do know is that if women are able to choose they tend to be more satisfied with their choice. I think it is important to note that in some ways inevitably we are discussing the pros and cons of abortion, but that in some ways this is not what this debate is about: this is a debate about whether or not women in Australia can have a choice which women all around the world have.

Senator POLLEY—To clarify one small point: some of the material that I have read suggests that it actually takes three days for a baby to die. That actually does have an impact on whether or not you should allow the TGA to actually make a decision—and that is based on some of the evidence of those mistakes in the past.

Dr Tippett—I am not sure why that would impact on the safety and efficacy evaluation of a drug. I can see that people may ethically and emotionally have difficulties with that if that is their perception. However, if you give misoprostol in a pregnancy that is still ongoing, you are more likely to have a pregnancy that does not abort. The only way you could ascertain that is to give women misoprostol and do an ultrasound scan to see when the foetal heart stops beating. We can easily search the literature to find that information for you but, as I said previously, that is going to vary with the gestation at which you give the medication. If you give the medication early I have no doubt that it is a shorter period of time than if you give it later.

Senator POLLEY—I would appreciate any further research.

Dr Tippett—I am more than happy to do that.

Senator NASH—You said in your opening address that the college believed that it was no longer acceptable that RU486 remain as a restricted good. Can you expand on why the college has taken that position and what you mean?

Dr Tippett—I think we have taken that position because in fact this is a medication which we believe women should have available to them because it has a proven record in women's health issues. You can argue as to why this medication, and this medication alone, has been put in that category. For instance, in some ways Viagra is a much more dangerous drug and there has never been a consideration that it be put into a restricted category. In many ways it is a similar health issue, but because it is not related to a procurement of abortion it is seen very differently. There does not seem to be any logic as to why one medication out of all the medications available is put into a separate category. We know why that is, but in fact logically it is very difficult to support the ongoing position.

Senator BOSWELL—The food and drug agency's figures show that the safety of RU486 deteriorates the later it is taken in pregnancy. They say that, if RU486 is taken seven weeks after conception, 23 per cent of women will not have a complete abortion and will require specialist care. Does that concern RANZCOG?

Dr Tippett—The internationally accepted figures are that, up to seven weeks, there will be two to three per cent of women who will not complete an abortion if they have mifepristone with misoprostol and, between seven and nine weeks, that increases to between three to five per cent.

Senator BOSWELL—I am sorry, it does say two to three per cent.

CHAIR—Can you repeat your question, Senator Boswell? I did not catch it.

Senator BOSWELL—It is two to three per cent. What is the optimum cut-off time for RU486?

Dr Tippett—It depends in which context it is being used. If you are using it for first trimester termination of pregnancy it is most effective and its safety profile is best when it is used less than 63 days from the last menstrual period, which is up to nine weeks. It has applications in other areas of women's health care, particularly with regard to later abortion. It is recognised around the world that it has value in that application. But if you are looking at it with regard to first trimester termination, up to nine weeks is where it is recommended. That is one of the reasons it is so important to establish accurate gestation if this medication is to be used. Then you are not going to have excess risk associated with the use of the drug.

Senator ALLISON—You represent gynaecologists. Do you have anything to tell the committee about gynaecological cancers and the role of mifepristone in treating those cancers in other parts of the world? Is this one reason you support removing the veto of the minister as it were?

Dr Tippett—I know that in fact there are applications in non-women's health areas but I am not across that information. I am sorry I cannot answer your question.

Senator ALLISON—It is a women's health area. They are gynaecological cancers, ovarian and so on.

Dr Tippett—I apologise for not having that information. My main area of practice is in high-risk maternity care. If you asked me a question about that I am sure I would be able to answer it.

Senator JOYCE—I am very impressed, Dr Tippett, with your technical capacity. I want you to define for me what you believe is an identifiable foetus, as has been talked about before. Do you think flushing an identifiable foetus down a toilet is a viable form of disposal?

Dr Tippett—If you are using an ultrasound machine to see if there is a gestation sac in the uterus, which is the first thing you see, you can—often depending on the resolution of your machine and the manner in which the ultrasound is used—usually identify a gestational sac in the uterus from about five weeks of gestation. At between 5½ and six weeks of gestation you can often see a foetal heart and a small embryo, which just comes up as a white, almost jellybean shaped structure. By seven weeks gestation, you can more clearly identify a foetus, as at nine weeks gestation.

Senator JOYCE—What do you mean by that?

Dr Tippett—If I put the ultrasound scan on someone who has nine weeks gestation, I can see a foetal head, a foetal tummy, legs, arms and a foetal heart. I can identify that reasonably easily. That is as one would expect. In regard to how one disposes of the foetus—

Senator JOYCE—So you would be able to see that when you passed the foetus out? You would possibly see feet, hands, a head?

Dr Tippett—It is extremely small, but women may see that, just as a woman does when she has a spontaneous miscarriage.

Senator JOYCE—But a spontaneous miscarriage is a possibility. There is a 100 per cent probability that you are going to miscarry with this.

Dr Tippett—Well, it is probably 98 per cent probability, but yes—but equally so. But these women have elected to have a termination of pregnancy. When they decide and choose what they are going to have, those issues need to be discussed with them. That is one of the reasons that some women might prefer to have a surgical termination. The woman has an anaesthetic, she goes to sleep, and as far as she sees it is all over. Clearly, emotionally it is not all over. Women need to adjust to having made a decision to have a termination and the procedure, whatever they do, but some women in fact prefer to have a medical termination, given the fact that they know that they will pass tissue and it may be identifiable tissue if the pregnancy is up to nine weeks gestation. That is a woman's choice, if she is informed of what is going to happen.

Senator JOYCE—Identifiable tissue, like my hand is identifiable tissue? That is a hand; it is identifiable tissue.

Dr Tippett—I am using it as a medical term. She will say, 'I think I passed a sac, some placental tissue.' People will bring in what they think is pregnancy tissue—sometimes they have had a spontaneous miscarriage at home—and it is not; it might be a blood clot. She may not actually see a foetus. It comes out in toto, in the sac. She may see it. But, as I say, in anything that we do with women, women must have good information. They must make an informed consent. If the woman is going to find that sight abhorrent and distressing, she may

well decide to have a surgical termination. But we know, and the evidence supports the reality, that some women prefer to have a medical termination, albeit that seeing foetal tissue may be very distressing. There is very strong evidence to support that.

Senator McGAURAN—Doctor, given the physical and emotional effects that we know of Viagra, and given the physical and emotional effects of RU486 on the mother—let alone on the child—and her health, were you being flippant when you made a comparison between Viagra and RU486? It sure sounded like it.

Dr Tippett—I apologise if I was perceived as being flippant. I believe strongly that because this is an abortifacient it has been put in a separate category, and I do not believe that there is any logical reason for that to be done. As I said, abortion is a reality in the world in which we live. We know that, if women are polled, probably 85 per cent of women will say that there could be a situation where they would choose to have an abortion. So women in this country believe that that is something they want to be able to access. Because of the politicisation of this debate, a choice in the way that is undertaken has been withheld from them, whereas in fact women in many other countries have a choice about a medical or a surgical termination. It is of even greater concern that the evidence currently supports that medical termination is probably a safer form of termination under seven weeks gestation than surgical termination of pregnancy. So, as a body which advocates strongly for the best health care for women, for women having good information and good choices, I do not think we could take any other position than to have a view that this medication should be assessed for its safety and efficacy by the Therapeutic Goods Administration.

Senator McLUCAS—Dr Tippett, earlier today Dr Sue Page said that an ultrasound is currently allowed under the MBS at a certain time, and I did not catch what she said. What is the current ultrasound schedule for a pregnancy?

Dr Tippett—I work as a specialist obstetrician, so I can do ultrasound whenever I want to. You are talking about referred and unreferred ultrasound. Once again, I would have to take that on notice.

Senator McLUCAS—That would be helpful.

Dr Tippett—I know that GPs can refer for one specialist ultrasound. But it has changed recently as well, so I would have to look that up for you.

Senator McLUCAS—Thank you.

Senator FIELDING—The AMA said earlier, when talking about the process of taking RU486, that women take an oral dose onsite and then go home, and then two to three days later they take a follow-up dose, administered by a doctor or self-administered. Family First is pleased that the Royal College of Obstetricians and Gynaecologists will be involved in drawing up guidelines about how women give birth to a foetus at home and dispose of it. But Family First is still extremely concerned about the psychological harm to women of disposing of their own foetuses. How will they be helped?

Dr Tippett—Because a woman passes a foetus at home does not mean to say that she has to dispose of her own foetus. New Zealand women come back to a clinic where they are given their misoprostol, and they will usually pass the foetus in that clinical setting. When they have

passed the foetus, they will then go home. That is one scenario. You could give a woman a receptacle so that when she passes the foetus she can put it in the receptacle and take it back to the doctor who initiated the procedure. This is an episode of care. It should not be seen as isolated bits of care. The medical practitioner can in fact dispose of the foetus. That may be a very reasonable option. I think they are very sensitive issues and that guidelines need to be drawn up following discussions with women's groups and with other professional bodies as to the most appropriate way to handle it. I have no doubt there is a lot of experience overseas. I have not seen clear guidelines. One of the concerns in North America is that there are not a lot of guidelines, and that may be one of the reasons why California has recently reported on some deaths there. We would hope that by putting in guidelines we could make it as safe as is possible.

Senator POLLEY—How late in the pregnancy can RU486 be used? At what time in that baby's short life would it be acceptable to use that form of abortion?

CHAIR—Dr Tippett, that was a question on notice. Would you mind answering that for us in writing rather than answering it right now?

Dr Tippett—Okay.

CHAIR—Are there any other questions for Dr Tippett to take on notice?

Senator BOSWELL—Yes, I have some in writing.

CHAIR—Thank you, Senator Boswell. Thank you very much, Dr Tippett, for your time today.

[1.03 pm]

VAN GEND, Dr David, Secretary and Spokesman, World Federation of Doctors Who Respect Human Life, Queensland Branch

CHAIR—Welcome. Thank you for waiting today. We are running over time and we appreciate your patience. You have been given information about parliamentary privilege and the protection of witnesses and evidence. We do not have a submission from you at this stage.

Dr van Gend—I did send one.

CHAIR—I beg your pardon. We have not read it, at least. We will do so after today. Would you like to make an opening statement?

Dr van Gend—To give the context of our organisation, which has been around for about 30 years internationally, let me quote the core part of the declaration of our doctors, which was drafted by Professor Jerome Lejeune, the great geneticist who discovered the basis of down syndrome, so you see where we the heart of this question lies. He said:

> Just as medicine is at the service of life when it is failing, so too it should serve life from its beginning.

The declaration also says:

> From the moment of fertilisation, that is from the earliest moment of biologic existence, the developing human being is alive, and entirely distinct from the mother who provides nourishment and protection.
>
> From fertilisation to old age, it is the same living human being who grows, develops, matures and eventually dies.

It goes on:

> When confronted with tragic situations, it is the duty of the doctor to do everything possible to help both the mother and her child.

The last sentence is key:

> The deliberate killing of an unborn human to solve social, economic, or eugenic problems is directly contradictory to the role of the doctor.

May I paraphrase that last sentence to say that the deliberate killing of an unborn child to solve social, economic or eugenic problems is directly contradictory to the role of policy makers as well. I will take that and focus very closely on the question faced by senators and MPs, which is whether the parliament retain policy discretion over the use of RU486 or whether it delegates it to an official body which is not accountable.

Before that, let me give these summary points if I may. Abortifacient drugs such as RU486 are unique in that no other drugs are designed to end a human life. Therefore their use demands a unique level of public scrutiny and accountability. The current regulatory arrangements in Australia for abortifacient drugs were instituted in 1996 with bipartisan support to ensure proper accountability by government on a matter of great public concern, and they should remain. However, if RU486 is found by the Therapeutic Goods Administration, the TGA, to be safe then valid medical indications for its use, including

certain cancers, hormonal diseases and medically essential termination of pregnancy should be authorised by government. Other uses for RU486 which are medically unjustifiable, such as taking the life of healthy offspring to relieve the social distress of parents should have no place in government policy or medical advocacy. Instead, the compelling policy task for both government and the medical profession together is to strengthen social supports for women distressed by unplanned pregnancy.

That is the shape of our concerns. May I focus closely on the key point: why the parliament should retain policy oversight of the conditions under which RU486 legitimately be used, rather than delegating it to a body such as the TGA, which has a narrow brief to assess drugs on the basis of efficacy, safety and quality, which is entirely proper to their official role but which has not got the brief to deal with the broader questions of our dealings with an innocent life—the justification of taking a life, the medical situations where abortion may be entirely necessary and justifiable. It is not for the TGA. Those policy parameters are for our elected members to guide the lower levels of assessment, like the TGA.

I focus on that one point. The essential question facing MPs and senators is: why should RU486 require special approval by government when all other drugs are simply assessed by the TGA? The answer is that abortifacients like RU486 are unique as drugs designed to take life. That fact is of obvious public concern. It explains why this drug demands the special attention of those elected to deal with such matters of public concern. Australians will differ on whether the life of a very young human being matters but there is no dispute that, after using RU486, where there was once a dynamic living creature and an unfolding human destiny, there is now death. So RU486 is uniquely contentious in its action, raising serious moral issues and obviously therefore requiring a special level of scrutiny and accountability by our elected representatives.

The current regulation of RU486, I remember very well, was established in 1996 on exactly this principle of accountability and with bipartisan support. On behalf of Labor, former senator Belinda Neal spoke with a moral seriousness that we need to get back into this debate. She said:

> ... we acknowledge that this issue raises large concerns within the community. It raises issues beyond purely health issues. These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability ...

The parliament in 1996 thereby aimed to prevent the recurrence of the debacle in 1994 where an anonymous official in the Department of Health approved the importation of RU486 without the minister being aware. As Senator Neal concluded:

> We wish to ensure that, in circumstances where this drug is to be imported or supplied in Australia, the minister be required to approve the drug and that notification of this approval be given in this chamber.

For the government, senator Bob Woods, who was Parliamentary Secretary to the Minister for Health and Family Services reassured the public and the AMA in these words:

> In terms of the AMA's perception that we are in some way banning a drug ... that is not the case. We are making the minister sign off, if you like, and making sure that public accountability is raised.

So the amendment put forward in 1996 by Senator Harradine was a professionally sound response to a health department lapse. It received bipartisan support. It has never banned

RU486. It is being used, as we speak, in medical trials for cancer therapy in Australia—it has never been banned. It is allowed for valid medical indications. As Senator Harradine explained in his explanatory notes in 1995:

> People on both sides of the abortion debate agree that the importation, trials, registration and marketing of such agents ... should not be left in the hands of bureaucrats and science technologists. There should be ministerial responsibility ... The amendments go no further than this.

Parliament is again to debate the regulation of RU486, but this time the stated aim is to remove this professional proper accountability. So once more a departmental official can approve RU486 without the minister taking policy responsibility or the parliament knowing. With this amendment bill for repeal of ministerial responsibility for approval of RU486, the parliament is being asked to support an amendment which undermines, for ideological reasons, proper ministerial accountability on a matter of public importance. It would be a triumph of underhandedness over transparency in public life. If this bill were passed, it would be an abandonment by parliament of their responsibility to grapple with difficult social and ethical questions, instead hiving the issues off to unelected scientists and officials who are not accountable for contentious decisions.

The TGA has a vital, proper but secondary role which is:

> ... to ensure the quality, safety and efficacy of medicines.

It has no brief to take into account the moral status of the life to be ended by RU486 or the justifiable conditions upon which that life may be ended. That is not in its brief. But without such ethical considerations no serious and responsible decisions can be made. That outcome, of course, is what supporters of unrestricted abortion want—an assessment devoid of the moral dimension, free from consideration of justice or medical justifiability, just assessing this abortion Pill as if it were a headache tablet. If this parliament votes to dodge responsibility, it will have lost an opportunity to make a vital, ethical distinction between abortions which are medically necessary and which we must support and provide RU486 for, if that is appropriate, and abortions which have no medical justification which are done for complex social, financial or personal reasons but which require a different policy approach. This parliament will, by default, give its imprimatur to the current practice of unrestricted abortion for non-medical reasons. The federal government has never had to commit itself one way or the other on the question of abortion for non-medical reasons. It is a matter for the states. Now, with this question, it is unavoidable that it will have to commit itself one way or the other, even if the commitment is by merely washing its hands of the lives in question.

If, however, this parliament recognises the need to retain policy responsibility on the use of this uniquely contentious drug, it will need to set parameters as to when the taking of life may be medically justifiable. And that is where the medical profession must help. The government and the profession should be establishing all valid medical indications for RU486—whether in certain cancers, hormonal diseases or medically essential abortions—and approve the drug for those uses. RU486 is already available for certain medical conditions, as the current cancer trials show.

Further, if authorities can define situations where abortion is medically essential and where RU486 is approved as safe by the TGA and considered preferable to surgical abortion by the

O&G specialists, then the drug should be authorised for such situations. In this way, RU486 could be accessed appropriately for these approved conditions through, for instance, the current system we have of authority prescriptions, which we use regularly for special drugs, such as narcotics, and where strict prescribing conditions must be met for their use. That is practically how it could be done.

But it is the government who has to set the policy parameters for this authorisation, but not by using base level criteria of safety, efficacy and quality, which the TGA properly exists to assess. The government must bring in more complex and significant criteria, including the issue of justice to the unborn child, the prohibition against intentional killing without due cause, and the medical justifications for necessary abortion. That is why the government needs to keep a policy watch over the lower levels of administration like the TGA, which quite properly make its assessment on simpler, technical criteria appropriate for most drugs but entirely inadequate for RU486.

Senator MOORE—To begin with, I find your comparison with a headache tablet quite offensive. We have had openness around this table so far, drawing out what people agree with and what they do not. I am offended by your comparison of these two things in your statement.

Dr van Gend—I am sorry you are offended, but I do not agree with your taking offence because I said that—

Senator MOORE—I am stating an offence, and that is enough. My question—

Dr van Gend—Can I relieve you of that?

CHAIR—Doctor, perhaps we can let Senator Moore finish her question.

Senator MOORE—I have listened to your evidence and my questions is: exactly where in any proposal that is being considered is there any compulsion on any doctor to prescribe the medication?

Dr van Gend—I do not think there is, no. If I may go back to that point about the headache tablet, I was saying that the TGA assess every drug, whether a headache tablet or any other medication, on the basis of efficacy, safety and quality. That does not do justice to a drug like RU486, which has far more complex dimensions of ethics, justice and justifiability. You cannot leave it with the TGA to do what they are asked to do, because those criteria they are given are inadequate. They are adequate for the assessment of a headache tablet; they are not adequate for the assessment of RU486.

Senator MOORE—There are several levels of assessment within the TGA. We will just have to agree to differ, but I am looking at the process.

Senator FIELDING—A recent literature review published by *Women's Forum Australia* states:

> The researchers found that women having medical abortion, like RU486, rated the procedure as more stressful and painful, and they experienced more post-termination physical problems and disruption to their lives. Women may not expect or are not told that they may see the foetus, and this was associated with more intrusive events—nightmares, flashbacks and unwanted thoughts related to the procedure.

It goes on to say:

The patient may expel the foetus at home.

Do you have concerns about the negative effects this drug might have on women?

Dr van Gend—I do have concerns, and I think those effects are very hard to assess. I think even the TGA would not have any way of predicting the impact of RU486 on women in profound psychological ways. To me, if you were talking about being kind to women as the only criterion, you would have a surgical abortion because the woman can be asleep at the time; she does not have to be aware of what is happening. But with RU486 she is entirely aware. She has to take the tablet herself, she has to go through a mockery of labour, where every pang speaks of death, not of life, and then she has to be there when the foetus is expelled. To me that is a recipe for deep disruption—to create a place of death in a woman where there should be a place of life is a profound psychological event.

But may I say, whenever questions of the risk to women, the harm to women, whether physical or psychological, are raised, I feel that is not quite the main point of the discussion. That is properly assessed by the TGA. That is properly assessed by the O&G college or maybe the College of Psychiatry, whoever are expert in this field, and that should come into the calculations of whether RU486 is approved. If it is found to be too damaging psychologically, if it is found to be too risky physically, that would be decided at those low levels of assessment, by the TGA.

The question for the parliament is whether or not you retain meaningful policy oversight so that you do not just say: 'Here is a box of RU486. Take it.' We know that in 99 per cent of cases it will be used for non-medical reasons. We know from research that in 60 per cent of those cases the reason will be financial stress and, in the other 39 per cent of cases, as listed in the *Medical Journal of Australia*, it will be issues of career conflict, lack of personal support, being too old or too young, having too many children and not spacing the children. This is documented and I can table that report. But the policy question for the parliament is: on what justifiable grounds will we allow the importation of this drug?

That is where I plead that the parliament or the government find a position where they will allow RU486 for medical indications, they will let it in for those cancers and hormonal diseases, but they will identify where abortion is medically essential. Those instances are rare but they are real. If the specialists say that RU486 would be better in those cases where abortion has to occur for medical reasons, I say let it come in. That is entirely ethical and proper and right. If the parliament were to say, 'Here is a drug which can be used with no restrictions; it can be used instead of creative policy initiatives to help women who are stressed financially or socially—just take it,' then the parliament have given their imprimatur to the misguided and medically degraded situation we face now where abortion is practised on demand for non-medical reasons.

Senator ADAMS—Thank you for appearing today. Given that the minister, and the minister alone, can make the decision unilaterally, what additional layer of public scrutiny is imposed? I will just go on a little bit with this. The minister is only required to inform the parliament within five sitting days once a decision has been made, not to bring the request to the parliament for debate. You did say that, which is why I am a little confused. The argument

about additional public scrutiny is flawed, as only one person is involved, and their response could be an emotional one. Would the pro-life lobby be happy for the minister to have the responsibility to make the decision if the minister of the day was pro choice, or would the pro-life lobby be seeking to introduce additional layers to prosecute their case? I want to get that clear.

Dr van Gend—I think it is an essential question. Frankly, there have been ministers in the position who were pro life, some who were pro choice and one who was neutral since the 1996 amendments have been in place. What the minister says is not the issue; if he says, 'Go for it with RU486,' so be it. My point is that at least the parliament has taken due responsibility to say, 'This will happen'. If you feel that it is too narrow for the health minister alone to have this discretion, and I really believe that is the nub of this argument—in particular, a health minister who a lot of people disagree with—may I suggest that the health minister would never be doing it on his own. He would have discussed it with cabinet, he would have discussed it with colleagues. It will be a government decision and he will not do it if the Prime Minister does not want him to do it. If not, could I ask that that possibility be raised, that the responsibility for the decision be distributed over the whole of cabinet, that it become a government decision, that it become transparently a policy decision of the government of the day. That may get around—

Senator FIELDING—Or a parliamentary decision?

Dr van Gend—It could be a parliamentary decision. That is more cumbersome and it would be hard. But the government of the day has the responsibility. Far be it from me to suggest how the mechanisms of government should work, but to me a brainwave would be for Mr Abbott to say, 'I'm an obstacle here.' Rather than jettisoning or throwing the baby out with the bath water, throwing out this completely respectable arrangement we have where the government is accountable for RU486, let RU486's approval, under whatever conditions it is approved, be seen as a government decision. Let it be a whole-of-cabinet decision. Let poor Mr Abbott be put to one side, if that will help, but do not throw out the principle that the government is responsible and accountable. That is the principle we have to keep.

Senator ADAMS—How can the cabinet and the minister have the expertise of the body that is set up to look at drugs, being the TGA? I really cannot see your argument there.

Dr van Gend—I agree with you. They have no expertise.

Senator ADAMS—So why should you not use a body which has all the expertise and research available to it to make that decision?

Dr van Gend—We are not disagreeing. I agree with you entirely. The TGA has all the expertise—with the O&G college and other learned bodies. It has all the expertise. It is not for the parliamentarians to debate the technical matters. The TGA has the expertise and it advises on whether this drug, as an entry-level issue, is safe and effective enough to use. If the TGA says that it is, it comes up to the government. At that point they say: 'Right, we now will define the parameters under which it will be used. We know it's safe enough to use; we have been given that assurance. It's not for us to question that. We will now define the policy parameters based on those broad issues of ethics, justice and the taking of life and so on.' They will say, I hope, 'It will be used wherever there is a valid medical need for it—cancers

and hormonal diseases, and abortions which must occur for medical reasons. But we will not pretend that the vast bulk of abortions are for medical reasons; we are past that. There is no pretence anymore. Where it is done for reasons of social and financial distress and other things, we will address that with other policy initiatives. But we are not going to have a policy for distributing a chemical for the taking of life of entirely healthy offspring from entirely healthy adults who are under some form of stress. That is not part of our policy. Our policy is to let it out for medically necessary abortion and other medical conditions.'

Senator POLLEY—Could I ask that the report you referred to earlier be tabled for the benefit of the committee?

Dr van Gend—Certainly.

Senator POLLEY—As I asked a former witness, what is the latest stage in the pregnancy that this drug could be used for aborting a baby? In addition, could you explain why you do not feel that RU486 should be used as an option for a non-medical abortion?

Dr van Gend—I think the previous speaker, Dr Tippett, alluded to the fact that it can be used late in pregnancy. For many years, one of the medical indications for RU486, as I understand it, has been management of stillbirth—late incomplete abortions—where the foetus dies in utero. That is a valid medical indication and, of course, if it is the right technique, it should be used.

But to answer the question of why I do not think it should be used, as I explained, I think it should be used where there is a necessary medical reason and I think it should not be used where it is part of abortion on demand for non-medical reasons. There is no medical justification for that. Medications are for medical conditions, not for forwarding one particular view of life or one particular campaign. I am very saddened to see that so many of our senior medical colleagues are falling back on campaign rhetoric rather than on medical justification. They are talking of 'increasing choice', as Dr Haikerwal did, of 'women valuing choice', as Dr Tippett did earlier today and of increasing women's 'reproductive control', as Dr de Costa did in a *Medical Journal of Australia* article, which I can table. She even titled that article 'It's time'. To me, that Whitlamesque gesture shows that this generation of senior doctors are captive in a way to the spirit of their age, which is entirely understandable and which is why they fall back on pro-choice rhetoric for justifying social abortion for non-medical reasons.

I feel that the deeper tradition of medicine has always been to justify abortion on medical reasons. That is why 'I will maintain the utmost respect for human life from the time of conception'—a sentence from the World Medical Association's founding declaration of 1948, the Oath of Geneva—was redeclared, although it was watered down in the sixties to something more innocuous. We are captives to our culture and we need to regain the criterion of abortion for medical reasons versus unjustifiable abortion for non-medical purposes.

Senator POLLEY—Could we table that second report too, please?

CHAIR—Could we have the second report?

Dr van Gend—Yes, certainly.

Senator McGAURAN—I have no questions.

Senator ALLISON—You make a good case for parliamentary oversight of policy decisions such as this. Isn't that what this bill puts forward? In addition, isn't it the case that there is, in fact, no parliamentary oversight at the present time, that the minister can decide to refuse an application and not indicate to the parliament that he has done so and that he can agree to grant exemptions or approval without providing the reasons to the parliament? There is no way that the parliament can disallow his decision. There is no way that the parliament can debate it or have a vote on it. Surely the process we are going through now is one that you would support.

Dr van Gend—Indeed, they sound like excellent amendments to the current bill. The current bill simply says, 'We don't want to know about it; give it to the TGA, because it's too hard.' That is what it looks like. It looks like an abrogation of responsibility. An issue like this, which is of such public concern and which is so complex ethically, is the proper responsibility of our elected representatives.

Senator ALLISON—No, it is not. On the one hand, you say that you agree that the TGA should be involved in the question about safety—

Dr van Gend—Absolutely.

Senator ALLISON—but what do you want the parliament to have the oversight over? In addition, how is that not coming through in the current debate and the vote that will be taken in the Senate and the House of Representatives, hopefully, in a few weeks?

Dr van Gend—The current vote will be taken only on sending it to the TGA. There will be no parliamentary awareness of whether the TGA approves RU486. There will be no parliamentary debate about the parameters for RU486. It will be simply like any other drug dealt with by the TGA.

Senator ALLISON—How can you know what the debate will be about?

Dr van Gend—But the point is that this bill is to leave RU486 under the judgment of the TGA alone. That is what the bill is about. It is to take it away from the health minister.

Senator ALLISON—That is what the health minister would do as well. We are talking about the parliament doing it and not the health minister, surely.

Dr van Gend—I am sorry if I am not making myself clear. The point is that the TGA is the right place to assess risk and quality, those technical matters. I agree that it is not for the parliamentarians to worry about the elements of risk and danger.

Senator ALLISON—No-one is arguing otherwise.

Dr van Gend—It is for the parliamentarians to decide the prior and higher question of purpose.

Senator ALLISON—Why aren't we doing that with this bill?

Dr van Gend—No. This bill is to say: 'We don't want to talk about RU486. It is for the TGA to decide.' Isn't this bill to say that there will be no policy setting on RU486? That is what it says. It says that it is not for the health minister to set standards on RU486; it is for the TGA alone. Am I mistaken in that?

Senator ALLISON—Once the health minister makes a determination, I would think it would be the same as the parliament agreeing to what it will be agreeing to at some time in the next few weeks. I cannot see the difference between the minister's decision and the parliament's decision in this instance.

Dr van Gend—But the minister can set parameters on how it can be used.

Senator ALLISON—Not at all. The minister simply approves or disapproves an application.

Dr van Gend—Yes—and, if the application is for unlimited abortion for non-medical reasons, he should disapprove it.

Senator ALLISON—But the states all have laws that limit the methods or criteria by which terminations can take place. That is a matter for the states, is it not?

Dr van Gend—The ACT does not; it has nothing. My point is simply that the current bill wants to leave the decision about RU486 with the TGA alone. Am I right?

Senator ALLISON—That is what the minister would decide as well.

Dr van Gend—No. The minister can approve, disapprove or give his reasons or request—

Senator ALLISON—He is not obliged to.

Dr van Gend—He can.

Senator ALLISON—He can, but he is not obliged to.

Dr van Gend—No, of course not. No-one is obliged to do anything, but there is that level of accountability which was brought up in 1996 and which was approved. I would support your suggestions to broaden that accountability. By all means, spell out more that the minister, the government or the cabinet has to give reasons why it will approve or not approve. I entirely support that. Let it spell out the parameters upon which RU486 can be used in the country. That is transparency. That is taking responsibility for a contentious social matter. That would be an improvement on the current situation. So I hope you move those as amendments but vote down the current bill.

Senator NASH—I wonder if the committee could have something clarified. I think Dr van Gend intimated that the TGA would evaluate the drug and then it would come to the minister. My understanding is that it is only the application that goes to the minister, then he decides if it will then be evaluated. Could we have that clarified at some point?

CHAIR—Do you mean under the proposal or under the present situation?

Senator NASH—Under the present situation. My understanding is that it is only the application that comes to the minister, and then he decides if it can be evaluated; my understanding is not that it is evaluated first, as Dr van Gend suggested.

Senator ALLISON—It is unclear in this respect.

Senator NASH—Yes. If we could have that clarified at some point that would be helpful. If we are talking about places where termination is lawful, how is it logical that surgical termination be allowed and medical termination not be allowed?

Dr van Gend—There is nothing logical about abortion at all in the way it is practised. We have a law in Queensland which says you cannot have an abortion except to protect the life of the mother. That was then interpreted by Justice McGuire along the same principles as the Menhennit ruling in Victoria. But in his ruling he says that 'the law in this state has not abandoned its responsibility as guardian of the silent innocence of the unborn'. The principle is there that the law is to say no to unjustifiable abortions. But, as you know and I know, it happens anyway, and it seems impossible to put any restriction on abortion even when it is flagrantly in defiance of the spirit of the law and sometimes the letter of the law. That is the reality.

But it is not irrational then for the federal government, faced for the first time with the question of whether it will enrich and enhance that shambolic practice that prevails at present, to say, 'Will we serve another dish in the smorgasbord of choice? Is that what we will do, without any consideration for the rights of the unborn child, without any consideration of the distinction between medically necessary abortion and medically unjustifiable abortion for social reasons?' Surely that is a valid distinction. When the federal parliament is asked whether or not to give RU486, they are being asked, 'Will we or will we not nail our colours to the mast on the current practice of social abortion for non-medical reasons?' Or will they take this opportunity to say: 'Yes, we support abortion where it is medically necessary upon medical advice. No, we do not support, enrich or cultivate the current practice of abortion for non-medical reasons, because we consider that wrong in practice, wrong in morals and wrong in policy. We will work with the medical profession to address the underlying stresses in creative ways. We will not simply give them a pill.' That is not irrelevant to the federal parliament.

Senator NASH—I would say that issue of choice is actually very important. I was listening very carefully to the things that you want precluded: the types of terminations under RU486 and the things that you see as being allowable. Those things that you want precluded are occurring today and, as difficult as the issue is, they are occurring today within surgical terminations. How can you say that it is all right for those things to continue to exist under surgical termination and then say that we cannot have a medical termination?

Dr van Gend—I am not saying that it is all right for that to continue at all. I am saying that it cannot be stopped.

Senator NASH—Then that is a different debate, and what you are saying does not relate to this bill. We are talking about the responsibility for determining the quality and safety of a drug. You are talking about a much broader moral issue. I accept that. That is understandable. But I make the point that it does not relate to this bill. I just wanted to raise that.

Dr van Gend—May I respectfully disagree. The TGA is the proper body to assess that level of criteria: safety, efficacy, availability.

Senator NASH—Exactly.

Dr van Gend—But this bill wants to leave it at that. This bill wants to say: all there is to talk about with RU486 is safety, efficacy and availability, and that is for the TGA. There is nothing else to talk about. That is wrong. It is a complex social issue which the elected representatives are paid to address. It is the responsibility of parliament to untangle these

matters and that untangling involves saying, 'Given that the TGA says it's safe, under what conditions will we, under a policy initiative, approve the use of this abortion drug?' Then the choice is between saying, 'We'll go holus-bolus with the current culture of social abortion on demand for non-medical reasons'—and that is an option, and I would respect that, but at least they are wearing that decision and taking responsibility—or the far preferable one that I wish the government would consider, which is to say, 'We will allow RU486 under authorised conditions, for medical conditions like cancers and hormonal diseases and for medically necessary abortion. We will release it for that, because that is our policy approach.' Do you see the two points?

Senator NASH—I do. I will finish, but I believe that what you are talking about is a debate we have already had, which is why we are now in a particular situation with lawful terminations.

Senator JOYCE—I agree with you. I think this is a triumph for underhandedness over transparency. As a parliament, we are shirking the true nature of the debate—that it should be about termination of life and not some discussion about the rights and responsibilities of the TGA. Nonetheless, we have to go through this whole farce of talking about abortion—that it is really there to take away a life and not to treat an ill, and we will somehow flick that off to the TGA. I will ask you a question and hopefully you will be able to clarify one issue. Earlier today the AMA said that there is no differentiation between the repercussions of a surgical abortion and those of RU486. However, it is on the record in other places, such as *The Annals of Pharmacotherapy*, that the anti-glucocorticoid actions that are taking place throughout the body inhibit the defence mechanisms through chemical regulators known as cytokines. In effect, this basically impairs the defence mechanism of the body to fight off an infection—because of the hormonal effects of the drug. That in itself exacerbates the effects of possible putrification. We do not get mummification of the foetus if it goes through the process of putrification and the inception of septic shock. So we have two completely different points of view. We have the AMA saying that there is no discernible difference—they have said it; it is on the record; the question was asked and they gave the answer—and we have the article in *The Annals of Pharmacotherapy* which has been reviewed by a journal for physicians and pharmacists, and there was a peer review. They are not pushing a position either way; they are just making a statement of fact. Who is telling the truth?

Dr van Gend—That is why it will be very hard for the TGA to come to a conclusion. It is not cut and dried. I will answer your question, Senator Joyce. Do you know how much I want to avoid an auction about side effects and whether this is better or worse than surgical? That is to miss the point of this bill, which is about whether we keep parliamentary oversight and responsibility or abandon it. One thing does need correcting. I will give an example of how murky this whole business of assessing risk will be. Dr Tippett made an erroneous statement earlier, only because the paper that she was referring to was published in November and this has come out only this week in the *New England Journal of Medicine*. The example concerns four Californian women who in the last two years alone died within a week of taking RU486. They died from the same overwhelming infection of the uterus, *clostridium* sordelii—a very rare condition.

The *New England Journal of Medicine* points out that the figure that Dr Tippett quoted of one in 100,000 deaths from RU486 is the same as the figure of one in 100,000 deaths from surgical abortion. She said it is the same risk—that the infections from surgical abortion result in the same rate of deaths. But the *New England Journal of Medicine* article of 1 December, 'Fatal Infections Associated with Mifepristone-Induced Abortion', makes the point that the more appropriate comparison is not with all surgical abortions but with surgical abortions in the same age bracket—that is, under eight weeks. The figure of one in 100,000 deaths from surgical abortions applies to all of them, from six weeks to 36 weeks. But if you look at the figure for under eight weeks, which is when mifepristone is recommended and used, it is only one-tenth—it is 0.1 in 100,000. That is the death rate from surgical abortions at under eight weeks. Therefore, the death rate from RU486 is 10 times that.

That is one point. It is part of the tangle that the TGA would have to face. I can table those papers—the *New England Journal of Medicine* editorial and the associated article on the four deaths in California—if that would be of value. But the point is that the FDA, the Food and Drug Administration, which is the equivalent of our TGA, as you may have heard, is convening a high-level scientific conference early in the new year with the Centre for Disease Control in Atlanta to untangle these questions of this extraordinarily high cluster of deaths in California, because as the drug company Danco said: 'We have no answers.'

I am not wanting to get into an auction of side effects. That is for the TGA. That is for the O&G college. It is nothing to do with politicians, respectfully. It is nothing to do with GPs, in a way, because we are not full-time epidemiologists. We leave that to our proper bodies. I am sure the TGA would be the last people in the world to say: 'We are the ones to rule on those higher criteria and we are the ones to decide on when it is justifiable to take a life, whether it is because of financial stress or whether it is for no reason or all or whether it is for serious emotional upset.' They would not be the least interested in that. That is not their job. That is not their brief. They will not even define what is medically justifiable. That is for the learned colleges.

Senator JOYCE—So when you are comparing apples with apples, it is 10 times more likely that you will die from RU486 than a surgical abortion, if that is the level of debate you want to go to?

Dr van Gend—I could not even be firm on that. That is certainly the fact from these figures, but the numbers are small. You cannot make firm conclusions on small numbers. I quite agree with that. It is not for us as GPs to pretend to know the balance of risk/benefit. I am saying that the balance of risk/benefit is not the main question.

Senator JOYCE—I agree with you.

Dr van Gend—Higher questions apply, and that is where the parliament has its duty.

Senator BOSWELL—Are you a member of the AMA?

Dr van Gend—Yes.

Senator BOSWELL—Did they consult you for your views?

Dr van Gend—No. They consulted me for my views four years ago when the last specialist doctor, Dr Adrienne Freeman, tried to get RU486 into Australia. The AMA asked

me to have a debate with her at the council meeting. We had a terrific debate. AMA Queensland did not support her application at that time. I do not know what has changed. But now the AMA has surprised us by coming out not talking about medical indications for abortion but talking pro choice rhetoric—'increasing choice'.

Senator BOSWELL—How did they reach their decision?

Dr van Gend—I do not know. But, as the rural doctor mentioned before, he consulted with his executives in the different states. I imagine it happened through executives talking to executives around the country. I am sure it was done quite properly. But it is an aberration. This is not the way the AMA has ever positioned itself before. Whether it is boots and all support of the culture of abortion on demand I do not know, but it gives the appearance of capitulating in a way to the demands of what one calls the pro choice rhetoric to allow it on grounds of choice—not on grounds of medical necessity, not on grounds of compelling medical need, which is valid, but on grounds of choice, which is a political position, not a medical position. That is why a number of people have rung me up—specialists, GPs—saying: 'We're going to leave the AMA, based on their handling of this,' to which I said: 'Don't. Stay there. Be part of the debate.' To their credit, the AMA is trying to have some debate on this. I have no problem with the transparency, if you like, or the accountability of the AMA; I just wish that they had not abandoned the traditional medical position, which is that abortion is justified on medical grounds, not on rhetorical, political grounds.

Senator NETTLE—Do you believe that women should have control over their own bodies?

Dr van Gend—Absolutely, but regrettably the other little body is not their body. Its heart beats at a different rate to their heart, it has a different blood group flowing through its veins and it has—

Senator NETTLE—And you believe that that should have precedence over a woman and her body?

Dr van Gend—I very much think that, if you are dealing with a situation of the healthy offspring of a healthy mother, where there is no medical indication for abortion and, very importantly, the baby was conceived through the consensual act of adults, the mother has a duty of care to that baby which is unmovable and she must most certainly defer to the life of that baby. But understand my criteria: they have consented to sexual activity, they have conceived a child, they are healthy and the baby is healthy. To keep it simple, to keep it in the normal mainstream of current abortion, I would say no, they have a duty of care. No-one can stop them having an abortion. I do not want to stop them. I want no power. But I would plead with them to do the right thing for their baby and for themselves. I see the women afterwards, which is not for us to go into now—it is the second death, if you like. It is not just the death of the baby; it is the deathly effects on some—the gentler—women that are to me as great a tragedy as the loss of the baby's life. But that is another matter.

CHAIR—Thank you very much, Dr van Gend, for your appearance here today.

Proceedings suspended from 1.52 pm to 2.20 pm

[2.20 pm]

SULLIVAN, Mr Francis, Chief Executive Officer, Catholic Health Australia

CHAIR—Welcome. I think you are very familiar with parliamentary privilege and the protection of witnesses and evidence. I understand you are preparing a submission but you have an opening statement to give. After that, we will ask you questions.

Mr Sullivan—I thank the Senate Community Affairs Committee for the opportunity to address you on the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005. From the outset, this bill cannot be considered devoid of the contentious issue of abortion. We appreciate that senators would prefer to restrict discussion to the technicalities or otherwise of the proposed amendment. However, it is the very fact that abortion is a contentious social issue which gives credence to the existence of the ministerial approval process in this case. Your deliberations will ultimately turn on retaining the ministerial approval or not, but they will be heavily influenced by your attitude towards the availability of abortion services in Australia.

It will be obvious to you that Catholic Health Australia strongly defends all human life, regardless of its circumstance. The dignity of human life is the foundational inspiration and motivation behind the Catholic Church's involvement in health care. At the same time, we acknowledge that others in the community take a different perspective. We would respectfully say that, as legislators, you need to find the balance between individual liberties and the protection of human rights when contentious social issues require regulation. This bill is such an occasion.

As it has been structured, proponents of the bill wish to posit all approvals with the statutory authority, the Therapeutic Goods Administration. Their argument rests on the grounds that the TGA has expertise which can determine safety and quality of medicines. This is so, although approval by the TGA does not guarantee that medicines will be properly administered or the planned outcomes always delivered. The TGA can make judgments over the relative safety and quality of medications and pharmaceuticals for use in Australia's health system. These are technical judgments. They should be devoid of community sentiment and rest on evidence. It is not our contention to question the competency of the TGA or its track record or to raise concerns over any future technical advice it may provide in relation to RU486. Rather, it is our contention that the issue of whether RU486 should be prescribed and administered falls into the realm of considerations relating to degrees of social acceptability. The judgment as to whether a particular medication should be accessible in the wider community is ultimately a political decision. It is a judgment based on what is socially acceptable, not just technically feasible.

This level of consideration does not fall within the competency of the TGA; the responsibility falls to the community's representatives, namely, the government of the day. Thus, in the first instance, as it currently stands, the maintenance of ministerial approval for the use of RU486 is consistent with the fact that abortion is a contentious community issue and there exists a significantly high degree of disquiet within the community over the acceptability of the use of RU486 to procure abortions. Moreover, from a public health policy

perspective, the issue is far from settled. Senators would be well advised to note recent information from the US Food and Drug Administration. It documents the incidence of 676 adverse effects, ranging from minor symptoms through to reactions requiring hospitalisation and even the recording of deaths.

Granted that these incidents are still relatively low compared with the number of sole doses of RU486, they have been troubling enough to elicit a change in the packaging advice for consumers. Since US doctors are not obliged to report all adverse incidents, it is still unclear what the potential impact of adverse reactions to the administration of RU486 is. This highlights another public health issue concerning the prescribing of RU486. To what degree are health professionals, namely, doctors and pharmacists, obliged to talk through the potential effects of RU486 with patients? Since RU486 is designed to be administered privately—usually in a person's home—how far does the doctor's, or patient's, duty of care extend beyond the surgery or pharmacy? In other words, since the drug has profound physical impacts on a woman and her foetus, what public policy safeguards have been designed to accompany any change in the approval process away from ministerial discretion? Moreover, can those safeguards deliver the degree of security that will appease the current community disquiet over the use of RU486? Furthermore, if ministerial approval is removed, the TGA is not a recognised body to make such determinations.

This is a social policy issue concerning the social order of a community, not a technical concern related to the relative efficacy of medications. Finally, it is important not to confuse the issue of contraception with that of abortion. RU486 is an abortifacient. It induces a chemical abortion. It is used to end pregnancies up to 49 days along. It is not a contraceptive. In a pluralist society, there are differing views about when human life actually begins. Thus, contraception has a significantly higher degree of community acceptability, because many people do not equate contraception with abortion. But make no mistake: RU486 is about abortion, not contraception.

It seems quite illogical to consider making yet another method of abortion more available when numerous community surveys indicate a significant degree of disquiet and concern over the present number of abortions that occur in Australia each year. In conclusion, from our perspective, this issue turns on whether the approval process should be shifted from that of a community oversight, by way of ministerial approval, to that of technical administration through a statutory authority. It is important to note that, when the parliament debated the Therapeutic Goods Amendment Bill (No. 2) 1996, the tenor of the debate and the most substantive issue raised, to install ministerial approval for the use of RU486, was couched in terms that the issues at stake were beyond just health concerns and the effectiveness of the drug, and thus it was deemed appropriate that responsibility for the decision lay with the minister of the day, not the TGA. Given that the issue of abortion and its availability remains unsettled in the community, it should follow that a legislative vehicle such as ministerial approval remain in the current act. Thank you very much.

CHAIR—Thank you, Mr Sullivan, for that opening statement. Could I ask you one question: it has been put to the committee that, if there is logic in having community oversight via ministerial discretion of chemical or medical abortion, what is the logic in not having that oversight over certain forms of surgical abortion? What is your response to that argument?

Mr Sullivan—The first logical point I made was about the extension of availability of abortion when there is a community concern—and senators will have to gauge the percentage of that—around the number of abortions this year or in a year. I would argue there is a question about logic in extending availability of abortion if we are trying to reduce the numbers. As to community oversight generally, given that we do have this question within the community, transparency is obviously preferable in any setting. That would obviously be our position. I appreciate that this debate is complex. Some people talk about privacy issues and the like. The fact is that this is a young debate, as far as this parliament is concerned—the last time was 1996—and, the way some things change, this is an infant. When we talk about settling a public issue, this issue is at its sharpest when we are talking about making a procedure more available, when there is quite a strong concern about the number of procedures already.

Senator MOORE—As you would expect, there is a wide range of differing views within the submissions we would be expecting as well as the stuff that we have already received. I would like to get on record your view of (1) the role of the TGA in terms of the safety aspects of this medication; and (2) the point that—and this is currently my understanding of the law in Australia—the legality of decisions about termination is held at the state level. So in the kinds of considerations that you are talking about there is a process of one level of oversight in terms of the availability of a process within a legal framework which is constitutionally held at another level. You began to talk a little bit about that. Just for the record, because I know you have thought about it, for the committee what are your views on those two things?

Mr Sullivan—There is no doubt that the TGA is the competent authority to advise on evidence based empirical data around the use of medications and pharmaceuticals. We are not suggesting that should ever change. So in the broad there is a general confidence. No-one has got a great track record on everything, but there is a general confidence around those approval processes vis-a-vis medication. One can only assume—because I am not a scientist or a lawyer—that safety approvals fall within a range of acceptability. One can only assume there is always going to be an error factor in any medication, either in its production or its administration—and there is probably history about that.

As I said in our preliminary statement, we would not question the competency of the empirical evidence around any medication that comes through the TGA. But the TGA is often asked to approve or not approve medications. Some groups are very keen for some medications to come onto the PBS and they do not get on there, because of other considerations which have less to do with a heightened, if you like, social or moral issue like this. They have more to do, maybe, with the consequence of costs to the system and the like. Who takes those decisions? The advice from the TGA is about the efficacy of the medication or pharmaceutical. The advice to government around either the impact on budget or the impact on access for various groups and so on is a different set of advice which one assumes is not coming out of TGA.

My first point is that it is not so much the interface of TGA, its advice and the states' administration of termination. The first point is that the TGA—and it is listed there in its web site—has very specific terms of competency and reference. Of course the state administrations do administer issues to do with termination and we know that in various

jurisdictions that administration is tighter or looser, depending on what has happened there historically. But the Commonwealth department, as we see across the health portfolio, has a significant impact on what happens in health because of its control over the pharmaceutical benefits schedule and people's access to it. I concede that there is not an easy, comfortable fit between what occurs with state administration and what occurs with the Commonwealth. To be honest with you, it is not something that I have thought a lot about recently, but I am happy to think some more about it for the record because it is an interesting interface.

Senator FIELDING—We heard before from Dr David van Gend about broadening public accountability beyond just the minister for health. What are your thoughts on broadening it to the entire government or further?

Mr Sullivan—I have some thoughts about that, but it is somewhat gratuitous because governments of both persuasions have set up processes. If I could, I would like to say a couple of things about this because I think it is important to round community oversight. If there is disquiet about a particular aspect of legislation or a vehicle that is used for approval, a government—and this parliament in particular—still has the option of making any vehicle a disallowable instrument. So, for example, in this case, if we want to be specific, there is ministerial approval around the RU486 issue, this committee might feel it appropriate to recommend, instead of changing the structure of the legislation, adding to it a provision that any ministerial approval is a disallowable instrument. That automatically brings into play the various components of the Senate and it goes beyond what I said in my introductory comment about the representatives today—namely the government or the parliament.

I would suggest that is worth consideration, particularly if, regardless of personal dispositions, the Senate in this case comes to a view—which I think you can justify—that this issue is contentious in the community. If it is contentious in the community it falls to the community's representatives to always strike a balance as we go. As I continue to say—and I do not mean this cynically—I think this is a young piece of legislation that we are dealing with. We are dealing with a particularly difficult issue for the community but also it is not settled, as other difficult issues in the past have become relatively settled. So you might want to entertain the notion of a disallowable instrument.

Senator FIELDING—I think the issue that is being grappled with here is that the bill is removing it from the minister's responsibility and putting it under the responsibility of the TGA. I think there was something put forward before, asking whether there is another option of looking at whether it should be a broader responsibility that is still parliamentary or some process involving elected members. Rather than just saying, 'No, it is either the minister or the TGA', there is another potential option which is broadening it out to the government as a whole or maybe parliament. I think that is the issue and I am just after your thoughts. I appreciate you sharing those thoughts, thank you.

Senator POLLEY—We have already heard arguments and evidence given today. In the community generally, I think the argument is about giving women the choice. If you look at medical terminations done surgically now and you compare that with the evidence that we have been given today about the length of time that that this process of using RU486 takes to complete the termination, I am not sure that that is a better choice for women. I was wondering something else, too, when I listened to some of the evidence that was given. I hope

it is not part of the push to have this drug brought onto the market because of cost—because it would be seen to be a cheaper option than a surgical procedure. I was wondering if you had any views on that. I also asked a question today, and it has been taken on notice. My concern is: how many weeks into the pregnancy can RU486 be administered? We have spoken today about up to nine weeks, but then we have had evidence that is can be used later in the pregnancy. I have concerns about that. I was wondering if you had any you would like to share with us.

Mr Sullivan—There are a lot of questions there.

Senator POLLEY—I only get one question. So, please, it is only one question!

Mr Sullivan—Then I will start with answer 1(a). Certainly, on the issue of choice, there is a strong voice in the community. Our position around choice—and I would like to expand on this important point—is that every person, regardless of any ethical situation they are in, should have enough information to make a fully informed choice. So, in a sense, we are very pro choice. We are also very strong about defending human life. That is the balance we try to make. In regard to the issue that you raise, where maybe some people are saying that this is giving more choice, our particular concern around the dilemma of abortion is the oftentimes fraught environment in which some people find themselves when they are having to make choices. Obviously, our view is that the interests of the unborn child do not get much of a look-in. Please do not read that incorrectly. I am not saying that people who choose terminations do so by knowingly and willingly devaluing other life. I understand the dilemmas. What I am saying is that it is somewhat of a superficial argument to simply say that having another available procedure enhances choice. I am not sure we fully understand what dilemma is about at times like that and how choice—anybody's choice—is inhibited by the emotional and psychological milieu in which it is being taken.

That is partly the answer to 1(a). I have forgotten some of the other parts to the question but may I say, on the issue of whether RU486 can be used beyond 49 days, that I am not expert enough to answer. I simply go on the published literature that says that it is used to terminate pregnancies up to 49 days. What else did you ask me?

Senator POLLEY—I asked about the cost. Some women may choose this method, as opposed to a surgical method, based on the cost.

Mr Sullivan—I think that, clearly, if the procedure goes as planned and there are no complicating factors, one would assume it is far more cost effective than hospitalisation or day surgery. I think that is a no-brainer. The reality of the matter, as I said earlier, is whether it is something we think we should be adding to the cocktail of services available at the moment so that we make abortion more readily available, when my sense of things in the public debate over the last year or so is that people are trying to think of ways in which we can reduce the incidence.

CHAIR—Senator McGauran?

Senator McGAURAN—I just need a clarifying question before I ask the main question. Mr Sullivan, I know you are from Catholic Health, but whom are you representing today?

Mr Sullivan—Catholic Health Australia.

Senator McGAURAN—Could I take that to be the Catholic church, the bishops or just Catholic Health? Are you representing the Catholic church?

Mr Sullivan—With regard to the Catholic church's involvement in hospitals, nursing homes, home care, medical research and so on, I represent them. With regard to a bishop in a diocese, I do not represent him—he represents himself. But I represent the formal body in the Catholic church related to health care and aged care matters.

Senator McGAURAN—I suppose that kills my next question, but I will ask it anyway. I want to know the depth or the measure of your argument that you come to us with today and how seriously the church is taking this. Given that it is a conscience vote, will the church be taking it beyond just presenting you at this committee? Is it going to be raised in parishes? Are you going to ask your parishioners to campaign against the local representatives? Is it that big an issue for the Catholic church?

Mr Sullivan—I think it is quite obvious where the Catholic church stands on abortion: it is opposed to abortion. Even if you have been surveying the Catholic press over recent months, this issue in particular has been highlighted as a concern for it. It would have only been two weeks ago that the Australian Catholic Bishops Conference put out a press release on this. So I think you could safely assume that the Catholic church's involvement in the debate will be more than moi.

Senator ADAMS—This is really a dorothy dixer that leads into my question. Do any of the organisations that you represent allow terminations?

Mr Sullivan—No.

Senator ADAMS—You are speaking about choice. None of the Catholic hospitals anywhere throughout Australia allow surgical terminations; therefore, for anyone who has to, for any reason—according to how their states legislate—have a surgical termination, they are only really left two choices: the private hospitals that are non-Catholic, which is not many; and the public hospitals. Therefore, with the RU486 being available as an alternative for people who have really decided, with the help that they have had, to go down this path, I can see that it is going to help out the situation of those who are not able to go into an acute setting to have a termination. I am trying to get the scenario that, as there are more and more Catholic hospitals available to the public as private hospitals, they cannot go there. That is limiting the area of the public hospitals where can go, because there are not as many available. Especially as I am from a rural area, as you are aware, can you see—it is probably hard from your point of view—any way that that would be able to help in this situation? I am not going into the choice bit; I am talking about women who have to have a termination.

Mr Sullivan—There are a couple of things about that. Firstly, there are 66 Catholic hospitals in Australia, 19 of which are public hospitals. So the remainder are classic private hospitals. We have a code of ethical standards that all of our facilities abide by. Clearly, Catholic hospitals not only do not do terminations, they do not directly refer people to terminations. However, I am struggling to think of a place in Australia where there is a Catholic hospital where there is not at least another hospital that is either private or state run. With regard to your assumption that people can be living somewhere where their only choice is a Catholic hospital, which will not be doing their termination—

Senator ADAMS—It was not really relating to that; it was just—

Mr Sullivan—I know; I am just trying to clarify it. I do not think that would be the case. Your question really turned on whether RU486 would be an advantage where a person has chosen to have a termination and there is maybe no hospital or day procedure in their town. Is that what you are asking me?

Senator ADAMS—I was just trying to work out the availability of public hospitals to have this drug, if the guidelines are to be that persons must have surgical backup anyway.

Mr Sullivan—Sure.

Senator McLUCAS—You made the point about the public disquiet about the number of abortions that are currently being performed, and figures came out yesterday. You seem to be saying that the introduction of RU486 will increase the number. I wonder what evidence you have to support that position.

Mr Sullivan—My answer possibly goes to the question I have just been asked. In other words, there will be a view, even around the committee, that this will make the availability of termination or abortion services more accessible. So it follows that, if something is more accessible, there will be the potential for it to be used, and I accept that. My assumption is that therefore the choice for abortion could be more easily facilitated because of access to RU486. That is how our logic goes.

Senator McLUCAS—Are you aware of the international evidence on when RU486 is introduced in any country?

Mr Sullivan—No.

Senator McLUCAS—The international evidence is that there is no increase in the number of terminations performed either medically or surgically. If you know that fact, I am interested in, working back, how you could be concerned that—

Mr Sullivan—I would work back. Again, if that is the case then there is no need to make it available.

Senator McLUCAS—There is no need to make it available because—

Mr Sullivan—If there is not going to be any change in the incidence or the behaviour then why make it available?

Senator McLUCAS—But what if it were deemed to be safer?

Mr Sullivan—The point is: if there has been no change in the behaviour and the incidence, what is the point of making it available?

Senator McLUCAS—If it is a safer form of procurement of a termination, would that not be an argument to then say, 'Let's provide that option to that person'?

Mr Sullivan—I understand. Our view is that obviously there are still question marks around the administration of the drug—the medication. There has been a trend—albeit at this stage minor—in adverse events in the United States, which may be masked by the lack of obligation for doctors to report all adverse events. So it raises question marks—I am not saying definitively. I am saying, though, the question marks were such that it did elicit a

packaging advice change to consumers, so that is interesting. But, generally, our view is that we would have concern that it would make access to abortion and termination services more readily available and in our country this could possibly lead to an increase in the number of abortions.

Senator McLUCAS—I do not know that the evidence is there.

Senator JOYCE—We established earlier on that abortions are 10 times more dangerous under the auspices of RU486 than surgical abortions in the same time frame. If we went by the TGA analysis, that should end the debate, but it has not, because the debate is not really about that at all: it is about bringing further validity to abortion. Just so we can step away from it being some Catholic thing, are you aware of any other churches or groups that have an issue with RU486 apart from the Catholic Church? Can you procure an abortion at the Wesley Hospital and, if not, why not? Are you aware of any philosophical views from other faiths or other churches or other providers of health facilities?

Mr Sullivan—I cannot speak for the Wesley Hospital or other ecumenical hospitals. There are some other hospitals. I know that within the tradition of most of the Christian churches there is a strong current that is anti abortion. The main issue among the churches is when life begins. I do not think there is much argument in the Christian churches about the taking of innocent life—they are pretty well one on that. The issue has always been around when life actually begins, and that debate, to some degree, ranges over some hours, not weeks. You will find that, generally speaking, most Christian denominational leaders would be opposed to abortion.

Senator JOYCE—Maybe that is peculiar to Christian churches. What about other faiths? What about Hindus or Buddhists or Jews?

Mr Sullivan—I am not an expert on other religions.

CHAIR—That is fair enough.

Senator NASH—I want to clarify something with you, if I can: in a society in which terminations are lawful and surgical termination is allowable, in a situation where the TGA were to deem RU486 as a safe drug, you say that that choice should be denied to women on the basis that it would be too easy to use it, as compared to surgical termination.

Mr Sullivan—Are you asking me that question?

Senator NASH—That is what it appears that you are saying to me—I am asking you to clarify whether that is your position.

Mr Sullivan—Our position is clear, as I have been saying: we do not support measures that would make termination and abortion more readily available. That is our working assumption, yes.

Senator NASH—Do you have a prescribed level of difficulty for termination for women?

Mr Sullivan—We oppose abortion, so I am not quite sure what that question means.

Senator NASH—What you are saying is that in your view RU486 will make it easier to obtain an abortion.

Mr Sullivan—I see.

Senator NASH—As I said, do you have a prescribed level of difficulty—of how hard an abortion should be to get—that in your view is acceptable?

Mr Sullivan—It would be fair to say that we do not think access to termination services should be easily obtained.

Senator NASH—Given that termination is lawful, you are saying there has to be a degree of difficulty for a woman to access an abortion.

Mr Sullivan—We think that it is important that before people take the choice to terminate there is a proper process through which everybody involved—and often we are talking about partners here as well—is able to consciously choose what they are doing in a non-pressured situation. The Catholic Church's teaching on the family per se means that we would have concern around minors accessing the medication unbeknownst to their parents.

Senator NASH—I would put to you that proper process and the difficulty of obtaining an abortion are two different things.

Senator ALLISON—Is it the case that the Catholic hospitals also do not provide tubal ligations or vasectomies or permanent or semipermanent contraceptive devices?

Mr Sullivan—That would be about right.

Senator ALLISON—I am interested in pursuing the point about how hard we have to make it for women before it is acceptable. Do you acknowledge that there are some women for whom the decision will be easier—if they are wealthy, if they live in a city, if they are articulate and so on? You understand my point. Is there a social issue associated with this which means that your position makes abortion acceptable for some women and not others?

Mr Sullivan—We would not accept that. I am not denying the fact that, if you are intelligent, wealthy and live at the right postcode, many things in the health system come easier to you than to others, regardless of whether it is termination services or the like. That in a sense is a second-order issue when we discuss this issue, because it applies to many things in the health system. Mental health services are a good example, if you want to talk about rural versus metro. However, given the fact that the Catholic Church position is that we do not support the innocent taking of human life through abortion, we would not put the framework around it that you are presenting. We believe all people in all situations where they are contemplating taking human life should be cautioned about taking hasty decisions, counselled about all the information and given enough space to make a fully informed conscience decision. If that is interpreted as stalling or in some way making it harder to make a decision then we would justify it on the grounds that these are grave decisions that require strong consideration.

Senator ALLISON—You are probably old enough to remember the days when abortion was entirely unlawful. That did not stop women procuring abortion. Do you agree with that proposition?

Mr Sullivan—The best way that I find to answer some of these questions is to say that we have found some people who believe that war is abhorrent taking us there.

Senator FIELDING—I have a question.

CHAIR—We do not really have time, Senator Fielding. We have less than an hour to hear two more sets of witnesses. Is it possible for you to put it on notice?

Senator FIELDING—Yes.

CHAIR—Mr Sullivan, thank you very much for your time today.

[3.03 pm]

COLEMAN, Mrs Marie Yvonne, Patron, Australian Reproductive Health Alliance

RICHARDS, Ms Christina, Chief Executive Officer, Australian Reproductive Health Alliance

VICK, Ms Lesley, Immediate Past President, Australian Reproductive Health Alliance

CHAIR—Welcome. You have been provided with information about parliamentary privilege and the protection of witnesses and evidence. We have only just called for public submissions, so we understand if you do not have one at this stage. Would you like to make an opening statement before we proceed to ask you questions?

Ms Richards—Yes. I would like to open and then hand over to Marie Coleman.

CHAIR—Could I draw to your attention the fact that the committee has about half an hour in which to hear this evidence, including questions.

Ms Richards—The Australian Reproductive Health Alliance mission is to promote public support for the enhancement of reproductive and sexual health in Australia and internationally and to promote the advancement of the status of women and girls. We serve a membership base that includes senior health professionals in the field of reproductive health, former federal and state parliamentarians, community based groups, academics and members of the public. We strive to ensure that the educational material we produce is evidence based and objective.

We understand that this inquiry today is not about the legality or otherwise of abortion, because it is already legal in this country, but about whether Australian women and their families should have access to another method and who is best positioned to decide that. We support the principle that the TGA is the appropriate body to address the safety and efficacy of all drugs to be used in Australia. I would like to ask Marie Coleman, as our patron, to read a statement that we have prepared on this. Thank you.

Mrs Coleman—This is a very short statement and it addresses the terms of reference. We fully support the principle that approval or otherwise of a particular drug intended for use on humans ought to be in the hands of an arm's length, technically and professionally qualified entity such as the Therapeutic Goods Administration and its panels of professional advisers. We believe that this should be the overriding principle regardless of the particular drug or the proposed use of a drug.

The TGA achieves its role of assessing whether or not a drug is safe and effective through evidence based methodologies. Using that framework, the TGA has already approved more than 50,000 therapeutic goods for use in Australia. In reality, this piece of legislation and the vote on it is about the integrity of Australia's framework for ensuring the quality, safety and efficacy of the medicines that we take. It is a vote about whether it is the TGA or the health minister who should make the critical decisions about the drugs that are made available to Australian patients. We hold the view that the nation is well served by the professional competence and integrity of the TGA, and we consider it to be the most appropriate body to address the safety and efficacy of all drugs used in Australia. We can see no reason to have a

separate process for one drug alone. I might mention that it is a drug which is not used exclusively as an abortifacient.

Senator MOORE—We heard evidence this afternoon from a doctor representing the World Federation of Doctors Who Respect Human Life. Without wishing to put his argument too shortly, it seemed to me that there was no disagreement that the TGA was the place for the medical assessment. The argument that was run was that, because of the issue that this drug was used for, it needed parliamentary approval on a higher plane. That is a short assessment. I would really like to get some response from you on that argument.

Mrs Coleman—As I have already said, the drug is used for a range of other treatments for other conditions and I do not think that should be lost. I believe there are four applications into the TGA for the use of this drug for specific purposes. That said, it seems to us that we have a framework in this country for independent assessment of the safety and efficacy of any drug. We then have a framework whereby we have extremely sophisticated arrangements through all of the colleges associated with the medical profession for setting guidelines for management and treatment protocols. We really think that that is where this drug, and any regime that should be set in place around it, should rest.

Ms Vick—I will add to that. Given that the legality of abortion, as we were discussing before, is a state matter, that is not really the issue here. The issue is that this is a chemical means of procuring abortion. Again, it comes back to the central point that Mrs Coleman is making, that the appropriate credentialled body to make that decision is the TGA rather than, with due respect to members of parliament, unqualified people in a scientific sense, even if it were to be broadened beyond the health minister.

Ms Richards—Can I just add to that? This is obviously a controversial drug and a controversial issue. The TGA has also looked at the issue of Viagra, for example. The number of deaths that Viagra causes is five times higher than those caused by RU486. If you are asking about controversial drugs and who decides about safety and efficacy, if you wanted to go down that path you would need to compare it with other drugs that have social and moral implications as well.

Senator MOORE—Are those figures from the US as well?

Ms Richards—Yes.

Senator MOORE—In terms of comparisons, they are US figures.

Senator FIELDING—Could you make some comments on this? The internationally recognised feminist Dr Renata Klein, who has worked on reproductive issues for 25 years, is strongly opposed to RU486 and says she is 'appalled by the misinformation by supporters of RU486 who claim chemical abortion is safe'.

Mrs Coleman—With the greatest of respect to Dr Klein, she is not medically or scientifically qualified to comment on this particular subject. Nobody has said that this drug is without side effects. I point out to you that I live on a dose of several drugs to deal with my asthma and not one of them is without side effects. It is a nonsense to pretend that something is completely safe. Having babies is inherently likely to be unsafe. Nothing in this world is completely safe, and if anybody were to argue that then they would be very foolish. We know

more or less what the risks are with this drug. We know what the risks are with other kinds of procedures. It is a matter for a doctor to make a decision as to whether or not something is an appropriate course of action given the circumstances of the particular patient.

Ms Vick—I would add to that, from a legal perspective—which is my area of competence—that, in terms of doctors providing any medical procedure to a patient, it is very clear that under the law in this country doctors are obliged to provide all information, including disclosure of risks, to patients so that patients can make a properly informed decision, because otherwise they are not giving informed consent. That has been reiterated and reconfirmed by the High Court numerous times—in Rogers and Whitaker in 1992 and so on. With a whole range of medical procedures, doctors are already obliged to disclose information, including risks—and including quite remote risks, I might say; that is the import of the case I mentioned a moment ago—and that would be equally true in this case because RU486 would be being dispensed under medical supervision.

Senator ALLISON—What do you think of the proposition that terminations should be made harder for women to get? Is there a role for counselling in all of this process of changing women's minds, as it were?

Mrs Coleman—We think that if we are talking about an appropriate health system, it should be feasible for a doctor to come to a conclusion as to which is the safest and most effective method of dealing with the issue. It should not be something which is made harder. If, indeed, we are endeavouring to reduce the number of abortions in this country, I would suggest that we need to put a great deal more effort into promoting sexual health knowledge and human relationships knowledge, starting with school children, and into making family planning services infinitely more acceptable and more accessible. These are the things which are likely to reduce the risks of unplanned pregnancies.

Senator ALLISON—Hasn't family-planning funding been reduced in recent years?

Mrs Coleman—I would have to ask Ms Richards to comment on some health figures. Perhaps she has them here.

Ms Vick—The other day, the Victorian health minister, Bronwyn Pike, commented to that effect, so I would assume that that is the case, at least in Victoria. I heard her say that.

Mrs Coleman—On the last part of your comment, counselling should not be about inducing somebody to change their mind, as if it comes in with a specific purpose. The requirement is to give people information on the basis of which an adult can make an informed choice. That is the crucial thing.

Ms Richards—I will just refer to the figures, Senator Allison. Funding to our family planning organisations has decreased. In 2001-02 the total figure was just over $13 million. The amount of funding to natural family planning or organisations not connected with family planning organisations has increased. Effectively what that means is that sexual health and family planning organisations are receiving less funding in 2002-03 than they were in 2001-02.

Senator POLLEY—I take exception to the comparison between Viagra and RU486. One is used to maybe even produce life; the other is to take away a life. I would like to put on the

record that I agree that the TGA are the ones that should make the judgments based on scientific evidence. But as a female, and from the evidence I have read and from the people who have already made contact with my office, I do not see that giving women another choice about how to have an abortion is actually giving women a better choice, as I have heard that it can take up to three days for that foetus to die.

Mrs Coleman—There are medical reasons which, not being a doctor, I will not go into in detail, but my understanding is that at eight weeks one is not actually dealing with a foetus; one is dealing with an embryo. So we are not dealing with an infant here; we are dealing with a piece of tissue.

Senator POLLEY—That is not the evidence that was put forward by the medical fraternity today.

Mrs Coleman—In any case, even if one is having a natural miscarriage it takes quite often a few days for the process to take place. If we are dealing with something which is up to 49 days, I think was the consideration, then, truly, when I went through menopause I would have had periods as heavy. I would think there would be quite a lot of women my age that would have an understanding that what one is having is an extremely heavy bleed. By and large, most menopausal women, and often younger women, learn to cope with that.

Ms Vick—I would have thought, too, that responsible adult women given full information, including disclosure of the sorts of issues you were talking about, are quite capable of making an informed decision for themselves.

Senator McGAURAN—I do not know whether to direct this question to you or the chair or, via the chair, perhaps to the secretary. I have just spoken to the secretary. You have come to us with no written submission. You have come to us with no identification of who you represent at all. I would like to ask you the question: who are you and who do you represent?

Senator McLUCAS—I will just hand over the information.

Senator McGAURAN—I know the name. But who are you? Am I to believe, Mr Chair, they are just a pro-choice lobby group? I would hope they would be more than that. So, please explain. Who are you?

Ms Richards—Would you like me to re-read our mission and our mandate, Chair?

Senator McGAURAN—Yes, please.

CHAIR—That was given in evidence before. I am not sure we need to have that.

Senator McGAURAN—Perhaps you could answer briefly, for my gratification.

CHAIR—Perhaps you could describe the constituent organisations or people who make up your organisation. That might be the best answer to that question.

Senator ALLISON—The point was made earlier on that those witnesses here today were here on the understanding that they were recognised as leaders in this field and that we knew there was not likely to be a submission made today or prior to today. I think that needs to be on the record, because it is an unfair accusation that is being made.

CHAIR—That is true. Basically they have been invited here by the committee.

Senator McGAURAN—Please indicate how you are leaders in this field.

Ms Vick—Before the CEO answers that, among other things, Senator McGauran, many members of the federal parliament are very familiar with the work of this organisation because it acts as the secretariat to the All Party Parliamentary Group on Population and Development—and there is at least one member of it present here today. That has been the case for the last 10 years. So it is well known in this parliament among parliamentarians.

Senator McGAURAN—So Ms Christina Richards works within this parliament?

Ms Vick—No. The organisation acts as the secretariat to the All Party Parliamentary Group on Population and Development.

Mrs Coleman—Of which a preceding chair was the Hon. Brendan Nelson. The current chair is—

Ms Vick—Michael Johnson.

Mrs Coleman—Mr Johnson from Queensland somewhere.

Ms Vick—Senator Allison is a member of the group. Senator McLucas is a member.

Senator McGAURAN—Nevertheless, who are you?

CHAIR—We have invited this group here, Senator—

Senator McGAURAN—I know.

CHAIR—I do not think we can question their credentials to be here today. I think they have to be taken as read, given that they are here at our invitation.

Senator McGAURAN—But they have not answered the question about their credentials for being here today.

Mrs Coleman—It is an organisation which is a registered company, a registered charitable trust. We publish an annual report. It is an incorporated entity. It is a perfectly respectable body.

Senator McGAURAN—And your qualifications to speak on RU486, please?

Ms Vick—We did not seek to do that. We are speaking on the governance issue, which is the content of Senator Allison's bill, with respect to who should make the scientific decision about allowing RU486 or not.

Senator McGAURAN—Well, we may as well invite a whole lot of other interested pro-life or pro-choice groups—

CHAIR—Senator, that is a matter for taking up with the committee, definitely not with the witnesses.

Senator McGAURAN—and that is what I recognise this group to be. I think it is a fault in the agenda.

CHAIR—That is fine. Take it up with me afterwards, but it is not a matter for these witnesses.

Senator McGAURAN—Where is the Women's Electoral Lobby? They have opened this up into a pro-choice versus pro-life debate. Everyone else before this had qualifications. They are doctors—

CHAIR—No. Senator McGauran, sorry—

Senator ALLISON—Catholic Health did not.

Senator McGAURAN—they know where they are coming from. They are based in health—

Ms Vick—No, Mr Sullivan did not have qualifications.

CHAIR—Senator McGauran—

Senator McGAURAN—they have hospitals—

CHAIR—Senator McGauran!

Senator McGAURAN—I do not think these witnesses should be here.

CHAIR—Senator McGauran, these people are here at the invitation of the committee. I do not propose to—

Senator McGAURAN—Unfortunately, we have come to a pro-choice—

CHAIR—invite them to the committee and then tell them they are not welcome to be here.

Senator McGAURAN—ending to this meeting.

CHAIR—Senator, I note your views, but I am sorry; we will move on to the next questioner. Senator Nettle.

Senator NETTLE—Because your organisation has experience in international population issues, I wanted to ask you about the recent decision by the World Health Organisation to add these drugs to their list of essential drugs for developing countries. Could you tell us a little bit about the work your organisation is aware of—how these drugs are being used in developing countries?

Ms Richards—The WHO recently listed mifepristone as an essential medicine. That was so recent—in the last six months—that I do not actually have any evidence of how it is currently being used. However, in countries where abortion is legal, I would imagine that just as emergency contraception is an added medicine that can be used, certainly in refugee and conflict situations, this will be a welcome addition to the suite of medications that can be used.

Senator NETTLE—Do you know what led the World Health Organisation to make that recommendation that it be listed as an essential medicine?

Ms Richards—The WHO, as you might imagine, conducts huge trials. Obviously, it was added not on the basis of any moral decision but on the basis of trials, efficacy and suitability for a whole range of conditions in which the WHO works.

Senator NETTLE—Thank you.

CHAIR—Senator Joyce.

Senator JOYCE—Obviously, if Ventolin brought about fatality to almost 100 per cent of unborn children under eight weeks, I imagine they would ban Ventolin as well. You believe strongly that this responsibility should be vested in the Therapeutic Goods Administration, don't you?

Mrs Coleman—Yes.

Senator JOYCE—Absolutely? Can you define the word 'therapeutic'; what does it mean?

Ms Vick—It is any good—and this is under their regulations—for which a therapeutic claim is made—

Senator JOYCE—What exactly does that—

Ms Vick—and that ranges from pharmaceuticals through to herbal compounds, for example, which the TGA also has responsibility for.

Senator JOYCE—But precisely what is your definition of 'therapeutic'?

Ms Vick—Do you want my definition or do you want me to quote theirs?

Senator JOYCE—Yours, or Mrs Coleman's or Ms Richards's.

Mrs Coleman—We are talking about a statutory authority established by legislation of this parliament. That act contains the definition of what is a therapeutic good, and it is our view that this falls within that definition.

Senator JOYCE—I can help you out. 'Therapeutic' is treatment of a disease or a disorder. Now, do you believe that pregnancy is a disease or a disorder—which one?

Ms Richards—Neither.

Senator JOYCE—I agree with you: neither. That is why it should not be under the Therapeutic Goods Act—because pregnancy is not a disease or a disorder. It is a natural progression of life. So why do we have to deal with pregnancy as a disease or a disorder?

Ms Vick—No, it is a question of dealing with the drug RU486, which is the appropriate domain of the TGA.

Senator JOYCE—But that is the whole point of the definition.

Ms Vick—The question of pregnancy is not the only context in which RU486 is used.

Senator JOYCE—You can use RU486 for other purposes, but you want to use it for pregnancy—the treatment of pregnancy as a disease or disorder. That is blatantly ridiculous.

Ms Vick—That is your view, obviously.

Senator JOYCE—Do you believe pregnancy is a disease?

Ms Vick—No, I do not.

Senator JOYCE—Do you believe it is a disorder?

Ms Vick—No, I do not.

Senator JOYCE—Well, what is it?

Ms Vick—But I believe, as is the case in many other countries, that a range of approved, safe options to women—

Senator JOYCE—But we have just proved before that this is 10 times more dangerous than surgery.

CHAIR—Senator Joyce, can we listen to the witness's answer please. Can we hear what the witnesses have to say in response to your questions.

Ms Vick—I was simply trying to make the point that this is a drug. Drugs come properly within the domain of the Therapeutic Goods Administration. I do not, to reinforce the question you asked before, believe that pregnancy is a disease or a disorder. But, for example, in several states of Australia, the legal framework for which termination is available relates to danger to the woman's mental or physical health. That is one aspect of the framework where the law provides for termination to occur—surgically at the moment. RU486 would simply be a chemical/drug approach to that situation.

Senator JOYCE—If I could tell you of a form of abortion that was 10 times safer than RU486, do you think that would be the rational path to take?

Ms Vick—I think the safest methods are the best, obviously.

Senator JOYCE—Well, that is surgical abortion.

CHAIR—I think we have pursued that line already. Senator McLucas has not had a question yet.

Senator McLUCAS—Under the way the current legislation is framed, can you tell me whether or not there is any opportunity, if the minister approved RU486, that there would be a requirement for the process of developing guidelines and ensuring that the prescribing was done correctly?

Ms Vick—I do not quite understand the question. Do you mean is there some process whereby the minister's thinking on the issue can be appealed?

Senator McLUCAS—No, if the minister approved the use of RU486 in Australia, does the legislation as it currently exists require the minister to make sure that there would be guidelines developed for its prescription, or could the minister simply approve it and then it is out there in the market?

Ms Vick—As far as I am aware, his approval is his approval and that is the end of the matter.

Senator McLUCAS—So by ensuring that the TGA go through that approval process, we would be more assured of having proper, sound guidelines for prescription that would come out of that approval process and the inclusion of the colleges et cetera?

Ms Vick—Yes, the new expert panels. Absolutely, that is our view.

Senator McLUCAS—So you would end up with a safer system if it went through the TGA?

Ms Vick—Yes.

Senator ALLISON—It still has to go through the TGA approval process of assessment and evaluation.

CHAIR—Yes, that is my understanding.

Senator FIELDING—Do you agree with Dr van Gend that RU486 is unique because no other drug ends human life?

Ms Richards—There are many other drugs that end human life, not just this one.

CHAIR—I think he meant end human life when taken as prescribed as opposed to accidentally or inappropriately.

Ms Vick—In utero?

Mrs Coleman—Because I do not have a scientific qualification, I am certainly not going to venture an observation on that.

Ms Richards—I have worked in palliative care and know that there are drugs that are used to help people as they are nearing death.

Senator FIELDING—So you do not agree that it is unique?

Ms Vick—It is clearly not the only drug that ends human life—and that includes deliberate.

Senator FIELDING—The question I asked, though, is: do you think it is unique?

Ms Vick—I said no, because clearly there are other drugs that also end human life.

Senator POLLEY—Would your organisation support any other drug that comes onto the market anywhere else in the world that does the same job? Is there any limitation to your support? If RU486 was to get approval and then along came two or three other drugs that did the same thing, would you be also advocating that they also be on the market?

Mrs Coleman—Just one moment: we are advocating that it be assessed by the TGA. That would be our position with any other new drug that was developed—that it should be assessed for safety and efficacy through the normal statutory processes.

Senator POLLEY—So you would welcome a dozen new drugs that did the same job?

Ms Vick—We would want the same process to apply with respect to all of them.

Senator FIELDING—Are you concerned for women who give birth to their own foetus at home and have to dispose of it themselves? Are you concerned about that at all?

Mrs Coleman—Could we make the point again that, up to 49 days, we are dealing with something that fits in with a particularly heavy period bleed. We are not talking about a small child.

Ms Vick—Frequently, a spontaneous miscarriage has to be dealt with by women at home too.

CHAIR—We have come to the end of the time we have allocated for this. If you are happy to take questions on notice, senators will provide them to you.

Senator McGAURAN—I have a point of order for the committee.

CHAIR—Okay; I thank these witnesses very much for their appearance today.

Senator MOORE—Chair, I think these witnesses deserve an apology for the process. No other witness today was asked to justify their appearance before the committee. I am sure that view is shared by the committee.

Senator McGAURAN—That relates to the point of order. The next people we are hearing from are the Women's Electoral Lobby of Australia. I would like to put it to the committee that we do not hear the Women's Electoral Lobby of Australia. I made the point for the previous group, and I certainly make it for this one with greater certainty: they have no expertise in this area other than a pro-choice opinion. If you allow them to come to the table, I would ask that you allow an equivalent lobby group in Sydney or Melbourne of pro-life measure to come to the table, such as the Women's Forum.

CHAIR—There is an answer to this question, but this is a matter for—

Senator McGAURAN—A dangerous precedent is being set, particularly with the Women's Electoral Lobby. Who let them in, I do not know!

CHAIR—Senator, this is a matter for a private meeting. As you have a point to raise, we will have a private meeting right now. I will suspend the public hearings and invite senators to gather around here for a private meeting.

Proceedings suspended from 3.32 pm to 3.37 pm

DUNDAS, Ms Roslyn, ACT Convenor, Women's Electoral Lobby Australia

CHAIR—I welcome Ms Roslyn Dundas from Women's Electoral Lobby Australia. I apologise to you, Ms Dundas, for the delay in receiving you today and the fact that there was some dispute within the committee in respect of the matter of your appearance. I can tell you that you have the full attention of the committee for what you have to say here today. I think you are very familiar with parliamentary privilege and the protection of witnesses and evidence. We have invited submissions and we have not received very many to date, so we realise that you may wish to take advantage of that chance to put in a submission at some point. Do you wish to make an opening statement before we ask you questions?

Ms Dundas—Yes.

CHAIR—Please proceed.

Ms Dundas—We thank the committee for inviting the Women's Electoral Lobby to take part in these hearings today. We will be providing a written submission but, considering the time frame in which we had to prepare for this particular hearing, I do not have a written submission to present today. The Women's Electoral Lobby—and I was not planning on doing this but I think it is important that I put this on the record now—is a national, independent political organisation dedicated to creating a society in which women's participation and potential are unrestricted, acknowledged and respected and in which women and men share equally in society's responsibilities and rewards. Our organisation has existed for 30 years in the Australian political spectrum and we have lobbied, on many different issues, for the rights of women to have their voices heard in political environments. As the issue that we are debating today is one that has become a political issue, that is why we are represented here, to present a political point of view in relation to the private member's bill that the committee is looking at.

WEL believes that RU486 should be assessed like any other drug. RU486 is the only medicine that is subjected to the restricted goods condition. In fact, the restricted goods definition exists just for drugs like RU486. Medicines used for other purposes besides abortion are evaluated and regulated by the Therapeutic Goods Administration and do not require an additional tick of approval from the Minister for Health and Ageing. The TGA is specifically charged with identifying, assessing and evaluating the risks posed by therapeutic goods that come into Australia, applying any measures necessary for treating the risks posed and monitoring and reviewing those risks over time. The TGA is regarded by this government—and has been by previous governments—as being the qualified body to manage the risks associated with any therapeutic good that is used or proposed for use in Australia. It is therefore reasonable to assume that it is also qualified to manage the risks associated with medications such as RU486.

Removal of the restricted goods definition and provisions in the act would mean that RU486 could be evaluated within the same framework as applies to all other drugs that are used in this country. It is reasonable to assume that this may provide potential sponsors the opportunity to bring this drug into Australia, but the process would be an evidence based evaluation by the TGA of the merits and risk profile of the drug—as it is with any drug.

RU486 is currently used in countries such as the United States, the United Kingdom, France and New Zealand. It is a safe and effective early alternative to surgical abortion, and it is a drug which has important uses in the treatment of cancer and other serious illnesses. It is also important to note that it is not a drug with just one sole purpose; it is a drug that has many purposes, and we are denying those therapeutic purposes being explored in Australia because of the current legislation. We see that the safest way to progress the scientific debate is through the TGA and the TGA alone.

CHAIR—It is fairly obvious, even from how things have transpired this afternoon, that the use of this drug is a very controversial issue in Australian politics. The procedure that it affects is also controversial. Doesn't that suggest that this issue is one with a very strong political dimension and, unlike any other drug that might be available to be regulated by the TGA, it ought to have a political oversight? Notwithstanding its efficacy or safety, doesn't it need to have that political process over it to decide whether it should be available or not?

Ms Dundas—With regards to the political dimension, Senator Humphries, if that means politicians having control over women's bodies and women's control of their bodies, then, sure, you can see it as a political issue. I believe that many women see it as a personal issue and as a decision that they take in consultation with their doctor and consider that the politics should be removed from it. There is a banner in this House that says, 'Trust the women': trust the women to make the decisions about their own bodies, trust the women to make decisions about their lives and futures, and trust them to do it under the guidelines that will be set down by the TGA in relation to RU486.

Senator MOORE—You have obviously thought about the issue. Your opening statement looked at the assessment of the safety and efficiency and so on of the drug, and we heard from the TGA this morning about this. In terms of the process that would follow any recommendation, does your organisation have any views about who should be involved in discussing or working through guidelines for how, in fact, the drug should be assessed as safe, how it could be implemented? There are two levels: there is the one level of decision about whether in fact there are occasions when it can be allowed into the country; there is the second level of how it should be used. We have heard people talk about guidelines to be developed and strictures put around the usage, particularly in regional and remote areas. Does WEL have any considerations about who should be involved in developing those guidelines?

Ms Dundas—It is my understanding that doctors have their own guidelines to follow, and that has been debated today. All sexual health and family planning clinics, to my knowledge, have guidelines that they utilise when discussing options around pregnancies and terminations with women. I would expect they would be engaged in any discussion about particular guidelines in relation to this drug specifically. We have faith in the TGA to do their job and to do their job well, and we would support that process to take place.

Senator FIELDING—Are you concerned about the effect on women of having to dispose of foetuses at home?

Ms Dundas—I trust women to have conversations with their doctor about the appropriate uses of any drugs that they partake of, the impacts that those drugs will have on them and on their bodies and the proper way of monitoring that. If a doctor feels that there is a risk that

something may not go smoothly then I would expect the doctor to recommend a different course of action. And I would expect a woman if she is in pain or in need of care to make contact with health professionals to help her through that. There is always concern that medication may not do the job that it is prescribed to do, that some people may have adverse reactions. I heard of a tragic case today of a child that has had a reaction to a meningococcal vaccination and has passed away. That was a very traumatic experience for that family. Drugs do have pros and cons and risks. As long as they are discussed fully and people are able to make an informed decision then we have faith in what will follow through.

Senator POLLEY—I guess you have more faith in the medical fraternity than I or a lot of people who have approached me. When I think about women's health I think of the fact that too many women have put their faith in their doctors and have become addicted to drugs dealing with depression and other psychological disorders. I am interested as a woman to see how you as a women can justify supporting the TGA when they have already made ill-informed decisions about some medications that have subsequently been removed. I am interested, given the fact that there is already acceptance within the community of terminations through surgical procedures, in why there is such strong support for a drug that is already on the market internationally from which women have died and where all the evidence at the moment—and no-one here today has been able to dispute it—is that it takes the foetus three days to die. How can that possibly be in the best interests of a woman, let alone the foetus?

Ms Dundas—Senator Polley, as another woman I think that is my individual choice to make: whether or not I will go through with a procedure, whether or not I will put a drug into my body and what the effects of that drug will be. I trust the TGA, as this government has and as previous governments have, to make that initial decision about whether or not that drug should be allowed into the country.

Senator POLLEY—I am only allowed one question.

Senator JOYCE—Ms Dundas, your group represents women and women's issues—is that correct?

Ms Dundas—On a political level, the Women's Electoral Lobby has the role of representing women.

Senator JOYCE—Going back through your life, when do you feel that you were first eligible to be represented by that group and why do you come to that position?

Ms Dundas—That is a very interesting question, Senator. I am not quite sure how it is relevant to the issue of whether or not little pieces of legislation should be changed.

CHAIR—I would have raised the same concern. Can you make it relevant to the inquiry?

Senator JOYCE—It is very relevant. You have obviously brought up the issue of your rights—'my body, my rights'—even though what is inside of your body has a different heartbeat, a different blood group, different DNA, is not permanent and has its own nerves.

Ms Dundas—But it does not have any legal rights until it is born.

Senator JOYCE—That is the whole point, and that is what I am getting to. So where, Mrs Dundas, when I go back through your life, do I get to a position where you actually had legal

rights? And what is the philosophical premise of you coming to that position that you have attained those legal rights?

Ms Dundas—As I understand it, international human rights law at this point in time explains that the right to life is given at the point of birth when independent breath is taken. It can then have retrospective effect, but it does not come into effect until somebody takes individual breath.

Senator JOYCE—So if I shoot a woman in the abdomen and do not kill her but kill the baby I have not actually committed a crime.

Ms Dundas—No, you actually have committed a crime by shooting a woman.

Senator JOYCE—But if I kill the baby, and not the woman, the day before it is born, as far as you are concerned that baby had no rights.

Senator ALLISON—Chair, I am not sure what relevance this has to the bill before us.

Senator JOYCE—It is very relevant. We are dealing with a group that says it is a women's electoral lobby. I want to find the point where, and the reason why, there is a philosophical premise of a person having a right. We cannot talk about medical issues, because we do not have the medical capacity to deal with those issues. We are talking to a group that represents women's issues and I want to find the philosophical point of where someone attained a right. That surely is a valid question.

CHAIR—Go ahead, Senator Joyce.

Ms Dundas—There are different laws in each state and territory relating to the Criminal Code and the penalties prescribed for somebody who causes physical harm to another human being, be it a woman or otherwise. Those laws are enforced by a judicial system not a political system. Judges take into account the emotional impact, the financial impact and all sorts of impacts that happen when those laws are put into place in our court system. I am not a lawyer, so I cannot speak as a judge about how those laws are implemented.

Senator JOYCE—So we cannot get any closer to knowing your view on whether a baby, on the day before it is born, has a right to life or not? You will not go on record to say whether it has a right to life or not?

Ms Dundas—As I have said before, international human rights law at this point in time conveys a right to life when individual life takes place.

Senator JOYCE—That is a very pure—

CHAIR—I think we will leave it there. I call Senator McLucas.

Senator McLUCAS—An issue that has been raised with us is whether another way of dealing with the legislation as it currently stands is to extend to the parliament or to the cabinet the power that the minister currently has. What is WEL's view on that as an alternative?

Ms Dundas—That is a very interesting question. This morning I was musing on the idea of whether or not we should hand that power to the cabinet, but then I realised there are only two or three women in the cabinet. This is a decision on which women will have to have the final say. Whether or not they take the drug, for whatever reason, is a decision that will rest with a

woman and her doctor. So I think that having different steps for the drug to follow on a different path devalues women and impacts on their ability to make decisions that affect their lives. So the Women's Electoral Lobby would not be happy with RU486, or any of these types of drugs, being in a separate category.

Senator NETTLE—Chair, I do not have a question but I want to put on the record two corrections of things that people have said today. Do you want me to do that now or afterwards?

CHAIR—Do it afterwards, if at all. I am not exactly sure whether standing orders allow that.

Senator NETTLE—We need to ensure that what is on the record is correct, and there are two instances of incorrect information that people have given to the committee today.

CHAIR—I will take advice on whether that is within standing orders. If it is, we will leave it until the end. Senator Allison has a question.

Senator ALLISON—Ms Dundas, I wonder if you could comment on the role of women in countries around the world where RU486 is available and has been for some time. Has it been seen as a women's issue in France, the UK and the United States as well? Could you inform the committee about women's role generally in reproductive health issues and their desire to have a say?

Ms Dundas—There is certainly a campaign across the world to provide women with more support for decisions that impact on their reproductive rights. There are also moves to ensure that a high level of information is available to women so that they can make informed choices. Unfortunately, this has not always been the case and women have not always had access to information, access to decision making and access to control over their own bodies. In places like Sweden and New Zealand a higher number of women have been engaged in political discourse and political debate and taking on positions of political power. In some places around the world there has been a more enlightened take on the role that women have with regard to their own bodies and decision making. It is disappointing that one of the countries that led the way in granting women the right to vote and to have a voice in political decision making is having this debate here in the 21st century.

Senator POLLEY—In relation to women's rights, I have some women activists from my state who have put a different perspective that I had not thought of, and I would be interested in your comments—that is, that this is actually a push by the pharmaceutical companies, which are dominated by males, and this is a quick fix from a male perspective, once again putting the onus back on women to have to make that decision. I would be quite interested to hear your perspective on that. I do not want to leave the impression that I am not a feminist and that I do not believe in equality for women. But I would be most interested to hear your perspective on whether or not it could possibly be a push by the males as a quick fix.

Ms Dundas—That is a very interesting point. The position of the Women's Electoral Lobby is that women should have access to a variety of contraceptive methods and, as I have stated before, the ability to have control over their own bodies and their decision making, and that should be supported through whichever means are safe and available. We know that—

Senator POLLEY—But this is not contraception, is it?

Ms Dundas—No. I am getting to your point, Senator Polley; I just wanted to put that on the record as a starting point. We know that men do not always take the same level of care that some women do when they are dealing with reproductive issues. Until we have greater education campaigns and greater access to a whole range of different contraceptive methods available for everybody to equally and easily access, we need to be looking at a whole range of options, and we see RU486 as just one of those options that should be available to the women.

Senator POLLEY—I will just clarify that we have already had the discussion today that RU486 is not contraception; it is a drug to terminate a pregnancy—very different.

CHAIR—We have heard that it can have a contraceptive effect in certain circumstances.

Ms Dundas—If being used at lower doses, it does have a similar effect to the morning-after pill. That is my understanding of the role of RU486.

Senator ADAMS—Yes.

Senator POLLEY—That was not the evidence—

Senator ADAMS—No, it can be used. From the point of view of rural women, have you had much feedback from your members? If the drug does become available, would your rural constituents be happy to use it—under their doctor's guidance, of course?

Ms Dundas—Of course under the appropriate guidelines. The Women's Electoral Lobby exist in every state and territory, and we have a national network that we use to communicate, share ideas and discuss issues. We have a well-developed health policy that recognises that women should have access, as I said before, to a whole range of different opportunities and abilities to make their own reproductive choices, no matter where they may reside. We recognise that it is extremely difficult at this point in time for women living in rural and remote areas to access abortions when they feel under pressure and where the town doctor has a certain view that may not facilitate them being able to access such a procedure. We also know that they will travel long distances, which can take a lot of time away from their responsibilities at home and in their current situation. So we think that women should have flexibility of choices and be able to work with their doctors or their sexual health clinic to find the option that best works for them, and we should not limit those options.

Senator FIELDING—The royal college said they would draw up guidelines for women about how to give birth to their foetuses at home and then options to dispose of their own foetuses. Do you think that is a good idea?

Ms Dundas—It is important that women have all sorts of different bits of information about procedures in relation to the administration of drugs, and their doctors should inform them of the risks that are associated with the medication.

Senator MOORE—Ms Dundas, it is very difficult if you have not heard what we have, but the royal college gave information that the recommendation from their New Zealand counterparts was that the supplementary processes were actually done within clinics and not necessarily at home.

With the development of the WEL consideration, how detailed was it? Did it go into the whole range of issues or did it just looked at this particular drug and its process for approval, rather than the degree of detail that some of the senators have asked about in their questions?

Ms Dundas—The Women's Electoral Lobby is a women's advocacy and political lobbying group. We are not a royal college of doctors.

Senator MOORE—You do have some members—

Ms Dundas—We do have some very well-informed members and quite learned members who have spent a lot of time working in sexual health and family planning. But our basic position, our main position, is that we see no reason why this drug, or any other drugs that do similar things, sits in a different category in this legislation and does not have the same approval mechanisms that every other drug does under the TGA.

Senator McGAURAN—Last question—probably it is fitting to finish on this note, given you speak of unfettered rights: what is the Women's Electoral Lobby's policy on a nine-month termination?

Ms Dundas—The Women's Electoral Lobby believes that women should be informed to make the right choices about their bodies in consultation with their doctors. We want abortions to be rare, and when they do occur we want them to be safe. The question that you ask about late-term abortions—it can be seen in Australia that they occur very rarely and that they occur for safety and medical reasons of, primarily, the mother, or if the foetus will not survive birth. We take the view that when that happens that decision is being undertaken by a number of doctors who have assessed the risks, weighed up the decision and come to a conclusion.

Senator JOYCE—Is that baby inside the mother the property of the mother, at nine months?

CHAIR—Sorry, we have a question from Senator McGauran; we will handle that. Please continue answering that question, Ms Dundas.

Ms Dundas—I have answered it but I would like to put on the record that the Women's Electoral Lobby hoped that this inquiry would stay on topic in terms of the legislation: the private member's bill that is before it in relation to RU486. I have no information that relates to RU486 being used to induce nine-month stage procedures. I do not think it would be able to work at such a stage.

Senator JOYCE—It could work.

Ms Dundas—In terms of how the inquiry is being focused, I do not see how that particular question relates to the private member's bill.

Senator McGAURAN—You challenge me to respond.

CHAIR—I do not think we should; no, I am sorry. In any case it is four o'clock and I said we would end the session at four o'clock. I thank you, Ms Dundas, for being here today and I am sorry that there were difficulties associated with your giving evidence, but we do appreciate the fact that you have done so.

Ms Dundas—Thank you, Senator Humphries.

CHAIR—Senator Nettle, did you have a correction to put on the record?

Senator NETTLE—The definition of a therapeutic good from the Therapeutic Goods Act includes:

... influencing, controlling or preventing conception in persons.

That was one matter. The other matter was the issue of the Italian trials of RU486. I wanted to let the committee know they have been operating again since early last month. Those were the two matters.

CHAIR—Thank you very much. I thank members for attendance here today. I thank Hansard, committee staff and our witnesses.

Committee adjourned at 4.04 pm