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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

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

FRIDAY, 3 FEBRUARY 2006

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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Friday, 3 February 2006

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, Ray, Siewert, Watson, Webber and Wong

Senators in attendance: Senators Adams, Allison, Barnet, Fielding, Humphries, Joyce, McLucas, Moore, Nash, Nettle, Polley and Webber

Terms of reference for the inquiry:

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

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Committee met at 8.36 am

ACTING CHAIR (Senator Moore)—Welcome. The Senate Community Affairs Legislation Committee is continuing its inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005. The committee is 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 this bill in order to inform the Senate in its deliberations on the bill. Along with the formal committee members, a number of participating senators have shown interest in this legislation and are here today.

[8.40 am]

WAINER, Dr Jo, Private capacity

JORDAN, Ms Lynne, Chief Executive Officer, Family Planning Victoria

BAYLY, Dr Christine Margaret, Associate Director, Women's Services, Royal Women's Hospital

FISHER, Ms Dale, Chief Executive, Royal Women's Hospital

OATS, Professor Jeremy, Clinical Director, Women's Services, Royal Women's Hospital

CHAIR (Senator Humphries)—Welcome. Do you have anything to add the capacity in which you are appearing?

Dr Wainer—I am the director of the Centre for Gender and Medicine at the Monash Institute of Health Services Research at Monash University.

CHAIR—The committee has received submissions from Dr Jo Wainer, the Royal Women's Hospital and Family Planning Victoria. Thank you very much for that. Would you like to make statements in support of the submissions before we proceed to ask you questions?

Dr Wainer—I assume that I have been invited to speak with this Senate inquiry because I have very extensive experience in the provision of abortion services and in early inquiry into, in particular, medical abortion. One of the things that I have learnt is that women will get an abortion if they need one, whatever it takes. I submit that the role of the state is to ensure that they are not harmed in the process. Women are entitled to believe that their government governs for them. They remember when deals are done to trade off best practice in their health care to secure a Senate vote. Australia has established international best practice in therapeutic goods through the Pharmaceutical Benefits Scheme and the Therapeutic Goods Administration, and I submit that the safest approach is to leave science to the scientists and ethical and moral decisions to the women and those who love them. Abortion is lawful and available, so there is no argument to support a unique process for a medication just because it induces abortion. Women can be trusted with a decision to mother or not mother. I ask you to hold women's wellbeing at the centre of your deliberations.

Ms Fisher—Thank you very much for the opportunity to address this inquiry. The Royal Women's Hospital is the largest specialist hospital in Australia dedicated to improving the health of all women. Family Planning Victoria is the largest provider of community based sexual and reproductive health services in this state. We are advocates for continuous improvement in women's health and wellbeing. In developing our health services, we strive to recognise and integrate the diverse needs, priorities and experiences of the women we care for. Our organisations support the passage of this bill because the Therapeutic Goods Administration is the specialist statutory body authorised to evaluate, approve and regulate drugs in the public interest.

The TGA's evaluation process requires a rigorous and robust assessment of scientific evidence and an examination of the risks inherent in any drug. The Australian parliament has endowed the TGA with all the necessary powers, authority and resources to evaluate and research the quality, safety and efficacy of a specific drug and to advise practitioners and the

broader community on its safe and effective use. The TGA has established a solid risk framework that provides doctors, health providers, pharmaceutical companies and consumers with consistency and clarity about the process for regulating access to new drugs. The public's interests are protected by the TGA's governance structure, accountability processes and clarity, which require reporting through the minister to parliament. The public's interests are not served by making exceptions to this stringent regulatory regime. There is no justification for a separate legislative framework for regulating access to RU486 or any other drug when the Australian parliament has already established an appropriate mechanism through the TGA that ensures both accountability and transparency.

Prof. Oats—Each year, the Royal Women's Hospital cares for more than 300,000 women from 165 different nationalities. We are committed to providing them with the highest quality health care and ensuring they are active partners in decision making about their health. As this inquiry is concerned with the repeal of ministerial responsibility for approval of RU486, we believe the following points are important to note. Women in the United States; 14 European countries, including the United Kingdom; New Zealand; and many other countries worldwide are able to access medical abortion by mifepristone, formally known as RU486. Although alternatives to mifepristone for medical abortion are available, they are less effective and, as a result, Australian abortion service providers almost exclusively perform terminations of early pregnancy by surgical procedure.

Research and international clinical evidence clearly shows that mifepristone, used in conjunction with prostaglandins, is a proven and safe method of inducing medical abortion. In the first trimester of pregnancy, medical and surgical abortions have similar outcomes in terms of their safety and efficacy. However, we believe that many women would prefer medical abortions as this method can be performed earlier in pregnancy than surgical abortion.

The Royal College of Obstetricians and Gynaecologists reports mifepristone and misoprostol is an appropriate, safe and effective method for mid-trimester medical abortion. The only research study of medical abortion in Australia recorded women were highly satisfied with this method. In addition, those women who had previously experienced a surgical abortion found a medical approach more acceptable. Nevertheless, some women will continue to want surgical abortion and therefore both options should be available through our healthcare system. Studies have shown that women value choice, have a strong preference for one or other approach and are more likely to be satisfied with a method they choose.

As an abortion service provider, the Royal Women's Hospital believes that access to medical abortion via mifepristone is a safe, reliable, non-invasive and effective option that should be made available to Australian women. However, we recognise and respect that ultimately the TGA as our statutory drug regulator is best placed and the appropriate body to evaluate and assess the quality, safety and efficacy of mifepristone for use in this country.

CHAIR—Thank you. We will proceed to questions and, as on the previous occasion, I will attempt to divide the time available to members in such a way as to give points of view on the committee fair and equal time in terms of questioning the witnesses. I would also remind senators to treat all viewpoints put to the inquiry today with the respect that any parliamentary inquiry ought to show towards those who show us the courtesy of presenting evidence to us.

Senator MOORE—It seems that there are very few questions to ask because your opening statements covered the process, but I would like to have some comment from any of you about the process. This legislation is looking at the process for evaluating a particular drug. Have any of you had experience in working with the TGA in other cases? I know that in your statement, Ms Fisher, you talked about exactly how the TGA operates. I would like to know whether you have had interaction with the TGA about the process and whether, in terms of this particular medication, it should be any different from any other one. I would like some comments from you, from your various perspectives in the profession, on that point alone.

Dr Bayly—I think all of us as clinicians have experience of new drugs coming in and have an understanding that the TGA is the body that assesses and evaluates those drugs. We are guided in our use of them by the TGA's evaluation outcomes and by it rendering those drugs available to us. Based on that experience and based on the international evidence, there is just no reason that this particular drug should be treated outside the TGA's normal process.

Prof. Oats—Also, there is continuing monitoring by the TGA of reports from worldwide as complications are reported about drugs, which are inevitable, and they are able to assess those professionally and with the expertise to see whether those complications are outside the expected and therefore change the balance of risk. I think the profession certainly has great confidence in the manner in which the TGA does that. I think their track record, certainly speaking as a professional, gives us confidence.

Dr Wainer—The critical issue is that the TGA is the body set up to evaluate scientific evidence and the argument that has been put for this particular medication is that it is doing something different from other drugs. That is true at one level but it is not doing anything different from a surgical termination. The outcome is not different; it is just the medical process that is involved. We have a very serious responsibility to women in this country to make sure that they have access to the best possible medical treatment for the termination of pregnancy, which is lawful and used by about one-third of the fertile women in Australia. This is a very normal process and we need the best possible ways to do that.

Mr Jordan—Speaking from the point of view of Family Planning Victoria, when the TGA calls for community based organisations to make submissions to the TGA, that has been a very transparent process from our perspective with regard to being able to represent a community perspective about the matter that they are investigating. We have benefited from that.

Senator MOORE—You have been involved in previous processes?

Mr Jordan—Yes.

Senator MOORE—On other medications?

Mr Jordan—Yes, on other medications.

Senator BARNETT—I have a question for the Royal Women's Hospital and Family Planning Victoria regarding the Royal Women's Hospital Melbourne submission No. 903. On page 3 of that submission it states in the second paragraph:

In the first trimester, medical and surgical abortions have similar outcomes in terms of their safety and efficacy.

There appears to be a good deal of evidence that would disagree with your view that there are similar outcomes. I am wondering whether you can describe to the committee the reasons for your view. I know that there is a footnote there referring to the Royal Australian and New Zealand College of Obstetrician and Gynaecologists, but I would like you to share your views with the committee and perhaps try to reconcile with us Dr Greene's findings of December just last year. In the *New England Journal of Medicine* he said that: the medical abortion has a maternal mortality rate approximately 10 times higher than surgical abortion carried out at the same gestational age. Would you care to respond?

Dr Bayly—In terms of the outcomes of medical and surgical abortion, they are both very similar in terms of the success of ending the pregnancy by the time the protocols are completed. There is some difference obviously in the nature of the experience for women. Side-effects are comparable; not exactly the same but they are comparable. Mortality rates are extremely low in those places where abortion is available safely, within the law and within the health care system. The mortality rates are comparable. The statistics to which you refer in fact do not reflect that sort of difference. In fact, the way they have been put suggests a lack of understanding of the statistics of very rare outcomes amongst very large numbers. In fact, the author does not draw the conclusion that you suggest—that there is a difference in mortality. Perhaps I will make a couple of comments of clarification on that particular paper. The author says:

> As tragic as the deaths of these young, healthy women are, they remain a small number of rare events without a clear pathophysiologic link to the method of termination.

As an aside, deaths from these causes do occur following surgical abortion and indeed in relation to childbirth.

The author further says:

> … that regulators should keep this rare complication in perspective and not overreact to scant data.

I think this example is one clear reason for the requirement that an expert body qualified to do so assesses this kind of evidence—and all of the evidence. I think that the TGA is well qualified and well placed to assess, interpret, understand, integrate and synthesise that evidence as presented in that paper—and the broader evidence. Indeed, as they unfold, emerging evidence and new things that occur can be taken into account by the TGA in its evaluation process and in its post approval monitoring.

Senator BARNETT—Do you accept that there are different views with respect to the safety and efficacy of the RU486 drug—the chemical form of abortion—compared to surgical abortion?

Dr Bayly—I think that the published clinical evidence, when taken overall, strongly supports very comparable outcomes from that point of view—that they are comparably safe and effective.

Senator FIELDING—This question is to anyone who wants to take it. Do you believe that it is the job of our elected leaders to reflect community attitudes and make policy?

Prof. Oats—In general terms, yes.

Senator FIELDING—I do not know whether you are aware of the independent research that shows that the community is concerned about the high number of abortions and wants that reduced. Isn't it the job of our elected leaders, not elected bureaucrats, to decide on this and other policy issues?

Ms Jordan—The numbers of lawful abortion services have been consistent over time. There has always been an amount of abortions that women seek and need over time. We believe that the TGA, as with any drug—and there is no reason that this drug should be treated any differently—is the appropriate authority to do that.

Dr Wainer—Abortion is used by women all over the world. The only thing that affects the abortion rate is the consistency of education of young people to help with managing their fertility, their sexuality and the power dynamics between men and women. In Australia, when abortion was unlawful, the Royal Commission on Human Relationships estimated there were 90,000 to 100,000 illegal abortions carried out in the country each year. The best estimate of the number of abortions today is about 80,000, so there is no increase in the abortion rate. Australia has an abortion rate of about one in four pregnancies being deliberately terminated. Worldwide, that figure is one in three. We have a comparatively low abortion rate compared with, for instance, America, which has a much higher teenage abortion rate. There is an attempt to 'awfulise' abortion by saying: 'This is unusual behaviour. It is aberrant behaviour. There is an increase.' None of that is true.

Senator FIELDING—That was not the heart of the question. I did not say that this would increase the number of abortions. That is the first thing I would like to respond to, with due respect. The issue at hand here is that this drug is different. It allows do-it-yourself abortions at home. That is a social policy issue that should be decided upon by elected members, not bureaucrats. I would like your views on that, please.

Ms Jordan—I would expect that, if the issue with regard to the sexual health and wellbeing of women and others is of as grave concern as you would suggest to those who are elected, there has been no increase in funding for community based sexual and reproductive health services for a significant period of time, and if—

Senator FIELDING—But, with respect, the issue at hand that I have raised and am just asking your opinion on is this: isn't having do-it-yourself abortions at home a significant shift and a social policy issue? Is that not substantially different from what we have at the moment with the current abortion process?

Dr Bayly—I think there is no suggestion that abortion should be do it yourself at home. There is no suggestion that medical abortion should be undertaken other than under medical supervision. This idea of do-it-yourself abortion is just wrong. It is just a misinterpretation of what is happening anywhere around the world and it is a misinterpretation of what is being discussed. There is no suggestion that it should be conducted other than under medical supervision, and the TGA is in the position to make statements and advise on—and place restrictions on access to—the drug.

Senator FIELDING—My question then is: is it not a fact that after taking RU486 and the follow-up drug the foetus would be expelled at home and therefore, as I was saying, it would be do it yourself at home, albeit prescribed, and the woman would have to then dispose of the

foetus? This is a significant shift in social policy and it is for politicians, elected members, to decide on this issue, not the TGA.

Dr Bayly—Again I would say it can in no sense be seen as do it yourself. The drugs are prescribed, and in most instances of overseas practice at least the beginning is directly supervised in a health care facility. There are detailed protocols, advice and information that are given to women. Follow-up is critical to ensure that they do proceed through each stage of the procedure: taking the second set of medication and so on. It is true that in some places, although not all, in the actual abortion the products of conception may be passed at home. That is not necessarily the case, and it can be conducted so that that happens almost exclusively in the health facility. Nevertheless, there are places where that happens and, yes, the woman may pass the tissue at home, but it is not a requirement for that to happen.

Dr Wainer—Can I comment, Senator, that women are actually very experienced at this: they have miscarriages. That is a common part of a woman's experience and nobody gets very alarmed about that, and this experience would be no different.

Senator POLLEY—I was wondering if somebody could explain to me where the therapeutic goods benefits of using RU486 for abortion are, because the TGA's therapeutic goods in every other instance that I can think of are there for benefit. I was wondering if someone could explain to me where the benefit is in the use of this procedure in a quite inhumane way—aborting a baby?

Dr Bayly—Abortion is an accepted medical treatment in this country. It is undertaken in the interests of the health of the woman seeking the abortion. Medical abortion is simply a method of abortion, so it is a form of medical treatment.

Senator POLLEY—I have had raised with me by countless pro-choice doctors that have concerns that in fact using RU486 may very well—and in fact their belief is it will—increase the need for surgical abortions and that women will not feel confident that they have properly and healthily removed the baby. So in fact that is going to cause more of a strain on the Australian health system and therefore it is not really going to achieve the set outcome of those people who are pushing strongly within the pharmaceutical and the medical fraternities.

Dr Bayly—I think that does reflect a lack of understanding of the process. These are aspects that the TGA is able to assess in assessing evidence about the efficacy of this medicine. I think there is no evidence from anywhere else that the outcome you suggested occurs. Follow-up regimens provide for ensuring the completeness of the procedure and for following up with appropriate treatment when that does not occur. I am aware of no evidence that would suggest that to be the case.

Dr Wainer—Can I also make a contribution on that. From the evidence that I have seen—and I think it would be better assessed by the TGA; I am not claiming to have the full expertise on it—about two per cent to three per cent of women who use medical abortion will require surgical intervention. That is two or three out of 100. That is 97 who do not. That is a very big saving on surgical facilities and cost to the government. It is also very helpful in rural areas, where you have a very limited access to surgical time, theatre time and doctors who have the capacity to do terminations, if they only have to do two or three instead of 100.

Senator POLLEY—You also have a great shortage in rural and regional Australia, which I represent, of access to medical treatment for any ailment. There is no guarantee that women are going to be able to access the proper care or choose to or even afford to follow up to ensure that the procedure is taken care of carefully. I do take exception to your suggestion that women who miscarry or who have an abortion and pass a baby are not going to be traumatised by that—that that is just part of a woman's life. I have lived on this earth for quite some time and I have actually been through all the processes, and I find it quite offensive that you would suggest that women are not affected by that.

Dr Wainer—I did not suggest that, Senator. I said that women are well accustomed to dealing with these difficult conditions and difficult issues. It is part of a woman's life.

Dr Bayly—Can I comment on that as well. I think the expectation of what is to occur with the experience of medical abortion is part of the discussion that happens beforehand and it is part of the woman's decision making about her method. Some women prefer to experience something they see as being more like a natural miscarriage. Others who are concerned about that aspect will choose surgical abortion. They will not choose medical abortion. The international evidence suggests that those women who approach this in an informed way and make that choice do not find the experience a major problem from that point of view.

Senator BARNETT—It disturbs me to hear Dr Wainer saying that what happens to a woman is the same as a miscarriage. I have some evidence in front of me from the Food and Drug Administration in the USA. It says that, of 237 adverse events reported involving haemorrhage after RU486, 42 women were faced with life-threatening blood loss needing two or more units of blood and 160 others had severe haemorrhage requiring blood transfusion. It does not sound like those similarities are clear. I am wondering what evidence you have to say that vaginal bleeding or miscarriage from a chemical abortion is not a problem for women.

Dr Wainer—I did not say that it was not a problem. I said that women are well experienced in dealing with these problems. From the experience of the woman, not from the science—the TGA and the scientists are in the best position to evaluate the science—there is no difference, except that she has made a decision about this whereas, if she is having a miscarriage, she has not made a decision. But the actual—

Senator BARNETT—There is no difference between a miscarriage and chemical abortion?

Dr Wainer—The physical experience would be the same.

Senator JOYCE—Something pricked my curiosity the other day. We have had a presentation by the AMA saying there are no problems with the course of this treatment, the course of this drug to stop a life—that is, mifepristone and misoprostol—but the makers of misoprostol have come out and said that they have an issue with it. Do you want to discuss why the makers of misoprostol, the prostaglandin, feel that they have a problem with the use of their drug as an abortifacient, I suppose—is that what it is?

Dr Bayly—The proven effective regimens about which we are talking for medical abortion include the use of mifepristone together with a prostaglandin. In many cases, but not all, that prostaglandin is misoprostol. All of the time when we are talking about mifepristone there is another drug to be used with it, so those safe and effective regimens about which the

international evidence exists also include the use of a prostaglandin. Those international regulatory authorities which have evaluated and approved mifepristone for medical abortion have approved its use in conjunction with a prostaglandin, and that has often, but not always, been misoprostol. It is very likely that an application for evaluation of mifepristone by the TGA would include misoprostol as part of that treatment regimen.

In fact, what happened in the United States in relation to misoprostol is that after it was approved with mifepristone for medical abortion the FDA, the Food and Drug Administration, the regulatory authority in the United States, required a change to the warning and product information accompanying misoprostol to indicate that it could be used in pregnancy in appropriate circumstances. The warning in relation to pregnancy for misoprostol relates to its use in the treatment of gastric ulcers, and the fact that it can cause uterine contractions is an unwanted side effect. However, when it is used for its prostaglandin effects in order to cause uterine contractions in medical abortion or in some other uses—for example, the induction of labour—the uterine contractions are a wanted effect.

The company itself has not chosen to sponsor research for this reason, and in fact it has not needed to because others have taken the responsibility for undertaking that clinical research. But there is in fact extensive clinical research and international published medical evidence supporting its use in this context.

Senator JOYCE—Undertaken by other people but not by the drug company that actually makes the drug misoprostol?

Dr Bayly—That is right, yes.

Senator JOYCE—Just for the record: it has been a bit surprising that, of all your learned colleagues who have come before this inquiry before, none of them seem to have raised the problems with misoprostol. You cannot hazard a guess as to why, being so across the medical issues, they have not brought up the fact that the drug company that makes the prostaglandin, the abortifacient, actually does not recommend its use for the process?

Dr Bayly—I do not see that as a problem. The evidence has been considered by all those regulatory bodies which have approved regimens including mifepristone and misoprostol. All of the regimens we are talking about include either misoprostol or another prostaglandin, so the misoprostol—

Senator JOYCE—Another prostaglandin such as what?

Dr Bayly—Gemeprost.

Senator JOYCE—I will go on to another thing. Professor Oats, I just want to get this absolutely clear. In the time frame for RU486 and the time frame of surgical abortion, you categorically say that that they have the same complication rate—that is, in the first eight weeks or whatever of using RU486 compared to the first eight weeks of surgical abortion, they are the same. Are you going to put that on the record?

Prof. Oats—Yes, the rates are comparable.

Senator JOYCE—What do you mean by 'comparable'?

Prof. Oats—They are equivalent.

Senator JOYCE—They are the same?

Prof. Oats—They are within the same statistical range.

Senator JOYCE—So anybody who gave evidence that they are not the same would be telling an untruth?

Prof. Oats—I think there is always interpretation of the available scientific literature, but—

Senator JOYCE—So is it up to contention or is it not?

Prof. Oats—I do not personally believe it is contentious, and that has certainly been the experience of many learned societies that have examined this evidence.

Senator JOYCE—What study do you base that on?

Prof. Oats—On published literature.

Senator JOYCE—Such as?

Dr Bayly—I think there is a very great deal of published literature. I am wondering if you have questions about any particular issues.

Senator JOYCE—I am really asking about evidence that has been given to this inquiry before that states that in the time frame of the first eight weeks RU486 has 10 times the complication rate compared to surgical abortions. As such, if that is the case, there will definitely be women walking around who will die because they use RU486 and who would have been alive had they had a surgical abortion.

Dr Bayly—I am not sure whether you were here when we discussed that particular issue, which I think related to mortality rates, earlier on. Would you like me to address that again in relation to the American paper?

Senator JOYCE—Could you just give a brief precis of it?

Dr Bayly—Yes.

Senator BARNETT—It is Dr Greene's paper. You can refer to him by name; that is fine.

Dr Bayly—Sure. It is an interpretation of statistics which is about very rare events in very large populations. The author himself does not conclude that there is a difference in mortality rates. He talks about a framework for comparing them and he makes the comment that there is:

… a small number of rare events without a clear pathophysiologic link to the method of termination …

And that:

… regulators should keep this rare complication in perspective.

So to suggest that there is a tenfold mortality difference is simply not substantiated in the literature. As far as the other question, about women walking around who would die if they had a medical abortion, is concerned, I think if they did not have a medical abortion they would be seeking a surgical abortion and similar numbers would die.

Senator JOYCE—Similar?

Dr Bayly—Similar numbers, yes. If they were refused access to abortion, they would be likely to be resorting to unsafe abortion and more of them would die.

Senator JOYCE—Surgical abortion as opposed to using RU486. You are saying that there is the same safety in RU486 as there is in surgical abortion. You are willing to go on the record and say that.

Dr Bayly—On the basis of current evidence, if you are talking about mortality rates—

Senator JOYCE—For the same period of time.

Dr Bayly—there is not evidence to support any difference in mortality rates.

Senator JOYCE—For the first eight weeks.

Dr Bayly—That is right.

Senator JOYCE—With the therapeutic goods, you take into consideration the welfare of the woman. Do you think you should take into consideration the welfare of the child that is being aborted, and, if not, why not?

Dr Bayly—I think there is very clear evidence world wide that if women do not have access to safe abortion they seek unsafe abortion and women die. It is very clearly a women's health issue.

Senator JOYCE—What about the child? What is the health issue for it?

Dr Bayly—Women seek abortion because they feel unable to continue with a pregnancy and are unable to offer any sort of life to the child that would result from that pregnancy.

Senator JOYCE—What about the rest of the witnesses? What are your views on the child? Do you think you should take into consideration the health issues of the child?

Dr Wainer—Can I just say that in Mali, an African country without the health services for women that we have here, one in seven women die from pregnancy related causes. Pregnancy and sex are very dangerous things for women. Women make a decision to mother when they can and they make a decision that they cannot mother when they cannot. Nothing has been able to change that anywhere in the world, and we have to respect that. We respect women's decision to mother; we have to respect their decision when they cannot.

Senator JOYCE—It is exceptionally dangerous for the unborn child.

CHAIR—I think we will leave it there. Thank you very much.

Senator NASH—I will come back to the terms of reference for the bill, which are about who should have the responsibility for approval and who is best able to determine whether this drug should be in the country. In the situation that we have where termination is lawful—and this is about a method of termination—given the disparity of views and understanding around this table, doesn't that make it even more obvious that it is the Therapeutic Goods Administration who should be determining the quality, safety and efficacy of this drug rather than the minister of the day?

Dr Bayly—That is the basis of our submission. As I say, they are in a position to consider all of the evidence that there have been interpretations given of today. All emerging evidence

is that the TGA is well equipped to consider all of the arguments and issues that have been raised.

Senator WEBBER—I also want to return to the role of the TGA, because I understand that that is basically what we are here to discuss. I am not a medical or scientific expert, so I do not actually have any day-to-day experience in dealing with the TGA. In your experience, can you tell me whether they will not only do the initial evaluation of any new drug that we look at using in Australia but will also have an ongoing role in monitoring the safety and use of that drug so that we can intervene if there is a problem and ban its use in Australia?

Prof. Oates—That is certainly my understanding and my experience. Not only do they get information from their comparative organisations overseas so they can tap into that information, they are also notified of any adverse outcomes from the administration of any of these agent's drugs within Australia. So they do have a continuing monitoring role and therefore, if adverse outcomes do become apparent and these become of concern, when they have been properly scientifically evaluated they are in a position to give advice about the continuation or discontinuation of the administration of that agent.

Ms Jordan—Including developing the guidelines for the use of this drug for the practitioners.

Senator NETTLE—Thank you very much for your submission and bringing your expertise along to the committee. I have two things to clarify. One of them is in relation to your submission where you talk about the study in which women who have had both medical and surgical experiences 80 per cent prefer to have the medical. Could you tell us which study that is from? A couple of people have mentioned it, and I want to check I have not missed one.

Dr Wainer—I did not reference this and I apologise for that. I cannot bring that to mind but I will send it to you if you want it.

Senator NETTLE—I would appreciate that. We have had other ones mentioned as well and I just want to check whether there are a number of them or whether only one has been done. That would be helpful.

Dr Wainer—That study was done very early in the usage of RU486 in France and when the UK was considering its introduction. It was in the 1980s.

Senator NETTLE—Thank you. The other issues that was raised in the hospital submission was about women who ring up in the very early stages of pregnancy and are dismayed to find out that they have to wait. I want to thank you for raising that issue, because it has not been raised all that much. I wondered if you could explain it for the committee. In the past in these discussions some people have found it difficult to understand why that is of concern to a woman. I was wondering if somebody at the hospital—I do know to whom I am asking the question—could explain that so that the members of the committee could understand that issue a little bit more.

Dr Bayly—Women who reach a decision for abortion having been through the very difficult process of confronting a difficult situation and reaching that decision would like to have the abortion done as early as possible. Medical abortion can be done earlier than surgical

abortion. If surgical abortion is done very early in pregnancy—before about 6½ weeks—there is a higher failure rate for the procedure and so it may have to be repeated if it is unsuccessful.

Senator NETTLE—So in your experience the issue is that having reached what is a very difficult decision for a woman to make they would like to proceed with the medical treatment that they are able to access in this country rather than have to wait through a period of uncertainty.

Dr Bayly—That is correct, yes. Those women who are aware of their pregnancy that early and reach that decision want it to happen. They do not want to prolong the distress by making it any later than it actually needs to be.

Senator JOYCE—What has a higher failure rate?

Dr Bayly—Surgical abortion, if undertaken very early in pregnancy, has a higher failure rate than if it is undertaken a bit later on—beyond about 6½ weeks.

Senator JOYCE—A higher failure rate than RU486?

Dr Bayly—A higher failure rate than later surgical termination.

CHAIR—Could I ask for some comment on a point made by another submitter, Dr Elvis Seman, who we are to hear from today. This goes to the question of the use of misoprostol. He says:

> The use of misoprostol in gynaecology is "off label". In other word it is not licensed by its manufacturer to be used gynaecologically, not even for dealing with miscarriages. Thus whilst the use of misoprostol in chemical abortion is legal, it is unethical ...

I wonder if there is anybody who can give us an indication of whether it is true or not that the manufacturer of misoprostol in fact does not authorise or foreshadow the use of this drug for that purpose.

Dr Bayly—The manufacturer has not researched the drug for that purpose but extensive research and clinical use has been undertaken by others for that reason. That is the clinical evidence and international evidence that we have been talking about. There is a very large volume of research and there are a number of international bodies—including the UK Royal College of Obstetricians and Gynaecologists, the American College of Obstetricians and Gynaecologists, and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists—which have recognised the adequacy of the published research to support the clinical use of misoprostol in obstetrics and gynaecology. And that is something that happens with other drugs as well. When there is a substantial body of clinical research to support a drug's use for indications other than perhaps those recommended by the company, good clinical practice will allow that to occur, as informed by the available research.

CHAIR—So you are saying that, ethically, there is no problem in using a drug for a purpose other than that which the manufacturer determines it should be used for?

Prof. Oats—Providing it has gone through that very rigorous evaluation that Dr Bayly referred to, yes.

Senator JOYCE—Is the other prostaglandin that you mentioned recommended as an abortifacient?

Dr Bayly—It has approved uses in obstetrics, certainly.

Senator JOYCE—Is it recommended as an abortifacient?

Dr Bayly—I cannot answer that question.

Senator POLLEY—A lot of evidence has been given to us based on other practices in other countries. Is it or is it not a fact, though, that in the United States it is not legally required that complications from the use of RU486 have to be reported? One could therefore argue that the basis on which a lot of evidence has been given to us is flawed and not accurate. I am not talking just about the deaths; I am also talking about the complications of infection and the added complications of psychological problems relating to those people who have chosen medical abortion over surgical abortion.

Dr Bayly—I am not aware of the specific reporting requirements in the United States. But there are established methods of seeking to assess complications and outcomes from medical treatments, and I think that similar techniques have been applied to outcomes of both medical and surgical abortion. That is what clinical research is about: describing those methods, applying them consistently and trying to get meaningful outcomes from that.

Senator POLLEY—Some would argue that in fact this form of medication is something that is being pushed heavily by the pharmaceutical lobby groups and so is driven by profit and expediency rather than the health of women.

Dr Wainer—It seems to me that these are excellent comments that speak to the passage of this bill, because the proper body to assess the questions that you have asked is the Therapeutic Goods Administration. They are the scientists with the expertise and the remit from the government.

Senator POLLEY—We do not always get it right.

Dr Wainer—I do not think anyone will always get everything right.

CHAIR—Dr Wainer, I follow that question up with a question that goes back to something you said at the beginning about leaving science to the scientists. Is this issue merely about the available application of scientific knowledge to particular medical situations, or is there not a broader social context here which needs to be factored into the available scientific options in a way that is not part of the TGA's present brief? For example, if you said that we should leave science to the scientists in the area of genetic engineering, would you not expect that there would be many things that science would be physically able to do by virtue of advances in technology but that the community as a whole might say that they do not wish to see occur? If that is the case, is there not an argument here for saying that, notwithstanding what can be done or what efficacy or availability of options might occur by virtue of this drug, there is a broader social issue which has to be brought in and that it is really beyond the scope of the TGA's brief?

Dr Wainer—Yes. The broader social issue in this debate is the question of whether women should have access to lawful abortion. That debate has been held extensively in this country. It has been settled on a state-by-state basis either by the application of the law or by passage of acts of parliament. That issue has been settled. Australia has long experience with that, so I do not think that it is relevant to this committee or this bill to consider those issues which are

properly considered by parliament. That is settled. It is a question for the Commonwealth parliament to consider. The subject of this inquiry is whether the Therapeutic Goods Administration is the appropriate body rather than the Minister for Health to consider the safety and efficacy of a form of administration of termination of pregnancy.

CHAIR—But the circumstances in which abortion can occur under that legislation just referred to varies fairly significantly between different jurisdictions in Australia, doesn't it?

Dr Wainer—No, not significantly. The underlying principles are all the same. It is about a termination being available if it is necessary for a woman's mental or physical health.

CHAIR—Would you accept that, where a drug like this is used, the circumstances in which an abortion might be procured are different to the circumstances in which it might be procured with a surgical abortion—that is, people may use that option where they would not use a surgical abortion, for instance?

Dr Wainer—No, I do not accept that. The decision to terminate a pregnancy is a very difficult decision. Women agonise over it and, once they have made it, they will do whatever it takes to get one. When abortion was unlawful in this country, women died because they needed that abortion. They were prepared to die. I have a book here which tells the stories of women who had abortions when they were illegal in this country. I recommend it to you if you want to understand that.

Senator JOYCE—Abortion is not illegal at the moment. That is not the argument. Do you know any drug company at all that recommends their prostaglandin as an abortifacient?

Dr Bayly—I think the issue here is that the TGA is able to assess the evidence that is available and make judgments about what is appropriate.

Senator JOYCE—But do you know of any drug company that recommends its prostaglandin as an abortifacient? The answer is yes or no.

Dr Bayly—I cannot provide any information about that.

Senator JOYCE—So the answer is no.

Senator MOORE—That is a little unfair. We are going to degenerate here.

CHAIR—Let us not put words into people's mouths.

Senator FIELDING—The abortion issue has been widely discussed, but there is a whole generation that has not had that debate and I think there has been a significant shift. Do-it-yourself at home abortion is a social policy issue that has not been debated. I would like to pick up a point made earlier. I do not know whether you are aware of the submission to this inquiry that quotes figures on death rates from the *New England Journal of Medicine*. The submission states:

> This means that for a country performing say 90,000 ... abortions per year, one would expect one maternal death from surgical termination every 11 years, whilst during the same interval one would expect about 17 deaths from chemical abortion.

You may be able to say that that is okay, but as a senator I am not convinced that we should change social policy and leave it to the bureaucrats to do.

Dr Bayly—The TGA is well equipped to assess the evidence, apply appropriate statistical analysis to individual papers and consider the whole of the evidence and make decisions about what is appropriate.

Prof. Oats—The published evidence is that when both medical termination and surgical termination are available there is, in fact, no change in the total number of terminations. I think that is important. We are talking about two methods, which, during particular gestations, are comparable from the evidence. Therefore, it is a matter of choice and the availability of another method of termination.

Senator JOYCE—So one complication as opposed to 17 complications is comparable?

Dr Wainer—The last time I looked—and others may correct me—one in 14,000 women in Australia dies from obstetric complications. Pregnancy is hazardous for woman.

CHAIR—I do not want there to be an engagement in this way with the witnesses, please. Questions and elucidation of information is what we are after here. Senator Adams has a question.

Senator ADAMS—Thank you for your submissions. As a midwife, I found them all very interesting. I wish to go back to the terms of reference of this inquiry. You are a body of experts on where evidence can be found. At the moment the Minister for Health and Ageing can approve whether or not this drug can be used in Australia. Where would the minister get information to make an informed decision about a drug such as this?

Prof. Oats—With due respect, I think one would have to ask the minister that. I do not think we are in a position to comment on where the minister would get sources. One would hope the minister would seek wide submissions, but that is the core of this matter: we believe there is a well-established professional group—the TGA—that is equipped to examine, collate and give recommendations on worldwide and local evidence.

Dr Bayly—The TGA has established sources for that sort of evidence, and I think it would be hard for the minister to go past the TGA.

Senator MOORE—As there are people here who are practitioners in the field, I would like to get something on the record about the process. If a woman is seeking information on the options that she has and what may happen, what is the requirement on the medical practitioner to provide information to that woman about the use of a process? It is difficult to ask about the use of RU486 in this country, because it is not being used, but, if someone is seeking information from a doctor, what is the requirement on the practitioner to provide information to them about the process, the risks and the final choice for the woman?

Dr Bayly—In general, informed consent would apply to any procedure, leaving aside the decision-making process about abortion, which is complex and which applies similarly whether medical or surgical abortion is to be considered. Medical abortion is not something that is available in this country but, with regard to those places which are offering it, our colleagues in New Zealand have developed some extensive guidelines, information for women, information for practitioners and information for referring doctors to assist in ensuring that information is comprehensively and appropriately provided and that appropriate

care can be given. Should medical abortion become available here, similar arrangements would be made and information would be developed.

Senator BARNETT—Just to follow up on Senator Fielding's question, in terms of the safety outcomes we have heard from Dr Bayly and Professor Oats that they are pretty much the same or comparable. You have used those words. I would like that on the record, if possible, from the other three witnesses if they have got a view on it. It seems to conflict with a whole range of views put to our committee, including from Dr Renate Klein. I will read to you from her submission, which says:

Five to 8% of women will then need a suction abortion as the RU 486/PG pregnancy termination was incomplete. If we were to assume that half of Australian women's abortions (40 000)—

she says—

were to be done using chemical abortion, this would mean that yearly—

each year in Australia—

between 2000 and 3200 women would have to undergo a second abortion ...

So that is another type of complication. For the record, can the other three witnesses before us put their views and respond to Dr Klein's assertion.

Ms Fisher—Because of the last 10 years of emerging evidence internationally, the Royal Women's Hospital are developing and would like to develop a service. We are a provider of abortion services to the women of Victoria. We believe medical abortion is an appropriate form of abortion and we would seek access to this drug and we would rely on the TGA for the guidelines to administer those drugs. Because I have not actually read the paper I would not like to actually comment on it.

Ms Jordan—Family Planning Victoria is not a provider of abortion services and hence I do not believe I am in a position to comment on that particular paper. We are a provider of counselling and support services that are often sought by women who experience unplanned pregnancies.

Dr Wainer—Surgical termination following the administration of medical abortion is a well-known possibility. It is well recognised. Yes, you are absolutely right; some women would have to have surgical intervention but it is very few compared with 100 per cent.

Senator BARNETT—What per cent?

Dr Wainer—The figures vary. It is less than 10 per cent. It is maybe two per cent; it may be three per cent. It depends in part upon on the gestation, and that is why there are gestational limits to the use of this medication. The more controversy there is around these issues, the more important it is that the TGA be the body to settle the question.

Senator BARNETT—Profess Oats and Dr Bayly?

Dr Bayly—I will just add to that that 95 per cent or thereabouts of those women who choose medical abortion have actually avoided a surgical procedure, and that is the attraction for those women who choose that method.

Senator BARNETT—What per cent require a second abortion—a surgical abortion?

Dr Bayly—It is not a second abortion.

Senator BARTLETT—A surgical abortion.

Dr Bayly—It varies according to the gestation. None of these figures are that fixed but it is around five per cent or a bit less depending on gestation and according to a range of different study reports.

Senator BARNETT—So the longer gestation, the higher the per cent?

Dr Bayly—That is right, yes, in general.

Prof. Oats—With regard to surgical termination of pregnancy, it is a well-recognised complication that there may be retained tissue and they may require a second evacuation of the uterus. So it is not against an all or none.

Senator JOYCE—Professor Oats, do you think your statistical sample of 38 Australian women is a reasonable sample? With your knowledge of statistics, do you think that is a reasonable group of people to draw up a study on? I am referring to page 2 of your submission. You have done an in-depth study on 38 women who have had an abortion in the past. It is saying they have a high level of satisfaction, whatever that means.

Prof. Oats—That is referring to the only published study in Australia.

Senator JOYCE—Do you think 38 people is a reasonable sample?

Prof. Oats—No. We are relying on much larger experience and much larger studies. We referenced that because that is the only study done within Australia.

Senator JOYCE—But do you think that is a reasonable sample?

Prof. Oats—Not to make major conclusions on, no.

Senator JOYCE—No, I do not think so either.

Senator FIELDING—Are you across the Southern Cross Bioethics Institute research at all? They have substantially higher numbers than 38. Have you come across that research in submission 1012?

Prof. Oats—I have not read that, no.

Senator FIELDING—Has anyone else at the table read that submission?

CHAIR—I think that is as far as we can take that.

[9.50 am]

FRANCIS, Ms Babette, Endeavour Forum Inc.

FRANCIS, Mr Charles, Private Capacity

MONGAN, Ms Carolyn, Councillor, Australian Capital Territory Right to Life Association

PIERCY, Dr Mathew, Medical Adviser, Right to Life Australia

TIGHE, Ms Margaret, President, Right to Life Australia

WOOLF, Ms Kath, President, Australian Capital Territory Right to Life Association; Spokesperson, Australian Federation of Right to Life Associations

CHAIR—I call the inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 back into session. I welcome to the table representatives of Right to Life Australia, the Australian Federation of Right to Life Associations and Mr Charles Francis. Do you have any comments to make on the capacity in which you appear?

Ms Francis—I am assisting Mr Charles Francis—junior counsel.

Mr Francis—I am here as a lawyer with experience in abortion cases. Also, I have studied the Danco cases.

CHAIR—Thank you very much to each of you for your appearance here today and for the submission which you have made to the inquiry. Evidence on parliamentary privilege and the protection of witnesses and evidence has been provided to you, I understand, so you understand what the rules are there. You each made submissions, but would you like to follow through now with an oral statement to support those submissions before we proceed to ask you questions. Perhaps we could start with the Australian Federation of Right to Life Associations.

Ms Woolf—The Australian Federation of Right to Life Associations submits that the decisions concerning the importation of drugs intended to cause the death of a human being, such as RU486, into Australia should be taken openly in the parliamentary arena. We therefore oppose this amendment bill, which would take the decision from the minister for health. Our particular concern is the misleading drafting of the bill. It should be noted that the discussion of the bill in the community and before this committee, because of its terms of reference, has been focused on the regulation of RU486 exclusively. I have not read all the submissions, but I cannot find one that does not do that, except ours. However, the bill provides for the repeal of section 6AA, 6AB and so forth of the Therapeutic Goods Act. Consequently the definition of 'restricted goods' goes.

Section 6AA, the first subsection of the act, says:

In spite of any other provision of this Act, a person must not, without the written approval of the Minister, import any restricted goods into Australia.

The dictionary of the act, in section 3 subsection (1), says:

"restricted goods" means medicines (including progesterone antagonists—

of which RU486 is one—

and vaccines against human chorionic gonadotrophin) intended for use in women as abortifacients.

This means that, if the bill is passed and those sections are repealed, ministerial responsibility approval not only of RU486 but of a whole host of abortifacient drugs and vaccines will be removed.

This effect is conceded, along with contradictions, in the explanatory memorandum to the bill. It says—and I will give this to the committee:

The purpose of this bill is to remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility—

and so on. Further down it says:

In 1996 amendments to the Therapeutic Goods Act were passed that placed medications such as RU486 in a special group of drugs known as 'restricted goods'.

… … …

The amendments to the Therapeutic Goods Act 1989 in this Bill will bring the approval process for medications such as RU486—

and so on. The contradictions in the memorandum are quite breathtaking. In one paragraph it is RU486 that is the subject of the bill—and indeed that is in its title and that is in its purpose clause, which is so significant in law. Then it switches to 'medications such as RU486'. The effect of the bill is indisputably to remove ministerial responsibility for approval of all drugs—present and future—that are or would be covered in section 31.

The whole mess is due to a wrong assertion by the bill's proponents in the explanatory memorandum. It is a single-line paragraph in the middle of the single page or so. It says:

RU486 is the only medicine that is subject to the restricted goods condition.

I have no idea how one could reach that conclusion. It is incumbent on the proposers of this bill to inform the parliament, this committee and the Australian public about exactly what they intend by this bill. Most importantly, would they please tell us what would be the full effect of its passage. That is the conclusion of that section.

Then there is the background to the Therapeutic Goods Administration amendment of 1996. As an abortifacient, RU486 was a prohibited import to Australia, unless exempted by the Department of Human Services and Health, pursuant to the Customs (Prohibited Imports) Regulations. RU486 gained access to Australia through the Clinical Trial Notification Scheme and was authorised by an unidentified official with the TGA prior to 1996, contrary to undertakings given to the parliament that no such exemption would be given unless the minister were consulted. The then health minister, Carmen Lawrence, maintained that having committees, such as the Victorian Family Planning Ethics Committee and the New South Wales Family Planning Association Ethics Committee, approving such trials was a very substantial responsibility and that leaving matters to medical experts was not satisfactory in these matters. The outcome is the restriction we now have in the act.

In view of the great faith in the TGA expressed by previous witnesses, I would like to comment briefly on the reviews of the TGA's effectiveness. During the 1994 hearings of the Senate estimates committee, Dr Malcolm Wright, the then head of the drug evaluation branch

of the TGA, admitted the TGA had not carried out any assessment of the quality, safety and efficiency of RU486, nor had it scrutinised legal and ethical implications of RU486 before the exception had been given for the clinical trials.

In my full submission, which the committee has, I have summarised for them, with attachments, all the audits that have been done on the TGA by the Australian National Audit Office from 1996 onwards until last year, including a consultancy done by Deloitte within the department. For the purpose of time, I will mention just two of those outcomes. In the follow-up audit of 2000, the National Audit Office said:

- as the TGA relies primarily for its evaluation of a drug on the data provided by the manufacturer, the ANAO renewed its recommendations—

this was going back to the 1996-97 audit—

that the TGA should improve its management of the monitoring of adverse reactions to registered drugs.

In their own employed consultancy done by Deloitte last year, Deloitte said:

- an analysis of the performance management system for the regulation of all therapeutic goods ... including improved means for public reporting of outcomes, indicators and targets had not yet commenced.

That is, the long series of recommendations made in these audits were barely under way.

I will speak very briefly indeed about the problems with RU486, because there is so much material before the committee. All I want to say is that initially there were extravagant claims that this drug would mean that women need not require the intervention of any medical personnel—that was actually said—interfering with the woman's right to an abortion. RU486 would enable women in rural and remote areas to have safe and easy chemical abortions. Even over-the-counter sales were once mooted by a gullible media. All this dangerously inaccurate propaganda has been retreated from, step by step, without apology, yet support for RU486 so far displayed by some witnesses to this committee focuses almost entirely on expanding choice in methods of abortion without sufficient regard for the safety of those choices. We are not necessarily allowed choices for our arthritis or other things. It is really to do with safety. In light of what is now known about the drug and the distress and danger it can cause to women, the present provisions for parliamentary scrutiny should remain.

I will conclude by saying that it is undeniable that drugs—not just RU486—to procure abortion have unique significance. They are not designed to cure any disease or medical condition; they are not therapeutic; they are intended exclusively for procuring the miscarriage of a pregnancy, absolutely irrespective of whether the pregnancy is a perfectly healthy one, as it would be in the vast majority of cases. Yet Senator Nash, in her second reading speech on 8 December 2005, argues that all medicines should be regulated by the TGA. Perhaps—but I do not think that drugs aimed specifically at aborting foetuses are medicines. I checked the dictionary, and *The Macquarie Dictionary* says that medicine is something that has an intended curative purpose. 'Therapeutic' had much the same definition. RU486 is the only medicine, so-called, that is subject to restricted goods condition. That is what Senator Nash said. That is clearly not the case. I would welcome any further questions on the list of prohibited imports, which list a whole range of abortifacient drugs which are presently acknowledged.

Abortion remains an issue of grave moral and social significance and is still governed by legal constraints in all Australian jurisdictions, with the exception of the ACT. There is doubt as to whether the prescription of RU486 or any similar abortifacient drug in early pregnancy would meet the legal tests in Australian states and the Northern Territory, because despite repeated assertions that abortion is legal in Australia, except in the ACT, there are sections in the Criminal Code in every other state and in the Northern Territory which set gateways into lawful abortion, they set conditions and so forth. In conclusion, we oppose the adoption of this amendment bill.

Mr Francis—Before I begin, I just want to mention that there is one very brief, small mistake in my typed submission. In the third paragraph I said that I had appeared in a case where foetal parts were expelled. In fact, I have appeared in two such cases. It is at the beginning of the third paragraph.

CHAIR—Is this the covering letter or is it the body of the submission?

Mr Francis—It is the submission. I do not think it is of significance, because I will be dealing with it in what I have to say.

CHAIR—I am sorry, what is the change that you suggest?

Mr Francis—Reading it, I say:

I have acted for and obtained damages for women psychologically traumatised by abortion, including a case—

it should be including two cases—

where a woman passed recognizable fetal parts.

CHAIR—Thank you very much for that.

Mr Francis—I practised law for 54 years and was awarded an AM for services to the law. I have lectured and advised on abortion problems and abortion cases in Australia and overseas. In particular, I have lectured at the House of Lords and at a medical conference in Buffalo, New York. Articles by me on these topics have been published in the United States and Australia.

Firstly, I want to deal with the Danco cases. The Danco cases are highly relevant to your inquiry. I have read three of the Danco briefs, and they contain a wealth of information about the problems and adverse effects of RU486. In these cases there are a wide range of allegations against Danco and Population Council, but in essence they are product liability cases conducted by a product liability firm. RU486 is alleged to involve unacceptable risks of serious injury or death.

Danco has never been a pharmaceutical company of repute. It appears to have been founded in or about 1995. Its founder and first executive director was exposed in 1996 as a disbarred lawyer and a convicted forger. The use of RU486 is forbidden in Canada and in China, where it is manufactured. The US FDA is at present conducting an investigation into RU486. There is also a bill before Congress, HR1079—it is known as the Holly bill—which is to provide for the banning of the use of RU486 until the FDA completes its investigation. With this information in mind, and having read the Danco briefs, as a senior lawyer

accustomed to advise in this field, in my view any minister or government would be grossly negligent to allow the importation of RU486 into Australia as an abortifacient.

Secondly, I want to turn to abortion and its effect on a woman's life. An abortion is ordinarily a very traumatic event in a woman's life. There is a wealth of medical and other material showing its adverse consequences. This was already well known prior to 1995. In my experience as a lawyer, abortion is particularly traumatic when the woman passes foetal parts which she sees and identifies.

The first abortion case in which I acted is known as Ellen's case. The plaintiff passed some foetal parts in her own home subsequent to a surgical abortion. Subsequently, she suffered severe psychiatric problems and was unable to work. This case was settled on 29 September 1998 and it is believed to be the first such case in the world to reach a conclusion. There was an excellent article in the *Herald Sun* giving a very accurate picture of the case and I have copies of that. I do not want to go into further detail; you have the opportunity to read about it if you want to do so.

Senator BARNETT—Could you table that?

Mr Francis—Yes, I am happy to table that. It is an article from the *Herald Sun*, 29 September 1998. The client who was worst affected by an abortion—of all the women for whom I acted—following a surgical abortion, passed in her own home two complete legs, a spinal column, a rib cage and heart and a head with glazed, staring eyes. Three years later, in August 2001, when her case was settled, she was still deeply disturbed and dysfunctional. She had continuing gross psychiatric depression and there was no immediate likelihood of her working again. Now, although they may be very small, seeing the foetus or foetal parts seems to bring home to the woman exactly what she has done. With RU486, this is likely to happen often. I point out also that, when a surgical abortion is performed, if it is competently done they check all the foetal parts to ensure there has been a complete expulsion of the foetus. If a woman expels the foetus in her own home, equally, she should check out the foetal parts, and that of course would be likely to be grossly traumatic to her. As legal adviser to an NGO, Endeavour Forum Inc. with special consultative status with the United Nations, I have gained added knowledge from those of its members and its associates who do post-abortion counselling.

Thirdly, I want to touch briefly on what Ms Woolf mentioned. The *Oxford Dictionary* definition of 'therapeutic' is curative or healing and the branch of medicine concerned with the treatment of disease. Consequently, abortifacients are not therapeutic goods and do not fall within the ambit of the Therapeutics Goods Administration's responsibility. I may say that the *Oxford Dictionary* is ordinarily used in the law to determine the definition of words. The question of whether we should import RU486 for the purpose of killing the unborn child is a very important social question. It is not a medical or a therapeutic question and it is far too important to be left to a bureaucratic body not directly responsible to the people. It must be the direct responsibility of the executive, either the minister or the cabinet. I see many other legal problems in the bill and what it proposes. Some of those problems will no doubt be raised by other witnesses. Thank you.

CHAIR—Thank you very much, Mr Francis. We have received the clipping that you tabled; thank you for that. Mrs Tighe?

Ms Tighe—A lot of the people behind say they cannot hear what we are all saying.

CHAIR—So I would encourage all of you to speak into the microphones.

Mr Francis—I brought in one of the briefs from the Danco case. I have three, but I think, if anyone wants to read about it, reading one brief will be sufficient—and I will tender that as a document.

CHAIR—You would like to table that document?

Mr Francis—Yes. I will table it. I am happy to table it. It is the Danco brief in Chanelle Bryant and Danco Laboratories.

CHAIR—Thank you. We will receive that document. Mrs Tighe?

Mrs Tighe—Thank you very much for the opportunity to address the senators. I would like to point out that, of all of the legislators around the table here today, none of them were in the parliament back in 1973 when some of us here were involved in opposing the infamous McKenzie-Lamb abortion-on-demand bill. I was around in those days; I freely acknowledge that. I would like to point out that, in dealing with this legislation, the federal parliament is really poised—assuming the Senate and the rest of the parliament accept the legislation—to give a final imprimatur on the abortion-on-demand practice which is occurring in this country, something which the federal parliament has never done before. There was another debate in federal parliament, in the Senate, on the motion of Senator Susan Ryan. I am not sure—what year was that, Kath?

Ms Woolf—1978.

Mrs Tighe—1978. And that was overwhelmingly defeated. Then there was the debate on federal government funding of abortions in 1979, known as the Lusher motion. As most people here realise, it is an absolute disgrace that Medicare is used to fund the killing of unborn children in this country. Having said that, that motion was passed. But although it was passed it was said that federal funds for abortion could only be used where abortions were legal. What we are talking about here today is unleashing into the community a practice of abortion which would apply willy-nilly—abortion on demand. As you know, it is the states' job to legislate on abortion. The three most populous states in this country—Queensland, New South Wales and Victoria—have never passed any legislation to allow the current abortion-on-demand situation that occurs in this country. Those three states are responsible for the greater number of abortions in this country. If this legislation is passed, the federal government, for the first time ever, will be giving a final imprimatur on the abortion-on-demand practice in this country, which would apply to all abortions—not only those that are, strictly speaking, illegal.

The current push to unleash RU486 in Australia is being represented here by the legislation before the Senate, which we are all concerned about today. It is not just an argument about ministerial responsibility for the use in Australia of this particular drug. The very reason the federal health minister has responsibility for the decision as to whether or not to allow RU486 to be used in Australia is that it is a drug designed with lethal intent—the intent being to kill

an unborn child and so end a pregnancy. When I was studying pharmacy, I was taught that there are two categories of drugs: therapeutic and prophylactic. Therapeutic drugs are to cure and/or alleviate a medical condition, and prophylactic drugs are to prevent an undesirable medical condition. It is the role of the TGA, properly, to scrutinise such drugs as to their safety and efficacy before allowing them onto the Australian market. RU486 does not fall into these categories. It is a drug, as I said earlier, designed to kill a developing child within a mother's womb. So what we are dealing with here is a moral and ethical issue—one that should be decided not by bureaucrats but by elected representatives responsible to the parliament and to the people.

The other thing I would like to say concerns the companion drug that is used following the administering of RU486: misoprostol, or the brand name Cytotec. I remember dispensing many of those over the years and just last night I read in the *Australian Prescription Products Guide* the description of Cytotec by the company that manufactures it. 'It is indicated in the treatment of acute duodenal and gastric ulcers. It is contraindicated in pregnancy.' It goes on to say:

misoprostol

—which is the chemical name—

must not be used by pregnant women, as it may cause miscarriage—

Miscarriages caused by misoprostol may be incomplete,

and this could lead to potentially dangerous bleeding, hospitalisation, surgery, infertility or death.

Women are advised not to become pregnant while taking misoprostol. And the company made it clear in an article in *the Australian* that this was something that they were not going to be responsible for. And yet this drug has been seized upon to be used in a manner for which it was never intended.

I will get back to what is at stake with this legislation. The proponents of the legislation are telling us: 'Other drugs are allowed to be used in this country. Why is there this problem with RU486? Why should the health minister, whoever the health minister may be in the future, have that power?' It is obvious that it is an ethical, social, moral and political issue. If that were not the case, why would there be a conscience vote allowed in this debate? A conscience vote is only allowed by the major political parties in relation to issues dealing with life and death—euthanasia and abortion.

Why has this legislation come about? I am challenging some of the people here today. I believe that a certain element in the federal parliament wants to see the practice of abortion in this country even more entrenched than it already is—one for every 2.8 live births—and government funded through Medicare. In other words, they have wall-to-wall abortion, it is government funded, but they are saying: 'Women must have more choices.' God help the women! Think of the children lost and the mothers harmed by all these abortions. Do we need more?

Protagonists of the legislation maintain that it will not lead to more abortions, but I absolutely refute that. With abortions today, women turn up at abortion clinics or major public hospitals—wherever they are done—but in many instances the referral comes from the GP.

He or she generally does not carry out the abortion. In this instance, GPs will be able to prescribe and administer RU486. It is not as though the young woman in question can be on the table and get off at the last moment, as has happened, and I have spoken to some who have done that. No: she will carry out the act of swallowing the pill. What if she has second thoughts after it has gone down? Too late! She has to go and have misoprostol. Some of them will not want to go back and have that, because they will think, 'What have I done?'

I believe that we will see more abortions. How will we know whether or not there are more or less? Will there be any restrictions on the number of RU486 prescriptions that doctors can write? As well as that, what about adherence to the law? There are laws on abortion in Tasmania, Western Australia and South Australia. As for the ACT, God help us! There you can kill a child up to birth. Nonetheless, even if there are restrictions—and some medical practitioners are being conscientious about the restrictions—who is to know? GPs just write the prescription and the poor unfortunate woman is the one who has to take the pill. She will then go away and feel guilt and grief, as many do. Believe you me, I have spoken to many women who have had abortions. You might wonder why they would ring me and tell me about it. In fact, the young woman in the case Mr Francis described rang me and told me of her experiences. It was very tragic listening to her describing her experience of retrieving the foetal parts from her toilet.

We know that in many instances RU486, and the subsequent misoprostol, can cause incessant heavy bleeding. I will not talk about the deaths or other aspects of the medical risks; I will leave that to me colleague. Nonetheless, there were obstetricians and gynaecologists from Mildura, in the north of Victoria, quoted in the *Sunraysia Daily* on 9 January as saying:

> Apart from giving the women an option to have either medical or surgical termination, the use of RU486 would enable most women to have the option of having the miscarriage at home and hence save all the travel time.

How many women have had miscarriages at home? I am fortunate that I never had a miscarriage at home. But, believe you me, it is very unpleasant for women who have had miscarriages. They grieve for that child. These are women who want the baby. This was the attitude of Professor Pettigrew and a couple of his colleagues in Mildura: 'Yes, they will be able to have the miscarriage at home.' God help us! That is how much concern is expressed for women.

I believe there are three reasons why this legislation should be opposed. Firstly, because the nature of RU486 is to kill. Secondly, I believe the health risks that are going to be inflicted upon Australian women are going to be even greater than we have already with surgical abortions. We know that from a recent New Zealand study of the effects upon mental health of women who have had abortions. I have spoken to women myself, and I know how many of them have been affected by it. Thirdly, if we allow this legislation to pass, we are going to further entrench within this country the practice of killing unborn children—one for every 2.8 live births. It is an absolute national disgrace and a great national tragedy when you think of all those children who have been lost and all those mothers who have suffered as a result.

My final word is this: I have talked to people who might have been aborted and I have talked to their mothers, who thought about an abortion because they were really up against it at the time—they were single mothers, for example—and I cannot help but contrast the ones I

know very well whose children are growing up with the unhappy women I have spoken to who really would love to have that child back. I think this is what we have to reflect upon if we are going to give the green light to even more abortions in Australia.

CHAIR—Do you wish to make a statement as well, Dr Piercy?

Dr Piercy—Yes, just a brief one. The debate on RU486 is more than a debate about which method of abortion is safer or about maximising so-called choice for women. RU486 represents in a very real sense abortion on demand. If the amendment under debate is passed and RU486 abortions are permitted by the TGA, abortion will become an entrenched part of Australian culture, sanctioned by the House, administered by the TGA and paid for by Medicare. This is the most compelling reason why I believe we must resist absolutely this move to allow RU486 into this country.

An RU486 abortion represents an unsafe abortion. The recent news that Italy has been added to the growing list of countries in which RU486 has been banned after the tragic deaths of previously healthy women should be cause for pause and consideration rather than building a case for rushing through legislation over Christmas that would seek to allow this dangerous substance to be unleashed upon our hapless populace, who neither know nor understand the dangers and risks involved.

CHAIR—Thank you very much to all of you who have made statements.

Senator MOORE—I only have one question, and it is to anyone. Ms Woolf, you mentioned the TGA specifically in your submission. I just want to know, as I asked the previous witnesses, about experiences that any of you have had in dealing with the TGA and what, if any, those have been.

Ms Woolf—No, of course I have not, because you would have to be a medical practitioner or make an application through a hospital institution. But the public have a lot of information about the TGA. You only have to look at the audits that were done from 1996 on. I think the ANAO is quite competent to deal with that. My previous remarks, and I have put them into my full submission, were not to denigrate the TGA and the job it does with many things, but there certainly are problems with the TGA. The *Australian* reported on one of the audits that I emphasised in my submission. It said that there were 26 recommendations from the ANAO in their latest audit of the TGA about management and documentation, which is poor, and there was another particular concern. The article says:

However—

it—

was moving—

it hoped—

... more swiftly to notify consumers about potentially dangerous medications.

The number of drugs given black-box warnings by the FDA—

in the United States—

has more than doubled in the past year. The warnings, which require drug companies to publicise potential side effects on product packaging, are the strictest a regulator can order.

The FDA in the period from January to September 2005 issued 57 black box warnings, which is just short of banning the drug. In relation to 20 of those 57 drugs, which are in Australia, the TGA has issued only five. The ANAO found that it is slow to follow up.

I do not see that I need any personal experience with the TGA. The three ANAO audits of 1996-97, 2001 and 2004, and the follow-up one of Deloittes said, as I said in my short submission today, that they really rely primarily for evaluation of a drug on the data provided by the manufacturer. We know how fraught this has been in relation to abortifacient drugs. I think Australia has been lucky in that sense not to have had the drug approved for the last nine years, because now the information is rolling in.

The ANAO renewed its recommendation that the TGA improve its management of the monitoring of adverse reactions to registered drugs. Unlike the evidence given on 15 December last year by the AMA, the TGA was not fearless in acting on Vioxx. Vioxx was universally recalled by its manufacturer. An analysis of the performance management of all therapeutic goods, as recommended by this series of audits, says Deloittes—the department of health's own consultancy—to follow up on these many recommendations about the TGA, has not yet commenced. I do not know why people would place such faith in the TGA, that in the present and in future the TGA is looking after and will look after this. The TGA has not looked after Australian consumers in respect of drugs we share with the US, where the FDA has issued at least four to five times as many black box warnings on the same drugs. The health consumers association also note that in the United States, when the FDA does issue these black box warnings, with all sorts of exclusions, they are put on the label. They are for the patients. In this country, those go to the doctors, not to the patients. So you are very reliant on things coming downstream and not getting lost on the way.

Senator MOORE—Through the medical process?

Ms Woolf—Yes. None of this is my assertion. These are the audits, and I have submitted them.

Ms Mongan—Could I just add that both Mrs Woolf and I have been senior officers in a government department for some time and we did deal with audits as part of our experience there. So it is not direct, but there is an indirect link in interpreting this information.

Ms Woolf—Even though they lammed programs that we were concerned with, I think the ANAO is a very fine organisation.

Ms Mongan—It really is. It is very good.

Senator MOORE—You are quoting in your submission and in your evidence the public ANAO reports and recommendations?

Ms Woolf—Yes, they are all on the ANAO web site.

Senator MOORE—Do the other witnesses have direct linkage with the TGA?

Mr Francis—The TGA has the reputation of being very slow. I have a daughter who is a cancer specialist, and she frequently complains about its slowness. In particular, she has complained about its slowness with Herceptin, which is a drug for breast cancer. Unfortunately, whenever they are slow, it is the minister who gets the blame.

Senator MOORE—This knowledge came through someone else, Mr Francis?

Mr Francis—Yes.

Senator MOORE—Does anyone else have experience with the TGA?

Dr Piercy—Yes, I can speak on my indirect experience of dealing with the TGA through a body I am associated with which deals with anaesthetic deaths. They were investigating deaths related to epidural infusion devices and rapid blood infusion devices. It was really pushing from the medical practitioners and coronial investigations that caused the TGA to act and place warnings on these devices rather than the TGA itself taking the initiative in these cases.

Senator MOORE—It was the medical profession in that case.

Dr Piercy—Yes.

Senator MOORE—I am interested about the process and whether the concerns you have raised would then be extended to other drugs.

Ms Woolf—Some of the proponents of the bill seem happy to—

Senator MOORE—I am talking about other forms of drugs, Ms Woolf. This particular legislation is looking specifically at one group, and I take your point.

Dr Piercy—I would like to comment on that. In the United States, the FDA has recently had egg on its face, if you like, following a number of deaths related to the analgesic Vioxx. That drug has subsequently had to be removed from the market. So these processes are not perfect. That drug was approved by the FDA following the assessment process which all drugs go through, and subsequently it was found that there was a statistically increased risk of myocardial infarction and the drug had to be removed. But, again, it was only after political pressure was placed upon the FDA and, following that, the TGA that the drug was actually removed.

Mr Francis—When the FDA approved RU486, under considerable political pressure from Clinton—they approved it in September 2000—the only basis on which they had the approval was one test in the United States and two tests in France. They then, as a subject of their approval, required that six further tests be carried out. Those tests have never been carried out and this is one of the matters raised in the Danco case, that RU486 for that reason, and others, is being distributed illegally in the United States.

Senator FIELDING—Margaret, you touched on the issue of setting policy with regard to supporting this bill. Do you agree that it is the job of elected leaders and members to make policy and it is the job of unelected bureaucrats to implement and advise on policy?

Ms Tighe—That is right but having said that I think it is the duty of every legislator to uphold the most basic of human rights—I am getting in a little commercial here—and the first of those is the right to life itself. Quite clearly, legislators are charged with the responsibility of making laws by which we are all meant to live and they also set the tone for the country. Legislation which is passed has a very educative effect upon members of the community. So you have a very heavy responsibility and I am sure you are all aware of that.

Senator FIELDING—In the submission that you have put together it seems to me that this is a major social policy issue. Do you think it is the job of elected leaders to decide on it?

Ms Tighe—I believe so. With that in mind, the statement I made earlier was that the first responsibility of any elected legislator is to uphold the most basic of human rights. I believe that that is the case. We know that some state parliaments have passed legislation relating to abortions. As I pointed out earlier, the most populous states have never passed legislation to allow the abortion on demand practice that is occurring in this country and they would be responsible for the greater number of abortions in this country. The way I see it, it is not the role of the federal parliament.

By passing this legislation and saying, 'Let's have RU486,' anybody can have it. Where are the restrictions—never mind about the legality or otherwise of abortion. It would be taking a monumental step which the federal parliament has never taken before in its long history since abortion was first debated in 1973—with the exception of the debate on federal government funding of abortion, but even that had the rider attached to it that abortions should only be funded if they are legal. We know that that is not happening in reality. By passing this legislation you are giving an added green light to the practice of abortion in this country instead of saying, 'Isn't it time we did something about it.' We are losing all these children and we are damaging all these mothers.

Senator FIELDING—I have one final question. Do you believe it is a dangerous precedent to allow unelected bureaucrats to make policy decisions?

Ms Tighe—I believe so, yes. They do not have to answer to the parliament or to the people. I have not commented—and I think Dr Piercy would like to—on the number of medical risks associated with the use of RU486. It is most important that they should be dealt with.

CHAIR—We will deal with that if there is a question on that subject from a member of the committee.

Senator POLLEY—I asked a question earlier this morning of our first witnesses in relation to the meaning of the word 'therapeutic' and I did not get a response. I take that to mean that they did not have an answer. So I do appreciate the contents of the submissions this morning that were given verbally.

But I do have concerns. I do not think that this is purely a matter of choice between being a pro-choice person or not. I see this as obviously a very unhealthy situation for the baby, but it is detrimental to the wellbeing of women. We have had a lot of evidence come before us about the psychological damage that is done in the longer term. We have had some evidence—and I would be most interested to hear Dr Piercy's evidence—as to the psychological damage and mental health. Also, a lot of the evidence that has been brought before us has been based on things that have happened in the United States. Quite frankly, I do not happen to think that because it happens in the US it is good for Australia. I would like to hear your evidence as to the medical and psychological damage that may be caused if this drug is allowed to come in for this purpose alone.

Dr Piercy—If I could table an analysis in a recently published article of the severe adverse events related to the use of mifepristone as an abortifacient, I think that would be very helpful.

Senator BARNETT—Where is that from?

Dr Piercy—*The Annals of Pharmacotherapy*.

Senator MOORE—I cannot hear anything you are saying.

Dr Piercy—I would like to table a document which deals with the severe adverse events which have been reported to the FDA regarding RU486. In summary, this report described a number of severe adverse events. It collated and reported them in this article which was written by a specialist obstetrician gynaecologist and a colleague. There were 237 cases of haemorrhage and 66 cases of infection. There was one fatal haemorrhage, 42 life-threatening cases and 168 serious cases of haemorrhage, with 68 cases requiring a blood transfusion. Seven cases of septic shock were reported—three fatal and four life-threatening—and 43 cases requiring IV antibiotics. Surgical interventions were required in 513 cases. There were 235 cases requiring emergency surgery. Emergency surgical cases included 17 ectopic pregnancies, 11 of which had been ruptured. There have now been 11—in the report it says eight—known deaths to date, including five due to septic shock, three of which have been linked to clostridium sordellii and two infection related deaths which are currently under investigation. I think that deals in a broad sense with the serious complications associated with RU486.

There has been a lot of discussion about mortality rates between surgical and medical abortion. It is important for the record to understand what Professor Greene—who is the Harvard professor of obstetrics and gynaecology—said in his article, because I think it has been a little misrepresented, that the rates were comparable. He draws his denominator of the number of abortions performed from the number of prescriptions of RU486. That is how he determines the denominator of the number of deaths versus the number of abortions which have been performed using RU486. He goes through that in some detail in his article. He says, 'These figures would suggest that the risk of death from infection is less than one per 100,000.' He then goes on to describe how the death rate for surgical abortion is calculated, and it varies according to gestational age. He states that the more appropriate comparison is the mortality rate for surgical abortion at less than eight weeks, because that is the time when RU486 abortions are performed. He says that the risk at that gestational age is 0.1 per 100,000. So there certainly is a difference. He does not say that these mortality rates are comparative. He says that they are different, and they should be put on record as something to take into consideration in public policy debates on this issue.

Mr Francis—Professor Brind, at the Baruch College in New York, has said that cytotec used in this way is likely to produce cases of liver cancer because it interferes with the metabolism of the liver. I would also point out that the use of RU486 will produce cases of breast cancer. But in that regard, it will be exactly the same as surgical abortion. You would not differentiate the figures between the two, but they are each a cause.

Ms Woolf—In fact, Professor Greene says that if you keep the gestational age the same for surgical abortion as for RU486 the rate increases from 0.1 per 100,000 for surgical abortions at the earliest periods up to 8.9. It is an enormous factor of increase if you hold the gestational age the same for surgical abortion and for RU486, because quite often all surgical abortion, as has been said, is lumped together, but the risk increases greatly as the period goes on. You

really need to take the mortality and infection rates for surgical abortions done up to seven or eight weeks, where they are very safe in these effects, and compare them with those for RU486 in the same period of time. The risks increase remarkably—up to ninefold or tenfold.

Senator POLLEY—We heard evidence this morning that the expelling of a baby at home is no different to what women the world over experience on a monthly basis. I have some concerns with that. Do you have a medical point of view, with your experience, that can enlighten us as to the likely impact of having an abortion at home, out of medical supervision?

Dr Piercy—You could draw on the cases that Mr Francis has discussed where the women were severely traumatised by the experience of passing foetal parts. To say that that is the same as a normal menstrual period is quite ridiculous.

Senator McLUCAS—According to some it is more like a miscarriage as opposed to regular monthly menstruation.

Senator MOORE—That is right. The word was 'similar', not 'the same'.

Ms Woolf—From one who has experience of miscarriages, the sheer volume of loss is not like an ordinary menstrual period. People are also ignoring the whole context in which this drug has been administered. Someone is deliberately inducing in herself a miscarriage. Therefore you are told it is part of the ordinary procedure by which this abortion, this miscarriage, is going to take place. Look at the evidence of two recent deaths in California. A young woman—16 or 17 years old—rang the surgery, and that is what you are supposed to do. She had had her RU486 and she had had her progestin based thing to help the contractions. She rang with a slight fever. They said: 'That's all right dear. It's all in the documentation. You will experience a slight fever.' She said, 'But I'm having terrible pain.' They said, 'Well, you are expelling a foetus.' I do not think people really realise what is happening. In another phone call she said, 'I'm bleeding.' They said: 'You'll have to expect that. What do you think's happening to you?'

If a woman who is continuing with a pregnancy starts losing blood or has a fever, what does she do? She goes off to hospital or to the emergency room. She seeks medical help, because this should not be happening—and she is right. She will be told to have bed rest. She may even be admitted or, if the miscarriage is going to proceed, it will be monitored. This is just commonsense. I am sure people around the table all have experience of this. But this woman was told that this was something she was doing at home. As I said in my full submission, a woman is left to be the manager of the fever, how much pain is appropriate and how much bleeding is appropriate—two pads full every two hours. This takes a woman not aborting herself off to hospital, definitely. But this person is told to stay at home and manage it. This is a great choice for women. This is why it is so dangerous.

Senator FIELDING—Did you want to follow up with someone the question I asked before?

Ms Woolf—I was going to mention Professor Greene's article with the greater death rate in the *New England Journal of Medicine*, but it was already covered.

Mr Francis—When the FDA approved RU486, they required that those who were prescribing it should have hospital facilities available with people in them expert in treating the problems of RU486. It is not just a matter of going to hospital; it is a matter of going to a hospital where they are familiar with the medical problems created.

CHAIR—Do you want to add something, Ms Mongan?

Ms Mongan—Yes. Could I add something about the particular drugs that are currently prohibited imports, because the Customs Act links into the TGA. Alprostadil, Carboprost, Dinoprost, Dinoprostone, Gemeprost and Misoprostol are currently also prohibited imports, as are vaccines against human chorionic gonadotrophin. I would like to refer the committee to Senator Harradine's tabling of the background on these, back on 9 May 1996, that is recorded in the Senate *Hansard*, where it explains the function of the vaccines against human chorionic gonadotrophin. I think that really should have some extra thought given to it as to whether that particular thing as well should be included in this without discussion, which it will be if this bill goes through in its current form.

Ms Woolf—Can I add that if you simply look at the Customs import regulations there seems to be not enough research gone into the drafting of the bill. There are the substances controlled under the Customs import-export legislation. At Appendix A—Substances subject to import controls, there is a whole list. Paragraph (d) lists all the drugs that Ms Mongan has just—and Ms Parker—mentioned. All of these are drugs which can be used for other things; we know that. They can be legally used for perhaps stomach ulcers or whatever. If their intention is to procure abortion, they require the approval of the minister for general distribution. 6AA if it is repealed—and 27AA and so on—cover all items in section 3(1):

restricted goods means medicines (including progesterone antagonists—

that is the second drug you take—

and vaccines—

as mentioned—

... intended for use in women as abortifacients.

So I still think there is an enormous responsibility on the proposers of this bill to tell us why the title says this is removing ministerial responsibility for RU486. It cannot do that unless it were drafted quite differently. It is removing it for all restricted goods such as are described in 3(1). And to give you a clue as to what already are abortifacient causing drugs if you want to use them for that purpose, they are in the import restrictions of Customs. I must return to the explanatory memorandum. It sometimes says 'RU486' and sometimes accurately says the effect of the bill will be to remove ministerial responsibility for medications 'such as RU486'. I wonder which it is.

CHAIR—I think we can perhaps come back to that issue.

Senator ADAMS—I would like to go back to the bill, and I did ask this question before. With the Therapeutic Goods Administration at the current time, they approve any drug or evaluate the drugs, and the minister—with RU486—has the right to approve that particular drug. Can any of you tell me where the minister will get the information needed to make an informed decision upon this particular issue?

Ms Woolf—We are not in a position to second-guess this minister or any other future minister.

Senator ADAMS—No, I am talking about any minister. It is the minister for health whether it is this one or one at any stage.

Ms Woolf—Anywhere he or she would wish. The TGA would have a role in that if it has data from the manufacturer, which is very limited data indeed. People can send in medical articles. I think this whole debate around the specific RU486 drug, which is marketed in the US as Mifeprex, has been very healthy and very useful. It has sent all of us to our medical journals. The Net is a marvellous thing. How would you have found what Professor Greene of Harvard had said? How would you have found all the FDA blackbox warnings? All these things have been contributed openly for people to look at. I cannot say that the FDA would not have done all of that. I have serious doubts, having read the audits, but if they had done it how would we have known? We have got a lot of educated people in this society with medical and many other sorts of degrees—and statistical degrees—and all of this information is there. The minister can seek it where he likes, including the TGA.

Ms Tighe—The bottom line in this debate is really the nature of it, isn't it? That is No. 1. That is why there has been this committee set up and that is why there is this great national debate and that is why there is going to be a conscience vote in the parliament. It is the nature of the drug—No. 1—because it causes abortions.

Senator ADAMS—To Dr Piercy, you made a comment that, if this drug were to be approved, it would increase abortions but, as a midwife, I have been sitting here thinking: 'Why is this going to increase abortions? Are women going to get pregnant just to have an abortion?' I do not think so. At the moment a woman has to go through certain and different states as to how she approaches this. If she makes a decision, it has to be an informed decision. There has to be a lot of medical involvement with this as to whether she has an abortion or not and whether she meets the guidelines to have an abortion or not. At the moment she can have a surgical abortion if she comes in under those guidelines and if the medical practitioners agree and all the other bits that go with that. But I really cannot see how this is going to increase abortions. I cannot see that anyone is going to get pregnant just to have an abortion.

Dr Piercy—If you look at certain sites in which RU486 has been introduced—there was one in the southern states of the United States where surgical abortion was the only method available, then RU486 was introduced into that site—abortion practice did actually change the numbers of prescriptions of RU486 and the numbers of abortions. Because it was available and did become more widely used, it certainly did change the practice of medicine with regard to abortion. So I cannot see really—

Senator ADAMS—You actually said abortions will increase.

Dr Piercy—Yes, I did say that.

Senator ADAMS—That is a very different thing.

Dr Piercy—I actually believe it will, and I think that is supported by the literature. I think to say that it will not is ignoring the ease of use of this medication: you only need to go to a

GP, have a prescription filled and then go home and have your abortion. That is quite a different scenario to having to present to a gynaecologist's rooms, go through the process of consent, have the operation, be booked on an operating list and have the procedure. It is quite different from having a prescription filled at a local general practitioner, going home and having the abortion.

Senator ADAMS—I do not agree. In all the other countries the guidelines are very strict. I was just in New Zealand when that particular study was done on the mental health side of women having abortions, and I have had a lot of discussions about the way this drug is used in New Zealand and the guidelines are very, very strict. Do you really believe that, if this drug were to come here, there would not be strong and very strict guidelines under which trained medical professionals have to work when a woman comes to speak to them about the fact that she has decided she wants to have an abortion?

Dr Piercy—I think you can make guidelines as strict as you like, but that does not require anybody to follow them. There are plenty of doctors who may not follow them. How many doctors in country areas have specialist skills in ultrasound interpretation or doing a haemoglobin? Is that accessible? Are laboratory facilities available for blood transfusion in these sorts of settings where this drug is being purported to be used by general practitioners? There would be women going home suffering severe complications, some of which require intensive care facilities which simply are not available in many parts of Australia. To say that a doctor can use this drug, it can be available at the local pharmacy, a woman can have an abortion anywhere we like and we just follow these simple guidelines is, to me, quite unsafe. I think that is the reason that this really needs to be considered.

Senator ADAMS—I would therefore argue against you as far as having 'just any GP'. They have to have surgical backup. They have to have a regional hospital nearby so that the patient, if need be, can have that access—and that will be part of the guidelines. As for the other evidence you gave as far as abortion increasing, all the evidence that I have seen and that we have had presented to us in probably nearly 5,000 submissions shows that abortion rates have not increased when there has been a choice of surgical or medical abortion.

Ms Tighe—Senator Adams, I would like to add to Dr Piercy's comments. You say you have worked as a midwife. You may not have encountered abortions. Well, you might have, so I will not ask you about that. What I wanted to say is: how much do you know about the practice of abortion in Australia today? You can find out a lot if you just sit on the phone one day and phone the various abortion clinics that advertise in the *Yellow Pages*. The main thing is to bring a certain amount of money and come fasting. As for counselling and informed consent, that is just ludicrous. That does not happen. Even when they had legislation in the ACT for a very short time, that was very quickly done away with because it was considered that that would only frighten people. That would not be followed up in your state either. I have had evidence to the contrary—that the informed consent that is supposed to be adhered to is just laughable. It is a matter of 'You're pregnant and you don't want the baby; we will oblige.' That is what happens.

In fact, the woman that Mr Francis referred to, who won damages because of the effects of the abortion on her, did not have that abortion at a common abortion clinic. She had it at the Royal Women's Hospital in Melbourne. She told me about what happened. She went with her

husband to seek advice about whether or not she should take this terrible step. They sat before one of the leading obstetricians and gynaecologists at the hospital and started to tell him what the problem was and why they were contemplating having this abortion. He said: 'You don't have to tell me all of that. You're pregnant and you don't want the baby—end of story.' I am afraid that is generally what prevails in Australia today.

Mr Francis—I would add that, in all of the cases I have seen, the counselling has been totally inadequate. Abortionists will not set aside the time to counsel women properly. To properly counsel a woman in relation to an abortion requires taking quite an elaborate family history and then warning her of the risks. The process would probably take well over an hour. Abortionists make their money out of doing abortions, not out of counselling.

Ms Woolf—A considerable percentage of people who come to pregnancy help or support services and have previously had abortions say that they received no counselling whatever. I would like to say in response to Senator Adams that I have no idea whether it is going to increase the rate of abortion. Who can tell? The fact is that it is a particularly brutal and barbarous way to inflict an abortion on the woman. Even if it were the same number, my view on surgical abortion is that, while I still oppose the taking of the life of the unborn, these people do have considerable practice. They do give you antibiotics on the spot. In most cases, the abortion will have been proficiently performed—to heck with the consequences later. But performing your own abortion at home and managing it over a period of up to 12 days is a barbarous imposition on women. I think it is ironic that it is the pro-life groups who are very concerned about this method of abortion and its effect on women. I think that concern is genuine and it has nothing to do in my mind with whether or not there will be more. I think it is extraordinary that so-called pro-choice groups seem to think that any choice is as jolly much fun as any other. All the evidence is to the contrary.

Senator BARNETT—We have had some debate this morning, both here and earlier, about the levels of safety and the risk of death when comparing chemical or medical abortions to surgical abortions. This morning I asked a number of questions about Dr Greene's paper in the *New England Journal of Medicine*. Dr Piercy, you have referred to it this morning. Clearly there appears to be a violent disagreement between the two main groups that we have heard this morning. You say there is a big difference in medical safety. This morning we heard that there is comparable or the same rates of safety in terms of surgical and medical abortions. You have referred to Dr Greene's paper—that there is a difference of one to 10 in terms of the levels of safety and risk of death. Firstly, could you table that document from the *New England Journal of Medicine* so that committee members can read for themselves the outcomes. Ms Woolf, you referred to it. Do you have any other evidence or views which support the difference in the levels of safety, risk of death and so-called health outcomes comparing surgical abortion to medical abortion?

Ms Woolf—One has to rely on the published data. You cannot take guesses. It is not a matter of ideology. It is a matter of data and facts. So I will just table the paper.

Dr Piercy—The whole reason that article was published in the *New England Journal of Medicine* at the time was that there was a cluster of four deaths in California which were all related to this Clostridium infection, which was previously very rarely seen. It was thought

that this was related to RU486 abortion, so they wanted to make practitioners aware that this is a potential complication.

The other important fact that they brought out in the article was the way in which these women presented. It was not in the usual way with discharge, fever, perhaps chills and so forth for an infection; they presented otherwise well, but with low blood pressure. The article was also published at this time so that practitioners would be aware of this toxic shock syndrome, which they think is a complication of the RU486 abortion. I think that is the best available evidence on the overall mortality data. As you might imagine, RU486 has not been around for a very long period of time and the number of deaths are accumulating over time compared to the number of prescriptions, so a death rate will become clearer with time.

Senator BARNETT—The second issue concerns some conflict about the need for surgical abortions following the use of RU486. Dr Bayly indicated that that occurred in up to five per cent of cases and Dr Wainer indicated in up to 10 per cent of cases. I have here the patient information sheet from the FDA in the USA. It specifically says:

The FDA is aware of four women in the US who died from sepsis after medical abortion with mifeprex and misoprostol ...

It goes on to say:

... about five to eight out of 100 women taking mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding.

Dr Klein says in her submission that five to eight per cent of women will require a follow-up surgical abortion. She equates those percentages to 2,000 to 3,200 Australians, if 40,000 Australians are taking RU486 each year. What is your view on those figures and which ones are right?

Dr Piercy—The five to eight per cent figure comes from an American study of RU486 in 2000, which was published in the *New England Journal of Medicine*. That study also described the rate increasing with gestational age and, for that reason, recommended that the drug not be used after seven weeks. When it was used up to 13 weeks, the rate was much higher.

Senator BARNETT—Ms Woolf, your submission referred to the definition of restricted goods. Thank you very much for that. This is an area of the debate that perhaps has not had adequate coverage to date. I think you have the list there; I would be happy if you wished to table it. Would you like to comment any further about the appropriateness of the types of goods that are restricted. Are they therapeutic or prophylactic? Are they designed to kill? What is their purpose?

Ms Woolf—On the list which Ms Mongan mentioned, a drug like misoprostol, which is from the prostaglandin group, was used in England for midtrimester abortions and sometimes to finish a natural death of a foetus in utero to start contractions. It was sometimes even used to promote delivery in overdue children. It was abandoned because from middle pregnancy on it is too dangerous. This is the second drug you take in the practice protocol for RU486. That one has some legitimate uses. It is already an abortifacient drug; it comes under the definitions in section 3(1). The others all have certain sorts of application, perhaps for stomach ulcers or something else. It says:

You must obtain permission from Therapeutic Goods Administration before you bring into Australia a medicine containing any substance listed below.

The paragraph is headed: 'Abortifacient substances for abortion, including ...'. But they can have other purposes with abortion not being the primary intent. If that is so, and that is what the TGA accepts as the truth, that is how they then should be prescribed. They are not for general release as an abortifacient because of the action of the act at the moment. They can be introduced into clinical trials, as we do now through another process already described by the TGA. That is fine. But they are not for general release with the purpose of procuring abortion. All these drugs would be available to be approved for abortion if the TGA were to approve them, if this bill were successful, without any further public discussion. It is just common knowledge. Again, I am totally puzzled as to why the statement in the explanatory memorandum says that it is the only medicine that is subject to a restricted goods condition.

I am also disturbed by the public misunderstanding that there is somehow a ban on RU486. There is not a ban on it. Some people seem to also think that if this bill is successful RU486 will be introduced. I would hope not, and we cannot predict whether, if our view prevails and the amendment bill is defeated, some minister may not subsequently approve RU486. The thrust of this whole debate is that it does have ethical and social significance and therefore it should remain in the parliamentary arena. We cannot predict what is going to happen or what minister will do what, and that is the plain truth of it.

CHAIR—Has the document that you referred to, Ms Woolf, already been tabled?

Ms Woolf—No. I will table it if you like—there is a little bit of scribble on it. If you go to the TGA web site, the links are there and they take you to the Customs regulations.

CHAIR—Can you table that so we have it on the record, thanks?

Ms Woolf—It is amazing what one can find out.

CHAIR—Is that other document you have on the table one that you also want to table? Okay—that is the article we have. That is fine. Do you want to add to that answer?

Ms Mongan—Yes. If I can explain the drugs on that list, they generally fall into three categories. They are either progesterone antagonists, which are outlined in Senator Harradine's speech of 9 May 1996; prostaglandins; or the vaccines against human chorionic gonadotrophin.

Ms Woolf—They bring about death and/or miscarriage in various ways and with various complications.

Mr Francis—In answer to the question that Senator Adams asked earlier about counselling for abortions and how the abortion industry functions, I was asked to write an article on this which was published in the United States, and I table that. It has a lot of information—if people want to read it.

CHAIR—Thank you very much. We will receive that article.

Senator NASH—I do not have a question, but I want to correct something for the record. Ms Tighe earlier made the challenge that some of the legislators around this table wanted abortion to be more entrenched than it already is. From my point of view, I have been on the record many times as saying I would prefer to see fewer abortions and that there should be

more education and prevention. In regard to myself, I certainly take exception to that and I refute that accusation.

CHAIR—I do not think we should have a debate on this. Being able to clarify those matters is a privilege that is reserved for senators.

Senator JOYCE—Professor Greene is a research person of good repute. There is no reason to doubt the paper he wrote for the *New England Journal of Medicine*. There is obviously a greater incidence of clostridium sordellii after the use of mifepristone. Would that be a fair enough statement?

Dr Piercy—It appears to be more common. It is hard to gain statistical information on that. The article which is in that paper describes four deaths.

Senator JOYCE—So there is a fair case that the incidence of complication from RU486 in the first eight weeks of a period of usage is far higher than the incidence of complication from surgical abortions. Is that a fair statement? The previous deputation wandered around this and said that there was not. They said that they are comparable, or similar, or the same. But they are not, are they? They are completely different.

Dr Piercy—Not according to Professor Greene.

Ms Woolf—He is a professor of obstetrics at Harvard and is also the practising obstetrician at their medical school.

Senator JOYCE—It is very important that we get on the record that the previous evidence we got was flawed.

Senator WEBBER—That is totally inappropriate.

Senator BARNETT—It is an interpretation.

Senator WEBBER—These are all opinions.

Senator JOYCE—So it would be a fair statement that women who otherwise would have had a surgical abortion but who take RU486 will—if these things play out in Australia—die.

Dr Piercy—Yes.

Senator JOYCE—Good. The next question I pose is to you, Mr Francis. If someone was to present to you as a client and say, 'My mother was given two alternatives, and they recommended the alternative which killed her,' do you think you would have an ability to raise a case against whoever made that recommendation?

Mr Francis—Yes, you would.

Senator JOYCE—Good.

Mr Francis—Although I do not approve of it either, if I were asked, I would say have a surgical abortion every time. It is much safer.

Senator JOYCE—That would be a legal premise, if you recommended something to someone that was explicitly more dangerous than an alternative that was available?

Mr Francis—Yes, you are negligent.

Senator JOYCE—And basically as a committee we would also be negligent in some form too by allowing that process to start?

Mr Francis—Yes. That, of course, is one of the main allegations against Danco, that they were negligent in recommending the drug at all.

Senator JOYCE—We have been glossing over the fact that we are killing a human life, but in the process we are also going to be killing a couple of mothers as well who would otherwise be alive?

Mr Francis—Yes.

Senator JOYCE—Our mercenary attitude means that we do not worry about that.

Mr Francis—I make this comment also: the average GP would not be in a position to know all the problems of RU486, and if he prescribed it he would do it negligently because he is not—

Senator JOYCE—Is that a defence that he could use? That he did not know that—

Mr Francis—No. He has a duty to inquire.

Senator JOYCE—So he would still be legally liable?

Mr Francis—Yes.

Ms Woolf—The FDA patient information sheet has a long list of women whose conditions are a contraindication for the prescription. There are a whole lot of conditions that a woman can have that this drug should not be prescribed for.

Senator MOORE—Aren't those black box warnings common process?

Ms Woolf—I was about to add that the black box warnings do not appear on the labels in Australia, as they do in the United States, so the woman would not know that these were contraindicated unless she were told.

Senator MOORE—You are actually stating a common practice.

Ms Woolf—We are relying a great deal on practice.

Senator JOYCE—It has also been put out by a doctor that it has been good for people in regional Australia. Do you think there is any reason RU486 would be any better for certain regions? Is there some access factor? We seem to have problems at the moment getting doctors out into regional areas of Australia because of the debacle in the health system. Nonetheless, do you think RU486 has a special application to regional Australia that is going to be of great advantage to those people?

Dr Piercy—I think it would be far more dangerous in regional areas.

Senator JOYCE—I think it would be too. What would happen if someone took the mifepristone, the antagonist, and then did not take the prostaglandin?

Ms Woolf—It is described in that article I circulated, that there is a high risk of abnormalities. The pregnancy can be carried to term. There is about a 20 per cent risk of severe abnormalities. The baby could be significantly compromised by a partial abortion and so forth.

Ms Tighe—I remember working in some country pharmacies. It was frequently the case that medicines were delivered out to the country to people who lived on farms a fair way out. They had been prescribed by the doctor but, in those instances, the woman would be taking it at home, and she would be given instructions to take the second dose so many days later. I could see it happening with this also.

Senator JOYCE—How long does septic shock take to kill you?

CHAIR—Senator Joyce, we really are running very low on time. We are going to have to move on to another witness. Senator McLucas has a question.

Senator McLUCAS—I have a couple of questions but I will put them on notice given our time. Dr Piercy, I think you said there was a southern state of the United States where, once RU486 was allowed, there was changed practice. Do you mean there were increased numbers?

Dr Piercy—There was certainly increased accessibility to abortion.

Senator McLUCAS—But my question was: were their increased numbers?

Dr Piercy—It was inferred from the article that that was the case.

Senator McLUCAS—Inferred. You then said—and I need this clarified—that increased numbers were supported by the literature. Can you provide that literature to the committee?

Dr Piercy—That article was describing the practice change that occurred as a result of the introduction of RU486 to that region of the United States.

Senator McLUCAS—In my research I have found no literature that says there are increased numbers. In fact, there are many documents that document an overall decline.

Dr Piercy—I can table that article if you like.

Senator McLUCAS—Thank you.

Senator NETTLE—I will only ask one question because I know time is limited. There was a study done in Adelaide—I am sorry I do not have all the details in front of me; I just thought of it while you were speaking—which interviewed women on their experiences post termination. I was quite surprised when I saw the studies of what the figure was of women for whom the predominant experience after having their termination was a sense of guilt about not feeling guilty for having had a termination, because a sense had been created in the community that a woman should feel guilty about having had a termination. There was a high proportion of women for whom that was not their experience. So, subsequently, they were experiencing the difficulty of being told by society that they were supposed to feel guilty about having a termination. I wanted to ask you what responsibility each of your organisations takes for creating an environment where these women experience grief, post a termination, because your organisations have been part of creating a culture of making those women feel that they should feel guilty when they have had a termination—when they have made a decision and decided that it is the very best thing for them to do.

Ms Tighe—The bottom line in the abortion debate is that we are talking about killing. The interesting thing is that this debate has been going on in the Western world since the passage of the UK Abortion Act in 1967. I began following it then, when I was a young mother with

two small children. Nonetheless, the issue has never gone away. It keeps on resurfacing and resurfacing. Why is that? It is because it is an act of killing. There are many women out there who are hurting following their abortions, not because somebody has made them feel guilty. I refute what you are saying. I think we have a duty to speak up for people who are having their lives snuffed out. I was most conscious when I first became pregnant myself, having had some difficulties for a couple of years—I knew that I was different then from how I had been a few weeks earlier—and I began to think of that child within me. Every woman knows that she has a child within her. She may want to get rid of it; she may be under a lot of pressure to get rid of it.

There are many women who are victims of the abortion mentality today who would never have had abortions once, had they been living in a different age. They are the ones who suffer the most. I believe we have a constant duty to speak out in defence of human life, because we know when human life begins. We can see it with our own eyes. You only have to show a photograph of a baby of three months gestation—less than that—to a child in kindergarten and ask: 'What is that?' They say, 'It is a little baby.' We want to deny the truth. I think we have a duty to keep on speaking out in defence of those children and in defence of the women who have been harmed and who will continue to be harmed following abortion.

Ms Woolf—As a representative of a number of state associations of right-to-life organisations, I flatly deny that anything I or my association or my members have ever written has ever said that women should feel guilty. We present the facts about the developing child. I ask you: who in Australia has started pregnancy help services? I started one in Canberra, because we realised that there was the problem. Do abortion services offer accommodation and baby clothes or offer to go to your exercise classes with you if you want to continue a pregnancy? Pregnancy help services will even be your birth companion and look after you for some weeks afterwards. In Canberra, we now have three houses on government lease—and I think Senator Humphries would know about them—which are all pushes by the pro-life movement and are for helping people who do decide to go ahead with their pregnancy but who have difficulties with poverty, unsupportive partners and so on. This is all an affirmation of the rights of women to choose to have the baby and an affirmation of the rights of the baby. I have never said that anyone should feel guilty. I think it more likely that our pro-abortion society and pro-choice propaganda are what induce the feeling in women that this is nothing. When they have the abortion, they find out that this is something.

Senator NETTLE—I understand the answers. You take no responsibility. Do you deny the results of the survey in Adelaide that some women feel guilty for not feeling guilty?

Ms Tighe—They may feel like that. Some of them that I have spoken to have not actually admitted these feelings until many years later. They deeply regret the fact that they had that abortion.

Senator NETTLE—That is not what I am talking about.

Ms Tighe—I know what you are talking about. You are saying that they feel bad because they really feel relief. That is what a lot of them would be thinking. Nonetheless, the guilt or the grief will come in later. I have spoken to many women who have had abortions—

Senator NETTLE—And I am not arguing about that.

Ms Tighe—and they have told me that themselves.

Senator NETTLE—I was just checking whether or not you accepted that there are some women for whom that is their experience, without making any judgment about it. I am just checking that.

Ms Tighe—I accept what you tell me, and I also accept that for many of them there is a sense of relief. I could sit here and regale you with lots of anecdotal evidence—

Senator NETTLE—I am sure you could.

Ms Tighe—I could—that I have not forgotten. I will just tell you this one little story. I gave a talk somewhere. This woman came up to me, and she said: 'I want to tell you what happened to me. When I was 18, I found I was pregnant. I lived in a country town, and I came to Melbourne, seeking an abortion.' She went to this nurse who apparently was able to procure abortions. It was not effective. She went home. She was still pregnant and so eventually she had a baby. She said, 'I might add she is the most beautiful daughter, and wasn't I lucky that it didn't work?' The girl was 18 years of age. She said, 'One day my 12-year-old son came home from school, and he said, "Mum, I want to go on this walk raising funds for Right to Life. Will you be able to sponsor me?" She said her first reaction was: 'Who's been talking to you?' Then she calmed down. But she had that guilt deep inside her that she had nearly killed that beautiful daughter. 'Who's been talking to you?' she said. That was her first reaction.

Mr Francis—Where the woman aborts at home, the feeling of guilt is likely to be greater, because she sees the foetus which she has killed.

CHAIR—We have to bring it to a close there. I thank the witnesses who have appeared in this session, for their submissions and for their oral testimony today. We are running over time and we have some sensitivity around the number of people we can get through today. I will suspend the committee for a short break. I ask you to be back in 10 minutes time so we can resume these hearings.

Dr Piercy—Can I table the information that was requested?

CHAIR—Certainly. Articles have been tabled by Dr Peircy.

Proceedings suspended from 11.21 am to 11.37 am

MEAD, Dr Cathy, National President, Public Health Association of Australia

SHELLEY, Dr Julia Meredith, Member, Public Health Association of Australia

TAFT, Dr Angela, National Co-convenor, Women's Health Special Interest Group, Public Health Association of Australia

CANNOLD, Dr Leslie, Member, Reproductive Choice Australia

BEAUMONT, Ms Marilyn, Executive Director, Women's Health Victoria

RICE, Ms Kerrilie, Policy and Research Officer, Women's Health Victoria

CHAIR—Welcome. Thank you very much to each of you for appearing today. I think information on parliamentary privilege and the protection of witnesses has been provided to you. I would now like to invite each of the organisations to make an opening submission, hopefully a brief one, before we proceed to ask you all questions.

Dr Cannold—Reproductive Choice Australia is a national coalition of over 20 organisations, including Sexual Health and Family Planning Australia, Children by Choice, the Public Health Association of Australia, the Australian Women's Health Network, the Women's Electoral Lobby and all state based pro-choice groups.

The bill, the terms of reference of this inquiry and this debate, as I have understood it, are not concerned with the morality, the political legitimacy or the legality of abortion. My understanding of what we are talking about here today is whether a single member of parliament or the Therapeutic Goods Administration should decide on the safety of RU486 and other abortifacients, and I am going to confine my remarks just to this issue.

I think one of the key things here is good governance. I think it is very important to avoid federal interference with state laws on abortion. As I think we all know by now in Australia, the states regulate abortion. The curtailment of the legitimate regulatory scope of the TGA by the Commonwealth could be seen to be trying to improperly interfere with state policy and law in this area, and I think that is something we might want to avoid.

It also seems to me to be quite vital to the health and wellbeing of all Australians that politics are kept out of medical decision making. Decisions about the health of all Australians need to be made on the basis of the medical evidence by the experts charged by government with precisely this risk assessment role. Since 1996, abortifacients like RU486 are the only medications the TGA does not have authority to evaluate and regulate. Yet, since its establishment in 1989, the TGA has fulfilled its responsibility to both assess and monitor the almost 50,000 other drugs on which Australians rely for their health. Indeed, assessing the risks associated with pharmaceuticals is actually one of the explicit functions of the TGA and one which the federal government has seen it to be capable of carrying out where other controversial drugs have been at issue.

The TGA also has the very prestigious status of being a World Health Organisation collaborating centre. That is not something that happens to every agency; it is a very high status, and it is an imprimatur from the Word Health Organisation that we are doing a good job and that the TGA is an organisation of which we can be very proud. For these reasons,

there seems to be little reason to accept the suggestion made by supporters of the effective ban on RU486 that the TGA lacks the ability to fairly and properly assess RU486 on the basis of the medical and scientific evidence. We very strongly reject those suggestions that the TGA is not up to the task.

The question needs to be asked whether this drug really is so different. Supporters of the effective ban have argued that there is a reason why abortifacients like RU486 should be singled out for different treatment. They say that the health minister rather than the TGA should decide. Then they give a number of reasons why that is so. First of all, they say that RU486 is a particularly risky pharmaceutical. In my other life, I am a bioethicist. I work as a philosopher. I have to say that this claim is completely illogical. It does not make any sense. The TGA is the body charged to assess the risk of drugs, so on what expertise and process do those who claim the drug is too risky for the regulator to assess the risk rely on? It does not make any sense.

I also wonder how an evidence based evaluation of the drug's safety can put women at risk. All we are talking about here is trying to get the facts. What sense does it make to deem a drug too risky to have its risks evaluated? We are being told that there is good evidence to say that this drug is not safe. If the evidence exists to support the claim that the drug is unsafe—and I think that this is a really important point—it seems to me that, if that were true, those people saying it would welcome the TGA evaluating the evidence, because they would be shown to be correct. I wonder why they are so afraid of having the TGA look at the drug if the evidence is on their side.

As far as I can understand it, the evidence does not support claims that RU486 is a particularly risky pharmaceutical. All drugs have risks and benefits, but 15 years of experience of the drug in European countries like France, the UK, Germany and Sweden have produced a large body evidence that clearly demonstrates the drug's safety and efficacy for use in inducing early miscarriage. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists says:

There is a substantial body of literature establishing the safety and efficacy of mifepristone—

that is, RU486—

when used in conjunction with a prostaglandin analogue ... to induce abortion.

Such evidence includes a meta-analysis of multiple studies conducted by the respected Cochrane collaboration. The World Health Organisation agrees that RU486 is safe and effective. In July 2005, it placed RU486 on its list of essential medicines and described abortion by surgical or medical means as 'one of the safest medical procedures'.

Sometimes the argument is made that this drug should be excepted and that is why the health minister should have control rather than the TGA. They claim that it is because this drug is the only one designed to end human life. This is incorrect. RU486 was designed by its healthcare company creator Roussel Uclaf as a treatment for serious endocrine conditions like Cushing's syndrome. That is what it was designed for. The discovery that the compound could induce very early abortions was an unexpected outcome of this early investigation.

Sometimes it is claimed that the reason we need to put this drug in a special category is that it is the only drug that has the effect of ending human life. Again, that is not correct. There are a number of

pharmaceuticals that are both registered in Australia by the TGA and used in a broad range of health care settings that can end human life, including morphine sulfate. Neither can it be said that RU486 is the only medicine capable of harming an embryo or foetus, or of causing miscarriage. Currently, the TGA lists around 55 drugs or categories of drugs that either 'caused, are suspected to have caused or may be expected to cause, an increased incidence of human foetal malformations or irreversible damage'. Those are called category D drugs. You can find this all on the TGA web site. The TGA also lists drugs that have a high risk of causing permanent damage to the foetus, and these are called category X drugs. These drugs include the antimalarial quinine, several vaccinations, numerous antiepileptics and the mental illness treatment lithium.

I think it is important at this point—and I do not know whether or not this has been said—to note that we consistently refer to this drug solely as 'the abortion pill'. Again, this is actually not correct. Like many drugs, this drug has many indications. Not only does it provide a non-surgical option for termination in the very early stages of pregnancy, it is indicated as therapy in a variety of serious and in some cases life-threatening medical conditions. These include inoperable meningiomas, Cushing's syndrome, breast and prostate cancer, glaucoma, depression, endometriosis and uterine fibroids. In addition, the drug has shown promise in the treatment of HIV-AIDS, dementia and progesterone-dependent uterine and ovarian cancer. More than women and couples have a stake in this debate, and more than those groups have a stake in getting access to this drug.

Arguments in favour of the ban seem to me not to be based in logic but in faith. 'The TGA cannot be trusted' and 'this drug is unique' are the two main arguments that have been put forward as to why the health minister rather than the TGA should decide. As I hope I have shown, both of these contentions lack a firm evidential and logical base. So what is the proper role for faith based arguments in a pluralist society, which is the kind of society that we live in? It is probably worth mentioning that, even though most people who oppose abortions in all circumstances and for all reasons are people of faith, it is important to recognise that 77 per cent of religiously identified Australians support a woman's right to choose. That is very important to remember, because I think often people think anyone who is religious opposes this drug. It is not true.

Australians of all religious and cultural backgrounds have good reasons to oppose the influence of faith rather than logic based arguments in policy decisions that affect all of us. This is because in pluralist democracies the religious and cultural rights and freedoms we enjoy depend on the refusal of government to favour one group's religious or cultural outlook over another's. As has been shown in many countries across the globe, the state's imposition of the values of one religious or cultural group on the whole can undermine national cohesiveness and sabotage democracy. Australians must hold to our principles that religion has no place in politics and that politics has no place in medicine. Upholding this conviction does not make our democracy values-neutral, but a unifying repository for values shared by most of the world's religions and subscribed to by the people of all successful democracies. These are values like justice, equity, respect, tolerance, honesty, integrity, personal responsibility and trust. This seems to me to make the solution to the dispute between those opposed to the effective ban on RU486 and those who support it—which is really a dispute about the acceptability of the risks associated with RU486—precisely the sort that should be decided by the expert government authority in an impartial, evidence based manner. Let the

TGA decide, and let responsible politicians and citizens alike respect and abide by the experts' ruling, whatever it is.

CHAIR—Thanks, Dr Cannold. From the Public Health Association, I welcome Dr Mead.

Dr Mead—I think we endorse what Dr Cannold says, so I will keep this very brief. We want to emphasise the importance of the need for assessment and approval of all drugs in Australia to be subject to good governance and consistent procedures. The Therapeutic Goods Administration is highly regarded; it is independent, apolitical and has a high level of scientific expertise in the range of disciplines that are required to assess a drug for its safety. This is an issue of governance and the expertise of the TGA. The TGA is responsible for the assessment of all other drugs in Australia, and it is appropriate that it be the body that assesses this drug.

We believe that there are no good public health reasons for isolating the assessment of RU486 in this way. In addition to limiting its access for termination of pregnancy, it restricts its use for other important therapeutic purposes. We would also like to reiterate that it is the role of TGA to assess the drug for its safety. It is not its role to look at accessibility of services in rural or regional areas. That is another issue altogether. We firmly believe that it is appropriate for the Therapeutic Goods Administration to assess this drug like it does for all other drugs.

CHAIR—Thanks, Dr Mead. Let us move to representatives of Women's Health Victoria.

Ms Beaumont—By way of introduction, I will talk a little bit about Women's Health Victoria. It has been in existence here in Victoria for about 20 years and operates at a state-wide level in facilitating women's informed decision making in all of their health decisions. We work with the service sector to ensure that the best, most independent, quality information is available to service providers to facilitate informed decision making around health decisions. As part of our statement of purposes, we also have a woman's right to choose and to control her body.

Our submission is that the TGA is an appropriate body for assessing therapeutic goods available to Australians, and RU486 should be included within that group for the TGA to assess. Service providers look to the TGA as a body of experts to enable them to make recommendations to their patients about what an appropriate drug regime is for all of the conditions which they present with. RU486 should be part of that group that is available to Australian women. All of the evidence will be put before the TGA about risks, benefits and contraindications. That process would be undertaken with any other therapeutic drug that comes before the TGA. The outcomes would be made known to the Australian public. That is the matter that is before the Senate committee, and we support the expert body—the TGA—to make the decision. It should not be in the hands of one member of parliament, based on unknown evidence, to say that this drug should not be available in Australia, when it is available in a number of other countries. There is significant evidence for its use. Over two million women have now had experience with it.

Our submission is that it should be available to women in Australia through a TGA process. The TGA is the body of experts that we trust for all other therapeutic goods that are available to us. It would be part of informed decision making for women, in conjunction with their

doctors, about whether or not they wish to use this therapeutic good. That is the same process that the TGA is involved in for any another health decision. Rather than go on in more detail, we are available to answer questions.

CHAIR—Thank you very much to all of you for making those submissions and opening statements. I will start by following up a point that you made, Dr Cannold, about politics playing no part in medicine. The processes whereby Australians have made decisions on the availability of surgical abortion have always involved political processes. Each Australian state and territory has had specific parliamentary debate and legislation to decide the circumstances in which surgical abortion will be available. Whether or not we agree with the outcomes of those debates, I assume we would all agree that it is appropriate for there to have been debate by elected representatives rather than by technicians, specialists or whoever about the circumstances in which those particular things might occur. Given that this is the equivalent debate at the federal level about the availability of drugs to facilitate chemical abortion, isn't it appropriate for that decision again to be made by elected representatives, or a representative accountable to other representatives, rather than by unelected, faceless bureaucrats?

Ms Beaumont—There are two points there. The first, as you were acknowledging, is that the states actually regulate the question about the legality of abortion.

CHAIR—Surgical abortion.

Ms Beaumont—I am trying to reel through all the different kinds of state legislation. Each state's legislation is different and I am not able to say offhand whether it specifies that. For instance, in the ACT there is no longer criminal legislation around abortion. It is regulated just in the health act. There are two issues here. The first is that I think it is not legitimate—and that is what I said in my opening statement—for the federal government to be trying to interfere with the capacity of the states to regulate on this issue. The only way that your argument would work would be where there is evidence to show that the rate of abortion actually increases when this drug becomes available. This is a question of fact; it is not a question of value.

There are facts and the facts are quite simple. The total rate of abortion does not go up. In fact, in Sweden the total rate of abortion went down. What we saw almost everywhere is a dramatic increase in the percentage of abortions that take place much earlier in pregnancy. That is a benefit of making this available to women that I do not think has been widely acknowledged. But I cannot really see why it would be legitimate for the federal government to interfere, because this is a state matter if we are just talking about whether abortion should be legal. Actually, it does not make any sense to me at all.

Dr Taft—I would like to make a comment on that. I think you are absolutely right. When it comes to the legislation on the availability of abortion, it is up to people's representatives, in the form of politicians, to legislate. That is the case and that is not what we are debating. That is for abortion of any kind. That is a different debate, about which there is a lot of concern and about which the Public Health Association agree. That is why we have called for reducing the circumstances that lead to it, which is unwanted and unplanned pregnancy, about which we are very concerned. It is also the right of politicians to make those changes, and it would be a

contribution of a health minister to bring in a national sexual and reproductive health policy which would contribute to bringing that down.

However, the point at issue is not whether it is medical or surgical abortion. Each state can decide whether or not it is in the Criminal Code. Some states have decided to take it out and make it a procedure like any other. It could be a medical procedure or a surgical procedure. What we are talking about here is the potential for women to have a choice about that procedure, given that currently under the common law it is available and legal. So the issue is not about whether abortion is illegal; the issue is whether the TGA or a health minister should make a decision about a particular drug. We see absolutely no reason why that should be the case.

CHAIR—Ms Beaumont, would you like to add to that?

Ms Beaumont—Access to medical or surgical abortion—whether it is a regulated service under the health act, which it is in the ACT and it potentially could be in any of the states, or whether it is still referred to in the Crimes Act—is a matter for the legislators and the governments.

CHAIR—Of the states and territories.

Ms Beaumont—Yes. But if it were covered by the health act only then the determination of the components of the health act would be a question for the legislators in the states. That is the case in the ACT. The question of abortion itself and whether or not that should be available to individuals is not only the prerogative of legislators. If it were part of the health act, regulated as any other health service, that would not necessarily be focused on only.

CHAIR—Could I just challenge the view that this is purely a matter for state and territory parliaments or governments. If the federal parliament, for example, decided to expressly ban, by legislation, the use of a chemical abortifacient or drug to procure an abortion, it would have the power to do that—there is no question about that—irrespective of whether state governments allowed it to occur through surgical procedures. Isn't that the case?

Ms Rice—The availability of abortion is regulated by the states and the territories through their legislation. As for the type of abortion, the TGA is an expert committee that has the ability to monitor drugs that are made available for use, has the ability to look at problems that people might be reporting—adverse events—and, if necessary, make recalls, which they have done in the past. That would apply in the same way: if there were a problem with a drug that had been approved and needed to be recalled then that would happen. The legality or otherwise of abortion per se is a matter for the states and territories. The decision about whether RU486 is available in Australia should be made by the TGA, who has all that information available to it and can make an independent, quality assessment.

CHAIR—I am not sure there is constitutional line anywhere that says that abortion is determined by state and territory governments. I do not know that that is actually the case.

Ms Beaumont—That is a fact.

CHAIR—But where do you obtain that?

Dr Taft—There is a draft Criminal Code which is the responsibility of federal government. It is up to each state legislature to decide whether or not they put that into effect. The reason

why in Western Australia and currently in New South Wales obstetricians are being prosecuted is that there is that capacity within the criminal codes of those states, even though there is common law—because common law is not as strong as criminal law. That is the reason why those people are being prosecuted. And a decision was taken by the legislature of the ACT and WA to take it out of the Criminal Code.

CHAIR—I think we are talking about surgical abortion rather than chemical abortion.

Dr Taft—No, they are not talking about any type of abortion. It does not specify. The Criminal Code does not specify.

CHAIR—With respect, the states cannot legislate for things that are not within their power. If they passed a piece of legislation that said abortions will be available under any circumstances, it would not override federal power to, say, ban abortions that were procured by chemical means.

Dr Taft—That is right. Federal government has the right to make criminal law and states have the right to do common law; it is with the magistracy, not with the—

CHAIR—Actually, courts make common law.

Dr Cannold—I think it is unclear to me—and you would need a lawyer here—whether or not, if the Commonwealth did make a decision to deny women access to a particular method of abortion, the states could contend that that was inappropriate interference in the regulatory scope that ought to belong to them. It would certainly be open to debate, I imagine; it is certainly not clear that that would be allowed.

Ms Beaumont—But if RU486 were approved by the TGA it would become part of what was available from those health services who offer abortion services to women, and the same regulation around abortion currently would encompass the use of RU486 and include all of the safety measures around that. So the qualification of the provider, their registration of the premises and all of those things which currently operate around surgical abortion would operate around medical abortion.

Dr Shelley—And in fact they operate around the other forms of medical abortion that are actually available in Australia although they are not widely used. There are numerous other drugs that can and have been used for abortion, and all of those are available; some have been used. And they are subject to the same regulations as surgical abortion in this country.

Senator FIELDING—I would like to pick up on the original thread that you raised, Dr Cannold. You said politics has no place in medicine. If you take that to the next step then who decides the appropriate boundaries of medical practices—when you come to cloning, when you come to other issues where there is a broad social policy decision to be made? Are you saying that these policy decisions should be made by bureaucrats and not elected members?

Dr Cannold—I am saying that I do not feel that I or, with all due respect to everyone sitting here, anybody here is the right authority to be making judgments about the health and safety of any drug, including RU486. We need to turn to the evidence to answer questions about the safety and efficacy of the drug. This debate has been conducted in this country largely around whether this drug is safe and effective. Therefore, it seems to me to be illegitimate for us to say, 'We are not going to allow that evidence about medical benefit.' It

also seems to me that most Australians would feel quite anxious to know that, instead of them getting access from the TGA in a timely manner to drugs deemed to be safe and effective, parliament are going to step in and say, 'We're sorry. We don't even want to know the answer to whether this drug is safe and effective,' or, alternatively, 'It may be safe and effective and cure your disease or deal with your medical health problem, but we're not going to allow you to have access to it anyway.'

Senator FIELDING—I think the question really being posed here is that this is a social policy decision that needs to be made. Research has been done that notes that Australians are genuinely concerned about the high number of abortions and want to see that reduced. That, combined with the fact that this issue is about do-it-yourself abortions at home, means it becomes a social policy issue that elected members should be making. What are your thoughts on that?

Dr Cannold—I have lots of thoughts on that, actually. The first one would be that I would argue that this is a question of method. This is really what I was trying to take up before: this is not a social policy debate about whether we are going to have access to abortion, because—

Senator FIELDING—It is at home.

Dr Cannold—I will get on to that in a minute. You are saying, 'Yes, this method makes some kind of difference.' But I am saying that it is a question of method. The outcome is the same: you are terminating a pregnancy. What this drug is enabling you to do—and this is really the only difference between the drug and surgical termination in terms of the outcome—is to terminate earlier than you would be able to do if you were using surgical means. I would argue that it is simply a question here of method. It is not a question of you deciding whether women ought to have access to abortion, because women have access to abortion in this country, and that is something that is regulated by the states.

I will go through the other things that you said. You referred to what you called research from the Southern Cross Bioethics Institute. That is not, in my view, legitimate research because it is not properly conducted. So I would not accept as legitimate the claims that Australians are particularly concerned about abortion. Instead, I would refer to the Australian National University study which shows that 81 to 82 per cent—I think it is 81.2 per cent—of Australians support a woman's right to choose. I think we need to be clear here that we obviously have questions of fact and questions of value. We all know that there is a dispute in this country between a very small minority and a much bigger majority about whether abortions ought to be available. The question here is whether, when we make decisions about RU486, that is for the federal government to make on the grounds that abortion ought or ought not be available to women. My understanding of the terms of reference of this committee and what your powers are is that that is not for you to decide. You can say to women, as has been said in the past 10 years, 'You may not use this method,' but by denying women access to this method, which is the situation as it stands, you are not able to rule out women's access to termination, because that is something that is controlled by the states.

Ms Beaumont—Can I raise the issue of doing it at home?

Dr Cannold—Sorry, I was going to take that up. That is a big issue.

Ms Beaumont—There is this whole idea that RU486 will enable women to somehow willy-nilly have access to something which is dangerous for them and they are going to be doing it at home. The reality is that women will make informed decisions in conjunction with their medical providers and will be involved in the administration of RU486 under the supervision of their medical providers.

Senator FIELDING—Would you deny that the abortion will occur and the foetus will be expelled at home?

Dr Cannold—It is an embryo.

Senator FIELDING—Do you deny that fact?

Ms Beaumont—That is right.

Senator FIELDING—So the answer to that question is yes?

Ms Beaumont—If you speak with women who have experienced extremely heavy and painful periods over a significant period of their lives, they will tell you it is a similar experience to that. The requirement not to have a hospital admission makes it cheaper for the woman, the health system and the taxpayer. The issue of supervision by medical providers is an absolute certainty in my mind. As for the need to train medical providers in its use, there is evidence that that has been effective in overseas countries. The approach to the provision of RU486 as a therapeutic agent by health service providers would be no different from the approach to the provision of other therapeutic agents.

Senator FIELDING—It is the community that needs to decide the appropriate bounds of medical practice.

Ms Beaumont—They are not involved in most of those decisions.

Senator FIELDING—Secondly—perhaps I can just continue my point—the issue in another submission and on a separate point was that the actual cost was higher for this type of abortion.

Ms Beaumont—Not from a hospital admission.

CHAIR—We are getting off the track here. I asked a question, which you followed up on, Senator Fielding. I have finished with that. We will now turn to Senator Moore for a question.

Senator MOORE—Each of you represents an organisation, every one of which has given a submission on the legislation before us, which concerns the use of RU486. Significant discussion has been had about the role of this committee and this piece of legislation. I am interested in a point that has been raised in the media that there has been an outburst of concern by people opposed to the legislation that has not been matched by people who support the legislation. I am interested in the response of groups and individuals who support the legislation to this statement: the vast majority of submissions we have received are from people who are concerned about the use of RU486 and who do not want the legislation passed, yet we are pursuing this process. I am interested in hearing from each of you in response to that.

Dr Cannold—One thing we have to keep in mind is that the vast majority of Australians support a woman's right to choose. From reliable data, which has been collected properly and

not from push polling, 81.2 per cent support a woman's right to choose. Reliable studies that have been done—a Newspoll survey that was done properly, without push polling—that asked people whether they supported women getting access to RU486 also came up with a clear majority in favour. Next week petitions will be presented to parliament. There will be well over 8,000 and possibly up to 9,000 or 10,000 signatures petitioning parliamentarians to act on this legislation and to vote to repeal these amendments. So there is clear public support and interest in this debate and, when the time comes, it will all be rolled out and made public.

Dr Mead—I do not think it is necessarily valid to judge public opinion by the number of submissions made to the Senate committee. Obviously the submissions provide the senators with a whole range of views and arguments, but the number of submissions received is not representative of a voting procedure. It simply reflects people's capacity to provide submissions and the range of organisations that have an interest in the issue. Dr Cannold has said that there is a measure of public opinion that has been done in appropriately valid ways and then there is a process of providing a range of arguments, which we are doing here, about the specific issue of the assessment of this drug and the role of the TGA versus the role of the minister. Obviously, when you put that issue on the table, the range of issues around termination of pregnancy and its availability will come out. But, in my view, the volume of submissions is not the measure of how to address this issue.

Ms Beaumont—Women's Health Victoria approached the opportunity to put a submission to the Senate committee as we would approach any Senate committee submission we put—and it is on behalf of the organisation. We could have approached this as a lobbying campaign and called on all of our members, whose numbers run into the hundreds, and all of the members of all of our networks, whose numbers run into the many thousands, to put individual submissions to this committee. We did not do that. We went about making a submission by putting together the evidence which we collect through our statewide clearing house. We pulled together all of the evidence, all of the information around the TGA processes and whether or not that was appropriate to assess applications for the use of abortifacients. That is the question before this committee; that is the question we addressed.

So we have not approached it through a broad based community lobbying campaign. We could well have done that. All of the support is out there in the community for a service that most members of the community assume is available to them. They are horrified to think that this is something that is still questioned, that is still having to be fought for, that is in fact a crime in some states, and that may be under threat through losing Medicare funding to access such services. Most members of the community that talk to me, and well beyond that, are appalled that it is still a question in Australian society.

Dr Mead—We are the same—we put in one submission on behalf of a large number of members. We chose not to go down the track of asking all our members to put in individual submissions.

Dr Taft—May I also say that I think that the people who sent in the overwhelming population of responses to this issue are not necessarily responding to the question of whether the health minister or the TGA should be able to assess the quality of RU486. It is largely around religious beliefs about the overall question of abortion, which is not what is really being debated. I recognise and respect the concern that people have about abortion—that is

truly legitimate—but I do not think people are writing in in response to whether or not this should be a decision taken by the health minister or the TGA.

Senator BARNETT—I would like to ask some questions about the submission of the Public Health Association—specifically, page 2. In your reference under risk factors, you compare RU486, which has an adverse drug event rate of a very low 0.137 per cent, with the over-the-counter drug Claratyne, which has an adverse event rate of 12 per cent—87 times higher than mifepristone. Can you confirm that fact for us today? Do you support it? Could you alert the committee as to what Claratyne is—I understand that it is for allergies?

Dr Shelley—There are quite a number of drugs available and legal in this country for which the mortality rate is considerably higher than that recorded worldwide for mifepristone.

Senator BARNETT—So you confirm what is in your submission?

Dr Shelley—Certainly.

Senator BARNETT—And is Claratyne used for allergies?

Dr Shelley—Claratyne has a high rate of adverse events. In the United States, which is where most of the information on deaths from mifepristone comes, they have also recorded more than double the rate of deaths from Viagra, for example, and from a wide range of other drugs.

Senator BARNETT—Is Claratyne used for allergies?

Dr Shelley—Yes.

Senator BARNETT—I have looked at your web site to find out—because there is no source for the evidence in the submission that you have put to the committee—and there is a reference to it on the web site, but the definition of 'adverse effect' and 'adverse event' is entirely different. In terms of RU486, we are talking about hospitalisation, in most cases, for bleeding and the like. In terms of Claratyne, what I have here before me is that we are talking about, according to your definition of an adverse event, dry mouth, headache, insomnia, fatigue, nausea, dizziness and so on.

Do you think it is fair to compare bleeding, the hospitalisation of a woman and the potential risk of death to an adverse event following the use of Claratyne, which is used for allergies and has adverse outcomes such as a dry mouth, a headache, nausea and dizziness? Is it appropriate? It is in your paper on page 2.

Dr Shelley—These are exactly the sorts of assessments that the Therapeutic Goods Association is best placed to address.

Senator BARNETT—I am asking you. It is on page 2 of your submission. You have compared the two. Is it an appropriate comparison?

Dr Shelley—Bleeding and subsequent hospitalisation is only one possible outcome or adverse event from the use of RU486.It is not the only one, in the same way that a dry mouth is only one of the possible adverse events from the use of Claratyne. Part of the reason for raising this is that none of us here is in any situation where we can appropriately address the pros and cons of any single drug. It is an incredibly complex task. It is a task that the TGA is

set up to do. We would totally support and recommend that the TGA is the right and only place to do that.

Senator BARTLETT—I put it to you that your submission leads me, as a senator reading your submission, to the impression that comparing RU486 with Claratyne is not a high risk or a cause of great concern. I put it to you that it is an inappropriate and unfair comparison.

Dr Taft—You are taking one line out of that. We make a lot of other points about Cochrane Collaboration and meta-analyses. Twelve million women worldwide have used this drug, and the World Health Organisation and Cochrane Collaboration—which was set up to provide evidence on any medical procedure or pharmaceuticals in order to assess whether they are safe—have concluded that the drug is safe. It may be an unfortunate analogy. I can see your point: I can see that that particular analogy is not a good one—I understand it comes from the RANZCOG web site, but I am not sure. I do urge you to look up and read the evidence, all of which is catalogued in our submission, especially the Cochrane Collaboration.

Senator BARNETT—Thank you for that.

Dr Mead—The point of including that illustration is, as we said, to show that the Therapeutic Goods Administration is the appropriate body to do the assessing, because reporting of things like adverse events is incredibly complex. As you say, an adverse event can range from minor things to serious things, and the importance of an adverse event needs to be considered relative to the drug or the procedure that causes the adverse event. So it is an illustration of the complexity of the issue and it is one of the examples of why we believe that the TGA is the appropriate body.

Senator BARNETT—I will go to the next paragraph. We have talked about Dr Greene's evidence in the *New England Journal of Medicine* in the US. You have quoted it on page 2. You say that Dr Greene:

> ... has argued that the overall mortality rate associated with medical abortion is small (1:100,000)—

I am quoting your submission. It goes on to say it is:

> ... no different to that posed by surgical abortion.

But we have had tabled before us today the exact article that you are referring to. It has been read to us as well. We have it here before us. It says there is a 10-fold difference—1:100,000 compared to 0.1:100,000. So it seems that it is pretty much the same or exactly the same. You say there is no difference. So on what basis—and you have referred to Dr Greene—would you say that it is entirely the same.

Dr Cannold—I am quite happy to answer this question.

Senator BARNETT—I would like an answer from the Public Health Association first. They are the authors of the submission. I am then happy to come to Dr Cannold.

Dr Shelley—Dr Cannold is a member of the Public Health Association.

Senator BARNETT—That is fine. Is she speaking on behalf of the Public Health Association?

Dr Shelley—Yes, in this instance.

Dr Cannold—I think Dr Green's article has been tragically misused; I suspect he would be appalled to hear how his article is being used by opponents of the drug. What I think is important to remember here is that he actually wrote the article in question to argue that the drug should not be restricted by the FDA, because the risks associated with surgical and medical abortion are nearly identical, at around one in 100,000. He then, as a statistician, decided that he would go on to just look at the numbers in the US and to take account of the four tragic and as yet unexplained, according to the FDA, deaths of women who had recently had a medical abortion.

Senator BARNETT—Do you have the article?

Dr Cannold—Yes, I have the article and you may also be interested—

Senator BARNETT—Could you read it, please?

Dr Cannold—I do not have it in front of me, but I have read it and I am quite familiar with it, so could you just let me get to the end of my answer? If you are not happy with my answer, then I am quite happy to answer you again.

Senator BARNETT—You said, 'He said,' and I—

CHAIR—Please let Dr Cannold finish her answer.

Dr Cannold—I was going to say that he also gave an interview on the article on the ABC's *Health Report* and he went on to explain precisely this matter because this part of the article drew attention from Norman Swan, who was the interviewer. So in my answer now I am going to take account both of his written work in the *New England Journal of Medicine* and the interview he gave, which anybody can find a transcript of on the web. He said that if you took account of these deaths and just used the procedures that had taken place in the US you might find that, if you calculated the mortality rate, the mortality rate associated with medical abortion might be 0.1 and the mortality rate associated with the surgical abortion would be one or around one.

He then went on to say that 10 times a very small number—and this is in the *Health Report*; you can go and look it up—is still a very small number. My husband is a statistician and he thought a good way of explaining this would be to say that if you had a grain of sand in one hand and you had 10 grains of sand in another it might be true to say that the 10 grains of sand were 10 times heavier than the one grain of sand but in fact both of them are pretty much the same. If you throw them both at your feet you might be able to say that you were 10 times as hurt by the 10 grains of sand but in fact the difference would be negligible.

What we are trying to do here, and what Dr Greene was trying to do, was to tell us something about whether there is a significant difference in the risk of dying faced by women if they choose medical versus surgical abortion. He was trying to say that the answer is that there is no significant difference because the rate and risk of dying is extremely low compared to a range of other drugs. It is about equivalent to aspirin, and much, much lower than Viagra or childbirth, which has eight to nine times the risk of dying. He was then saying that in absolute terms the drug is very, very low risk and in relative terms there is a negligible difference between the risks, which are very, very low.

Senator BARNETT—I would like to ask a question regarding the US FDA. In your submission on the top of page 3 you say that it recently reaffirmed the safety of medical abortion for American women and authorised its continued use. I am wondering what evidence you have to say that because I have looked at the US FDA site and rather than reaffirmation of its safety it warns of the danger of sepsis, and it refers to the four deaths in the USA from RU486. Likewise, we have had a US congressional inquiry that has just been established to look into the deaths from RU486. We have a US bill and 79 sponsors in the House of Representatives to suspend the licence of RU486. In Canada, of course, the licence concluded some years ago. I am wondering on what basis you would say it has been recently reaffirmed.

Dr Taft—Could you just tell us how long ago that recent challenge—

Senator BARNETT—You try to answer the question and I am happy to help in any way. It is in your submission at the top of page three. I am asking you a question.

Dr Taft—As far as we know, RU486 is licensed by the FDA. There have been lots of attempts recently by those with strong religious convictions to try to overturn that and to try to rescind it. As far as we understand, it is still licensed for use.

Dr Shelley—It is political.

Dr Taft—Yes.

Senator POLLEY—I would just like to clarify the misconception presented in your opening statement that it is only Christians who actually have concerns about the use of RU486. In fact, there are many people who do not necessarily share Christian values who actually have concerns about it. I wanted to clarify that. We are not here to debate abortion. What we are here to debate is whether or not the minister should be able to retain a right as a policymaker representing the government on the welfare of the Australian community. It concerns me that Italy has banned the use of RU486. I would be interested in your comments on that.

The other thing that you said is that other evidence that has been provided to us was done through push polling. I am not sure about that and those people have not come before us yet to clarify that. I would just like to make a comment in relation to any petitions. Ninety-nine per cent of the time, people sign petitions without having a full knowledge of the impact or a full understanding of what they are actually signing. If you ask people in the street now what RU486 does, they will say it aborts a baby. That is fine. Do they understand the implications and how long it takes for that baby to die? That is something quite different.

I am concerned from a female's point of view about women's health. I would just like to know from a medical point of view and from a women's health perspective how a medical abortion, which is over and done with very quickly, is not as good as something where we are reliant upon the medical fraternity and pharmaceutical lobbyists pushing and lobbying for a change so that we can have a pill. Sure, women take the pill under supervision but, unfortunately, when that baby is expelled it is not necessarily while they are under medical supervision. The psychological and health implications of that are of grave concern. So from my perspective it is not a matter of whether you are pro-choice. It is about women's health. This has been pushed by the medical fraternity and pharmaceutical companies and it has been

said here today on a number of occasions that it is a quick fix. It is less cost-effective. Those are the issues that concern me. I would be interested in your response.

Dr Cannold—I would just like to correct the record. I did not say that only Christians were concerned about abortion. What I said—and this can be found in a published peer review journal called *People and Place* in a 2004 article by Katharine Betts—was that the vast majority of the small percentage of Australians who are opposed to choice are religiously identified. The biggest groups are Catholics and evangelicals, but most of them are religious. I then went on to say that that does not mean that most religious people are against choice, because the vast majority of religious people are for choice. But of that small group of people who are against choice, nearly all of them are in fact religiously identified. That is the data and, again, it is just a fact.

As to Italy, my understanding is that what you have just said is incorrect. The drug is in fact not banned there. I think it is probably important to recognise that we are not the only country where there is controversy about abortion. All we are really being told when we find out that there is political controversy in another country is that we are not alone in this. We are not really being told anything about whether the drug is safe and effective or ought to be available.

Senator BARNETT—You referred to the drug not being banned in Italy. The advice I have is that it has just been banned.

Dr Cannold—Yes, but that is incorrect as far as I understand. We have people who work in Italy as abortion service providers. There was a brief period where the drug was suspended, but that suspension has been lifted.

Senator NETTLE—I corrected the record in the last hearing. I said that they had restarted the trials again in Italy at the beginning of December last year.

Senator BARNETT—I am talking about the last couple of days. But we will get advice on that.

Dr Cannold—Again, it is a question of fact. Surely we can find it out. As to the petitions not being legitimate—

Senator POLLEY—I did not say they were not legitimate. I am saying that a lot of people, when they sign petitions, do not understand the implications of them and they can be used for political purposes.

Dr Cannold— Yes, I understood what you were saying. My only point would be that you are politicians and I assume that what you are interested in is public opinion. Often we hear that that is something that is of concern. So I think it is important that we do make statements about what public opinion is, and what is and is not a reliable measure of it. Certainly, I would agree with what has been said here before that this ought not to be a question of whether the man in the street does or does not believe in this drug or does or does not believe in anything else. It should be a question about what the evidence is on the safety and efficacy of the drug.

Finally, I would say that, if it is that you are concerned about women's health, I would think that anybody who feels this way would really want to have an expert evaluation done about what are the precise risks and the benefit profile of this particular drug. I also note that,

just as you are a competent, capable, rational, autonomous person who can make decisions based on information you get about the risks and benefits of a particular drug—I am sure you have done it many times in your life, and when you go into a doctor's surgery you will do it again—women also, all of us, are capable. I would like the freedom to make that choice. I would like to have a disclosure made to me about the risks and benefits of this drug, should I ever need it, or any other drug, and I would like to make a choice that is based on my own needs and my own values.

Ms Beaumont—You have referred to a few things that you said that Women's Health Victoria have said—that is, it is a quick fix and it is cheap. That is not what we said. We said that it is able to be assessed by the TGA as effective in its administration under supervision and, because it does not require a day hospital visit and possibly anaesthesia and so on, it is more cost-effective for the health system. The TGA process has involved a number of drugs that it has endorsed for distribution—including information about contraindications, side-effects—and then, after some period of time, has withdrawn them from use and then, after some period of time, has re-released them for a series of other conditions. Thalidomide is a good example of that. It is that process that we say should be allowed to have a say around this drug. Put all of the information before it.

Ms Rice—The Australian Drug Evaluation Committee, which is the expert subcommittee in the TGA that does the evaluation and brings together all the reports that come in, was actually established in 1963 after the thalidomide experience. They have recently, in 2003, decided that we could use it again. They are qualified to make those decisions. We put faith in them to make the decisions; we entrust that decision to them. We have done for many years; we should continue to do so, and this drug should be exactly the same.

Senator MOORE—I would like to place on record that Vioxx was not withdrawn by the TGA; it was withdrawn by the manufacturer of it after complaints. I do not share your confidence in its ability to be able to make a judgment on whether or not this is in the best interests of women's health—and the other issues—because, whether we like it or not, the community do—

Senator ALLISON—Chair, we are running out of time and there are a lot people who have not had a chance to ask a question. I ask you to rule against arguing as opposed to asking questions of witnesses.

CHAIR—If there is a question that this leads to, then that is fine.

Senator MOORE—No.

Senator BARNETT—On that point, I need to ask Ms Beaumont a question. You put on the record to our committee earlier that it was cheaper to use RU486 than surgical abortion. Can you confirm that? If so, can you tell us what the cost is?

Ms Beaumont—I do not know the exact cost. I do know that there is a cost for a day procedure, there is a cost for anaesthesia, there is a cost for travel to a central place for surgical abortion to the woman, and the process might include a number of days stay away from home. I can give you a calculation of that, but not at the moment.

Senator BARNETT—Can you do that by Monday?

Ms Beaumont—Certainly.

Senator BARNETT—Would that be possible?

Ms Beaumont—Sure.

CHAIR—Yes, that would be great. Take that on notice, thank you.

Dr Taft—I want to address the issue of cost. If the evidence is that in countries where RU486 is available there is no increase in abortions—they remain the same and it is just that women choose to take it—then it is not going to result in an increase in health service costs to this country, which I think is what you are getting at: if they are equal, as well as if there is a reduction.

CHAIR—We are running seriously short of time. I understand you have got to go somewhere, Senator Joyce, so a quick question from you.

Senator JOYCE—I would like to put this on the record; I would like to help you out. I will retract that statement about shooting a mother. I think that was unreasonable; I should not have said it. My position is, though, that a baby in anybody's body is no more that person's property than a baby in a pram is the property of the pram. What I would like to ask is: at what stage do you think a person in their human development actually attains rights? At what juncture? We have been talking about the rights of the unborn. What time do you think they actually attain rights? I will put that one on notice because I have to go.

You mentioned that we do not know what the effects of the drug are. You also quoted the college of gynaecologists, who have said this process is fair and reasonable. Can you just explain, therefore, why none of the companies we can find out who develop prostaglandin actually recommend it for this abortifacient use? Could you just clear that up, because not one of the prostaglandin manufacturers want it used as an abortifacient? It is just a simple question: when do you think a child attains its rights, or do you think it does not have any?

Dr Cannold—I am a philosopher so I am quite happy to take that one up. I just wanted to ask the chair something. Do you want me, as a philosopher, to talk about that broader question of when an embryo takes on and acquires a right to life or is that something that is outside the terms of reference of this committee?

CHAIR—To be frank with you, I think it is outside the terms of reference. Witnesses have raised today questions about general availability of abortion and I might suggest that this issue, strictly speaking, is outside the terms of reference. You might care to take the question on notice and give information to the committee on notice.

Dr Cannold—I am happy to give Senator Joyce my book. I have written a whole book about the philosophy of abortions.

CHAIR—For the benefit of the rest of us, you might want to take that question on notice.

Dr Cannold—Do you want the answer?

CHAIR—If you want to take that question on notice, we will be happy to receive an answer but I do not think we need to take up the time of the committee now with getting evidence on that.

Dr Cannold—There was a question about misoprostol.

Dr Shelley—I am happy to answer that. I have actually done research on misoprostol and a range of other things. My understanding is that whether any drug company chooses to seek licence for a particular indication for their drug is purely a commercial decision on their part. I do not think that we can answer on behalf of any of the drug companies as to why or why not they choose to make those decisions. The reality is that misoprostol and other prostaglandins are used very broadly in a whole range of obstetric and gynaecological indications. They are used in all of those capacities in what is known as off-label mode and as a whole range of drugs for a whole lot of purposes.

Senator JOYCE—Why wouldn't the drug companies recommend them for that use?

Dr Shelley—I cannot answer for the drug companies.

Senator JOYCE—Could it be that they think it is dangerous?

Dr Shelley—You would have to ask them that. I have no idea, but the medical profession certainly uses prostaglandins very broadly for a whole range of indications in obstetrics and gynaecology.

Senator JOYCE—They would know a fair bit about the drugs they make, wouldn't they? That would be a fair statement.

Dr Shelley—I would presume so, yes.

Ms Beaumont—If I might deal with the first issue that Senator Joyce raised, Women's Health Victoria's submission started out by saying that we take issue with the violent statements that enter the public arena and make headlines by senators using this inquiry to say things like: shooting a woman would not be a crime unless you killed her baby. We took issue with that in our submission. It is incumbent on public figures who have the capacity to make headlines to also retract that in the public arena and not mumble it as they begin their questions in this hearing.

CHAIR—I take the point you have made. I think it is a matter for Senator Joyce to take up. I think he will read the transcript if not hear this relayed by the senators. We are running seriously short of time. I want to proceed quickly. Senator Adams has a question.

Senator ADAMS—I have got a question which I have asked all groups. Coming back to the terms of reference, as far as whether the minister approves this drug or the Therapeutic Goods Administration do, at the moment, because the drug has not been approved, the Therapeutic Goods Administration have not been able to evaluate or do any of the work needed to say whether this drug is safe or not. The minister has said that the drug cannot come into Australia. So can you tell me this: if the Therapeutic Goods Administration have not done that work, where would the minister have got the advice and information to make this decision?

Dr Cannold—I think that is one of the concerns that we have, that there really does not seem to be any clarity—and no reasons certainly have to be put on the table—as to why he is making his decision and what sort of advice he has received in order to make it. A further argument that Reproductive Choice Australia would be making is that it would be important there be that. That is why we think the Therapeutic Goods Administration is the proper authority, because it would be important for a medical decision to be made on medical and

scientific grounds. We have already got that situation and we have also got a panel of experts who are actually specifically able, in a way a health minister may or may not be, to evaluate that evidence. It seems completely redundant to try to set up the health minister to do something similar because we have already got a government agency explicitly charged with doing it in the right way, which is with people who understand the medical and scientific evidence and are going to make decisions according to the medical and scientific evidence, because it is a medical and scientific question.

Ms Rice—Can I also add that the data standards that the TGA use when collecting information are based on EU standards, are used internationally and are highly regarded. One of the things about the TGA is that they provide independent quality checks at every level. I do not see how the health minister or any one single person could possibly bring the expertise that the committees of the TGA can bring to this type of decision making.

Dr Taft—I thought it was the role of the TGA to advise the health minister, and the health minister needs the TGA to do its work. It has got toxicology, pharmacology, clinical advice and epidemiology—and that is its role. How the health minister could do it without the TGA I find amazing.

Senator NASH—Very briefly and again coming back to the term of reference which is about assessing this drug, it is not the bill saying this drug should be here in Australia; it is about saying the drug should be assessed by the most appropriate body. The bill says that we believe that the TGA is the most appropriate body to do that. Do any of you have any reason not to have complete confidence in the TGA to be able to evaluate that drug?

Ms Rice—No.

Ms Beaumont—We have complete confidence in the TGA.

Dr Taft—It is a world renowned organisation and I think countries are actually jealous that we have got the TGA, so we are very, very confident in it.

Dr Cannold—I also think it is important to point out that the TGA has actually been nominated by the government in previous situations where controversial drug uses have come up. The government itself has actually said, 'This is a really controversial use. We are going to turn to the TGA and let it give us some impartial evidence based advice.' For instance, in New South Wales when they proposed the cannabis trials for pain relief—a controversial use of a drug—it was the federal government who said, 'We need the TGA to help us out here. This is controversial. We need an evidence based evaluation from an impartial source.'

Dr Shelley—If we are talking about women's health, in a recent case with evidence from the United States about possible harm from HRT, again the government turned immediately to the TGA.

Senator McLUCAS—I have one issue. I understand that one of the effects of the current situation is that people who wish to use Mifepristone in the treatment of brain cancer have been allowed to import the drug but cannot find a doctor willing to prescribe the drug. Firstly, do you know of that? Secondly, what is the reluctance of those doctors to prescribe Mifepristone in that circumstance?

Dr Cannold—I know something about one case of this. I understand it is not an isolated case, but I only know the details of one case. My understanding is that the woman has been diagnosed with an inoperable brain tumour, which was found because she was losing her hearing in one ear. She needed to have access to this drug because the only alternative for her, which was surgery, had a very high risk of leaving her quite disabled, without both hearing and sight. Some of the surgeons would not even do the operation. But when she went to try to get access to the drug she had a lot of difficulty. There was a significant amount of red tape, which all of these very sick patients have to go through in order to get permission from the TGA to import the drug.

Exactly what you said then happened. She finally was able to get that permission but the doctors would not take on what they saw as, and were told so presumably by their medical defence funds, a medicolegal risk because the drug was not registered for approval in Australia. So in fact she could not get a doctor to sign off on getting the drug imported for her. It is now a year after she was diagnosed with a very, very serious disease. She is already at risk of seizure and, of course, it has been very stressful trying to get access to a supply of this drug to deal with this inoperable tumour. So it is difficult because, without the drug being properly registered, doctors really do not know a lot about it, they have not had a lot of experience with it and they are concerned if they are being told by their lawyers that they are taking a risk because the drug is not registered in Australia. Many of them are just stepping back and saying, 'We're not going to have anything to do with it until the TGA registers it.'

Senator McLUCAS—So, in fact, it is an effective ban for use.

Dr Cannold—Both for other uses and—

Senator McLUCAS—And for abortion.

Dr Cannold—Yes. As you know, the attempt of the legislation was to try to exempt the other uses of the drug and patients who needed it for those other uses, but I think this case illustrates that certainly in at least some situations those exemptions have not really been successful.

Senator ALLISON—The point was raised this morning that psychologically this drug is very dangerous. I wonder if anyone is familiar enough with the work done overseas on studies to inform the committee about the findings of those studies with regard to women's satisfaction and women's ongoing problems associated with its use.

Dr Shelley—Again, this is an important area for the TGA to evaluate. Their evaluation covers clinical effectiveness, epidemiological evidence, pharmacological evidence et cetera and would include the psychological effects of the drug, if the drug itself has psychological effects. And, beyond the psychological effects of the drug, it is difficult to disentangle the effects of abortion from the effects of the method of abortion. However, with regard to miscarriage, on which there is quite a bit of evidence of surgical in comparison to medical procedures, where women have choice over the method, on the whole there is no difference in outcome and there is certainly no difference in the psychological outcome at all.

Dr Cannold—There is also data from RANZCOG and from the World Health Organisation. According to the World Health Organisation, women's experience of

spontaneous miscarriage and of induced miscarriage using medical abortion is very similar. They experience cramping and they bleed. In terms of what the Royal Australian—

Senator BARNETT—Are you talking about physical experience or overall experience?

Dr Cannold—I was just going to go on to the psychological experience. So that is a physical experience that women—

Senator BARNETT—There is a difference.

Dr Cannold—Yes, I recognise that, Senator Barnett, and that is why I was about to move on to the next aspect of what I was going to say. RANZCOG has also noted that women who choose medical abortion do not cite the passage of a sac as a concern. This may be because up to nine weeks pregnancy, which is the time in which RU486 is indicated, the only products a woman will see are placental tissue and blood. I am quite happy to pass this around—this is an image of a gestational sac at five weeks. I think it gives us a good image of what we are talking about. Inside there is an embryo which is somewhere around the size of a grain of rice, either quite a bit smaller than a grain of rice or perhaps twice the size of a grain of rice at the very end, which is nine weeks gestation. That will be inside of this very small sac. I am happy to pass around that image just so that we can get an experience.

To see that sac, a woman would have to pore through what is on her sanitary pad to find it, and then she would have to open it. Very few women do that, and that is probably why women tell researchers that they do not see the passage of the sac as an issue in medical abortion. There has been no evidence thus far that they are concerned about it, and therefore I suspect there will eventually be no evidence to show they are traumatised by it.

Dr Shelley—I think the other thing is that there is a minority of women—again, this is a matter of choice—amongst those women who choose to have a medical procedure rather than a surgical one who would actually prefer to live through that experience, to know what they are doing to their bodies, to see the results of that and to be responsible and actively involved in that. That is a choice made by a small minority of women.

Senator BARNETT—The level of trauma is the same.

Dr Shelley—The level of trauma is the same—there is no trauma. That is the first point to make. In terms of psychological outcomes, the results are exactly the same, whether it be induced termination of pregnancy or miscarriage. The results are the same regardless of whether it is a surgical or a medical procedure.

Senator WEBBER—I just have one question, returning again to the terms of reference and the role of the TGA. It would be true to say, wouldn't it, when the TGA assesses any drugs that we want to use in Australia, not only do they look at all independent evaluation and evidence and what have you about their safety and advise about whether we should use them but they then also look at guidelines under which they should be used? So, because this drug cannot actually be used in Australia at the moment, we cannot speculate on the conditions and the guidelines under which the TGA will say it can be used until it is sent to that independent body.

Dr Shelley—That is correct.

Dr Taft—That is absolutely core, because for a range of things, including emergency contraception, for example, those guidelines should be for how it should be marketed and how women should be informed so that they can make an informed choice. So the notion that women will go willy-nilly and not make a judgment about where and when they go to their doctors and where or whether they terminate I think is insulting.

Senator FIELDING—Do you agree that the reason there is a conscience vote on this issue—and, indeed, the reason why we are here today—is that this is a major social, moral and ethical issue?

Dr Taft—Unplanned and unwanted pregnancy is a very important social issue, Senator Fielding, and I do hope that you will be lobbying government to have a national policy to reduce unplanned and unwanted pregnancy. That is really the key social issue, not whether RU486 should be approved as a choice when either contraception has failed or for whatever reason women are faced with an unwanted pregnancy and choose to terminate it.

Senator FIELDING—I do not think the term of reference is referring to unwanted pregnancies; I think the terms of reference are about who the decision maker is. I just ask the question again: do you agree that the reason why there is a conscience vote—politically, by politicians, by elected members—and the reason why we are here today is that this is a major social, moral and ethical issue?

Dr Taft—It is a political issue.

Ms Beaumont—We are here today because of a deal that was done by Senator Harradine sometime in the past. We welcome the cross-party bill that has been brought before the parliament and the opportunity to rectify that deal that was done. That is why we are here today. We are not here today because it existed without that arrangement; we are here today because of the deal that was done with Senator Harradine some time ago.

Senator FIELDING—I asked a question. On the basis of what I have just asked, is it yes or no?

Dr Mead—The decision to make it a conscience vote, as I understand, is made by the political parties themselves. So it is a decision by the parties.

Senator FIELDING—From all the evidence I have heard so far, and there is still some to come this afternoon and on Monday, this is a major social and ethical issue.

Ms Beaumont—The decision before the committee is about the process of assessing a drug.

Senator FIELDING—I have heard nothing to the contrary from you to support unelected bureaucrats making the decision not politicians.

Ms Beaumont—We entrust the qualified experts who make up the TGA to make decisions about all of the therapeutic goods that are made available to the Australian public through the health system. We trust that system for everything else. We trust that system for this. This drug, RU486, should be put through that scrutiny by the experts. We do not believe that parliamentarians as individuals have the expertise and the depth of expertise the TGA can call on. That is the question.

Senator FIELDING—The question that has been put by the Senate is a question of who determines the policy.

CHAIR—Senator Fielding, I think that is as far as we can take this. We have run out of time.

Proceedings suspended from 1.01 pm to 1.48 pm

SEMAN, Dr Elvis Ivan, Private capacity

WOOD, Dr Graeme Walter, Private capacity

CHAIR—Welcome. Do you have any comments to make on the capacity in which you appear?

Dr Wood—I have been a general medical practitioner for almost 30 years.

Dr Seman—I am a consultant gynaecologist. I head a urogynaecology clinic at Flinders Medical Centre and I am a senior lecturer at Flinders University of South Australia.

CHAIR—Thank you both for appearing today and for the submissions you have given us. I think information on parliamentary privilege and the protection of witnesses regarding evidence you give has been provided to you. I invite you to make opening statements supporting your submissions, then we will proceed to ask you questions.

Dr Wood—I thank the members of the committee for all the work you have been putting in and for the opportunity to appear before you. I have worked as a country GP in the town of Kerang for almost 30 years, and it is my belief that, particularly in country settings, RU486 should not have a place in termination of pregnancy as the risk of complication from both heavy bleeding and serious infection would be significantly higher. Termination of pregnancy frequently also leads to emotional scarring of the woman and a diminishing of self-respect. I ask: why bring forward a more dangerous agent which, to the uninformed or partly informed, appears to be a simpler answer than surgical abortion and therefore puts even more women at risk? I therefore believe the current situation of control of the use of RU486 should be maintained.

Dr Seman—I am here as a gynaecologist, because I want the safest options for women. RU486 has been misconstrued by the press as a better abortion option for women. If women are to have an abortion, the facts show that chemical abortion is more dangerous. If we introduce RU486 for chemical abortion into Australia, this will be our future: 17 times as many women will die from early abortion; for every death, there will be at least 70 near misses from severe bleeding, serious infection and ruptured ectopic pregnancy; 23 per cent of babies who survive the abortion will be malformed by the chemicals used; women will suffer more pain and psychological distress; and women using the chemical method will be aborting any time, anywhere, with many of them seeing or feeling the foetus. How horrifying is this?

Also, women's sexual organs and eggs will have more chemicals in them. What impact will this have on their children's sex organs? Doctors' workload and stress will increase, not decrease, especially in rural Australia. There will be less money to spend on other areas of women's health. The community will be angered that distinguished medical bodies had given RU486 counterfeit legitimacy through their support and failure to warn of the dangers. Society will seriously question why the safeguard of ministerial responsibility for RU486 was removed by our elected politicians. It is our collective duty of care to now go through the facts with a fine-tooth comb to ensure that women are protected against unsafe abortion choices. I thank you for inviting my participation, and I welcome your questions.

CHAIR—Thank you very much to both of you for your submissions and statements today. Dr Seman, I was struck by a comment in your submission:

The use of misoprostol in gynaecology is "off label" .

You also say that it is not actually in accordance with the intention of the manufacturer for it to be used in conjunction with RU486. I put that point to representatives of the Royal Women's Hospital earlier today. I asked, 'Is it really appropriate for that kind of unethical use of a drug to occur for a purpose other than that intended by the manufacturer?' They made the claim that such things can occur if there are tests appropriate to facilitate another purpose or a broader purpose for the drug that is being put on the market. Do you have a comment on that process? Do you consider that misoprostol has, in the circumstances, been appropriately tested for that use additional to the one that the manufacturer specifies for it?

Dr Seman—I think the point that you raise is a significant negative. I know that there are other examples of drugs that can be used off label that do not necessarily have such a controversial application. However, I know in South Australia our medical defence organisation have said that even for uncontroversial uses, such as medical termination, medical treatment of a miscarriage or even induction of labor after a baby has died, they will not give medicolegal cover. You will not be indemnified if you are using a drug with off-label status. I can only speak about the defence organisation that I am with.

Senator MOORE—I just have a question about the role of the TGA. In both your submissions you talked about whether this drug should be used. That has been the focus of your submissions. I would like to find out whether either of you have done any work or had any relationship with the TGA and whether you are aware of how they operate. Within that process, the TGA has a role, in my understanding, in developing effective guidelines. Should a drug pass the series of tests that they have and be able to be used, they can then determine protocols for how it is used and put guidelines into the process. I want to tease out whether you are aware of that and whether you have any concerns about that, because it seems that the submissions are based on unsafe usage of the drug. So what are your expectations of TGA, and what is your experience with them?

Dr Seman—Generally speaking, I really do not have any difficulties with the TGA. I have had some dealings with drugs that are used for bladder conditions, Tolterodine being a specific example. I do know that the TGA globally has a good reputation. However, in this specific instance, I do not think it is appropriate and I need to make a very important point here: if it were not for this inquiry, views such as mine or those of Dr Wood would not be heard. I am a member of some very distinguished medical organisations, such as the Royal Australian New Zealand College of Obstetricians and Gynaecologists, the AMA and NASOG, and I have written to their leaders. Their view is that they do not feel that there is a safety issue here, when the data strongly suggests that there is. My concern is that, because these organisations have such a strong pro-choice influence, they in turn would influence the TGA and, therefore, something that is potentially dangerous would be passed. That is my concern.

Senator MOORE—The influence.

Dr Seman—Because of the potential that pro-choice bias is blinding us to some of the dangers.

Dr Wood—I will mention an article I read in the *Australian* this week which suggested, from somebody working closely with the TGA, that the TGA was not an appropriate body for

making decisions on the basis of the use of RU486. I must admit that it does puzzle me enormously as to why there is a push to get RU486 anyway when surgical abortion has been made so readily available and—as Dr Seman has pointed out, and as articles that I too have read say—when there are so many queries over the safety of the drug in the first place. That is not quite answering your question.

Senator MOORE—The bill in front of us is looking specifically at the assessment process. I was wanting to find out your own knowledge and experience of the current assessment process. You are both aware of it in your profession but you have not had personal experience working with them. If there is time, Chair, I have another question, but we will go from there.

Senator POLLEY—We have had a lot of evidence given to us over the course of today and in the previous hearings. We are trying to limit the debate. To me, I do not see it as a pro-choice issue or not. It is a medical procedure that I have concerns about. I have some information that details that it actually takes up to three days or more for the abortion process and for the baby to die. Could you comment on that. My concern is obviously for the baby's health but also the health of the women who are going through this. We have had diverse opinions about whether or not it is more traumatic or less traumatic. I am more concerned about the medical complications. Could you share with me your experience.

Dr Seman—I have had no personal experience with its use as an abortifacient and I guess most Australian doctors are in this position, so we are all reading the same literature. While surgical abortion is normally a 30-minute procedure under a GA day surgery, chemical abortion with RU486 is a two-stage procedure. The commonest regimen involves giving RU486 to begin with. It is a hormonal drug. It induces abortion in about 60 per cent of women. For the remainder, a second drug is given two days or so later, which is also a hormonal medication. That increases the abortion rate to over 90 per cent.

The range that I have requoted is that most will abort within nine to 16 days but you have got about nine per cent whose bleeding goes on for over 30 days and a very small number for whom it goes on for 60 days or more. So in comparison to surgical termination, which is a day procedure with return to normal activity usually within a couple of days, we have got a much longer range and it is going to take a lot longer. During that time, women will feel sicker because 23 per cent will experience side effects that are graded as serious or severe. They will need more help at home. They will be less able to work so their work colleagues will need to fill in more for them. So it is a very different scenario. I hope that answers your question.

Dr Wood—Thinking particularly of general practice in a country setting and with regard to that prolonged bleeding and that uncertainty as to when the abortion takes place, for women living well out of town—I have patients who have to travel more than 60 kilometres to our local hospital—if that sudden heavy bleeding were to occur in that type of setting it would put them very much more at risk than if they had had a surgical termination in the hospital. You will be aware of the increasing difficulties with blood banks in rural communities because of the pressures on the Red Cross. It is more difficult to get blood now in rural communities. Sometimes there is a delay of 24 hours, and occasionally even 48 hours. Putting a woman into

a situation where she is potentially more at risk of heavy bleeding with those sorts of limitations is taking a very unnecessary risk and putting the woman at risk.

While at the moment the bulk of patients from our area wishing to have a termination would go to Melbourne to a tertiary hospital, the concept of a simple approach just by taking tablets would put more pressure on doctors to comply with the patient's request, who may say: 'Think of the money that I won't have to pay and all the inconvenience et cetera.' That is to put the women at the very sorts of risks that I have mentioned.

Senator BARNETT—Dr Seman, thank you for your submission and your supplementary submission. Your comments with regard to the levels of safety struck me, because we have had some debate around the table from some of the witnesses earlier in the day about it being comparable or the same. Other witnesses have different views. You have expressed a view on page 2 of your substantive submission, saying:

... recent US data shows it is three times that of early surgical abortion—

that is, the maternal death rate from RU486. Then on page 134 of the Senate report, in your supplementary submission, you say:

... chemical abortion has been promoted as being of equivalent safety to early surgical abortion when current US data show a 3 to 17 times higher death rate from early chemical abortion.

You then go on to report Professor Greene's article from December last year, saying, in terms of Australia:

This means that for a country performing say 90,000 early abortions per year, one would expect one maternal death from surgical termination every 11 years, whilst during the same interval one would expect about 17 deaths from chemical abortion.

So are you telling the committee that, over the next 11 years, 17 Australian women would die if they used RU486?

Dr Seman—That is absolutely correct. This is what I find so puzzling in representations from other medical bodies of which I am a member: they have no concerns about the safety. You really have to read things very carefully and re-read them to try and nut out what is the truth. The three times death rate came from Philip Darney of San Francisco in a letter to the editor in *Contraception* in 2005, whilst Professor Greene, who is an O&G professor at Harvard and an associate editor of this prestigious journal, published further information. He was writing about deaths from infection. In the calculations he made he was comparing deaths from infection from chemical abortion with all deaths from early surgical abortion. But if you put together all the deaths from chemical abortion, and there are eight, and then the denominator becomes 460,000, and you put that on the calculator, the result is 1.73—that is, 1.7 per 100,000—whereas the equivalent rate for early surgical termination is 0.1 per 100,000. You could still argue that it is safer than giving birth to a baby and you could argue that it is rare—and indeed it is—but the point is that these are not equivalent death rates. We have one author saying that it is probably three times and someone else is clearly demonstrating 17 times.

Because abortion is such a commonly performed procedure, small differences become big differences—17 deaths versus one over 11 years if you were doing 90,000 a year—but in addition to that, and this is what really concerns me, for every death there are many more near

misses. You may be familiar with the publication by doctors Garry and Harrison, two gynaecologists who analysed severe adverse events reported in relation to chemical abortion. There is an under-reporting of adverse events, but I read it and did my calculations. For every woman who dies from chemical abortion, there are at least 70 more who have suffered near misses. They categorised the adverse events as 'life threatening', 'serious' and then the rest. If you put together 'serious' and 'life threatening', there are 70. So, for every death there are at least 70 either life-threatening or serious presentations. The deaths are just the tip of the iceberg in terms of what doctors will have to deal with. There are also adverse events with surgical abortion, but they are fewer in number. That is the point.

Senator BARNETT—The levels of safety are entirely different. You cannot say that they are the same in your view.

Dr Seman—On the current data before us, you can categorically state that early surgical termination of pregnancy is a safer option than chemical abortion and, conversely, chemical abortion is more dangerous than early surgical termination.

Senator ADAMS—Thank you both for your submissions. I would just like to put something forward on the terms of reference, the minister currently having the approval for the introduction of the drug into the country and whether the TGA is a suitable body to do the evaluation and all of the other things that go with it. Obviously, at the moment that cannot be done—they cannot evaluate it because the minister has not given the authority to have the drug evaluated by the TGA. Can you tell me how or from where the minister—whether it be a male or female health minister—would get information from if the TGA was not the suitable body to give that information or research it? In order to make an informed decision that the drug should not be able to come into the country, where would that information come from?

Dr Seman—I think that, as with any debate, you need to hear both sides of the story. All of us have our biases. But the one thing that all of us should have in common, whether we are for or against abortion, is seeking out what is the safest thing for women and with which method fewer women will die so we do not have significant morbidity. It is not easy. I am a gynaecologist and a lecturer. I had to read and re-read these papers to try and get to the nitty-gritty. I do not have an easy answer. But the principles are that both sides must be heard and the focus should be primarily on safety—to not do harm.

Dr Wood—From my perspective at present the minister has the right to decide whether it is used at all. In most cases, if it came to the push, it would be for other than terminations of pregnancy. When there is so much conflicting evidence as to the safety of the drug for use in terminations, I wonder really whether the minister would see a place for its use in that situation at all anyway, whether he was pro-life or otherwise. There are just so many question marks over its use.

Senator ADAMS—Dr Wood, I note that you are a rural practising doctor. I have a submission here from the Broome Regional Aboriginal Medical Service. It is signed by six general practitioners working in the Kimberleys. I am also from Western Australia. They say:

As practising rural and remote doctors concerned about the disadvantage faced by local women in this respect, we urge you to support the use of RU486 in early termination of pregnancy particularly in rural

and remote settings. With appropriate patient selection policies and procedures RU486 can be safely used in regional Australia.

They go on to say that they have back-up in three of their towns and that would be where their patients would be if surgical intervention had to happen. Can I have an idea from you on that? That is from six people working in pretty remote Australia.

Dr Wood—I would be concerned that they may well feel that is their only option because of their isolation and they see difficulty obtaining access to surgical terminations.

Senator ADAMS—For surgical termination they go to Perth, but they do D and Cs, miscarriages and everything in those three places.

Dr Wood—I would see that it is giving a second-rate service to their community and putting them at greater risk by introducing the drug. As we say, it is not a clean drug in very many respects. Also, I just wonder about the particular population they are dealing with. I read the submission of Dr David Gawler, who is working up in—

Senator ADAMS—I read that too. That is why I read this one out.

Dr Wood—I think he raises some very valid points, some of which will be reflected in my community, not nearly as isolated as Broome. But I wonder about the safety of taking this easy short cut. As my wife reminds me, short cuts are very often the long way around and much more dangerous.

Senator ADAMS—I have just come back from New Zealand, and they are using the strategy. Their guidelines are absolutely straight down the line. If we were to have those guidelines, if this drug were introduced, I do not believe it would be a short cut. I believe it is an option that they can use, especially in that area, if they have the surgical backup.

Dr Seman—I am from Broken Hill originally. I have practised as an obstetrician in Woomera, Lameroo and lots of country places, so I am quite familiar with the system and the patient assisted transport scheme. I know this is expensive. It is very inconvenient for those women to travel to the city, but mark my words: this is money well spent if fewer women are going to die from it. So that is where I would like to see my money spent: sticking to the safer, albeit at times less convenient, option.

Consider this as well, because of all the adverse things that can occur: women will come back haemorrhaging severely—not a lot, but they will. This is a real panicky sort of situation for doctors in the country. They have got to summon a colleague who can give the anaesthetic, then urgently deal with the haemorrhage. Worse still, there is ectopic pregnancy. It is terrifying to see a young woman come in in haemorrhagic shock from a ruptured tubal ectopic pregnancy. This is an emergency. They may or may not be able to deal with it up there. They will have to evacuate these particular women to Perth; they may die along the way. And this is an important point: with surgical termination you can confirm you have terminated a pregnancy from inside the womb at the time. You have got an early warning system of an ectopic pregnancy. This does not exist with chemical abortion, because the tissue that is passed by the woman is never analysed—but that is the nature of it—and, furthermore, the drugs induce symptoms that can mimic an ectopic pregnancy. This is why in the adverse event report 11 out of 17 of the ectopics that were reported had ruptured. So you are going to have a delay in diagnosis of ectopic pregnancy. This is uncommon, but we are talking about

uncommon things, because our safety is so good at the moment we must not compromise it. To reiterate, I would rather see my money spent more expensively sending some of these isolated women to the city to have a safer procedure.

Senator WEBBER—My question is fairly brief. A lot of people talk in their submissions in favour of maintaining the current system, which is that the minister will deal with this drug in this instance. We have had people say that they do not trust the TGA because of all the pro-choice pressure or what have you that they will come under. At the moment it is well known that our current minister for health has a particular moral and ethical view on termination of pregnancies. If we had a pro-choice minister for health and if he or she decided to remove that veto, should that minister therefore be allowed to say, 'Yes, the drug should come in,' and therefore there is no role for the TGA?

Dr Seman—What we have now, whether you are for or against it, is open public accountability. That is the most important thing. Whether you are for or against abortion, that minister must accept responsibility and parliament must know about it. That is a wonderful safety mechanism. We must protect such safety mechanisms, not get rid of them. So pro-choice, pro abortion or pro-life—really it does not matter what their stance is; at the end of the day the analysis must come down to safety. That is where surgical abortion wins over chemical abortion.

Senator WEBBER—But my question is: who should conduct that? At the moment, it is the minister. This bill does not just propose to bring the drug in; it proposes that it should be treated like every other drug and be assessed by the TGA, which is not the current status. If we have a pro-choice minister who removes the right of veto and says, 'Yes, I am going to let the drug in,' who should do the assessment? Should it be the TGA? Should it be a non-medical minister for health? Who should do it?

Dr Wood—It would surely be the minister in conjunction with the information that he is given. But, again, there is that public accountability.

Dr Seman—I agree with that. That is important. It must be the minister who accepts the responsibility, and both sides must be heard, not just one side.

Senator WEBBER—That is the current system. The TGA makes a recommendation to the minister. It is just that this one is not being assessed by the TGA.

Dr Seman—No, because the TGA is subject to pro-choice influences. The only reason that we are here, and that people who are concerned about this issue are having a say, is that this whole thing is being debated.

Senator ALLISON—Can I ask you to repeat that statement? 'The TGA is subject to pro-choice influences.' Is that what you said?

Senator WEBBER—That was part of his earlier evidence.

Dr Seman—Potentially, it would be, because—

Senator ALLISON—Potentially?

Dr Seman—Yes. Had it been asked in this situation, it would have consulted the same experts that you have heard reporting today.

Senator NASH—You have raised something, Dr Seman, that from my recollection I do not think anybody else has during these hearings. You said in your opening statement that babies would be malformed by chemicals used. Can you let us know what evidence you have that you base that on?

Dr Seman—In the paper by Margaret Gary and Donna Harrison that I alluded to earlier, they made an analysis of pregnancies that survived following chemical abortion. The available information suggests a malformation rate of 23 per cent. Of pregnancies that survive the abortion, 23 per cent will have abnormalities.

Senator NASH—Can you table that so we do not take up time? Does that contain figures of how many of those pregnancies go on after the intended medical termination?

Dr Seman—I would have to spend some time reading it, but it is in there, yes.

Senator NASH—Can you provide that figure on notice to the committee, because I think it is very important in the context of that statement? Could you do that perhaps by Monday?

Dr Seman—Certainly.

Senator NASH—Thank you.

Senator BARNETT—Could you table that document?

Dr Seman—I would be delighted to table the document. It is in there. You just have to go through and make the calculations.

CHAIR—In order to help us with our constraints on time, if you could pull out the figure and give it to us separately, that would be very convenient. Thank you very much.

Senator McLUCAS—It has been brought to my attention that one of the consequences of the current situation is that people who wish to use mifepristone for purposes other than inducing a termination are essentially not able to do so. Technically they are—that is, they can get approval from the minister to import the drug—but, in one case that I am aware of, a person who has an inoperable brain tumour cannot find a doctor willing to prescribe her that drug. The reason is that the TGA has not done the assessment and registered the drug in Australia. That is a consequence of the current situation. Do you have a view on that circumstance?

Dr Seman—As a gynaecologist, my focus is mainly gynaecology, and I do not know a lot about the other indications. However, they would seem to be uncontroversial indications. If there is adequate information to say that these medications would be of potential benefit, where the benefits would outweigh the risks, then it would make good medical sense to have them approved for that purpose. I would personally not have any objection to that.

Senator McLUCAS—That is correct. The problem is that the medical fraternity are, clearly because of their legal advice, very reticent—in fact, refusing—to prescribe mifepristone to this particular woman because it has not been assessed by the TGA.

Dr Wood—On that issue, where there has been such reticence in an area where it has been asked for, we get this situation coming up a number of times with different drugs. Often they are anecdotal reports, such as 'this drug may be useful for this particular condition'. But when it comes to evidence supporting that it is found to be lacking and so the general consensus is,

'No, it is not appropriate.' Sometimes there will be a doctor who will stand up, say 'I really feel this drug needs to be used' and make an application, and the drug becomes available. I think it is that type of setting that the present legislation allows for, so that if a woman or man—whoever—needs this particular drug for a purely medical condition then, while they may not get support from their first or second doctor, if it is bona fide potentially of good effect, then I would have thought that they should be able to find a doctor who would support that.

Senator McLUCAS—This woman is highly motivated. It is over 12 months since she has been diagnosed with this tumour. She has been through the complete regime of getting it approved by the minister and now cannot find a doctor willing to prescribe it. That is because the TGA has not done the assessment.

Dr Seman—Is that only because of TGA, or because of indemnity problems?

Senator McLUCAS—It is because of indemnity issues, but doctors are very reticent—

Dr Seman—That is very unfortunate.

Senator McLUCAS—without the assessment being done. That is a result of the current system.

Dr Wood—It is something that occurs with quite a number of drugs from time to time, because Australia has required such a very high level of accountability and safety in the drugs.

Senator McLUCAS—We do—a very high level of safety.

Dr Wood—It is one of the reasons we are here today: because our concern is that people are now seeking to overturn that.

Senator McLUCAS—That very high level of safety that you have alluded to, Dr Wood, is delivered by the TGA: is that correct?

Dr Wood—Yes.

Senator ALLISON—Dr Seman, you pointed to public accountability as being one of the reasons for your taking this position and saying the parliament must know about the decision made. Is it your view that the parliament should be entitled to know the reasons for the decision, and do you think the parliament should be entitled to know when a decision to reject an application for RU486 was made?

Dr Seman—I would have answer yes to both.

Senator ALLISON—Are you aware that that is not the case under the current law?

Dr Seman—No.

Senator ALLISON—If I may be permitted another short question: Dr Wood, can you tell the committee why you think that termination should not be easier to procure? Your submission says that you believe that 'to make termination of pregnancy, by whatever means, easier to procure is to see the incidence of women traumatised' and so on, or hardened to it, and 'a rise dramatically in the future' of terminations. On what do you base that last part of my quote, and can you explain why it is you think that termination should be harder for women to procure?

Dr Wood—When surgical terminations were first put forward because of the number of women having illegal terminations and infections and so forth—

Senator ALLISON—You were practising at the time that terminations were illegal?

Dr Wood—I came in just following that. I am old, but not quite that old! It was because of the background of what was going on at the time. It was thought—and I have just been rereading a book based on the repeal of the abortion law in England—that, with the incidence of illegal abortions being performed at the time, there would therefore be a very small increase in the number of abortions being performed as a result of legalising abortion, of making it more freely available, and that what would occur would be a total shift from the backyard abortions to tertiary hospitals. The author writes: 'How mistaken we were. The incidence of abortion dramatically rose following that.'

Senator ALLISON—Do you have the figures you can provide the committee that demonstrate that?

Dr Wood—I have the book which would have the figures, yes.

Senator ALLISON—Perhaps you can provide the committee with the excerpts from whatever you are quoting from.

Dr Wood—Or the whole book—I do not mind; either way. My concern is that I cannot see any reason why the same type of thing would not occur, making termination that much easier than it already is. It is not the insurmountable situation that the woman facing the backyard abortion went through prior to the liberalisation of the abortion laws. I would see it more a push for convenience; but, as I have said before, that push for convenience is a push for something that is far less safe than what is being offered at the moment. Dr Seman mentioned the risks of bleeding. There is the risk of serious infection, and I think in his submission he mentioned that. So I would see that by opening up the, shall I say, floodgates to making abortion that much easier and steering to a direction that puts the woman at increased risk of infection we might be going back to the very sort of thing that we were trying to leave behind when surgical termination was first introduced—that of seeing more and more women with their health extremely compromised.

Senator ALLISON—So does your experience lead you to suggest that termination should not be legal?

CHAIR—We did want to try to compress the number of questions, Senator Allison—okay, one last question.

Senator ALLISON—Does your experience lead you to suggest that it was a mistake to make termination of any sort legal? Should we return to the days when it was not?

Dr Wood—I cannot give a short answer on that. There is a yes and a no.

CHAIR—I am not sure this is really relevant to the inquiry either, Senator Allison.

Senator ALLISON—It is in the submission—it is all related to this question.

CHAIR—Okay.

Dr Wood—I see a safer approach for termination having been offered through surgical termination for the woman who decides that is her only option. I see to introduce medical

termination as a backward step. I think we have made available abortion to women in our community. I think we are going backwards by opening up what I would predict to be a floodgate of medical abortions with increasing complications from that, if we went that way.

CHAIR—Thank you, Dr Wood. Senator Nettle, do you have a question?

Senator NETTLE—Are you aware of any evidence—certainly there has not been any that I have seen or that has been presented to the committee—of anywhere around the world where there has been an increase in the number of abortions when a medical procedure has been an option for women in making that choice?

Dr Wood—I have seen, where the surgical options are freed up, a vast increase. When I say, 'I have seen', I have read of and I am basing my opinion on that. When other drugs have been introduced, like the wonderful new Cox2 inhibitors for arthritis—

Senator NETTLE—If you were able to provide the committee with any article in a peer review journal, a medical journal or anything like that, which indicated that, that would be helpful. All of the articles in the peer review medical journals that I have read—and they have been provided to the committee—have indicated that there has not been any increase in the number of abortions with the introduction of medical terminations. Sure there is a change in the number of who gets what procedure, and that is a part of choice. In fact, in Sweden I understand that there was a decrease in the overall number of terminations that were provided after the availability of RU486. I am quite happy for you to take that on notice. If you can provide any evidence, any peer review journal or medical journal from anywhere around the world, that would be something new for this committee to see.

Dr Wood—It would be and I am sorry I cannot offer that. I have only got evidence of increased incidence after surgery, and my information goes back to the change that occurred in communities when that was introduced.

Senator NETTLE—You have no evidence of any increase in the number of abortions where medical abortion has been introduced. Is that correct?

Dr Wood—Correct. I do see it from other drugs, though.

Senator NETTLE—But not in relation to terminations?

Dr Wood—Not for RU486.

Senator BARNETT—This is a follow-up to a number of questions relating to medical indemnity and specifically to the impact on women's health in rural and regional Australia. One of the major reasons for the RU486 legislation that is now before us that has been put into the public arena is that it would deliver safer and easier access to abortion for women in rural and regional Australia. Firstly, you have put to us that that is not the case. I would like you to confirm that and the reasons why. Secondly, what will it mean for GPs, in particular in rural and regional areas, with regard to medical indemnity issues? How will it affect them?

Dr Seman—Access, in a sense, will be easier because women will be able to have their abortion at home rather than having to travel. But, in terms of real accessibility, the system that we currently have with the PAT scheme still ensures access. It will have medico-legal implications. I am not a general practitioner. I might have to defer here to Graeme.

Senator BARNETT—Will it be safer or less safe for women in rural and regional Australia?

Dr Seman—I would have to say it will be less safe (a) from the viewpoint of mortality, anyway, but (b) you will have women presenting with some emergencies. In spite of the multiskilling and expertise of country GPs, it is still harder to deal with emergencies in a country setting than in the city. On that basis, I would expect there to be greater mortality and morbidity.

Dr Wood—I would concur.

Senator BARNETT—What about the medical indemnity issue? Do you have a view on whether it will be easier or harder to access for GPs in rural areas to prescribe and to look after their women patients in the light of the increased safety risks for those women?

Dr Wood—I think that may vary from medical indemnity provider to medical indemnity provider. I cannot readily answer that. I was interested to hear Dr Seman talk about the South Australian experience.

Senator POLLEY—In regional and rural areas—I have a particular interest coming from Tasmania—I have had experience where general practitioners have not always been as mindful as they should have been in responding to patients in relation to other female tests that need to be done on an annual basis. Is there not also a problem with a lack of availability of GPs in rural and regional Australia to have access in the first place? What guarantees could be put in place to ensure that women had the follow-up procedures and that in fact it was not going to be a greater burden on our health system for women to have to go through a medical attempt to have the abortion but then to go on and have the surgical abortion?

Dr Wood—I can only say we have just lost two doctors from our country town this last month, so we are feeling the pressures. It becomes increasingly difficult.

Dr Seman—Time is at an absolute premium. Then, when you have additional emergencies to deal with, it means all the elective stuff has to wait. Looking at the need for surgery, according to the literature, from two to 10 per cent—most often they quote five per cent—will need a surgical procedure. So you have to deal with all of the medical abortion issues and the additional visits from your patients and then up to one in 10 will need a bit of a hurry up at the end with a surgical procedure. That puts a lot of extra pressure on doctors.

Senator POLLEY—So the argument put forward from regional and country areas—which is that it will enable women to have access to abortion without having to go away for a surgical procedure and the community becoming aware of that—in fact, could have worse implications for women?

Dr Seman—There will be less confidentiality, because it goes on for longer: 'What are you doing at home? Why have you been home for the last two weeks? Why aren't you at work? Why have you been to the doctor four times?' Country towns are small places. I would expect that probably there would be less confidentiality rather than more.

Dr Wood—I accompanied, in an ambulance, a woman with a major fulminate infection; she pulled through with the loss of limbs. Some of the papers that Dr Seman has quoted

mention the increased risk of fulminate infection, and I certainly would not want to put my patients in any situation that could increase such a risk.

Dr Seman—Infection with clostridium sordelli, which is very rare—in the literature we have only seen it in connection with chemical abortion—is hard to pick because it mimics many of the symptoms that women have while undergoing a chemical abortion. Of the five cases that have been reported, which were autopsied, none had retained tissue in the womb and they died quickly. It suggests that this combination of drugs in a very small number of women may suppress immunity enough to increase their chance of an overwhelming infection. This is rare stuff, but we are talking about rarities because surgical termination is so safe.

Senator ADAMS—Just on that infection, that was not conclusive. They still have not proven that the combination of those drugs caused that infection, as far as my reading and research goes and what we have been given here.

Dr Seman—It is the most plausible explanation on the basis of (a) there being no retained tissue—normally retained tissue predisposes to infection, so the abortions were complete; and (b) otherwise healthy young women succumbed so quickly. Somehow—and we do not quite know how and it happens very rarely—for these young healthy women, there is some compromise of their immunity so that, in spite of a complete abortion, the clostridium will overgrow and overwhelm their system and they will die from it.

Senator ADAMS—It seems strange that no cases have been reported in Europe, even with the 1½ million women there on which research has been done, and that it is only in the States that these cases have come up. I have looked into that very closely. As I have said, coming back from New Zealand only three weeks ago, I studied up on exactly what they were doing and their protocols. I am a little worried that a number of our witnesses do not realise how rigid those protocols will be for whichever medical clinic or whoever looks after these women. It will not just be an abortion or termination on demand—I do not even like the word 'abortion'; none of us does, but it is a fact of life. I am just worried in that you have spoken of extra surgical cases that will occur. With chemical terminations, the use of surgical terminations will definitely decline, as has been given in other evidence. I just wanted to correct those things.

Dr Seman—We are in an amazingly advantageous situation. The rest of the world has had experience. We have not, so we can look at it, and I think we always have to err on the side of safety. America have good standards, and if they are reporting this it could apply to us. It may not; our experience could be like the Europeans', but we have to err on the side of safety. Sorry, what was your other point? I had a comment to make, but I have lost my train of thought.

Senator ADAMS—It was on the extra surgery that was taking up theatre time. What we have seen is that the countries that have been able to do the chemical termination have reduced their use of theatre.

Dr Seman—This is an important point: surgical termination is self-sufficient. It does not rely on any other method of termination for treatment, whereas chemical abortion relies on surgery for backup. So when you have chemical abortion you have to have two systems in

operation. For surgery you only need one. I know some people have seen that as a downside and that, if a lot of chemical abortions were taken up, there would be a surgical deskilling of those abortion providers who did the surgery. They would be the consequences.

Senator BARNETT—Does that automatically mean it costs more?

Dr Seman—I can only quote what I have read, and that is that in the United States a chemical abortion costs up to twice as much as a surgical abortion from abortion providers. But that is the maximum that I have seen.

Senator McLUCAS—Does that include the cost of staying in either a hospital or a surgery?

Dr Seman—It is related to the cost of the medication, the extra visits, the time spent in counselling and the ultrasound scans that are done.

CHAIR—Thank you very much, Dr Seman and Dr Wood, for your appearance today and for your submissions.

[2.47 pm]

PLATT, Ms Rhiannon, Women's Officer, Women's Department, Monash Student Association

WICKHAM, Ms Sarah, National Women's Officer, National Union of Students

COCKBURN, Dr Sally, Private Capacity

CHAIR—Welcome. Thank you very much to all three of you. I think you have all received information about parliamentary privilege and the protection of witnesses and evidence. We have the submissions which you have made to the inquiry. Thank you very much for those. I now invite you each to make a short statement in support of those submissions, if you like, and after that we will ask you questions.

Dr Cockburn—Thank you very much for inviting me to lodge a written submission and to appear here before the committee. I am a practising GP with over 23 years of clinical experience and I am active in public health and professional education policy. I have served on various government and community based committees, and my submission is No. 701.

The bill before the parliament is not about whether particular drugs are safe but about who is qualified to decide about their safety. The Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 in my view must be passed to restore the full powers of the Therapeutic Goods Administration to treat people according to best clinical practice by doctors, to enable doctors to treat people with best clinical practice.

The powers of the Minister for Health and Ageing in this matter should be revoked because politics has no place in legal clinical decisions between a patient and her doctor. As it stands, the minister for health has ultimate responsibility, and the safety evaluation for RU486 is not transparent or accountable; it is seriously flawed. Firstly, a parliamentarian is not required or expected to have any medical qualifications or expertise, and the current minister has stated publicly that he does not feel qualified to evaluate medical procedures. Secondly, if a minister for health wanted proper advice on drug safety, normally he or she would turn to Australia's respected drug authority, the TGA. However, in the case of RU486 the TGA cannot give an answer because since 1996 they have been prohibited from even assessing the drug without the express written permission of their minister. So, if the minister is waiting on local safety data for approving RU486 evaluation, it will become ridiculously circular and a classic catch-22. The issue before the parliament is about process and good governance.

Opponents of the bill try to claim that RU486 is too unsafe to be evaluated by the TGA, but this is nonsensical. A drug cannot be too unsafe to be evaluated for its safety by the independent accountable organisation set up for that very purpose and the one which evaluates every other drug in this country. If the opponents of the bill are so confident that this drug is unsafe, then surely the TGA will prove the point for them. As has been mentioned earlier, they fear that it may be hijacked by the pro-choice lobby. Surely they have a chance to have their input as well. To put this in context, there has been no proof anywhere in the world that RU486 causes death. To put this in context using population statistics and death rates, a person is at least 15 times more likely to die from aspirin than RU486.

The TGA is the ordained and respected umpire. They use proper risk management approaches to drug evaluation. Passing this bill will not automatically make these drugs available to the public, so please let the TGA do its job. People argue that opponents of the bill use distorted and out-of-context data. That reinforces the need to let the independent umpire, the TGA, decide. In many cases, the opponents' arguments about the safety of RU486 for women's health are only a thin veil. Often it is not the drug that they oppose but abortion itself. While they have every right to hold this personal opinion and every right not to have an abortion themselves, they have no right to impose their views on the rest of Australians or obstruct the choices of women who qualify under the law to access abortion. These laws have been set at a state level and, currently, in appropriate clinical circumstances, a woman may choose to terminate her pregnancy in Australia. However, her options are limited to surgery.

This bill is not about abortion. The opponents claim that the population statistics indicate medical abortion is not as safe as surgical abortion. They claim it is about social policy. These people, in my view, miss the point that in a clinical situation, while we take population statistics into account, when I am talking one-on-one to a patient it is her individual risks that mean something. That is what she must base her opinion on and what I must base my advice on. There are clinical cases where medical abortion will be more appropriate than a surgical abortion, and those women are currently being discriminated against by the law as it stands.

Parliamentary interference in drug evaluation is not required when the drug's intended use is legal. The current ministerial micromanagement of RU486 will not reduce the number of abortions in Australia. Women will continue to access surgery. Those that legitimately seek to obtain medical abortion and can afford to do it need only buy a ticket to New Zealand. The best way to reduce abortions is through prevention of unwanted pregnancies through improved sex education and contraception availability. But very often it is the same extremist minority, which opposes this bill, that is actually opposing those options as well.

As a medical practitioner, my personal moral view must not cloud the advice I give to patients. I need to present my patients with the range of options that are appropriate for their individual clinical circumstances so they make informed decisions. However, currently, when it comes to advice about clinical options for abortion, my practice is compromised and my patients' choices are limited since the act of parliament in 1996 where women's reproductive choices were used as currency in a political deal. Even if some people in the community mistakenly perceive this bill as being about abortion, chances are if they were properly informed they would approve of its passing, because legitimate research shows that over 80 per cent of Australians agree with a woman's right to choose abortion and that only 9.4 per cent of Australians disagree.

Abortion is accessible under the law. Once a woman qualifies, the mode is a clinical decision made by that woman with advice from her doctor. No politician, religious zealot or moral extremist has any place in that decision. I want to practise good medicine for my patients. I implore you to let me have access to the best information for my patients. I need the TGA's advice, and the people of Australia deserve fact not opinion. They need the TGA's authority to form conclusions on RU486.

Ms Platt—I am the democratically elected representative of close to 12,000 women students at Monash University Clayton. On behalf of the Monash Student Association

Women's Department I urge you to support this bill. Restore the proper duties of the Therapeutic Goods Administration and allow them to assess all drugs before they are released in Australia, including RU486. Those who firmly believe that this drug is not safe should welcome the vindication that an assessment will bring. If indeed the drug is not safe, it will not be distributed by the TGA. If the TGA finds it to be safe, as many other countries have, then more choice will exist for women with unplanned pregnancies.

I particularly want to draw your attention to the benefits that this drug, if assessed by the TGA and found to be safe, could have for students, the people I represent. Students need more choice when considering termination because surgical abortion is not always an appealing option. For many students who have a surgical abortion, this is their first experience of surgery. This is often a terrifying experience. To add to that traumatic experience, many young women are terrified by the antichoice protests that usually occur outside the clinics they have to go to to access it.

Surgical abortion requires the student to take a lot of time out from university to miss classes, lectures and tutorials as they go to appointments, have the procedure done, go to follow-up appointments and then spend time in recovery. And although universities do have methods whereby students can access special consideration extensions and explain their reasons for being absent from class, because of the culture surrounding abortion it is often embarrassing and difficult for women students to come forward and tell their faculty about what is a very personal experience for them. By providing students with another option—that of medical abortion facilitated through RU486—it would make their life a bit easier and the experience less traumatic. It would also be able to be done at a much earlier stage, which would benefit many students. Many students do not want to wait through weeks and weeks of worry before they are able to have a surgical termination.

I would particularly like to draw your attention to students in regional and rural areas and the possible benefits this drug could have for them. Women who study outside major metropolitan centres suffer more disadvantage than those in cities when confronted with the crisis of an unwanted or unplanned pregnancy. To access abortion, these women must travel to urban areas for services, leaving behind their studies, classes, support systems and obligations. Students in particular, as I have already said, cannot afford to miss their studies, classes and support systems. The semester moves so quickly that they will be left behind in their work. In addition, many students are living well below the poverty line because student income support is completely inadequate, so they could not afford the travel and accommodation it would take to travel to a metropolitan area.

The introduction of RU486 could benefit these women, as regional medical practitioners could prescribe and supervise a medical abortion and organise any backup necessary. This would be well set out by the Therapeutic Goods Administration with their assessment. They would put stringent and strict conditions on the dispersal of this medication. This would take much of the burden from women in regional areas, particularly students. I ask you to consider students' experiences and, if this drug is allowed to be assessed and is found to be safe by the TGA, the benefits this could have for students' lives. Thank you for hearing me.

CHAIR—Thank you, Ms Platt. I now call Ms Wickham.

Ms Wickham—I am the 2006 National Women's Officer for the National Union of Students. NUS is the peak representative body for higher education students in Australia. It is a voluntary federation of student organisations who, through their internal democratic processes, elect to become affiliate members. Currently, NUS has over 70 member organisations from across the country, with a combined membership of over 650,000 university students. As well as a national office based in Trades Hall, Melbourne, NUS also has state and territory branches in the ACT, Queensland, New South Wales, South Australia, Victoria, Western Australia and Tasmania.

It has been official NUS policy since 2002 that RU486, as an alternative, non-invasive medical abortion method, be made available to Australian women. Abortion is a very difficult decision facing all women. An average of one in three women has an abortion during some stage of her lifetime and this is a constant issue faced by university students. With student income support currently set below the poverty line, it is hard enough for students to support themselves while studying, let alone a child. NUS believes in offering as much choice as is available to women to assist them through this difficult period. With the appropriate regulations set by the TGA, there will be many advantages to making a medical method of abortion available to women studying at university.

For Australian women who choose to terminate their pregnancy there is only one option, surgical abortion, which is not a very accessible alternative for university students. It is an extremely traumatic and painful experience. For the average university student, a surgical abortion is their first experience of surgery, and it can be an extremely frightening and isolating situation. Also, with the availability of medical methods of abortion, patients can avoid anaesthetic—something which many women students desire to do. In order to undergo a surgical abortion procedure, the patient must forfeit hours of their time to attend preliminary appointments and examinations, followed by the actual surgical procedure and the recovery period, as explained by Rhiannon. For university students this is highly inconvenient, particularly with respect to fixed class and tutorial timetables as well as constant streams of essays and assessments. This something that is almost impossible.

For rural and regional women students the situation is even worse, with access to abortion being severely limited. These students must travel to urban areas for treatment, leaving behind all their support networks whilst further disrupting their daily routines. For rural and regional women, huge travel and accommodation costs must be incurred, meaning that abortions almost become impossible.

Currently, all Australian women are disadvantaged by their access to abortion. NUS believes that all patients deserve to be given the best possible information and advice by their doctor. However, this is not happening at the moment. The TGA are being obstructed from doing the job that the government has qualified them to do with every other drug apart from RU486. It is their role to manage the risks associated with any drug. It is up to the TGA to assess the risks of RU486 and whether it is safe to be used by Australian women. Australian women are capable decision makers, and the introduction of a medical method of abortion would be a positive step in assisting and supporting them to make abortion as quick and as relatively painless and stress free as possible in this tough period.

This public inquiry is not about the morality of abortion, its legality or even the safety of RU486. It is about good governance and good policy; it is about who will decide if RU486 is safe and effective enough for Australian women. The National Union of Students upholds that it is the Therapeutic Goods Administration, not politicians or religious leaders, who should decide if RU486 poses an unacceptable level of risk to Australian women. The introduction of RU486 as an alternative, non-invasive medical method of abortion would be a huge benefit to all university women students, and it is wrong to allow one man to decide the freedom of choice and reproductive rights of all Australian women. NUS strongly supports this private member's bill, as all medical decisions should be made on the basis of rigorous and up-to-date medical evidence, and there is simply no-one better to evaluate this than the Therapeutic Goods Administration.

CHAIR—Thank you to the three of you for those opening statements.

Senator MOORE—Up until now I have kept my questions very much to the bill itself and the issue of the TGA, but I am going to stray with you. We have heard a lot of evidence. I know you have all been following the debate about the perceived greater safety risks of this particular method of abortion. We have heard evidence about the two-part process and the fact that people may not be able to understand that or fulfil their responsibilities—that whole issue about this being more unsafe. Everybody seems to have a pole to support whatever they are saying—sometimes the same pole for totally different views. Nonetheless, as you have each mentioned it in your statements, what is your perception of the way women would choose if the safety aspects were passed by the TGA and the drug became available—which is not what we are talking about? If women were making the choice, how do you think they would approach that, and what would their understanding of the complexities of this particular method of termination, as opposed to the other one, be?

Dr Cockburn—As I am in clinical practice, I would probably see these women. I have also visited a clinic overseas and sat in on a clinical consultation for provision of this drug.

Senator MOORE—Where was that?

Dr Cockburn—Marie Stopes International Clinic in the United Kingdom.

Senator MOORE—So it was a UK process?

Dr Cockburn—Yes. Obviously, when a woman comes in with an unwanted pregnancy, usually she either has made up her mind or is pretty close to it, but it is my job as a GP at first to assess whether she is clinically appropriate for that termination under the law. First it is appropriate for me to find out that she is not being coerced. It is also important for me to put the facts towards her so that she may make an informed decision about whether she actually wants to go ahead with that abortion.

Let us take it as a given that she has decided she wants to go ahead with it. As far as working out what would be her best clinical option, if in the hypothetical case RU486 and misoprostol were available we would obviously look at her needs socially and her needs medically. As my colleagues have pointed out, some women have fear of surgery and some women have fear of being confronted by protestors. That would be a valid decision once she has qualified for the abortion under the law, because I am now talking about social and clinical reasons for the decision of what type of abortion she has.

As far as the clinical decisions for whether it should be medical or surgical, obviously I would look at the safety data. As I said earlier, there is no proof that RU486 has killed anybody. There is an associated risk of any procedure. As I said earlier, 15 people in 100,000 will die from taking aspirin, and I think it is very important to note that. I would look at what her risks are from an anaesthetic and what her risks are from having a surgical procedure. For example, if she had had a surgical abortion before and she had had Asherman's syndrome, which is where the uterus sticks together, it would not be good for her to have another surgical procedure. It may be dangerous. I would put the options to her, I would listen to her concerns and we would come up with a decision that way. It would be ultimately her choice with my clinical advice.

Senator MOORE—What about the particular issue of the two-part process that has been raised by a number of people giving evidence?

Dr Cockburn—I think it would be naive to think that surgery was a one-step shop—that someone just goes in and basically has a suction termination of pregnancy and goes away and never comes back. There is a follow-up appointment generally in two weeks for the same reasons that we will have follow-up appointments with a medical termination, to make sure that that termination is complete. The woman will also be advised to come back if she is still bleeding. The circumstances are very similar. If she is still bleeding she will go back to her doctor. It is quite interesting: when this whole thing was coming up, I was managing a woman who was having a miscarriage. It is the same management for miscarriage. If she is still bleeding I need to find out whether she has actually still got a foetus, an embryo or whatever—parts of that pregnancy—still in place. I would do a blood test to find out and, if necessary, I would do an ultrasound. It is the same follow-up.

Coming back to the two-part procedure, to go back to your original point, they come in and are given the RU486 or mifepristone by the clinician on the spot. They do not take it home. They then come back 48 hours later, although some evidence is showing that 24 hours may be useful. They are then given the misoprostol. Some women will actually complete their termination within 20 minutes, and maybe up to four hours after that in most cases. It is absolute rubbish to say that their termination will go on for up to 16 days because they made bleed, but they also may bleed from a clot in their uterus after surgery. So clinically it is very important to understand that distinction.

Ms Platt—I believe that women will take into account many factors of their current situation when deciding their options. Providing them more choice—by allowing this if it is proved to be safe—is the best option because they can look at the amount of time they have to spend, their current situation, if they have proper support networks, if they have a doctor that they trust, if they have a hospital they can access, if they have proper Medicare and insurance, and that sort of thing. They can take into account lots of factors, including their support system and their study, the amount of time they can take off work, the support they will get from their workplace and that sort of thing. By allowing this, it will just provide them with more choice and more options.

Senator MOORE—Do you have any particular comment on the two-part process?

Ms Platt—As Sally has said, the surgical abortion also requires lots of follow-up and different types of processes. I think women will be very informed about this process at the time and they will have informed consent when they agree to it. I think most women will take this into account when making the decision—that they understand that most procedures require additional appointments and follow-up.

Ms Wickham—I completely concur with Rhiannon. University students are smart. They understand this process. As long as it is outlined by their doctors and the TGA, they are quite capable of making these decisions, apart from the fact that this could be a more attractive option because women students could be scared of surgery and anaesthetics. The fact that it might be over quicker is something they might consider but, as Rhiannon said, they are quite capable of making these decisions themselves.

Senator POLLEY—I listened carefully to what you were saying in your opening statements and then again to the answers to Senator Moore's questions. I have to say that I am a little concerned that people would still think that this is a quicker option, so I would need to clarify that as the student body's representatives you actually think that this form of abortion is quicker than a surgical procedure.

Senator MOORE—I thought Ms Wickham's comment was exactly the opposite, that the surgical one may seem quicker but that was part of the decision. I am sorry; that is how I heard your response.

Senator POLLEY—If I could continue, I would have thought too that the amount of time that students lose from their study and from university would in fact be shorter if it was undertaken by a surgical procedure that had been carried out in an hospital. I also have grave concerns that we would all be so naive to think that all women would actually follow up on a procedure like this as they would for any other procedure, where they are having any other treatment. There are women who do not access doctors automatically afterwards to do the follow-up procedures. I was most interested to see whether you thought that this was a quicker and a better alternative for young women.

Ms Wickham—To be honest, I cannot evaluate that as it is not an option yet in Australia. I could not say that it would be a shorter or a quicker option compared to surgical abortion. I think women will make this decision on their individual needs. I think time and travel is an issue, and that is more of an issue for any rural woman accessing abortion. And obviously women who study are also in rural areas. More to the point is the issue that a medical based abortion could be less harmful to younger women.

Dr Cockburn—Can I put that in the personal context of the woman that I saw. It is very important to understand that you are policy makers, and I respect you for that. I am a clinician who deals with the individual. If I have an individual before me, your policy will affect that individual. If I have got a woman before me who has the reasons to require a medical abortion or, more to the point, not have a surgical abortion, then your policy will prevent that woman having that medical abortion. And if it is that she is not appropriate to have surgery but she needs the abortion, if she has got a husband who is beating her and she has only got two hours to get out of the house before he finds out that she is there, she can come, she can get that medication and go home before he has time to find out that she is there and beats her. And it is

my job as a clinician to make sure that she has the best clinical options available to her. I understand you make policy, but I deal with individuals.

Senator BARNETT—Is that a real-life scenario?

Dr Cockburn—I have had that sort of situation before, yes. Not in terms of abortion, because the medical abortion was not available, but, yes, I have had a woman who had a partner who would not let her out of the house for more than two hours. It was a radio call that I had some years ago to my radio program. Her husband even told her that he knew where all the CASAs were, that if she tried to go to a women's shelter he would find her. She did not know how to leave him because he was violent. Do not underestimate the sorts of situations that women find themselves in, and please remember: while your policy is for everybody, I am dealing with the individuals.

Senator POLLEY—We have had figures put to us throughout the course of today and our previous hearing. I am curious to know: with abortion now freely available in all states, why is it a necessity to have a medical procedure as opposed to a surgical one which is proven to be a safe option? Can you provide evidence of any women who have been denied access to an abortion through a surgical procedure?

Dr Cockburn—I do not understand the relevance, Senator.

Senator POLLEY—We already have access available for women to undertake surgical procedures which are safe.

Dr Cockburn—Some women are not clinically appropriate to have surgical abortion. In some women it may be not appropriate to have a surgical abortion. Those women deserve an option, because they do not have an option other than surgery—although they could go and buy a plane ticket and go to New Zealand, but that would disadvantage my colleagues here who cannot afford to buy a plane ticket and go to New Zealand. At the moment, as it stands I cannot give that woman—my patient who trusts me for medical advice—advice on whether this drug is safe because the TGA cannot tell me. I know overseas information and, based on the 35 countries where this is safe and the 20 million women who have taken it, it would appear that the overseas evidence says it is safe, but I want the TGA to be able to tell me, not the minister for health—with all due respect.

Ms Wickham—The difference here is also the amount of time. Medical abortions can occur much earlier than surgical abortions, so that will benefit some women who need to get the process over with a lot earlier. That is what we are referring to when we refer to a quicker process.

Dr Cockburn—I will comment on that too. You can take these drug combinations as early as four weeks—as soon as you find out that you are pregnant. One of my colleagues said earlier today that at that stage you are talking about a grain of rice sized embryo—not to diminish the importance of a pregnancy at any time. However, the passing of that termination can in fact be a lot less traumatic procedure than to know you are pregnant but have to wait four or five weeks before you can have the termination that you are clinically and legally entitled to. These young women would have to live with the nausea, the symptoms of pregnancy and possibly even the social stigma associated with that. It could interrupt their studies and severely affect their academic procedures. I deal with these women every day. I

have to speak to them and I have to answer their questions. I implore you to think of that when you are making your policy.

Senator ADAMS—Thank you very much, all of you, for your submissions. Dr Cockburn, let us get back to the terms of reference. You have mentioned that at the moment, because the drug has not been given the authority to come into the country, the TGA has not been able to evaluate it. Can you tell me where the minister for health would be getting his information from?

Dr Cockburn—God only knows. I really have no idea where he would be getting his information. He certainly asked his chief medical officer for some advice on a narrow point, but he has been found to have misinterpreted that advice. If the minister is seeking advice from his chief medical officer and misinterpreting it, I worry about what other advice he may be misinterpreting. I believe Benjamin Disraeli once said: 'There are lies, damned lies and statistics.' I implore you, ladies and gentlemen, to be very careful when people give you statistics, because we can all choose statistics to support our cases. You need to be extremely careful of that. Many of the statistics that are put before you are confusing. As far as where the minister would get his advice from, I do not know.

Let me point out one thing, though, that no-one has brought up about this amendment. Item 23AA in the Therapeutic Goods Act says:

In spite of any provision of this Division, restricted goods must not be evaluated or registered or listed without the written approval of the Minister.

This was added by Senator Harradine's amendment in 1996. It is very important because it is different to what the secretary had as authority beforehand. The word 'evaluated' has been added here, and it has created a classic catch-22—that is, the minister would normally seek advice from the TGA, but if he goes to the TGA they say, 'Sorry, Minister, we can't even assess this drug unless you sign it off.' He says, 'But I want to know whether I can sign it off, and I'll only do that if I know it's safe.' 'But we can't tell you whether it's safe.' It is an absolutely circular process. As was pointed out earlier, I cannot see why anyone who thought this drug was unsafe would not allow the TGA to assess it, because they have the right to put their submission to the TGA like anybody else.

Senator BARNETT—Thank you. Ms Wickham, in paragraph 2 on page 3 of your submission, you say:

Although RU 486 has an extremely low adverse drug event rate a mere 0.137% even compared to the over-the counter drug Claratyne which has an adverse rate of 12%.

What is Claratyne used for?

Ms Wickham—I got this from a web site that had some evidence. Claratyne is a drug that I do not know much about. I would like to hand that over to Dr Cockburn to answer.

Dr Cockburn—In that situation, my colleague has given you some evidence. She does not need to know the clinical application. Claratyne is an antihistamine medication. You take it if you have allergies.

Senator BARNETT—Thank you, Dr Cockburn. My question was to Ms Wickham. I understand that you are representing the National Union of Students?

Ms Wickham—Yes.

Senator BARNETT—We have a submission before us from you, and I am reading from it. You are not sure of the source, but you think it is a web site that you have referred to—

Ms Wickham—No. I found this on the Reproductive Choice Australia web site. It is information they put together.

Senator BARNETT—Do you still stand by the statement that it is such a big difference—87 times more serious?

Ms Wickham—As far as I can tell, yes. I think this is a good case for why the TGA needs to look at this information. As we have discovered today, there are all sorts of quotes, statistics and arguments floating around. Some give a pro-choice slant and some give an anti-choice slant.

I think that the best way for all of this to be solved is to pass the amendment to make the TGA responsible for giving an unbiased opinion on this. This is something I am willing to stand by, but it seems to have been an issue throughout all of today. Arguments and for and against ratios are given. I think the best way to clear this up would be to let the TGA do its job.

Senator BARNETT—May I just draw your attention to the *Hansard* of this morning's evidence where we had the same debate with the Public Health Association of Australia. On questioning, they said that it was not an appropriate comparison. Have a look at their testimony. In particular the adverse events from Claratyne, for example, were dizziness, headache, nausea and so on. The adverse events referred to when we talk about RU486 are hospitalisation and the events as a result of hospitalisation. There is a clear difference between the definition of an adverse event from RU486 and an adverse event from Claratyne, which is an entirely different type of drug.

Dr Cockburn—Chair, I think it is a little bit harsh for the senator to be grilling my student colleague on clinical drug matters. She has made a statement, and she has told you where she got it from—

CHAIR—I understand what you are saying, but that is really a matter for Senator Barnett rather than me.

Senator BARNETT—With respect, through you, Chair, it is related to the submission before us. Ms Wickham, it is an assertion made in your submission, and I am seeking your response to it. The second question I have is from the first paragraph of page 2 of your submission where you say:

> In order to undergo this medical procedure the patient must forfeit hours of their time to attend preliminary appointments and examinations, followed by the surgical procedure and the recovery period. For university students this is highly inconvenient use of time particularly in regards to their fixed class and tutorial timetables and constant stream of essays and assessments.

I guess you are drawing a comparison there to RU486. With use of RU486, would your fellow students be going to classes during the time period when they have the drug and when the abortion takes place—up to 12 or 14 days? What will they be doing during that time? Are they

going to continue to go to their fixed classes and to follow their tutorial timetables? Will they still be able to meet those requirements?

Ms Wickham—Yes, I think so, on doctors' recommendations. As far as I can tell—and I am not a doctor—through abortion or the termination of pregnancy it is actually not much different to the menstrual cycle and females still attend classes and can actively participate in classes and tutorials at that point of the month. So I would say yes.

Dr Cockburn—With respect, if I can just make comment on that again, it is a very clinical question that you have asked my colleague. I have actually seen a patient who has had this drug, and she was going home to pick up her children from school straight after taking the drug. This is very important, and I think it highlights why the TGA needs to tell us the story.

Senator BARNETT—Finally, Ms Platt, you said to the committee earlier, on the record: 'if RU486 was proved to be safe'. Is it safe?

Ms Platt—That is my whole point. I am not a doctor; I am a student studying arts. I have no experience to make this judgment. The only body that can make this judgment is the Therapeutic Goods Administration. Please allow it to do its job. The health minister also cannot make this decision. He has no medical degree and no experience in this area. We must allow the TGA to assess this.

Senator BARNETT—Based on the research you have done, you are not sure whether it—

Ms Platt—It is not my job to decide that. It is the TGA's job.

Senator BARNETT—Do you have an opinion?

Ms Platt—No, and I do not need to have an opinion.

Senator BARNETT—Okay, thank you.

Senator MOORE—Chair, I would just ask that in future, when Senator Barnett talks about the time it takes for this process, he could use the term 'the time it takes' rather than putting down '12 to 14 days' all the time, because that is—

Senator BARNETT—I said 'up to'.

Dr Cockburn—It does not take that length of time, in fact. You are incorrect.

Senator MOORE—It would just be better in terms of the debate, Chair.

CHAIR—That is a matter for the committee to form an opinion about, based on evidence.

Senator ALLISON—Dr Cockburn, you have pointed out the catch-22 impossibility of anyone evaluating this—the minister or the TGA. What is often cited is the higher level of public accountability of the current process. Do you have any remarks to make about that, and what did you glean from your visit to the UK with regard to their public accountability on this decision making?

Dr Cockburn—To answer your first question first, I understand that at the moment, the way the act stands, the minister for health may not tell us whether he has not approved an application, but he must put before the parliament within five days his approval letter. It does not actually state what the parliament can do with that knowledge. It does not state whether the parliament can override him. I presume you can put an act in place and wait six months

and do something, at which time that woman is probably languishing. But, as far as I am concerned, the catch-22 situation is that we will never get an answer while we have a minister who is trying to get his response from the TGA but the TGA cannot answer until he makes it safe. I hope that answers your question.

The TGA is ultimately responsible to the secretary. The way it would work is that the TGA would evaluate this drug as it would evaluate any other drug. To override the Customs Act, which stops anyone importing this drug at the moment, that would be referred to the secretary. If the TGA deemed that this drug was safe and effective, the secretary would then sign off that the Customs Act could be overridden. That is what would usually happen, in fact. That is what was happening before, while the TGA was actually allowed to look at this drug. That was changed in 1996 but, as I said earlier, the thing that was brought in and put on top of that was the fact that they were not even allowed to evaluate it. So the key point is that they are not even allowed to assess it for us.

With regard to the accountability in England, I am not quite clear on the legislative situation. However, I know that the clinic has protocols. They have medical advisers that make their protocols. I am sorry—I am not sure about their relationship with the national health system, but I know that Marie Stopes International, which was the clinic I visited, certainly has medical protocols. The people there try to do world's best practice in this area. We would be in a very good position if this drug was ever made safe. We have world's best practice to look at to make sure that we can make this drug as safe as possible.

By the way, there is just one more thing, if I may. Just to give you a better example than Claratyne—I can give you the reference if you would like it—a person taking aspirin is 150 times more likely to die than a person having an abortion under eight weeks. Even with your worst-case scenario, a person taking aspirin is more likely to die from gastric haemorrhage than someone taking RU486, and I am happy to provide that reference for you.

Senator WEBBER—Ms Wickham, this question unfortunately is not quite on the terms of reference, but you have to indulge me here. Your organisation is a national organisation—correct? So, in my home state of Western Australia, you would represent regional campuses of universities?

Ms Wickham—Yes.

Senator WEBBER—That includes the campuses we have in, say, Bunbury, which is over 200 kilometres south of Perth; Geraldton, which is 500 kilometres north of Perth; Kalgoorlie, which is 600 kilometres east of Perth; and Broome, which is thousands of kilometres to the north of Perth?

Ms Wickham—Yes, that is correct.

Senator WEBBER—You would have a network on all of those campuses?

Ms Wickham—Yes.

Senator WEBBER—When other senators say that surgical terminations are freely available everywhere, in Western Australia in fact they are only available in Perth?

Ms Wickham—Yes.

Senator WEBBER—So, if we allow a medical termination, the students that go to university in, say, Broome would therefore have to pay $700 or $800 to come to Perth for a surgical termination—just to get there and back, without the cost of the termination?

Ms Wickham—Correct.

Senator WEBBER—So when we say that they are freely available everywhere—

Ms Wickham—It is absolutely incorrect.

Senator WEBBER—It is that regional network, in terms of providing for young women on campuses—this actually does give them a realistic option?

Ms Wickham—Absolutely—in regional campuses all across the country. No students have much of a support network at the moment, unfortunately. The voluntary student unionism legislation has really cut funding to all sorts of support networks, particularly for young women. Women's departments and women's networks will now have to be funded voluntarily, so we will see the close of any sort of rural support network, and medical abortions would absolutely help out these women all across Australia, particularly in Western Australia.

Senator McLUCAS—A number of people have expressed concern that, given it is a two-part treatment for medical termination, potentially they might not come back to have the second part of the treatment. If that occurred and you were the prescribing doctor—

Dr Cockburn—I would not prescribe it in the first place. I would not prescribe a medical abortion to a woman who did not agree. Can I give you another example. Category X is a category within our PBS which has drugs which cause severe foetal malformation. I know that point has been brought up. I will give the classic example of isotretinoin, which is used for acne. You may know it as Roaccutane. This drug is well known to cause severe foetal abnormalities. It is prescribed to young women who, I am sure my colleagues know, are in that age group that has acne. The thing about this drug is that I must get agreement from the woman that, if she is going to take it, she will take contraceptive agents. If she says she will not take those, she does not get the drug. The same would apply with this. If this woman did not give me an undertaking that she would come back for her second dose, I would not prescribe it. I would say, 'Maybe you're better suited to a surgical abortion.' So, again, it is a clinical decision.

Senator McLUCAS—Let us take it another step further. You have taken that precaution and you have only prescribed it to a person who you believe will reattend your surgery. Then the person does not come. What would you do then?

Dr Cockburn—My normal clinical practice, of course, would be to take contact details for this woman. I would make absolutely certain that, if that woman did not reappear, my clinic would be onto her very quickly. I would contact her personally if my staff could not get her. We do this all of the time. This is normal clinical practice to follow this up. It is caring practice—that is what we do.

Senator McLUCAS—Just as a final judgment, what likelihood is there, do you imagine, that someone would not reattend given the seriousness of the—

Dr Cockburn—I think it is an insult to suggest that a woman who is seriously going to decide to have an abortion and has made that big decision in her life is going to actually take

that lightly. Once it is explained to her that there is a chance of not having a complete abortion with the first drug but taking the second one makes it very likely that she will —and that she will not be able to tell, because she may be bleeding but she may not have passed it—I think it is highly unlikely. I think it is entirely insulting to suggest that any woman would do that to her own body.

CHAIR—I come back to the issue that was raised at the beginning of the evidence that you gave about the idea of politics intruding into the clinical relationship between a woman and her doctor. When the original legislation that put in place this restriction was put forward in 1996—

Dr Cockburn—In 1996, was it?

CHAIR—In 1996 this amendment was put in place at the behest of Senator Harradine to ensure that there would be ministerial approval before there could be TGA approval of this drug. In that debate then Senator Chamarette, who was a Greens senator from Western Australia at that time, said:

There is not only a health issue in the narrow sense—that is, whether the drug is safe—but also a question of whether the availability should be limited for ethical or policy reasons in the context of social policy ...

I ... affirm the right of this parliament to have scrutiny over such issues.

Putting to one side the question of whether the scrutiny is there with the way the minister at the present time makes that decision as opposed to a broader body of people such as cabinet or a parliamentary committee or whatever, isn't it true that, with the controversy and intense social divisions in this community about issues like abortion, there should be that overview by elected politicians as opposed to nameless bureaucrats or—

Dr Cockburn—We can find out their names. They all have names.

CHAIR—Okay, but to the general public they do not have names. You and I could not name the people who are making those decisions.

Dr Cockburn—There is FOI. We like FOI.

CHAIR—The point I am making is—

Dr Cockburn—They are not nameless people, Senator. I think that is a bit emotive. They are actually committees of people—experts—who make those decisions. They are not nameless bureaucrats.

CHAIR—The point I am making is that these people are making decisions on technical grounds and on the grounds of the medical efficacy of a particular drug.

Dr Cockburn—Exactly—

CHAIR—But isn't there a broader social issue about these things? Take the example of abortion legislation in every state and territory. The framework for abortion in states and territories has already been determined not by committees or advisory committees like those in the TGA but by politicians elected by the public of Australia.

Dr Cockburn—Exactly, and those laws at the moment allow a woman to have an abortion. Those are state laws.

CHAIR—They allow it in widely varying circumstances.

Dr Cockburn—I am talking about the clinical circumstances that allow a woman to have an abortion. It is legal.

CHAIR—Sure, but those decisions have been made by politicians who are accountable to the electorate.

Dr Cockburn—Therefore we have nothing to argue, Senator, because they have already been made.

CHAIR—In that context—the context of surgical abortion—they have been made.

Dr Cockburn—No, the legislation does not refer to surgical or medical abortion; it refers to abortion. What you are proposing to do is to limit a woman who has the legal right to have an abortion. You are proposing to limit her so that in appropriate clinical circumstances she may not have a medical abortion. I would absolutely state that it is not a politician's decision as to whether I should recommend to a woman that she should have this drug or that drug. Would you like to come into my practice and sit beside me and tell me whether I should prescribe Amoxil or Rulide for sinusitis? That is what you are actually proposing, Senator. Without wanting to belittle the process, it is the same situation: you are wanting to come into my practice and tell me how this woman is best clinically treated for a legal procedure. If you wish to make abortion illegal, why not put up a bill to that effect?

CHAIR—I make the point, though, that there has already been parliamentary debate and it is accepted that the community has the right to have debate at the parliamentary level about whether or not abortion should be available and in what circumstances.

Dr Cockburn—Yes, and I have this conversation with my local minister, Senator.

CHAIR—Let us assume we can project ourselves back in time, 30 or 40 years—

Dr Cockburn—Can I project you to my current local minister, who I went to see?

CHAIR—Could I just finish my question, if you do not mind. Let us cast our minds back—let us pretend we are 30 or 40 years in the past and we are about to decide whether abortion should be legal, whether the then common law ban on abortion should be—

Dr Cockburn—I am glad we are not there anymore, Senator.

CHAIR—Indeed. But let us pretend we are there. Would you have said at that stage that the decision on whether women should have access to abortion should have been made by officials of a department of health of a state or—

Dr Cockburn—Senator, I am going to have to ask you to put your chairman's hat on here and maybe take yourself to task, with all due respect, because abortion is not within the terms of reference of this bill. This bill is about whether or not it should be the minister or the TGA who decide. The issue of abortion we fought in the seventies. We won. It is finished.

CHAIR—With great respect to that point of view, the issue of whether abortion of this kind should be available is a different issue and is an issue which is to be decided at the federal level, as opposed to issues about surgical abortion which have been determined in the past at the state level.

Dr Cockburn—I totally disagree. It is not about surgical abortion at a state level. It is about abortion at a state level. The analogy I could bring to you is: you are telling me whether I should do a laparoscopic cholecystectomy or an open operative cholecystectomy for a patient with a gallbladder. You are talking about two different clinical procedures for a legal clinical option. It is a clinical decision.

CHAIR—I am sorry, I do not agree with what you say.

Dr Cockburn—You have every right to disagree with me, Senator, but you have no right—

Senator BARNETT—Dr Cockburn, you can't—

Dr Cockburn—I am sorry, Senator Barnett, I did not know you were the chair. Senator Humphries, I must say—

Senator BARNETT—On a point of order, Mr Chairman.

Dr Cockburn—Oh, please, Senator!

Senator BARNETT—Chair, I am aware of your attempts to ask some questions—

Dr Cockburn—And I have attempted to answer them.

Senator BARNETT—and I think it would be excellent if Dr Cockburn had the opportunity to answer you when you have finished asking your question.

Dr Cockburn—I am sorry, I thought you had asked it, Senator. You have asked it five times.

CHAIR—I do not think we are getting anywhere with that line of questioning, so—

Dr Cockburn—Senator, you have every right to your opinion, as does Senator Barnett, as does Senator Allison, Senator Moore and all of you around this table, and every parliamentarian. You have every right to your opinion; the nine per cent of Australians who agree with your anti-abortion stance have every right to theirs. And I would stand in the way of anyone who came and tried to make anyone have an abortion. But it is inappropriate for you to make us have your personal view imposed upon us for a legal procedure.

CHAIR—Dr Cockburn, I am not suggesting that there should or should not be access to abortion by individual women. I am trying to determine, as part of this process, who makes that decision.

Dr Cockburn—The TGA.

CHAIR—That is your point of view; you have put that point of view. I am arguing that there should be political oversight of that process, because that is what the Australian community expects with respect to public policy input on such an important issue.

Ms Platt—I do not think the public expects that at all. I do not think the public expects a particular party that is in control at the time or particular ministers with their own agenda and their own views and their own morals to make that decision. The public believe that we have put our trust in the Therapeutic Goods Administration. It is the legal body that determines whether drugs are safe and should be accessed, and I think that is what the public respect.

They do not think it is right that that can change with the whims of government and the whims of ministers.

CHAIR—Can I correct something you have said there. This is not determined along party lines. Issues to do with abortion have always been determined, in federal and—as far as I am aware—every state and territory parliament, along personal conscience lines. So individuals make those decisions irrespective of what party they belong to.

Ms Platt—But the decision is being made by the minister. The minister is a representative of the party. He is responsible, at the moment, for personally making that decision, which would be affected by that. I do not believe that is right. It should be the TGA, which is not biased and which will not be affected by that.

Dr Cockburn—The people of Australia have not had a chance to elect a government on the basis of abortion. My local member did not tell me his views on abortion before he was elected.

CHAIR—Did you ask him?

Dr Cockburn—Yes, I did.

CHAIR—He would not give you his views?

Dr Cockburn—Correct. He was evasive on the issue.

CHAIR—Well, I have to say most members of parliament that I know of are asked by their electors about that subject and they do give an answer.

Dr Cockburn—What is your view, Senator Humphries?

Senator HUMPHRIES—I have been opposed to abortion, and I have stated that view on all six or seven occasions I have been elected to parliament, at different levels, in this country. Let me say: there are lots of issues where ethical considerations come in and members of parliament have to make decisions on those bases. I will give you an example, to ask you to comment on. We have a debate that has been taking place for some years in Australia about reproductive technology and issues like genetic engineering. You might say that politics should not intrude on the right of a scientist to develop and use technology which allows a person, say, to design the genetic make-up of their child. You might say that if science can do it—

Dr Cockburn—I actually do not see the relevance to this bill—

CHAIR—then politics should not intrude in that. But politics does intrude in that.

Dr Cockburn—Yes, but I do not see the relevance to this bill. It is not an analogy you can draw. The reason you cannot draw the analogy, with respect, is because what we are talking about is a legally accessible procedure with various clinical options. With the legal procedure, you are proposing to limit the clinical options that a woman can have. It is not about whether it is ethical or not, as far as the procedure is concerned. That has been decided. You are saying I cannot give her information. I am prepared to abide by the TGA's decision. If the TGA believe it is unsafe then I know that they will find it that way, and I am prepared to abide by that. At the moment I do not even know whether it is safe in Australian terms.

CHAIR—We will have to agree to differ about that matter. There being no other questions for these witnesses, I thank you all for your appearance here today.

Proceedings suspended from 3.42 pm to 3.53 pm

[3.53 p.m.]

EGAN, Mr Richard, Member, Festival of Light

PHILLIPS, Ms Roslyn, Research Officer, Festival of Light

PIKE, Dr Greg, Southern Cross Bioethics Institute

KLEIN, Dr Renate, Private Capacity

CHAIR—We are quorate, so I call to order the last session of today's hearing of the Senate Community Affairs Legislation Committee. I welcome Dr Klein, the Southern Cross Bioethics Institute and the Festival of Light. Thank you all for appearing today and for the submissions you have made to the committee. I think you have all been supplied with information on parliamentary privilege and the protection of witnesses and evidence. I now invite each of you to make a short opening statement. At the end of that we will proceed to ask you some questions. Perhaps, Dr Klein, you might like to kick off.

Dr Klein—Thank you for allowing me time to address the inquiry of this Senate committee. I want to start by saying that it is really important to note that a vote against the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 in favour of keeping the 1996 amendment is not a vote against Australian women and their right to have access to safe abortion technology. Current best practice, which is suction abortion with a local or general anaesthetic, something which is over in 10 minutes, is far preferable to the always—and I want to stress 'always'—unpredictable and thus never safe combination of RU486 and a prostaglandin. That takes days and can be incredibly painful both physically and emotionally and may have long-term effects on the health of women.

Before I continue with RU486, I want to emphasise that I believe efforts need to be made to work towards better access to suction abortion, especially for women in remote locations. Campaigns are also needed to enable women to continue with their pregnancy, if they so wish. Importantly, public debate has to focus on the role of men in unintended pregnancies, to document the high percentage of sexual coercion in relationships, which leads to pregnancies and abortions. In a 2003 Australian study, it was as high as 21 per cent, which is not acceptable. The number of unintended pregnancies can be reduced—and that is what we should focus on, instead of campaigning for a highly unsuitable chemical abortion.

Promoters of RU486 insist that the debate over RU486 is one between pro-life and pro-choice values and argue that the current health minister is biased because he is not in favour of abortion. They say, therefore, that the TGA is better suited than Mr Abbott to assess chemical abortions. I fully support a woman's right to a safe abortion, yet I contend that the brief of the TGA to assess quality, safety and effectiveness of the drug as well as its funding arrangements does not enable it to fully canvass the range of scientific, social and ethical issues emanating from the complexity of RU486 prostaglandin abortions.

If the Senate were to approve the bill and shift the responsibility of RU486 to the TGA, what exactly would the TGA evaluate? The initial approval process of RU486 in France has had a chequered history—incomplete trials, women dropping out and trials paid for by the French manufacturer, Roussell Uclaf. That is all documented in the book I have here. In the nineties, during the US approval of RU486, the FDA criticised the French trials but used them

in their own process. That in turn was full of flaws and revealed the political bias of the Clinton administration, which quickly approved RU486. For instance, the FDA fast-tracked approval for RU486 under the accelerated approval regulation, which is normally reserved for drugs that treat life-threatening diseases. The FDA allowed the applicants, the Population Council Inc. and Danco, to have only one trial instead of two, which was also uncontrolled, and waived the extra trials needed when a drug is given to people under 18. Importantly, it approved RU486 for abortion, despite the refusal by Searle—the manufacturer of the necessary second chemical, misoprostol.

All of this is important in the Australian context. Given that the TGA works on a full cost recovery basis, a user-pay basis, and does not receive funds from the Department of Health and Ageing to cover drug application costs, it is unreasonable to believe that it would be able to force any RU486 applicant to pay for entirely new trials in Australia that by necessity will take years. Pfizer, which now distributes misoprostol in Australia, has come out this week and repeated Searle's earlier point that misoprostol must not be used for abortion as it has never been trialled for this purpose. Pfizer stated that trials for abortion will take years. Who would pay for them, as the TGA clearly cannot, when the manufacturer itself is not interested? I contend that if the responsibility for RU486/PG abortion were to shift to the TGA, it would be highly likely that it would indeed rely on the FDA approval data, including off-label use of misoprostol. By association, it would also rely on the French data, which, as I have already said, are very compromised.

The TGA is also likely to rely on: the claim made by promoters that RU486 abortion has been used by millions of women; and new studies that—we dissected them in our book—are full of inconsistencies. There is no hard data for the claim that millions of women have used and liked RU486 but, even it were true, numbers by themselves are meaningless. Other drugs and devices such as Norplant, DS—the Dalkon Shield—et cetera and, most recently, HRT were also used by millions of women, causing serious damage to their health before finally being exposed by medical research, as—in the case of HRT—increasing the risk of breast cancer as well as cardiovascular events.

If the TGA were to treat RU486 as well as misoprostol together as just another drug then chemical abortion might well gain approval, just like Vioxx did, in spite of the already apparent problems that were known to the manufacturer. Endorsements of RU486 abortion by professional bodies such as the RANZCOG and the AMA are understood by the general public to be the result of these bodies' own trials—which they are clearly not. The voluntary reporting in Australia of adverse effects by medical professionals and pharmacists would make it unlikely that the public would be fully informed of problems with chemical abortion. That is due to fear of the kinds of reprisals from anti-abortion advocates that have been seen in other countries. Also, the merging of the TGA with New Zealand's Medsafe could bring in RU486 on a technicality. These are all good reasons why the public needs to hear about any developments from its politicians via the health minister.

As I point out in detail in my submission, RU486/PG abortion is an incredibly cumbersome process that 're-medicalises' rather than 'de-medicalises' abortion, because of the need for multiple doctors' visits and repeated pelvic examinations, including ultrasounds. So it is not

instrument free and it is also more expensive than suction abortion. In New Zealand, it costs as much as $1,000. In Europe, it is usually around $600.

For many women it is contraindicated: for instance, for those under 18 and over 35, heavy smokers, those taking anti-inflammatory drugs or those who have asthma—as well as any cardiovascular risk factors. The adverse reactions are severe and include: heavy bleeding necessitating blood transfusions; severe pain necessitating opiate painkillers, because codeine blocks prostaglandin action; perforation of the uterus from severe PG action; heart attacks and infections, which have led to five documented deaths from toxic shock syndrome. All in all, we know of nine deaths from RU486 abortion, but I am sure there are many more, because many deaths would not have been recognised as being due to RU486. Also, the risk of death from RU486 abortion within the first seven weeks of pregnancy has been estimated as 10 times higher than that from conventional suction abortion.

I ask you, really: why would anyone in their right mind try to say that such a procedure is safe and a good choice? And I have not even mentioned the heavy-duty emotions for women during days of waiting for the product of conceptions to emerge. Even if this is very small, some unlucky women may see limb like structures in their bloody pad. To make light of all of this, as we have heard, by comparing it to a miscarriage, is (a) insulting for women who have had miscarriages and (b) not true.

I want to finish by pointing out that it became evident quite early in the trials in the eighties that RU486 is unsuitable as an abortifacient because of its multiple sites of action in the body. It does not just act on the uterus to interrupt the pregnancy. Most notably, it is also an antiglucocorticoid agent—and thus may be a good drug for Cushing's syndrome—but this is also the reason why it lowers the body's ability to fight an infection. The 1996 amendment does not ban RU486, as we have heard incessantly in the media, and indeed research into RU486 is ongoing in Australia for a number of indications. But if there were to be a chemical for abortion you would need one that was specific in its action on the developing pregnancy, and RU486 is not.

To finish up, no-one should be under the illusion that chemical abortion is primarily designed to give women in Western countries more choice. Instead it was and remains an aggressive instrument of population control to contain the number of fertile women in non-Western countries. Indeed, there is a current massive push into the so-called Third World by the ICMA, the International Consortium for Medical Abortion. In my view, the Australian Senate and your committee in particular has a great opportunity to make sure that Australian women remain RU486 free and that no lives are lost unnecessarily. I have added a summary of the points I have made. If you want copies of that, I have a few here. Thank you very much for listening to me.

CHAIR—Thank you. Could you table that statement you have given us?

Dr Klein—Yes.

Dr Pike—Thank you to the committee for the opportunity to address you all. I want to focus some comments specifically on the nature of this social policy question. I frame it that way because I do believe it is very much a social policy question, despite the fact that this bill has sometimes been construed as being merely about operational matters. The fact that there

are a huge number of submissions and the fact that there are strongly worded submissions from both sides and so on—perhaps the likelihood of what this really means if it were to go to the TGA for approval—does mean that we are really talking about a major social policy question. How that is handled will say something to the Australian people.

I think that what it will say is that, if our elected representatives do make a comment by way of this bill on this social policy question, they are endorsing the status quo on abortion. Perhaps going one step further, that endorsement—expanding in a broad sense the abortion industry and the ability of abortion providers to provide more widely—will look like power to the abortion industry. I do believe that the social policy questions should remain with our elected representatives, because that gives all of us a voice, and the TGA of course has the capacity to carry out what it does, but that is really an operational matter. But this is a serious social policy question.

In about April last year, the Southern Cross Bioethics Institute undertook a major survey of Australian attitudes to abortion. We undertook that particular four-stage research, which is now reaching its conclusion, primarily because we felt that there was an inadequacy in a lot of the research which had been done before and there was a lot of nuance in the way Australians think about this very complex moral, ethical, social, political issue. What we found was rather surprising, and I have to say that some of it took me by surprise, and some of the views that came out from average Aussies were not what I might have wanted to say, but 87 per cent of people in the stage 1 survey did say that they would like to see a reduction in the numbers of abortions but that abortion ought to remain legally accessible.

There were many other findings in that study, far too many for me to go into on this occasion. But the point I really want to make is that there is a sense in which any endorsement of abortion, any expansion of power for the industry, any widening of the access to abortion, will be perceived by the Australian people in that very way, and it will go against what I think they have already expressed, as we have found in this survey, which is that they want a roll-back, not a roll-on. If indeed that sentiment is accurate, and I have strong reasons to believe it is, that sense of a roll-on is one which is very much within the responsibility, I respectfully suggest, of our elected representatives. Thank you very much.

CHAIR—I call Mr Egan.

Mr Egan—Thank you, Chair. The Therapeutic Goods Administration can only, as we all know, assess drugs for quality, safety and efficacy. I think the act specifically says efficacy is to be understood as doing what the applicant for an approval says the drug should do. In this case we are talking about a drug whose purpose is to terminate the life of an unborn child in order to end a pregnancy. The TGA cannot consider the meaning of that act in any way at all. It would be exceeding its brief if it gave any consideration to that. It cannot take the position, one that a substantial number of Australians take, that in a pregnancy there are two patients, the woman and her unborn child. The TGA is simply prohibited by law from considering that, because it is looking at the efficacy of the drug for the purpose, which in this case, if there were an application, would be to end the life of the unborn child.

It is clear then that a drug of this kind raises broad social and ethical questions, whatever position one takes on them. We have certainly heard today from other witnesses a passionate

defence of a woman's right to choose. There are others who feel passionately for the right to life of the unborn child. But the TGA simply cannot consider those issues. I think it is just impossible to say that, when the federal parliament is faced with the question of who should make the decision on a drug of this kind, it then has to also pretend that this drug is no different from any other drug. It clearly is different from any other drug, and that is why there is this impassioned debate between two points of view.

So for the parliament to decide that this drug is going to be treated like any other drug is to take a position on the abortion question. It is to say that abortion is simply another medical procedure; it is another therapy. What illness is it curing, some of us would ask. That is what this bill is inviting the federal parliament to do: to really take a position on the abortion question. Those who are pretending that this is just a matter of mechanics or procedure really have not explained to us why then there is a conscience vote on this question. If it is a matter of procedure, it should have been left to the government to determine what was the best procedure in these circumstances. The fact that the Prime Minister has given a conscience vote means he is acknowledging—and so is Mr Beazley and the Labor caucus—that this does engage the abortion question—otherwise there would be no conscience vote.

Simply observing that abortion is legal in some states and territories in some circumstances cannot absolve the federal parliament of its specific constitutional responsibilities which have to do with the import of drugs. I draw a parallel with the euthanasia question. Euthanasia law is a matter for the states and territories—sorry, not for the territories since 1996. But euthanasia law is a question for the states at least, and yet the federal government has control of Customs. It was quite proper for Senator Ellison, as minister for customs, to take steps to stop the import of exit bags from Canada. The federal government, within its sphere—its constitutional areas of responsibility—can engage with questions of life and death, even if the states have some jurisdiction on the same matters. This is a question of the import and licensing of a drug, which is clearly a Commonwealth constitutional responsibility, and it is a drug for the purpose of causing abortion, so it does engage the Commonwealth in its responsibilities—and to say the matter has been decided by the states really is no argument at all.

As a layman with no medical expertise trying to read up on this question—and I have read as much of the medical literature as I can understand and follow—I have certainly been dismayed by the very glib assurances from the Australian Medical Association, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal Australasian College of Physicians and the Royal Australian College of General Practitioners, all of whom simply misquote or misuse the data that is available. I am quite prepared to say that on the record. On the Greene article particularly, I have read those submissions very carefully and I have gone back and read the Greene article several times—and it has been debated several times today—and those who can go on asserting that the Greene article suggests a comparable rate of maternal mortality simply are getting it wrong. It is a concern though that the TGA, who live in the real world—I think it was discussed earlier whether they are nameless or not; I am sure they have names—are going to be influenced, just as much as every politician and every other contributor to this debate and to the committees who made those decisions for the AMA and RANZCOG, by their position on the abortion question.

I think there will be tremendous pressure on the TGA, as there was on the Food and Drug Administration, to give this drug the green light, because by doing otherwise they would be standing up and saying, 'We are not going to let this abortion drug into the country,' and all the flak that has been directed at one particular minister for health would then be directed at the TGA. As for all those who have come here and told us, 'Yes, we will leave the decision to the TGA,' I would be prepared to put money on it that they would not do any such thing if the TGA's decision went against the outcome they would like to see.

The Food and Drug Administration is now under serious scrutiny from the US Congress. There is a congressional subcommittee on drug policy that has written a very detailed letter to the FDA demanding it explain why it has been so slow to pull this drug off the market after five deaths in the United States—one from ruptured ectopic pregnancy and four from sepsis. Canada is a jurisdiction which has a very liberal abortion law and a far less effective pro-life political movement than the United States—I follow these things closely and I can assure you that that is the case. Nonetheless, after the death of just one woman in September 2001 during an RU486 trial in four cities—she was the first death recorded from toxic shock syndrome, Clostridium sordellii infection—Canada stopped the trials and has not licensed the drug to this day, and there is no sign of them licensing the drug.

Italy banned the drug two days ago, on 1 February. They suspended trials last September when there were troubles with the trial at the University of Turin, or Turin hospital, and the health minister announced just two days ago that imports of RU486 to that country would cease, except for individual applications with detailed epidemiological and clinical justification. There is a bill before the US Congress with 79 co-sponsors to have the controller general suspend the sales of RU486 and the FDA licence until the controller general has investigated the FDA approval process and verified that it was conducted properly. There are some serious doubts about that.

To pick up the point other witnesses made earlier today, ministerial responsibility for abortion drugs—not just RU486 but the anti-pregnancy vaccine and others; Dr Klein knows much more about this than I do—was brought to an end in 1996. Despite the mythology, there is no way—and I followed the politics of this very closely at the time—that it was a horse-trading deal with Senator Harradine over Telstra or any other matter. It was in May 1996 that the amendments were passed. Senator Harradine did not gain the balance of power in the Senate until August 1996, when Senator Mal Colston defected from the Labor Party. He was not in a position to leverage the government over Telstra on that issue. Furthermore, what leverage did he use with the Labor Party? Labor supported this amendment, and Senator Belinda Neal made some very pertinent comments on the question—they are there in the *Hansard* for all to read.

Senator Christabel Chamarrette, from my state of Western Australia, was certainly pro-choice. I knew Senator Chamarrette and I knew her position well. Her comments were mentioned earlier. So it was brought in, in fact, after the scandals of the 1994 trials at Family Planning in Victoria and in New South Wales, where an official of the TGA approved the import of the drug for a clinical trial. What was the evaluation? It was, 'Has the $90 application fee been received?' That was all. A receipt was issued. That is all in the *Hansard*

of the time. Those who are reopening this debate 10 years later would do well to go back and see what led to the enactment of this legislation in the first place.

Just further, it has been said that we will not know if the minister refuses an application. Is anyone seriously proposing that Professor Caroline de Costa will not tell us if the current minister for health or any subsequent minister for health refuses her application? Will anyone tell me that there will not be a senator asking a question of the minister at the next estimates committee or in the parliament on this question, and pursuing his reasons for refusing it? There may not be some formal mechanism for him to have to report it, but I think it is ludicrous to suggest a refusal of an RU486 application in the current political climate is not going to be subject to parliamentary and public scrutiny. In terms of the so-called catch-22, the minister of course can ask the TGA to evaluate the drug—not, of course, in terms of the specific meaning in the act, with all the processes that are involved in that, but there is certainly nothing to stop him asking the Therapeutic Goods Administration, or any other body of experts that he cares to, for advice.

Also, it seemed to be suggested earlier in the day by one witness who seemed a bit confused about this question that, if there were a pro-choice minister, somehow they could approve the drug all on their own. Clearly, at the moment it is a two-step process. The minister has to first give the green light and then the TGA carries out its formal processes. That would obviously apply if a minister did agree. I think that is sufficient comment for now.

CHAIR—Thank you to all three of you for your testimony today.

Senator BARNETT—Firstly, Dr Klein, thank you for your submission. There is a lot of information in there which I have been absorbing. I want to pick up and clarify a few of your points for the record. In terms of the safety issue there has been some debate today about whether RU486 has the same level of safety as surgical abortion. I would like you to respond to that. On page 8 of your submission you say:

> RU 486/PG abortion carries with it a *ten times higher risk* of the woman dying ...

So we have that risk of death, infection, bleeding and so on. Could you comment on the levels of safety and the impact of both. I am also interested in whether you have a view on whether rural and regional women are at a higher risk or a lower risk in terms of their access to appropriate medical care.

Dr Klein—I will start with the last question. Chemical abortion is especially inappropriate for women living in remote areas. In fact, if it does come in, especially if it comes in with the relaxed protocol that the US is now using, we will see catastrophes. In the US they do not insist that the woman has an ultrasound to find out the age of the pregnancy. They also give the women the prostaglandin to take home so she can insert it into the vagina as she will. The problem with all of this is that we do not know how each woman will react. For some it will be fine, but others will have very severe reactions.

So, if you are living in the bush, it is quite clear that, if you do not have a medical centre near you, you may die of a haemorrhage or a cardiac arrest. The infections are possibly even more dangerous because women do not get a fever from them, so the adverse effects they have are exactly the same as they expect from the RU486 and prostaglandin abortion. There has been considerable discussion in the media about this. I think yesterday there was another

article in the *Sydney Morning Herald* that said it was especially good for women in remote areas. If anything, it is especially dangerous for women in remote areas, which makes it also very dangerous for women in the Third World. It is unethical.

The second question was about the comment that it can lead to death rates that are 10 times higher than those related to what is called surgical abortion. I do not use the term 'surgical' because it conjures up a picture of a knife going into a woman. A suction abortion does not use knives, so it is really the wrong term. I think the language being used in this debate has been very emotive. The term 'surgical abortion', as against the nice, soft 'medical abortion', has been used wrongly. It was Professor Greene who made this comment after he looked at the recent deaths and so on. He very clearly specified, and I hope I have done that too in my submission, that that is only when you look at the first seven weeks of pregnancies. It is dangerous to use statistics, and nobody knows absolutely for sure, but it should make us think and cause us to reflect on whether this is really such a good alternative.

This goes to the rest of the safety questions that you asked. Having read all this literature, it is all in my head at the moment—I can hardly sleep; I just think about RU486; it is incredible—and the studies are so inconsistent. You can hardly compare oranges with apples. Also, and I did give an example in my submission, it also depends on how you see RU486. I read about all the side effects. I read that so many women need blood transfusions and others need severe opiate painkillers, and at the end of the paper the researchers say, 'There are no noticeable side effects.' Somebody who is already positively disposed to RU486 reads that paper and says, 'Yep, that is on the good side.' Let's face it: we can find papers that say, 'It's the best thing since sliced bread. There has never been anything better; it's wonderful. Let all women use it,' and others that say, 'This is really very dangerous.' I think reality lies somewhere in the middle.

But when you consider this question, and when you are making your recommendation, remember that we are not talking about a disease. We are not talking about an illness for which there is no other remedy and for which RU486/PG might be a lifesaver. We are not talking about that. We do actually have an abortion technique that has been practised. There are problems with it occasionally, but nothing compared to those with RU486. You never know with RU486. You do not know how you are going to react.

Senator BARNETT—Thank you. In your submission you referred to the merits of an expert committee that you would like to see set up. This evidence is new to the committee. Can you describe to us the nature of the committee? You talk about a GP, an ethicist, a pharmacist and social and natural scientists on this expert committee. Tell us the reasons why you think there is merit in that, and the nature of that committee and how it would work.

Dr Klein—This was an idea I came up with because I think we are in such an unfortunate situation. When you look at the population at large, they are really divided. They are divided into those who think it is very good and others who mostly are against abortion and therefore do not want to have a further means of abortion. Then there are people like me, who stand in the middle. As I said at the beginning, I defend a woman's right to an abortion, and we will need good abortion techniques, but that is just not RU486—a chemical abortion.

So I thought, 'This debate is not going to go away.' You could recommend to the Senate to keep the amendment, and the Senate would accept that. But the other side is not going to go away, because this is part of an international push for RU486. I mentioned in my submission, and again today, the International Consortium for Medical Abortion. This is an organisation that has got members from the Population Council on it. They are very aggressive in pushing RU486, and they are not going to give up. I really do not think the debate will just go away. Alternatively, if it gets to the TGA, then I would hope that, at best, you would see lengthy deliberations and maybe more trials. So I thought that the health minister could have his own committee to advise him in making his decision. I am saying that this committee would be under the health minister, not under the TGA; I think it should be directly under the health minister. That was an idea; I am not even sure if your committee has the power to recommend something like that. But I would see that as a positive step forward.

Senator MOORE—Only on this drug?

Dr Klein—That is an interesting question. There are many other drugs that also irritate me greatly: for example, some of the contraceptives that are being trialled. In fact, I got very irritated when I learned that Implanon, a contraceptive which is the new generation Norplant, is now also being trialled with RU486. I have serious problems with such experimentation on healthy women. Norplant is something that Australia never got; I think there was never even a drug application launched. But it got removed from the US market because it led to blindness in women. Who would think a contraceptive would lead to blindness? You can test for it. And yet that came out. I would not mind having such a committee consider Implanon, but I guess that is another committee and another question.

Senator MOORE—But the committee you have suggested, that Senator Barnett was referring to, was particularly for this drug?

Dr Klein—It was for what is currently a restricted good, RU486, and then also the antipregnancy vaccine which, thankfully, is shelved for the moment and I hope will stay on the shelf, because that is equally unethical.

Senator POLLEY—Thank you very much for your evidence. The concern you have expressed about whether or not you are pro-choice does not enter this debate. I have concerns because I do not think anyone who has come here in support of the amendment has been able to clarify in my mind that taking a pill to abort a baby is a better procedure because it is in the interests of the unborn child and/or the mother. I have concerns about the length of time the baby takes to die, and I was wondering whether or not you had a view on that. For those women who make that choice, it is their right to have an abortion. But to me, as a woman, that is a huge burden for someone to carry. We may when we are young think we can make that decision because it is just another pill that a man prescribes to us. But to me that has a profound effect, and it is keeping me awake at night, to be honest.

Dr Klein—I agree with you. These are issues for, as you say, people who are pro-choice. I do not describe myself as pro-choice; I say I am for a woman's right to have an abortion if she needs one. But the people who say that abortion is just a choice do not talk about these things. Yes, chemical abortion—and we have testaments from women who have gone through it—is really very emotionally draining. Picture yourself: you have taken these two chemicals and

nothing is happening. You have got some bleeding, which is not evidence that the embryo has actually come out, and you are doing whatever you do—you may have your other children with you, you may be on a bus or somewhere, and all of a sudden you start haemorrhaging like crazy. You run to a bathroom and look at your pad and you actually can see little limb like structures. Who needs that? Abortions are very draining on women and I do not think women just go and say, ' I'll have another one'—that is a myth. So this is to virtually see in your pad something that, in my books, has the potential to become a child—I am not saying it is an unborn child but it has the potential to become a child—and to actually think, 'My God—and I gave it a chemical that virtually starved it.' That is the other thing—you really cannot get around it and describe it differently: RU486 sits on the receptor and actually makes it so that the developing embryo does not get any nutrients. And that takes hours. For people who are pro-life, it is horrendous to even think of what is going to happen.

The other thing is that it is entirely in women's hands and so if something goes wrong what is said to women—we have examples in our book—is: 'Well, you shouldn't have smoked in between the RU486 and the prostaglandin,' or 'You shouldn't have had a gin and tonic, so it's all your fault.' We are adding to this whole thing that it is all the woman's fault if something goes wrong. If something goes wrong in a suction abortion she is there in the doctors' premises and they have to deal with it.

I have read statements from women who had RU486 abortions in England and I found them so upsetting. They said: 'I really had time to think about what I was doing. It lasted for days. I was bleeding for days, not much was happening and I was thinking I was being punished and it really must not happen again.' In my books, it is hard enough for women to go through an abortion. As I mentioned in my paper, many women are put in a situation where they sexually coerced. They think: 'I can't have another child with this person. I have to get out, and so I cannot have another child.' For those women to then go through this is very inhuman and much, much worse than a suction abortion.

Dr Pike—I think what Dr Klein has just said is probably the best that I have heard on this issue of the TGA not being able to address those sorts of issues. I spent 15 years of my life as a medical research scientist so I am familiar with how medical research is conducted. Medical research seldom looks at these sorts of emotional and psychological issues. I just do not think the TGA has the capacity to do that sort of thing at all. These are big questions and they go far beyond papers in the *MJA*.

Senator FIELDING—Dr Pike, the research that you have done looks reasonably thorough. You may want to make a comment about the thoroughness of the research, because someone this morning remarked that they did not think the research was of any use. My question is: have your surveys looked at community attitudes to RU486 and, if so, can you tell the committee what the researchers found?

Dr Pike—It is a pity I was not here this morning to hear those comments.

Senator MOORE—They will be on the record.

Dr Pike—Thank you. But I meant in terms of responding now. The research itself was conducted by two researchers of the highest calibre. Those researchers put a distance between

themselves and the marketing company that carried out the research—a reputable company, Sexton Marketing, in Adelaide. It abides by the code of ethics of its peak body.

As I mentioned before, some of the key findings of the research were the ambivalence that the average Australian appears to have about this complex issue, in terms of wanting legal access but wanting numbers reduced—being troubled by abortion. Stage 1 looked at that broad picture. Stage 2 went into focus groups. One of the interesting observations from stage 2 was that, when told about what abortion entails and the circumstances surrounding it, people have very complex views. It is not a simple yes in favour of abortion or no, not in favour. It is very complex, and they are deeply troubled, so there is that moral ambivalence where people will say, 'I am personally opposed to abortion, but I am deeply troubled by women not having access.' I think there are a whole lot of questions that we asked that flowed on from there about alternatives that women might be given so that choice can be genuine.

At this stage, no questions on RU486 are available, but I can say that certainly I would be very surprised if the public do have the information necessary to form a view. I suspect that they would probably think that this is just a pill you pop. When they are told the details, I suspect they might start to think very carefully about the types of things that Dr Klein has outlined.

Dr Klein—But they have to be told the details.

CHAIR—I am told it was described as 'push polling'. Would you think that was a fair description?

Dr Pike—That it was not. Yes, I am aware of that comment, but it certainly was not that at all. This is a marketing company of the highest standard, and they carried out their research in accordance with all of the normal ethical parameters and social research guidelines, so there certainly was not push polling.

Senator NETTLE—I have a question in relation to that issue. I do not know; you might want to take this question on notice—it is an on-notice question, I suppose. My question is whether we are able to get a copy of the questions that you asked in the polling. From reading the information in your submission I can guess what the question might have been for some of them by what you are reporting. But then there are other ones—for example, when you talk about people not accepting the 'foetus is not a person' argument, I do not know how you asked about the 'foetus is not a person' argument. So, until I see your questions—

Dr Pike—Of course.

Senator NETTLE—I am not able to say that it was not push polling. If I get a phone call from somebody who says, 'I was called by Sexton Marketing; I was asked this series of questions; I have been called by polling companies before, and this clearly struck me as push polling'—somebody, for example, who has worked in the polling industry—then that is what I hear, and if I am not able to see the questions it is difficult to disprove that. So maybe you could take that one on notice.

Dr Pike—Can I make a comment?

Senator NETTLE—Sure.

Dr Pike—There is a four-stage research project. The first stage was the polling of 1,200 Australians. A difficult decision was made about the release of the results from that stage, because we felt it was a critical question of interest to the Australian public and to politicians, to whom we in fact sent a copy of that set of results. The difficulty then arose that, if we released the questions at that same time—planning stage 2 as focus groups, stage 3 as a broader set of questions to poll the Australian population and stage 4—as any researcher worth their salt would know, the risk of contaminating was very high, especially on such a controversial issue. So, whilst this was a very difficult call, we did make it. But those questions will certainly be released. Stage 4 has been completed at this point of time. I believe that my colleagues who are the primary researchers on this are negotiating publishing arrangements, so I am not able to push them in such a way as to jeopardise the completion of the work and the publishing.

Senator NETTLE—Can you let us know what the time frame is.

Dr Pike—Sure. I will take that on notice.

Senator NETTLE—The NHMRC of course issues ethical guidelines for medical research. Was the following of those guidelines part of the research project?

Dr Pike—Under the current National Health and Medical Research Council research on human subjects document, released in 1999, this does not constitute human research. That is going through draft 2 at the moment. I was at extensive consultation on that recently. That stage 2 is a broadening of the guidelines. But certainly under the existing guidelines it does not constitute human research. However, we are a bioethics institute and we deal with ethics all the time, so that is our business of—

Senator NETTLE—Can you also take on notice the Newspoll question. I note you said you did a Newspoll in May.

Dr Pike—Sure.

Senator NETTLE—Another organisation, called the Knights of the Southern Cross, made a submission to this inquiry. You are probably aware of them.

Dr Pike—Yes.

Senator NETTLE—They describe themselves as an order of Catholic men committed to promoting the Christian way of life throughout Australia. On their web site they list the Southern Cross Bioethics Institute as a branch of the Knights of the Southern Cross. I note that you describe yourselves as an independent, non-sectarian organisation. Why do you do that when the Christian men's organisation tell me that you are a branch of them?

Dr Pike—The Knights of the Southern Cross are a Catholic men's group. I will state up front that I am not a Catholic, but it is a pity that that matters. I am not aware that they say that on the web site. We are not a branch. We were started as an initiative of Southern Cross Care, the largest provider of aged care in South Australia. Southern Cross Care was started some 30 years ago by the Knights of the Southern Cross, so the Knights—perhaps a fading organisation as they age—were certainly involved with the starting of the institute, but things have changed over time. We are certainly an independent institute. Southern Cross Care is our

primary funder. We receive no funding from any religious body. We receive no funding directly from the Knights. There are private donations made by individuals.

Senator FIELDING—Dr Klein, knowing your public support for abortion, why do you think there are so many women's groups so in favour of this drug and of seeing it given to women, knowing, as you say, that lives could be lost unnecessarily?

Dr Klein—I find it very difficult myself, but I think I can understand some of the reasoning, especially when you look to what is happening in the US—in some states it is getting very hard for women to get an abortion. So maybe the reasoning goes: 'It will get tougher for women to get a suction abortion, where they go into a clinic. Therefore there has to be an alternative.' And in comes this enormous propaganda machine for RU486. We also live in a pill culture—we all pop pills. So this idea then comes in: 'You can just take a pill and do not have to go to a doctor.' And let us face it, suction abortion is not nice—let me tell you that as a woman. So they think: 'That's great. Let's do it.' Then, sadly, I think some of the people quote one another instead of actually going into the research. When we started this project on RU486—and we did the first six years of it—we were not convinced that this was a bad thing. We approached the subject quite openly. But when you read these research papers and you see all the inconsistencies, you think, 'Good grief,' and then you see how somebody just quotes it.

As I said before, we still hear in the media that RU486 is banned and that it is safe. Every day I get another RU486 Google alert that tells me somebody is saying RU486 is safe and it is good for women in the country. I think it is a legitimate need to make sure that we do not go back when times when women could not get a safe abortion. If that were the case, I would have to do something too, and I would have to join the marchers on the street. But, as I have argued, this proposal is in fact going back to the bad old days of backyard abortions, because if you take these pills in the middle of your farm somewhere or you are an Aboriginal woman out there and you then bleed to death, how is that different from the coathanger? I am trying to come at it from that angle, but it has cost me a lot of friends and support. I really stand very firm on it. I am not alone—I have my two co-authors and I have many other people standing with me, but it is very difficult to run that line. And yet you have to, because if this comes in we will see many, many more adverse effects. It is not a question of if, it is a question of when.

Senator McLUCAS—Dr Klein, you seem to be saying that you do not think the TGA is the appropriate entity to do an evaluation of RU486 in this circumstance. I think the argument in your paper is that this is because they run on a full cost-recovery basis. Does that mean that you think that the TGA cannot evaluate any drug in Australia?

Dr Klein—Personally, I was actually quite shocked to find out that the system had been changed. I believe it was only changed in 1995 or 1996. I think it would be far more preferable if there was an authority that was funded by the government and not funded really, in a way, by industry. But we have that now, so we have to deal with it. I go back to what I said here and in my submission: for me, RU486 is not a drug like any other. I hear the arguments that Richard and Greg are making about it being a drug that ends the lives of unborn children; that is not my argument. My argument is quite simply that, in itself, it is a

very complicated, very unreliable drug because it has these various sites of action: it does not just work on the developing embryo, as I said—so how are you going to evaluate it?

Also, it has such a long and chequered history—it has been a political football from its very beginnings. Then, to add to this, it does not work without the prostaglandin in most cases, and the prostaglandin is not even allowed in by the manufacturer because it has never been tested, never been trialled, for abortion. So what would the TGA actually evaluate? If it only evaluates RU486 we do not get the full story. And how can it evaluate the prostaglandin when that has never been trialled? So what do you do? I know that some medical doctors have said, 'We will use prostaglandin; we have used it in obstetrics for a long time.' But we have detailed very unfortunate situations in our book. For example, the German women's movement in the 1970s, for instance, opposed the use of prostaglandin for abortion, and in Brazil, where women do not have access to legal abortion, a lot of them use prostaglandin to induce abortions. A lot of the abortions are incomplete and so the children are born with malformations.

For me, it is unacceptable that a drug like that, which has not been trialled, should come in on an off-label basis. To go back to your question: what would the TGA evaluate? If the TGA had lots of money it could say, 'Okay, we will pay for new independent research in Australia,' but they do not have that.

Senator McLUCAS—My question went to whether the TGA is competent to assess any drug in Australia.

Dr Klein—I do not want to say that the TGA is not competent to assess drugs, although I would prefer, as I said, that it was an independent body that was funded by the government. But I am saying that it is not competent to assess RU486 and prostaglandin, for the reasons that I have given.

Senator McLUCAS—Because of the complexity in their indication.

Dr Klein—Yes—and one is not even officially sanctioned and trialled by the manufacturer.

Senator McLUCAS—But used for many years in obstetrics.

Dr Klein—Yes, with many dire consequences. To my knowledge, there have never been any laboratory experiments to compare the interaction of RU486 and prostaglandin. That is basic stuff, but it cannot happen because all the manufacturers—and there have been other prostaglandins; Misoprostol is just the latest—Schering, Searle and now Pfizer have never said it could be used for abortion. They have always distanced themselves. It is an anti-ulcer drug.

Senator McLUCAS—You said, Dr Klein, that the medical evidence went from: 'This drug is extremely dangerous,' to 'It is extremely safe'—and the answer is somewhat in the middle. How does the minister make a judgment, then, about whether or not to ask the TGA to assess it?

Dr Klein—Richard detailed the history of how this amendment came about in Australia. It did not just come about. It came about because we did have trials of RU486 in Australia that were done very unethically—they had to be stopped in Melbourne because the women were not given decent consent forms. So there is a history to that. The minister got given these

powers to have a look at applications; it is not that the minister then can actually say, 'Yes, we will have it,' or 'We will not have it.' The minister has to actually deal with this. I think Australia is in a very good situation having such an amendment. Other places do not have that. In the US, the FDA let it in. So we have to get it away from the minister, especially as the minister is Mr Abbott, with his anti-abortion views.

Senator McLUCAS—Keep it away from the current minister?

Dr Klein—Yes.

Senator McLUCAS—I think that is very important.

Dr Klein—What I try to say in my talk is that the fact that the minister will know if there are applications being made to use it as an abortifacient—not for other applications—means the minister can actually then inform you members of parliament and, I suppose, the House of Representatives as well, and then the public hears about it. I think that is a great and fantastic situation that Australia is in. So I really hope we will keep this amendment.

Senator McLUCAS—But it does lead to the situation where a women with a brain tumour cannot use mifepristone.

Dr Klein—No, I do not agree with that. I saw the very emotional *7.30 Report* and I also have a quote from the same person, although I did not know it was her until I saw her on television. That was an incredibly emotional appearance. It was not a very fair program because only towards the end did it say that the TGA had given her permission to use it. Then it said, 'But no doctor would give it because there was no medical indemnity.' Lots of people in this country, especially for cancer treatment, use drugs because they are desperate and they are just going to go for it and try it. My point is we really do not need that for abortion. If this woman wants to use it for Cushing's syndrome, for her brain tumour, then she should go for it. The woman in America is obviously using it. It helps her. I am not 100 per cent sure, but I think RU486 for brain tumours is still in the experimental phase. I do not think it has been licensed. But I really do not want to be quoted on that because I have not done the research on this. It is wrong that people who are in this situation could not get access to this drug. She got it.

Senator McLUCAS—She has got the approval—that is right.

Dr Klein—She did get it. The TGA gave it to her.

Senator McLUCAS—But no-one will prescribe it to her.

Dr Klein—Yes, well—

Senator McLUCAS—Because it has not been evaluated.

Dr Klein—That is right. But I think it has nowhere been passed as a vehicle of treatment. I think even in the US it is experimental. Again, I want to say I am not 100 per cent sure. The American woman said on the *7.30 Report* that she had received it via the Feminist Majority. The Feminist Majority is a bit like Reproductive Choice here. They are very much in favour of it. So they would give it to her. That made me think that it has probably not been licensed there either, but I am not 100 per cent sure.

Senator WEBBER—You say in your evidence that you do not think the TGA is the appropriate body because it cannot deal with the complexity of RU486. Do you think therefore it is the appropriate body to deal with the complexity of drugs that deal with not rejecting transplant organs, complex heart disease and what have you? Where do we draw the line on what is too complex for the TGA or is everything too complex for them? Should we just get rid of them and start again?

Dr Klein—As I have said twice already, I would be much happier as an Australian citizen if I knew there was an independent committee. I was actually quite shocked when I found out that it was not.

Senator WEBBER—But it is not the independence—it is the complexity I am talking about.

Dr Klein—I know. You have heard me say what I think about the complexity of RU486 and prostaglandin. I can only repeat that. Put that together with the arguments that Dr Pike and Richard Egan have put forward—they are not my arguments but a lot of the people in Australia have those views—and it is a very complex picture. It is more complex even than a drug that is used for transplants.

Senator WEBBER—So RU486 is more complex than complex heart treatments and antirejection drugs?

Dr Klein—Yes, because it also has the social and ethical sides to it as well. Senator Polley was asking me about the emotional repercussions for women. I think Dr Pike commented on that, saying, 'How can the TGA evaluate that?'

Senator WEBBER—If a panel of experts cannot, who can? Who in Australia can do that?

Dr Klein—We are having a discussion now. Your committee is in the situation where you can actually recommend—

Senator WEBBER—So we can but they cannot?

Dr Klein—No, you can recommend something. I have said very clearly that I would be very happy if this drug was kept out of Australia. I am almost positive that, if the TGA does look at it then, given its limited means, it will come in. So, of course, I want your committee and the Senate to reject the bill.

Senator ADAMS—Dr Klein, you did comment on rural and remote situations for this drug. I have a submission, No. 606, which I suggest you read. You would probably get some quite good information from the Broome Regional Aboriginal Medical Service. Six doctors have sent this submission to us urging us to support the use of this drug in early termination of pregnancy, particularly in rural and remote settings. They are saying here that, with appropriate patient selection, policies and procedures, RU486 can safely be used in regional Australia. They feel that they have the back-up of the surgical situation that they have in the Kimberleys at the top of Western Australia. In Broome, Kununurra and Derby they have obstetricians and gynaecologists with surgical back-up if need be as they have to have for spontaneous miscarriages. They can do very few terminations because of their surgical limitations and the number of cases that they have sitting on their waiting lists. Their patients have to go to Perth, which is a long way away and they have no support. These doctors are

really saying that they would far rather have their patients up there under their care. If the patient comes from a remote area and they decide that the patient is capable of having a medical termination rather than a surgical one, they could have them there and be able to look after them safely. What do you have to say about that?

Dr Klein—I can understand that they are saying that, but, because I have come to the view that I have by doing all of the research on these drugs, I just think it is not safe enough. They may say it is safe but they have not used it. They have not actually seen the complications that can happen. I want to make two other comments. They say that there are not opportunities to have suction abortion in these remote areas. I really think we also have to seriously think about reducing the need for abortions. I said that at the beginning.

Senator ADAMS—I think everyone in the room would agree with that.

Dr Klein—The committee may not have had time to read all the submissions but people have put in submissions saying, 'Let's have it.' Somebody was asking me why pro-choice people want it in general. It is almost this despair about what do women do, especially those in very remote areas, when they find themselves pregnant and cannot or do not want to keep the child? The point is that we must not forget what we are offering. What if an Aboriginal woman—or any woman—takes these pills, does not go to the clinic and dies a miserable death? What is the general public going to say to you then?

Senator ADAMS—I do not think any medical practitioner is going to allow anyone to go through a chemical termination—

Dr Klein—But it is not about the medical practitioners not allowing them. If you were my doctor, you would not know what I was going to do when I left this room. I am not saying that women are dupes, or silly or this, that and the other. Often women do not go back. One of the problems with the studies on RU486 is that many women never go back for the controls. They do not go back for the ultrasound to check whether they have had a completed abortion. Women have terribly busy lives and do all sorts of things. It is true. If you read the studies, this is what you will find. It is a very difficult question. From my stance, I would find it unethical to make RU486 and prostaglandin accessible to Aboriginal women. Without any doubt, they have serious side effects and could cause death.

Dr Pike—I just want to note on that count about doctors' views that it was reported that roughly 200 medicos from Queensland—you may have seen this—have decided to consider the removal of their memberships from the AMA because of this issue. As far as doctors go, some are obviously seriously concerned about RU486. In this case, it is quite a large number of doctors and they are concerned enough to resign from their membership of the AMA.

Senator BARNETT—Two hundred GPs?

Dr Pike—Two hundred GPs were reported in the *Courier Mail*.

CHAIR—Can I exercise my privilege as chair to ask the last question. Mr Egan, you have already commented on this to some extent. Perhaps Dr Pike and Dr Klein can comment on the argument put already today that, because the political debate about abortion has already been had at the state and territory level, there is not really any choice for the federal government

process but to approve RU486 since it facilitates an option already legally available to women. What is your response to that argument?

Dr Klein—Maybe I did not quite understand what you were saying, but as far as I am concerned no state government can use RU486 at the moment; it has to come in federally first.

CHAIR—The argument is that state parliaments have already approved abortion; therefore, RU486 is really only another form of abortion and the federal government should facilitate its availability in accordance with the decision made by state and territory parliaments.

Dr Klein—As I said—and I do not want to repeat myself—it is not a good alternative because of the complexity of the two drugs and the many uncertainties with it. I also do not think this argument holds because we have an abortion method—in fact, we have two: with or without general anaesthetic. So it is not that the states will have 'legalised' abortion and there is not a method; there is a method. We are talking about something extra. So I cannot see quite see how that argument holds.

Dr Pike—I do think RU486 is in a different category—point No. 1. Point No. 2: we have had 30 years to look at what has happened, and certainly our research shows that it is far from a settled social policy question. People are deeply concerned. They do not necessarily understand what has actually been happening over 30 years. When you say that 98 per cent of aborted foetuses are healthy, people tend to be shocked by that. So, whilst that was passed, things have happened in that time to make people ask: 'What have we allowed?'

CHAIR—I thank all three of you for your appearance here today and for the written evidence as well as the oral testimony you have put before the committee.

Committee adjourned at 5.05 pm